ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAMES: Inorganic Ammonium Salts

IUPAC Name(s): Not relevant

EC NUMBER(S): Not relevant

CAS NUMBER(S): Not relevant

CONTACT DETAILS OF THE DOSSIER SUBMITTER:
ANSES, REACH Unit

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A. Proposal

A.1 Proposed restriction

Background:
In France, the Directorate of Housing, Urban Planning and Landscape (DUHP) was informed by the European Cellulose Insulation Manufacturers Association (ECIMA) and the French Scientific and Technical Centre for Building (CSTB) that a growing number of householders were complaining about an ammonia smell following the installation of cellulose insulation for sound or thermal insulation in their homes. In 2012, ECIMA had recorded 115 reports and had conducted in situ measurements indicating ammonia concentrations in air of up to 5 ppm.

The products in question were cellulose insulation materials blown or sprayed (flocking) into attics or walls. Until 2011, boron salts were added to these insulation materials as a flame retardant and antifungal treatment. Boric acid has been substituted because of its reproductive toxicant classification (Category 1B according to Regulation (EC) No 1272/2008 on classification, labelling and packaging - CLP). Manufacturers have replaced these boron salts by flame retardants containing ammonium salts, which account for 6 to 12% of the total mass of the products.
According to ECIMA, by the end of 2012, around 20,000 homes in France had been fitted with this cellulose insulation containing ammonium salts, all manufacturers combined.

On 14th of August 2013, the French Republic informed the Commission, the European Chemicals Agency (ECHA) and the other Member States, in accordance with Article 129(1) of Regulation (EC) No 1907/2006 (safeguard clause), that it had justifiable grounds for believing that urgent action is essential to protect the public from exposure to ammonia released from ammonium salts in cellulose insulation materials used in buildings. The French Republic adopted a provisional measure on 21st of June 2013 and published it in the Official Journal of the French Republic on 3rd of July 2013.

The Order of 21st of June 2013 on the prohibition of placing on the market, import, sale and distribution and manufacture of cellulose insulation materials with ammonium salts additives prohibits the placing on the market, import, possession with a view to sale or distribution, sale or distribution and production of cellulose insulation materials containing ammonium salts as additives. These products must also be withdrawn from the market in France and recalled at the expense of the person responsible for first placing them on the market.
A translation in English of the French Order is available in Annex 1.

Following the Commission Implementing Decision of 14th of October 2013 authorising the provisional measure taken by the French Republic, and according to Article 129.3 of REACH Regulation, an annex XV restriction report has been prepared within three months of the date of the Commission decision.

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has been mandated by FR-MSCA to prepare this annex XV restriction report.

A.1.1 The identity of the substances

Inorganic ammonium salts are added to cellulose insulation for their flame retardant properties.
These substances used as additives in cellulose insulation may lead to emission of ammonia gas under certain conditions. Such ammonium salts identified are the following:

- ammonium sulphate [CAS No 7783-20-2]
- ammonium dihydrogenorthophosphate [CAS No 7722-76-1]
- diammonium hydrogenorthophosphate [CAS No 7783-28-0]

Other ammonium salts may be used[1], such as ammonium chloride [CAS No 12125-02-9], sulfamate [CAS No 7773-06-0], polyphosphate [CAS No 68333-79-9] or bromide [CAS No 12124-97-9]. This is not an exhaustive list.

The substance of concern is ammonia, anhydrous [CAS 7664-41-7].
Different cofactors promote ammonia emissions. The stability of ammonium salts in such materials may be affected by:

- Humidity rate, considered as a major factor;
- Other cofactors that may influence the stability of additives in the final product:
  - ✓ pH (e.g. in case of plaster board contact);
  - ✓ Ventilation;
  - ✓ Temperature;
  - ✓ Content of carbon / calcium carbonate in the paper used as raw material;
  - ✓ Formulations, composition of other additives (reactivity with other chemicals such as biocides added to the mixture);
  - ✓ Production process (dry *vs* wet);
  - ✓ Type of installation (wet spray, “crusting” on the top of cellulose insulation, vapor barrier applied, distance to the roof in attic, etc.).

A.1.2 Scope and conditions of restriction

Substances in the scope of that restriction proposal are ammonium salts that are used in cellulose insulation for their flame retardant properties. These salts can lead to ammonia emissions - which is an irritant gas for mucous membranes and respiratory tract.

The conditions of the restriction are the following: Ammonium salts may be used only if emission of ammonia is below a threshold based on the DNEL for the general population (subacute, inhalation route) and with respect to specific testing parameters.

Column 1. Designation of substance	Column 2. Conditions of restriction
Inorganic ammonium salts	Shall not be placed on the market in cellulose insulation after 12 months after of entry into force of this Regulation, unless: - Emission of ammonia gas of such materials is below **3 ppm** according to the horizontal measurement/test methods of Technical Specification CEN/TS 16516 and: - Specific test parameters are applied in terms of duration (14 days), relative humidity (90 +/- 5), “Attic insulation” area specific emission rate (1.25 $m^3.m^{-2}.h^{-1}$), and “Wall insulation” area specific emission rate (0.5 $m^3.m^{-2}.h^{-1}$). Cellulose insulation thickness and density are adapted to the foreseen

[1] Flame Retardants: A General Introduction. WHO IPCS, Environmental Health Criteria 192. 1997.

	use.

Table 1: Proposed restriction

Scope:

1-Inorganic ammonium salts

As far as the problem of gas-phase ammonia emission by cellulose insulation is currently understood, it is hypothesized that the release of ammonium ion in wet conditions is a necessary step. This hypothesis seems to be coherent with the fact that relative humidity (% RH) during the CSTB tests (see section B.9.3) plays a crucial role with a clear increase of ammonia emission for values > 80% RH close to the breakpoint in humidograms of several inorganic ammonium salts[2,3,4]. Moreover, this hypothesis seems to be coherent with the known chemistry of ammonia[5,6].

In inorganic salts of ammonium the strength of the chemical bonds between ammonium and the counter-anion is weak (ionic bonds based on van der Waals forces). As a consequence when these inorganic salts are hydrated (most of them being spontaneously hygroscopic with few exceptions) chemical bonds can be broken by water. This dissociation is induced by dipolar moment of water molecules and the free ammonium ion can then undergo supplementary chemical/biochemical reactions or equilibriums to transform into gaseous ammonia.

$$NH4^{+} + H_2O \leftrightarrow NH_3 + H_30^{+}$$

For instance ammonium sulphate is highly soluble in water and must be stored in a dry place. In the presence of moisture or in solution, it decomposes into a strong acid (sulphuric acid) and ammonia gas. In contact with an alkaline functional group, it reacts to release ammonia gas. Lime, plaster and cement are all alkaline and can theoretically react with ammonium sulphate. In one of the dossiers (CCTV 2013a) the release of ammonia occurred after the laying of a concrete screed that might have promoted such a reaction, while in another dossier it occurred when in contact with Placoplatre® plasterboard partitions.

For these reasons it appears coherent to extend the field of the proposed restriction to the entire family of “inorganic ammonium salts”. No specific data from scientific literature or experimental results (CSTB tests, Maupetit F, 2013a,b) has been identified that could help to modulate this option: during the tests performed by the French CSTB in 2013, at least 3 different inorganic salts demonstrated the capability of gas-phase ammonia generating when incorporated in cellulose insulation (see section A.1.1 for the identity of these substances).

2-Cellulose insulation

This restriction proposal is based on French toxic-vigilance data. All cases were related to a recent installation of cellulose insulation. Dynamic tests performed by the French Institute CSTB have verified the stability of additives for such materials treated with ammonium salts, in conditions of high humidity (at 90% RH) that may be encountered in reality. Additives are in the form of powder (solid form) and are mixed with cellulose fibers. The 11 tested cellulose insulation materials all presented in varying degrees ammonia emission profiles (from few ppm to more than 200 ppm), reflecting instability of ammonium salts in these products.

CSTB has tested 2 bio-based insulation materials treated with ammonium salts by liquid impregnation, to compare with cellulose insulation results. For the same test conditions, only

[2]http://www.atmos-chem-phys.net/6/755/2006/acp-6-755-2006.pdf
[3]https://uwspace.uwaterloo.ca/bitstream/handle/10012/3683/Rocsana%20Pancescu%20Thesis_5_.pdf?sequence=1
[4]https://pubweb.bnl.gov/~xujun/research/98JPCpaper.pdf
[5]http://nepis.epa.gov/Adobe/PDF/30000I7U.PDF
[6]http://www.geo.uu.nl/Research/Geochemistry/kb/Knowledgebook/NH4_dissociation.pdf

residual concentrations of ammonia have been detected (less than 1 ppm). Liquid impregnation leads to a better stabilization of ammonium salts compare to a mix of a powder (solid form of the salts).
According to these data, this proposal focuses on cellulose insulation materials only.

3. Proposed test
The test proposed is based on the Technical Specification CEN/TS 16516: "Construction products - Assessment of release of dangerous substances - Determination of emissions in indoor air".
This standard is used to simulate, in a reduced scale test chamber, volatile pollutant emissions of a construction product used in a defined reference room (see section B.9.3).
Emissions are generated in the test chamber under conditions which are kept constant during the test. These conditions are selected so that the test results can be expressed in terms of chemical concentrations in the air of the reference room and then compared to a specific threshold.
The specific emission rates determined using this Technical Specification are associated with application of the product in a defined European Reference Room under specified climate (temperature and humidity) and ventilation conditions.
According to the standard, the temperature during the emission test shall be 23 ± 2 °C and the relative humidity (RH) as input to the emission test chamber of 50 ± 5 %. However, as wet conditions (rain, fog, etc.) were considered as major conditions favoring ammonia emissions and the appearance of odors, a “worst-case” relative humidity of 90% is proposed to test the stability of ammonium salts.

Apart from the relative humidity which is a deviation from the CEN/TS 16516 standard, specific parameters are proposed regarding cellulose thickness and density.
Insulation thickness varies among Member States depending on national weather conditions and building regulations. Insulation thickness applicable in roofs in Europe could therefore be up to 10 times much important in the Nordic countries than in the South of Europe, as illustrated in the following Figure (Papadopoulos 2005). The range 10-30 cm seems the most realistic practice in European countries.

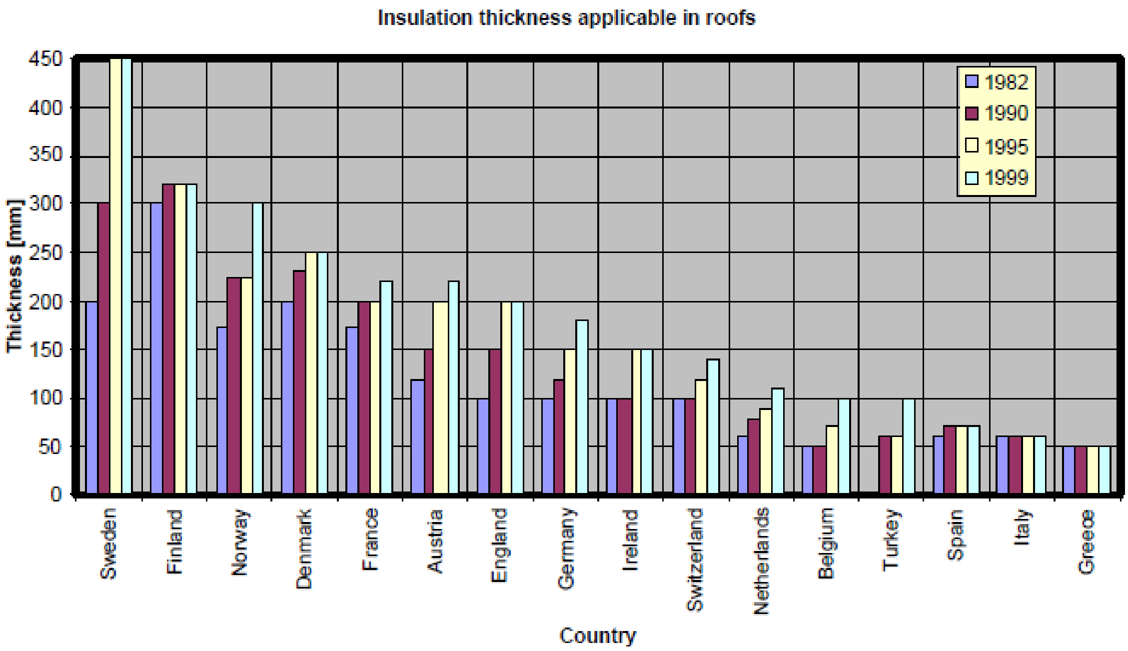


Figure 1: Evolution of insulation thickness applicable in roofs in Europe (Papadopoulos 2005)

The value of cellulose insulation density of 40 $kg.m^{-3}$ corresponds to French practices for attic insulation. The amount of cellulose insulation implemented, was established from data communicated by ECIMA[7] to CSTB (dated 12/11/2012). The very large majority of use of cellulose insulation was attic insulation by spreading the cellulose insulation on an open horizontal surface. The use by injection into the walls seems exceptional. On construction sites where complaints were observed (in France), the average quantity of cellulose insulation implemented was 12 $kg.m^{-2}$ with an average thickness of 30 cm, giving a density of 40 $kg.m^{-3}$.
It should be noted that density may be higher for wall insulation (through insufflation or injection) as explained in section B.2. Attic scenario is preferred as it corresponds to most of health issues identified by toxic-vigilance in France.

According to what was reported by CSTB institute on the analysis of ammonia emissions from cellulose insulation tested in 2013, all French cellulose isolation containing ammonium salts, which emitted ammonia under humidity rate of 90%, emitted during the first 14 days (see CSTB confidential annexes). Therefore, the duration of the whole test procedure for measuring ammonia emissions per each sample of cellulose insulation can be reduced to 2 weeks. CEN/TS 16516 standard refer to the measurement of short-term emission at 3 days and the measurement of long-term emission at 28 days after material installation in the test chamber.

Specific “cellulose insulation” test parameters proposed are summarized in the following Table:

Parameters	Reference room (according to ISO 16000 standards)	Units
Duration	14	d
Temperature	23 +/- 2	°C
Relative humidity	90 +/- 5	% HR
« Attic insulation » area specific emission rate	1.25	$m^3.m^2.h^{-1}$
« Wall insulation » area specific emission rate	0.5	$m^3.m^2.h^{-1}$
Cellulose thickness / density[8]	30 cm / 40 $kg.m^{-3}$	cm / $kg.m^{-3}$

Table 2: Specific “cellulose insulation” test parameters proposed

For the general population in this exposure situation, the proposed (ANSES) subacute-inhalation DNEL for irritation is 1.3 $mg.m^{-3}$ (1.7 ppm). Considering ammonia concentration in living rooms are expected to be approximately two times lower[9] compared to emissions measured in the dynamic “worst-case” test proposed here, the threshold of 3 ppm is proposed.
This value is similar to the mean odour detection threshold (ODT) of 2.6 ppm calculated by Smeets et al. (2006).

To conclude, the dynamic test at 90% RH can be used to verify the stability of the additives for such construction products treated with ammonium salts under conditions of high humidity that can be found in reality. CSTB tests have shown the **technical feasibility** of this test[10]:

[7] European Cellulose Insulation Manufacturers Association.
[8] Parameters used in CSTB tests (based on data communicated by ECIMA - European Cellulose Insulation Manufacturers Association).
[9] If the air flow conditions are the same in different test chambers used between these two types of tests, see section B.9.1.
[10] See confidential annex (not published): development of a standardized method of characterization of ammonia emissions from building products treated with ammonium salts. CSTB. Final report (19 September 2013). Report SC-2013-106.

- Some biobased construction products treated with ammonium salts pass these tests successfully. As such, they have no ammonia emission profile (more or less rapid increase followed by a slow decrease) but a residual ammonia concentration below 1.7 ppm (generally below 1 ppm).
- The 11 cellulose insulation products tested in this study and in a previous study all had varying ammonia emission profiles, thus reflecting the unstable nature of the ammonium salts additives in these products (from 6-7 ppm to more than 200 ppm).
- For these 11 products, the ammonia emissions were always released before day 14 of the test (out of a total test duration of 28 days or more), which should enable the duration of the dynamic test at 90% RH to be decreased to 14 days.

Regarding **economical feasibility**, this test is estimated to cost around 1000 euros per material placed on the market. This cost has been included in the socio-economic analysis (section F).

4. Justification to propose a transitional period of 12 months

On one hand, in principle, the transition period should give enough time to all relevant stakeholders (manufacturers, importers, wholesalers and retail sellers) to enable them to adjust their production and sales processes under technical, economic, practical and regulatory point of views once the proposed restriction has come into force, namely taking into consideration the fact that many manufacturers and installers of cellulose insulation are small and medium sized companies.

On the other hand, for the implementation of this specific restriction proposal there is a need to be in coherence with the use of the article 129 which supports a short transitional period after entry into force of the restriction.

The main reason why the cellulose insulation industry will need a transitional period is represented by the time needed to carry out the **R&D** in order to develop a safe and environmental alternative formulation (e.g. boron and ammonium-free) with the same capacity of fire retardation if the dedicated emission test show that the cellulose insulation releases ammonia over the threshold of the proposed restriction. It is very difficult to estimate the time needed for developing a new formulation but the research process by the industry seems to be already on going and the first results of the French research project should be available already by the end of 2014.

From the stakeholders' consultations it seems that, if alternative fire retardants would have to be added again as powder formulation, no major investment in new machinery nor major adaptations of the equipment seem to be required by the cellulose insulation industry. However, in some cases according to the chemical properties of the substances in the alternative blends, the production process might need to be slightly changed which could imply minor investment costs in order to ensure the technical feasibility.

Considering the fact that cellulose insulation is a product that takes a lot of space, stocks' levels are relatively low. In average, during the stakeholders' consultation, the volumes of final products stored by the European cellulose insulation industry were found limited to less than a week of production. Therefore, the depletion of stocks can be done quite quickly and it is not considered as a relevant element for establishing the transition period of the proposed restriction.

The time required for the adoption of the testing method does not seem in contradiction with the 12 months proposed by this restriction. According to the restriction proposed, no development of a harmonised EU standard on the measurement of ammonia emissions is needed but only an adaptation of the testing parameters.

Some time could be needed for practical and regulatory reasons by responsible EU **Public Authorities** to inform markets and all concerned actors (EU and non-EU authorities) about the change in EU legislation and to get prepared to enforce the restriction.

The few **importers of cellulose insulation** could also need some time to inform non-EU suppliers (especially from Switzerland) and customers about the change in EU regulation and to take the necessary measures in order to comply with this restriction.
On the other hand, as the cellulose insulation can have a long service period of around 60 years it is important to avoid having a too long transitional period as this will increase the exposure potential for the general public to ammonia and the costs that occupants will have to afford to re-insulate their housings.

In coherence with the article 129 of REACH Regulation and for the reasons mentioned in Section D.3, a transitional period of 12 months is considered reasonable for cellulose insulation market operators and for public authorities to adapt to the requirements of the proposed restriction and to minimize the transaction costs related to dissemination of information and to perform voluntary compliance control measures. For the proposed restriction therefore a shorter transitional period could involve implementation problems on the EU market, a longer one would create a risk for human health and would not be in coherence with the need of urgent action for this restriction.

- *Any derogations, conditions and/or monitoring obligations*

Cellulose insulation can be installed indoor or outdoor. It could be argued that cellulose insulation to be installed outdoor should be exempted because it would eventually emit outside the living environment. Such products could be labeled, specifying that the article is only intended for outdoor use. However, in practice it seems very difficult to ensure that this type of cellulose insulation, that is exactly the same as that meant to be installed indoor, would not be installed inside the living environment, namely if such products would become less expensive than the others. Forum will assess the enforcement problems related to this option of labeling for outdoor cellulose insulation and RAC and SEAC will assess if an exemption should be foreseen. However, for the dossier submitter of the proposed restriction no exemptions should be foreseen as potentially all cellulose insulation may be installed indoor and it may contribute to direct human exposure.

The test proposed is based on the Technical Specification CEN/TS 16516: "Construction products - Assessment of release of dangerous substances - Determination of emissions in indoor air". The specific emission rates determined using this Technical Specification are associated with application of the product in a defined European Reference Room under specified climate (temperature and humidity) and ventilation conditions. This European Reference Room corresponds to a little living room and is not directly applicable in this proposal for industrial premises, warehouses, commercial areas or places of public assembly (different dimensions and ventilation conditions).

Concerning the monitoring obligation, the detection limits of the analytical methods must be sufficient to respect the proposed ammonia threshold.

A.2 Summary of the justification

A.2.1 Identified hazard and risk

The isolation with cellulose insulation represents a minority part of the market for insulation, but its growth is exponential. Until end of 2011 most of the cellulose insulation was treated with boric acid / borates in France for biocidal and flame retardant properties. Ammonium salts were used as alternatives because of reprotoxicity classification (Repr. 1B) of boric acid / borates.

However, in France[11] it was decided to ban adjuvanted cellulose with ammonium salts because these salts might lead, under certain conditions (especially of humidity), to ammonia emissions. Due to the high volatility of ammonia, it spreads preferentially in the attic rather than residential premises but may enter the living rooms.

Hazard

Acute and chronic toxicity of ammonia via the inhalation route is mainly due to the irritating effects of the substance, in the airway or ocular mucosa.

The dose-effect relationship for ammonia is summarized in the table below (inhalation exposure):

Concentration of NH_3 in ppm in the air	Probable effects from acute exposure
< 1 - 17	Limits to olfactory detection (habituation)
5-20	Discomfort in non-accustomed individuals
25-50	Slight irritation in nose and throat
50-80	Mild irritation in eyes and throat
100-140	Irritation in eyes, nose, throat, watery eyes
2500 - 4500 (accident)	Bronchospasm, pulmonary oedema, fatal in approximatively 30 min
10,000 (accident)	Rapid death by suffocation and pulmonary oedema, skin damage due to corrosivity

Table 3: Summary of dose-effect relationship for ammonia (inhalation exposure)

The different selected human health risk values (HRV) found in the literature and the DNEL derived by the lead registrant for the general population are therefore all based on these effects.

The (ANSES) subacute inhalation DNEL of 1.3 $mg.m^{-3}$ (1.7 ppm) used in this proposal is also based on this critical effect, taking into account susceptible population sub-groups such as asthmatics.

Exposure and risk

Few data regarding ammonia exposure of general population is available in relationship with cellulose insulation. Dynamic tests performed by the French Institute CSTB have verified the stability of additives for such materials treated with ammonium salts, in conditions of high humidity (at 90% RH) that may be encountered in reality. All 11 tested cellulose insulation materials presented in varying degrees ammonia emission profiles (from 6-7 ppm to more than 200 ppm), reflecting instability of ammonium salts in these products.

Ammonia concentrations have been calculated using the Well-Mixed Room (WMR) model and results of CSTB tests. In particular the statistical distribution of the levels of relative humidity (weekly average) measured inside French housing and ammonia emission rate for the less stabilized cellulose insulation tested have been used (worst-case approach). Risk characterizations ratio (RCR) calculated with these exposure estimates and with the proposed subacute inhalation DNEL for irritation are above 1.

The number of exposed persons is subject to great uncertainty given the uncertain future development of this young market and in view of the eventual changes of the specific concentration limit value of boron compounds in mixtures. The boron-based formulations (blends including, among other substances, boric acid and/or borax) dominate the market (around 95%) and are the

[11] French decree of the 21st of June 2013 on the prohibition of import, sale, distribution and manufacture of cellulose wadding insulation materials with ammonium salt additives.

most used compounds in the different formulations added to cellulose insulation manufactured within (and outside) the European Union. About 250,000 tonnes of cellulose insulation are yearly placed on the EU market. The volume of cellulose insulation containing ammonium salts currently marketed inside the EU is estimated at 15,000 tonnes (around 5%, both produced and imported).

French toxic vigilance data identified in 2012 and in the first semester of 2013 about 40 people showing irritation of the upper airways, cough, and/or bronchospasm symptoms. In few cases the symptoms were more severe such as asthma decompensation. Over the same period, 20,000 housings were insulated in France. Near the odour threshold, persons exposed to ammonia can experience annoyance and believe the odour to be a nuisance. A Manufacturers Association (ECIMA) identified more than 100 complaints in France and on Internet forums many complaints were made, indicating that toxic vigilance data could be underestimated.

Other possible sources of ammonia

Ammonia is used in household cleaners, floor waxes and window cleaning products. Household ammonia cleaners typically contain lower levels of ammonia (between 5 and 10% in water).

However, for each French toxic vigilance dossier, people lived in a house insulated recently with cellulose insulation. It could be a new building or an old renovated housing. For each situation one or more exposed person smelled a characteristic odour of ammonia gas ("urine", "cat urine"). As part of the corrective measures, cellulose insulation was removed in most of the dossiers, which was followed by a rapid recovering of the symptoms - when they were present - and a rapid disappearance of the unpleasant odour.

Despite the lack of robust measurements data, the French committee of toxic vigilance coordination CCTV has considered – in the majority of the cases - likely the causality of cellulose insulation with regard to the origin of symptoms (see annexes 3 and 4).

A.2.2 Justification that action is required on a Community-wide basis

The proposed restriction covers cellulose insulation containing ammonium salts and placed on the European market.

The justification to act on a Community-wide basis origins from the need to avoid different legislations among the Member States with the risk of creating unequal market conditions:

- The proposed restriction would remove the potentially distorting effect that current (French) and potential future national restrictions may have on the free circulation of goods;
- Regulating ammonia emisions from cellulose insulation through Community-wide action ensures that all producers in different Member States are treated in an equitable manner;
- Acting at Community level would ensure a ‘level playing field’ among all producers and importers of the cellulose insolation.

Although no health cases due to emitted ammonia were found in other Member States than France up to date, there is no reason to believe that ammonium salts used in cellulose insulation in other EU Member States could not develop similar heath issues in the future. Several cases of ammonia exposure have been reported from treated cellulose insulation in the US.

A.2.3 Justification that the proposed restriction is the most appropriate Community-wide measure

In summary, the main conclusion of the analysis on the effectiveness/risk reduction capacity of the proposed restriction, as indicated in section E, are:

- **Risk reduction capacity:** the proposal is targeted to allow a complete reduction of the identified risks (i.e. eye and respiratory irritation) for consumers in all Member States. The restriction proposal is expected to regulate the exposure to indoor ammonia emissions from cellulose insulation containing ammonium salts.
- The proposed threshold for ammonia emission is **3 ppm** based on the **subacute inhalation** DNEL for general population should not represent a complete ban, as confirmed by several stakeholders (cellulose insulation manufacturers and formulators).
- **Implementability:** in the best case (no emission from the European cellulose insulation containing ammonium-based formulations) the implementation by the industry will only consist in proving through emission tests the lack of ammonia emissions. If this would not be the case, the stabilization of ammonium-based blends remains a feasible option (this fact is confirmed by formulators). Moreover, even if boron is not considered by the DS as a desirable option, currently it still remains for the industry the best technically, economically and legally feasible option. Therefore, in all cases, there are no concerns regarding implementability of this restriction given the possibility to stabilize and given the availability of boron-based formulations although this option is not desirable under a health view point. Industry actors concerned will be able to comply with this restriction at least in the short run by using boron, while consumers could decide to choose another cellulose insulation material.
- **Coherence with art. 129:** given the existence of an economically and technically feasible (although not desirable) alternative blend and the possibility to further stabilise ammonium-based formulations, the restriction shall be applicable 12 months after amendment of Annex XVII of the REACH Regulation enters into force.
- **Proportionality:** if the current cellulose insulation on the EU market does not emit ammonia, as claimed by the industry, the main cost elements of the proposed restriction would be reduced only to the cost of testing ammonia emissions (around 1000 euros per year per manufacturer). In case the cellulose insulation is proven to emit ammonia, the main costs would be the R&D to find such new formulations and the additional price of the formulations, in front of a risk reduction capacity of 100%. Moreover, as in the future it can be expected that the specific concentration limit of boron compounds could be lowered from 5.5% to 0.3% this restriction would leave a door open to the main currently existing alternative blend based on ammonium salts without condemning the cellulose insulation industry[12]. Therefore in terms of proportionality versus risk reduction capacity, this option is considered to be the most proportional measure (estimated total cost values at EU level).
- **Enforceability:** the compliance to this restriction on ammonia emissions from cellulose insulation by all relevant actors (producers, importers, and distributors) can be checked by the responsible authorities. The required control of producers, importers, and distributors is in line with regular monitoring procedures and shouldn't entail any specific challenge.
- **Monitorability:** results of the implementation of this restriction on ammonia emissions from cellulose insulation may be primarily monitored through enforcement by measuring the ammonia emissions from cellulose insulation materials which are placed on the EU market. Tailored indicators such as "Number of cellulose insulation which emit ammonia

[12] Communication of ECHA on Boric acid, Disodiumoctaborate tetrahydrate, Disodiumoctaborate anhydrate, 21 March 2014: http://echa.europa.eu/fr/view-article/-/journal_content/title/rac-delivers-sixteen-clh-opinions

above the established limit” or “Number of RAPEX notifications related to cellulose insulation emitting above the established limit” or “Number of dossiers opened by Poison Centres related to health cases from cellulose insulation” can be suggested in order to assess the effects of this restriction proposal.

As reported in section C, among all the existing techniques or process changes to be combined with the use of the available ammonium-based formulations in order to avoid/reduce ammonia emissions (such as degassing/or a standard storage period prior to use, vapour barriers, liquid impregnation, etc.) are not sufficient to address the problem only the stabilization of the blends seem effective in terms of risk management and economic proportionality.

Based on the arguments described in section E, it is concluded that a restriction based on ammonia emission under REACH Regulation is the most realistic, effective and proportionate option to manage the health risks related to ammonia emission from cellulose insulation.

The proposed option establishes a ban on the placing on the market of all cellulose insulation (no matter if intended for indoor or outdoor use) emitting more than **3 ppm** of ammonia within 12 months after adoption (i.e. phase-out by beginning of 2017). Analytical methods exist for determining the emissions of ammonia from cellulose insulation based on technical specification CEN/TS 16516. The harmonization at European level of the proposed test method, including sampling and sample preparation techniques, is recommended in order to guarantee the reliability and reproducibility of analytical results across Member States.

This option seems a fair option for the industry as it leaves a door open for the use of ammonium salts in stabilized blends if the manufacturer of cellulose insulation demonstrates that it does not emit more than the established limit. This means that those manufacturers who would have succeeded to stabilize their ammonium based formulations would be allowed to keep placing on the market their cellulose insulation.

B. Information on hazard and risk

B.1 Identity of the substances and physical and chemical properties

B.1.1 Name and other identifiers of the substances

Inorganic ammonium salts are added to cellulose insulation for their flame retardant properties. Such ammonium salts identified are the following:

- ammonium sulphate [CAS No 7783-20-2]
- ammonium dihydrogenorthophosphate [CAS No 7722-76-1]
- diammonium hydrogenorthophosphate [CAS No 7783-28-0]

Other salts may be used[13], such as ammonium chloride, sulfamate, polyphosphate or bromide. For most manufacturers, the exact composition of the additives is unknown: it is therefore not possible to establish an exhaustive list of ammonium salts that are used as flame retardant in cellulose insulation.

The substance of concern is ammonia, anhydrous [CAS 7664-41-7]. This section focuses therefore on that substance:

Substance name: ammonia, anhydrous IUPAC name: ammonia EC number: 231-635-3 CAS number: 7664-41-7 Molecular formula: H_3N

B.1.2 Composition of the substance

Not relevant for this proposal.

B.1.3 Physicochemical properties

Data mainly obtained from the public registration on the ECHA website (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances; date of access November 28th 2013).

Property	Value	Remarks
Molecular weight	17.03 g/mol	
Physical state at 20°C and 101.3 kPa	gaseous	Colourless, ammonia-like odour
Melting/freezing point	-77.7 °C	
Boiling point	-33 °C	
Vapour pressure	8611 hPa at 20°C	
Surface tension	No data are available for anhydrous ammonia	This endpoint is waived in accordance with Column 2 of Annex VII of the REACH Regulation as the substance is a gas at room temperature.
Water solubility	482 g/L at 25 ° C	Very soluble in water

[13] Flame Retardants: A General Introduction. WHO IPCS, Environmental Health Criteria 192. 1997.

Property	Value	Remarks
Partition coefficient n-octanol/water (log value)	0.23 at 20 °C	
Flash point	No data are available for anhydrous ammonia	This endpoint is waived in accordance with Column 2 of Annex VII of the REACH as the substance is an inorganic gas
Flammability / Explosive properties	Flammable gas	Anhydrous ammonia was found to be flammable, with a lower explosion limit of 16% and an upper explosion limit of 25%
Self-ignition temperature	651 °C	
Oxidising properties	Not predicted to be an oxidising agent	This endpoint is waived in accordance with Column 2 of Annex VII of the REACH Regulation as the substance is incapable of reacting exothermically with combustible materials on the basis of its chemical structure
Granulometry	Not relevant	This endpoint is waived in accordance with Column 2 of Annex VII of the REACH Regulation, as the substance is a gas
Stability in organic solvents and identity of relevant degradation products	No data	A waiver is proposed for this endpoint in accordance with column 2 of Annex IX of the REACH Regulation as the substance is inorganic
Dissociation constant	9.25 at 25°C	
Viscosity	Not relevant as the substance is a gas	

Conversion factor: 1 mg/m^3 = 1.414 ppm (v/v)

Table 4: Physicochemical properties of anhydrous ammonia

B.1.4 Justification for grouping

This restriction proposal addresses inorganic ammonium salts. For most manufacturers, the exact composition of the additives is not publicly available: it is therefore not possible to establish an exhaustive list of ammonium salts that are used as flame retardant by the cellulose insulation industry. The grouping of ammonium salts is justified since their use in cellulose insulation for their flame retardant properties might lead, under certain conditions – especially of humidity, to ammonia emissions which is the substance of concern of this proposal.

B.2 Manufacture and uses

Cellulose insulation is composed of around 85-90% fibers from recycled paper (mostly newspapers, phone books, shipping boxes, etc). The remaining 10-15% is composed of a blend of fire retardants and anti-fungal agents. Loose-fill cellulose insulation is therefore considered as a mixture. Cellulose insulation compressed in rigid or semi-rigid panels are considered as articles according to the definition given in the article 3.3 of REACH Regulation.

The level of details of data provided in Material Safety Data Sheets consulted varies strongly among manufacturers. The following examples show detailed and less detailed information provided in the MSDS of some cellulose insulation:

- 88 % cellulose insulation + 12 % ammonium dihydrogenorthophosphate [CAS No 7722-76-1].

- 91 % cellulose insulation + 9 % “mineral nitrogen salt”.
- Cellulose insulation + “flame retardant” or “proprietary blend of inorganic flame retardant”.

In these reported cases the mixture in not classified according to CLP Regulation 2008/58/EC (as inorganic ammonium salts are not classified).

For confidentiality reasons, only scarce information were obtained on the exact ammonium-based formulations used (including exact type and amounts of ammonium salts and biocides used) in cellulose insulation production inside and outside the EU. The type and relative percentages of each substance used by manufacturers of cellulose insulation are likely to differ considerably depending on the national requirements for obtaining the Technical Approval in terms of biocide and flame retardation, on the strategic choices done by the manufacturer in terms of Euroclass, on the functions covered by the substances used and on relative prices.
Confidential compositions of formulations tested by CSTB in 2013 are available in a separate annex.

About 250,000 tonnes of cellulose insulation are yearly placed on the EU market. The volume of cellulose insulation containing ammonium salts currently marketed inside the EU is estimated at 15,000 tonnes (around 5%, both produced and imported).
The boron-based formulations (blends including, among other substances, boric acid and/or borax) dominate the market (around 95%) and are the most used compounds in the different formulations added to cellulose insulation manufactured within (and outside) the European Union.
According to several formulators, a typical boron-based formulation is 4% boric acid + 8% aluminium hydroxide / trihydrate or magnesium sulphate as the most used fire retardants for cellulose insulation. Boron compounds are used in the limit of their specific concentration limit (according to CLP Regulation).

B.2.1 Manufacture, import and export of a substance

Manufacture

The production process of cellulose insulation widely used all around Europe starts with recycled newsprint/paper, which is initially ground down into small bits, around 5 cm long. Afterward the paper is sorted out and waste - such as plastic wrapping, metals (staples...) - is removed.
Next, additives are added to aid in fire-retardation and to prevent mould growth. The blends t of additives are in the form of powder (solid form) and are mixed with fibers. This process may be followed by a high speed fiberization process by a grinder that diminishes the size of the fibers to about 4 mm. Lastly, the insulation obtained is weighed and compressed (to maximize the amount transported and reduce transportation costs) before being bagged.
Throughout the process, a filtration system may allow the collection of paper dust.
Major steps of the process are synthesized in the following Figure:

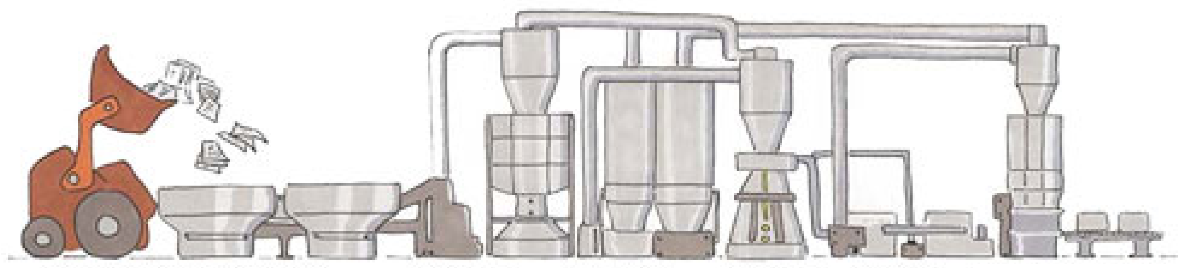


Figure 2: Cellulose insulation manufacturing (NrGaïa website, 2013)

From one plant to another the manufacturing process is not exactly the same, although all main phases are very similar. For example, some plants use refiners that reduce additives into very fine powder while others use the blends of additives exactly as delivered by the formulators. If the blend powder would be too fine it could block the machineries (distribution, aspiration or filtration systems).

According to the European Cellulose Insulation Association (ECIA), the overall estimated European production of the cellulose insulation is of around 250,000 tonnes per year. The European actors involved in the production and sale of cellulose insulation are between 40 and 50.
The estimated market value for such volumes of cellulose insulation is around 100 million of Euros per year.
The following Table presents the number of identified producers of cellulose insulation inside the EU, estimation of the number of employees in production of cellulose insulation in the EU and the share of EU production in the internal market.

	Inside the EU	Outside the EU but exporting to the EU
Number of identified producers of cellulose insulation	40	10
Number of identified producers of cellulose insulation with ammonium salts	6	?
Number of employees in production of cellulose insulation	400-500	?
Number of employees in production of cellulose insulation with ammonium salts	25	?

Table 5: Main data on the production of cellulose insulation inside the EU

Employment

Based on indications from a stakeholder, ANSES assumes that between 400 and 500 staff is directly employed in producing cellulose insulation products in the EU. This estimate is based on simple equation suggested by the industry. To produce 10,000 tonnes per year around 12 people are needed in the production department, two people are needed in the office and 5 people in the selling department. This gives 17 people per 10,000 tonnes per annum. If the EU market of cellulose insulation is around 250,000 tonnes then a good estimate would be around 500 employees. However, highly automated production processes might considerably reduce the personnel needed for the production.
Direct employment in the European production of cellulose insulation containing ammonium salts (estimated at around 15,000 t/year) should be around 25 persons. Indirect employment (distributors and installers) should be much larger but it is hardly feasible to estimate.

Import and export

The fact that cellulose insulation is a cumbersome material with a low added value highly increases the costs of transport and consequently the prices of cellulose insulation when it is transported. Therefore, the cellulose insulation being imported into the EU or exported outside the EU represents a very little share of the market. Import and export flows seem to concern mainly neighboring countries such as Switzerland.

According to ECIA[14], import and export of cellulose insulation are 1 to 2% of the total EU market of cellulose insulation. The percentage for import and export of cellulose insulation containing ammonium salts is estimated to be negligible if considered that less than 5% of the EU market use ammonium. Therefore, an estimate of less than 200 tonnes of EU imported and exported cellulose insulation still containing ammonium salts might be considered as a correct estimation. The main non-EU producer, Isofloc from Switzerland, claims not using ammonium salts in its production that is exported to Austria, Italy and France, but other smaller non-EU producers exporting to the EU might still use such formulations and export their cellulose insulation to the EU market.

Second hand market

Although cellulose insulation is a recyclable and reusable product, there should be no or very little second hand market in consideration of the fact that the installation and removal costs are quite high. It is assumed that people moving to a different building will not remove their insulation from the old place to the new one.

B.2.2 Uses

Cellulose insulation is used in wall and roof cavities (attic) to separate thermally and acoustically the inside and outside of the building.

The common standard by which insulation is measured, R-value, is the level of resistance to heat flow. R-value measures conductive resistance – the ability of a material to impede the flow of heat along the continuous chain of matter that makes up a solid material. Most of a home’s heat is typically lost through conduction. Cellulose is not unusual in this regard. Like many insulation materials, it provides an R-value of approximately R-3.5 per inch of thickness. The higher the R-value, the greater the insulating effectiveness.

The most common types of materials used for loose-fill insulation include cellulose, fiberglass, and mineral (rock or slag) wool. All of these materials are produced using recycled waste materials. Cellulose is primarily made from recycled newsprint. Most fiberglass contains 20% to 30% recycled glass. Mineral wool is usually produced from 75% post-industrial recycled content. These three materials can be compared as such[15]:

- Cellulose: R-value/inch = 3.2–3.8
- Fiberglass: R-value/inch = 2.2–2.7
- Rock Wool: R-value/inch = 3.0–3.3

[14] European Cellulose Insulation Association.
[15] Source: US Department of Energy. http://energy.gov/energysaver/articles/types-insulation

Depending on insulation needs and the building, there are several methods of application:

1- Spreading in the open air or blowing cellulose insulation

Spreading the air was performed by blowing dry the fibers on an open horizontal surface. At a density of between 30 and 40 kg/m^3, cellulose insulate floors and uninhabitable attics.

Figure 3: Illustration of spreading in the attic (NrGaïa website, 2013)

The use of this method requires special attention to the design of the partition to prevent dampness and condensation by penetration.

2- Insufflation or injection of cellulose insulation

Dry cellulose insulation can be insufflated / injected with a density between 45 and 70 kg/m^3 under pressure to a closed horizontal or vertical surface.
This method has a good ability to complete and fill the empty space with a seamless insulating layer and without compaction. Cellulose insulation may be applied for floors, walls and partitions.

Figure 4: Illustration of injection of cellulose insulation (NrGaïa website, 2013)

3- Flocking or wet screening of tissue

The flocking of tissue involves projecting the wetted material (with or without natural binder) at a density between 40 and 50 kg/m^3 on open vertical and horizontal walls (limited thickness).
The flocking of cellulose insulation provides a compact surface and without any subsidence.

Figure 5: Illustration of cellulose insulation flocking (NrGaïa website, 2013)

Cellulose insulation may also be used as articles (semi-rigid panels), as illustrated in the following figure.

Figure 6: Illustration of cellulose insulation panels

Cellulose insulation is flammable, and prone to smoldering. In order to prevent flaming or smoldering combustion, cellulose insulation is treated with flame retardant additives.

Ammonium salts are used as additives of such materials for their flame retardant properties. This use corresponds to the scope of this restriction proposal.
The mechanism for imparting durable flame retardation to cellulose is that of increasing the quantity of carbon, or charcoal, formed instead of volatile products of combustion, and flammable tars. Salts that dissociate to form acids or bases upon heating are usually effective flame retardants. Salts of strong acids and weak bases are the most effective compounds. Ammonium and amine salts are generally effective, as are Lewis acids and bases, either by themselves or when formed in combustion (WHO 1997).

To illustrate that property, ammonium salts such as monoammonium phosphate or ammonium sulphate are used in some fire extinguishing powders.

Ammonium salts have many other uses especially in the manufacture of fertilizers.

B.2.3 Uses advised against by the registrants

Not relevant in this proposal.

B.2.4 Description of targeting

Ammonium salts are used as additives in the cellulose insulation for their flame retardant properties. This use corresponds to the scope of this restriction proposal. The use of ammonium salts as flame retardants in any other type of insulation, any other mixture or article is not covered by this restriction proposal. Moreover, other uses of ammonium salts, are also not covered by the restriction proposal.

B.3 Classification and labelling

B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Ammonia, anhydrous [CAS No 7664-41-7]

CLP Classification (Table 3.1):
Press.Gas
Flam. Gas 2 – H221 (Flammable gas)
Skin Corr. 1B – H314 (Causes severe skin burns and eye damage)
Acute Tox. 3 – H331 (Toxic if inhaled)
Aquatic Acute 1 – H400 (Very toxic to aquatic life)

B.3.2 Classification and labelling inventory: industry's self classification(s) and labelling

Other Hazard Classes and Hazard Statement Codes notified according to CLP criteria and mentioned in some of the 38 Aggregated Notifications (CLP inventory consulted in November 2013):
Eye Dam. 1 - H318 (Causes serious eye damage)
STOT SE 3 - H335 (May cause respiratory irritation)

B.4 Environmental fate properties

B.4.1 Degradation

If released to the atmosphere, the half-life for ammonia in the atmosphere was estimated to be a few days; the reaction with acid air pollutants results in the formation of ammonium aerosols that can be removed by wet or dry deposition (HSDB[16]).

[16] Hazardous Substances Data Bank. Website consulted on November 2013. http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

B.4.2 Environmental distribution

Not relevant in that proposal.

B 4.3 Bioaccumulation

Not relevant in that proposal.

B.4.4 Secondary poisoning

Not relevant in that proposal.

B.5 Human health hazard assessment

Ammonia (CAS No 7664-41-7) has both natural and anthropogenic sources. It is a key compound in the global nitrogen cycle. It is formed in the body during decomposition of organic materials. Information on the distribution of endogenously-produced ammonia suggests that any NH_4^+ absorbed through inhalation would be distributed to all body compartments via the blood, where it would be used in protein synthesis or as a buffer, and that excess levels would be reduced to normal by urinary excretion, or converted by the liver to glutamine and urea.

This section does not present a full hazard assessment of ammonia, as this substance has already been subject to numerous reviews and risk assessment reports (e.g. ATSDR 2004, WHO IPCS 1986). In the following, endpoints are presented and briefly discussed only if they are relevant for this restriction proposal. Moreover, **this section focuses on inhalation route** which is the most appropriate route for a gas in this restriction proposal. Local airways effects are also especially of concern as this restriction proposal comes from toxic-vigilance data: mainly symptoms of mucosal irritation (nose, eyes, throat) and airways (cf section B.10 risk characterization).

Most of the information presented in this section is based from the following sources:

- ✓ Toxicological profile for ammonia, ATSDR, September 2004
- ✓ The INDEX Project - Critical Appraisal of the Setting and Implementation of Indoor Exposure Limits in the EU, Joint Research Center, January 2005
- ✓ Chemical Safety Report, Lead Registrant of ammonia (anhydrous), August 2010
- ✓ Risks related to gaseous emissions of green algae to the health of surrounding populations, walkers and workers. ANSES. June 2011 (French)
- ✓ The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals: 137. Ammonia. NR 2005:13

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Absorption (inhalation exposure)

Inhaled ammonia is mostly retained in the upper respiratory tract and is subsequently eliminated in expired air. Absorption data from human inhalation exposure support that only small amounts of ammonia are absorbed into the systemic circulation (Silverman et al. 1949; WHO 1986).

At low concentrations, inhaled ammonia dissolves in the mucous fluid lining of the upper respiratory tract and little reaches the lower airways. At ammonia levels associated with ambient air (i.e., 1 - 200 $\mu g.m^{-3}$), very little, if any, is absorbed through the lungs.

Experiments with volunteers show that ammonia, regardless of its tested concentration in air (range = 40–350 mg/m^3), is almost completely retained in the nasal mucosa (83–92%) during short-term exposure, i.e., up to 120 seconds (Landahl and Herrmann 1950). However, longer-term exposure (10–27 minutes) to a concentration of 350 mg/m^3 resulted in lower retention (4–30%), with 244-279 $mg.m^{-3}$ eliminated in expired air by the end of the exposure period (Silverman et al. 1949), suggesting an adaptive capability or saturation of the absorptive process. Nasal and pharyngeal irritation, but not tracheal irritation, suggests that ammonia is retained in the upper respiratory tract. Unchanged levels of blood-urea-nitrogen (BUN), non-protein nitrogen, urinary-urea, and urinary-ammonia are evidence of low absorption into the blood.

Absorption (through the eye)

Ammonia is readily absorbed into the eye; it was found to diffuse within seconds into cornea, lens, drainage system, and retina (Beare et al. 1988; Jarudi and Golden 1973). However, amounts absorbed were not quantified, and absorption into systemic circulation was not investigated.

Distribution (inhalation exposure)

Ammonia that reaches the circulation is widely distributed to all body compartments although substantial first pass metabolism occurs in the liver where it is transformed into urea and glutamine.

Information on the distribution of endogenously-produced ammonia suggests that any NH_4^+ absorbed through inhalation would be distributed to all body compartments via the blood, where it would be used in protein synthesis or as a buffer, and that excess levels would be reduced to normal by urinary excretion, or converted by the liver to glutamine and urea. If present in quantities that overtax these organs, NH_4^+ is distributed to other tissues and is known to be detoxified in the brain (Takagaki et al. 1961; Warren and Schenker 1964).

Metabolism and elimination

Ammonia and ammonium ion are metabolized to urea and glutamine mainly in the liver (Fürst et al. 1969; Pitts 1971). However, it can be rapidly converted to glutamine in the brain and other tissues as well (Takagaki et al. 1961; Warren and Schenker 1964). Studies using low levels of ammonia show that inhaled ammonia is temporarily dissolved in the mucus of the upper respiratory tract, and then a high percentage of it is released back into the expired air.

Absorbed ammonia into the systemic circulation is excreted by the kidneys as urea and urinary ammonium compounds (Gay et al. 1969; Pitts 1971; Richards et al. 1975; Summerskill and Wolpert 1970), as urea in feces (Richards et al. 1975), and as components of sweat (Guyton 1981; Wands 1981), but quantitative data are lacking.

B 5.2 Acute toxicity

There are many cases of human deaths resulting from inhalation of ammonia reported in the literature (as reviewed in ATSDR 2004). Most of these reports relate acute accidental exposure to ammonia gas. A review of the old literature on ammonia toxicity cites acute exposure to 5,000–10,000 ppm as being rapidly fatal in humans (Henderson and Haggard 1927; Mulder and Van der Zalm 1967) and exposure to 2,500–4,500 ppm as being fatal in about 30 minutes (Helmers et al. 1971; Millea et al. 1989). Immediate deaths resulting from acute exposure to ammonia appear to be caused by airway obstruction while infections and other secondary complications are lethal factors among those who survive for several days or weeks.

Several studies on human acute toxicity are also available.
In an inhalation exposure study (Silverman 1949), 7 male human volunteers were exposed to ammonia at a concentration of 500 ppm for 30 minutes using an oral-nasal mask. All 7 experienced upper respiratory irritation, which lasted up to 24 hours in 2 of the volunteers. Two subjects experienced marked lachrymation, in spite of the exposure being by oro-nasal mask. No coughing was noted.
In an inhalation exposure study, six humans were exposed to 30 and 50 ppm for 10 minutes (Mac Ewen et al. 1970). Four out of six human subjects described moderate irritation of the nose and eyes when exposed to 50 ppm (but not 30 ppm). All of the subjects rated the odor as "highly penetrating" at 50 ppm and 3 subjects gave the same rating to 30 ppm.
In another study, ten human subjects were exposed for 5 minutes to concentrations of 32, 50, 72 or 134 ppm in a dynamic chamber. 3 subjects exposed to 72 ppm of ammonia gas for 5 minutes experienced eye, nasal, and throat irritation (Industrial Bio-Test Laboratories 1973).

More recently, a study investigated the acute respiratory effects of low ammonia exposure on healthy persons (Sundblad B-M 2004). Twelve healthy persons underwent sham or ammonia (5 and 25 ppm) exposure randomly in an exposure chamber on three occasions. The exposure duration was 3 hours, 1.5 hours resting (seated) and 1.5 hours exercising (50 W on a bicycle ergonometer). Symptoms were registered repeatedly before, during, and after the exposure on visual analogue scales. Bronchial responsiveness to methacholine, lung function, and exhaled nitric oxide (NO) were measured before and 7 hours after the exposure. In addition, nasal lavage was performed, and peripheral blood samples were drawn before and 7 hours after the exposure.
This study showed that the inhalation of ammonia (5 and 25 ppm) causes symptoms but no inflammatory reaction in the upper airways, no alteration in the levels of exhaled NO, and no alteration in bronchial responsiveness to methacholine in healthy persons. The ratings of irritation and CNS effects were all significantly higher during exposure to 25 ppm of ammonia than during the control exposure. With 5 ppm of ammonia some of the ratings (discomfort of the eyes, solvent smell, headache, dizziness, and feeling of intoxication) were significantly increased. Furthermore, for all the ratings except "fatigue" and "feeling of intoxication", there was a clear and significant dose–response relationship.

Studies in animals indicate that the acutely lethal exposure concentration depends on the exposure duration. Exposure frequency also appears to be an important factor in determining lethality. Continuous exposure to 653 ppm for 25 days resulted in nearly 64% lethality in rats, whereas intermittent exposure (5 days/week, 8 hours/day) to nearly twice this concentration was tolerated for 42 days (Coon et al. 1970). It appears that male rats are more sensitive than female rats to the lethal effects of ammonia (Appelman et al. 1982; Stupfel et al. 1971). Animals exposed to acutely lethal concentrations show severe lesions in the respiratory tract that are similar to those observed in humans.

The available human and animal data provide strong evidence that acute-duration exposure to ammonia can result in site-of-contact lesions primarily of the eyes and the respiratory tract. Even fairly "low" airborne concentrations (35 $mg.m^{-3}$, i.e. 50 ppm) of ammonia produce rapid onset of eye, nose, and throat irritation, coughing, and narrowing of the bronchi. More severe clinical signs include immediate narrowing of the throat and swelling, causing upper airway obstruction and accumulation of fluid in the lungs. This may result in low blood oxygen levels and an altered mental status. Mucosal burns to the tracheobronchial tree can also occur. Children may be more vulnerable to corrosive agents than adults because of the smaller diameter of their airways (JRC, 2005).

Ammonia is classified Acute Tox. 3 – H331: Toxic if inhaled.

B 5.3 Irritation

The irritant properties of ammonia have been extensively studied in human studies.
Ammonia is an irritant and the primary and most immediate effect of ammonia exposure is burns to the skin, eyes, and respiratory tract. The topical damage caused by ammonia is probably due mainly to its alkaline properties. Its high water solubility allows it to dissolve in moisture on the mucous membranes, skin, and eyes, forming ammonium hydroxide, which causes liquefaction necrosis of the tissues (Jarudi and Golden 1973).

The eye is especially sensitive to alkali burns. Ammonia combines with moisture in the eyes and mucous membranes to form ammonium hydroxide. Ammonium hydroxide causes saponification and liquefaction of the exposed, moist epithelial surfaces of the eye and can easily penetrate the cornea and damage the iris and the lens (CCOHS, 1988; Way et al., 1992). Damage to the iris may eventually lead to cataracts (CCOHS, 1988).

Irritant properties have been described in several reported cases of accidental exposure (ATSDR, 2004). Exposures to levels exceeding 50 ppm result in immediate irritation to the nose and throat; however, tolerance appears to develop with repeated exposure. Exposure to an air concentration of 250 ppm is bearable for most persons for 30–60 minutes. Acute exposure to higher levels (500 ppm) has been shown to increase respiratory minute volume. Accidental exposures to concentrated aerosols of ammonium salts or high concentrations of ammonia gas have resulted in nasopharyngeal and tracheal burns, airway obstruction and respiratory distress, and bronchiolar and alveolar edema. Ammonia vapor readily dissolves in the moisture present on the skin, eyes, oropharynx and lungs forming ammonium hydroxide which dissociates to yield hydroxyl ions (ATSDR 2004).

The epidemiological study of (Holness et al. 1989) evaluated sense of smell, prevalence of respiratory symptoms (cough, bronchitis, wheeze, dyspnea, and others), eye and throat irritation, and lung function parameters (FVC, FEV1, FEV1/FVC, FEF50, and FEF75)[17] in humans exposed for an average of 12.2 years in a soda ash plant. The cohort consisted of 52 workers and 35 controls. The subjects were assessed on two workdays: on the first workday of their workweek and on the last workday of their workweek (they completed a questionnaire on their work history and their symptoms and underwent spirometry at start and end of their position). Spirometry was performed at the beginning and end of each work shift, so that each worker had four tests done. To determine the exposure levels, exposed and control workers were sampled over one work shift; the average sample collection period was 8.4 hours.
The mean TWA (time-weighted average) exposure concentration was 9.2 ppm (6.4 $mg.m^{-3}$) and is chosen as a NOAEC by ATSDR, OEHHA and US-EPA to derive a chronic human health risk value (see construction methods below).

In (Verberk 1977) study, sixteen volunteers - 8 experts (20-53 yr) and 8 non-experts (students, 18-30 yr) - were exposed for 2 h to ammonia. Eight of them (experts) knew the effects of ammonia from the literature, but had had no personal contact, whereas the remaining eight subjects (non-experts) were students from a non-science faculty and were not familiar with ammonia or experiments in laboratory situations. All members of a group were exposed on the same day to one of the concentrations tested (50, 80, 110, or 140 ppm).
Vital capacity (VC), forced expiratory response in 1s (FEV1) and forced inspiratory response 1s (FIV1) were determined. Before leaving the test chamber, every subject described at least one

[17] FVC: forced vital capacity. FEV1: forced expiratory volume in 1 sec. FEF: forced expiratory flow (50/75 = fraction remains of the forced vital capacity).

symptom as “unbearable”; three times this was irritation of throat, two times urge to cough, and one time each for smell, irritation of eyes, nose or breast, headache, and general discomfort. All subjects perceived a hypo-esthesia of the exposed skin and two noted excessive lacrimation. There were no effects on VC, FEV1 or FIV1. Subjective responses (smell, irritation of eyes and throat, discomfort etc) were recorded every 15 minutes and appeared more pronounced in the non-expert group; 140 ppm was not tolerated by the latter for 2 hours. The results of the study indicate that a level of 140 ppm ammonia is not tolerable by those not acclimated to exposure, due to irritant effects. It is noted that at the lowest concentration, no significant deterioration of lung function appears. Only eye irritations are present. The threshold of 50 ppm can be considered a LOAEC that protects the most important effects in the airways, despite the choice of tests used to characterize the pulmonary effects.

Since ammonia is a respiratory tract irritant, persons who are hyperreactive to other respiratory irritants, or who are asthmatic, would be expected to be more susceptible to ammonia inhalation effects. The results of an epidemiological study of a group of workers chronically exposed to airborne ammonia indicate that ammonia inhalation can exacerbate existing symptoms including cough, wheeze, nasal complaints, eye irritation, throat discomfort, and skin irritation (Ballal et al. 1998).

B 5.4 Corrosivity

Ammonia has corrosive properties and is classified Skin Corr. 1B H314: Causes severe skin burns and eye damage.
Dermal Corrosion is the production of irreversible damage of the skin; namely, visible necrosis through the epidermis and into the epidermis, following the application of a test substance for up to 4 hours.

Due to these properties, massive exposure to ammonia can cause eye damage, skin burns, severe inflammation of the respiratory tract (laryngitis, tracheobronchitis, and pulmonary oedema), and death.

B 5.5 Sensitisation

There is no data on skin sensitisation provided by the lead registrant of ammonia: no *in vivo* testing is indeed required if the substance is classified for corrosivity (REACH Regulation No 1907/2006/EC, annex VII, 8.3). No data has been identified in the literature.

Ammonia is not known to be a respiratory sensitizer. Several case reports describe occupational asthma that developed due to exposure to aerosols that contained ammonium compounds (Ballal et al. 1998; Lee et al. 1993; Weir et al. 1989).

Exposure to ammonia may also result in an exacerbation of preexisting asthma. Shim and Williams (1986) surveyed 60 patients with a history of asthma worsened by certain odors. Nearly 80% of these patients claimed to have an exacerbation of asthma following exposure to household cleaners containing ammonia.

B 5.6 Repeated dosed toxicity

Studies with read-across compounds provide information on the systemic toxicity of ammonia and its salts (via oral route).

A 4-week screening study in the rat with diammonium phosphate (confidential study report, 2002) revealed only minor effects on weight gain and clinical chemistry parameters. A NOAEL of 250 mg/kg bw/d can be determined for this study, equivalent to 68 mg/kg bw/ammonia. A 90-day study in the rat with ammonium sulphate showed only minor effects at high dose levels (diarrhoea, renal pathology); a NOAEL of 886 mg/kg bw/d was determined, equivalent to 225 mg/kg bw/d ammonia (Tagaki et al, 1999).

Renal effects have been observed in animals following repeated oral doses of ammonium chloride. These effects may be secondary to chronic acidosis produced from the interaction of ammonium chloride with water (which results in an increased H+ concentration) rather than from a direct effect of ammonium ion on the kidney. Renal enlargement, increased blood ammonia content, and increased urinary ammonia have been reported in rats exposed to 180–433 mg/kg/day for 3–7 days (Benyajati and Goldstein 1975; Janicki 1970; Lotspeich 1965), but are unlikely to be indicative of renal pathology.

For the inhalation route, a number of non-standard studies of various duration and in different species are available in the literature. The data indicate that the primary effect of exposure to inhaled anhydrous ammonia is local irritation of the respiratory tract.
In (Broderson 1976) Sherman and Fischer rats were exposed to environmental ammonia, derived from natural sources for 75 days, or to purified ammonia for 35 days. Rats were either inoculated intranasally with *M. pulmonis* prior to exposure, or left untreated. The average ammonia concentrations were 105 $mg.m^{-3}$ (148 ppm) for 75 days and 175 $mg.m^{-3}$ (247 ppm) for 35 days exposure. Ammonia exposure (from either source) significantly increased the severity of the rhinitis, otitis media, tracheitis and pneumonia (including bronchiectasis) characteristic of murine respiratory mycoplasmosis (rats infected with M. *pulmonis*). The prevalence of pneumonia showed a strong tendency to increase directly with environmental ammonia concentration. Rats not infected with *M. pulmonis*, developed anatomic lesions limited to the nasal passaged following ammonia exposure.
Histological changes in the olfactory and respiratory epithelia of the nasal cavity were similar for all exposed rats. The LOEC was an average exposure level of 105 $mg.m^{-3}$ for 75 days.

In a 50-day study (Stolpe & Sedlag, 1976), male Wistar rats were exposed to two concentrations of ammonia gas (35 or 63 $mg.m^{-3}$), continuously for 50 days. Concurrent controls remained untreated. There was no mortality at either concentration, and no treatment-related clinical effects were observed. No information on any local effects. Body weight gain and food intake, as compared to control values, were not significantly affected by ammonia exposure. At 63 $mg.m^{-3}$ rats showed increased haemoglobin and haematocrit levels compared to controls. The NOAEC was 35 $mg.m^{-3}$ (50 ppm).

B 5.7 Mutagenicity

In vitro

The mutagenicity of anydrous ammonia was investigated in a Ames test in S. *typhimurium* TA98, TA100, TA1535, TA1537 and TA1538) and in E. *coli* WP2 *uvrA* (Shimizu 1985). The test method (OECD Guideline 471) was modified appropriately to investigate a volatile test substance. Studies were performed in duplicate in the presence and absence of an exogenous metabolic activation system (Aroclor 1254 -induced male Sprague-Dawley rat liver S9 fraction). No evidence of mutagenicity was seen under the conditions of this assay: ammonia was negative for genotoxicity in S. *typhimurium* and E. *coli* with and without metabolic activation.

Visek et al. (1972) noted reduced cell division in mouse fibroblasts cultured in media to which ammonia and ammonium chloride were added. The effect was noted in cultures irrespective of pH.

In vivo

The potential for the genotoxicity of ammonium chloride was investigated in a bone marrow micronucleus assay in mice (OECD Guideline 474) (Hayashi 1988). Male ddY mice were administered ammonium chloride by single intraperitoneal injection at dose levels of 0, 62.5, 125, 250 or 500 mg/kg bw or as four injections within 24 hours at dose levels of 31.3, 62.5, 125 or 250 mg/kg bw. The maximum dose of ammonium chloride was determined by pilot experiments using the multisampling at multi-dose levels method. Dose levels of up to the maximum tolerated dose were used. Mice were killed 24 h after administration and femoral bone marrow cells were harvested, fixed and stained. 1000 PCEs per animal were scored using a light microscope and the number of micronucleated erythrocytes (MnPCEs) recorded. No evidence of genotoxicity was seen under the conditions of this assay.

Human data

A single study examined the genotoxic effect of ammonia in humans (Yadav and Kaushik 1997). Analysis of blood samples from 22 workers exposed to ammonia in a fertilizer factory and 42 control workers not exposed to ammonia showed increased frequency of chromosomal aberrations (CAs) and sister chromatid exchanges (SCEs), increased mitotic index (MI). Moroever, the frequency of CAs and SCEs increased with exposure duration.

No detail was given as to how well the exposed and control group were matched for age, smoking habits etc. Furthermore, it appears that gaps were included in the cytogenetic analysis. Given these limitations and the small size of this study, the low levels of ambient ammonia and the likely exposure to other chemicals no conclusions can be drawn regarding the mutagenicity of ammonia (HPA 2011).

Conclusion

No clear conclusions could be provided on the clastogenic and mutagenic properties of ammonia.

B 5.8 Carcinogenicity

One of 10 adult male mice exposed to a vapor of 12% ammonia solution for 15 minutes/day 6 days/week for 8 weeks had mitotic figures with an intact basement membrane and a carcinoma in situ in one nostril and one mouse had an invasive adenocarcinoma of the nasal mucosa (Gaafar et al. 1992). However, there is no conclusive evidence that ammonia played a role in the induction of the carcinoma.

No evidence of carcinogenicity was seen in a rat dietary study with ammonium sulphate (Ota et al, 2006). The NOAEL for this study was 0.6% (dietary level) equivalent to 256 and 284 mg/kg bw/d in males and females respectively [67 and 74 mg/kg bw/d ammonia equivalents].

A study report (confidential, 1992) investigated the promoting activity of ammonia on stomach cancer in rats. No guideline was followed. The test material was administered as a 0.01% solution in water (i.e. aqueous ammonia) by oral route. After the rats were treated with 0.01% ammonia solution for 24 weeks there was a significantly higher incidence of gastric cancer (percent of animals with tumors and number of tumors per rat). 3 out of 37 rats in the treated group, and 0 out of 3 rats in the control group had metastasis of the liver. The number of rats with gastric tumours was 12/39 in the control group and 26/37 in the treatment group. The number of gastric cancers per

tumour was significantly higher in ammonia treated rats than controls, 2.1 and 1.3 respectively. All animals showed signs of gastritis.
Ammonia was found to be a local irritant and may consequently act as a promoter of gastric carcinogenesis.

Carcinogenic effects would not be expected from exposures insufficient to cause irritant effects. There is no conclusive evidence that ammonia is carcinogenic, though it can produce inflammatory lesions of the colon and cellular proliferation, which could increase susceptibility to malignant change (JRC, 2005).
Ammonia has not been evaluated and thus not classified for carcinogenic effects by the International Agency for Research on Cancer (IARC).

B 5.9 Toxicity for reproduction

A guideline-comparable two-generation study (equivalent to OECD 416) with ammonium perchlorate did not identify any effects on reproductive parameters (York et al, 2001). This study examines the effects of ammonium perchlorate on the male and female reproductive systems in rats, and on the growth and development of offspring. Adult Sprague-Dawley rats (30/sex/group) were given continuous access to ammonium perchlorate in their drinking water at doses of 0, 0.3, 3, and 30 mg/kg/day. A read-across is proposed by the lead registrant of ammonia as ammonium perchlorate will dissociate in aqueous solutions to give ammonium and perchlorate ions.
The study did identify effects on the parental thyroid associated with perchlorate exposure; however findings are not attributable to ammonium. The results of the study therefore suggest that exposure to ammonium is not associated with reproductive toxicity.

In a non-guideline farm animal reproduction study, no statistically significant differences were noted in ovarian or uterine weights of pigs exposed to about 7 or 35 ppm ammonia for 6 weeks (Diekman et al. 1993). No unexposed controls were included in that study.

No information was identified regarding reproductive effects of ammonia in humans following inhalation exposure.

No clear conclusions could be provided on the reproductive effects of ammonia and ammonium ion.

B 5.10 Other effects

Immunological effects
Secondary infections often complicate the clinical outcome of burns and respiratory lesions related to exposure to highly concentrated aerosols derived from anhydrous ammonia (Sobonya 1977; Taplin et al. 1976). However, there is no evidence that the decreased immunological resistance represents a primary impairment of the immune system in humans following exposure to ammonia.

Nevertheless, studies in animals have shown that acute and long-term exposure to ammonia can decrease the resistance to bacterial infection and decrease immune response to infection. A significant increase in mortality was observed in mice exposed to ammonia for 168 hours followed by exposure to the LD50 of *Pasteurella multocida* (Richard et al. 1978). Exposure of rats to ammonia at ≥25 ppm for 4–6 weeks following inoculation with *Mycoplasma pulmonis* intranasally significantly increased the severity of respiratory signs characteristic of murine respiratory mycoplasmosis (Broderson et al. 1976). Guinea pigs exposed to 90 ppm ammonia for 3 weeks

developed a significant decrease in the cell-mediated immune response to challenge with a derivative of tuberculin (Targowski et al. 1984).
Furthermore, the response of blood and bronchial lymphocytes to mitogens (phytohemagglutinin, concanavalin A, purified protein derivative of tuberculin) was markedly reduced. The hemodynamic response (increased total pulmonary blood flow resistance) to E. coli endotoxins in the lungs of pigs was eliminated by exposure to up to 100 ppm ammonia for 6 days, which may affect the ability of the lungs to resist bacterial infection (Gustin et al. 1994). Also, a reduction in gamma globulin concentration was reported in pigs exposed to 100 ppm ammonia for 31–45 days (Neumann et al. 1987).

Odour perception

Odour is characterized as sharp, pungent and intensely irritating.
Reported odour threshold values range from 0.03 to 37.5 mg/m^3 (0.041 to 53 ppm) with a geometric mean of 11.8 mg/m^3 (17 ppm) (AIHA, 1989)

Other estimates of odor thresholds for ammonia widely vary from 0.03-72 mg/m^3 (Ferguson et al., 1977; Henderson and Haggard, 1943; Ruth, 1986). Near the odor threshold, persons exposed to ammonia can experience annoyance and believe the odor to be a nuisance.

Odor and lateralization (irritation) thresholds (LTs) for ammonia vapor were measured using static and dynamic olfactometry by (Smeets et al. 2006). The purpose of the study was to explore the test–retest reliability and comparability of dynamic olfactometry methodology, generally used to determine odor thresholds following European Committee for Standardization guidelines in the context of odor regulations to outside emissions, with static olfactometry. Within a 2-week period, odor and LTs for ammonia were obtained twice for each method for 24 females. No significant differences between methods were found: mean odor detection thresholds (ODTs) were 2.6 ppm for either method (P = 0.96). Mean LTs were 31.7 and 60.9 ppm for the static and dynamic method, respectively (P = 0.07).

People that are unusually susceptible

Persons who suffer from severe liver or kidney disease may be susceptible to ammonia intoxication, as NH_4^+ is biotransformed and excreted primarily by these organs (Córdoba et al. 1998; Gilbert 1988; Jeffers et al. 1988). Individuals with hereditary urea cycle disorders are also at risk (Schubiger et al. 1991). Levels that are likely to be encountered in the environment, with the exception of those resulting from high-level accidental exposures, are insignificant, due to the low absorption rate, in comparison with levels produced within the body (WHO 1986).

Furthermore persons who are hyperreactive to other respiratory irritants, or who are asthmatic, would be expected to be more susceptible to ammonia inhalation effects.

Dose-effect relationships in man after exposure to ammonia via inhalation

The Nordic Senior Executive Committee for Occupational Environmental Matters initiated a project in order to produce criteria documents to be used by the regulatory authorities in the Nordic countries as a scientific basis for the setting of national occupational exposure limits.
The document aims at establishing dose-response/dose-effect relationships and defining a critical effect based only on the scientific literature. For ammonia, the final version was accepted by the Nordic Expert Group in September 2005 with irritation as critical effect.

The table below summarizes dose-effects relationships.

Concentration (ppm)	Duration	No. of exposed	Effect
5	180 min	12	No upper-airway inflammation or increased bronchial responsiveness. Increased symptom ratings for discomfort in the eyes, solvent smell, headache, dizziness, and feeling of intoxication. Ratings correspond to "Hardly at all"
9.2 (time-weighted average)	Chronic exposure	58	No effects on respiratory or cutaneous symptoms, pulmonary function, or odour sensitivity
0.03-9.8	Chronic exposure	77	No effects on respiratory symptoms
10-20	240 min	43	Increased symptom ratings in 33 non-habituated volunteers for: sum of symptom scores, and olfactory symptoms
12	2 min	1	Asthma, rhonchi in both lungs
16-25	30 min	6+8	Neither healthy subjects nor asthmatics showed significant change in pulmonary function or bronchial hyperreactivity
25	180 min	12	No upper-airway inflammation or increased bronchial responsiveness. Increased rating for all symptoms: discomfort in the eyes, nose, throat and airways, breathing difficulty, solvent smell, headache, fatigue, nausea, dizziness and feeling of intoxication. Irritation ratings correspond to "Somewhat"
<=25 (geometric mean)	Chronic exposure	138	Increased relative risk (95% CI) for wheezing 2.26 (1.32-3.88)
>25 (geometric mean, maximal exposure level 185 ppm)	Chronic exposure	17	Increased relative risk (95% CI) for cough 3.48 (1.84-6.57), wheezing 5.01 (2.38-10.57), phlegm 3.75 (1.97-7.11), dyspnoea 4.57 (2.37-8.81), bronchial asthma 4.32 (2.08-8.98)
20 and 40	240 min and 2x30 min	43	Increased symptom ratings in 33 non-habituated volunteers for sum of symptom scores, olfactory symptoms, irritative symptoms
30	10 min	5	No irritation in 3/5 and "just perceptible" irritation of eyes and nose in 2/5
50	10 min	6	"Moderate" irritation of eyes and nose in 4/6
50	240 min	43	Increased symptom ratings for sum of symptom scores, olfactory symptoms, irritative symptoms. Conjunctival hyperaemia in 3 of 33 (9%) non-habituated
50-80	120 min	16	VC, FEV, and FIV did not decrease more than 10%. Mild irritation in eyes and throat
100	5-30 s	23	Increased nasal airway resistance during the exposure periods. Nasal irritation in 11/23
110	120 min	16	VC, FEV, and FIV did not decrease more than 10%. Irritation in eyes and throat, cough
140	<=120 min	16	VC, FEV, and FIV did not decrease more than 10%. Intolerable for 8/16
>150		6	All subjects experienced lachrymation accompanied by dryness of the nose and throat during occasional excursions above 150 ppm in semi-controlled exposures to ammonia in an ammonium bicarbonate plant
1700 (retrospective estimates)	Accident		Coughing and laryngospasm along with oedema of the glottic region
2500-4500 (retrospective estimates)	Accident		Fatal in approximately 30 min

Concentration (ppm)	Duration	No. of exposed	Effect
10,000 (retrospective estimates)	Accident		Rapid respiratory arrest. Anhydrous ammonia in concentrations of 10 000 ppm sufficient to evoke skin damage

Abbreviations: CI: confidence interval, VC: vital capacity, FEV: forced expiratory volume, FIV: forced inspiratory volume.

Table 6: Dose-effect relationships in man after exposure to ammonia via inhalation (The Nordic Expert Group, 2005)

B 5.11 Derivation of (ANSES) subacute DNEL for irritation

Acute and chronic toxicity of ammonia via the inhalation route is mainly due to the irritating effects of the substance, in the airway or ocular mucosa. The different selected human health risk values (HRV) found in the literature and the DNELs derived by the lead registrant for the general population are all based on these effects.

Acute exposure

Two acute human health risk values (HRV) were identified in a collective expertise report (ANSES 2011), based on human data:

Office of Environmental Health Hazard Assessment (OEHHA) - 1999	
HRV	Acute reference exposure level: **REL_A = 3.2 mg.m^{-3} (4.5 ppm)**
Key studies	Industrial Biotest Laboratories, 1973 MacEwen *et al.*, 1970 Silverman *et al.*, 1949 Verberk, 1977
Exposure route	Inhalation
Tested concentrations	No information
Exposure duration	1 hour
Study population	Human
Critical effect	Moderate ocular and respiratory irritation
Critical concentration	Exposure concentrations of 4 studies were adjusted for one hour, from equation $C^{4.6} \times t = k$. The coefficient 4.6 was calculated from a log-normal probit analysis of all data from the four studies (the value of 4.6 was finally adopted after a X^2 analysis). A BMC_5L_{95}[18] of 9.5 mg.m^{-3} (13.6 ppm) was calculated from the log-normal probit model.
Assessment factor	AF = 3 (interindividual)

[18] BMCL: A statistical lower confidence limit (here 95%) on the concentration at the BMC. A BMC is a concentration that produces a predetermined change in response rate of an adverse effect (here the benchmark response is 5 %).

Agency for Toxic Substances and Disease Registry (ATSDR) - 2004	
HRV	Acute minimal risk level: **MRL_A = 1.19 mg.m^{-3} (1.69 ppm)**
Key studies	Verbek *et al.* (1977)
Exposure route	Inhalation : 1 exposure at Day 1 + 1 new exposure at Day 8, at one of the tested concentrations
Tested concentrations	50, 80, 110 or 140 ppm (35 ; 57 ; 78 or 99 mg.m^{-3})
Exposure duration	2 hours
Study population	16 volunteers: 8 "experts" knowing, by the scientific literature, the toxic effects of ammonia but had never been in contact 8 "non-experts" with no scientific knowledge on this subject neither on controlled studies
Critical effect	Mild irritation of eyes, nose and throat in 8 subjects 'non-experts' (concentration-dependent increase in the number of complaints of nuisance odor, irritation of eyes and throat, coughing and general discomfort)
Critical concentration	LOAEC = 35 mg.m^{-3} = 50 ppm
Assessment factors	AF = 30 10 to protect sensitive sub-groups 3 for the use of a LOAEC
Comments	Several limitations have been identified in the key study: - There is no "control" group, individuals exposed only to air; - Subjective response rate is higher in patients 'non-experts'; - No statistical analysis of results was performed. However, this study highlights events of discomfort among healthy individuals at concentrations of 50 ppm (35 mg.m^{-3}), an effect thought to be harmful and to be avoided.

MRL_A proposed by ATSDR is based only on the study Verbek et al. (1977), unlike the OEHHA which compiles the results of four different studies, including also that of Verbek. As indicated by the ATSDR, this study includes a number of important limitations on the characterization of adverse effects and their statistical interpretation.

The OEHHA has compiled the results of several different studies (including Verbek et al., 1977) by means of a benchmark dose modeling, whose main interest is to have a confidence interval for each of the values describing the dose-response relationship. The OEHHA has finally chosen the lower limit of the confidence interval of 95% associated with a 5% increase in the incidence of respiratory and eye irritation compared to control concentration (BMC_5L_{95}). However, this approach raises the question of the relevance of the meta-analysis and compilation of different experimental data (different experimental protocols, access to personal data etc.).

In the REACH registration dossier[19], the same LOAEC (50 ppm or 36 mg/m^3) was used by the lead registrant but with an assessment factor of 5 to cover intraspecies (general public). No assessement factor for LOAEC/NOAEC extrapolation is proposed. The resulted short-term inhalation DNEL is 7.2 mg/m^3.

[19] Chemical Safety Report, Lead Registrant of ammonia (anhydrous), August 2010.

Chronic exposure

The three chronic HRV found in the literature (scientific reports) for ammonia are all based on the same key study (epidemiological study in the workplace, Holness et al. 1989).

US-EPA - 1991	
HRV	Reference Concentration: **RfC = 0.1 mg.m^{-3} (0.14 ppm)**
Key studies	Holness *et al.* (1989) strengthened by Broderson *et al.* (1976)
Exposure route	Inhalation
Tested concentrations	A *time-weighted average* (TWA) was defined from the exposure concentrations in exposed subjects and control group, on an average of 8.4 hours
Exposure duration	12.2 years on average
Study population	52 men working in a factory manufacturing sodium carbonate Control group: 35 subjects
Critical effect	Lack of evidence of impaired lung function or subjective symptoms
Critical concentration	NOAEC = 6.4 mg.m^{-3} (TWA) Time adjustment: $NOAEC_{ADJ}$ = NOAEC x 5/7 x 10/20 = 2.3 mg m^{-3}. The time adjustment is based here on the number of days worked per week (5 days out of 7) and on the capacity of ventilation between days worked or not (10 vs. 20 m^{3}/day).
Assessment factors	AF=30 10 to protect sensitive individuals; 3 to account for the lack of data on chronic toxicity and reproductive toxicity as well as the small difference between the calculated NOAEC in humans and the LOAEC identified in animals.
Comments	The proposed RfC is supported by the results of a study conducted in animals (Broderson *et al.*, 1976). This study shows an increase in the severity of rhinitis and pneumonia with observation of respiratory inhalation injury in rats. For this study, a LOAEC is determined at 17.4 mg.m^{-3}. Allometric adjustment is applied to the LOAEC taking into account a $RGDR_{ET}$ (regional gas dose ratio, extrathoracic) of 0.1068. This factor takes into account the rate of ventilation in rats and humans and saturation data. $LOAEC_{HEC}$ is calculated as follows: $LOAEC_{HEC}$ = LOAEC x $RGDR_{ET}$ = 1.9 mg.m^{-3}. This value is considered little different from the $NOAEL_{ADJ}$ determined from human data. However, the approach of calculating the HRV from Holness et al (1989) study has two advantages: - using human data overcomes uncertainties on inter-species; - the critical concentration corresponds to a no-effect threshold, unlike the adverse effects observed with threshold defined from the animal study.

OEHHA - 1999	
HRV	Chronic reference exposure level: **REL_C = 0.2 mg.m^{-3} (0.28 ppm)**
Key studies	Holness *et al.* (1989) strengthened by Broderson *et al.* (1976)
Exposure route	Inhalation
Tested	A *time-weighted average* (TWA) was defined from the exposure

concentrations	concentrations in exposed subjects and control group, on an average of 8.4 hours
Exposure duration	12.2 years on average
Study population	52 men working in a factory manufacturing sodium carbonate Control group: 31 subjects
Critical effect	Respiratory symptoms, eye and nasal irritation
Critical concentration	NOAEL = 6.4 $mg.m^{-3}$ (TWA) Time adjustment: $NOAEC_{ADJ}$ = NOAEC x 5/7 x 10/20 = 2.3 $mg.m^{-3}$. The time adjustment is based here on the number of days worked per week (5 days out of 7) and on the capacity of ventilation between days worked or not (10 vs. 20 m^3/day).
Assessment factors	AF = 10 10 for interindividual variability
Comments	The key study is the only study evaluating chronic toxicity of ammonia, driving in humans and published in a scientific peer-reviewed journal.

ATSDR - 2004	
HRV	Chronic minimal risk level: **MRL_C = 0.07 $mg.m^{-3}$**
Key studies	Holness *et al.* (1989)
Exposure route	Inhalation (occupational exposure)
Tested concentrations	A *time-weighted average* (TWA) was defined from the exposure concentrations in exposed subjects and control group, on an average of 8.4 hours
Exposure duration	12.2 years on average
Study population	52 men working in a factory manufacturing sodium carbonate Control group: 35 subjects
Critical effect	Olfactory perception, worsening of respiratory symptoms (cough, bronchitis, wheezing, dyspnea, etc.), irritation of the eyes and throat and changing parameters of pulmonary function.
Critical concentration	NOAEC = 6.4 $mg.m^{-3}$ (TWA) Time adjustment: $NOAEC_{ADJ}$ = NOAEC x 8/24 x 5/7 = 1.5 mg m^{-3}. The time adjustment is based here on the number of days worked per week (5 days out of 7).
Assessment factors	AF = 30 10 to protect sensitive individuals 3 for the lack of studies of reproductive toxicity
Comments	The subjects of the study population have been analyzed in the first and last days of the work week. No association was observed between increased duration of exposure to ammonia and the severity or frequency of respiratory symptoms. However, confidence levels and duration of exposure is low.

The determination of the critical concentration is based on the same approach by the three organizations. The differences are based on:

- The time adjustment: ATSDR considers a daily and hourly adjustment, while the US-EPA and OEHHA consider a daily and respiratory adjustment considering a higher respiratory volume during the professional activity.

- The application of an assessment factor for the lack of data: in addition to the interindividual assessment factor of 10, ATSDR adds a factor of 3 to account for the lack of data on reproductive toxicity. The US-EPA also applies this factor, which includes the uncertainty associated with the lack of data on reproductive toxicity and chronic toxicity, as well as the small difference between the NOAEC derived from human data and the LOAEC derived from animal data.
- The analysis of animal data confirming the choice of the key study: the US-EPA and OEHHA propose to confirm the results obtained by data from a study conducted in rats (Broderson *et al.*, 1976.). This study provides a detailed description regarding its non-standardized operating mode, report the US-EPA and OEHHA.

In the REACH registration dossier[20], the starting point used to derive the long-term inhalation DNEL (NOAEC of 20 ppm, 14 mg.m^{-3}) is derived from the weight of evidence from the human studies, based on the results of the human volunteer studies (not cited in the discussion part of the CSR for the DNEL derivation). An assessment factor of 5 is used to cover intraspecies (general public): the resulted long-term inhalation DNEL is 2.8 mg.m^{-3}. To support that choice, a threshold of 18 mg.m^{-3} (25 ppm) for respiratory irritation is given, based on the results of the human volunteer studies.

GESTIS - International limit values for chemical agents[21]

This database contains a collection of occupational limit values for hazardous substances gathered from various EU member states, Australia, Canada (Ontario and Québec), Japan, New Zealand, Singapore, South Korea, Switzerland, and the United States as of August 2013. Limit values of more than 1,700 substances are listed.

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m³	ppm	mg/m³
Australia	25	17	35	24
Austria	20	14	50	36
Belgium	20	14	50	36
Canada - Ontario	25	/	35	/
Canada - Québec	25	17	35	24
Denmark	20	14	40	28
European Union	20	14	50	36
France	10	7	20	14
Germany (AGS)	20	14	40	28
Germany (DFG)	20	14	40	28
Hungary		14		36
Ireland	20	14	50	36
Italy	20	14	50	36
Latvia	20	14	50	36

[20] Chemical Safety Report, Lead Registrant of ammonia (anhydrous), August 2010.
[21] http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Internationale-Grenzwerte-f%C3%BCr-chemische-Substanzen-limit-values-for-chemical-agents/index-2.jsp. Website consulted in March 2014.

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m³	ppm	mg/m³
New Zealand	25	17	35	24
Poland	/	14	/	28
Singapore	25	17	35	24
South Korea	25	18	35	27
Spain	20	14	50	36
Sweden	20	14	50	36
Switzerland	20	14	40	28
The Netherlands	/	14	/	36
USA - NIOSH	25	18	35	27
USA - OSHA	50	35	/	/
United Kingdom	25	18	35	25

Table 7: Occupational limit values according GESTIS database (March 2014)

Remark:
European Union : Indicative Occupational Exposure Limit Values and Limit Values for Occupational Exposure
France: Restrictive statutory limit values
Germany (AGS): 15 Minutes average value
Germany (DFG): STV 15 minutes average value
Ireland: 15 minutes reference period
Latvia: 15 minutes average value
Sweden: Ceiling limit value, refers to a 5 minutes period.
USA – NIOSH: 15 minutes average value

Choice of the (ANSES) subacute DNEL for irritation used in this proposal

Emission tests performed with EN ISO 16000 standards show an increase of ammonia concentrations in the first 2 weeks of testing (14 days), passing through a maximum value and then slower decrease emissions. Considering that these tests were performed in a worst-case situation - relative humidity of 90% which maximizes the emission of ammonia during the first two weeks, the exposure is considered as subacute (defined here as between 1 and 14 days of exposure).

Similarly to ATSDR and the lead registrant of ammonia, ANSES proposed the LOAEC of 50 ppm from the epidemiological study of Verbek *et al.* (1977) as a starting point. This value corresponds to the identification of moderate irritative symptoms as stated in the dose-effect relationship for ammonia (see Table 6). Perception, odour or general discomfort are not covered.
An assessment factor of 3 is used due to the use of a LOAEC.

Considering people that are unusually susceptible, especially asthmatics, an additional assessment factor of 10 to cover intraspecies (general public) is used.
For the general population, the resulting (ANSES) subacute inhalation DNEL for irritation is 1.3 mg.m^{-3} (1.7 ppm).
This value is similar to the acute minimal risk level (MRLA) defined by ASTDR. It is lower than the mean odor detection threshold (ODT) of 2.6 ppm calculated by Smeets et al. (2006) for ammonia.

B.6 Human health hazard assessment of physico-chemical properties

Not relevant for this proposal.

B.7 Environmental hazard assessment

Not relevant for this proposal.

B.8 PBT and vPvB assessment

Not relevant for this proposal.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

Summary of the existing legal requirements

In the building construction sector, certain legal requirements are relating to products and processes (e.g. CE marking for construction products), others apply to structures built (e.g. regulations accessibility, acoustics, fire, earthquake, thermal...). It is difficult to avoid the confusion between mandatory texts and voluntary texts. The confusion is all the greater when the regulator uses the standard as a reference.

The CE marking is the only regulatory requirement on construction products, provided that the product is described by a harmonized European standard.

Loose-fill cellulose insulation (LFCI) products are concerned by the following recent European standards:

EN 15101-1:2013

This European Standard specifies requirements for loose-fill cellulose insulation (LFCI) products for the thermal and/or sound insulation of buildings when installed into walls, floors, galleries, roofs and ceilings. This is a specification for the loose-fill cellulose insulation (LFCI) products before installation. This European Standard describes the product characteristics and includes procedures for testing, marking and labelling and the rules for evaluation of conformity.

(Date of publication: 2014-03-31)

EN 15101-2:2013

This European Standard specifies requirements for in-situ formed loose-fill cellulose insulation (LFCI) products when installed as thermal insulation into walls, floors, galleries, roofs, lofts and ceilings. This Part 2 is a specification for the installation checks for the installed products. It specifies the checks and tests to be used for the declarations made by the installer of the product. This European Standard does not specify the required level of all properties to be achieved by a product to demonstrate fitness for purpose in a particular application.

(Date of publication: 2014-03-31)

These standards focused on thermal/corrosion/mould fungi resistance, reaction to fire, and durability of the construction product.

Concerning hazardous substances, the standard EN 15101-1:2013 refers to national regulations. A database hold by DG Enterprise and Industry (Construction Unit) is cited: the CP-DS database[22], designed to help all interested parties to identify all relevant regulations in the field of dangerous

[22] http://ec.europa.eu/enterprise/construction/cpd-ds/

substances in construction products (in particular for the emission of dangerous substances from construction products into indoor air, soil and ground water). Under the Construction Products Regulation n° 305/2011 common assessment methods are developed by the European Committee for Standardization (CEN), and are used in European harmonised standards and European Approval Documents. The information in the database regarding the European and notified national regulations and national contact points has been provided by the regulators of the countries involved. Unfortunately no information is available from numerous Member States.
In particular there is no information regarding the regulation of ammonia emission, which depends of several cofactors as explained below.

Factors influencing ammonia exposure and effectiveness of the implemented risk management measures

Several cofactors were identified as potentially intervening in the ammonia emissions from cellulose insulation.
Under humid atmospheric conditions, ammonium salts might react with water molecules to off gas ammonia, under normal ambient conditions (temperature and pressure). This factor is considered as major and has been demonstrated by CSTB tests (at 50%, 70% and 90% RH).
Other potential cofactors have been cited by stakeholders (French manufacturers of cellulose insulation and formulators):

- ✓ The origin and quality (alkaline pH) of the paper used to produce cellulose seems to play an important role in ammonia emissions.
- ✓ The lack of sufficient ventilation seems to be a cofactor of a high concentration of ammonia in indoor air. The installation of a ventilation system in the houses might be the cause of the diffusion of ammonia into the living space instead of limiting the emissions into the attics.
- ✓ In most cases, the way cellulose insulation is installed seems to be a cofactor that might increase or limit/prevent indoor ammonia emissions (e.g. on an airtightness floor, with waterproof structural elements / roof, and avoid material wetting by water penetration or condensation).
- ✓ Physical means such as vapour barrier[23] may also influence ammonia emission. In some countries such as Germany these barriers are sometimes used by the installers to avoid blown cellulose insulation installed inside building cavities from migrating into the living space. Vapour barriers should also prevent cellulose insulation from humidity. According to the CSTB, vapour barriers are meant to have two main effects: they limit the transfer of water vapor for the cellulose insulation (limiting the contribution of the "H_2O" reagent for the reaction of the ammonium ion), and where there is degradation (e.g. a water inlet cover or a water damage) they limit the portion of the ammonia released into the living space of buildings. So this type of installation would limit the health problems to the occupants. However, vapour barrier are expensive to be installed and are mainly used in new houses insulated with cellulose.
- ✓ Ammonium salts might be absorbed and then released by other surfaces such as plaster boards with alkaline pH. This factor seems to play a role in ammonia emissions and in their duration. Technical advices concerning the proper installation manner are provided by the manufacturers to the installers but this does not seem to have completely avoided installation problems.
- ✓ A peculiar installation process used mainly in France in order to make sure that the cellulose insulation is well separated from the living space is the practice of crusting that means adding water on the top of the cellulose insulation. As indicated by several manufacturers,

[23] A vapour barrier refers to any high-density material for damp proofing (typically a plastic or foil sheet but sometimes a paint-like coating) used to prevent water vapour from moving from one area to another.

such way of installation might cause a limited indoor ammonia emissions but only once immediately after the crusting. However, no direct relation was found between the French cases and this installation practice.

- ✓ Emission of ammonia and ammonia smell might result from the instability of fire retardant and biocide blends as the various chemical additives might react among them.
- ✓ Emission of ammonia and ammonia smell might also result from the type and the quantity of ammonium salts used. As discovered during the stakeholders' consultation, many manufacturers (namely members of ECIMA) seem to prefer to use more additives than strictly necessary and pay more in order to be sure that their products would have a better Euroclass[24]. This is used as a commercial tool and it might have implications in terms of stability of the formulations. As reported by CSTB concerning the results of the tests on emissions carried out after the French cases, it seems likely that the composition of the ammonium based formulations added in cellulose insulation has a strong influence on ammonia emission levels. Nevertheless, it is not possible, based on available data, to make any relationship between the emission profile in the standard conditions with the type of salts used, nor the concentration of ammonium in the blend.

Measures to reduce the ammonia emission rates from cellulose insulation without substituting ammonium salts as flame retardants were considered. The existing alternative techniques in order to reduce the ammonia emissions have been explored (see details in section C.1.2):

- **Degassing prior to use**

A longer period of storage and/or the degassing of the cellulose insulation materials following the production and prior to its installation would not necessarily result in ammonia emission unless the storage takes place under high humidity conditions. Indeed, tests chamber emission profiles (see section B. 9.3) demonstrate that most cellulose insulation do not emit ammonia in low humidity rate but strongly emits ammonia under high humidity conditions.

- **Improved ventilation**

If the installation is not properly done it could even contribute to the diffusion of the emitted ammonia into the living space instead of reducing the emissions.

- **Vapour barriers**

According to the CSTB, vapour barriers are meant to have two main effects: on one hand, they should prevent cellulose insulation from entering into contact with water and taking humidity by limiting the amount of water vapour passing through walls, ceilings and floor assemblies of buildings and, on the other hand, where there is ammonia emission, they might limit the proportion of the ammonia released into the living space of buildings. So this type of installation could limit problems with ammonia emissions but also with moisture, mould, rot, odours, bugs and the associated health issues to the occupants. Technically, according to their degree of permeability, some of these materials are only vapour retarders.

- **Liquid or spray impregnation method**

According to some formulators, a liquid impregnation method for adding the blends to the cellulose insulation compared to the one currently used by all European manufacturers (powder blend) could eventually lead to a better and more stable mixture of the cellulose insulation and the blend and therefore to lower ammonia emission patterns. Nevertheless, according to the cellulose insulation

[24] In France, there is a strong competition in terms of image on the level of reaction to fire (Euroclass) of products. Some manufacturers have strengthened the content of fire retardants in their products for reaching very good levels of Euroclass

manufacturers and formulators taking part to the French substitution group, adding such a liquid blend seems to create excessive moisture to the cellulose insulation and to lower the thermal performances of the product. Moreover, such production change would imply that the manufacturers change the whole process and replace the machineries.

- **Improvement of the packaging**

This option refers to the possibility of improving the packaging (water proof) of the cellulose insulation in order to avoid it to become humid before being placed into the market in order to avoid ammonia emissions once installed. However, cellulose insulation can take humidity also during and after its installation, retailers selling cellulose insulation containing ammonium salts cannot know if once installed the cellulose insulation that they are selling would emit or not ammonia.

- **Stabilization of the currently used powder formulations**

Concerning the stabilization of the powder formulation, according to the formulators, this option seems feasible.

To conclude, in terms of suitability only a better stabilisation of ammonium-based cellulose insulation seems to be a good technique, in the respect of the conditions described in this restriction proposal.

B.9.2 Manufacturing

Not relevant for this proposal.

B.9.3 Emission tests performed on cellulose insulation

Based on reported cases, several experiments were conducted to evaluate, in controlled conditions, the emission of different cellulose insulation (Maupetit 2013a, b). The samples all came from insulations materials present in the French market.

These experiments were based on EN ISO 16000 standards for the characterization of volatile pollutants from construction products: EN ISO 16000-9: Indoor air - Part 9: Determination of the emission of volatile organic compounds from building products and furnishing - method of the emission test room (AFNOR, 2006). This standard has been included in horizontal EU testing method CEN/TC 16516 (see annex 2).

This standard is used to simulate, in a reduced scale test chamber, volatile pollutant emissions of a construction product used in a reference room defined conventionally (volume, ceiling area, air exchange rate, see details in the annex 2). The temperature during the emission test shall be 23 ± 2 °C and the relative humidity (RH) as input to the emission test chamber of 50 ± 5 %.
Tests have been carried out in these conditions. As wet conditions (rain, fog, etc.) were considered as conditions favoring the appearance of odors, tests were also carried out at 70 % RH and 90% RH (Maupetit 2013a,b).

The amount of cellulose insulation implemented, was established from data communicated by ECIMA[25] (dated 12/11/2012). The ECIMA set up a watch group intended to collect information in a database on work sites that had received complaints and where the cellulose insulation treated with ammonium salts may have been replaced. This database was sent to the French Scientific and

[25] European Cellulose Insulation Manufacturers Association

Technical Centre for Building (CSTB) for analysis. The aim of CSTB study was to characterise the ammonia emissions from cellulose insulation present on the French market and attempt to understand the emission mechanisms.
The very large majority of use of cellulose insulation was attic insulation by spreading the cellulose insulation on an open horizontal surface. The use by injection into the walls seems exceptional. On construction sites where complaints were observed (in France), the average quantity of cellulose insulation implemented was 12 kg.m^{-2} with an average thickness of 30 cm, giving a density of 40 kg.m^{-3}.
The test samples have been prepared in accordance with these parameters.

A translation in English of the 2 CSTB reports are available in confidential annexes.

"Worst-case" scenario (Maupetit 2013a,b)

The tests were performed by placing a sample directly in the emission test chamber, which is to make the assumption that the attic was insulated with 12 kg.m^{-2} of cellulose insulation and is in direct contact with the indoor air. **This hypothesis represents an upper bound approach to reality**: the air in the attic is *a priori* more ventilated than the reference room (the 0.5 h^{-1} exchange rate is more representative of living rooms) and a partition (at least, plasterboard) separates cellulose insulation of the living rooms, which is expected to limit NH_3 emissions.

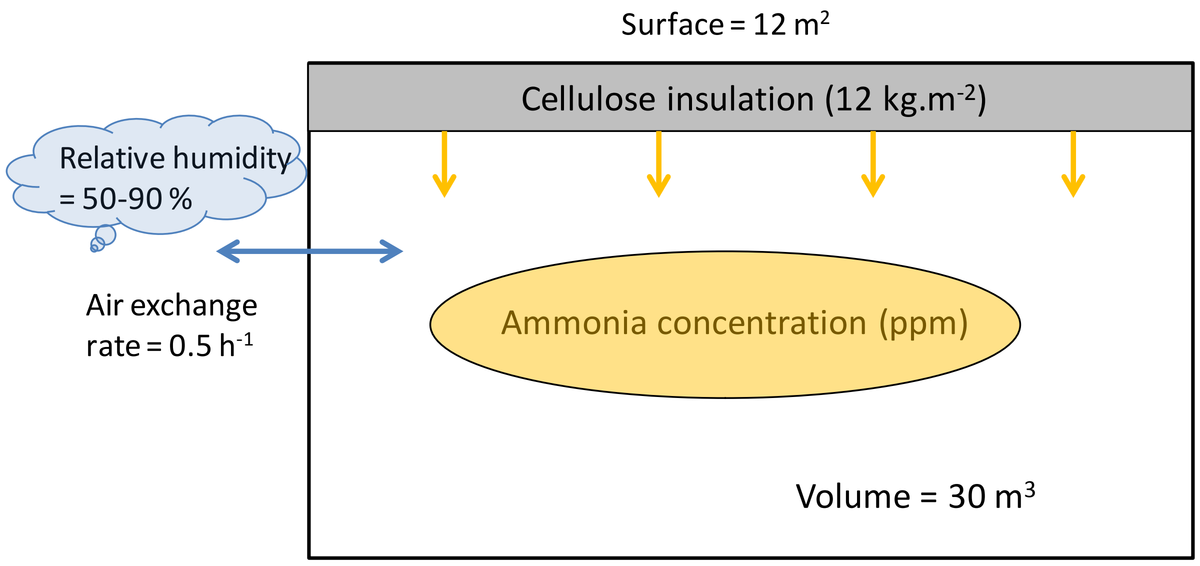


Figure 7: "Worst-case" emission scenario test for cellulose insulation (Maupetit, 2013a)

The reference room and test chamber parameters are shown in Table 8. A reference room is needed since it is not possible to evaluate emissions by testing in all possible use scenarios. This reference room is no test chamber; it only serves as reference value for evaluation of test results in terms of their impact on the indoor air concentration. The test chamber simulates the parameters of the reference room in a smaller scale. The key point here is the respect of the area specific air flow rate and the loading rate which must be the same to compare measured ammonia concentrations to the proposed threshold.

« Worst case » scenario	**Reference room (CEN/TS 16516)**	**Test chamber (CSTB 2013)**	**Units**
Qa (Airflow)	15	0.06	$m^3.h^{-1}$
Volume	30	0.051	m^3
n=Q/V (Air exchange rate)	0.5	1.176	h^{-1}
S	12	0.048	m^2
L=S/V	0.4	0.941	m^2/m^3
Area specific air flow rate	**1.25 (ceiling)**	**1.25**	**$m^3/(m^2.h)$**
Loading rate	**12**	**12**	**kg/m^2**
Cellulose mass	144	0.576	kg

Table 8: "Worst-case" emission scenario test parameters

The scenario used for these tests (12 $kg.m^{-2}$ of cellulose insulation) has been translated into mass of cellulose insulation introduced into the test chamber. The mass of cellulose insulation required for each test (576 g) was placed in a stainless steel container and then placed in an emission test chamber, as illustrated below. Cellulose insulation has been spread in the container as performed by professional installers in order to simulate as closely as possible the implementation of the product blown into the attic, the test specimens were prepared using a "powered blower", as used by professionals.

Figure 8: Cellulose insulation test specimen in a test chamber (CSTB 2013)

Ammonia concentrations were measured with a photoacoustic monitor INNOVA 1412 LumaSense, which has a detection limit of 0.2 ppm.
The tests were conducted in parallel in several emission test chambers: measurements of ammonia concentration in each of the test chambers were performed for 30 to 60 minutes at least every day. The analyzer performed a measurement every 90 seconds and ammonia concentrations measured over the 30-60 minutes period were averaged each day.

First study (Maupetit, 2013a, see confidential annex)
In a first series of experiments, eleven samples of ammonium-based cellulose insulations materials were studied. These products were either sent for testing to the CSTB by their respective manufacturers or were taken from the available supply of products at CSTB for thermal resistance tests:
Series of tests at 50% and 90% RH were conducted on these products. In parallel with the ammonia emission tests, the cellulose insulation test specimens were regularly weighed in order to assess possible water uptake of the material over time.
An insulating wool and hemp wood treated with ammonium salts by liquid impregnation has also been tested.

The tests at 50% RH for more than 28 days of 4 cellulose insulation materials treated with ammonium salts rose relatively low ammonia emissions (concentrations < 2 ppm).
The tests were then performed at 90% RH on eleven products (including the four previous ones).

During the tests at 90% RH, the whole 11 cellulose insulation products tested showed the similar emission profile of ammonia concentration: an increase - in the first 2 weeks of testing, passing through a maximum value and then a slower decrease of emissions.
The products tested were divided into three groups with different ammonia emission to 90% RH profiles (see Figure 9 below):

- For one product, emissions remained low (about 6 ppm max), compared to other products.
- For 3 products of 11, ammonia emissions rapidly increased from the first test week, then reached a maximum concentration in the range of 60 to 100 ppm after about 2 weeks of test, which was followed by slow decline in these concentrations.
- For the 7 remaining products the same type of profile was observed (rapid increase in concentrations of ammonia and slower decrease) but the maximum concentrations achieved were much higher (150 to 350 ppm).

On the contrary, the insulating wool and hemp wood treated with ammonium salts by liquid impregnation (IBSA in Figure 9) did not show the same ammonia emission profile during the 28 days of testing at 90% RH. A residual concentration ammonia (around 1 ppm), however, was measured.

The water content in the material appears to play a significant role in ammonia emissions from the cellulose insulation treated with ammonium salts:

- Release of emissions when the water content in the material (estimated through the increase of material mass) reaches 4 to 5% by mass;
- Slow reduction in emissions if the water content decreases.

It should be noted that for one product (sample E), emissions started from the first day of testing (40 ppm), suggesting that initial water content in the product facilitates the release of ammonia. Indeed, this product has a water initial content greater than the 10 others.

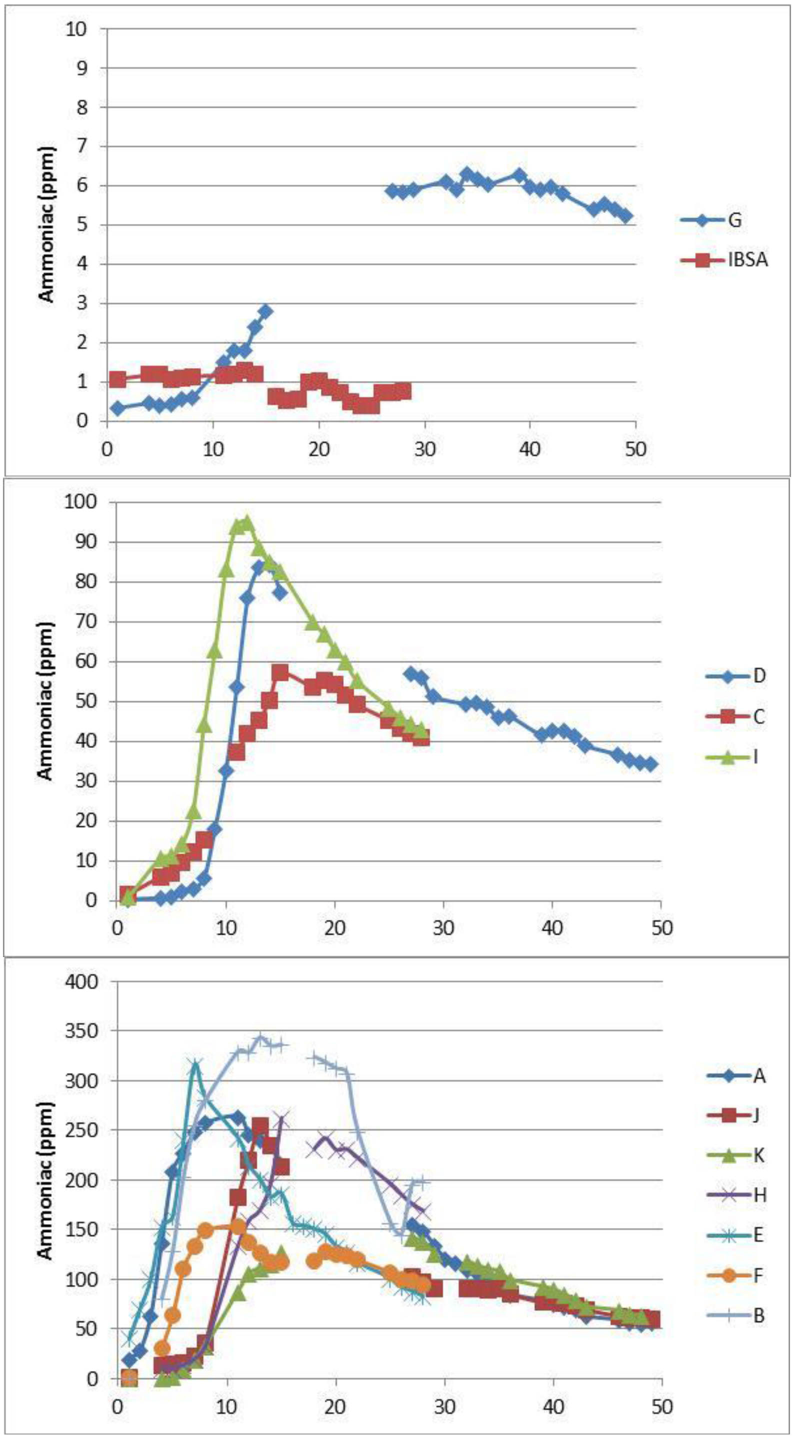


Figure 9: Average ammonia concentrations in the tests chamber (ppm) for the 11 tested materials (A to K) + IBSA (insulating wool and hemp wood treated with ammonium salts by liquid impregnation) - Tests at 90% RH

The tests at 90% RH for at least 28 days have shown that in these conditions, all French cellulose insulation materials tested showed ammonia emission profile of a greater or lesser intensity, contrary to another type of insulation material (IBSA), treated with ammonium salts. After passing through a maximum value, ammonia levels then decrease more slowly than they have increased. This can be explained by the water saturation of the product. Ammonia emission peaks have always occurred before 14 days.

It should be noted that this protocol, especially with the extreme conditions of relative humidity (air renewal to 90% RH continuously for 28 days), allow to thoroughly test the stability of the adjuvant (ammonium salts) used in the insulation (ammonia release or not).

Second study (Maupetit, 2013b, see confidential annex)
In a second series of experiments, additional studies at 50% and 70% relative humidity were performed. 4 previously tested products that had rather different ammonia emission profiles were selected for this new study. The 70% level of RH corresponds to the maximum mean values measured inside French housing (value above the 95th percentile)[26].
In addition, 2 biobased insulation materials treated with ammonium salts (IBSA) were also tested for comparison with the cellulose insulation products:

- IBSA 1: wood fibre and hemp product treated through liquid impregnation (panel);
- IBSA 2: cotton fibre product treated through liquid impregnation (in bulk).

On this test series at 70% RH (until 28 days), the following was observed:

- ➢ An increase in ammonia emissions from the product A (40 to 60 ppm) and product B (4 to 10 ppm).
- ➢ Ammonia emissions from the product C and product D at 70% RH remained at about 1 ppm or less.
- ➢ No ammonia emission profile for the IBSA 1 and IBSA 2 products during the 28 days, but a residual ammonia concentration of less than 1 ppm.

These tests confirm the several products emit ammonia even in less humid conditions. However, the tests at 70% RH are therefore not stringent enough for testing the stability of the additives in such products treated with ammonium salts, compared to tests performed at 90% HR with the same products (first study).

"Attic insulation" scenario (Maupetit 2013b, see confidential annex)

The second study explored a new scenario. This scenario used for the previous tests mimicking a "worst case" emission scenario (insulation in direct contact with the indoor air) is an upper bound approach which strongly favors ammonia emissions. Thus, the ammonia concentrations measured in the emission test chambers are not representative of the concentration in the living rooms. Emission measurements couldn't be directly compared with human health reference values (DNEL).

In order to get a protocol more representative of real emission, another test scenario was proposed ("Attic insulation" scenario).
Two test chambers were used and were separated by a plasterboard. The sample is placed in a first test chamber (which simulated the attic) and the second one is empty and simulates the living room located near the attic. The main differences between the two test chambers representing the attic and the closest living area are the following:

- ➢ Relative humidity: attic = 90% RH, living area = 50% RH
- ➢ Mass of cellulose insulation present: attic = 0.572 kg, living area = 0 kg

The volume of the attic is equivalent to that of the living area below (30 m^3).

[26] The statistical distribution of the levels of relative humidity (weekly average) measured inside French housing by the Indoor Air Quality Observatory (OQAI).

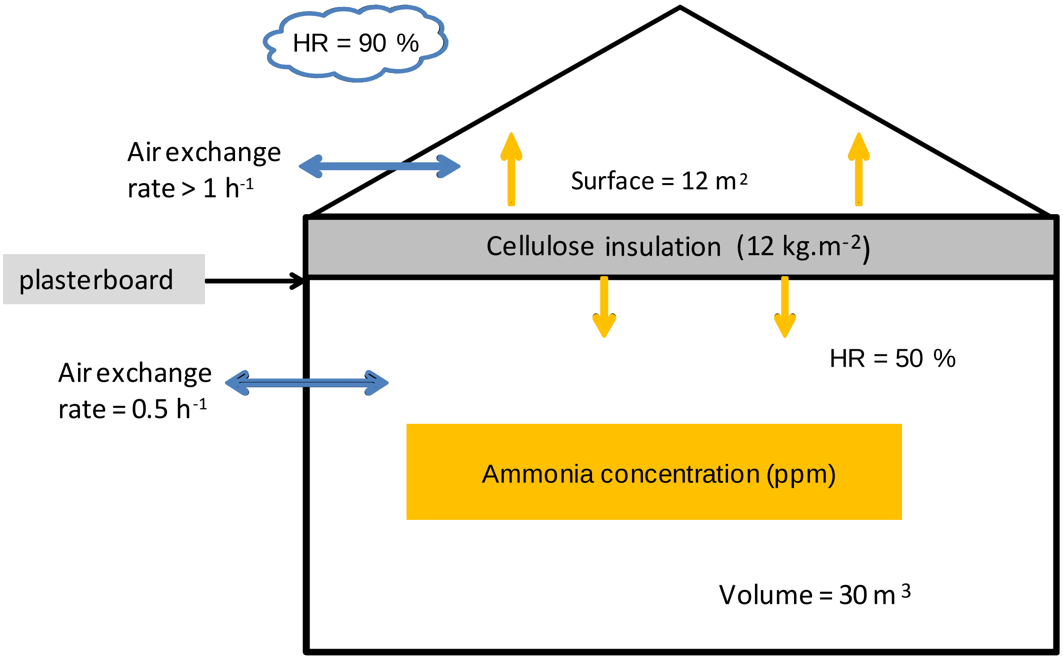


Figure 10: "Attic insulation" emission scenario test for cellulose insulation (Maupetit, 2013b)

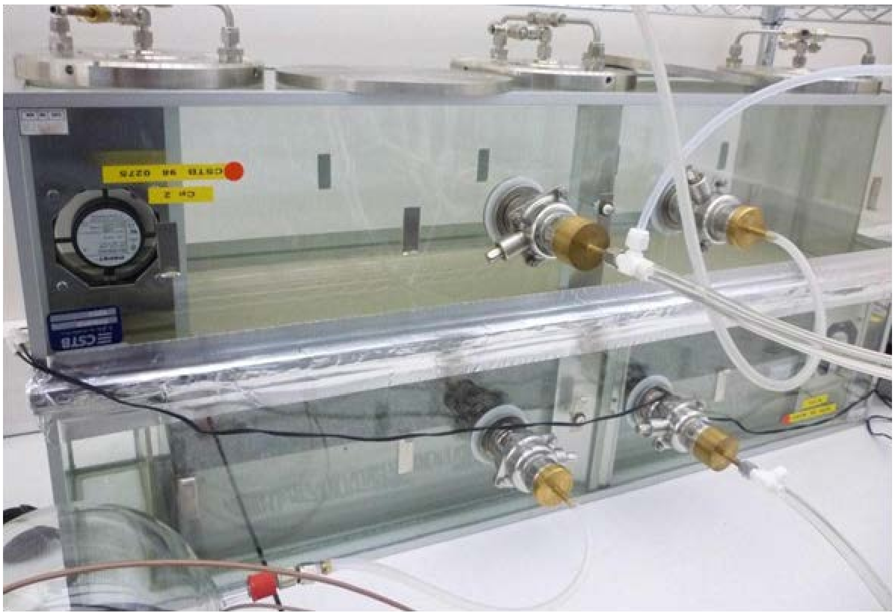


Figure 11: "Attic scenario" experimental test chamber (CSTB 2013)

For this test, a product that was recovered at the end of its first series of tests was used. This specimen had therefore spent 4 weeks at 70% RH and 1 week at 90% RH. Its ammonia concentration had reached its maximum value and had begun to decrease.

The results of this "attic insulation" scenario showed that the flow of ammonia remain similar, leading to lower ammonia concentrations by 2-fold (mainly because of the higher volume of the chamber) compared to the worst-case scenario. It was also demonstrated that ammonia concentrations in the living room were around 80% on average of those measured in the attic.

Considering the same ammonia flow and ammonia mass balance, **one should obtain a resulting ammonia concentration approximately two times lower** in each compartment of the test scenario "attic insulation" compared to single compartment of the dynamic "worst-case" test if the air flow conditions were the same in different test chambers used between these two types of tests.

This type of test is complex to implement and requires the use of two identical test chambers. Given the technical difficulties to put in place the "attic insulation" scenario, it was concluded that the worst-case protocole should be preferentialy used as a practical "routine" reference test.

Conclusion on the chosen test in this proposal

Dynamic tests at 90% RH verify the stability of additives for such materials treated with ammonium salts, in conditions of high humidity, but that may be encountered in reality.
For the 11 French materials tested, ammonia emissions have always triggered before 14 days (considering a total test duration of 28 days or more), which allows to consider reducing to 14 days the duration of the proposed test.
"Attic insulation" test is complex and requires the use of two identical test rooms which makes it difficult to propose it as a reference test from an economic point of view. The preliminary tests demonstrated that emissions profiles are similar in both configurations.

The "Worst-case" emission scenario is sufficient to test the stability of ammonium salts in cellulose insulation and is retained in this proposal, given the ammonia concentration in a single test chamber will be two times higher than in a more realistic design ("attic insulation" scenario).

B.9.4 Consumer exposure: measured indoor air ammonia concentrations

A few data are available regarding ammonia indoor concentrations in relationship to cellulose insulation with ammonium salts. They are reported hereafter.

A measurement campaign has been conducted in December 2012/January 2013 and in April 2013 in 17 French construction sites where cellulose insulation with ammonium salts was installed (CETE 2013). The choice of the testing sites was based on a voluntary basis by industry: 14 sites were considered litigious with complaints due to suspected ammonia emissions.

Two kinds of measurements have been done with colorimetric tubes: a measurement with a diffusion tube (detection limit of 2.5 ppm, 8 hours) and a spot measurement (detection limit of 0.25 ppm).
Results are synthesized below:

Date	Concentration in ppm (attic) Spot/Through diffusion	Concentration in ppm (life-place) Spot/Through diffusion
December 2012	NA/NA[27]	3/2,7
	1/NA	0.75/NA
	NA/NA	NA/NA
	1.25/3,1	2/NA

[27] NA means that it has not been found a change in color of the tube, or the concentration of ammonia is too low to achieve the lowest value of the range of detection tubes.

Date	Concentration in ppm (attic) Spot/Through diffusion	Concentration in ppm (life-place) Spot/Through diffusion
	0,3/NA	2/NA
	1/ND	0.25/ND
	2.5/2,9	2/NA
April 2013	NA/NA	0.4/ND
	0.25/NA	0.25/NA
	0.25/NA	0.25/NA
	0.25/NA	0.25/NA
	0.25/NA	0.25/NA
	NA/NA	NA/NA
	0.8/NA	NA/NA

Table 9: French measurements campaign results (CETE 2013)

The French committee of toxic vigilance coordination (CCTV 2013a,b) reported a few measurements data given in relationship with cases of exposure to emissions from cellulose insulation have been brought to the attention of French Poisonings Centres in 2012:

- Dossier 1: 5 to 9 ppm (Measured by: Municipal Health Service);
- Dossier 2: 2.1 to 2.8 ppm (Measured by: Local Health Agency);
- Dossier 3: 0.5 to 1.7 ppm (Measured by: Cellulose Insulation Manufacturer).

And in the first semester of 2013:

- Housing 1: 0.7 ppm (0.5 $mg.m^{-3}$) (Measured by: Private laboratory);
- Housing 2: < 0.25 ppm (0.178 $mg.m^{-3}$) (Measured by: Local Health Agency);
- Housing 3: 0.06 to 0.22 ppm (0.042 to 0.157 $mg.m^{-3}$) (Measured by: Private laboratory);
- Housing 4: no ammonia detection (Measured by: Local Health Agency).

Despite the very low number of field data available, they demonstrate the presence of ammonia in housing where cellulose insulation with ammonium salts has been installed. The concentration remains moderate.

B.9.5 Consumer exposure: estimated indoor air ammonia concentrations

Based on available data from the CSTB tests, an exposure scenario based on a "well-mixed room" model was established in order to roughly estimate the possible concentration in a room in which ammonium based-cellulose insulation has been installed and to which consumers may be exposed. The parameters of the standard room are given in the Table below:

Scenario parameters	Modelled room
Cellulose insulation mass	144 kg
Cellulose insulation density	12 $kg.m^{-2}$
Reference room flooring surface	12 m^2
Reference room volume	30 m^3
Air exchange rate	0.5 h^{-1}
Air flow	15 m^3/h

Table 10: Exposure estimation for consumers – main parameters

Within the framework of the "well-mixed room" model (see following box), the steady state concentration C is given by:

$$C = \frac{G(RH)}{Q}$$

where

- the emission rate G(RH) (mg/h) is a function of relative humidity RH;
- Q is the airflow of the room (m^3/h).

In order to evaluate the variability of the exposure concentration C, the distribution of the two variables Q and G(RH) were estimated.

Box 2: Well-Mixed Room (WMR) model

The WMR models the concentration C of an airborne pollutant released, with a generation rate G, into a box of volume V with highly turbulent internal airflow and out airflow rate Q. The WMR model is used with the following assumptions: a perfectly mixed room, an equal airflow into and out of the room, no pollutant in the incoming ventilation air, and the absence of significant sinks of pollutant in the room. The general time-dependent mass balance can be written as:

$$V\frac{dC}{dt} = G - QC$$

with the initial condition: $C(t=0)=C_0$.

Assuming G is independent of time (constant emission), the solution of this equation is given by:

$$C(t)=C_0 \times exp\left\{-\frac{Qt}{V}\right\} + \frac{G}{Q} \times \left[1 - exp\left\{-\frac{Qt}{V}\right\}\right]$$

where the steady-state concentration, G/Q, is reached for time larger than V/Q.

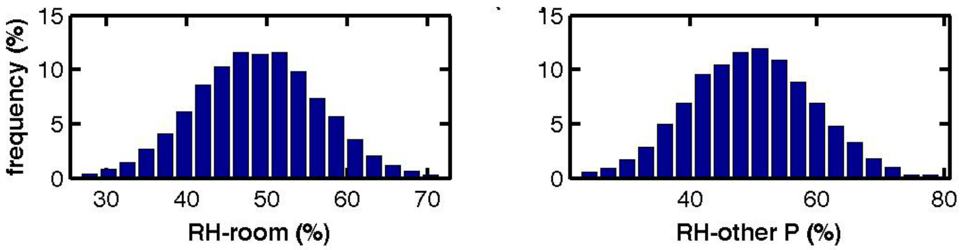
- *Modeling Q distribution*

The airflow in the standard room of 30 m^3 was calculated as a normal distribution with an average of 15 m^3/h and a variation coefficient of 10%. The minimum was set at 3.25 m^3/h.

- *Modeling G_{moy} distribution*

The Table below shows the statistical distribution of the levels of relative humidity (weekly average) measured inside French housing by the Indoor Air Quality Observatory (OQAI)[28]. These measurements were taken in a bedroom and in another living area (generally the living room):

[28] OQAI (2007). Observatory for indoor air quality – National housing campaign: State of the air quality in French housing, Final report, Report DDD/SB-2006-57 (updated May 2007).



	Bedroom	Other
Minimum	25.5	21.1
P25	42.8	41.9
P50 (median)	48.7	49.5
P75	54.3	56.1
P95	63.1	64.7
Maximum	72.8	80.8

Table 11: Statistical distribution of the levels of relative humidity in % (OQAI 2007)

As demonstrated in CSTB's tests, the maximum concentrations measured in the tests chambers during the CSTB tests for the less stabilized cellulose insulation material tested were:

RH (%)	**NH_3 (ppm)**	**G (mg/h)**
50	4	0.168
70	50	2.1
90	250	10.5

Table 12: Ammonia emission concentrations and rates according stationary values of the CSTB dynamic tests

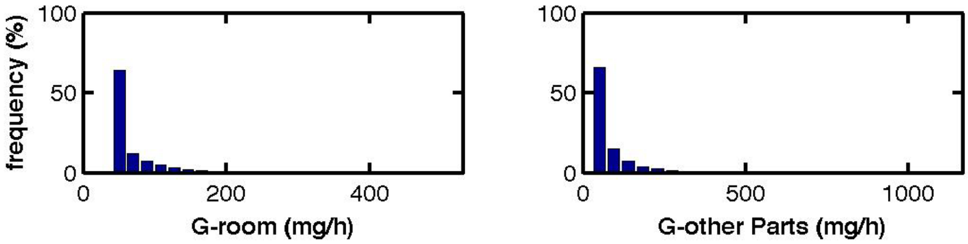
Using data from the CSTB tests, the emission rate in a standard room, G_{moy} can be well approximated by the expression:

$$G_{moy}(RH) = \begin{cases} G_{50} = CF \times 0.168 \text{ mg/h} & ; \quad 20\% \leq RH \leq 50\% \\ G_{50} \times exp\{0.1034(RH - 50)\} & ; \quad 50\% < RH \leq 90\% \end{cases}$$

Where:

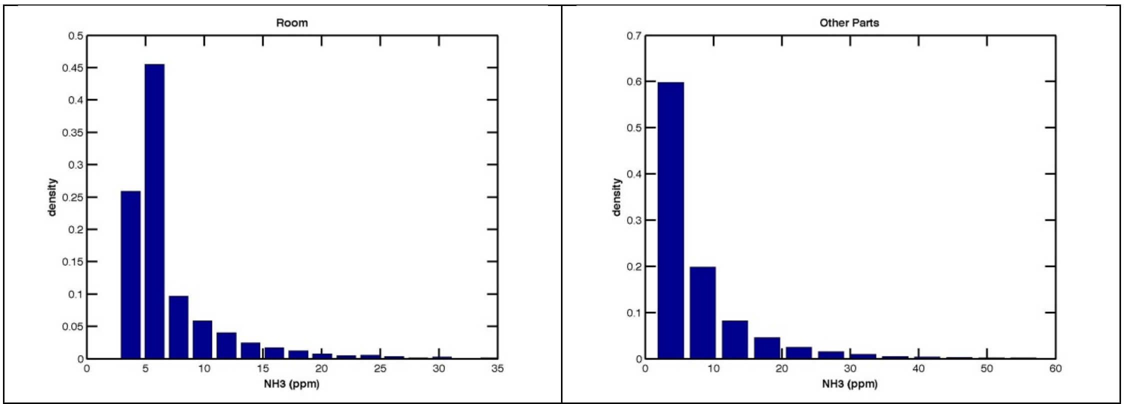
- The emission rate is assumed constant and equal to G_{50} for RH between 20% and 50%)
- G_{50} is calculated using a charge factor CF for mass scaling between the tests chamber and the standard room, given that the emission rate (in mg/h) is proportional to the amount of cellulose installed in the standard room. Indeed, for the test experiments cellulose insulation mass was 0.576 kg while, for the reference room, the cellulose insulation mass corresponded to 144 kg. CF = 144 /0.576 = 250.
- The emission rate increases exponentially between 50 and 90% RH, the slope of the curve is obtained by fitting the experimental data.

Combining the modeling of G as a function of RH and the statistical distribution of RH allow estimating the statistical distribution of G:



Results: estimated exposure levels to ammonia:

Based on Q and G distributions and using the Monte-Carlo approach, the distribution of exposure concentration could be established:



Distributions of exposure concentration (ppm) to NH3

	Bedroom (ppm)	Living room (ppm)
Minimum	3.736	3.736
P25	4.740	4.786
P50 (median)	5.291	5.455
P75	7.410	9.158
P95	16.510	24.80
Maximum	54.76	120.9

Table 13: Estimated exposure levels to ammonia (statistics summary)

It should be noted that these estimates represent an upper bound approach to reality:

- Values of the CSTB dynamic tests for the less stabilized cellulose insulation tested have been used. However, the CSTB tests demonstrated the worst material emitted ammonia in the same order of magnitude than the other materials.

- It has been assumed that emissions occur directly in the room (no attic, no partition with plasterboard at least). The installation of cellulose insulation inside walls and not necessarily in the attic cannot be excluded. However, the tests performed at the CSTB showed that the plasterboard does not constitute any barrier to ammonia emission.

B.10 Risk characterisation

B.10.1 Risk calculation ratios calculated with ammonia estimated concentrations

Ammonia concentrations have been calculated using the Well-Mixed Room (WMR) model and results of CSTB tests. The statistical distribution of the levels of relative humidity (weekly average) measured inside French housing, and ammonia emission rate for the less stabilized cellulose insulation tested have been used (worst-case approach).

		Bedroom		Living room	
	Subacute inhalation DNEL for irritation	Concentration (ppm)	RCR	Concentration (ppm)	RCR
Minimum	1.7 ppm	3.736	2,2	3.736	2,2
P25		4.740	2,8	4.786	2,8
P50 (median)		5.291	3,1	5.455	3,2
P75		7.410	4,4	9.158	5,4
P95		16.510	9,7	24.80	14,6
Maximum		54.76	32,2	120.9	71,1

Table 14: Risk characterization ratios (RCR) calculated with ammonia estimated concentrations

The calculated RCR are above 1 with the proposed subacute inhalation DNEL for irritation.

B.10.2 Risk based on toxic-vigilance data

Few data regarding exposure of general population is available and the representativeness of these few data to a chronic exposure of the general population is questionable. Nevertheless, toxic vigilance data clearly demonstrated that the risk presented by ammonia emitted from cellulose insulation exists.

The French committee of toxic-vigilance (CCTV) has published in February 2013 the conclusions on a retrospective study performed between 1 November 2011 – 31 December 2012 on exposure to volatile compounds emitted by cellulose insulation material (CCTV 2013a, see **detailed report in annex 3**).

Ten records with 19 exposed people were collected between February and November 2012, 8 out of 10 cases were collected in the last months of 2012. There were 14 adults aged 32 to 70 years-old and 5 children.
In 9 cases out of 10 complainants felt a smell that alerted them. Fifteen cases presented with symptoms of irritation of mucous membranes (nose, eyes, throat) and airway irritation. The final severity was rated mild or moderate according to the Poisoning Severity Score[29] grading.
Ammonia was detected in the indoor air of three houses with values of 0.5 to 9 ppm. Some measurements were above the subacute DNEL and even the odour detection threshold. As these were instantaneous spot measurements, the occurrence of exposure to higher concentrations cannot be excluded (e.g. in case of rainy weather).

[29] Persson HE, Sjöberg GK, Haines JA, Pronczuk de Garbino J. Poisoning severity score. Grading of acute poisoning. Clinical Toxicology 1998: 36 (3): 205-13.

For each French toxic vigilance dossier, people lived in a house insulated recently with cellulose insulation. It could be a new building or an old renovated housing. As part of the corrective measures, cellulose insulation was removed in most of the dossiers, which was followed by a rapid recovering of the symptoms - when they were present - and a rapid disappearance of the unpleasant odour. Despite the lack of robust measurements data, the French committee of toxic vigilance coordination CCTV has considered – in the majority of the cases - likely the causality of cellulose insulation with regard to the origin of symptoms (see annexes 3 and 4).

Over the same period, 20,000 housings were insulated in France. The European Cellulose Insulation Manufacturers Association (ECIMA) identified more than 100 complaints over the same period and on Internet forums many complaints were posted.

A second report from the French CCTV has collected information on exposure situations between 1st January and 5th July 2013 (CCTV 2013b, see **detailed report in annex 4**). Fourteen records (14) totalling 43 patients were collected during this period. Only four measures in indoor air were carried out in suspected housing: 3 showed low concentrations of ammonia (0.06 to 0.7 ppm) and one did not confirm the presence of this gas. Nevertheless, in all records, one or several patients smelled an odour sometimes characteristic of ammonia gas ("urine" or "cat urine" smell).
19 children and 24 adults were exposed, and the clinical signs observed are irritation of the upper airways, cough, and/or a bronchospasm. Severity grading was estimated zero or low for 41 patients and moderate for 2 patients.
Among the 43 exposed persons, 21 remained asymptomatic. The remaining 22 presented with one or more symptoms corresponding to mucous membrane irritation of the upper airways or of the bronchus.
In particular, a child – with a history of asthma, otherwise stabilized by treatment – has developed an asthma decompensation condition during the 3 months after moving into a new home. The child was hospitalized for one month in a specialized center. It seems that the symptoms disappear when the child leaved the house for several days.

Synthesis of new cases since 5th July 2013 (with cellulose insulation installed before French restriction) and new data on cases already identified by the French CCTV:

- 7 new cases most of which are still being followed and for which it is difficult to decide on causality either because the name of the cellulose insulation is missing, either because no mention of smell is specified in the dossier. There are still no serious cases. In one case, measurements were made on several occasions in the home in the presence of odour. The results are below the standards (see TRVs in the CCTV report - retrospective study in annex 3).
- Regarding known cases either from the retrospective study either from the prospective study (second report) in which an evolution has occurred: 12 dossiers, for which a follow-up was known, show that - in the vast majority of cases - no measurement of ammonia has been performed. There are only 3 dossiers for which measurements have been done (one for which the results are not known). These 2 dossiers providing measurements (apart from those already known in the report of the prospective study – in annex 4) had negative results, but the measurements were made outside the presence of the odour. They are non-contributory.
- In terms of symptoms, no serious cases have been found. 2 children (2 different dossiers), including one with a history of asthma, showed an increase in respiratory symptoms without that we can exclude the responsibility of the exposure to ammonia from cellulose insulation.
- As part of the corrective measures, cellulose insulation was removed in 7 of 12 dossiers, which was followed by a rapid recovering of the symptoms - when they were present - and a rapid disappearance of the unpleasant odour.

Regarding occupational exposure, the RNV3P (French National Network for Monitoring and Prevention of Occupational Diseases) identified five cases where signs of irritation *a minima* were observed, including one case of *de novo* asthma: five patients from the same company (plumbing) were referred by their company's occupational doctor to the Prevention of Occupational Diseases Centre of Nancy (France). Exposure conditions were the following:

- Intervention on a construction site of a building for the installation of sanitary facilities when it had been flooded;
- Cellulose insulation had been placed, but not covered in some flats;
- Other complaints from construction workers reported (due to the smell of ammonia).

One patient was exposed very slightly and did not show any symptoms. Two patients had symptoms of irritation of the respiratory tract with at least discomfort lasting during exposure (short-term period).
The two other patients had asthma-like symptoms. None had a history of asthma, neither childhood asthma, nor atopic. One had a sinonasal polyposis which was diagnosed in 2005. Positive methacholine test confirmed bronchial hyperresponsiveness in this patient (but was negative in the second case).

A quick enquiry was posted to the EAPCCT[30] forum in order to gather information collected by other EU Poison Information Centres (PICs); this enquiry was also sent personally to several PICs in Europe. No other cases have been reported to the Belgian PIC, nor in Germany (Göttingen, München, Erfurt).

Based on the cases reported in France, ANSES clearly is of the opinion that there is a risk for human health related to ammonia emitted in certain situations from cellulose insulation.

B.11 Summary on hazard and risk

Hazard
Acute and chronic toxicity of ammonia via the inhalation route is mainly due to the irritating effects of the substance, in the airway or ocular mucosa.
The dose-effect relationship for ammonia is summarized in the table below (inhalation exposure):

Concentration of NH_3 in ppm in the air	Probable effects from acute exposure
< 1 - 17	Limits to olfactory detection (habituation)
5-20	Discomfort in non-accustomed individuals
25-50	Slight irritation in nose and throat
50-80	Mild irritation in eyes and throat
100-140	Irritation in eyes, nose, throat, watery eyes
2500 - 4500 (accident)	Bronchospasm, pulmonary oedema, fatal in approximatively 30 min
10,000 (accident)	Rapid death by suffocation and pulmonary oedema, skin damage due to corrosivity

The different selected human health risk values (HRV) found in the literature and the DNEL derived by the lead registrant of ammonia for the general population are therefore all based on these effects.

[30] European Association of Poison Centres and Clinical Toxicologists.

The (ANSES) subacute inhalation DNEL of 1.3 $mg.m^{-3}$ (1.7 ppm) used in this proposal is also based on this critical effect, taking into account susceptible population sub-groups such as asthmatics.

Exposure and risk

Few data regarding ammonia exposure of general population is available in relationship with cellulose insulation. Dynamic tests performed by the French Institute CSTB have verified the stability of additives for such materials treated with ammonium salts, in conditions of high humidity (at 90% RH) that may be encountered in reality. All 11 tested cellulose insulation materials presented in varying degrees ammonia emission profiles (from 6-7 ppm to more than 200 ppm), reflecting instability of ammonium salts in these products.

Ammonia concentrations have been calculated using the Well-Mixed Room (WMR) model and results of CSTB tests. In particular the statistical distribution of the levels of relative humidity (weekly average) measured inside French housing and ammonia emission rate for the less stabilized cellulose insulation tested have been used (worst-case approach). Risk characterizations ratio (RCR) calculated with these exposure estimates and with the proposed subacute inhalation DNEL for irritation are above 1.

The number of exposed persons is subject to great uncertainty given the uncertain future development of this young market and in view of the eventual changes of the specific concentration limit value of boron compounds in mixtures. The boron-based formulations (blends including, among other substances, boric acid and/or borax) dominate the market (around 95%) and are the most used compounds in the different formulations added to cellulose insulation manufactured within (and outside) the European Union. About 250,000 tonnes of cellulose insulation are yearly placed on the EU market. The volume of cellulose insulation containing ammonium salts currently marketed inside the EU is estimated at 15,000 tonnes (around 5%).
For the purpose of socio-economic analysis, the number of avoided exposed persons per year has been estimated at 300 in year 2017 at the European level (see section F.1.1.3).

French toxic vigilance data identified in 2012 and in the first semester of 2013 about 40 people showing irritation of the upper airways, cough, and/or bronchospasm symptoms. This people lived in a house insulated recently with cellulose insulation. In few cases the symptoms were more severe such as asthma decompensation. For each situation one or more exposed person smelled a characteristic odor of gas ammonia ("urine", "cat urine") having diffused into the living rooms due to its high volatility.
Over the same period, 20,000 housings were insulated in France. Near the odour threshold, persons exposed to ammonia can experience annoyance and believe the odour to be a nuisance. A Manufacturers Association (ECIMA) identified more than 100 complaints in France and on Internet forums many complaints are made, indicating that toxic vigilance data should be underestimated.

Based on these observations, ANSES clearly believes that there is a risk for human health related to ammonia emitted in certain situations from cellulose insulation.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

C.1.1. Alternative thermal insulations materials

Aside cellulose isolation, there are plenty of other thermal insulation materials currently available on the EU market, each with its own set of characteristics such as R-value (see section B.2.2), price, health and environmental impacts, flammability, and levels of sound insulation.
Due to the fact that this dossier focuses on cellulose insulation only, an exhaustive and full assessment of each of these thermal insulation materials was not carried out.

Mineral Wool
Mineral wool actually refers to glass wool, rock wool or slag wool. Mineral wool can be purchased in batts or as a loose material. Most mineral wool does not have additives to make it fire resistant, making it poor for use in situation where extreme heat is present. However, it is not combustible. When used in conjunction with other, more fire resistant forms of insulation, mineral wool can definitely be an effective way of insulating large areas. Mineral wool has an R-value ranging from R-2.8 to R-3.5.

Fiberglass
Fiberglass is quite cheap and the most common insulation currently used. It is made of fibers of glass able to minimize heat transfer. The handling of fiberglass is dangerous since fiberglass is made out of finely woven silicon, glass powder and tiny shards of glass. These can cause damage to the eyes, lungs, and even skin if the proper safety equipment isn't worn. Nevertheless, when the proper safety precautions (eye protection, masks, and gloves) are adopted, fiberglass installation can be performed without incident. Fiberglass is an excellent non-flammable insulation material, with R-values ranging from R-2.9 to R-3.8 per inch.

Polyurethane Foam
Polyurethane expanding foams are an insulation material based on a two-component mixture of isocyanate and polyol resin sprayed onto roof tiles, concrete slabs, or into wall cavities. They are relatively light, weighing and they have an R-value of approximately R-6 per inch of thickness. There are also low density foams that can be sprayed into areas that have no insulation. Another advantage of this type of insulation is that it is fire resistant.

Polystyrene
Polystyrene is a waterproof thermoplastic foam which is an excellent sound and temperature insulation material. It comes in two types, expanded (EPS) and extruded (XEPS) also known as Styrofoam. The two types differ in performance ratings and cost. The more costly XEPS has a R-value of R-5.5 while EPS is R-4. Typically the foam is created or cut into blocks, ideal for wall insulation. The foam is flammable and Hexabromocyclododecane (HBCD) is used as fire retardant. Polyisocyanurate, similar to polyurethane, is a closed cell thermoset plastic with a high R-value making it a popular choice as an insulator as well retardants.
Other natural insulation materials are fibers such as hemp, sheep's wool, cotton, and straw.

C.1.2. Alternative techniques still using ammonium salts in cellulose insulation

Measures to reduce the ammonia emission rates from cellulose insulation without substituting ammonium salts as flame retardants were considered. We explored the existing alternative techniques in order to reduce the ammonia emissions below the proposed restriction threshold (in line to what briefly indicated in section A.2.3).

Degassing prior to use

A longer period of storage and/or the degassing of the cellulose insulation materials following the production and prior to its installation would not necessarily result in ammonia emission unless the storage takes place under high humidity conditions. Indeed, tests chamber emission profiles (see section B. 9.3) demonstrate that most cellulose insulation do not emit ammonia in low humidity rate but strongly emits ammonia under high humidity conditions. The peak of emission after 14 days quoted in this dossier refers to the materials tested under high humidity conditions, but no test were performed to assess the whose duration of emission; it is therefore not possible to know when the cellulose insulation will stop emitting ammonia. Moreover, there is no indication on whether the cellulose is still fire resistant after all “releasable” ammonia has been emitted. Anyway, this option would be very costly for the industry which will need to stock a larger amount of cellulose insulation (that is very cumbersome so probably new stock houses would have to be built or rented as the current turnover of stocks is much quicker than 15 days). Therefore, this option is not considered technically, nor economically feasible.

Improved ventilation

As explained in the paragraph on cofactors to ammonia emissions, improved ventilation in the house seems to be able to lower the concentration of ammonia in indoor air in case of ammonia emissions. Mechanical ventilation systems can reduce the heat loss while at the same time highly improving indoor air quality.
However, the installation of a mechanical ventilation system is expensive (low economical feasibility). Moreover, if the installation is not properly done it could even contribute to the diffusion of the emitted ammonia into the living space instead of reducing the emissions. Therefore, this option is considered as technically, but not economically feasible

Vapour barriers

A vapour barrier refers to any high-density material for damp proofing (typically a plastic or foil sheet but sometimes a paint-like coating) used to prevent water vapour from moving from one area to another. According to the CSTB, vapour barriers are meant to have two main effects: on one hand, they should prevent cellulose insulation from entering into contact with water and taking humidity by limiting the amount of water vapour passing through walls, ceilings and floor assemblies of buildings and, on the other hand, where there is ammonia emission, they might limit the proportion of the ammonia released into the living space of buildings. So this type of installation could limit problems with ammonia emissions but also with moisture, mould, rot, odours, bugs and the associated health issues to the occupants. Technically, according to their degree of permeability, some of these materials are only vapour retarders.
As explained in the paragraph on cofactors to ammonia emissions, in some European countries physical means such as vapour barriers are sometimes used by the installers to avoid blown cellulose insulation installed inside building cavities from migrating into the living space. However, the installation of vapour barriers is expensive (ranging from 1000 to 3000 € per living unit insulated). Associated to the cellulose insulation (considering an average price of 2000 € for insulating a house, see detail in section F) it would make this type of thermal insulation not competitive anymore on the market in terms of prices (low economic feasibility).

Liquid or spray impregnation method

According to some formulators, a liquid impregnation method for adding the blends to the cellulose insulation compared to the one currently used by all European manufacturers (powder blend) could eventually lead to a better and more stable mixture of the cellulose insulation and the blend and

therefore to lower ammonia emission patterns. Nevertheless, according to the cellulose insulation manufacturers and formulators taking part to the French substitution group, adding such a liquid blend seems to create excessive moisture to the cellulose insulation and to lower the thermal performances of the product. The possibility of putting the cellulose insulation into an oven in order to reduce the HR of paper/newspapers was explored and rapidly set aside for environmental and economic reasons. Moreover, such production change would imply that the manufacturers change the whole process and replace the machineries generating important sunk costs that would seriously affect the rentability of the cellulose insulation sector. So both technically (because of the mould) and economically (due to high sunk costs) this option is widely recognised as unfeasible by the stakeholders of the cellulose insulation sector.
As for the liquid impregnation, according to the cellulose insulation manufacturers and formulators taking part to the French research project (see box 2 below), spraying the cellulose insulation with the blend of additives does not seem technically and economically feasible with due to the acceptable limit of humidity for the paper and to the current manufacturing processes.

Stabilization of the currently used powder formulations

Concerning the stabilization of the powder formulation, according to the formulators, this option seems feasible both technically and economically.
The stabilization of the powder formulation is one of the options left open to the manufacturers of cellulose insulation (in collaboration with their formulators).
As underlined by the formulators consulted, this option seems technically feasible, given the proposed limit value of 3 ppm for this restriction proposal. However, it is not possible to determine *ex ante* how long it will take to find a stable blend, nor how much the research concerning the stabilization will cost. These uncertainties did not prevent the dossier submitter from attempting a monetary quantification (included in section F of this restriction dossier) of the additional costs to be afforded for the stabilization of the formulations by the industry if their cellulose insulation would be proven emitting ammonia above the limit value set by this restriction proposal. The resulting costs of the stabilization scenario seem economically affordable compared to the expected benefits.

Improvement of the packaging

This option refers to the possibility of improving the packaging (water proof) of the cellulose insulation in order to avoid it to become humid before being placed into the market in order to avoid ammonia emissions once installed. However, cellulose insulation can take humidity also during and after its installation, retailers selling cellulose insulation containing ammonium salts cannot know if once installed the cellulose insulation that they are selling would emit or not ammonia. This option seems not very useful first and foremost as most of the packaging currently used is already water proof.
Therefore, although both technically and economically feasible, avoiding humidity before the installation of the cellulose insulation through packaging appears as an option having a very limited risk reduction capacity.

The “crusting technique”

As reported by CSTB, the crusting refers to peculiar technique mainly used in France. After the application of the cellulose insulation, its surface can be sprayed with a little quantity of water without pressure. As it dries, the cellulose insulation forms a small "crust", which should avoid the cotton wool from moving around in the air. Anyway, such technique doesn’t seem compatible with the cellulose insulation containing ammonium salts given its capacity to emit ammonia in case of humidity.

The table below summarizes the findings for each alternative technique option in terms of technical and economical feasibility and risk reduction capacity of each alternative technique considered**.** Overall in terms of suitability only a better stabilisation of ammonium-based cellulose insulation seems to be a good technique.

Techniques	**Technical feasibility**	**Economical feasibility**	**Risk reduction capacity**	**Overall suitability**
Degassing prior to use	Low	Low	Low (It might not be fire resistant)	Not suitable
Improved ventilation	Medium	Low	Low	Not suitable
Water proof packaging	High	High	Low (cellulose insulation might emit ammonia for having taken humidity during and after installation)	
Vapour barrier	High	Low	Medium	Not suitable for economic reasons
Liquid and spray impregnation	Low	Low	Medium	Not suitable (it lower the thermal performances and increase the mould)
Crusting	High	High	Low (it causes ammonia emissions)	Not suitable to avoid ammonia emissions
Stabilization of ammonium based blends	High	High	High	Suitable

Table 15: Assessment of alternative techniques still using ammonium salts in cellulose insulation

C.1.3 Alternative compounds as flame retardants in cellulose insulation

On the market of cellulose insulations, only two main types of blends are currently used: the boron-based formulations and the ammonium-based one. Other chemical substances are used as fire retardants or as biocides in a variety of different ammonium-based and the boron-based blends in cellulose insulation, according to the stakeholders' consultations. However, currently, no ammonium-free and boron-free formulations are used by the cellulose insulation industry, nor already available on the market. Research is on going to find other types of blends without ammonium and boron.

Boron-based formulations

The boron-based formulations (blends including, among other substances, boric acid and/or borax) dominate the market (around 95%) and are the most used compounds in the different formulations added to cellulose insulation manufactured within (and outside) the European Union.

Other substances in the formulations

From the consultations with cellulose insulation manufacturers, formulators and Member States, other chemical substances are currently being researched as flame retardants or already used in the blends in addition to ammonium salts or boron compounds:

- other aluminium salts (aluminium sulphate [CAS No 10043-01-3], aluminium hydroxide [CAS No 21645-51-2]), aluminium trihydrate [CAS No 8064-00-4];
- magnesium sulphate [CAS No 7487-88-9];
- zinc chloride [CAS No 7646-85-7];
- sodium salts;

- amines blended with “alkaline earth metal” salts;
- calcium salts;
- lime, gypse, and bauxite;
- barium salts;
- whey/soda;
- “bio-material”;
- antipyrin.

From the information received from the industry, in boron-based formulations, magnesium sulphate [CAS No 7487-88-9] and aluminium trihydrate [CAS No 8064-00-4] seem to be the most used fire retardants for cellulose insulation. Other alternatives reported by some Member States in their questionnaire are not sufficiently described in order to assess them.

Magnesium sulphate and aluminium trihydrate are currently used in boron-based formulations in order to lower the boron compounds concentration in the cellulose down to 4%. However, when asked concerning the possibility to make a formulation only with these two flame retardants - and without boron compounds - a manufacturer of cellulose insulation explained that without boron the product did not pass one of the two tests to check fire retardation. Another manufacturer of cellulose insulation who is currently testing a boron-free magnesium-based formulation explained that the final product containing this blend passed all fire retardation tests but the additives caused technical problems to the machinery while blending them with the cellulose insulation.

Concerning alternative blends, aside the magnesium-based formulation, according to a formulator, blends containing phosphorus compounds are being tested by the industry at present, but no further details were provided. In addition, many phosphate-based compounds seem to have some or all the characteristics to be used in cellulose insulation materials as substitutes for boric acid, borax and polyborates (Source: US Patent 2013/0014672 A1; 17 January 2013).

Box2: Information on a national collaborative research project

Currently, in France a collaborative research project funded by the French Ministry of Housing is carried out with the official objective to replace boric acid (and ammonium salts) as additives in the cellulose insulation. This project brings together several public stakeholders (CSTB, DHUP) and the private sector (8 producers of cellulose insulation,i.e. 10 factories producing or selling in France, 4 formulators of chemical additives and technical French authorities). Initial results of the research will be made available by the end of 2014 to all producers having a production unit in France. The study should be completed by June 2015, which is the deadline of validity of the French technical advice with boron salts.

The research of a new flame retardants for the cellulose insulation focuses on replacement of boric acid but, after the cases of ammonia emissions in France, almost all formulations proposed were also ammonium-free.

The specifications set by the project on the demand of the cellulose insulation manufacturers include the following technical and economic elements: the formulation must reach a Euroclass C in order to avoid potential fire, it must be chemically stable during the whole life cycle of the cellulose insulation and compatible with other biocidal additives in the formulation. Finally, the formulation should be economically viable, to avoid an increase of the market price of the finished product (target of 100 Euros per tonne of finished product).

The initial focus of the research project has been to verify the reaction to fire of the various samples of the cellulose fibers mixed with the proposed fire retardants. Each sample of powder additives without boron and without ammonium salts has then been tested to evaluate the reaction to fire according to the standard EN11925-2 "Ignitability to the small flame test" through the application of a flame. The samples should reach at least the minimum thresholds required by using the standard EN11925-2, and, by the initial phase, they should meet at least the European fire class E. Several samples of the first two series of tests carried out

at factory level did not pass such test. It should be noted that the small flame test is less restrictive than the SBI test (single burning item) which is required for the cellulose insulation. The exact contents of the formulations tested are not known.
One of the products tested by some plants was very irritating and it released a strong odour. In order to avoid the same issues as in the case of ammonium salts, this product is being further tested to examine the nature and degree of its emissions though the development of an emission test that could be used in the future also to identify and characterize the various emissions of other alternative products. At this stage, it is very difficult to anticipate what could be the future emissions, but it is certain that they should not be limited to ammonia emissions.
The report of the first two meetings of the project concludes that, at this stage the formulations currently tested in this framework represent interesting potential alternatives to be further explored, but the project is still far from having found a final solution meeting all stated requirements.
The possibility of a liquid blend was excluded by the group due to excessive moisture after adding it to the cellulose insulation. The addition of the liquid adjuvant seems to lower the performances of the product if papers and newspapers have a RH > 6% which is the case most of the times. The possibility of an oven to reduce the RH of paper/newspapers was explored and rapidly set aside for environmental reasons.
Exploration of spraying additives seems hardly compatible with current manufacturing processes due to the acceptable limit of humidity for the paper in order to mantain the thermal performances and to avoid fungal development.
Given the fact that from one plant to another the manufacturing process is not exactly the same, even if the blend would be a too fine powder, the formulation could block the machineries (distribution, aspiration or filtration systems) of the plants of some manufacturers

According to a formulator, the target price established by this research project (maximum 100€/t of produced cellulose insulation with a rate of 10% which actually means purchasing a product 1 €/kg or 1000 €/t) in order to find alternatives to boron and ammonium for cellulose insulation does not seem achievable by the formulators and producers of additives without using in the formulation boron or ammonium compounds in view of the current prices of the alternative chemical substances. According to the same formulator, it seems too early to set an acceptable price limit, given that the R&D on this subject is still on going. According to this formulator, it is however certain that most European and French producers will have to accept additional costs compared to the formulation of boric acid if they do not wish that formulators will be blocked and limited in their R&D by the economic equation. According to the same formulator, it is clear that the current approach of manufacturers of cellulose insulation of targeting a final price competitive with mineral wool will have to change if boric acid will be shut down from this use.
In conclusion, economic aspects seem to have played a critical role in terms of difficulties met up to date to find alternative solutions for boric acid substitution. To date, the results on the reaction to fire are not conclusive due to the low performances to fire of the products tested. Formulators of additives keep working on the improvement of the tested products in close collaboration with the cellulose manufacturers. However, the project is also looking for new formulators working on the fireproofing of the paper for the cellulose insulation sector.
The searching for an antifungal solution will come in a second phase after the tests concerning the reaction to fire will be concluded and the flame retardant component of the blend will be validated. However the formulators taking part to the project seem rather confident on this point of finding the right biocidal additive.
Any interesting future finding coming from this project made available to the DS would be incorporated and assessed in the updated versions of this report.

C.2 Assessment of alternatives

C.2.1 Boron compounds

C.2.1.1 Availability of boric acid / borates

Borates are naturally-occurring minerals containing boron. The element boron does not exist in nature by itself: boron combines with oxygen and other elements to form boric acid, or inorganic salts which are generically referred to as “borates”.

Boric acid and sodium tetraborates are used as flame retardants in a range of applications including cellulose insulation. Borates suppress a fire by melting and covering the flammable substrate in a layer of char, excluding oxygen from the flame.
Borates may also be used as biocides: There are several types of borate wood preservatives used to treat solid wood, engineered wood composites and other interior building products like studs, plywood, joists and rafters.

Use of borates as flame retardant is minor according to the European Borates Association (EBA): 3% of the total tonnage, corresponding to about 6 t/y for Cellulose Insulation (Austria transitional annex XV dossier for Boric acid (crude natural), 1 December 2008).

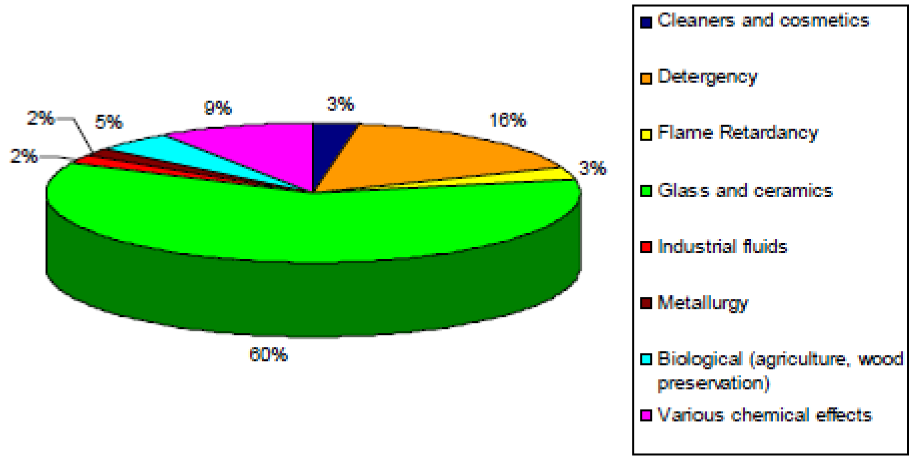


Figure 12: Division of boric acid and sodium tetraborates (sodium tetraborate anhydrous, sodium tetraborate pentahydrate, sodium tetraborate decahydrate) by end use application (year 2007 data) (EBA, 2008)

C.2.1.2 Human health risks related to boric acid / borates

Classification&Labelling
Pursuant to the first ATP to Regulation (EC) No 1272/2008 (Commission Regulation (EC) No 790/2009) as of 1 December 2010, boric acid is listed in Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/20083 as follows:

Repr. 1B H360FD (May damage fertility. May damage the unborn child.) Specific Concentration limits: Repr. 1B; H360FD: C ≥ 5.5 %

According to the first ATP to Regulation (EC) No 1272/2008, the corresponding classification in Annex VI, part 3, Table 3.2 of this Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) will be as follows:

Repr. Cat. 2; R60-61 (May impair fertility. May cause harm to the unborn child)

Specific Concentration limits: Repr. Cat. 2; R60-61: C ≥ 5.5 %

Specific concentration limits of other borates are adjusted according to the molecular weight of the substances where the basis was the concentration limit of 5.5% for boric acid. Expressed as boron content the specific concentration limit would be 1% B for all substances.
In the future it can be expected that the specific concentration limit of boron compounds could be lowered from 5.5% to 0.3%[31].

Hazard characterization summary

Boric acid is considered as a SVHC; annex XV dossier for the identification as SVHC of boric acid (Germany / Slovenia, 2010) is available on the ECHA website[32].

The following summary on toxicity of Boric acid is based on the Proposal for identification of a substance as substance of very high concern (Boric Acid, CAS No 10043-35-3 / 11113-50-1). Germany / Slovenia Proposal. February 2010.

Toxicokinetics (absorption, metabolism, distribution and elimination)

The toxicokinetics of boric acid has been investigated by different uptake routes (oral, dermal, inhalation) in various animal species as well as in humans.
Absorption of boric acid via the oral route is nearly 100%. For the inhalation route also 100% absorption is assumed (based on animal studies performed with boron oxide).
Dermal absorption though intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used as a realistic worst case approach. Boric acid is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2 - 3 higher than in other tissues. Boron is excreted rapidly, with mean elimination half-lives of 1h in the mouse, 3 h in the rat and 13.4 h in humans (range 4 – 27.8 h), and has low potential for accumulation. Differences in renal clearance are the major determinant for the observed species differences. Boric acid is mainly excreted in the urine.
From a poisoning case with boric acid in a pregnant woman it could be deduced, that boric acid (or borates in general) is able to cross the placenta.

Repeated dose toxicity

The haematological system and the testes have been identified as the major targets after oral repeat dose exposure to Boric acid. Studies after repeated dermal or inhalation exposure to boric acid are not available. A NOAEL for effects on testes and the blood system of 17.5 mg boron/kg bw/day can be derived (with a LOAEL of 58.5 mg boron/kg bw/day) from two 2-year studies in rats on boric acid.
Results obtained with boric acid can be supported by findings obtained from other borates thus indicating that the boron ion is the toxicologically relevant species.

Summary and discussion of reproductive toxicity

Results from animal experiments demonstrate that boric acid adversely effects fertility and development. Feeding studies in different animal species (rats, mice and dogs) have consistently demonstrated that the male reproductive system is the principle target in experimental animals, although effects on the female reproductive system have also been reported. Testicular damage ranging from mildly inhibited spermiation to complete atrophy has been demonstrated following oral administration of boric acid. Effects on fertility were observed at lower dose levels compared to

[31] Communication of ECHA on Boric acid, Disodiumoctaborate tetrahydrate, Disodiumoctaborate anhydrate, 21 March 2014: http://echa.europa.eu/fr/view-article/-/journal_content/title/rac-delivers-sixteen-clh-opinions.
[32] http://echa.europa.eu/documents/10162/9289e7af-16aa-47c8-8e3a-20179670803d.

dose levels, where signs of general toxicity appeared. 17.5 mg boron /kg bw/day was derived as a NOAEL for male and female fertility.

Developmental toxicity of boric was investigated in the rat, the rabbit and the mouse. In two independent rat studies, the reduction in fetal body weight at 0.1% or 0.2% boric acid in feed from GD 0 to 20 was comparable, maternal toxicity in mice and rats was not striking, since effects on food and water consumption were minimal. Observed weight gain changes seemed to be secondary to developmental toxicity, because body weight gain corrected for gravid uterine weight was not significantly reduced. Studies in rats failed to provide evidence for any treatment related renal pathology. Thus, in the rat, developmental toxicity (decreased foetal weight: at 13.7 mg boron/kg bw/day) occurred in the absence of marked maternal toxicity. For developmental toxicity, a NOAEL of 9.6 mg boron kg bw/day has been derived.

The adverse effects of boric acid on development and fertility observed across species were very similar, both in nature and effective doses. Further, the adverse effects obtained with boric acid are comparable to those obtained from other borates thus confirming that the Boron ion is the toxicologically active species. The available data on toxicokinetics do not indicate major differences between laboratory animals and humans. It is not known whether there are significant differences in the toxicodynamics between humans and laboratory animal models and in the absence of such knowledge it must be assumed that the effects seen in animals could occur in humans. On the basis of toxicokinetic and toxicodynamic considerations it is assumed that the animal data are relevant to humans. This is further underlined by the fact that (1) there are indications that boric acid is able to cross human placenta and that (2) up to now, epidemiological studies in humans are insufficient to demonstrate the absence of an adverse effect of inorganic borates on fertility.

Exposure potential

Consumer Exposure to boric acid has been addressed recently by the Transitional Dossier for boric acid (CAS 10043-35-3), which also focuses on disodium tetraborate anhydrous (CAS 1330-43-4), disodium tetraborate pentahydrate (CAS 12179-04-03) and disodium tetraborate decahydrate (CAS 1303-96-4)[33].

The risk-characterisation assessment for boron exposure via consumer products was not derived due to the lack of information on all possible applications.
Conclusion (i) is therefore reached:

- There is a need for better information to adequately characterize the risks for consumers from boron exposure via boric acid and sodium tetraborates.

A report on borates in consumer products has been carried out on behalf of the European Commission (RPA, 2008). It covers boric acid and a number of other boron compounds, principally boric oxide, sodium borate and sodium perborate, which also have been classified as Reprotoxic Category 1B. The study approach involved a review of the relevant literature and consultation with the relevant industry stakeholders in the EU in order to identify the range of uses for borates.
Quantitative exposure estimates were provided for fertilisers, detergents, mattresses and starch adhesives. However other uses such as in cellulose insulation were discussed only on the basis of plausibility argumentations: according to the RPA report, these products (identified as data gaps on consumer exposure to boron) will lead to negligible consumer exposure, because of their low volatility and considering they will be handled by consumers only on an occasional (less than

[33] Boric acid (boric acid crude natural). Transitional Annex XV dossier. Austria. 1 December 2008.

weekly) basis. Without more robust data on consumer exposure, this conclusion might be not valid and more details are necessary to support them.

Germany / Slovenia have discussed consumer exposure estimates from single uses of boric acid in their annex XV SVHC dossier[34].

Few data are available on borates consumer exposure related to their incorporation in Cellulose Insulation. As the vapour pressure of boric acid is negligible, inhalation exposure is only expected from uses giving particles or aerosols.
Boric acid is used as a flame retardant (with also fungicide properties) in cellulose insulation material. In this application, shredded post-consumer recycled paper is mixed with boric acid, other borates or with a mixture of boric acid and other borates. The resulting product is blown into attics and in cavity walls. In a study on dust monitoring in construction work, manual installation of cellulose insulation was documented with respirable particle concentrations of 2.75 mg/m³ (BTU 2000). With a boric acid concentration of 5% with another 5% disodium decaborate (Seppele 2009), 0.3 days exposure time, 60 kg body weight and an inhalation rate of 33 m³/day (default for a 60 kg person at light exercise) an inhalation exposure of 0.004 mg boron/kg bw/day from 0.023 mg boric acid/kg bw/day can be calculated. Another 0.0025 mg boron/kg bw/day derives from disodium decaborate. This kind of consumer exposure will be limited to occasional projects.

C.2.1.3 Environment risks related to boric acid/borates

This section presents conclusions from the transitional annex XV dossier of boric acid (boric acid crude natural) prepared by Austria (version of 1 December 2008).

Conclusion (i) is reached for Sewer treatment plants (STP), surface water, sediment, marine and terrestrial compartments:

• There is a need for better information to adequately characterize the risks from the releases of boric acid and sodium tetraborates.

The information requirements are:

- Good quality data to improve PNECs;
- Information on local exposure and emissions to the STPs for producing/importing and processing sites;
- Information on local exposure and emissions to the aquatic compartment for producing/importing and processing sites;
- Information on insects to improve the PNEC,
- Information on local exposure and emissions to the sediment compartment for producing/importing and processing sites;
- Information on local exposure and emissions to the marine compartment (including sediment) for producing/importing and processing sites;
- Information on local exposure and emissions to the atmosphere for producing/importing and processing sites.

Due to the low volatility of the inorganic borates, emissions to air will be very low.

[34] Boric acid (CAS No 10043-35-3 / 11113-50-1). Proposal for identification of a substance as substance of very high concern. February 2010.

The potential for secondary poisoning is not significant (Boron should be considered as fulfilling the criteria for Toxicity, but not for Bioaccumulation according to the definition of Annex XIII of REACH Regulation. Therefore boron does not meet the criteria as either PBT or vPvB.).

Other information regarding regulatory status
Boric acid is a Substance of Very High Concern and is on the Candidate List.
13 SiA notifications (substances in articles) are available[35] for this substance (CAS No 10043-35-3, 11113-50-1). Cellulose insulation is included in the identified uses.
There is no information whether boric acid or borax would be prioritized by ECHA for the inclusion on the authorization list.

Regulation (EU) No 528/2012: the use of boric acid and borates in cellulose wool with the claim of biocidal function other than wood preservation is not allowed in accordance with current EU biocides Regulation.
It should be noted that if the supplier claims that boric acid / borax is added only for its flame-retardant properties and does not further mention or claim biocidal properties, then the use is not subject to the requirements and approval procedure. However, for many product sheets, it is claimed that the insulation material is protected against decay from mold, fungi and pests.

C.2.2 Classification&Labelling of other alternatives

The Table below summarizes harmonized and notified classification and labelling according to CLP criteria[36] for inorganic salts that constitute the main potential alternatives to ammonium salts as fire retardants.

Substance identification	Harmonized/Notified classification and labelling (please note that classification may vary between notifiers)
Aluminium hydroxide [CAS No 21645-51-2, EC Number: 244-492-7]	*Notified classification (for some notifiers):* Skin Irrit. 2, H315 – Causes skin irritation Eye Irrit. 2, H319 – Causes serious eye irritation STOT SE 3, H335 – May cause respiratory irritation
Aluminium sulphate [CAS No 10043-01-3, EC Number: 233-135-0]	*Notified classification (for some notifiers):* Eye Dam. 1, H318 – Causes serious eye damage Met. Corr. 1, H290 – May be corrosive to metals Acute Tox. 4, H302 – Harmful if swallowed Skin Irrit. 2, H315 – Causes skin irritation STOT SE 3, H335 – May cause respiratory irritation Aquatic Acute 1, H400 – Very toxic to aquatic life Aquatic Chronic 1, H410 – Very toxic to aquatic life with long lasting effects Aquatic chronic 2, H411 - Toxic to aquatic life with long lasting effects Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects
Aluminium trihydrate [CAS No 8064-00-4]	No information
Magnesium sulphate [CAS No 7487-	*Notified classification (for some notifiers):*

[35] Echa website consulted the 3 December 2013.
[36] C&L inventory database consulted the 3 December 2013.

Substance identification	Harmonized/Notified classification and labelling (please note that classification may vary between notifiers)
88-9, EC Number: 231-298-2]	Acute Tox. 4, H302 – Harmful if swallowed Skin Sens. 1, H317 – May cause an allergic skin reaction Skin Irrit. 2, H315 – Causes skin irritation Eye Irrit. 2, H319 – Causes serious eye irritation STOT SE 3, H335 – May cause respiratory irritation
Zinc chloride [CAS No 7646-85-7, EC Number: 231-592-0]	*Harmonized classification (annex VI of CLP Regulation):* Acute Tox. 4, H302 – Harmful if swallowed Skin Corr. 1B, H314 – Causes severe skin burns and eye damage Aquatic Acute 1, H400 – Very toxic to aquatic life Aquatic Chronic 1, H410 – Very toxic to aquatic life with long lasting effects *Supplementary notification (for some notifiers):* STOT SE 3, H335 – May cause respiratory irritation

Table 16: Harmonized and notified classifications and labelling of alternatives according to CLP criteria

C.2.3 Economic feasibility of alternative blends

Prices of the formulations widely vary from formulator to formulator, from location to location, according to the traded volumes, the relative percentages of chemical substances used in a given blend and according to the relative percentage of blend used in the cellulose insulation.

According to a formulator, a typical boron-based formulation (4% boric acid + 8% aluminium hydroxide) to be added to cellulose insulation at a rate of 12% would cost around 75€ per tonne of produced cellulose insulation. If the volumes purchased are important, the price of a basic boron-based formulation could decrease down to 60 to 65€/t of cellulose insulation treated.

The table below, based on data provided by a formulator and counter verified with cellulose insulation manufacturers, provides the ranges of price level of certain chemical substances used in the cellulose insulation.

Substance	CAS Number	Price €/t	Percentage needed
Boric acid	10043-35-3	670-700	4%
Ammonium sulphate	7783-20 - 2	300-450	3%
Monoammonium phosphate dihydrogenorthophosphate	7722-76-1	800- 1500	3%
Diammonium hydrogenorthophosphate	7783-28-0	1300 – 1500	3%
Magnesium sulfate heptahydrate	10034-99-8	400-500	8%
Magnesium sulphate	7487-88-9	N.A.	N.A.
Zinc chloride	7646-85-7	N.A.	N.A.
Aluminium sulphate	10043-01-3	N.A.	N.A.
Aluminium trihydrate	8064-00-4	N.A.	8%
Aluminum hydroxide	21645-51-2	320-350	8%

Table 17: Ranges of price level of certain chemical substances used in the cellulose insulation (information provided by a formulator)

All substances indicated in the table are easily available on the market at European level.
Moving from the standard chemistry of ammonium sulphate or sulfamate to more complex and stable ammonium compounds, prices might increase up to 4 times per tonne.

The fact that the amount of boric acid are less important than that of magnesium sulphate in table below does not mean that the formulations based on boric acid are not the market leading blends but it refers only to the fact that a typical boron-based formulation would contain 4% of boric acid and 8% of magnesium sulphate.

Alternatives	Tonnes per annum for Flame Retardants (estimate from stakeholders consultation)
Boric Acid	7000
Ammonium Salt Blend	4000
Magnesium Sulphate	12000
Aluminium Trihydrate	2000

Table 18: Tonnes per annum of relevant flame retardants in cellulose insulation (data provided by stakeholders)

At European level, the total quantities of alternative substances entering into the formulations used by the European cellulose insulation industry depend on the relative percentages of different substances used in a given blend by each manufacturer and on the percentages of total formulations used in the cellulose insulation by the manufacturers.

The main issue to take into consideration while considering ammonium (and boron) substitution is the economical feasibility of the replacement of ammonium salts by other alternatives which are more expensive than ammonium salts (and boron compounds). According to ECIA, ammonium salts (especially ammonium sulphate and mono- and diammonium phosphate) are the least expensive options after boron compounds. Indeed, according to ECIA and to most of the cellulose insulation industry actors (see Section G), the use of other formulations may increase production costs compared to blends based on ammonium or boron salts of a factor of 2 up to 6. According to a formulator alternative formulations that could be used for cellulose insulation would cost up to 1.5 euro per kg which would confirm a factor 2. Factor 6 seems to be an overestimation.
For the manufacture of cellulose insulation, the loss of profit could be then significant especially because they are not likely to pass such costs to the supply chain at least on the short term.

For manufacturers of cellulose insulation, under an economic and technical point of view, compared to the use of ammonium salts in the blends, the best possible scenario would be that the alternatives could have the a higher effectiveness both in terms of flame retardation and biocidal function for a lower price.

Effectiveness/price	higher effectiveness	same effectiveness	lower effectiveness
higher price			*worst scenario*
same price		*intermediate scenario*	
lower price	*Best scenario:* *boron compound*		

Table 19: General Principles of possible scenarios for substitution

The assessment of alternatives to ammonium salts as fire retardants in cellulose insulation shows that blends based on boron compounds are the most likely alternatives for the cellulose insulation industry exactly because they represent for the market the best possible case ever, having at the same time the best performances in terms of fire retardation and anti mould for the lower price. This explains why around 95% of the market has already spontaneously adopted boron-based formulations. Even if the DS considers boron based blends as not desirable for its health risks, for the industry this is still the easiest and cheapest alternative, still legally allowed.
The worst case scenario would be a blend having a lower effectiveness for a higher price.
The intermediate scenario would be somewhere in-between the two above mentioned extreme cases, i.e. a blend with the same effectiveness for a higher price or a lower effectiveness for the same price. For instance, if the alternative blend is less efficient in terms of fire retardation than a formulation based on ammonium salts then manufacturers should put a higher dosage in order to obtain the same performances against fires and mould.

Considering that the price of boron compounds is lower than that of ammonium salts and that they are already used by most of European manufacturers, it seems obvious that the Industry will spontaneously adopt this solution for the replacement of ammonium salts as it will decrease the production costs. It worth's reminding once again that under the limit of 5.5% the boron-based blends are a technically, economically and legally feasible option, although this limit might be lowered in a next future.

In France following the Order of 21st of June 2013 the cellulose insulation industry had to switch back from ammonium-based formulations to boron-based blends. However, the substitution of ammonium salts with boron salts is not a long-term solution considering the reprotoxic effects of boron and the possible future changes in the concentration limit. Boron has been identified as SVHC, and is consequently on the candidate list for authorisation route. Consumer exposure to boric acid has been addressed recently by the Transitional Dossier for boric acid, which also focuses on disodium tetraborate anhydrous, disodium tetraborate pentahydrate and disodium tetraborate decahydrate (Austria, 2008). Few data are available on borates consumer exposure related to their incorporation in cellulose insulation. The risk-characterisation assessment for boron exposure via consumer products was not derived due to the lack of information (conclusion (i) reached).
Therefore, **in the framework of this restriction proposal, boron compounds cannot be indicated as a desirable alternative, although it is still legally allowed within the limit of 5.5%** (according to entry 30 of annexe XVII of REACH Regulation).

D. Justification for action on a Community-wide basis under article 129 of REACH regulation

D.1 Considerations related to human health risks

Following the French national restriction, within 60 days of receipt of the information from France the Commission took the decision to authorise the French provisional measure. Taking into consideration the fact that the provisional measure taken by France consists in a national restriction on the production, placing on the market and use of ammonium salts contained in cellulose insulation, France is initiating a Community restriction procedure by submitting by the 15th of January 2014 to ECHA an Annex XV dossier within three months of the date of the Commission decision (14th of October 2013).
According to the safeguard clause foreseen by article 129.1 of REACH regulation, France has justifiable grounds for believing that urgent action is an essential and appropriate provisional measure to protect human health at EU level to avoid that ammonia could be released by cellulose insulation.

Although no cases were confirmed in other Member States than France, there is no reason to believe that in the future ammonium salts used in cellulose insulation in other EU Member States could not develop similar heath problems. Moreover, several cases of ammonia exposure have been reported from treated cellulose insulation in the US[37].

Cellulose insulation containing ammonium salts is produced and used throughout the EU (with the exception of France having recently established a national restriction). Six different manufacturers have been identified in Germany, Sweden, Latvia, Belgium and Denmark. It has been established that cellulose insulation is a local market, most producers selling their production within 500 km around the production site. The presence of cellulose insulation containing ammonium salts is very likely in several countries in the EU. Moreover, most of the European manufacturers of cellulose insulation containing ammonium salts buy their blend of additives from the same formulators who sold the same or very similar formulations to the French manufacturers which experienced emission cases. Consequently, the ammonia emissions originating from the cellulose insulation containing ammonium salts could concern all Member States, even though consumers complains concerning ammonia emission have not been confirmed by other Member States up to date. Moreover, the climatic conditions in France (namely the humidity rate) which are among the main cofactors possibly causing the French cases of ammonia emissions are very similar to those of other Member States at least in Central Europe.
Furthermore, under a business as usual scenario, due to the foreseen evolution of the cellulose insulation market in the future (estimated growth of 2.2% per year) and due to the fact that most of the current manufacturers of cellulose insulation using ammonium-based formulations have spare production capacities, there could be an increase of the current volumes and percentage of cellulose insulation containing ammonium salts which could emit ammonia.

Some European manufacturers still produce cellulose insulation containing ammonium salts around Europe using the same production process as in France and the number of cofactors that can cause release of ammonia make very complex to manage the related risks for human health. Therefore, it is not possible to completely exclude the possibility that the same ammonia emissions and related health issues could happen at present or in the future somewhere else in Europe. It should be emphasized that the ban of boron-based formulations in France has lead to the placing on the market of ammonium-based formulations. With a possible ban of boron base formulation in the

[37] http://www.sciengineering.com/newsletter/AmmoniaConcern.pdf

future (because of a possible more sever classification, or because of negative reaction of the market towards boron), the ammonium–based cellulose insulation may increase all around Europe.

D.2 Considerations related to internal market

The proposed restriction covers cellulose insulation emitting ammonia that is marketed among all Member States, most of which have not yet established national restrictions. The cellulose insulation containing ammonium salts which could potentially emit ammonia is both produced in and imported into the EU. The justification for addressing the risk on a Community-wide basis originates from the need to prevent the fact that identified risks could be managed differently or not managed at all by each Member State. If member states will not take any legal action the health risks will persist. If different national restrictions would be adopted by Member States, the legislative requirements would differ in terms of allowed concentrations or emission rates, targeted products, and duration of the legislation. Such differences and the non homogeneity of the legislation across the Community will probably result in the creation of unequal and imbalanced conditions within the internal market and in export/import difficulties that would not allow these products to circulate freely within the EU.

The proposed restriction would remove the potentially distorting effects that the current (French) and eventually other future national restrictions may cause on the free circulation of cellulose insulation containing ammonium salts both produced in and imported into the EU. In facts, regulating ammonia emissions in cellulose insulation through a Community-wide action ensures that all European producers of the cellulose insulation in different Member States, as well as importers of cellulose insulation, are treated in an equitable manner ensuring a ‘level playing field’ among all producers and importers of these products.

D.3 Justification to propose a transitional period of 12 months

On one hand, in principle, the transition period should give enough time to all relevant stakeholders (manufacturers, importers, wholesalers and retail sellers) to enable them to adjust their production and sales processes under technical, economic, practical and regulatory point of views once the proposed restriction has come into force, namely taking into consideration the fact that many manufacturers and installers of cellulose insulation are small and medium sized companies.
On the other hand, for the implementation of this specific restriction proposal there is a need to be in coherence with the use of the article 129 which supports a short transitional period after entry into force of the restriction.
The main reason why the cellulose insulation industry will need a transitional period is represented by the time needed to carry out the **R&D** in order to develop a safe and environmental alternative formulation (e.g. boron and ammonium-free) with the same capacity of fire retardation if the dedicated emission test show that the cellulose insulation releases ammonia over the threshold of the proposed restriction. It is very difficult to estimate the time needed for developing a new formulation but the research process by the industry seems to be already on going and the first results of the French research project will be available already by the end of 2014.

From the stakeholders’ consultations it seems that, if alternative fire retardants would be added again as powder formulation, no major investment in new machinery nor major adaptations of the equipment seem to be required by the cellulose insulation industry. However, in some cases according to the chemical properties of the substances, the production process might need to be slightly changed which could imply minor investment costs in order to ensure the technical feasibility.

Considering the fact that cellulose insulation is a product that takes a lot of space, stocks' levels are relatively low. In average, during the stakeholders' consultation, the volumes of final products stored by the European cellulose insulation industry were found limited to less than a week of production. Therefore, the depletion of stocks can be done quite quickly and it is not considered as a relevant element for establishing the transition period of the proposed restriction.

Some time could be needed for practical and regulatory reasons by responsible EU **Public Authorities** to inform markets and all concerned actors (EU and non-EU authorities) about the change in EU legislation and to get prepared to enforce the restriction.

The few **importers of cellulose insulation** could also need some time to inform non-EU suppliers (especially from Switzerland) and customers about the change in EU regulation and to take the necessary measures in order to comply with this restriction.

On the other hand, as the cellulose insulation can have a long service period of around 60 years it is important to avoid having a too long transitional period as this will increase the exposure potential for the general public to ammonia and the costs that occupants will have to afford to re-insulate their housings.

For the above mentioned reasons and in coherence with the article 129 of REACH Regulation, a transitional period of 12 months is considered reasonable for market operators throughout the cellulose insulation supply chain and for public authorities to adapt to the requirements of the proposed restriction and to minimize the transaction costs related to dissemination of information and to perform voluntary compliance control measures. For the proposed restriction therefore a shorter transitional period could involve implementation problems on the EU market, a longer one would create a risk for human health and would not be in coherence with the need of urgent action for this restriction.

D.4 Summary

The proposed restriction covers cellulose insulation placed on the European market and emitting ammonia in a conventional test.

Although no health symptoms due to emitted ammonia were found in other Member States than France to date, there is no reason to believe that ammonium salts used in cellulose insulation in other EU Member States could not develop similar heath issues in the future. Several cases of ammonia exposure have been reported from treated cellulose insulation in the USA.

Moreover, the justification to act on a Community-wide basis also origins from the need to avoid different legislations among the Member States with the risk of creating unequal market conditions:

- The proposed restriction would remove the potentially distorting effect that current (French) and future national restrictions may have on the free circulation of goods;
- Regulating ammonia emisions from cellulose insulation through Community-wide action ensures that all producers in different Member States are treated in an equitable manner;
- Acting at Community level would ensure a 'level playing field' among all producers and importers of the cellulose insulation.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

In ammonium-based blends, different types of inorganic ammonium salts are used in cellulose insulation for their flame retardant properties. These salts can lead, under certain conditions (namely of humidity), to ammonia emissions. Ammonia is an irritant gas for mucous membranes and respiratory tract.
Ammonia is volatile and even if it spreads preferentially in the attic rather than residential premises, it may enter the living rooms.
Few data regarding ammonia exposure of general population is available in relationship with cellulose insulation. However French toxic vigilance data identified in 2012 and in the first semester of 2013 about 40 people showing irritation of the upper airways, cough, and/or bronchospasm symptoms. In few cases the symptoms were more severe such as asthma decompensation.
Over the same period, 20,000 housings were insulated in France. Near the odour threshold, persons exposed to ammonia can experience annoyance and odour nuisance. A Manufacturers Association (ECIMA) identified in 2012 more than 100 complaints in France and on Internet forums many complaints were made, indicating that toxic vigilance data should be considered as underestimated.

It is very difficult to foresee if and how the European industry as a whole or individual companies would react if their product would emit ammonia. The decisions on whether to stop the production and to organize the replacement of the cellulose insulation and the reimbursement of customers for the problems generated by ammonia emissions would depend on a set of different factors such as the extent of the reported cases and to which extent the image of the product/company has been worsened, the country specific regulation, the company specific context (namely the commercial strategies) behind the choice of the blend used, etc.
It is therefore not correct to extrapolate at European level the reaction of manufacturers in France due to the specific circumstances that had brought the French manufacturers to use ammonium-based formulations instead of boron-based blends. The following box explains the reactions of different French cellulose insulation manufacturers after the cases and before the French restriction.

Box 3: reaction of the French manufacturers after the cases of ammonia emission in France
In France, until 2011, cellulose insulation was treated with boron-based formulations as a flame retardant and antifungal treatment. Boric acid is classified as toxic for reproduction Category 1B. In 2011, going voluntarily beyond the European legislation (REACH states that the concentration of boron salts in the finished product – as mixture - should not exceed 5.5%), French authorities (CCFAT/DHUP Direction of habitat, urban planning and landscapes) decided to stop providing technical approvals to French boron-based cellulose insulation, completely prohibiting boron salts in the cellulose insulation. The technical approvals for the construction materials issued by the CCFAT is a voluntary assessment carried out on request of a manufacturer on the technical suitability of the products in terms of quality, safety and sustainability in the work. The Technical approvals provide a recognized technical security to the market and to insurers but are not mandatory for placing the products on the market.

Following the denial of technical approvals, there has been a sudden switch of the French production of cellulose insulation from the boron based formulations towards ammonium-based formulations. A number of cases of irritation symptoms due to ammonia emissions from cellulose insulation have been reported to the French poison centers. After a few weeks, following the installation of the ammonium-based cellulose insulation, strong smells and cases of exposure of occupants and professionals to ammonia started to be reported to different French poison control and monitoring centers and by the European association of the manufacturers of cellulose insulation (ECIMA). A campaign of measurement was organised in the houses concerned by the emissions. ECIMA has identified 115 alerts and directed measures on site reports of concentrations of ammonia in the air up to 5 ppm. According to the ECIMA, in late 2012, all manufacturers combined, in France approximately 20,000 building units were insulated with cellulose insulation containing ammonium salts.

The products in question are mainly loose cellulose insulation, blown or projected into attics, but also cellulose insulation panels installed inside the walls. The CCFAT asked the French manufacturers of cellulose insulation to work in collaboration with CSTB to establish the causes of these ammonia emissions. The reported complains discredited the entire cellulose insulation industry which had a clear common interest to solve the problem. However, it is very likely that the number of cases reported represents an underestimation of the real number of persons having had such symptoms as probably a majority of them have been consulting only their doctor or haven't been consulting at all. Moreover, in many cases, the symptoms might have not been easily linked to the recent installation of cellulose insulation.

According to ECIMA, after the cases many French cellulose insulation manufacturers (namely members of ECIMA) decided to stop the production of cellulose insulation with ammonium salts since the end of the month of October 2012 while another part of the industry kept producing ammonium-based cellulose insulation. ECIMA members were alerted by the consumers' complains and it was crucial for them to substitute ammonium salts. Before the national restriction, some members of ECIMA, having experienced health cases, had already stopped the production and recalled their stocks of cellulose insulation containing ammonium salts to their warehouses to be destroyed. In order to protect the consumers' health, in some cases, producers members of ECIMA also decided to pay the necessary works to take away the cellulose insulation emitting ammonia and to reinstall a new ammonium-free insulation.

However, at least one French producer did not change its strategy not even after the cases experienced by the company and kept producing large quantities of cellulose insulation containing ammonium salts until the French restriction and had to pay a lot to recall all products containing ammonium salts to its warehouse immediately after the restriction.

After a certain number of complains of health cases, the French authorities decided to take urgent action. By Decree, in June 2013, the French Ministry of Ecology, the Ministers of Social Affairs and health and the Minister of labour jointly signed a national restriction on cellulose insulation containing ammonium salts. The French restriction entered into force in July 2013 prohibiting the placing on the market, import, distribution, sale and manufacture of cellulose-based insulation which would use as an adjuvant ammonium salts. These compounds, used in substitution to the boric salts for their properties of flame retardant agent, were accused of releasing ammonia after installation of thermal insulation in the form of panels or loose cellulose insulation. In November 2012, CSTB had issued an alert note which stated: "the strong, unpleasant smell could be caused by instability of certain additives (ammonium salts), used in certain types of cellulose insulation".

In France cellulose insulation products containing ammonium salts have been removed from points of sale and recalled at the expense of the person responsible for the first placing on the market, according to the text of the French Decree. Since the first complains in France, and mainly after the French restriction on ammonium salts, the production of insulation containing those salts has significantly decreased in Europe (namely because it is forbidden in France).

Although cellulose insulation has a relative small market share, in France the use of cellulose insulation was quite popular as "environmentally friendly and sustainable» building material.

According to ECIMA, after the French restriction, French manufacturers had to go back to the previous formulations with boron salts as flame retardant, as at the end of 2011. In this phase of research of suitable alternatives, French manufacturers and suppliers have benefited of an exceptional temporary extension of two years for the validity of technical approvals for the cellulose insulation with boron salts in order to get enough time to develop new formulations at least as powerful as that containing ammonium salts.

According to the French enforcement authorities (DGCCRF), no new cases of ammonia emission from cellulose insulation were reported after the entry into force of the French restriction on cellulose insulation containing ammonium salts due to newly installed insulation. Due to the recent implementation of the French restriction, to date it is however unclear to what extent cellulose insulation containing ammonium salts has completely disappeared from the French market.

It worth's remembering that the costs of re-insulation cannot be considered as already internalized by the manufacturers of the cellulose insulation as, even in case of ammonia emissions, the costs of re-insulation will be covered by the insurance companies and not directly by the manufacturers.

The number of avoided exposed persons per year has been estimated at 300 in 2017 in the European Union (see section F 1.1.3 Exposed population estimation for the calculation details). These estimations are subject to great uncertainty given the uncertain future development of this young market after the French cases.

In France, boric acid has been substituted in cellulose insulation because the French authorities decided to stop providing technical approvals to boron based cellulose insulation placed on the French market, completely prohibiting boron salts in the product. Manufacturers have replaced these boron salts by flame retardants containing inorganic ammonium salts.
At the European level, a similar switch from boron to ammonium salts may happen if the boron-based blends happen to be prohibited, due to changes of the specific concentration limit of boron compounds in mixtures or due to an inclusion of boron to the Annexe XIV (authorisation). In this case, the number of avoided exposed persons would be greater.

E.1.2 Risk management options

Six potential risk management options have been taken into consideration in order to formulate our Community-wide restriction proposal.
These options are the following:

- Under REACH Regulation: restriction on ammonia emissions, composition-based restriction, authorisation.
- Other Community-wide risk management options: Construction Products Regulation, providing information to retailers and consumers through labeling. voluntary agreement by the industry,

Each of these options is discussed in details in section E.2.

E.2 Assessment of risk management options (RMO)

E.2.1 RMO 1: Restriction on ammonia emission

E.2.1.1 Effectiveness

E.2.1.1.1 Risk reduction capacity

On the basis of the available information, there is sufficient evidence to support robust conclusions on the fact that the proposed restriction on emissions will be effective in avoiding any human health risks and related negative health impacts by eliminating the exposures associated with the ammonia emitted by cellulose insulation. This RMO is expected to result in a **complete** risk reduction of ammonia emissions from cellulose insulation both for occupants and professionals. It is expected that any health impacts arising after implementation of the proposed restriction would be due to historical legacy of previously installed cellulose insulation.

The environmental risk related to ammonium salts in cellulose insulation is considered insignificant as the quantity of ammonia that may be released into the atmosphere from the cellulose insulation is very small compared to other sources of ammonia such as agriculture or livestock keeping.

A too rapid switch might compromise the effectiveness of the restriction bringing to a bad substitution as it has already happened in France for the change from boric to “instable” ammonium salts when the Committee in charge of the French Technical Approvals stopped providing approvals for cellulose insulation containing boric acid or other classified borates.
Moreover, the effectiveness of the restriction may be compromised if the European industry switches to boron-based or to alternatives whose health and environmental effects are not well known yet. Before switching their production towards one of the existing alternative blends (such as those listed in Section C), actors will have to assess properly the associated risks in order to make sure that the use of alternative formulations of fire retardants and biocides with a same level of efficiency does not pose any health or environmental risk.

E.2.1.1.2 Proportionality

The assessment of proportionality of the proposed restriction is based on a quantitative socio-economic analysis of the costs and benefits, based on established procedures underpinned by a robust methodological approach for calculation of the costs for the industry compared to welfare and consumers surplus changes for reducing human health risks. This socio-economic analysis is fully detailed in section F of this dossier.

The following table provides estimates over time of accumulated benefits (avoided costs for re-insulation and re-housing) and of accumulated costs (R&D, TAs and testing) of the proposed restriction in millions of euros, under the assumptions done in Section F.

	2017	2020	2025	2030
Total accumulated benefits (in M€)	0.33	1.38	3.3	5.44
Total accumulated costs (in M€)	0.41	0.77	1.41	2.12

Table 20: Estimates of accumulated benefits and accumulated costs in millions of euros, under the considered assumptions

It can be noted that neither the costs nor the benefits of this proposed restriction are very high and that the benefits overcome the costs after less than one year after the entry into force of the restriction. The monetised net benefit of the proposed restriction is significantly growing over time as compared to the baseline scenario under which the cellulose insulation containing ammonium salts keep being installed in the EU and thus the exposed population would increase. Therefore, under the assumptions done in the SEA, costs associated with the proposed restriction can be considered not to be disproportionate to cost savings and benefits.
It can be concluded that the proposed restriction on ammonia emissions from cellulose insulation under article 129 of REACH Regulation seems to be socially and economically proportionate.
However, it worth’s remembering that a critical issue while assessing the benefits of substituting blends containing ammonium salts with alternative formulations is the fact that the substances contained in the alternatives (like those containing boron compounds) might also pose health or environmental problems.

E.2.1.1.2.1 Minimal costs for the industry after restriction - keeping business as usual: costs of the testing

If the cellulose insulation containing ammonium salts currently on the EU market is proven not emitting ammonia, as most European manufacturers claim, the producers of cellulose insulation will certainly decide to keep their business as usual (by doing nothing). In such case, after the entry into force of the proposed restriction, the only costs to be afforded by the manufacturers would be the costs of emissions testing to prove that their cellulose insulation is not concerned by the ammonia emissions.
Obviously, for the industry, in terms of costs, this “doing nothing” scenario corresponds to the best possible scenario.
Concerning the testing costs of the proposed restriction, a certain number of assumptions had to be made:

- The cost of testing taken into account into the calculations refers only to the manufacturers producing cellulose insulation containing ammonium salts. The testing costs that will probably have to be afforded by the whole industry (including by the manufacturers using boron) as a tool to build confidence concerning the cellulose insulation sold on the EU market has not been considered as it is not strictly mandatory according to the scope of the restriction;
- The cost of testing for ammonia emissions will be of about 1000 € per test and the test will be done in average every three years as it is considered taking place while requiring the Technical Approvals (TAs).

E 2.1.1.2.2 Costs of substitution and costs of stabilization

Aside the costs for emissions testing, for the cellulose insulation industry, the main costs for substituting ammonium salts as fire retardants or for stabilizing ammonium-based formulations seem to be those related to R&D to find a suitable and economically feasible alternative or increased costs of the alternative formulations, temporary production downtime and employment losses, new technical approvals (ETAs and national), new trainings to staff and installers, withdrawal and loss of value of the stocks of raw materials (ammonium-based formulations) and of the cellulose insulation, and minor investment to readapt the machinery.
Some of the costs mentioned (e.g. ETA and national technical approvals, testing, R&D, adaptation costs, etc.) can be considered as sunk costs on already made investments in case of a premature end of the production of cellulose insulation containing ammonium salts. Some of the related costs impacts can be minimized or completely avoided if the companies would make the right choices before the entry into force of the proposed restriction.
In terms of timing almost all these costs will occur immediately before or just after the entry into force of the proposed restriction.

Concerning research and development, only large companies will likely have the necessary financial means and technical know-how to carry out effective programs of **R&D** to find alternatives which will be safe both for human health and the environment, and at the same time cost efficient and technically feasible. Small and medium sized companies, but also some large companies, will most probably buy formulations at increased prices which will incorporate a share for remunerating the investment in R&D carried out by the producer of the new or stabilised chemical formulation. Due to lack of information concerning the real price of ammonium and boron-free formulations which are not yet on the market, a factor 2 price compared to the present ammonium-based formulations has been assumed (the suggestion came from a formulator). This price of 1500 euros per tonne corresponds to the lower bound indicated by the cellulose insulation industry (ECIA quoted a factor 2 to factor 6). This assumption is also supported by that fact that the French research project on new safe formulations settled a goal of a limited increase of price of 100 euros for additives per ton of cellulose insulation. If we consider 10% of additives on the cellulose insulation, and an average price of 750 euros per tonne of formulation, the 100€ increase correspond to a factor 2.3. Factor 2 seems therefore a realistic assumption.

It was assumed that only 10% of the market would wish to use a more expensive, ammonium and boron-free formulation and that the majority of manufacturers would substitute with boron without costs' increases.

It is assumed that the costs of substitution will not be passed on along the supply chain down to EU consumers (i.e. the price of the cellulose insulation would remain the same).

Based on information on **price difference** (between ammonium salts and its substitutes) and on the quantity/percentage of alternatives that is expected to be used in order to replace ammonium salts, changes in the per-unit operating costs may occur. The final price of the formulation will depend on the relative percentage of the different substances added to the formulation (for instance 4% of boric acid + 8% magnesium sulphate or of aluminium trihydrate in a **typical boron-based formulation**) and on the final percentage of the formulation added to the final products (generally between 10 and 14% depending on the blends).
The prices of the alternative formulations without ammonium salts and without boron, considered in the socio-economic analysis could either increase or decrease in a next future according to several different factors such as availability, competition, patents, purchase volumes, types of contracts, business relationships with suppliers, etc.
In the absence of sufficient elements to define such future trends, the prices were assumed to be stable.

Concerning a **typical ammonium-based formulation** during the stakeholders' consultation it was not possible to gather precise information on the different substances (for instance ammonium sulphate, ammonium mono or poly-phosphate, other additives such as biocides, etc) added to the formulation and their relative percentages. However, according to information from consultation with formulators of fire retardants and cellulose insulation industries, the final price of the formulation for ammonium-based formulations would range between 750 and 900 € per tonne of formulation euros and it would have to be added in a percentage of 10% of the total weight of the final product.

Formulations	Cost (Euro) / Tonne	Average percentage added to the final product
Boron-based	715	12%
Ammonium-based	750-900	10%
Ammonium and boron-free	1500 (assumption)	10% (assumption)

Table 21: Average costs of the main formulations added to the cellulose insulation (ANSES estimation from stakeholders' consultation)

This Table provides the estimation of the average prices of the main formulations used to treat the cellulose insulation.

Considering the scenario of a **substitution with boron**, the prices of the formulations would remain almost the same (or would even slightly decrease) as the prices of ammonium based formulations.

Considering the scenario of a substitution with boron-free formulations, it seems reasonable to assume that the prices of the most cost-effective alternatives throughout the scenario period will be higher than the prices of ammonium and boron based formulations that are currently the cheapest formulations already largely adopted by the EU market (according to stakeholders). However, from the available information it is not possible to establish an average price difference for alternative formulations compared to ammonium based ones. Most probably, in a longer run after the entry into force of the restriction, after carrying out the necessary R&D other alternatives than boron-based formulations will enter into the European market at a reasonable price.

Immediately after the entry into force of the restriction, manufacturers of cellulose insulation containing ammonium salts may face, at least temporarily, **production downtimes and market shares' losses**, namely if the restriction was to be implemented in a very short-term. However, this would happen only if substitution or stabilization strategies would have not been anticipated by the industry. This category of cost is therefore considered as avoidable by the industry.

The main unavoidable costs for the cellulose insulation industry are expected to be the costs related to **testing** ammonia emissions and those of obtaining new **technical approvals at European** (ETAs) and national level.
Relevant information concerning ETAs' costs are reported by the following website of EOTA: http://www.ubatc.be/media/docs/pdf/Algemene_Goedkeurings-_en_Certificatiekosten_2011-07-01_EN-FR-NL.pdf

	Cost of a technical approval (in Euros)	Duration of validity (in years)
First application	15,000	3
Revision	10,000	3
Extra charge for a variation (ie, walls in addition to the roofs)	7,000	3
Average program for a first application, non-certification	30,000	/

Table 22: Costs of national technical approvals in France (CSTB estimation)

These prices include only the technical assessment procedure. The average duration of validity can be considered of 3 years, even if it can go up to 5 years in certain cases.
The total costs of ETA and TA used in the calculation is 50,000 euros for an average duration of validity of 3 years **(for a total of 300,000 euros for the six companies still currently producing with ammonium).** The cost of TAs at national and European level is considered as a one-off cost which will be afforded before or during the first year following the restriction. The costs related to technical approvals during subsequent years are counted as operational costs that the companies would have sustained even under the baseline scenario to renew the TAs and ETAs.

National technical approvals are voluntary approvals but in practice they become the main entry barriers of the cellulose insulation sector as they become necessary for insurability reasons and therefore to sell in each different European country. National technical approvals foresee different requirements (in particular for fire retardant properties) and their costs vary among Member States.
Taking into consideration the fact that the restriction proposal will probably not enter into force before 2017, some manufacturers of cellulose insulation might potentially have to renew the ETAs or national technical approvals they already got some months before their natural end of validity in the absence of this proposed restriction.
In monetary terms, the costs of European and national Technical approvals are estimated at around 50,000 euros to be paid just once by each of the six identified companies currently producing cellulose insulation with ammonium salts (300,000 euros in total for all companies).

These costs represent the main additional costs of the proposed restriction. This estimation represents an overestimation of the costs as it refers to the worst case of substitution for a company producing 100% of its production with ammonium. If the company has already a part of the production containing boron-based formulations and it decides to switch its ammonium-based production into boron, ETAs and TAs for such type of cellulose insulation would already exist (and be paid). Moreover, in case of stabilization of ammonium-based formulations, since the cellulose insulation will be treated with a slightly different more stable formulation, the manufacturers would probably have to require only minor modifications of the European and national technical approvals with lower impacts in terms of costs.
After the first change of European and national Technical approvals due to the proposed restriction, the costs of TAs renewals are not taken into account in the costs calculations as the manufacturers would have to pay for the renewal even under a business as usual scenario in case of continued use of the ammonium-based formulations. Hence, the total cost for technical approvals due to the restriction is estimated to be 300,000 € maximum.

The **training costs** will have to be considered only if the new formulations imply changes in terms of production and/or installation. However, these training costs have to be considered as operating costs as such training are organised regularly by the manufacturers of cellulose insulation even under a business as usual scenario.

As far as **depletion of stocks** is concerned, the level of the stocks of final products is very low due to the fact that cellulose insulation is cumbersome. According to the cellulose insulation manufacturers consulted, it corresponds to less than a week of production.
According to the cellulose insulation manufacturers, the level of stocks of the formulations is higher than that of final products but according to the stakeholders consultation it correspond to two to four weeks of production.
The fact that the restriction proposal foresees a period of adaptation of 12 months should allow to deplete the stocks of cellulose insulation containing ammonium and to avoid ordering a new stock of formulations the very weeks immediately before the entry into force of the restriction.

According to stakeholder consultation (industry actors and ECIA), manufacturers of cellulose insulation containing ammonium salts generally believe to be able to use the same plants for producing cellulose insulation using less hazardous fire retardants or stabilized formulations with **minor changes in the production** process and production equipment, namely if ammonium salts will be substituted by another powder formulation (and not by a liquid formulation). However, it still depends on the substance that will be chosen for the new formulation, on its density and on the percentage which will have to be added to the final product. For instance, in case of major differences in terms of density from the previously used ammonium-based formulation and the new one, there would be small adaptation costs (namely concerning the change of the filters and relative quantities of the new formulation to be added). In the calculations it was assumed that a **powder formulation** would be used and that no costs of adaptation will have to be afforded by the industry. This assumption could slightly underestimate such costs.
There are clear indications that in case the ammonium-free alternative would have to be introduced as **liquid formulation**, **major modifications** of production processes and equipments used and thus substantial changes in per-unit investment costs should be expected. These changes would imply a higher level of sunk costs. Up to now, these types of formulations are not considered as economically-viable alternatives.

As mentioned above, most of these potential negative impacts could be avoided if appropriate substitution or stabilization strategies would be in place before the entry into force of the restriction. Depending on the strategies adopted for instance, the production downtime, as well as the reduction of the market value and of the stocks' value can be even completely avoided by the industry quite easily. Therefore, being avoidable, such costs are not included in the costs calculations for the proposed restriction.

In order to reflect the cost increase, the manufacturers will have to decide to reduce their profit margins or to increase the final prices of their cellulose insulation. According to the manufacturers consulted, the additional costs would not be easily passed on to the final consumer because the consumers could decide to buy a different thermal insulation due also to the losses in terms of image of the cellulose insulation. Therefore, it was assumed that the industry will have to accept reduced profits at least temporarily.

E.2.1.1.2.3 Benefits

As re-insulation costs are substantial, the main benefits to society from reducing emissions are represented by the **avoided costs of re-insulation**.
Re-insulation implies temporary re-housing for taking away the old cellulose insulation and reinstalling the new thermal insulation.
According to stakeholders' consultation, the time needed for such re-insulation is estimated at two and half days which implies the cost of two overnights for a standard family of four.

A detailed analysis of the benefits and on their quantification is provided in section F.

E.2.1.1.3 Other costs and economic effects

The stakeholders' consultation (detailed information on consultation can be found in Section G) indicates that only around 5% of the cellulose insulation sold on the EU market contains ammonium salts and ammonium-free alternative already exist and mainly consist of boron-based formulations (around 95%).

During the consultation process, manufacturers of cellulose insulation using ammonium-based formulations which are the most directly concerned stakeholders of this restriction proposal were asked what type of impacts a restriction would have on their activities. From the received answers, the impacts of this restriction proposal seem to be minor and they are represented by the potential additional costs which are discussed in section F.

Consequently, the proposed restriction provides a good balance between costs and benefits.

E.2.1.2 Practicality

E.2.1.2.1 Implementability

As explained in the previous sections, the suppression or reduction of ammonia emissions can be done either by stabilizing the ammonium-based formulations used or by replacing ammonium salts by alternative blends containing boron currently available on the market compounds or probably in the future without boron if the research and development will come out with a different blend.

Concerning the stabilization of ammonium-based formulations, it is difficult to know if it is technically and economically feasible as it depends on the number of attempts that would be necessary through the research and development process to find an efficient and cost effective formulation. As confirmed by the formulators and the cellulose insulation manufacturers, the emission limit of 3 ppm proposed by this restriction seems to be technically and economically feasible without obliging the ammonium salts' substitution. Therefore the proposal is not expected to result in a total ban of cellulose insulation containing ammonium salts. During the stakeholders' consultation, many manufacturers of cellulose insulation claimed that the formulations used are already stable and they do not emit ammonia. In case a manufacturer of cellulose insulation would be able to prove that its products are not emitting ammonia, the implementability of the proposed restriction would be quite straight forward and the producer would have to do and to afford nothing else than testing.

Moreover, the tests carried out by the CSTB on different French cellulose insulation materials demonstrate that the emission limit does not represent a ban as the test of 2 biomaterials have shown emissions of just a residual concentration of ammonia (around 1 ppm).
Other thermal insulation materials which could contain ammonium salts and potentially emit ammonia are not covered by the scope of the proposed restriction due to the fact that no alerts concerning their ammonia emissions were reported anywhere in Europe.
Substituting ammonium salts in cellulose insulation by other alternative flame retardants seems to be technically feasible although some economical difficulties might arise if a substitute other than boron-based would be implemented.

Consequently, the EU and non-EU manufacturers should be able to comply with the restriction proposal at least by one of the two alternative ways by either stabilizing the formulations in order to avoid ammonia emissions, either by substituting the currently used formulations.

Emission tests for ammonia is already technically feasible, even though a standard need to be developed further and adapted to cellulose insulation. Moreover, to date industry actors concerned by the proposed restriction are only a few but they might increase in case of a revision of the specific concentration limit for boron salts. The need of a long enough adaptation period, namely to carry out R&D, was mentioned for complying with the proposed restriction. A delay of 12 months seems to allow adapting the production techniques to the alternative formulations and to implement an adequate control of the supply chain. Micro and small firms may encounter more difficulties for the implementation of the proposed restriction as reported in the Section F.
In France, no major problems for the implementation of the national restriction have been observed according to the DGCCRF[38]. Due to the recent implementation of the French restriction, to date it is however unclear to what extent cellulose insulation containing ammonium salts has completely disappeared from the French market.

Finally, concerning the possibility of exemptions, it could be argued that cellulose insulation may be installed outdoor and should be exempted because it would eventually emit outside the living environment. Such products could be labeled, specifying that the article is only intended for outdoor use. However, in practice it seems very difficult to ensure that this type of cellulose insulation, that is exactly the same as that meant to be installed indoor, would not be installed inside the living environment, namely if such products would become less expensive than the indoor's ones. Forum will assess the enforcement problems related to this option of labeling for outdoor cellulose insulation and RAC and SEAC will assess if an exemption should be foreseen. However, for the dossier submitter of the proposed restriction no exemptions should be foreseen as potentially all cellulose insulation may be installed indoor and it may contribute to direct human exposure.

[38] French Directorate General for Competition, Consumption and Fraud.

E.2.1.2.2 Enforceability and manageability

According to stakeholders' consultations (industry actors, MSCAs, consumer groups and laboratories), and given the availability and the expected future development of analytical methods to measure ammonia emissions in cellulose insulation, this restriction proposal is also expected to be easily manageable by the authorities.
The proposed restriction is easily understandable by affected parties and relevant information is easily accessible. Thus, the restriction is considered to be easily manageable by all stakeholders within the supply chain.

Box 4: Analytical methods for ammonia (according to ATSDR 2004)

The detection limit of analytical methods for determining ammonia in air depends on the amount of air collected in a liquid or solid adsorbent. Sampling is performed with passive samplers or by drawing a volume of air through the adsorbent using a pump. Particulate contaminants such as ammonium salts may be removed by a prefilter. For determination of ammonia in the ambient atmosphere, larger volumes of air must be sampled than those appropriate for determinations of ammonia in occupational settings (e.g., industrial, agricultural) where ammonia levels are higher. Improvements in methodologies have led to development of techniques that permit continuous monitoring of atmospheric ammonia down to 0.1 $\mu g.m^{-3}$ (Pranitis and Meyerhoff 1987). Several passive monitoring systems report detection limits of 0.05–1.0 $\mu g.m^{-3}$ and have collection rates ranging from 2.7 to 2,000 mL/minute (Kirchner et al. 1999).
One method used for ambient atmospheric sampling employs a specially designed flow-through, ammonia-selective electrode with a sniffer tube, whereas the methods used for occupational settings often use passive collectors with media (usually acids impregnated onto filters) housed within protective cases. Ammonia concentrations on these passive collectors are then determined by a wide range of methods, including colorimetric assays (e.g., indophenol determination), the Berthelot reaction, or ion chromatography (Kirchner et al. 1999).

Ammonia may be present in air in both the vapor phase as ammonia gas and in the particulate phase as ammonium salts. While some analytical methods may distinguish between these phases, most standard methods do not. Methods have been developed that determine gaseous ammonia alone or gaseous and particulate forms of ammoniacal nitrogen separately. These methods use filter packs or sampling tubes coated with a selective adsorbent (denuder tube) to separate the phases (Dimmock and Marshall 1986; Knapp et al. 1986; Rapsomanikis et al. 1988). In these methods, gaseous ammonia is trapped by acids that act as adsorbents (e.g., citric acid, oxalic acid, phosphoric acid) on a coated filter or denuder tube (Kirchner et al. 1999). In filter methods, errors may arise due to ammonia interactions occurring on the filter and volatilization of retained ammonium salt (Dimmock and Marshall 1986; Rapsomanikis et al. 1988). There is evidence that ammonium nitrate in particulate matter is in equilibrium with ammonia. The presence of ammonium nitrate may lead to overestimation of the actual concentration of ammonia, but underestimation of the concentration of ammonium (Doyle et al. 1979).

The CCOHS (Canadian Centre for Occupational Health and Safety) gives the following analytical methods for ammonia[39]:

- OSHA Analytical Methods:
  OSHA METHOD ID-188 - OSHA Analytical Methods Manual. Fully validated method. Collection on carbon beads (treated with sulfuric acid) sorbent tube. Desorption with deionized water. Analysis by ion-exchange chromatography (IC). Estimated detection limit: 0.60 ppm.

- NIOSH Analytical Methods:

[39] Canadian Centre for Occupational Health and Safety. Ammonia gas. CHEMINFO Record Number: 48 (2/10/2014).

NIOSH METHOD 6015 - NIOSH Manual of Analytical methods. Partially evaluated method. Collection on sulfuric acid treated silica gel sorbent tube. Analysis by visible absorption spectrophotometry.
NIOSH METHOD 6016 - NIOSH Manual of Analytical Methods. Fully evaluated.
Collection on: sulfuric acid treated silica gel sorbent tube. Analysis by: ion-exchange chromatography (IC) conductivity detection.

- Direct Reading Instrumentation:
  Methods of detection in commercially available devices which may be suitable: electrical conductivity analyzer, potentiometric analyzer, colorimetric analyzer, aerosol formation detection system, infrared photoacoustic analyzer.

- Colorimetric Detector Tubes:
  Commercially available

- Passive Sampling Devices:
  Commercially available.

E.2.1.3 Monitorability

E.2.1.3.1 Direct and indirect impacts

Monitoring activities for the implementation of the proposed restriction will be carried out by the existing authorities responsible for enforcement of the REACH restrictions in the different Member States and by the laboratories which will be in charge of performing the ammonia emission tests.
It may be highlighted that in the monitoring of the implementation of the proposed restriction micro and SMEs might be favored compared to larger companies. In facts, on the market SMEs still using ammonium salts for their production of cellulose insulation could be identified with more difficulties and thus relatively less controlled and impacted than larger companies which are more easily identified.

E.2.1.3.2 Costs of the monitoring

The efficacy of the enforcement and the compliance with the proposed restriction at EU level can be monitored by using the following three indicators:

1.Monitoring of ammonia emissions from cellulose insulation placed on the EU market at Member State level: this monitoring implies extra costs for testing emissions that may vary between Member States and between laboratories. According to the laboratory of CSTB, testing cellulose insulation with method developed by the CSTB indicatively costs about 1000 Euros. These costs are not expected to have a significant impact on the cellulose insulation industry, if compared to the cost of the European and national technical approvals. Moreover, even if a method for testing ammonia emissions from cellulose insulation is available and already used some costs to harmonize and standardize it might occur.
Costs for measuring emissions may increase due to the difficult identification and localisation of some market actors. Consequently, authorities may choose to carry out only partial controls on the emissions from cellulose insulation produced by manufacturers using ammonium salts without making further controls on cellulose insulation containing other fire retardants; in this case, costs would be reduced but monitoring would be limited.

2.Monitoring of the dossiers opened by the Poison Centers health cases related to ammonia emissions by cellulose insulation at EU-level after the entry into force of the restriction.

3.Monitoring of notifications of any violation of restriction to the EU Rapid Alert System for Non-Food Products (RAPEX). Indicators such as "% of cellulose insulation which have ammonia emissions above **3 ppm**" or "Number of RAPEX notifications related to cellulose insulation emitting ammonia over the limit value of **3 ppm**" can be used to assess the results of the implementation of this restriction by monitoring the ammonia emission of cellulose insulation which is placed on the market.

The effects of the proposed restriction can be monitored over a proposed period of X years to assess whether further measures would be needed for elimination of the risk of exposure to ammonia emissions from cellulose insulation.

E.2.1.4 Overall assessment of RMO 1 based on ammonia emission

This restriction has been chosen as the best risk management option. the risk to be addressed concerns ammonia emitted by cellulose insulation. This option applies to whatever ammonium salt would be used in the composition of marketed cellulose insulation. Such restriction would enter into force within 12 months after the restriction's adoption (i.e. no ammonium salts by beginning of 2017).

Inorganic ammonium salts shall not be used as additives in cellulose insulation unless emission of ammonia of such materials is below 3 ppm according to EN ISO 16000-9:2006 standard. The threshold of 3 ppm is based on the sub chronic inhalation DNEL for the general population. Specific test parameters are proposed in terms of duration, temperature, relative humidity, "Attic insulation" area specific emission rate, "Wall insulation" area specific emission rate and Cellulose thickness / density.

Considering the ammonia threshold of 3 ppm the enforceability does not appear to create any difficulty given the fact that the detection limit for the photoacoustic analyzer INNOVA 1412 LumaSense used by CSTB in the tests is of 0.2 ppm (as presented in section B.9.3). Analytical methods for determining ammonia in air have been discussed by ATSDR (see previous box 4). The proposed threshold of 3 ppm is adapted to analytical *state-of-the-art* for ammonia measurement.

E.2.2 RMO 2: Composition-based restriction

This restriction option would restrict the placing on the market of any cellulose insulation containing inorganic ammonium salts. It is impossible to rely the ammonium content to ammonia emission, the concentration limit should be set at the minimum level, such as a quantification limit. In practice it means that production and placing on the market of cellulose insulation containing inorganic ammonium salts would be banned. Such restriction would enter into force within 12 months after the restriction's adoption (i.e. no inorganic ammonium salts by beginning of 2017).

The main advantage of this restriction option would be the fact that, if an exhaustive list could be drafted, it could theoretically provide a 100% reduction in the number of new cases of professional installers as well as EU consumers exposed to ammonia emitted from newly installed cellulose insulation containing ammonium salts. However, it is very difficult (and almost impossible) to identify and to draft an exhaustive list of all possible inorganic ammonium salts that could be used

as additives in cellulose insulation. Moreover, it would penalize materials with inorganic ammonium salts that do not emit ammonia at all or above the threshold without health effects.
Such a restriction on inorganic ammonium salts in cellulose insulation materials would be quite easily enforceable.

Key points of this restriction option are:

- **Risk reduction capacity:** This RMO could allow an adequate management of the identified risks (i.e. eye and respiratory irritation) for consumers in all Member States only if an exhaustive list of inorganic ammonium salts can be drafted. This restriction option is therefore expected to only partially lower the exposure to indoor ammonia emissions from cellulose insulation containing inorganic ammonium salts as it is considered fairly impossible to identify and draft an exhaustive list of inorganic ammonium salts that could be used as additives in cellulose insulation. The risk reduction capacity values would depend on the exhaustiveness of the list of inorganic ammonium salts and it can be realistically estimated in a range **from 75% to 95%.**
- **Implementability:** Even if the use of boron compounds is not considered by the DS as a desirable option, still currently it remains for the industry the best technically, economically and legally feasible option. Therefore, there are no concerns regarding implementability of this restriction given the availability of boron-based formulations although this option is not desirable under a health view point. Industry actors concerned will be able to comply with this restriction at least in the short run by using boron, while consumers could choose another cellulose insulation material. If the drafted list of inorganic ammonium salts would not be exhaustive the manufacturers could still switch to different inorganic ammonium salts not included in the list.
- **Coherence with art. 129:** Given the economical and the technical feasibility of alternatives, the restriction shall be applicable 12 months after amendment of Annex XVII of the REACH Regulation enters into force.
- **Proportionality:** The implementation of this restriction option on the content of inorganic ammonium salts in cellulose insulation may be very costly for the industry currently using ammonium-based blends if the manufactures would switch to a boron-free blend and it would stay more or less at the same level of price (excluding the costs for new TAs) if the industry will switch to a boron-based blend at least in the short term. The data available seems to indicate that for this restriction on the placing on the market of cellulose insulation containing one or more inorganic ammonium salts included in a list the main cost elements would be the R&D to find such new formulations and the additional price of the formulations, while cost elements like a change of manufacturing process and changes in production equipment seem to be of less likely. Moreover, as in the future it can be expected that the specific concentration limit of boron compounds could be lowered from 5.5% to 0.3% this restriction banning the main alternative blend based on ammonium salts – in an economic point of view - would largely affect the cellulose insulation industry until a third type of blend will be found. Therefore in terms of costs versus risk reduction capacity, this option is considered not proportional to the risks that it might only partially reduce as it will result in major wider socio-economic losses.
- **Enforceability:** The compliance to the restriction on placing on the market of cellulose insulation containing inorganic ammonium salts by all relevant actors (producers, importers, and distributors) can be checked by the authorities responsible for enforcing the restriction. The required control of producers, importers, and distributors is in line with regular monitoring procedures and shouldn’t entail any specific challenge.
- **Monitorability:** The implementation of this restriction option on the content of inorganic ammonium salts in cellulose insulation would primarily be monitored through

enforcement by checking the ammonium concentration from cellulose insulation which are placed on the EU market.

E.2.3 RMO 3: Authorisation

According to the REACH Regulation, Authorisation (Title VII) is a way for limiting the use of substances of very high concern which are defined according to paragraphs (a) to (f) of Article 57 of the Regulation. Paragraphs (a) to (e) are not applicable to ammonium salts which are not classified as dangerous substances. Concerning paragraph (f), it is excluded that ammonium salts may give rise to “equivalent concern” to the substances listed in points (a) to (e). A complete ban of ammonium salts in all products (including for instance fertilizers) may be not at all justified. Therefore, in this specific case of cellulose insulation containing ammonium salts emitting ammonia, the authorisation process of the REACH Regulation is not an appropriate management option. Furthermore, the authorisation route would have meant that the risks to consumers and to professional installers related to imported cellulose insulation placed on the EU market would have not been addressed. Lastly implementing the authorisation process would have taken much longer than passing via the restriction route.
Therefore, under REACH Regulation only a restriction could be considered as an appropriate risk management option.

E.2.4 RMO 4: Construction Products Regulation (EU/305/2011)

Construction Products Regulation[40] does not currently regulate indoor emissions of ammonia from the manufacture and use of the cellulose insulation containing ammonium salts.

Construction Products Regulation refers to the following key points:

<u>1-Declaration of Performance (DoP)</u>
The Declaration of Performance (DoP) gives the manufacturer the opportunity to deliver the information about the essential characteristics of the product he wants to deliver to the market.
The manufacturer shall draw up a Declaration of Performance when a product covered by a harmonised standard (hEN) or a European Technical Assessment (ETA) is placed on the market. The manufacturer, by drawing up his DoP, assumes the responsibility for the conformity of the construction product with the declared performance.
On the basis of the information contained in the DoP, the user will decide to buy, amongst all the products available on the market, the one which better fits for the use he intends to make with such product and he assumes the full responsibility of such decision.

<u>2-Harmonised European standards (hEN)</u>
The harmonised European standards (hEN) on construction products together with the relevant horizontal standards on assessment methods for:

- resistance on fire, reaction to fire, external fire performance, noise absorption,
- construction products in contact with drinking water,
- release of dangerous substances into indoor air, soil and (ground)water.

[40] Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

3-European Technical Assessment (ETA)
EOTA is the European Organisation for Technical Assessment in the area of construction products, according to Article 31 of the Regulation (EU) No 305/2011.

The European Technical Assessment (ETA) is a document providing information on the assessment of the performance of a construction product, in relation to its essential characteristics.
The ETA provides a way for the manufacturer to CE-mark a product (Art. 4 (1) of the Construction Products Regulation).

The ETA is valid in all 28 European Member States and those of the European Economic Area, as well as in Switzerland. It may be recognised also in countries where a mutual recognition agreement is concluded with the European Community. The ETA is the basis for a Declaration of Performance (DoP) by the manufacturer.

4-CE Marking
The CE marking follows the Declaration of Performance (DoP)
The European Technical Assessment provides for a (voluntary) basis for CE marking of construction products. Other routes are shown in the graphic below:

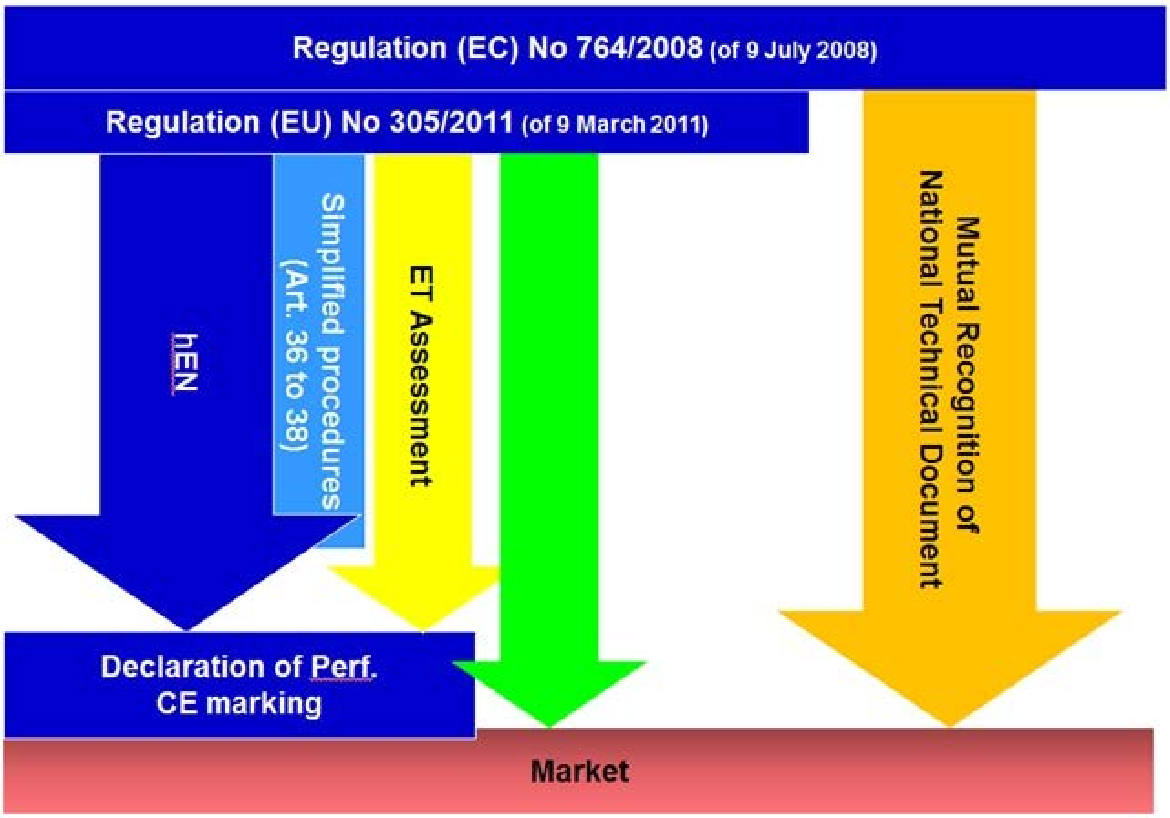


Figure 13: Different routes of CE marking and marketing of construction products (EOTA 2013)

5-National technical approval
Despite CE Marking and European Technical Assessment (ETA), it is important to emphasize that national technical approvals – even if it is a voluntary action - are often necessary to put a construction material on a national market.
According to Industry representative's consultation, national technical approval's requirements are considered stronger than ETA. Additional tests may be required.

Discussion
Emission of dangerous substances into indoor air is covered by the basic requirements for construction works (annex I of Regulation No 305/2011):

> *3. Hygiene, health and the environment*
> The construction works must be designed and built in such a way that they will, throughout their life cycle, not be a threat to the hygiene or health and safety of workers, occupants or neighbours, nor have an exceedingly high impact, over their entire life cycle, on the environmental quality or on the climate during their construction, use and demolition, in particular as a result of any of the following:
> (a) the giving-off of toxic gas;
> (b) the emissions of dangerous substances, volatile organic compounds (VOC), greenhouse gases or dangerous particles into indoor or outdoor air;
> […]

In the Chapter VIII "Market surveillance and safeguard procedures", Article 56 foresees a procedure to deal at national level with construction products presenting a risk when a product "does not achieve the declared performance and presents a risk for the fulfillment of the basic requirements".

The provisions apply to authorities and companies placing such construction products on the market. Article 58 of the Regulation states: 'Where, having performed an evaluation pursuant to Article 56(1), a Member State finds that, although a construction product is in compliance with this Regulation, it presents a risk for the fulfilment of the basic requirements for construction works, to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the construction product concerned, when placed on the market, no longer presents that risk, to withdraw the construction product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, which it may prescribe.' This part of the Construction Products Regulation applies in conjunction with the Regulation on accreditation and market surveillance (765/2008).

Representatives of DG ENTR/B1 have been consulted by the dossier submitter and explained that these "safeguard procedures" apply to a construction product (cellulose insulation here) and not to chemicals or additives of this product (inorganic ammonium salts in this case). No similar cases as stated in this proposal (emission of a hazardous chemical from a construction product) have been identified to be managed with this regulation's clause.

Furthermore, the creation of harmonized standards at European level through Harmonised European standards (hEN) or European Technical Assessment (ETA) is a long procedure (6 years estimated). This delay is not adapted to an urgent action as proposed by Article 129 of REACH Regulation.

Considering the level of information available, no clear conclusion could be done by the dossier submitter on the effectiveness of this RMO to manage the risk linked to ammonia emissions even if it seems not adapted to chemical regulation in a limited time-frame due to urgent action.

Key points of this risk management option are:

- **Implementability:** The Construction Products Regulation 305/2011 contains only generic provisions on protection of workers and general public from chemical exposure and risk without specifically regulating indoor emissions of ammonia. It concerns products and not chemicals used as additives: even the implementability of Art 56.1 of the Regulation which presents a procedure to deal at national level with risky construction products and that of art.

58 do not seem so straight forward in providing sufficient grounds for obliging the manufacturer of the cellulose insulation to adapt its products in order to prevent such cases.

- **Risk reduction capacity**: As explained above concerning the implementability of this RMO, it is not sure that this option could allow an adequate management of the identified risks (i.e. eye and respiratory irritation) for consumers in all Member States.
- **Monitorability:** The implementation of this risk management option may be monitored quite easily by the Construction Products Competent Authorities at Member States' level.
- **Coherence with art. 129:** Given the long timing needed to develop harmonised European standards, the implementation of this option is expected to take around 6 years; therefore it is not considered coherent with the need of urgent action to solve the problem of indoor emissions of ammonia.
- **Proportionality:** Once the harmonised European standards will be settled, the implementation of this risk management option does not imply important costs.

E.2.5 RMO 5: Providing information to retailers and consumers through labelling

This option takes into consideration the possibility of labelling the cellulose insulation placed into the EU market for providing information to retailers and consumers concerning the content of ammonium salts.

However, before the installation, retailers selling cellulose insulation containing ammonium salts cannot know if once installed the cellulose insulation that they are selling would emit or not ammonia.

For consumers the fact that the cellulose insulation is labeled as containing ammonium salts while placed into the market does not seem to be sufficiently informative for avoiding buying the cellulose insulation containing ammonium salts because consumers might be unaware of the related risks of ammonia emissions.

For the occupants of already insulated buildings, it will be difficult to identify if the insulation previously installed in their apartment/house contains (or not) ammonium salts and if it could potentially emit ammonia, even if the cellulose insulation was properly labeled while placed into the market. It worth's remembering that the cellulose insulation might emit ammonia throughout its lifetime. Once the cellulose insulation is installed, a house may change owners/tenants several times within the estimated lifespan of cellulose insulation that is of 60 years. Therefore, the occupants that could be exposed in the future might be different from the one who took the "buying" decision informed by the label.

Key points of this risk management option are:

- **Risk reduction capacity:** This RMO does not seem to allow an adequate management of the identified risks (i.e. eye and respiratory irritation) for consumers in all Member States as not informative enough. This option would not remove the risk for occupants who entered the living unit after the installation of the ammonium based cellulose insulation, nor for consumers not informed enough concerning the fact that ammonium salts could eventually emit ammonia.
- **Coherence with art. 129:** This RMO would be applicable in a relatively short time.
- **Monitorability:** The implementation of this risk management option may be monitored by the competent authorities by checking the labelling of cellulose insulation which is placed on the EU market.
- **Proportionality:** The implementation of this increased labelling obligation for cellulose insulation containing ammonium salts would imply some additional costs for the industry

for changing the labels on the packaging without guaranteeing the same level of benefits than the proposed option.

In conclusion, the RMO option of providing information to consumers and retailers through labelling does not seem to be sufficiently effective to avoid health risks related to ammonia emissions from cellulose insulation.

E.2.6 RMO 6: Voluntary agreement from the industry

In the case of cellulose insulation, a voluntary action by industry could be a very effective way to retrieve from the market ammonia emitting cellulose insulation, and consequently reduce the risk of ammonia emissions. Moreover, a voluntary agreement, in order to minimise the costs for the industry, generally foresees a mid- or long-term plan to phase out the production of the dangerous chemical or for promoting chemical stabilization of additives. In a way, for the industry, these types of agreements are not legally binding but they certainly become socially binding, if there is a strong social control by the civil society.
In principle, the option of a voluntary agreement would need the coordination from one (or more) strong and well organized actor(s), representing the whole European cellulose insulation industry, wishing and able to lead the process and to manage and monitor the implementation of an eventual Voluntary Commitment of the industry. The association promoting the agreement should have the necessary organisational infrastructure and financial means, as well as the political strength to have a real influence on the EU manufacturers currently using ammonium based formulations in order to avoid free riding.
At present, none of the two identified associations (ECIMA and ECIA) seems to have such characteristics. In facts, ECIMA members are mainly the French manufacturers who are not allowed to use ammonium salts anymore according to the French restriction. ECIA does not seem to be in the position to take the lead on the phase out or on the stabilization of ammonium-based formulations given that it is a very young association (founded in September 2013), not yet officially recognised as legal identity, and that most of its 14 members (on a total of more than 40 EU producers) are not concerned by the problems related to the use of ammonium (because they are mainly using boron-based formulations).

Some of the European consulted companies currently manufacturing cellulose insulation containing ammonium salts expressed their strong interest towards the possibility of establishing a voluntary agreement and probably in a next future they will try to communicate among them in order to find a common ground to prepare a voluntary agreement and to ensure its compliance. However, at present, the industry hasn’t formulated official commitment in order to prevent the release of ammonia or to control the concentration of ammonium salts in cellulose insulation placed on the European market.
Consequently, although this option could be a very effective and the most proportionate risk management option for industrial actors, by the time ANSES was submitting this dossier this option seemed difficult to be realised in the short run.

Key points of this risk management option are:

- **Risk reduction capacity:** in principle, this RMO could allow an adequate management of the identified risks (i.e. eye and respiratory irritation) for consumers in all Member States depending on the exact content of the agreement proposed by the industry and on if and to what extent the agreement will be maintained by each manufacturer (no or minimal free-riding). However, at present, there is a lack of a strong actor able to lead the process and to prevent free-riding. The two existing European associations seem to lack the political will or the capacity to promote and to effectively monitor an eventual voluntary agreement at EU scale.

- **Coherence with art. 129:** this RMO could have been applicable in a relatively short time if a lead organization would already exist and if the agreement would foresee a short timing.
- **Proportionality:** the implementation of this risk management option will most probably imply little costs for the industry which will tailor the proposed voluntary agreement on its needs and times. Therefore, this RMO is deemed to be proportional as compliance costs are minimized and of acceptable order of magnitude, wider socio-economic effects are avoided and substantial risk reduction can be achieved. However, the industry did not yet come out with a voluntary agreement.
- **Enforceability and monitorability:** a voluntary agreement being not legally binding, enforcing and monitoring the implementation of this risk management option strictly depend on the content and the seriousness of implementation of the agreement proposed by the industry and on the social pressure put for instance by stakeholders' NGOs.

E.2.7 Comparison of the risk management options

Restriction based on ammonia emission has been chosen in this restriction proposal.

In order to allow a comparison with the other RMOs, the overview table below provides an indicative qualitative scoring of the different risk management options against each of the main criteria and parameters usually used in restriction dossiers for assessing (and eventually discarding) the risk management options. Such criteria are risk reduction capacity, costs and benefits proportionality, effectiveness**,** practicability, monitorability and the specific need of a short timeframe for it implementation as foreseen by the article 129 namely for this proposal.
This scoring used is qualitative (quantitative assessment was not feasible) and based on a simple appraisal of the degree (high, medium or low) to which each option is suitable in terms of the other above mentioned criteria and parameters and likely to be coherent with the concept of urgent action foreseen by the article 129. The table underlines the main areas of difference among the identified RMOs and it allows a qualitative comparison of the analysed risk management option against effectiveness/practicality/monitorability. Therefore, some risk management options have not been considered further as not feasible, less suitable for reducing the risks or because a too long timeframe would be needed for their implementation.

Option	**Risk reduction capacity**	**Monitora-_ bility**	**Enforca-bility**	**Propor-tionality**	**Practica-bility**	**Coherence Art 129**
RMO 1: REACH restriction on ammonia emissions	High 90%-100%	High	High	High	High	High
RMO 2: REACH restriction on ammonium salts content	High 75%-95%	Low	Low	Medium	High	High

Option	Risk reduction capacity	Monitora-_ bility	Enforca- bility	Propor- tionality	Practica- bility	Coherence Art 129
RMO 4: Construction Products Regulation	High 90%-100%	High	High	High	Medium	Low
RMO 5: Voluntary industry agreement	High/Medium 50-100% Depending on the agreement proposed	Medium (not legally binding)	Medium (not legally binding, risk of free riding)	High (the industry will minimize the costs)	Medium	High/Medium Depending on the timing of the agreement proposed
RMO 6: Information to consumers and retailers through labelling	Low 30%-50%	Medium	High	High	High	Medium

Table 23: Indicative qualitative scoring of each of the RMOs against each of the criteria according to its degree of suitability (high, medium, low)

E.3 Main assumptions used and decisions made during analysis

All assumptions of this restriction proposal were clearly stated and justified all along the document. The main hypotheses are summarized in section F.6. Stakeholder consultation questions and results are fully reported all along this document.
The main overriding assumption of this dossier is that the current production of cellulose insulation is optimized with respect to cost and hence that any change in the production process imposes an additional burden to manufacturers.

E.4 The proposed restriction and summary of the justifications

Based on the arguments above, it is concluded that, given the current situation, a restriction on emissions under REACH Regulation is the most realistic, effective and proportionate option to eliminate the health risks related to ammonia emissions from cellulose insulation.
The proposed option establishes a restriction on the placing on the market of all cellulose insulation (no matter if intended for indoor or outdoor use) emitting more than **3 ppm** of ammonia within 12 months after adoption (i.e. phase-out by beginning of 2017). Although test exists for determining the emissions of ammonia from cellulose insulation based on ISO 16000-9 standard, a critical issue with regard to enforceability is the availability of harmonized analytical methods enabling to analyze ammonia emissions with acceptable sensibility. The harmonization at European level of the existing test methods, including sampling and sample preparation techniques, is recommended in order to guarantee the reliability and reproducibility of analytical results across Member States.

This option seems a fair option for the industry as it leaves a door open for the use of ammonium salts if the European manufacturers of cellulose insulation are able to demonstrate that their cellulose insulation does not emit more than the established limit. This means that those manufacturers who already use a stable chemical formulation or who would have succeeded to stabilize their ammonium-based formulations would be allowed to keep placing on the market their cellulose insulation without any additional cost than the cost of testing emissions. Moreover, the restriction proposal based on the measure of ammonia emission from cellulose insulation which is placed on the EU market seems to be scientifically more correct.

Concerning the issue of which type of cellulose insulation should actually be covered by the restriction and which cellulose insulation could be exempted, it is important to remind that cellulose insulation can indeed be installed indoor or outdoor. It could be argued that cellulose insulation to be installed outdoor should be exempted because it would eventually emit outside the living environment. Such products could be labeled, specifying that the article is only intended for outdoor use. However, in practice in terms of monitorability it seems very difficult to ensure that this type of cellulose insulation, that is exactly the same as that meant to be installed indoor, would not be installed inside the living environment, namely if such products would become less expensive than the indoor's ones. Forum committee will assess the enforcement problems related to this option of labeling for outdoor cellulose insulation and RAC and SEAC committees will assess if an exemption should be foreseen. However, for the dossier submitter of the proposed restriction no exemptions should be foreseen as potentially all cellulose insulation may be installed indoor and it may contribute to direct human exposure.

In summary, the key points of the restriction proposal are:

- **Risk reduction capacity:** the proposal is targeted to allow a complete reduction (risk reduction capacity value expected at EU level of 100%) of the identified risks (i.e. eye and respiratory irritation) for consumers in all Member States. The restriction proposal is expected to eliminate the exposure to indoor ammonia emissions from cellulose insulation containing ammonium salts.
- The proposed threshold for ammonia emission is **3 ppm** based on the **subacute** DNEL for general population does not represent a complete ban, as confirmed by several stakeholders (cellulose insulation manufacturers and formulators).
- **Implementability:** in the best case (no emission from the European cellulose insulation containing ammonium-based formulations) the implementation by the industry will only consist in proving through emission tests the lack of ammonia emissions. If this would not be the case, the stabilization of ammonium-based blends remains a feasible option (this fact is confirmed by formulators). Moreover, even if boron is not considered by the DS as a desirable option, currently it still remains for the industry the best technically, economically and legally feasible option. Therefore, in all cases, there are no concerns regarding implementability of this restriction given the possibility to stabilize and given the availability of boron-based formulations although this option is not desirable under a health view point. Industry actors concerned will be able to comply with this restriction at least in the short run by using boron, while consumers could decide to choose another cellulose insulation material.
- **Coherence with art. 129:** given the existence of an economically and technically feasible (although not desirable) alternative blend and the possibility to further stabilise ammonium-based formulations, the restriction shall be applicable 12 months after amendment of Annex XVII of the REACH Regulation enters into force. This period is considered sufficient to adopt the proposed emission test developed by the CSTB and based on standard 16000 which does not seem to require a long period.
- **Proportionality:** if the current cellulose insulation on the EU market does not emit ammonia, as claimed by the industry, the main cost elements of the proposed restriction would be reduced only to the cost of testing ammonia emissions (1000 euros per year

per manufacturer). In case the cellulose insulation is proven to emit ammonia, the main costs would be the R&D to find such new formulations and the additional price of the formulations, in front of a risk reduction capacity of 100%. Moreover, as in the future it can be expected that the specific concentration limit of boron compounds could be lowered from 5,5% to 0.3% this restriction would leave a door open to the main currently existing alternative blend based on ammonium salts without condemning the cellulose insulation industry. Therefore in terms of proportionality versus risk reduction capacity, this option is considered to be the most proportional measure (estimated total cost values at EU level).

- **Enforceability:** the compliance to this restriction on ammonia emissions from cellulose insulation by all relevant actors (producers, importers, and distributors) can be checked by the responsible authorities. The required control of producers, importers, and distributors is in line with regular monitoring procedures and shouldn't entail any specific challenge.
- **Monitorability:** results of the implementation of this restriction on ammonia emissions from cellulose insulation may be primarily monitored through enforcement by measuring the ammonia emissions from cellulose insulation materials which are placed on the EU market. Tailored indicators such as "number of cellulose insulation which emit ammonia above the established limit" or "Number of RAPEX notifications related to cellulose insulation emitting above the established limit" or "Number of dossiers opened by Poison Centres related to health cases from cellulose insulation" can be suggested in order to assess the effects of this restriction proposal.

F. Socio-economic Assessment of Proposed Restriction

Costs and benefits figures are drawn from the consultations carried out at European level.
In the confidential excel file available to the RAC and SEAC rapporteurs, the sources of the confidential figures are provided. Such file should allow concluding on the validity of the given quantitative values, as well as on the assumptions and calculations done.
Whenever possible in both cases of confidential and non confidential data, the information provided by either a cellulose insulation manufacturer or a formulator were counter-checked using one or more different sources, before being validated and adopted in the costs and benefits calculations.

F.1 Human health and environmental impacts

F.1.1 Human health impacts and benefits of the proposed restriction

According to the French Committee of Toxic Vigilance Coordination (CCTV), 10 dossiers with 19 exposed people were recorded between February and November 2012. There were 14 adults from 32 to 70 years and 5 children. Fifteen cases were symptoms of mucosal irritation (nose, eyes, and throat) and airways.
14 dossiers for a total of 43 patients were recorded during the period January - July 2013. In all dossiers, one or several patients smelled an odor characteristic of ammonia gas ("urine" or "cat urine" smell). Among the 43 exposed persons, 21 were asymptomatic. The remaining 22 presented one or more symptoms corresponding to a mucous membrane irritation of the upper airways syndrome or of the bronchus. In the calculation of the benefits we assumed that half of the exposed people had symptoms.
Over the same period, 20,000 housings were insulated in France. Over the same period the European Cellulose Insulation Manufacturers Association (ECIMA) identified more than 100 complaints (this share has been taken into account in our calculations) and many complaints were made on Internet forums. CCTV data should therefore be underestimated.

Although to date no cases were found in other Member States than France, there is no reason to believe that ammonium salts used in cellulose insulation in other EU Member States could not develop similar heath issues. Several cases of ammonia exposure have been reported from treated cellulose insulation in the US.

Under a business as usual scenario (i.e. without any restriction), the main costs originating from buildings emitting ammonia would be the following[41]: **costs of illness** (COI) until the house is reinsulated and, in case of re-insulation, the **costs of temporary re-housing**, the **costs of re-insulation** including the **cost to destroy the emitting cellulose insulation** should also be added.
Therefore, in case the proposed restriction would be approved, the main benefits would include lower health risks in terms of better indoor air (it could depend on the choice of the substitute), which means avoided future cases, reduced symptom days and reduced COI, plus the costs savings from reduced need for re-insulation (including the destruction of the cellulose insulation emitting ammonia) and from reduced need for re-housing.
Under the business as usual scenario, such costs would have to be afforded mainly, but not exclusively, by the occupants of the buildings. In the case of the COI these costs would be up to the health systems and probably the costs of re-insulation would be covered at least partially by the insurance companies of the installers or of the manufacturers of the cellulose insulation. In any case, no matter who in principle would have to afford such costs if the proposed restriction would

[41] The potential increase of risk of fires due to ammonium salts decrease in the cellulose insulation has not been evaluated. Although it is not completely excluded, this risk has not been considered in this restriction dossier.

be adopted, the above mentioned avoided costs and costs' savings will have to be considered as benefits of the restriction.

The health cases due to cellulose insulation containing ammonium salts installed in France before the French restriction have not been taken into account in our calculations as they would have taken place even under the baseline scenario of this proposed restriction.

Under the substitution scenario, an exact quantification of the real health benefits of this restriction proposal would depend also on the alternative formulations (boron-based or other) which will be chosen and on their potential adverse health and environmental effects of the chemical substances contained in such blends. In the case of a substitution with less safe formulations for instance, there could even be negative health benefits.

Instead of choosing a time period for the analysis it was decided to carry out a break even analysis starting from the estimated date in which this proposed restrictions would most probably enter into force (beginning 2017) in order to identify after how many years the benefits will overcome the costs. This choice was done because a large part of the costs for the industry (mainly the changes of ETAs and TAs) will occur immediately before or just after the entry into force of the restriction while the benefits as well as a remaining part of the costs (cost of testing and increased costs of the substitute blend) of the restriction will occur after the restriction. So the choice of a more or less long period of analysis could have affected the proportionality. Anyway, from the break even analysis, the proportionality was demonstrated existing since the very beginning.

Figure 14: Illustration of the increase of the stock of living units insulated with cellulose insulation containing ammonium salts

F.1.1.1 Willingness to pay to avoid odour nuisance and respiratory symptoms

In response to SEAC relevant comments, the DS carried out a review of recent literature on the monetary valuation of odour nuisance and respiratory problems.
The determination of people's willingness to pay to avoid odour nuisance and respiratory symptoms can be done either directly by using the contingent valuation method (CVM) namely through stated preferences or indirectly by using revealed preferences (e.g. hedonic pricing of property market values, cost of illness, human capital surveys and Quality Adjusted Life Year studies).

In both cases of odour nuisance and respiratory symptoms, the contingent valuation method seems to be the most appropriate. Odour nuisance and respiratory symptoms have a negative impact on life quality and human welfare and in some cases people might be willing to pay to avoid them. CVM uses surveys in which people are asked to state the maximum amount they are willing to pay for a certain improvement in the current situation (willingness to pay) or the amount they would be ready to accept as compensation for a worsening of the situation (willingness to accept).

Authors	**Year**	**Type of study**	**Type of problem**	**Context**	**Country/region**	**WTP or hedonic price conclusions**
Eyckmans, De Jager, and Rousseau	2013	hedonic valuation study	odour nuisance	animal waste processing facility	Flanders	house prices in zones with moderate and severe nuisance were 5% and 12% lower depreciation of EUR 10,000 and 24,000 per dwelling, respectively WTP EUR 500 (1200) per household per year
Longo and Hughes	2007	hedonic valuation and stated preference	odour nuisance, brownfields and cultural heritage externalities	Review of 12 hedonic valuation and 4 stated preference studies related to *urban, periurban and rural service supply.*	various	loss in property values of about EUR 3,000 to EUR 10,000, or about 3% to 10% on the value of a property wtp ranging from few cents to more than EUR 80 per household per year
Palmquist	1999	Hedonic models		Natural land use		
Remoundou and Koundouri	2009		health impacts (mild symptoms, without losses of working days or hospital treatment	Environmental Effects on Public Health		

Authors	Year	Type of study	Type of problem	Context	Country/region	WTP or hedonic price conclusions
Bogaert et al.	2005		odour nuisance	waste water treatment plants and composting facilities	Flanders	wtp ranging between EUR 60 and EUR 137 per household per year
Navrud	2001		light' health symptoms	air pollution	Norway	wtp *at least* EUR 1 to 2 per symptom day avoided for all symptoms, and possibly substantially more.

Table 24: Summary of the consulted literature on the monetary valuation of health symptoms and odour nuisance

In conclusion, after a careful review of the existing literature, most of these studies seem to concern country, substance or situation specific circumstances which are very different from the one we are considering in this restriction proposal. Therefore, available empirical evidence in terms of stated preferences does not fit the case of ammonia emissions where the occupants of the living unit might not be willing at all to pay in order to avoid odour nuisance and respiratory symptoms since they have already paid for the installation of a thermal insulation that was not supposed to emit ammonia. It worth's remembering that in France the installation of the cellulose insulation emitting ammonia is considered as defected product and it should involve the obligation of replacement of the defected insulation by the insurance of the professionals who made the installation, or, in the case of failure, by the insurance of the owner or of the occupant of the house. The fact of extrapolating the WTP for respiratory symptoms and odour nuisance coming from surveys carried out in completely different contexts such as air pollution or proximity to land filling, animal waste processing or waste water facilities in order to derive the annual willingness to pay per household affected by odour nuisance and respiratory symptoms due to ammonia emissions from cellulose insulation could be very dangerous. The hedonic pricing of houses does not seem to fit the case of ammonia emissions form cellulose insulation either as it is not acceptable that the occupants would suffer a depreciation of their house do to the installation of a thermal insulation that was meant to increase its market value (therefore a we can expect a willingness to accept and a willingness to pay equal to zero). In such case, the re-insulation would be the chosen option to recover the lost market value and the affected household would probably bring to court their installers or manufacturing companies in case the costs of re-insulation would not be spontaneously covered through the insurances of such companies.

Given that specific scientific studies looking at the WTP for irritation or odour from ammonia have not been found, the generic available evidence from other contexts has not been used by the DS. The use of the cost of re-insulation still seems more appropriate to the specific circumstances of this restriction dossier.

F 1.1.2 Costs of illness (COI)

In general, **symptoms** from ammonia emissions are **not severe, reversible** and last rapidly without secondary effects. Therefore, no extended medical monitoring is expected after the **exposure is over** and symptoms cease. However, the type of health symptoms will vary from one individual to another according to their previous medical history and sensitivity to ammonia exposure. Therefore, in some cases, the health effects of ammonia emissions might become **severe** for instance for individuals suffering **of chronic respiratory problems such as asthma**.

No specific studies were found presenting an estimate of the costs of illness due to indoor ammonia emissions from cellulose insulation. Some of the key assumptions made are based on expert judgement (public health expert).

It is very difficult to estimate a realistic number of exposure and symptom days per year and over a longer period of time because this calculation should take into consideration the number of building insulated with cellulose insulation, when these building could potentially start and stop emitting ammonia, the number of exposed population, the conditions of humidity causing the emissions, if and when the occupants are re-housed elsewhere, the share of population affected by asthma exposed to ammonia from cellulose insulation and if and when the cellulose insulation is removed.

For the **normal population** exposed to ammonia emissions from cellulose insulation the **number of symptom days** is likely to correspond to the **number of exposure days** which means the days during which the occupants live into the housing unit which emits ammonia (one day per exposure case, but every day if the exposure is continued over time in case the cellulose insulation is not removed). If the conditions of humidity causing the emissions stop or if the cellulose insulation is removed then their symptom days should stop too.
In cases of high exposure to ammonia emissions, a medical consultation (General Practitioners and a consultation in emergencies of hospitals) and the exams of blood electrolyte, blood gases, chest front x-ray would be needed, as well as medication costs for the affected individuals.

For the specific population of asthmatics, the **number of symptom days** is likely to be higher than the **number of exposure days** which means that symptoms would persist even if emissions or exposure cease.
Patients with symptoms, especially if such symptoms are severe, in order to avoid further exposure, may need to immediately re-insulate their house. In case of re-insulation, it is assumed that the number of **symptom days** of the occupants per year would be negligible.
If insurance companies of the installers or of the manufacturers will repay such costs it can be assumed that 100% of the emitting living units will be reinsulated within a period of one year. The impact of this assumption, based on what happened in the French cases, has been tested by a sensitivity analysis by reducing it to a lower percentage.
Due to the high costs of such re-insulation (in the calculation 4,000 euros per standard loft), if the insurance companies would not intervene the re-insulation might not be accessible to all consumers, mainly considering that they already recently spend for the first insulation. In such cases, the remaining people still living in emitting lofts that will not be reinsulated would continue suffering from the health symptoms, at least from time to time.

Given all uncertainties surrounding the number of emissions, exposure and symptoms days and the difficulties to make assumptions on when emissions, exposure and symptoms will occur and how long they will last, the benefits deriving from the avoided COI were only qualitatively assessed. Anyhow, given the high cost of re-insulation, these avoided costs for the health sector are expected to be low compared to the avoided costs of re-insulation.

F 1.1.3 Exposed population estimation

Several assumptions had to be done while estimating the benefits of the proposed restriction.

Both the estimates on the volumes of European cellulose insulation containing ammonium salts and the French exposition rate per tonne are used to derive the European exposed population. Therefore, the number of European cases avoided per year is based on the French cases. Using the French rate of exposed population per tonne of cellulose insulation containing ammonium salts installed should be considered as an overestimation for the European exposed population and for their health impacts, given that no cases were reported by Member States competent authorities. Changing the assumptions on the exposed population would impact the estimated health benefits, while the costs of the restriction would remain the same.
The estimates are based on assumption suggested by the industry that in average each apartment is insulated using one tonne of cellulose insulation and that one insulated apartment is inhabited in average by four persons (standard family).
It is assumed that the number of **new health cases** due to ammonia emission from cellulose insulation would already be reduced from the first year of the restriction being in force. Over a longer period of time, on one hand, already installed insulation could start emitting all over their service life and even afterwards, on the other hand the number of people with symptoms could gradually decrease given that at a certain stage some occupants will probably decide to re-insulate their house.

In principle, immediately after the entry into force of this restriction proposal, the number of cases from newly installed insulation will be negligible.

The key assumptions under this section are the following:

- French producers stopped producing cellulose insulation containing ammonium salts after the national restriction was put in place (July 2013) (0% of the current French production of cellulose insulation contains ammonium salts).
- According to the general estimation done by IAL consultants for the thermal insulation market, yearly growth rate of the cellulose insulation sector was estimated to be 2.2% (the same as the general estimated growth rate).
- Based on the average sized loft, an average of 1,000 kg (1 tonne) of cellulose insulation per house insulated (data from ECIMA and some EU manufacturers).
- The rate of European population potentially exposed to indoor ammonia emissions and presenting symptoms per building unit insulated with cellulose insulation containing ammonium salts is assumed to be the same observed in France using ECIMA data: 100 building units on 20,000 insulated with cellulose insulation containing ammonium salts (**rate of 0.5%**).
- An average of **4 persons** living in each insulated apartment and exposed to the ammonia emissions; **two of them** (50%) will develop health symptoms.
- Cellulose insulation containing ammonium salts is assumed to be able to emit ammonia all along its service life (60 years according to Building Research Establishment).
- 1-2% of the cellulose insulation currently placed on the EU market is imported and exported.
- An amount of 250,000 of cellulose insulation yearly placed on the EU market.
- 15,000 tonnes of the cellulose insulation (6%) currently marketed inside the EU (both produced and imported) contains ammonium salts, giving an estimate of **15,000 building units** with cellulose insulation containing ammonium salts.

In quantitative terms, as shown in the table below, given the assumptions done, during the three years period 2017-2020, persons will be exposed and living units will need to be re-insulated. (the

calculations of estimated concerned persons each year is given in the excel file made available to the RAC and SEAC rapporteurs).
Once again, these estimations are subject to uncertainty given the uncertain future development of this young market after the French cases and the eventual changes of the specific concentration limit of boron compounds in mixtures

	Effects in year 1 2017	Effects in year 2020[42]
New number of living units emitting every year	75 (15,000*0.5%)	82
Number of avoided exposed persons per year[43] (considering 100% re-insulation)	300 (75*4)	327
Number of avoided persons presenting symptoms per year	150 (75*2)	163

Table 25: Estimations on emitting living units, on exposed people and on people presenting symptoms

Calculations based on the above mentioned assumptions done for the proposed restriction are provided in a separate excel file (made available to the RAC and SEAC).

F 1.1.4 Costs of re-insulation and costs of temporary re-housing

As re-insulation costs are substantial, the main benefits to society from reducing emissions are represented by the **avoided costs of re-insulation**.

Box 5: Re-insulation after the French cases

In France, most of the costs of re-insulation were afforded by the industry. It was done by some companies on a voluntary basis to better their company's image after the reported cases. A French manufacturer indicated that the costs of taking out the emitting insulation and replacing it were covered by their insurance company and that they only had to afford the cost of the new cellulose insulation.

Re-insulating a standard loft apartment emitting ammonia would cost in average around **€4,000**, almost double the cost of the initial insulation. The reason for "almost double" would be the cost of taking out plus the insulating once again (cost of removal of the old insulation, cost of replacement and cost of destruction of the off gassing cellulose insulation).

Re-insulation implies temporary re-housing for taking away the old cellulose insulation and reinstalling the new thermal insulation. According to stakeholders' consultation, the time needed for such re-insulation is estimated at two and half days which implies the cost of two overnights for a standard family of four. An average cost of 200 € per night for the standard family has been used for the calculation.

The following table illustrates the annual cost savings at the end of the initial year after the entry into force of the proposed restriction, and at the end of year 2020 compared to the baseline scenario.

[42] Taking into account a yearly growth rate of the cellulose insulation sector estimated at 2.2%.
[43] These estimations are subject to great uncertainty given the uncertain future development of this young market after the French cases and in view of the eventual changes of the limit value for the classification of boron compounds.

	Effects in year 1 2017	Effects in year 2020
Saved cost of avoided re-insulation (in euros)	300,000 (4,000*75)	326,627
Saved cost of avoided re-housing (in euros)	30,000 (400*75)	32,633
Total benefits (= saved costs re-insulation plus re-housing (in euro)	330,000	359,290

Table 26: Estimated monetised annual benefits of the restriction proposal for the first year immediately after implementing the proposed restriction and in 2020

F 1.1.5 Other avoided costs not considered in the calculations

In addition to the COI and the cost for odor nuisance, which have been qualitatively assessed, the calculation of the benefits does not include an estimation of the following cost elements:

- Avoided costs of production losses (working days lost) for the occupants of a living unit emitting ammonia: this benefit element deriving from the proposed restriction was not included in the calculation because based on medical expert estimates, a normal person exposed to indoor ammonia emission from cellulose insulation would not need to be absent from work. However, in case of patients already suffering from asthma, the worsening of the previously existing health situation could imply several days of work lost per year due to the symptom days.
- French costs after the proposed restriction as the French restriction is already in place. Unlike for costs that the French manufactures already sustained during the year 2013, after the end of the French restriction (July 2013 – July 2015) avoided health cases from newly installed French cellulose insulation could be eventually included in these calculations since probably the French national restriction will be already over (unless it will be renewed). However, it is unlikely that after the French restriction and before the proposed restriction, French manufacturers would take the risky decision to start again producing cellulose insulation treated with ammonium-based formulations.

Therefore, even if, French avoided cases during the considered period that start from 2017 could be attributed to the proposed restriction (and not to the French restriction that will probably be already over), most likely, there will be no newly installed insulation emitting ammonia. The French stock of potentially emitting living units existing at year 2013 (i.e. 20,000 units) cannot be taken into consideration in the benefits calculation since the related health cases will occur in France even under the baseline scenario (i.e. even without the proposed restriction). Therefore, in any case the benefits of the proposed restriction should not be affected by the French share of health cases that could occur in the future.

F.1.2 Environmental impacts

The risk addressed is focused on the human health effects. The relatively small quantities of ammonia formed from the cellulose insulation containing ammonium salts are estimated to contribute insignificantly to the total environmental load of ammonia from human activities (mainly from agricultural and livestock keeping activities).

If the cellulose insulation industry would substitute with a less environmental alternative fire retardant or if it would lose market shares in favour of less environmentally friendly types of thermal insulation, there might be negative environmental impacts.

F.2 Economic impacts

F 2.1 General economic information on the cellulose insulation production process, on prices and on production trends

The data reported in this paragraph were provided by several manufacturers or associations of manufacturers of cellulose insulation consulted (Univercell/Soprema, Dammstat Werf, ICELL, Excel fiber, ECIA, ECIMA, etc) and formulators of ammonium-based formulations (Haffner International, THOR, Ecochem)[44]. The data used during the calculations do not represent a real average in terms of arithmetical mean of the above mentioned obtained data, but the data that were quoted and/or confirmed by several actors were preferred. It is worth remembering that the volumes of the building units to be insulated, the number of kg per cubic meter, as well as prices of raw materials such as recycled paper (pre or post consumers) or formulations (boron or ammonium based) and the prices of final cellulose insulation (loose or panels, for attic or walls insulation, including or not installation, etc.) can change a lot from country to country according to climatic conditions, from producer to producer, from installer to installer and according to the type of production (containing boron or ammonium) and the type of installation (new or old buildings, insufflations in attics or installation into walls, wet or dry installation, thickness installed, etc.). Therefore, in several cases ranges which seemed realistic according to the available information had to be used.

The production process and the supply chain for cellulose insulation are quite simple (low technology level needed) and generally are located geographically close to the place of origin of the newspapers' stocks and close to the reference market.
One tonne of cellulose insulation is sold between € 500 and € 650 ex factory price (an average price of € 550 has been used for the calculation), while a DIY[45] consumer would buy it between 900 and 1,200 Euros per tonne at a retailer. In general, cellulose installations are competitively priced with fiberglass and less expensive than foamed-in-place applications. The price of cellulose insulation installed by a professional installer ranges from 50 to 70 euros per m^3 (an average price of € 60 has been used for the calculation). In average, a cubic meter of cellulose insulation is equivalent to a range from 28 to 35 kg (an average of 33 kg has been used for the calculation) in case it is insufflated and to 55 kg if applied to walls. A realistic range would be between 1,600 and 2,100 Euros per installed tonne in attics and a range between 3,000 and 3,600 Euros per installed tonne in walls. An overall average price of € 2,500 per installed tonne has been used for the calculation.

The price of recycled paper and newspapers varies a lot according to the countries. This price increased sharply between 2010 and 2012, from € 120-130 per tonne up to € 240 per tonne during certain periods, in particular because of the entry of Chinese market actors buying large stocks of paper to be recycled and the decrease in the number of newspapers, with challenges for the manufacturers of cellulose insulation in terms of security of supply and of prices' volatility which might cause tensions on their business models. The current prices of European recycled paper and newspapers range between 150 and 200 Euros per tonne (an average of 170 Euros per tonne has been used for the calculation).

All the above mentioned figures are summarized in the Table below:

[44] See dedicated confidential annexes.
[45] Do It Yourself.

	Low range (€/t)	High range (€/t)	Most frequent value (€/t)
Ex factory price of one tonne of cellulose insulation	500	650	550
DIY price of one tonne of cellulose insulation	900	1,200	?
Price of one tonne of cellulose insulation installed in attics	1,600	2,100	?
Price of one tonne of cellulose insulation installed in walls	3,000	3,600	?
Price of one tonne of recycled paper and newspapers	120	240	170

Table 27: Summary of the prices per tonne of cellulose insulation and newspapers

One tonne of a typical boron-based formulation as well as an ammonium based formulation would cost an average of € 750, so if a formulation is added in a percentage of 10% of the total weight of the cellulose it means that in a tonne of final product the value of additives would be around 75 Euros. However, it is difficult to assess the contribution of the fire retardants and biocide to the final production cost of the cellulose insulation as the quantities/percentages used change from manufacturer to manufacturer. Moreover, it is not easy to have access to the exact formulation that would allow more precise calculations.

Loose cellulose insulation as cellulose panels are relatively cumbersome and not easily compressible. This fact highly increases the cost of transportation and its impact on the consumer price (where the interest of a local valorisation in short circuits).

During the last five years, the production and use of cellulose insulation, as those of thermal insulation in general, have increased. Most European manufacturers of cellulose insulation started their production between 2010 and 2012. The European cellulose insulation market is therefore very young and rapidly expanding.
The rapid evolution of the cellulose insulation market is linked to a certain number of measures (EU and national building regulations requiring insulation for saving energy and the existence of National fiscal and grant aids for insulation) put in place at European and at Member states level for reducing emissions and energy consumption by at least 20% by 2020 as foreseen by the Kyoto protocol. However, the sector is also affected by several threats such as the fact that insulation provide long payback period versus high upfront costs, and this can become a serious issue namely during periods of economic crisis. The decreased availability of newspaper feedstock (mainly due to the high volumes shipped to China and to the diffusion of e-newspapers) affect the margins of profit for the industry while ammonia emission cases occurred in France affected the image of the sector, at least in France.
The starting point for quantifying the costs for the industry is to estimate the amount of cellulose insulation containing ammonium salts placed on the EU market (produced and imported) and possibly the share that is currently emitting ammonia. From stakeholders’ consultations, it was estimated by ANSES that even if the amount of cellulose insulation containing ammonium salts for 2013 is of around 15,000 tonnes, the volumes that could be placed on the market in the future in the absence of a restriction is estimated to increase moderately (2.2% yearly consistent with the study of IAL consultants and with EU engagements to reduce energy consumption by 2020) because of a general trend. Although these quantities could increase much more for some manufacturers which are only using a very small share of their capacity of production these potential increases were not taken into consideration as it is extremely difficult to know if and when they will occur. These quantities could also drastically decrease if, following the restriction, in the future the current

manufacturers using ammonium-based formulations would decide to switch their production to boron or to a new alternative blend.

The tonnage of EU cellulose insulation is assumed to be about 250,000 tonnes in 2017 while the tonnage of EU cellulose insulation containing ammonium salts is assumed to be 15,000 tonnes in 2017 the year of the entry into force of the restriction.
The maximum estimated quantity of ammonium salts to be replaced by alternative fire retardants would be about 1,500 tonnes in 2017 (10% of 15,000 tonnes).

After this panorama of general economic information, the impacts on the different actors along the supply chain of the cellulose insulation and on the related sectors will be taken into consideration.
The proposed restriction on ammonia emissions would impact in a more or less important manner and direct way different industries and different actors in each supply chain. The impacted sectors include formulators and producers of fire retardants (mainly of formulations based on ammonium salts, but also indirectly producers of boric salts, formulators of boron-based formulations and of other fire retardants), post consumers newspapers/ recycling societies, manufacturers of cellulose insulation, manufacturers of other types of thermal insulation, building industry, installers of thermal insulation, retailers of insulation materials and the users of these products. In addition, some of the actors in the supply chain of alternative thermal insulation products will be impacted.

F 2.1.1 Impacts on the formulators and producers of ammonium salts for the cellulose insulation industry

Restricting the placing on the market of cellulose insulation emitting ammonia might impact those producers who are currently manufacturing formulations containing ammonium salts used in the production of cellulose insulation and whose formulations would be proven not to be stable.

Currently, two of the main European suppliers of ammonium salts for the cellulose insulation industry identified during the stakeholders’ consultation are based in Germany (Haffner and Brenntag) and one is based in Belgium (Ecochem). Other 8 companies based mainly in Germany, but also in Belgium and in the Netherlands were identified as former suppliers of ammonium-based formulations to the French cellulose insulation industry before the national restriction (see confidential annex on formulators).
During the stakeholders’ consultation, it was found that almost all current suppliers of ammonium salts to the EU cellulose insulation industry and some previous suppliers to the French cellulose insulation industry are carrying out R&D to either stabilize their ammonium-based formulations (due to the French restriction this type of research does not concern the formulators supplying the French market) either to find alternative formulations. However, it is not known how many of these formulators already started producing alternative ammonium-free (and boron-free) formulations.

In general it was found that none of the current suppliers of ammonium salts produces or sells only ammonium salts or only to the EU cellulose insulation industry. Most of these producers were found having diversified both in terms of range of products and in terms of target markets (geographically and in terms of sectors) and target clients. If compared to the overall total volumes of chemicals produced and/or sold by these companies, the volumes of ammonium-based formulations for the cellulose insulation industry could be considered as minimal.
One formulator said that for their company the volumes and market value of ammonium-based formulations produced for and sold to the cellulose insulation sector were just negligible.

In case, the EU producers of ammonium salts also produce other fire retardants alternative if, on one hand, potentially they could lose a market, on the other hand, they could convince their customers to switch to other alternative formulations in their portfolios. Moreover, most of these producers could keep selling ammonium salts to the agricultural sector as fertilizers.
Under such scenarios, no significant impacts are expected by the eventual decrease in demand for ammonium salts, aside the costs needed to carry out the R&D. Therefore, for the suppliers of ammonium-based formulations, the proposed restriction is likely to imply some sunk costs on investments already done mainly in terms of R&D and production plants' adaptations due to a premature end of the production of the ammonium-based formulations for the cellulose insulation industry. A shorter phase-out period than that the one proposed by this restriction would increase potential losses of return on investment unless alternative markets are found. According to the stakeholders' consultation, if the alternative formulation found would still be a powder, for the chemical supplier the plants used for manufacturing ammonium-based formulations could most probably be re-used to manufacture alternative formulations, implying lower expected level of sunk costs.

In conclusion, even if, as a consequence of the proposed restriction, some EU and non-EU formulators, producers or suppliers of ammonium-based formulations could eventually lose their EU cellulose insulation market, overall production volumes of the formulations for the cellulose insulation, sector competitiveness and employment are not expected to change in a significant way.

Specific confidential data concerning the formulators and the formulations of ammonium salts for the cellulose insulation industry are reported in a separate confidential annex.

F 2.1.2 Impacts on the producers of boron and on the formulators of boron based formulations for the cellulose insulation industry

The main producers of boron compounds are based in Turkey, Chile and USA (US borax). The manufacturers of cellulose insulation either buy directly boron compounds from these non-EU suppliers (and then make the blend themselves), either buy the boron-based formulations already prepared by EU and non-EU formulators, who are in some cases the same preparing and selling the ammonium-based formulations.
As a consequence of the restriction, in case of a substitution with boron based formulations these companies might gain additional shares of the EU cellulose insulation market. However, an eventual change of the limit value concerning the use of boron compounds might make them lose important market shares (not only in the cellulose insulation market). Anyway, this is out of the scope of this restriction proposal.

F 2.1.3 Impacts on the cellulose insulation industry as a whole and on the manufacturers of cellulose insulation without ammonium salts

Since most of the cellulose insulation placed on the EU market (around 95%) does not contain ammonium salts, the overall economic and social impacts of the proposed restriction on the cellulose insulation industry would likely be minimal. The proposed restriction is not expected to have a negative impact on the competitiveness of the EU industry as a large part of it (all French manufacturers since the national restriction and all European manufacturers using boron) already produces without ammonium salts and it is therefore to a large extent already complying with the requirements of this restriction proposal.

From the stakeholders' consultation, it was found that companies which manufacture cellulose insulation without ammonium salts (mainly containing boron) should not be significantly impacted by the implementation of the proposed restriction neither in terms of their production, neither in terms of their shares on the EU market.
If, on one hand, there could be some minor impacts in terms of loss of the image of the cellulose insulation as a whole, on the other hand, eventually, the proposed restriction could provide companies already producing and selling ammonium-free cellulose insulation with a competitive advantage in comparison with the EU manufacturers currently using ammonium-based formulations. The restriction may also give a first mover advantage to those that develop and market technically and economically feasible ammonium-free and boron-free alternatives.
Therefore, overall, given that the market is already heavily dominated by cellulose insulation containing boron salts, macro-economic impacts on the cellulose insulation industry as a whole from the proposed restriction are not expected to be significant. However, the proposed restriction is estimated to have some negative impacts limited in particular to the few companies currently producing cellulose insulation containing ammonium salts as described in the following paragraph.

More details concerning the cellulose insulation industry are included in the Annex concerning EU manufacturers of cellulose insulation.

F 2.1.3.1 Impacts on manufacturers of cellulose insulation containing ammonium salts

According to the stakeholders' consultations carried out by Dossier Submitter, only six EU manufacturers of cellulose insulation were identified in Sweden, Germany, Latvia, Belgium and Denmark as still using formulations containing ammonium salts as shown in Annex concerning EU manufacturers using ammonium salts. However, it is not known if and at what level their cellulose insulation does emit ammonia once installed. Other EU manufacturers using ammonium salts than those identified by Dossier Submitter might exist.
These manufacturers, who are currently using ammonium salts in their production, will probably be the market actors mostly impacted by the implementation of the proposed restriction having to face the higher costs.
In general, during the market analysis, it was observed that the manufacturers of cellulose insulation containing ammonium salts can be divided into two main categories:

- For some EU manufacturers the ammonium-based production represents only a (more or less) relatively small percentage specifically produced for a "niche market" of clients, namely for very ecological timber frame construction, who would not accept cellulose insulation containing boron. It was found that this first category of manufacturers mainly produces and places into the market boron-based cellulose insulation. Technically, to have a part of the production with boron and a part without boron is not easy because the plant would need to be cleaned up between the two productions in order to avoid the mix.
- For the second type of producers the ammonium-based cellulose insulation represents the totality of their production and for them its continuation is therefore a strategically critical issue, namely considering that they already invested a lot on it, having based all their market communication on the fact that all their products were boron-free.

It may be wrongly concluded that the first category of companies could more easily switch their ammonium-based production to boron based formulations. Although this change would certainly represent a technical simplification of the production process and it would also economically reduce the costs (being the boron-based formulation in average slightly cheaper), under a commercial view point this substitution would probably represent a net market loss.

The specificities concerning manufacturers identified and consulted during the stakeholders' consultation as still using ammonium salts are reported in a confidential annex to this report.
As far as the impacts on production volumes and competition are concerned, from the stakeholders' consultation, it was found that companies which manufacture cellulose insulation containing ammonium salts want to maintain their production of cellulose insulation and their market shares on the EU market.

In any case, the restriction proposal is not expected to bring to the closing of small European production sites, as confirmed by the French situation where none of the small companies has left the market while shifting their production of cellulose insulation back to boron, although some changes in the property have been registered. Therefore, it is expected that the production of cellulose insulation itself will not be highly impacted and the current total volumes of cellulose insulation produced and marketed will be maintained (and will probably increase due to the sector's growth) in the future.
In the worst case scenario, if the current manufacturers will not switch to other fire retardants, this restriction proposal may simply redistribute sales to existing ammonium-free manufacturers and to manufacturers of other thermal insulation products.

After the entry into force of the proposed restriction, the manufacturers of cellulose insulation containing ammonium salts will have to choose one among the following options:

- Doing nothing else than testing if their cellulose insulation does not emit ammonia.
- Stabilization of the currently used formulations;
- Substitution with boron based formulations or with other types of formulation;

The first above mentioned option, corresponding to a business as usual scenario, does not imply specific additional costs, aside the cost of testing emissions, while the last two options will imply some (slightly different) additional costs. According to the proposed restriction, these additional costs, called respectively costs of substitution and costs of stabilization, will have to be afforded by the industry if their cellulose insulation emits ammonia above the limit value set by this restriction proposal (under a doing nothing scenario).

Only some of the cost elements for substitution or for stabilization have been taken into account in the costs' calculations of the proposed restriction. The reasons why some stabilization and substitution costs were not included in the calculation are given in the related paragraphs.

It worth's remembering that overall it is not possible to determine *ex ante* which scenario (doing nothing, stabilizing and substituting) will be adopted by the six manufacturers of cellulose insulation containing ammonium salts as it depend primarily by the current situation (ammonia emissions or not, types and stability of formulations used, prices of the alternative blends, etc.), but also by the commercial strategies that are implemented by each actor ("boron-free", etc.).

The estimation of the costs of testing emissions is detailed in section E.2.1. The average duration of validity can be considered of 3 years, even if it can go up to 5 years in certain cases. After the first change of European and national Technical approvals due to the proposed restriction, the costs of TAs renewals are not taken into account in the costs calculations as the manufacturers would have to pay for the renewal even under a business as usual scenario in case of continued use of the ammonium-based formulations.

Hence, the total cost for technical approvals due to the restriction is estimated at a maximum of 300,000 € (50,000*6 companies).

	Approximate Cost per sample €	Unit of time for the test trial
Dynamic test in emission test room	1000	14 trial days
Dynamic test in emission test room	2000	28 trial days
Test scenario with the attic insulation	4000	28 trial days
Rapid static test	200	24 hours

Table 28: Average cost of ammonia emission tests (CSTB estimation)

Similarly, the assessment of costs of substitution/stabilization is detailed in section E.2.1 For the quantitative assessment of the substitution cost, it was assumed that only 10% of the market would wish to use a more expensive, ammonium and boron-free formulation and that the majority of manufacturers would substitute with boron without costs' increases. Moreover, it is assumed that the alternative blend would cost twice the price the ammonium-based blend.

	2017	2020
Costs of ETAs and TAs	300,000	0
Increased costs of new formulation	112,500	120,089
Tests costs	2,000	2,000

Table 29: Costs of the proposed restriction in 2017 and 2020 under a facto 2 assumption

Box 6: The costs of the French restriction

Before the French restriction, French manufacturers or EU manufacturers selling to France were the main producers of cellulose insulation containing ammonium salts. The substitution and the compliance costs, already sustained by such manufacturers and by other French actors of the cellulose insulation supply chain after the French restriction, should not be taken into consideration in the calculation of the costs of this European restriction proposal as they occurred beforehand and they have to be attributed to the French restriction. Moreover, it is assumed that at present the French production of cellulose insulation containing ammonium salts is equal to zero according to the French restriction.
Therefore, due to this restriction proposal on emissions, aside new test on ammonia emissions, for the French stakeholders no additional costs have been taken into consideration in the costs' calculations in this dossier.

The specific impact of the proposed restriction on employment is briefly discussed in section F.3 (Social impacts).

Contractual agreements, negotiation powers, communication and mutual confidence between recycling companies and manufacturers of cellulose insulation, between formulators and manufacturers, between manufacturers and their distributors and between manufacturers and their installers may sometimes reduce the need for testing ammonia emissions in cellulose insulation and therefore its test frequency. However, at least during initial phases immediately after the restriction, some testing on ammonia emissions might be necessary to ensure that cellulose insulation sold on the EU market complies with the restriction's requirements and to impose sanctions if it is not the case.

F 2.1.3.2 Additional voluntary costs

Some manufacturers and importers of cellulose insulation may decide to afford additional costs in order to comply, certify and/or communicate further through voluntary activities such as carrying out more frequent compliance controls, labeling their cellulose insulation or certifying that it is not emitting ammonia (or even not containing ammonium salts at all), in compliance with the proposed restriction. Such marketing and communication costs on the substitution or stabilization of the formulations are meant to better the image of the product and of the company. It is very difficult to assess the exact extent of such additional voluntary costs which depend on a large extent on the commercial strategies that will be adopted by each manufacturer. Moreover, for the industry communicating about the absence of ammonia emissions may be a good marketing point that might compensate a small reduction of profit through increased market shares.
Therefore, such voluntary costs have not been added to the estimated substitution or stabilization costs.

F 2.1.4 Economic impacts along the supply chain: compliance and voluntary compliance costs

As mentioned above, the potential additional costs associated with substituting the ammonium salts or for stabilizing the ammonium-based formulations contained in the cellulose insulation is unlikely to be passed along the supply chain down to the consumers of cellulose insulation. If ever a part of it would pass along the supply chain and down to final consumers, the potential costs' increase is estimated to be of a magnitude that would only generate very low impacts along the supply chain.
Building upon the available information, potentially, due to the proposed restriction, other actors along the cellulose insulation supply chain, such as distributors, retailers, importers and installers, might have to afford some costs, mainly related to compliance controls, but also for voluntary labeling and certification, etc.

Box 7: reaction of the supply chain to the French restriction

At least in France, but probably also elsewhere in Europe, after the French cases, cellulose insulation retailers and importers set stricter requirements for their suppliers. Cellulose insulation manufacturers were required not to use ammonium salts in their production.

F 2.1.4.1 Impacts on distributors and retailers

Cellulose insulation is distributed and sold in Europe by several different types of companies ranging from timber frame constructors, other building companies, insulation contractors, thermal insulation distributors, "do it yourself" shops and retailers, etc. Many of the distributors and retailers are SMEs, but a few of them, such as "do it yourself" shops, are large companies. Given that most distributors sell several types of thermal insulation, they are not expected to be affected by this restriction proposal on the cellulose insulation, even in the worst case, of market shares' reduction for the cellulose insulation as they will keep selling other thermal insulation materials. No specific SME related impacts have been identified. Impacts for a distributor might take place only in the case the distributor would have an exclusivity contract with a manufacturer which would be highly impacted by market losses, which is considered as very unlikely.

F 2.1.4.2 Impacts on installers

Cellulose insulation can be installed both by professional installers including building companies and by DIY consumers.
In case of stabilization or of substitution of the formulations used in the cellulose insulation no major additional costs of installation are expected, therefore the negative economic impacts on professional installers are expected to be insignificant. Installers are not expected to be significantly affected, not even under the worst scenario, in case of important losses of market shares for the cellulose insulation. According to the French national association of installers (SNI), on the demand of their clients they will keep installing other thermal insulation materials. Many of the professional installers are SMEs but no specific SME related impacts have been identified.
The economic impacts on DIY consumers will be analysed in the paragraph concerning the impacts on consumers.

F 2.1.5 Impacts on import and export

No cellulose insulation seems to be imported into the EU from places as far as the USA or Canada, or from anywhere East of the EU. Import and export seem therefore to be limited to cross border phenomena.
One manufacturer of cellulose insulation declared that it is not economically profitable to sell farer than 800 km. Another manufacturer considers that a distance of 1000 km from the production site to the final market would be the maximum geographical limit for economical reasons. However, during the stakeholders' consultation, some internal sales were found in Europe much over this distance (Dammstatt selling from Berlin to Spain and to Ireland).

Due to such transportation limit, it was found for instance that North American but also other closer non-European producers of cellulose insulation developed business partnerships in terms of transfer of know-how or they directly invested in production plants in Europe to avoid transportation costs. For instance, Ciur in the Czech Republic and Igloo in France have partnerships' agreements with Canadian companies while Isofloc Holding AG based since 1992 in Bütschwil in Switzerland belongs a production plant in Kassel (Germany), Isofloc Wärmedämmtechnik GmbH, and in 2010 they bought Dammstatt WERF GmbH, a German cellulose insulation manufacturer with a plant in Berlin.
Some imports of cellulose insulation seem to come from the Swiss plant of Isofloc AG, producing for the Swiss market but also exporting to European markets such as Austria, France and Italy. However, according to what they claim, at present Isofloc in its Swiss plant of does not produce anymore cellulose insulation with ammonium salts (but only with boron) as they used to do until recently, although Dammstatt still produces cellulose insulation containing ammonium salts in its German plants for a niche application.
Little information is available concerning the exact number of non-EU manufacturers producing cellulose insulation with ammonium salts for the EU market, the EU manufacturers producing ammonium-based cellulose insulation for the non-EU market, the number and type of importers of cellulose insulation containing ammonium salts into the EU, volumes of imported and exported cellulose insulation containing ammonium salts and potentially emitting ammonia. However, export and import volumes of the cellulose insulation containing ammonium compounds are unlikely to be significant compared to the internal EU trade volumes. Exporters and importers are assumed to be only a few and most of them are assumed to export and import cellulose insulation mainly with boron (without ammonium salts).

According to ECIA, import of cellulose insulation, as well as export, would represent around 1 to 2% of the total EU market (an average of 1.5% was used in our calculations). As a result of this gap of information for quantification, the costs for imported cellulose insulation are not included in the cost calculations of the socio economic analysis. It is however expected that cellulose insulation containing ammonium salts produced outside the EU and present on the EU market would be around the same percentage on the total volumes imported as those produced in the EU. As a result, it is expected that, due to the proposed restriction, the total additional costs for non-EU producers wishing to keep selling their cellulose insulation on the EU market would be very low but of the same magnitude of the costs faced by the EU producers.
In the case the proposed restriction on cellulose insulation emitting ammonia will be approved, there is likely to be little changes in both imports and exports trade flows of cellulose insulation, as well as investment flows. Since the import market is very small and already heavily dominated by cellulose insulation containing boron compounds, significant negative impacts on investment and trade flows are unlikely.
No competitiveness impacts with non-EU competitors are expected as the restriction includes the imported cellulose insulation.

The European manufacturers of cellulose insulation containing ammonium salts identified during the stakeholders' consultation were not found exporting outside the EU, but there might exist others not yet identified which could export to non6EU countries. In principle, European manufacturers of cellulose insulation containing ammonium salts exporting outside the EU could still export their ammonium-based cellulose after the restriction as export is not covered. However, after the entry into force of the proposed restriction, the new production for the EU market will either have to be ammonium-free, either to contain stabilized ammonium-based formulations. It is therefore likely that, if a ammonium-based production exported currently exist in the EU for the non-EU market, due to the restriction, it could decrease. In this case, some minor losses of export revenues could take place.

As far as **import** is concerned, non-EU manufacturers, producing cellulose insulation with ammonium salts for the EU market would face the same additional compliance cost as EU manufacturers (higher costs of flame retardants, costs to change the production, costs of stocks, new training for staff and installers, building up compliance procedures, testing, etc).
It might take some time before the non-EU producers of the imported cellulose insulation would adapt their production. At least temporarily, this fact might lead to increased market shares for the EU producers. However, this effect has not been quantified in the calculations.
The importers are likely to require proof that the imported cellulose insulation containing ammonium salts complies with the restriction and this documentation will have to be provided by the foreign producers who will likely bear the related costs (and not the EU importers). As for the EU production, due to competition with other importers to supply the EU market of cellulose insulation, but also with EU manufacturers of cellulose insulation and of other thermal insulation materials, additional costs would probably not pass to the EU consumers. For imported ammonium-based cellulose insulation a need for an extensive compliance control is expected to last when all suppliers will have taken into account the proposed restriction in their cellulose insulation materials. The time allowed for complying with the proposed restriction should allow informing the non-EU manufacturers. Testing ammonia emissions (cost of testing around 1000 € as mentioned before) will likely be required mainly by those importers and retailers who don't trust their non-EU suppliers concerning ammonium salts contained in cellulose insulation.
It is expected that the need for such testing will be reduced over time as the restriction becomes fully known and non-EU manufacturers will have adapted to the new requirements.

In conclusion, major additional administrative costs to EU importers and exporters due to the implementation of this restriction proposal are unlikely.

F 2.1.6 Administrative costs and costs of the monitoring for Public Authorities

The regulatory burden for Public Authorities includes all administrative costs related to additional monitoring and reporting requirements due to the proposed restriction.
Given the fact that Member States are already supposed to have an enforcement authority in charge of controlling the implementation of regulations, the proposed restriction proposal is not expected to require the creation of a new authority nor to restructure an existing authority. Moreover the existing public authorities are already performing some controls on cellulose insulation to make sure that it complies with the present regulation. Therefore, the administrative compliance costs foreseen for monitoring this restriction proposal are expected to represent only a very limited expenses' increase in their budgets to the need to test ammonia emissions or a slight change in their priority targets.
It is not easy to establish what test frequencies might apply for ammonia emissions in cellulose insulation following the proposed restriction. Based on what happened after the French restriction (see box 3), it seems reasonable to assume that EU and non-EU manufacturers will probably make voluntary efforts in testing ammonia emissions in cellulose insulation to give confidence to the market.

Although no additional efforts are expected for the authorities to enforce the proposed restriction compared to the baseline (business as usual) situation, the adoption of the proposed restriction will indeed imply some costs related to the whole process of submission of an Annex XV restriction dossier, the organisation of discussion meetings of RAC and SEAC at ECHA and of adoption by the Commission involves human and economic resources for travel expenses, time and salaries of the participants.

F 2.2 Impacts on other thermal insulation sectors

The proposed restriction on ammonia emissions from the cellulose insulation might have some side effects on other thermal insulation sectors. Aside the obvious, but remote, positive impacts for these sectors in case of an increase of the demand of other types of thermal insulation, manufacturers will be probably avoid the use of ammonium salts or try to stabilize the formulations in the fear that in the future these additives might be restricted in a similar manner.

F.3 Social impacts

The main social impacts of the proposed restriction might concern the direct and indirect employment related to cellulose insulation, as well as the effects on European consumers of cellulose insulation in terms of changes in their preferences. Such impacts will be analyzed in the following two paragraphs.

F.3.1 Potential impacts on employment

Based on the equation suggested by a manufacturer of cellulose insulation, ANSES assumes that around 425 staff is directly employed in producing cellulose insulation products in the EU. This estimate is based on the assumption that to produce 10,000 tonnes per year around 17 people are needed (12 people in the production department, 2 in the office and 5 in the selling department). If the production process is highly automatised, these figures would probably represent an overestimation.

	Production t/year	Direct employment
Cellulose insulation containing ammonium salts	15,000	25
Cellulose insulation containing boron salts	235,000	400
Cellulose insulation	250,000	425

Table 30: Estimates of direct employment in the European production of cellulose insulation in 2017, based on the information provided by a cellulose insulation manufacturer

Indirect employment (distributors and installers) should be much larger but it is hardly feasible to estimate.
According to the industry itself, restricting the placing on the market of cellulose insulation emitting ammonia is not expected to highly affect the employment of current manufacturers of cellulose insulation and of ammonium salts due to the fact that no closing down and no relocation out of EU (very local market) are expected.
Therefore, if the proposed restriction is implemented, employees are not expected to become redundant. This fact is based on the assumption that, by restricting ammonia emissions, the labour inputs required in the production of stabilized ammonium salts or in the production of ammonium-free cellulose insulation should remain the same. Anyway, the minor negative impacts to employment which could occur in the supply chain of cellulose insulation products should be balanced by positive impacts in other sectors.
For instance, even in the (worst) case if the end-users will opt for installing an alternative thermal insulation, employment in the cellulose insulation industry would decrease in favour of an increase in the employment of other thermal insulation materials which are also produced in Europe. Therefore, as these impacts on employment occurring under a scenario of changes in consumers' preferences would mainly be distributional, overall, under a macroeconomic European perspective, there should be no net losses of European employment. Some adjustment costs should be expected to redeploy staff due to temporary unemployment in order to find new jobs or to be trained to better adapt to the new tasks. However, in practice, such costs are quite difficult to be estimated.

F.3.2 Impacts on consumers and households: changes in the consumers' preferences and "surplus"

The demand for cellulose insulation is based on complex **consumers' preferences** that take into consideration elements of very different nature. The criteria taken into account by consumers while making choices on the type of insulation to be installed in their houses include technical characteristics such as better performances/effectiveness (thermal energy + phonic conservation, reduced heat losses, fire retardation capacity in terms of Euroclass, low environmental impact of « green insulation »), health considerations concerning indoor air quality and economical characteristics such as price considerations on full cost (= insulation material + installation) and long-term heat cost savings from insulating. The ease of installation and the price at factory are probably the most important criteria orienting their choices of the do it yourself consumers which can be considered as a special category of consumers/installers. This has implications mainly while assessing the eventual impacts of an increase of costs.

In general, the type of formulations of fire retardants and biocide used in the cellulose insulation is not expected to have high direct impacts on consumers' preferences. However, there are some **consumers very sensitive to health issues** who would change their preferences towards other types of thermal insulation in case of a substitution of the ammonium salts, namely with boron-based formulations.
Indeed, stabilizing or substituting the ammonium-based formulations might have more or less strong indirect impacts due to the price increase according to the type of consumers and to their preferences.

For the **final consumer** choosing to have the cellulose insulation installed by a professional, the price increase due to the stabilization or replacement of the formulation accounts for a very minor proportion of the price of installed cellulose insulation, as installation costs are much higher.
However, according to the consultations with the cellulose insulation industry, a major increase of the pricing of the cellulose insulation might change drastically the choices of some consumers concerning thermal insulation toward a different type of insulation such as glass or rock fibers. According to the EU manufacturers, this is also due to the fact that the image of the product has already been largely affected by the French emissions' cases.
Therefore, the **costs' increase** due to the stabilization or substitution of the formulations currently used is unlikely to be fully passed along the supply chain as manufacturers are afraid to lose market shares, and they seem to prefer and to be ready to partially reduce their profit margins, at least temporary, instead of increasing their prices with the risk of becoming less competitive on the thermal insulation market. Only minimal increases of consumers' prices have to be expected with very low impacts on consumers' preferences. Furthermore, consumers who pay for installation of the cellulose insulation by professional installers will be only moderately affected by an eventual increase of the price of the fire retardants used as their price represents a very little share of the final price including installation. That means that a higher price of the new formulation or increased costs would have a relatively small impact on the final price including installation paid by the end users.

A part of the present demand, namely do it yourself consumers **(DIY) consumers** and consumers who have low spending possibilities, might have very high price elasticity. This is explained by the fact that DIY consumers seem to be more price sensitive than consumers of cellulose insulation including installation, as they might decide to do the installation on their own because of economical reasons. In the case of do it yourself installation, the full cost will correspond to the cost of the cellulose insulation plus the costs of blow-in machine and other materials needed for the installation less the fiscal incentives. Following the proposed restriction if the cost of the cellulose insulation will increase due to an eventual increase of the price of the fire retardants, DYI consumers would be highly affected as the price increase might represent a relatively large share of their final price. Therefore, in case of a price increase, they might easily change their initial preferences concerning cellulose insulation deciding to buy and install another thermal insulation material.

In conclusion, no significant social impacts are expected for consumers due to the proposed restriction as, if ever the manufacturers of cellulose insulation will decide to pass on a part of the cost increase on EU consumers the resulting price increase would be very moderate, otherwise it could change consumers' preferences, mainly of DIY consumers. In both cases (moderate increase or switch to another thermal insulation), this restriction proposal is not expected to have a major negative impact on consumers.

On the other hand, if the restriction proposal would not be approved, the consumers could be highly negatively impacted. The occupants of an emitting loft will have the choice either to afford

important cost of replacement (including re-housing during re-insulation) or to keep supporting the disagreements and the health symptoms due to the emissions.
The high costs of re-insulation (almost double the initial price of insulation including installation) could represent a real problem mainly for some DIY consumers and consumers who have low spending possibilities and might be obliged to keep living in an unsafe living environment. Under a consumer point of view, without the proposed restriction the expected negative impacts would be very high either in economic terms, either in terms of heath.
The table below shows the estimated number of consumers based on the assumption suggested by the industry that one tonne of cellulose insulation is needed per flat insulated.

	Production t/year	Consumers (households)
Cellulose insulation containing ammonium salts	15,000	15,000
Cellulose insulation containing boron salts	235,000	235,000
Cellulose insulation	250,000	250,000

Table 31: Estimated number of consumers of cellulose insulation in Europe in 2017, based on the information provided by the industry (1 tonne = 1 living unit insulated)

F.4 Wider economic impacts

Considering the low number of manufacturers still producing with ammonium salts, as well as the volumes produced yearly by these manufacturers, the proposed restriction will only have marginal economic impacts in terms of costs on actors in the cellulose insulation supply chain. The total current production of cellulose insulation in the EU is not likely to be significantly affected (decreased) by this restriction proposal because of a worsening of the product image.

For the next few years the growth rate of the cellulose insulation industry could be lower than that experienced during the last few years. However, this potential reduction of the growth trend is not exclusively due to the restriction but also to a certain number of other factors affecting the market (economic crisis, decrease of the fiscal incentives provided by member states for insulating, increased price of newspapers, etc). Therefore, no major wider economic impacts are expected due to the proposed restriction.
In addition to the reduction in health impacts within the Union, the proposed restriction will likely imply a reduction in emissions of ammonia, and subsequent positive health impacts, in countries outside the EU were are located the manufacturers of imported cellulose insulation who might decide to change the formulation used also for their internal market.

F.5 Distributional impacts

F. 5.1 Impacts on SMEs

Aside a few large companies, most of the impacted actors along the cellulose insulation supply chain (producers, distributors, installers, etc) and in the other sectors impacted (producers of alternative thermal insulation materials) are SMEs.
In particular, as no major economies of scale seem to exist in the production of cellulose insulation, most of the manufacturers producing cellulose insulation containing or not ammonium salts are small or medium sized companies. Therefore, restricting the placing on the market of cellulose insulation emitting ammonia will mostly affect small and medium size enterprises (SMEs).

However, there are a few larger companies too on the EU market which will also be impacted by this restriction proposal.

Although the restriction treats all companies in the same manner all across the EU and, small and medium sized enterprises might have lower financial means than larger companies to make the necessary R&D to find a suitable alternative. However, as the change in the use of flame retardants does not seem to require any major investment in equipment, but only slight modifications of the production process, this cost should not be a particularly impact on SMEs. However, it is not expected that SMEs will be affected much more than the larger companies in the sectors in question with respect to the technical compliance. As suppliers of fire retardants who could stabilize the current formulations or supply the alternatives are large companies, it is expected that they will provide general advises to their customs when it comes to slightly adjusting production processes to the technical characteristics of the new formulations. The industry consultations suggest that most European manufacturers have already taken steps towards searching alternatives.

F. 5.2 Geographical impacts

Under a geographical view point, the introduction of an EU restriction on cellulose insulation emitting ammonia will mainly have effects in those countries that are more directly concerned, such as the countries where cellulose insulation containing ammonium salts is still produced, such as Sweden, Germany, Latvia, Belgium and Denmark, but also the countries to which such insulation is sold and installed (Scandinavian countries, Baltic region, Germany, etc) and where emissions' cases could appear.

In France, there is already a national restriction requiring the industry to move away from the ammonium salts in cellulose insulation. Thus, French manufacturers have already replaced the ammonium salts so this restriction proposal would induce relatively small impacts on the French market. Thus, aside the French case, distributional impacts across different Member States are estimated to be minor.

F.6 Main assumptions used and decisions made during analysis

Section F provides quantified estimates of the socio-economic impacts of having in place a restriction prohibiting ammonia emissions compared with the baseline scenario of continued use of ammonium salts.

This comparison was based on the following key assumptions:

- French producers stopped producing cellulose insulation containing ammonium salts after the national restriction was put in place (July 2013) (0% of the current French production of cellulose insulation contains ammonium salts).
- According to the general estimation done by IAL consultants for the thermal insulation market, yearly growth rate of the cellulose insulation sector was estimated to be 2,2% (the same as the general estimated growth rate).
- Based on the average sized loft, an average of 1,000 kg (1 tonne) of cellulose insulation per house insulated (data from ECIMA and some EU manufacturers).
- An average of 4 persons living in each insulated apartment.

- Cellulose insulation containing ammonium salts is assumed to be able to emit ammonia all along its service life.
- According to Building Research Establishment (BRE), service life/average duration of cellulose insulation is assumed to be of at least 60 years. The real duration of the insulation once installed is much lower as real estate properties might be considered changing owner more frequently than that and the new owner might decide to change the already installed insulation before its estimated lifespan.
- An average percentage of 10% of ammonium-based formulation used on the total weight of the cellulose insulation.
- No significant difference in effectiveness of alternative fire retardants compared to ammonium salts.
- 1-2% of the cellulose insulation currently placed on the EU market is imported and exported
- An amount of 250,000 tonnes of cellulose insulation yearly placed on the EU market.
- 15,000 tonnes of the cellulose insulation (6%) currently marketed inside the EU (both produced and imported) contains ammonium salts. The remaining cellulose insulation marketed in the EU contains boric acid.
- an average price of € 550 has been used. (consultations showed that one tonne of cellulose insulation is sold between €500 and €650 ex factory price
- An average price of 750€ / tonne for ammonium-based formulations.
- An average price of 750€ / tonne for boron-based formulations (price difference 0€ / tonne compared to ammonium salts).
- For ammonium and boron-free formulations the price was assumed to be of 1500€ / tonne (twice the price of the present formulation with ammonium salts), which means that factor 2 was assumed as correct instead of other factors up to 6(sensitivity analysis carried out on this point).
- 10% of the current volumes of cellulose insulation with ammonium-based formulations would accept to pay double the price (1500€ / tonne), while the remaining 90% would either switch to boron-based formulations or the manufacturers would stop their production.
- The additional costs would not be passed on the supply chain down to the final consumer.
- The EU building units yearly emitting ammonia (and causing health cases) per volumes in tonne of cellulose insulation is assumed to be the same percentage of the installed cellulose insulation containing ammonium salts and emitting ammonia observed in France every year (using ECIMA data: 100 building units on 20000 insulated with cellulose insulation containing ammonium salts).
- The European population potentially exposed to indoor ammonia emissions and presenting symptoms per building unit insulated with cellulose insulation containing ammonium salts is assumed to be the same observed in France (2 persons on an average family of 4).
- The average final cost including installation for insulating a loft would be around €2.5K if done by professionals.
- The price of the same installation done by a “Do it yourself” consumer is much lower (price at factory + the pricing for renting a machine to blow the cellulose insulation and for all other installation materials needed).
- Re-insulating a standard loft apartment emitting ammonia would cost in average around €4K, almost double the cost of the initial insulation. The reason for “almost double” would be the cost of taking out plus the insulating once again (cost of removal of the old insulation, cost of replacement and cost of destruction of the off gassing cellulose insulation).

- The number of days needed to reinsulated a loft emitting ammonia is estimated at two to three days.
- Alternatives are assumed to be available in sufficient amounts to cover the increased demand caused by changes in the market, following the proposed restriction.
- After the entry into force of this restriction proposal it can be assumed that emissions from newly installed cellulose insulation would be negligible.

Calculations based on the above mentioned assumptions done for the proposed restriction are done in a separate excel file).

F.7 Uncertainties

Most of the assumptions made in the calculations of costs and benefits of this restriction proposal were based on the stakeholders' consultations carried out by ANSES, by cross checking the information provided by different stakeholders (ECIMA, ECIA, manufacturers of cellulose insulation and producers of ammonium formulations for the cellulose insulation industry). Due to the number and the extent of the assumptions made and of the associated uncertainties, the estimates for the costs and benefits of this restriction proposal are uncertain.
The main uncertainties linked to each assumption made are discussed in different subsections of this background dossier.

Despite the short delay linked to art 129 a rapid sensitivity analysis was carried out in order to asses to which extent some assumption might impact the socio-economic proportionality of this restriction proposal by changing both its costs and benefits.
Throughout the analysis a 4% discount rate has been used as this is in line with the discount rate which is commonly used by restriction dossiers submitted to ECHA.

The most important uncertainties of this analysis concern:

- Amounts of cellulose insulation containing ammonium salts produced in the EU market;
- Volumes of cellulose insulation emitting ammonia, in presence of various possible cofactors of emission;
- Number of European living units emitting ammonia, exposed population, persons presenting symptoms;
- When the cellulose insulation would start emitting ammonia once installed;
- Existing alternative formulations having health and environmental risks assessed;
- Future trends in terms of manufacture and sales of the cellulose insulation with respect to the baseline scenario and if restriction is introduced. In this analysis the baseline scenario is based on a growth rate based on recent historical trends;
- The volumes and future trends of the import and export flows. As a result of this uncertainty import and export are not included in the estimated emissions or in the calculated costs;
- Changes in industrial processes in order to replace the fire retardants and the additional costs a premature replacement of these would entail;
- How the costs are passed down along the supply chain.

F.8 Summary of the socio-economic impacts

The Table below presents a qualitative summary of the main expected socio economic impacts due to the proposed restriction on different actors along the supply chain and down to the final consumers of cellulose insulation and of other industries that might be affected by this proposal restriction.

For each stakeholder (importers, manufacturers and formulators of ammonium salts/cellulose insulation with or without ammonium, etc.) the second column indicates an overview of the potential economic impacts expected (positive, negative or no impacts) after the entry into force of the proposed restriction on emissions. The third column presents for each actor the detailed costs and benefits related to this restriction proposal.

Some of the negative impacts faced for instance by manufacturers of cellulose insulation containing ammonium salts would be compensated by positive impacts on other actors or sectors such as the occupants of the buildings, on insurance companies or on the producers of cellulose insulation containing alternative fire retardants or on manufacturers of other types of thermal insulation.

Stakeholders	Overall impacts	Type of costs - impacts on sales etc
Formulators and manufacturers of ammonium-based formulations	No impacts in case the formulations are proven stable or minor negative impacts to stabilize their formulations or to produce alternative ones	decrease in the demand loss of market shares (but it represents a little share on their total business), additional costs for R&D
Formulators and suppliers of other formulations (flame retardants + biocide)	Potential positive impacts if they produce a safe, environmentally friendly and technically and economically feasible alternative	Potential increase in the demand, Potential gain of market shares Potential additional investments to increase the production capacity
Manufacturers of cellulose insulation containing ammonium salts	No impacts in case the formulations are proven stable or minor negative impacts to stabilize their formulations or to produce alternative ones	Possible decrease in demand Potential loss of market shares Potential additional costs to substitute or to stabilise ammonium-based formulations (higher price of other flame retardants, stocks, R&D to change the formulations, new suppliers, new ETA, new national technical advices, new training for installers, costs of testing) no new investment if the formulation is still a powder reduced profits Exporters of cellulose insulation with ammonium salts : still possible to sell abroad unless non-EU consumers' preferences change No major additional costs
Manufacturers of cellulose insulation without ammonium salts	No or very minor impacts (slightly positive or slightly negative)	Possible decrease/increase in demand, market shares & profits No additional costs According to the reaction of the market
Manufacturers of other types of thermal insulation	No or minor positive impacts	Potential additional sales due to increased demand if consumers preferences change Potential additional revenues
Importers of other formulations	Potential positive impacts if they import a safe, environmentally friendly and technically and economically feasible alternative	increased demand No additional costs

Stakeholders	Overall impacts	Type of costs - impacts on sales etc
importers of cellulose insulation containing ammonium salts	minor slightly negative impacts	Additional costs for communicating about the restriction and for analytical testing for ammonia emissions from cellulose insulation. Additional costs to change supplier if their suppliers can not comply and alternative suppliers will be more expensive
Importers of cellulose insulation without ammonium salts	slightly positive impacts	increase in the market shares
Installers and retailers of cellulose insulation	No major impacts	Need of new training if the new formulation implies some changes during the installation phase No major additional costs
Laboratories testing ammonia emissions	Potential positive impacts	additional revenues Additional turnover from increased demand for tests
End-users of cellulose insulation (consumers and DIY consumers)	Positive or negative impacts in terms of health benefit according to the alternative chosen No or slightly negative impacts in terms of price increase	High benefits: lower COI, lower costs of re-insulation/ temporary re-housing if the alternative is safer Lower risks of fire Potential slightly higher price - though likely to be a minor increase

Table 32: Summary of economic impact on different stakeholders inside and outside the cellulose insulation sector

In quantitative terms as shown by the graph below resulting from our calculations, under the assumptions done in this proposal and detailed above, since the first year of entry into force of the restriction (foreseen for 2017) the costs of this proposed restriction (costs' curve in red in the graph) are not disproportionate compared to the benefits (benefits' curve in blue in the graph).

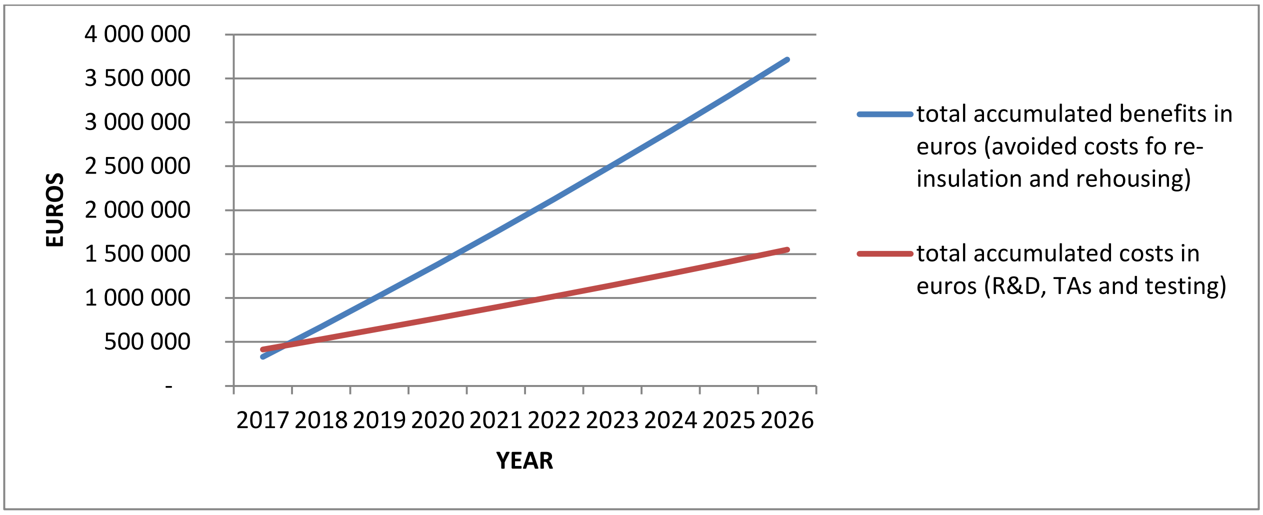


Figure 15: Proportionality of accumulated costs and benefits of the proposed restriction

<u>Sensitivity analysis</u>

A sensitivity analysis has been performed in order to test the robustness of cost-benefits analysis when the most critical parameters vary. In particular, three parameters were tested : the impact on

the ratio of cases in Europe, the price of the new formulations compared to the ammonium-based one, the number of EU manufacturers who would accept to pay such an increase of price.
The excel file containing all calculations of costs and benefits is available for the rapporteurs of RAC and SEAC. A sheet on the sensitivity analysis is inserted in the excel file describing in details the various parameters used leading to the estimations and the drawn conclusions.

From the sensitivity analysis carried out, it was found that the proportionality between costs and benefits is still guaranteed although postponed in time if the ratio of emissions cases in Europe (number of emissions cases per tonne) is reduced by 50% (50/20000 instead of 100/20000) compared to that reported in France. The figure below shows that, by reducing the ratio of cases of 50%, the proportionality of accumulated costs and benefits of the proposed restriction will be attained during the year 2021, i.e. four years after the entry into force of the proposed restriction.

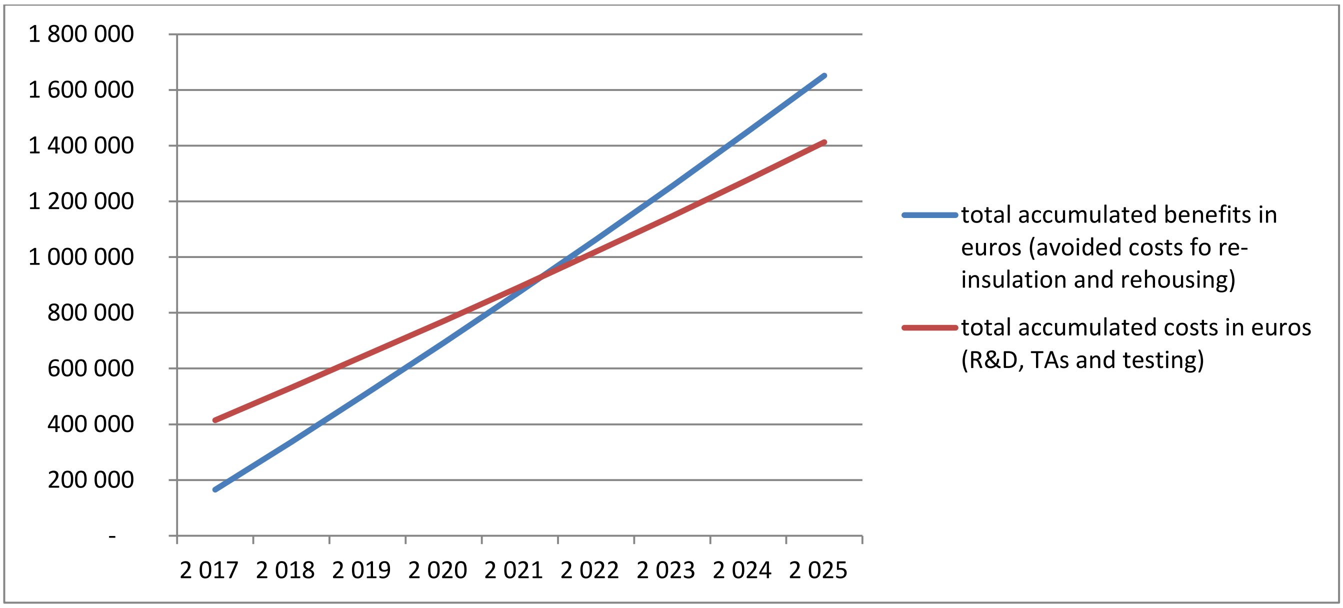


Figure 16: Sensitivity analysis of the proportionality of costs and benefits of the proposed restriction reducing the ratio of cases of 50%

Concerning the increased price of the formulation, the proportionality would cease if a formulation costing double the price of the present ammonium-based ones would be used in more than 30% of current EU production containing ammonium salts (which seems very unlikely) or if a formulation costing four times the price of the present ammonium-based ones (factor 4) will be used in more than 10% of the current production volume (which even seems more unlikely).

It is worth remembering that the benefits taken into account in the calculation do not include the health benefits so they can be considered as an underestimation.

G. Stakeholder consultation

G.1 Stakeholders' consultations and meetings organised by ANSES

Although this restriction dossier was carried out under article 129 of REACH Regulation in a short timing, a large but targeted stakeholders' consultation process was undertaken in order to obtain information on the manufacture of cellulose insulation and on the possible impact of the restriction based on ammonia emissions.
The consultation mainly aimed at gathering useful data for the development of the dossier in order to define the scope of the restriction proposal and to carry out the required socioeconomic analysis.
For this consultation, various questions tailored on the very nature of each different type of actors were asked to key stakeholders identified as the most relevant for each different issue. In some cases more detailed information was requested through follow-up questions.

The stakeholders' consultation took place between August and December 2013. During the months of September, October and November 2013, ANSES invited and was invited by a number of stakeholders to several different meetings with the aim to gather information, which has been taken into account in sections C, E and F of this dossier.
The stakeholders met or interviewed over the phone represented the French public authorities, EU and non-EU cellulose insulation manufacturers, importers and retailers, installers, producers of ammonium salts, formulators and producers of alternative fire retardants, key trade associations representing these sectors, and companies with experience in the analyses of ammonium salts in cellulose insulation.

ANSES carried out a rapid survey on the Internet on EU and international forums on DIY building renovation in order to have an idea of the type and the number of complaints from European clients due to the release of ammonia gas by cellulose insulation using ammonium based formulations. Complains were present only on French and US websites.
The following subsections present the interested parties who have been contacted.

A second round of consultations of key stakeholders was carried out by the Dossier submitter (in March-April 2014) in order to respond to the relevant recommendations raised by the RAC and SEAC rapporteurs during the conformity check period.

G.2 EU formulators and suppliers of formulations

G.2.1 EU associations of formulators

EFRA is the European Flame Retardants Association and represents the leading organisation which manufacture, market or use flame retardants in Europe.
Pinfa is the Phosphorus, Inorganic and Nitrogen Flame Retardants Association representing the manufacturers and users of non-halogenated phosphorus, inorganic and nitrogen flame retardants (PIN FRs).
Both EFRA and Pinfa were consulted by ANSES in order to gather information on the impacts of the proposed restriction on the sector of fire retardants. EFRA and Pinfa consulted their networks of members but at the date of the submission of this proposal no feedback were received by the two networks on the potential impacts of the proposed restriction.
If feedback will be received, containing crucial information for further developments, it will be made available for the consideration of the Committees in the opinion making process.

G.2.2 Formulators and producers of ammonium salts

Producers of ammonium salts for the cellulose insulation industry were identified through the consultations with European manufacturers of cellulose insulation, via information coming from the French Public Authorities and via internet searches. These producers were contacted by phone or met during field visits in order to get information on the potential impacts of the restriction proposal on the industry. Several Producers of ammonium salts for the cellulose insulation industry have been contacted and two of them, namely Haffner International and Ecochem, were met during the visits to ICELL and Dammstatt respectively.

The main subjects of discussion were to know if they are carrying out R&D in order to find alternatives to ammonium salts as fire retardants in the cellulose insulation and if they consider their formulations stable or subject to be further stabilized.
The producers of chemicals which were contacted provided also some information on the availability, price and effectiveness of alternatives compared to ammonium salts and boron compounds. Suitable alternative blends, their technical and economic feasibility, time needed to carry out R&D, and compliance costs were also discussed. The outcome of these discussions has been taken into account in section C, E and F in this dossier.

G.2.3 Producers of boron salts

As producers of ammonium salts, some producers of boron salts for the cellulose insulation industry were also identified and contacted by phone in order to get information on the potential impacts of the restriction proposal on the industry.

G.3 EU manufacturers of cellulose insulation

G.3.1 European Associations of cellulose insulation

The European Association of cellulose insulation manufacturers (ECIMA) and the European Association of cellulose insulation (ECIA) were consulted by ANSES in order to assess to potential impacts of the proposed restriction on the cellulose insulation industry.

ECIMA represents 10 production plants of 4 French manufacturers and 4 European and Swiss manufacturers (3 of which distribute a portion of their production in France). ECIMA provided relevant information and report concerning the undergoing public-private research project carried out in France to define new stable formulations without ammonium and without boron salts. This association is considered very French and therefore a new European association (ECIA) has been created in September 2013.

The newly created association of the European cellulose Industry, **ECIA**, currently represents 14 European manufacturers, mainly using boron-based blends. Consulted concerning the possibility to take the lead in the case of voluntary agreement, the Chairman of ECIA declared that it would be difficult to convince its members and even more to have any kind of influence on manufacturers who did not joined the association. ECIA informed that a restriction would not have any significant impact on the cellulose insulation sector as only a few companies across Europe still use ammonium salts. A meeting was organised by ANSES the 5th of November 2013, in order to exchange with the President of ECIA, Mr. Izod (Excel fiber) and with Mrs. Gross (Isocell) on this restriction proposal and to gather further information on the cellulose insulation industry.

Contributions from the consultation with ECIMA and ECIA have been taken into account (see section B, E and F in the dossier) mainly concerning the following issues: possible cofactors facilitating emissions of ammonia from cellulose insulation, a reasonable transitional period in order to adapt, average tonnage of cellulose insulation used per unit of building insulated, main data on European production and import of cellulose insulation, type and volumes of cellulose insulation containing ammonium salts, process for treating cellulose insulation with ammonium salts and adaptations needed in case of a substitution, strategies adopted by the federation and by its members in order to reduce ammonia emissions, level of stocks of cellulose insulation containing ammonium salts and time needed by manufacturers for their depletion.

G.3.2 EU manufacturers of cellulose insulation containing ammonium salts

ANSES carried out an extensive market survey and consultations in order to get a clear picture of the cellulose insulation market and to identify the EU and non-EU manufacturers and to quantify the volumes of cellulose insulation containing ammonium salts produced and imported in the EU. The websites of all identified EU manufacturers of cellulose insulation were analysed to make a first short list of the producers using ammonium salts. These producers were contacted by phone as well all other producers who did not make any declaration on their webpage concerning the fire retardants used in their production.

G.3.2.1 Industry's auditions in Sweden and in Germany

At the end of November and beginning of December 2013, the economist in charge of the SEA of the proposed restriction, member of the dossier submitter team, took part in two different "study trips": one to the Swedish production site of ICELL and its formulator Haffner International and the other to visit Dammstatt and its formulator Ecochem in Berlin. The aim of these two "study trips" was to learn about the production process of cellulose insulation containing ammonium salts and to obtain further information concerning the use of ammonium-based blends and their possible substitution or stabilization and concerning the potential impacts of the proposed restriction in terms of additional costs.
Examples of topics discussed include: quantities and percentage of cellulose insulation containing ammonium salts produced yearly, production and installation processes, possible factors causing ammonia emissions, potential measures to prevent such problems, potential alternatives to ammonium salts, etc.

G.3.2.2 Batimat

The 6th November 2013 one member of the dossier submitter team went to the construction exposition Batimat held in Paris. Four European manufacturers of cellulose insulation exposing at the Batimat and both the Chairmen of ECIA and of ECIMA were met at this occasion.

G.3.3 EU manufacturers of cellulose insulation using alternative fire retardants

Concerning the methodology used to carry out the consultation of the manufacturers of cellulose insulation.
Firstly the producers included in the list of ECIMA (European association of cellulose insulation)contacted by mail. ANSES received from one of these manufacturers a confidential excel file, including among other information, a list of around 40 competitors (all EU and a few non EU manufacturers of cellulose insulation according to its knowledge of the market) with contacts and

web pages. Firstly the list was checked on the internet in order to check if it was complete which was definitely the case. Then all web pages of the EU (and a few non EU) manufacturers of cellulose were consulted in different languages. On the basis of this list, 3 short lists were made (1 of those who declared on their web pages to use boron, 1 of those who declared to use ammonium and one of those who did not declare anything). Because of the time shortage due to art 129, direct contacts were taken only with the companies of the last two short lists to ask directly if they used ammonium and all other information needed in such case (production volumes, possible health and environmental hazards, reported cases, type of salts used, etc). Then this information was cross checked with some ETAs found on the web and with the declaration made by the formulators which I contacted in parallel. Almost all French manufacturers were consulted in order to try to understand what happened in France and which were the main impacts of the French restriction on the French companies.
All identified manufacturers of cellulose insulation who did not declare in their internet websites the type of formulation used were contacted via direct e-mails and some of them also by phone, in order to obtain information on if they use ammonium-free and boron-free alternative blends (formulations used, their costs and availability, etc.). However through the in depth Internet searches and stakeholders' consultations, no European manufacturers of cellulose insulation were identified using alternative to ammonium and boron salts.

G.3.4 Non-EU manufacturers of cellulose insulation

It was not easy to identify and to consult the non-EU producers and companies importing from countries outside the EU. ANSES contacted the non-EU manufacturer Isofloc from Switzerland, with the aim to discuss and collect information on the use of ammonium salts in their manufacturing of cellulose insulation and their export to the EU. Isofloc is not producing nor exporting to the EU cellulose insulation containing ammonium salts.

G.4 Installers' association : French Syndicat national de l'isolation (SNI)

The French installers' association, Syndicat national de l'isolation (SNI), was consulted in order to understand the economic impacts of the French restriction on the French installers and in order to assess the potential impacts of the proposed restriction on the European installers of thermal insulation material, including cellulose insulation. No specific economic impacts were quoted by the French installers given that they keep installing boron-based cellulose insulation and other thermal insulation materials even after the French restriction.SNI was also asked about the exposure of French installers to ammonia emissions from cellulose insulation containing ammonium salts, but no cases were reported.

G.5 EU Public Authorities

G.5.1 French **Public Authorities and technical bodies**

G.5.1.1 French Ministry of Ecology (DHUP)

The Directorate of Housing management, urban planning and landscape (DHUP) was consulted as a major actor in standardization of building construction products. Furthermore, DHUP leads the collaborative research project funded by the French Ministry of Housing and carried out with the official objective to replace boric acid (and other boron salts classified Repr. 1B) as additive in cellulose insulation materials. This project brings together several public stakeholders (CSTB, DHUP) and the private sector (8 producers of cellulose insulation producing or selling in France, formulators of chemical additives, technical institutes). The results will be made available by the end of 2014 to all producers having a production unit in France.

G.5.1.2 French Scientific and Technical Center for Building (CSTB)

CSTB, the French Scientific and Technical Center for Building, is a public organization for innovation in building which performs four key activities, namely research, expertise, evaluation and dissemination of knowledge in the construction sector. Its field of expertise covers construction products, buildings and their integration into districts and cities. The CSTB was questioned concerning possible cofactors that could explain the French cases of ammonia emissions, possible reasons that could explain the fact that no cases of ammonia emissions were registered in Europe, regulatory requirements in terms of fire resistance and for the choice of Euroclass for cellulose insulation, average cost of a vapor barrier, differences between ETA and national technical advices in France and in Europe, their costs and their implications in terms of insurability, and estimated costs of emission tests.

G.5.1.3 French committee of toxicovigilance (CCTV)

The French committee of toxicovigilance (CCTV) was consulted in order to get a better understanding of the French dossiers concerning the exposed people which were recorded in France between **February 2012** and July 2013. The data provided by the CCTV were extremely useful in order to assess the main symptoms and heath effects from ammonia emissions from cellulose insulation in France (mainly irritation of nose, eyes, throat and the mucous membrane of the upper airways), and the number of complaints related to the total number of housings which were insulated in France using cellulose insulation containing ammonium salts. The follow-up of several dossiers showed that these symptoms/odours disappeared once the cellulose insulation with ammonium salts was removed and/or replaced.

G.5.1.4 French Directorate for Competition Policy, Consumer Affairs and Fraud control (DGCCRF)

The DGCCRF, the French Directorate for Competition Policy, Consumer Affairs and Fraud control, is the French authority in charge of the enforcement and control of the French restriction.
The DGCCRF and its laboratory were contacted in order to obtain information on the enforcement of the French restriction since its entry into force in July 2013. This consultation was carried out with the purpose to get some insights on the enforcement issues that could arise in the implementation of the proposed restriction.

The questions asked concerned mainly the kind of controls they carry out on cellulose insulation, the methods used to measure ammonia emissions from cellulose insulation, the problems met during enforcement, the costs of their tests and test frequency, the performed analyses and their results (number of non-compliant articles containing ammonium found on the French market).
According to the DGCCRF, no controls related to ammonia emission from cellulose insulation were conducted in France after the entry into force of the French restriction on cellulose insulation containing ammonium salts. Due to the recent application of the French restriction the requested data were not yet available, but the DGCCRF did not meet nor foresees to meet any major problems for the enforcement of the French restriction.

G.5.1.5 French National Network for Monitoring and Prevention of Occupational Diseases (RNV3P)

The (French) National Network for Monitoring and Prevention of Occupational Diseases (RNV3P) is a network for monitoring and prevention in occupational health, grouping together the 32 Occupational Disease Consultation Centres (CCPPs) and some occupational health services (SSTs) associated with the network in France. This network collects in a permanent national database on occupational diseases data from each consultation (patient's demographic data, diseases, exposures, activity sector and workstation).
The RNV3P was consulted concerning the five French cases of workers from the same company (plumbing) who were exposed to ammonia emitted from cellulose insulation materials.

G.5.2 Consultation with Member States Competent Authorities

In July 2013, France published on CIRCABC a questionnaire with the aim to gather by mid September 2013 information on number of registered health cases linked to indoor ammonia emission from cellulose insulation, quantities of the cellulose insulation manufactured with and without ammonium salts, imported and exported, ammonium salts alternatives, existence of national risk management measures and monitoring programs taken at national level. The same questionnaire was sent by ANSES to the REACH Competent Authorities of all Member States through RiME's contacts.
An additional delay was agreed for receiving such questionnaires by the Competent Authorities of Member States.

Finally, filled questionnaires were provided by Germany, the Netherlands, Norway, Bulgaria, Poland and Ireland. The United Kingdom and Sweden, which did not have all the required information to fill the questionnaire, provided back less formal feedbacks on the consultations carried out.
No health cases were reported by the MSCAs outside France.
The model of questionnaire is provided in Annex 5.
A summary of the responses to the questionnaire of the MSCAs is provided in the following table. The main information received is summarized below:

	Manufacturers of CI in the country (with and without AS)	**Alternatives to Ammonium salts**	**Information on R&D**	**Comp lains**	**Cases**
Germany	NA	Magnesium sulphate Aluminium trihydrate	NA	NA	NA
Netherlands	10	Boron	NA	NA	NA
Norway	1		NA	NA	NA
Bulgaria	0	Bisquaternary ammonium compound (negligible emissions) Boron	NA	NA	NA
Poland	1	Boron	Aluminium hydroxide but dustyness	NA	NA
Ireland	3	Mixture of agricultural gypsum, Magnesium	NA	NA	NA

		hydroxide, polybore borax, decahydrate borax			

Table 33: Main information collected from the MSCA's consultation

G.5.3 Consultation with EU Poison Information Centres (PICs)

ANSES contacted the European Association of Poison Centres and Clinical Toxicologists.(EAPCCT) forum in order to gather information collected by other EU Poison Information Centres (PICs); this enquiry was also sent personally to several PICs in Europe. Answers were obtained from the Belgian and the Germany PIC. No other cases were reported by these PICs.

G.6 European Organisation for Technical Assessment (EOTA)

EOTA is the **European Organisation for Technical Assessment** in the area of construction products. Taking into consideration the fact that most of the EU producers of cellulose insulation received ETA approvals from EOTA national organizations, ANSES contacted EOTA European offices, based in Brussels, as well as several EU national offices in order to discuss concerning how the technical assessment process is carried out for the cellulose insulation industry in the EU and the prices of ETAs.
According to the Belgian Technical Approval Body (UBATc) delivering ETA's, in case boron is used in the production of cellulose insulation, at the moment of the assessment of the cellulose insulation, ETA's certification should verify that its percentage falls within the values imposed by REACH (i.e. 5,5%). According to UBATc, at present, given the current French restriction on ammonium salts, the presence of ammonium salts in the cellulose insulation is also verified by the European national Bodies of Technical Approval. Therefore, currently, in Europe an ETA cannot be delivered anymore for cellulose insulation that would contain ammonium salts because it could be sold in France too.

G.7 Workers' unions: European Trade Union Confederation (ETUC)

Since 1973, ETUC, the European Trade Union Confederation, represents 85 trade union organisations at European level, defending the common interests of workers. ETUC prepared a list of substances of very high concern that cause recognised occupational diseases to be included on the European candidate list of substances for authorisation under the REACH rules.
ETUC circulated in their European network information concerning the proposed restriction by requesting feedback on any problems observed in the construction sector. ETUC secretariat indicates that no data were received about the exposure of workers (employees of manufacturers of ammonium salts and cellulose insulation containing ammonium salts and installers of such products).
If relevant feedback will be received, it will be made available for the consideration of the Committees in the opinion making process.

G.8 Consumers' Groups: European Consumers' Organisation (BEUC)

The European Consumers' Organisation**,** the BEUC, which represents more than 40 European national consumer organisations, was contacted by e-mail in order to know if they received

consumers complains concerning ammonia emission from cellulose insulation. BEUC contacted its members but did not receive any information concerning consumers' complains.
If relevant information will be provided, it will be made available for the consideration of the Committees in the opinion making process.

G.9 Environmental NGOs

The stakeholder consultation addressed also some environmental NGOs.

ClientEarth is an NGO of environmental lawyers, based in Brussels, working to ensure that environmentally sound laws are made, and then rigorously enforced. ClientEarth team works also on the implementation of REACH on toxic substances. ClientEarth contacted its network concerning this restriction proposal but it did not receive any relevant information.

ANEC represents the European consumer interest in the creation of technical standards, especially those developed to support the implementation of European laws and public policies. ANEC, the European consumer voice in standardization, was also informed concerning the restriction proposal.

G.10 SME umbrella organisation

UEAPME is the European SME umbrella organisation representing the interests of European crafts, trades and SMEs at EU level. UEAPME is a non-profit organisation incorporating around 80 member organisations from 34 countries consisting of national cross-sectorial SME federations, European branch federations and other associate members, which support the SMEs. UEAPME represents more than 12 million enterprises, which employ around 55 million people across Europe. UEAPME was consulted in order to assess the potential impacts of the proposed restriction on SMEs. **UEAPME** was informed concerning the restriction proposal as it might impact some SMEs (cellulose manufacturers, ammonium salts formulators, installers, retailers, etc).

G.11 DG ENTREPRISE/B1

In order to assess if the Regulation No 305/2011 could be a suitable option to manage the risk of ammonia emissions from cellulose insulation, the DS contacted 2 members of DG ENTR/B1. The main questions discussed concerned the possibility to use the "safeguard procedures" of Chapter VIII for managing the risk discussed in this restriction dossier, how long would it take for developing European harmonized standard for indoor ammonia emissions though the Regulation 305/2011, what could be the applicability and enforcement by European authorities and companies of the safeguard clause to the case of ammonia emissions from cellulose insulation. The results of this discussion are reported in section E 2.4. of this dossier.

G.12 Forum and the Forum WG Enforceability on Restrictions

The DS asked the French member of Forum to consult the Forum regarding certain aspects of the monitorability and the enforceability of the proposed restriction. The guide for developing Forum advice on enforceability of restriction proposals, which illustrates all elements that are considered by the Forum when assessing the enforceability of Annex XV dossiers, has also been considered by the DS in the preparation of the relevant section of this report.

H. Other information

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Annex 1: French Order of 21 June 2013 on the prohibition to place on the market, import, sell, distribute or manufacture cellulose insulation materials with ammonium salt additives

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Decrees Orders Circulars

GENERAL TEXTS

MINISTRY OF ECOLOGY, SUSTAINABLE DEVELOPMENT AND ENERGY

Order of 21 June 2013 on the prohibition to place on the market, import, sell, distribute or manufacture cellulose wadding insulation materials with ammonium salt additives

NOR :
DEVP1315203A

The Minister for Social Affairs and Health, the Minister for Ecology, Sustainable Development and Energy and the Minister for Labour, Employment, Vocational Training and Social Dialogue,

Having regard to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, in particular Article 2 thereof;

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures;

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and in particular Article 129 thereof;

Having regard to Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products;

Having regard to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, in particular notification No 2013/259/F;

Having regard to the Environmental Code, and in particular Article L. 521-6 thereof,

have adopted the following:

Article 1 − The provisions of this Order shall apply to cellulose wadding insulation materials with ammonium salt additives.

Article 2 − The placing on the market, import, possession for sale or distribution, sale or distribution and manufacture of the materials referred to in Article 1 shall be prohibited.

Article 3 − The products referred to in Article 1 shall be withdrawn and recalled.

Article 4 − The costs relating to the implementation of this Order shall be borne by the party responsible for the first placing of the products on the market.

Article 5 − The Minister for Social Affairs and Health, the Minister for Ecology, Sustainable Development and Energy and the Minister for Labour, Employment, Vocational Training and Social Dialogue are responsible, each within their areas of competence, for the implementation of this Order, which shall be published in the *Journal officiel de la République française* (French Official Gazette).

Done on 21 June 2013.

Minister for Ecology, Sustainable Development and Energy
For the Minister and by delegation:
Director-General for risk prevention,
P. BLANC

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Annex 2: Standard for the characterization of volatile pollutants from construction products

Horizontal EU testing method: Technical Specification CEN/TS 16516

On the basis of the EU-Mandate M366 the working group of the European Committee for Standardization CEN/TC351/WG2 developed a harmonised testing method for evaluation of VOC emissions of construction products. This method determines the specific emission rate of volatile organic compounds from a construction product into indoor air. This can be converted into a concentration in the air of the reference room by calculation.

The title of the harmonised testing method, having been adopted as draft on Sept 6th, 2012, is "Construction products - Assessment of release of dangerous substances - Determination of emissions in indoor air". The publication of the harmonised testing method as CEN technical specification (CEN/TS 16516) was published recently (in October 2013). The publication of the harmonised testing method as EN standard then is scheduled, after a series of interlaboratory tests for reasons of the reproducibility of the method, for 2015/2016.

The according product standards (hEN's) will then have to be completed by product-specific precepts for sampling and sampling preparation.

In the future national approvals will be superseded by the CE marking, the exact date of this, however, has not been set yet.

This method uses a test chamber in which emissions are generated under conditions which are kept constant during the test. These conditions are selected so that the test results can be expressed in terms of chemical concentrations in the air of the reference room.

This determination of emission into indoor air is to be carried out on products under their intended conditions of use. The intended use of a construction product is generally specified in the corresponding harmonised product standard (hEN) or EAD. The specific emission rates determined using this Technical Specification are associated with application of the product in a defined European Reference Room under specified climate (temperature and humidity) and ventilation conditions. A reference room is needed since it is not possible to evaluate emissions by testing in all possible use scenarios.

The selection of one emission scenario and one reference room for evaluating emissions to indoor air is in general accordance with the approach taken in existing European national regulations and voluntary schemes relating to emissions from construction products into indoor air.

The aim of this Technical Specification is not to develop a new testing method but to combine by normative references the use of existing standards[46] complemented, when necessary, with additional and/or modified requirements so that – according to the horizontal concept specified in mandate M/366 – construction products can be evaluated under comparable conditions with regard to emissions into indoor air.

Reference room dimensions:

The Technical Specification CEN/TS 16516 specifies a European reference room being mandatory for all products and purposes of use. This reference room is no test chamber; it only serves as reference value for evaluation of test results in terms of their impact on the indoor air concentration.

Sizes of the reference room:

[46] Such as ISO 16000-9:2006 which specifies a general laboratory test method for determination of the area specific emission rate of volatile organic compounds (VOCs) from newly produced building products or furnishing under defined climate conditions.

Area: 3 x 4 m (12 m^2)
Height: 2.5 m
Volume: 30 m^3

Main parameters of test chamber:
The test chamber simulates the parameters of the reference room in a smaller scale.
Temperature: 23 ± 1 °C
Relative humidity: 50 ± 5%
Air change rate/h: 0.5 (deviation 0.25 – 1.5)
Loading factor: Floor, ceiling: 0.4 m^2/m^3
Walls: 1 m^2/m^3
Area specific air flow rate: Floor, ceiling: 1.25 $m^3/(m^2.h)$
Wall: 0.5 $m^3/(m^2.h)$
The size of test chamber depends on sample. It should be 20 l minimum

Product sampling and transport to the laboratory
Studies of the emission of volatile compounds from building products in test chambers require proper handling of the product prior to testing, and during the testing period.
CEN/TS 16516 describes how to prepare a sampling plan and sampling strategy, specifications for packaging and transport of laboratory sample, and the procedure of handling and storage of product samples in the laboratory.
Main of these specifications comes from ISO 16000-11:2006 standard (Part 11: Determination of the emission of volatile organic compounds from building products and furnishing -- Sampling, storage of samples and preparation of test specimens).

Annex 3: Retrospective study of exposure cases recorded by the French poison control and monitoring centres between 1 November 2011 and 31 December 2012

National network of poison control and monitoring centres (CAPTVs). Report in response to the solicited request from the Directorate General for Health. February 2013.

Data sources and collection

The CAPTV network's National Database on Products and Compositions (BNPC) and National Database on Poisoning Cases (BNCI) were queried over the period November 2011 - December 2012 concerning data from the 10 French CAPTVs.

Data analysis

Query criteria: the products and compositions database was queried in order to identify agents corresponding to the request and, where applicable, obtain their compositions.
Dossiers were also searched in the National Database on Poisoning Cases (BNCI).

Severity

Severity was analysed according to the Poisoning Severity Score[47].

Causality

Causality was assessed using Version 7.1 of the method for calculating causality in toxicant monitoring (see end of annex), which considers the following determinants: exposure [E], symptomatology [S], chronology [C], objective factors for causal characterisation (assays, metrology, diagnostic tests, etc.) [L], whether or not there is another etiological diagnosis [D], bibliographic data [B]. The causality indicator has five levels: very likely [I4], likely [I3], possible [I2], not excluded [I1], causality zero [I0].

Results

Articles and products concerned: query of the French database of products and compositions

Since December 2012, 12 agents based on cellulose insulation treated with ammonium salts have been created in the BNCI.

Agent name	Number of dossiers concerned in the investigation
X1	1 dossier, 3 exposed subjects
X2	1 dossier, 2 exposed subjects
X3	2 dossiers, 5 exposed subjects
X4	
X5	1 dossier, 1 exposed subject
X6	
X7	
X	

[47] Persson HE, Sjöberg GK, Haines JA, Pronczuk de Garbino J. Poisoning Severity Score. Grading of acute poisoning. Clinical Toxicology 1998: 36 (3): 205-13.

Agent name	Number of dossiers concerned in the investigation
X8 X9 X10 X11 X12	3 dossiers, 4 exposed subjects

The brand names of the cellulose insulation are known in 8 dossiers out of 10. For the other two dossiers, the investigation is still ongoing.

Number of cases of exposure and trend: a search of the database of poisoning cases
The initial sorting of data from this period led to the isolation of 22 dossiers including one duplicate (between the poison control centres in Rennes and Angers). Eleven dossiers were excluded as they did not involve pollution of indoor air by cellulose insulation.
Ultimately, 10 dossiers on exposure to fumes from cellulose insulation were selected with 19 people exposed.

Exposed individuals
The cases involved 14 adults aged from 32 to 70 years, and 5 children aged 7 months, 1.5, 4.5, 7.5 and 9.5 years. The gender distribution was 9 women/10 men.

Date of occurrence
All the dossiers resulting from the call relate to the year 2012; two dossiers in February and April, and all the others from August 2012 onwards, which was the date from when most manufacturers placed the cellulose insulation on the market.

Month	01	02	03	04	05	06	07	08	09	10	11	12
Dossiers		1		1				1	1	3	1	2
Exposed individuals		1		3				1	2	7	1	4

Level of exposure and investigations conducted
Of the 19 exposed individuals, 18 were subject to daily exposure, either because they lived in a house in which insulation work had been done, or because their job involved laying the cellulose insulation and therefore handling it for several hours a day.
Atmospheric measurements were taken for only three dossiers (10 ppm = 7 mg/m^3). The results were as follows:
- 5 to 9 ppm (SCHS Nantes investigation);
- 2.1 to 2.8 ppm (ARS Bordeaux investigation);
- 0.5 to 1.7 ppm (analyses conducted by a distribution manager).

The investigation revealed the presence of controlled mechanical ventilation (CMV) for three dossiers (negative pressure in the dwelling) and forced-air mechanical ventilation (FAMV) for two dossiers. For the other dossiers the investigation reports have not yet been received.

Nature of the symptoms

In 9 dossiers out of 10, one or more of the exposed subjects smelled an odour, and for some of them a smell characteristic of ammonia gas was mentioned.

In total, 15 of the 19 exposed subjects had one or more symptoms corresponding to an irritative syndrome of the mucous membranes, of the upper airways or bronchi.

Symptoms	Number of patients	Remarks
Cough	11	
Bronchospasm	1	
Other respiratory signs	3	1 difficulty breathing. 3 "bronchiolitis"
Nasal irritation	7	
Irritation of the pharynx	5	
Irritation of the eyes	12	

The “bronchiolitis” was first diagnosed in two children aged 1.5 and 4 years: the elder had already had bronchiolitis at the age of 6 months, while the second had no previous history in this regard. This syndrome labelled as “bronchiolitis” by the attending physician appeared two days after the insulation was laid, and was associated with a syndrome of mucosal irritation in the parents. The children's symptoms disappeared with symptomatic treatment even while exposure to the ammonia continued.

The second diagnosis labelled as “bronchiolitis” was in a 7-month-old baby with no prior medical history, although the dossier contains very little detail.

Duration of symptoms

Symptoms were related to exposure in most dossiers, and were resolved as soon as the room was aired, or the exposed individuals went outside. In the other dossiers, the patients were still being exposed at the time of our study.

Severity

The final severity of the clinical pictures in the 19 exposed subjects assessed according to the PSS was as follows: severity was assessed as zero for 3 patients (who were not symptomatic), low for 12 subjects and moderate for four.

Causality

Causality for each dossier is shown in the summary of cases in the table below. The causality of cellulose insulation with regard to the origin of symptoms is likely or possible in eight dossiers out of 10. It is doubtful in one case where the exposure history is insufficient, and was deemed zero in one case where there was overlap with a concomitant viral syndrome.

CAPTV	**Date**	***(French) department / county***	**Case summary**	**Causality**
Angers	10/10/2012	44	Cellulose insulation recently laid in the attic (following flooding); 3 weeks later, the occupants noticed a strong smell, which was amplified when using the CMV. They were symptomatic. Measurements of NH_3 confirmed exposure to 6-9 ppm	Likely

CAPTV	Date	*(French) department / county*	Case summary	Causality
Bordeaux	24/10/2012	86	A company laid cellulose insulation in the attic. The 4 family members (including 2 children) began suffering from a mucosal irritation syndrome 48 hours after installation; CMV runs continuously and cannot be switched off (inaccessible). NH_3 measurements confirmed exposure to 2.1-2.8 ppm. Bronchiolitis in the two children cleared up with symptomatic treatment, even while exposure to ammonia continued.	Likely
Bordeaux	20/12/2012	33	The exposed individual carried out the work himself in his home under construction; he used two types of cellulose insulation; he applied this in the walls and ceilings, over several weeks. It was only after a concrete screed was laid that an unbearable smell appeared, requiring the patient to air the house permanently and cease working indoors. No symptoms other than the discomfort from the odour.	Possible
Lille	20/10/2012	59	Occupational exposure (use of a powered blower) of a man who had been installing cellulose insulation without problems for 5 years. For 2 months he had been laying a new wadding (cellulose insulation) and noticed that the smell had changed. After 3 days on a new site he complained of an ammonia smell and he and three other colleagues felt an irritating sensation. He had a cough and difficulty breathing, which were treated with a bronchodilator and one week on sick leave. He had worn a simple mask during installation.	Likely
Lyon	18/12/2012	38	Cellulose insulation laid in the attic, brand unknown; an ammonia smell appeared when the FAMV was on. The smell was present throughout the house and disappeared as soon as the FAMV was switched off. The father had a cough that coincided with the periods of exposure and during the period when the FAMV was on, the 7-month-old child had a bronchiolitis that cleared up when the FAMV was switched off, but also with medical treatment for the bronchiolitis. Symptoms were correlated with the ammonia smell.	Likely
Lyon	10/04/2012	73	House undergoing work; cellulose insulation; time to onset of symptoms unknown, but the patients left the house after 5 days of exposure. Father aged 43 years and children aged 9.5 and 7.5 years had an irritative syndrome that persisted for 16 days after cessation of exposure.	Possible
Marseille	10/02/2012	34	Two weeks previously, the patient had himself used cellulose insulation when working on his home, initially without a mask, causing cough and rhinitis, and then with a mask. Overlap with a concomitant febrile viral syndrome with respiratory symptoms that persisted a further 8 days after cessation of exposure to the cellulose insulation.	Zero
Marseille	25/09/2012	34	A company laid cellulose insulation, releasing an unbearable ammonia smell in the attic. A 70-year-old couple living on the floor below was bothered by the smell but had no other symptoms. The installer was concerned about the danger of ammonia for this elderly couple.	Likely
Marseille	10/08/2012	83	Work under the roof was carried out over the patient's workplace; in the morning, the 52-year-old woman smelled a suffocating odour after being exposed for 2 hours (she left her office as the smell was unbearable); the brand of cellulose insulation is not known; the patient immediately experienced throat irritation, fatigue, hot flushes, and ENT dysesthesia that persisted for several hours.	Not excluded (doubtful)
Toulouse	22/11/2012	82	Cellulose insulation sprayed throughout the house (ceiling and walls) before the seals had been done. Strong smell, sensation of irritation of the eyes and nose. Detection of ammonia at 0.5 ppm (dwelling) and 1.7 ppm (garage and storeroom) measured by the manufacturer who came to investigate. Airing the attic removed the smell in the dwelling. Sealing work for the insulation is pending.	Likely

Discussion

This retrospective study describes the first cases of exposure, suspected or proven, to fumes from cellulose insulation containing ammonium salts flame retardant. This cellulose insulation was laid as insulation by the householders themselves or by specialist companies, blown or sprayed (flocking) into inaccessible attic areas or walls.

Only 10 dossiers on exposure to fumes from this cellulose insulation were recorded by the CAPTVs in 2012, while this new cellulose insulation containing ammonium salts was installed in as many as 20,000 dwellings.

However, numerous complaints about this new cellulose insulation have been brought to the attention of the cellulose insulation manufacturers (115 cases by the end of 2012) as well as on Internet forums. It can be assumed that for some cases of exposure or olfactory discomfort, complaints were brought to the attention of the installer without the CAPTVs being informed.

It is also conceivable that fumes in the uninhabited parts of dwellings fitted with this new cellulose insulation were unable to reach the adjacent dwellings.

It should be noted that in several dossiers identified in this series, the role of controlled mechanical ventilation (CMV) or forced-air mechanical ventilation (FAMV) was mentioned. In the original dossier that led to the national alert, the health technician who carried out the investigation had indeed found that the cellulose insulation was in direct contact with the CMV motor in the attic, which could generate heat and facilitate the diffusion of ammonia gas inside the dwellings.

Cellulose fibres

Mucosal or respiratory diseases related to cellulose particles are rare; one study of acute exposure in employees installing cellulose insulation has been reported. In a questionnaire, the employees described symptoms of cough, wheezing, signs of irritation in the nose, throat and eyes, and symptoms limited to the upper airways. The analysis of the cellulose dust showed that the particles had an average size of 28 µm (5-150 µm), and that their concentration could exceed the ACGIH threshold limit value of 10 mg/m^3. The authors demonstrated that the dust concentration was higher when applying dry cellulose than during wet application. In this study, the effects were related to cellulose particles, whereas the cellulose insulation contained different flame retardants such as boric acid, borax and ammonium sulphate, and some also contained gypsum and starch. Ammonia was not analysed in the ambient air and the potentially toxic effects of the flame retardants are not discussed.

For chronic exposure, studies conducted mainly in the paper manufacturing sector have demonstrated signs of upper airway irritation, chronic bronchitis or asthma, and spirometric impairment (decreased FEV and FVC) in workers exposed to paper dust consisting mainly of cellulose fibres. The risk of pulmonary fibrosis, cancer and mesothelioma cannot be assessed on the basis of the available studies.

The hypothesis of a pathology induced directly by volatilised cellulose fibres in the ambient air is unlikely, because the cases in the series presented here occurred concurrently with the use of ammonium salt flame retardants. Moreover, in the only documented case of occupational exposure, the complainant clearly stated that he had installed cellulose insulation containing boron salts with a powered blower for 5 years without any grounds for complaint, and it was only with the use of the new cellulose insulation containing ammonium salts that the irritative syndrome experienced by him and his three colleagues began.

Chemical reactivity of ammonium sulphate

Ammonium sulphate is highly soluble in water and must be stored in a dry place. In the presence of moisture or in solution, it decomposes into a strong acid (sulphuric acid) and ammonia gas. In contact with an alkaline functional group, it reacts to release ammonia gas. Lime, plaster and cement are all alkaline and can theoretically react with ammonium sulphate. In one of the dossiers

in this series the release of ammonia occurred after the laying of a concrete screed that might have promoted such a reaction, while in another dossier it occurred when in contact with Placoplatre® plasterboard partitions.
Ammonium sulphate is an unstable compound and can cause explosive exothermic reactions with oxidants. It reacts violently with nitrates, nitrites, sodium, potassium or metals (iron, zinc), or strong oxidisers such as chlorates. Ammonium sulphate reacts with sodium hypochlorite (bleach) and produces trichloramine (NCl_3) which is extremely irritating to mucous membranes and the airways.

Exposure to ammonia

The cases of exposure to ammonia gas in the retrospective series presented here were confirmed by measurements of ammonia in ambient air in three dwellings from the 10 dossiers recorded.
In physico-chemical terms, ammonia gas (NH_3) is lighter than air. This suggests that it would spontaneously fill the space in the attic rather than the living area situated below and should not significantly bother the occupants if the attic is aired and the partitions have been properly sealed. However, the use of CMV and especially FAMV, noted in several dossiers, appears to promote the diffusion of ammonia.
The exposure levels measured between 0.5 and 9 ppm were highly consistent with the detection of the ammonia smell and also with the irritative syndromes of the mucous membranes or airways experienced by the exposed subjects. As these were instantaneous spot measurements, the occurrence of exposure to higher concentrations cannot be excluded.
The threshold at which the human sense of smell perceives ammonia in prolonged or repeated exposure varies greatly, from a few tenths of ppm to 53 ppm. Indeed, prolonged or repeated exposure leads to tolerance, and the gas's irritating effects are then perceived at higher concentrations than initially.
Because of this phenomenon of "olfactory fatigue", smell cannot be considered an adequate warning sign for preventing a situation regarded as hazardous during chronic exposure.
From the environmental perspective, the normal atmospheric concentration is from 0.3 to 0.6 ppb (parts per billion).

According to the US Agency for Toxic Substances and Disease Registry (ATSDR), the public health guideline value, known as the "minimal risk level" (MRL), for ammonia by inhalation is 1.7 ppm for acute exposure of less than 14 days.
Toxicological reference concentrations (RfC) are an estimate of human exposure by inhalation over a lifetime without appreciable risk of deleterious effects (including in groups at risk). The US EPA proposes a RfC of 0.1 mg/m^3.
The ATSDR also proposes a long-term MRL (more than 1 year) of 0.1 ppm.
The US Office of Environmental Health Hazard Assessment (OEHHA) proposes a toxicity reference value (TRV) of 0.3 ppm (0.2 mg/m^3).

The occupational exposure limits (OEL) in workplace air have been established in France for anhydrous ammonia (NH3) at 10 ppm or 7 mg/m^3 for 8 hours of work 5 days a week, and at 20 ppm (14 mg/m3 for 15-min exposure). These proposed limits are higher in other countries (20 ppm over 8h for the European Union, 25 ppm for the USA (threshold limit value and time-weighted average: TLV-TWA) and 25 pmm in Quebec (time-weighted average exposure value: VEMP).
The dose-effect relationship for ammonia is shown in the table below, with varying results depending on the sources used:

Concentration of NH_3 in ppm in the air	Probable effects from acute exposure
< 1 - 17 - 53	Limits to olfactory detection (habituation)
20	Discomfort in non-accustomed individuals
32 - 50 (5 min)	Slight irritation in nose and throat

135	Irritation in eyes, nose, throat, watery eyes
300	Immediate hazard to life and health
500 (30 min)	Severe irritation of respiratory tract and effects on breathing
1720 - 3000	Violent cough
2500 - 7000 (30 min)	Bronchospasm, pulmonary oedema
5000 - 10,000 (30 min)	Rapid death by suffocation and pulmonary oedema
150,000	Lower explosive limit

Toxicological review

Acute inhalation toxicity of ammonia has been characterised experimentally by an LC50 in rats for two-hour exposure to 7600 mg/m^3 (around 10,800 ppm) and in mice for 10-minute exposure to 10,150 ppm. At these high concentrations, ammonia causes severe irritation, then corrosive lesions to ocular mucous membranes, the respiratory tract and skin. Animal autopsy shows ulcerations in the ocular and respiratory epithelia, acute haemorrhagic pulmonary oedema and sometimes atelectasis.

As ammonia is highly soluble in water, ammonia retention is always higher in the upper airways, where lesions are always more severe than in the lower parts of the respiratory tract (bronchioles and alveoli). Indeed, when in contact with moisture, ammonia (NH_3) is rapidly converted to ammonia solution (NH_4OH) causing caustic burns to the skin and mucous membranes. Penetration of ammonia gas in the respiratory tract has been studied in animals and humans: most of the NH_3 (transformed into ammonia solution) is retained in the upper airways. Thus in rabbits, when the atmospheric concentration is 2000 ppm, that measured in the trachea is no more than 100 ppm.

Finally, respiratory absorption of ammonia is considered very low and is never responsible for hyperammonaemia. The absorbed ammonium ions are converted into urea and used for synthesis of amino acids.

Acute exposure to ammonia gas in humans immediately causes irritation to ocular mucous membranes and the upper respiratory tract. At higher concentrations, a tracheobronchial irritation is observed, with cough, bronchospasm and respiratory distress. Effects on the eyes include conjunctival hyperaemia, watery eyes, corneal ulceration, iritis, cataract and glaucoma. Finally, chemical burns to uncovered skin parts are possible. Respiratory (bronchial stenosis, bronchiolitis obliterans, bronchiectasis, pulmonary fibrosis) and ocular sequelae (corneal opacities, cataracts, glaucoma) are possible.

Chronic exposure reduces the perception by smell. One study in workers exposed for an average of 16 years (without measurements of ammonia in ambient air) found a non-significant decrease in vital capacity and FEV1.

Health investigations

Some poison control centres reported difficulty in getting their ARSs to carry out measurements of ammonia in ambient air and the corresponding investigations. Of the three metrological analyses of ammonia conducted, on two occasions the investigation was conducted by an ARS or a local health and safety service (SCHS) and in the latter case, the analyses were carried out by a firm that sells the cellulose insulation.

Conclusions

This retrospective study reveals that the health investigations are insufficient, despite these being essential for an adequate analysis of the contributing factors and for assessing the risks. To rectify this, the ARSs must be informed about the need to actually carry out the metrological analyses, in order to optimise the partnership with the CAPTVs.

The moisture content of cellulose insulation seems to be a factor contributing to the release of ammonia, however the application of dry cellulose fibres promotes the spread of cellulose particles likely to cause respiratory diseases among workers. The chronic risks associated with cellulose fibres have been insufficiently documented. Mechanical ventilation seems to play a part in the diffusion of ammonia in the dwellings.
On the basis of the available data, pollution of dwellings by ammonia released from cellulose insulation treated with ammonium salts appears too low for long-lasting effects on the occupants' health to be expected as a result of brief exposure of a few weeks. However, it is enough to be very disagreeable, due to the indoor air concentrations being well above the recommended TRVs for protecting public health in the event of long-term exposure.
The individuals concerned can therefore be reassured, but the removal of the ammonia-releasing insulation materials is to be advocated and replacing ammonium salts as fire retardant in cellulose insulation has already been recommended.

Annex: Causality Calculation Method V 7.2 (French Toxicant Monitoring Coordination Committee, April 2013)

Causality in toxicant monitoring is a probabilistic scalar indicator of the strength of the link between exposure to a xenobiotic and the appearance of a symptom, syndrome or disease. The indicator has 6 conditions and 5 levels, and the following can be distinguished:
- Causality very likely **[I_4]**
- Causality likely **[I_3]**
- Causality possible **[I_2]**
- Causality not excluded **[I_1]**
- Causality zero **[I_0]**
- Causality inapplicable **[Ii]**

This assessment is only made once progression has stabilised and all the information contributing to qualification of the various factors is known.
There are six determinants (or criteria) that contribute to causality:
Exposure: It must be possible **[E_1]** or very likely **[E_2]**, i.e. perhaps found without metrological or analytical certainty. Causality is zero if it does not exist **[E_0]**.
Symptomatology: It must be present **[S_1]** and specified. If this is not the case **[S_0]**, causality is inapplicable. It concerns both clinical and paraclinical effects.
Chronology: The timing of the onset of symptoms in relation to exposure is determined on a scale of three. It can be evocative **[C_2]**, possible **[C_1]** or inconsistent **[C_0]**.
The presence of objective factors for causal characterisation: The causal link is reinforced by objective factors: reliable tests, assays of xenobiotics consistent with the observed picture, etc. It is measured on a scale of three: presence of convincing evidence **[L_2],** absence of convincing evidence **[L_1]** or the presence of contrary evidence **[L_0]**.
The existence of other diagnostic hypotheses (differential diagnosis): The presence or absence of another diagnostic hypothesis leading to the picture being considered must be taken into account and affects the strength of the causal link, etc. It is measured on a scale of three: no other hypothesis can be accepted **[D_2],** there is no convincing evidence of another diagnostic hypothesis or other unformulated hypothesis **[D_1],** or another diagnostic hypothesis is confirmed [**D_0**].
Extrinsic link: This is estimated based on data from the literature (bibliography). This link is measured on a scale of three: likely link **[B_2]**, possible link **[B_1],** never described **[B0].**

Detailed definitions of the conditions for the determinants:
Exposure [E]

Very likely	**[E_2]**	Exposure found, perhaps without analytical/metrology certainty.

Possible	**[E_1]**	Exposure is possible, but there is nothing to formally certify it
Excluded	**[E_0]**	There is objective evidence to exclude any possibility of exposure (tablet ultimately found, etc.)

Symptomatology [S]

Present	**[S_1]**	Clinical or paraclinical symptom/syndrome observed or alleged.
Absent	**[S0]**	No symptoms were observed or alleged. The causality of an absence of symptoms (probability of observing nothing) has not been considered in this version of the method.

Chronology [C]

Evocative	**[C_2]**	*Direct chronological relationship: Exposure – Symptoms – …* *i.e.:* Reproduction of effects after re-exposure **OR** Illness occurring during exposure or within an interval that does not exceed the expected peak plasma
Consistent	**[C_1]**	Onset of symptoms after cessation of exposure but at a distance in a way that is consistent with the nature of the effects **OR** Persistence of symptoms without modulation despite the rhythmic nature of exposure **OR** Persistence of symptoms after the end of exposure
Inconsistent	**[C_0]**	Onset of symptoms before the start of exposure **OR** Symptoms occurring too early or too late, given the nature of the effects and their mechanism (when it is known)

Objective factors for causal characterisation [L]

Presence of convincing evidence	**[L_2]**	Positive specific diagnostic or therapeutic test: for example, positive lymphoblast transformation test for suspected berylliosis **OR** Concentrations of the toxin or its metabolites in biological fluids or tissues at levels for which similar effects to those observed have been reported **OR** Convincing environmental metrology data (atmosphere or surface, for example) associated with the exposure **OR** Convincing situation with reference to an available occupation-exposure matrix **OR** If the effect is local, evocative topology
Absence of convincing evidence	**[L_1]**	No specific diagnostic test **OR** Specific diagnostic test not performed **OR** Concentrations of the toxin or its metabolites in biological fluids or tissues not measured or that cannot be interpreted (no reference value)

Presence of contrary evidence	**[L_0]**	NEGATIVE sensitive specific diagnostic test **OR** Concentrations of the toxin or its metabolites in biological fluids or tissues at levels inconsistent with the observed effects

Other diagnostic hypotheses (differential diagnosis) [D]

Exclusion	**[D_2]**	Other diagnostic hypotheses have been studied and rejected
Absence	**[D_1]**	No formal confirmation of another diagnostic hypothesis **OR** Other hypotheses not mentioned
Confirmation	**[D_0]**	Another diagnostic hypothesis has been accepted

Extrinsic link [B]

Likely link	**[B_2]**	Sufficient clinical or epidemiological evidence in humans **OR** (Sufficient evidence in animals **AND** limited evidence in humans)
Possible link	**[B_1]**	Limited clinical or epidemiological evidence in humans **OR** Sufficient evidence in animals
Never described	**[B_0]**	Picture not yet mentioned in the literature

A causality calculator is available from http://tv.toxalert.fr

Annex 4: Exposure to volatile products from cellulose insulation: a prospective study of exposure cases recorded between 1 January and 5 July 2013.

National network of poison control and monitoring centres (CAPTVs). Report in response to the solicited request from the Directorate General for Health. September 2013.

Materials and methods

Data sources and collection:
The cases were identified from dossiers reported to the CAPTVs between 1 January and 5 July 2013, meeting the following environmental and medical criteria:
- suspected exposure to volatile products in an enclosed space (housing, public establishment, workplace);
- combined with recent insulation work using cellulose insulation carried out a few days or weeks before the complaints and in any case after November 2011;
- possible confirmation of detection or quantification of ammonia from measurements of indoor air;
AND
- complaints punctuated by exposure to the air in these places and especially perception of an odour;
- olfactory discomfort mainly from an ammonia odour;
- irritative syndrome: nasal, ocular, pharyngeal, of the upper airways or respiratory tract (persistent cough).

The environmental circumstances relating to the buildings and the number of people exposed (cases) were to be completed by the relevant ARS Territorial Directorate.
The clinical manifestations in the reported cases were completed by the CAPTVs.
Individual medical records were established for each patient and the information was recorded in the CAPTV information system (SICAP), in a folder created by the CAPTV during the initial call. These guide sheets and the SICAP medical records were then sent to the CAPTV Bordeaux, which was in charge of collating all the national dossiers. The guide sheets were destroyed after the data had been recorded in the SICAP folder.

Data analysis:
Data analysis was based on all the SICAP folders and guide sheets received between 1 January and 5 July 2013.
Severity was analysed according to the Poisoning Severity Score[48].
Causality for the cases was assessed for the agent/symptom combination according to Version 7.2 of the method for calculating causality in toxicant monitoring (see end of previous annex). For dossiers involving multiple exposed individuals within a single household, causality was assessed for the most symptomatic patient. In all cases, the most severe symptom was used.

Results:
Articles and products concerned
Since December 2012, 12 'article' type agents based on cellulose insulation treated with ammonium salts have been created in the BNPC.

[48] Persson HE, Sjöberg GK, Haines JA, Pronczuk de Garbino J. Poisoning Severity Score. Grading of acute poisoning. Clinical Toxicology 1998: 36 (3): 205-13.

BNPC agent name	Number of dossiers concerned in the investigation
X1	3 dossiers, 7 exposed individuals
X2	1 dossier, 2 exposed individuals
X3	
X4	
X5	1 dossier, 2 exposed individuals
X6	
X7	1 dossier, 6 exposed individuals
X8	1 dossier, 1 exposed individual
X9	
X10	
X11	
X12	
---	---
UNKNOWN	4 dossiers, 14 exposed individuals
---	---
Names of agents not in the BNCP mentioned in observations	
X13	2 dossiers, 8 exposed individuals
X14	1 dossier, 3 exposed individuals

For four dossiers, it was not possible to establish the exact name of the cellulose insulation in question, including one which may have involved a mixture of several products. For three dossiers, the cellulose insulation was identified but had not yet been registered in the BNPC. Documentation and creation of the agent are under way.

<u>Number of cases of domestic exposure and trend</u>
Fifteen (15) exposure situations were recorded by the CAPTVs during the study period.
One (1) dossier was excluded because the cellulose insulation had been laid in September 2010, which was before the cellulose insulation containing ammonium salts had been placed on the market.
Ultimately, 14 dossiers on exposure to fumes from cellulose insulation were selected.

Exposed individuals:
The 14 dossiers concerned 43 people.
The exposed people were 19 children (aged from 10 months to 12 years for those whose age was known) and 24 adults (aged from 30 to 64 years for those whose age was known); precise age was known for only 26 patients.
Sex was known for 34 patients: 18 women and 16 men.

Date of occurrence:
All the dossiers resulting from the call cover the period from 1 January to 30 June 2013 (period defined in response to the request from the DGS).

Time distribution of reports during the first half of 2013:

Month	01	02	03	04	05	06
Dossiers	1	3	3	2	1	4
Exposed individuals	1	14	8	5	4	11

For three dossiers, the cases were reported on respectively 3 and 5 July 2013. These dossiers have been included in the prospective study (added to the dossiers from June) because of the detailed information available for these cases and in order to increase the robustness of the study.
The investigation was therefore conducted for cases reported to the CAPTVs between 1 January and 5 July 2013.

Level of exposure and environmental investigations conducted
Of the 43 exposed individuals, 41 were subject to daily exposure because they lived in houses in which insulation work had been carried out. For the other two patients, exposure was lower because it concerned a house under construction.

Only four dossiers documented measurements of atmospheric ammonia concentrations, taken from the indoor air of the dwellings. The measurement results are as follows:
- Dwelling 1: 0.7 ppm (0.5 mg/m^3) (private laboratory investigation);
- Dwelling 2: <0.25 ppm (0.178 mg/m^3) (ARS investigation);
- Dwelling 3: 0.06 to 0.22 ppm (0.042 to 0.157 mg/m^3) (private laboratory investigation);
- Dwelling 4: no ammonia detected (ARS investigation).

The environmental investigations also revealed the presence of mechanical ventilation (MV) for four dossiers (negative pressure in the dwelling). For three dossiers, there was no MV in the dwelling. For seven dossiers, the investigation reports submitted did not specify whether or not there was MV. Moreover, it was not possible to establish the exact nature of the MV in the dwellings of the exposed subjects (i.e. controlled or forced-air).
A new set of measurements should be taken soon in one of the dwellings.

Nature of the symptoms
In all the dossiers, one or more of the exposed subjects smelled an odour, and for some of them a smell characteristic of ammonia gas was mentioned ("urine", "cat urine").
In total, 21 of the 43 exposed people were asymptomatic. The remaining 22 presented one or more symptoms corresponding to an irritative syndrome of the mucous membranes of the upper airways (ENT) or bronchi.

Symptoms	Number of patients	Remarks
Cough	9	1 patient hospitalised
Bronchospasm	1 asthma decompensation (hospitalisation)	
Other respiratory signs		3 (difficulty breathing)
Nasal irritation	13	
Irritation of the pharynx	13	
Irritation of the eyes	19	

Other	2 (nausea), 8 (headache)	

Two patients were hospitalised in connection with one of the symptoms shown in the previous table.
- A 64-year old man carried out work in his house, laying a known brand of cellulose insulation (09/2012). Four weeks later, he noticed a smell that persisted even after the carpets were cleaned. He also complained about the appearance of various symptoms: ENT irritation, sinusitis and respiratory distress requiring emergency hospitalisation for 24 hours on two occasions (in April and June 2013). The radiological and clinical assessment (chest scan and lung X-ray) failed to identify any cause. The patient was known to be a smoker, and stopped in April 2013 because of the symptoms. Due to the persistence of the disorders, an allergy assessment was requested: a link with the work in his house was then suspected by the allergist. Note that the subject's wife was also affected but her symptoms were very mild, limited to a simple ENT irritation. The patient was aware of the first CCTV report (cf annex 2, retrospective study) and contacted the ARS in order that an environmental investigation is carried out. Measurements of indoor air were taken but the results are not yet known. New measurements should be taken. The cellulose insulation is still in place but the patient has since left his home.
- A six-year-old child, a known asthmatic. The child developed asthma decompensation in the 3 months after moving into a new home, whereas this asthma had previously been stabilised. The child was hospitalised for one month in a specialised centre; it seems that the symptoms disappeared when the child was away from the house for several days. Corrective measures have been implemented in the dwelling. The pneumologic assessment conducted after these works showed an improvement in the forced expiratory volume in one second (FEV1) correlated with the disappearance of the ammonia smell. It should be noted that this assessment was conducted at the end of the summer when humidity levels that might promote the offgassing of ammonia gas are lower.

Duration of symptoms
Symptoms were related to exposure in most cases, and were resolved as soon as the room was aired, or the exposed people went outside. Some patients are still currently exposed.

Severity
The clinical symptoms of the 43 exposed subjects were reviewed: severity was assessed as zero for 21 asymptomatic patients, low for two subjects and moderate for two.

Causality
Causality for each dossier was assessed using Version 7.2 of the method for calculating causality from April 2013 (see end of previous annex); causality could not be calculated for two dossiers because the exposed subjects exhibited no symptoms. Causality was assessed as "Possible" in one dossier, "Likely" in nine dossiers and "Very Likely" in two.

Summary of symptomatic cases:

French department / county	**Case summary**	**Severity**	**Causality**
37	Wadding (known brand) laid in the attic; appearance of an odour three days later; ENT irritation in one of the family members who is permanently at home; no measures taken; replacement of wadding requested,	4 exposed subjects 1: PSS1 3: PSS0	E1S1C2 L1D1B2 Likely

French department / county	**Case summary**	**Severity**	**Causality**
	done?		
72	Wadding laid in May 2012 (precise nature unknown); intermittent unpleasant smell; no other symptoms; no air measurements; no corrective measures taken for the wadding. Interference with a recent smell of water-based paint. The annoyance has disappeared since the summer and with the paint being covered over.	4 exposed subjects: 4:PSS0	E1S1C1 L1D1B2 Possible
33	Patient moved into a new apartment in November 2012, while the insulation (known brand of wadding) was laid in mid-September; unbearable smell immediately obliging the subject to stay elsewhere for 1 month; on her return the odour persisted and the patient experienced ENT irritation, nausea and headaches. Air measurements were taken on 20 February 2013: NH3 at 0.7 ppm; installation of a CMV system as a corrective measure. OK since.	1 exposed subject: 1: PSS1	E2S1C2 L2D1B2 Very likely
33	The patient carried out work in a new house intended for rent: wadding (known brand) was laid by a company in mid-September 2012; rainy weather; smell quickly became unbearable, the patient (as well as one worker) had difficulty breathing, eye and throat irritation and cough as soon as he entered the house, no measurements taken; the wadding was removed by the company three weeks later.	2 exposed subjects 2: PSS1	E2S1C2 L1D1B2 Likely
59	Wadding (known brand) laid in October 2012 and since then the couple have smelled an unpleasant odour and experienced nasal and eye irritation. Air measurements carried out <0.25 ppm. Corrective measures?	2 exposed subjects 2: PSS1	E2S1C2 L1D1B2 Likely
76	Wadding (known brand) laid in September 2012 in the dwelling house; 4 weeks later, rainy weather, an odour appeared along with eye and nasal irritation and an incessant cough; emergency hospitalisation necessary on two occasions; measurements taken but are they "unusable"? The wadding was to be removed and replaced with wadding treated with a boron-salt flame retardant, but the patient refused; expert assessment under way; new air measurements will be taken in September.	2 exposed subjects 1: PSS2 1: PSS1	E2S1C2 L1D2B2 Very likely
69	Wadding (known brand) laid in December 2012; following water damage in late December, appearance of an unpleasant odour; ENT irritation with cough in the whole family; no air measurements taken; wadding removed.	6 exposed subjects: 3: PSS1 3: PSS0	E2S1C2 L1D1B2 Likely

French department / county	**Case summary**	**Severity**	**Causality**
74	Wadding (known brand) laid in spring 2012; doubt about the date of purchase (maybe 2010?); unpleasant odour with the appearance in May of ENT irritation for the two parents; children asymptomatic; no air measurements performed. No corrective action; the patients have been better since the ambient humidity	4 exposed subjects: 2: PSS1 2: PSS0	E2S1C2 L1D1B2 Likely

Exposure cases identified by the RNV3P

The National Network for Monitoring and Prevention of Occupational Diseases (RNV3P) is a French network for surveillance and prevention in occupational health which, since 2001, has brought together the 32 occupational disease clinics (CCPP) in mainland France and a sample of the occupational health services (SST) associated with the network. The network's mission is to gather data from each consultation in a permanent national database on occupational diseases (patient demographics, diseases, exposure, industry sector, occupation). The network's experts then investigate the diseases and establish the connection, if any, with the occupational origin.
Data entry is performed within the CCPPs and the data are stored in local databases. After being anonymised, these local data are exported annually for centralising in the national database. The local CCPP bases from year N are centralised in March-April of year N+1. The 2001-2012 national database is currently being created. As the substitution of boron salts by ammonium salts dates from February 2012, querying the 2001-2011 national database would not provide any relevant information.

Materials and methods

To find the consultations that took place in 2012-2013 on potential exposure to cellulose insulation, the occupational disease clinics and inter-company services of the RNV3P were approached directly via the network's mailing list. They were asked to trace cases potentially related to the installation of these insulation materials.
Only the CCPP Nancy carried out consultations with workers exposed to this cellulose insulation containing ammonium salts. The patients came for consultations between late January and early February 2013.

Results

Five patients from the same plumbing company were sent by their occupational physician to the CCPP Nancy. These five workers had been on the construction site for a new building (47 homes) to install bathroom and toilet facilities on the site after it had just been flooded (storms). Cellulose insulation (known brand) had just been laid in the dwellings, but not covered in some apartments. It seems that there were other complaints from construction workers (linked to the smell of ammonia) following this flooding, but no-one apart from these five sought medical advice. Of the five patients who consulted a physician:

- Patient 1: was very slightly exposed and showed signs of low-intensity ENT irritation,
- Patient 2: showed symptoms resembling de novo asthma during exposure. This patient had no history of asthma, including in childhood, nor inherited predisposition. The consulting physician assumes that the symptoms were exacerbated after exposure to the release of ammonia,
- Patient 3: showed symptoms of ENT and respiratory irritation, with possible asthma symptoms not clinically confirmed,
- Patient 4: showed symptoms of ENT and respiratory irritation,
- Patient 5: presented some clinical signs of irritation.

Follow-up visits were scheduled for these patients:

- Patient 1: remained exposed for about 2 months (duration of the works), no further progression of symptoms,
- Patient 2: asthma worsened after exposure decreased, requiring medical attention. A challenge test with the cellulose insulation was negative,
- Patient 3: the symptoms of ENT and respiratory irritation disappeared in a few weeks,
- Patient 4: did not participate in follow-up visits,
- Patient 5: the symptoms disappeared quickly.

Discussion

A toxicological review of ammonia was developed in the report resulting from the retrospective study and will not therefore be detailed here.
This prospective study, which followed the retrospective study, describes the cases of exposure, suspected or proven, to cellulose insulation containing ammonium salt flame retardants. This cellulose insulation was laid by the householders themselves or by specialised companies, blown or sprayed (flocking) into attics or walls.
Only 14 dossiers on exposure to fumes from this cellulose insulation were identified by the CAPTVs during the first half of 2013, despite the very many homes that have most likely been fitted with this new cellulose insulation containing ammonium salts since July 2012.
However, numerous complaints about this new cellulose insulation have been brought to the attention of the cellulose insulation manufacturers (115 cases by the end of 2012) and consistent information has also been circulating on Internet social forums. It can be assumed that for some exposure or olfactory discomfort, complaints were brought to the attention of the installer without informing the CAPTVs.

It is also conceivable that fumes in the uninhabited parts of dwellings fitted with this new cellulose insulation were unable to reach the adjacent dwellings.
It should be noted that in several dossiers identified in this series, the role of controlled mechanical ventilation (CMV) or forced-air mechanical ventilation (FAMV) was mentioned. In the original dossier that led to the national alert, the health technician who carried out the investigation had indeed found that the cellulose insulation was in direct contact with the MV motor in the attic. The presence of MV could facilitate the diffusion of gases including ammonia inside the dwellings. However, in our study, there were cases of symptomatic exposure in which the dwelling was not equipped with MV.
Ambient humidity seems to be a contributing factor although it has not been possible to confirm this: in several dossiers, rainy weather was reported at the time the smell appeared; in one dossier, the smell was concurrent with water damage. In another, the smell appeared after the cellulose insulation became soaked following a fluid leak.

Finally, in one dossier, it was reported that the occupant of the house used bleach extensively without airing the house. Bleach vapours react chemically with ammonia to release chloramine that is also highly irritating, and perhaps contributed further to the appearance of symptoms.
The hypothesis of a pathology induced directly by volatilised cellulose fibres in the ambient air can be excluded because the cases occurred concurrently with the use of flame retardants containing ammonium salts, and mucosal or respiratory conditions related to cellulose particles are rare.
In this study, from a clinical perspective, the symptoms reported among the exposed subjects are similar to those that had been noted during the retrospective study, essentially involving discomfort related to the smell in all cases, and ENT and eye irritation in the vast majority of cases. However, two cases of moderate severity were identified, that required hospitalisation:

-In one of the two cases, the patient was a 6-year-old child, an asthmatic, who experienced asthma decompensation after moving into the new dwelling. Measurements of indoor air were carried out by a private company funded by the lessor. The exact nature of the cellulose insulation is not known; there is a doubt about the single-agent nature of the exposure, as the occupants kept a sample of the cellulose insulation that shows two types of material of different colour. The telephone survey conducted by the relevant CAPTV was unable to find out more. The symptoms still persist in the child; the damp insulation was partially removed (this insulation had been dampened by a leak from the roof) along with a piece of soaked plasterboard. An improvement in lung function test results was noted after the partial withdrawal of the cellulose insulation, but this test was conducted in late summer, during the "dry" period; if other factors such as mould, for example, contribute to the clinical picture, they are not present at this time either. It would seem preferable to await the arrival of the rainy season in order to assess whether the partial corrective measures are sufficient. In this type of dossier, it would be very useful to know the exact nature of the cellulose insulation in question. Measurements of indoor air were taken but not during any wet period, thus yielding low results that contribute very little. Moreover, insofar as the cellulose insulation was only partially removed, a second series of measurements could be recommended, once the humidity returns, and/or if the patients complain again.

-The other case involved a 64-year-old man without any previous history other than smoking, who developed a persistent cough with difficulty breathing that sometimes progressed, justifying emergency hospitalisation on two occasions. Nevertheless the lung function tests performed were shown to be normal, and asthma was not diagnosed during these hospital assessments. Symptoms persisted even after the subject stopped smoking permanently. Nevertheless, the patient got better when he left his home and the symptoms

This study was unable to reach a conclusion insofar as the exposure levels could not be assessed from indoor air measurements in most dossiers. Although the ARSs were informed of the need for such measurements, many of them did not have the equipment to obtain them. The need to call on private laboratories and the absence of associated funding therefore meant that they were not done. In other cases, the ARSs did not obtain measurements due to a lack of information about the laboratories able to carry them out. Finally, in at least two cases, the measurements contributed little, as they were taken during a period unsuitable for the study, when the weather had been dry for several days or even weeks so that there was no longer any smell in the dwellings. These measurements were negative. In one of the homes, the measurements should be redone during rainy weather.

Concerning occupational exposure, one patient without any history of asthma presented an asthmatic condition. Challenge tests with the cellulose insulation were negative. This patient's asthma worsened after exposure and required follow-up treatment. No further information could be obtained on any of the reported cases.
Moreover, insofar as the manufacturers had been informed of the problems related to this new cellulose insulation, they sometimes went ahead and replaced it, even before the technicians who could have conducted the measurements could be mobilized, thus precluding any procedures that the ARSs could have undertaken.

Finally, for the corrective measures, there were two types of replacement: replacement of the entire insulation (five dossiers) or partial replacement of the insulation assumed to be the cause due to moisture (three dossiers). Partial replacement does not remove the risk of exposure recurring, since the remainder of the insulation could again cause a release of ammonia. To our knowledge, the period during which the insulation could potentially release ammonia has not been established. In three dossiers, no corrective measures were considered. In one dossier, mechanical ventilation was installed.

In every case where corrective measures have been undertaken to date (during the "dry" period), the clinical signs have disappeared.

In addition, there is also a question about the materials in contact with this insulation: in at least two cases, the patients reported that the plaster in contact with this insulation was impregnated, with a ring appearing. In the corrective measures, it may also be necessary to replace the impregnated plaster, or if it is not removed, to take further air measurements to ensure that this plaster does not itself release ammonia due to it having been soaked.
Corrective measures were taken in nine dossiers; nevertheless, replacing the insulation raises the question of the nature and toxicity of the replacement products. In addition, there are few human data on the toxicity of cellulose fibres. Occupational exposure can induce effects on the eyes and mucous membranes of the airways. It would therefore be worthwhile conducting a risk assessment for these fibres. One patient refused to have the insulation replaced by insulation containing boron salts, given his knowledge of the reasons that led to its withdrawal. There is therefore a fundamental problem with the nature of the insulation products to be used, to which patients and especially professionals are exposed for many years.

Finally, besides the safety of using this insulation, it may be necessary to reconsider the flame-retardant effectiveness of cellulose insulation treated with ammonium salts if a part of the flame retardant has been released into the air.

Conclusion:
Only 14 dossiers on exposure to fumes from cellulose insulation were brought to the attention of the CAPTVs over the period studied, unevenly spread across the country. Ammonia was demonstrated at low concentrations in the air in few cases. Such concentrations correspond to a minimal level of health risk.
Without being able to formally establish this, moisture level seems to play a part in this offgassing. The conclusions of this prospective study reveal insufficient environmental investigations, related to a lack of measurements of ammonia in the air of suspect premises, or related to a lack of relevance of the measurements taken (performed too late, or not during wet periods). In this type of exposure, it is essential to perform the measurements very quickly, at the time of exposure. Furthermore, in some cases, there is the problem of precise knowledge about the cellulose insulation actually installed, which may sometimes even be a mixture of several types of insulation.
Nevertheless, corrective measures involving complete removal of the wadding were implemented in five cases, and partial measures with partial removal of the wadding in three other cases, which could lead to new episodes of offgassing from the insulation that was not removed.
The role of plasterboard or other materials in direct contact with the insulation and their replacement has not been mentioned, despite some boards bearing traces of liquid impregnation.
Finally, there is the question of replacement of this insulation containing ammonium salts by other insulation materials whose toxicity needs to be assessed.

Annex 5: Model of questionnaire provided to Member States Competent Authorities

QUESTIONNAIRE
AMMONIUM SALTS USED IN CELLULOSE INSULATION

Objective:
Collect information for a possible **Restriction proposal** according to **Art. 129** of REACH Regulation (Safeguard clause, **three-month process**).

Context:
The isolation with cellulose insulation represents a minority part of the French market for insulation, but its growth is exponential. Until End of 2011 the cellulose insulation was treated with boric acid / borates for biocidal and flame retardant properties. Ammonium salts were used as alternatives because of reprotoxicity classification (Repr. 1B) of boric acid / borates.

However, it was decided to ban adjuvanted cellulose with ammonium salts in France because these salts can lead, under certain conditions of temperature and humidity, to ammonia emissions - which is an irritant gas for mucous membranes and respiratory tract. Several cases of mucosal and airways irritation have been diagnosed and related to a recent installation of such insulating materials. More than one hundred complaints have been reported by the Union of manufacturers of cellulose insulation between February and November 2012.

Due to the high volatility of ammonia, it spreads preferentially in the attic rather than residential premises; however it is possible that ammonia enters the living. Furthermore, the ammonium salts are used for their flame retardant properties. The dissipation of ammonium may lead to a loss of efficiency and may increase the risk of fire.

Hence, following the **French decree of the 21st of June 2013** on the prohibition of import, sale, distribution and manufacture of **cellulose wadding insulation materials with ammonium salt adjuvants**, the French CA is about to prepare a restriction proposal.

In this context, we would greatly appreciate to receive information from other member states on this topic.

The questionnaire is structured as follows:

Section A	Contact details
Section B	National market of cellulose wadding insulation materials with ammonium salt adjuvants
Section C	Information on exposure / risk related to ammonia emissions
Section D	National regulation / ammonium salts alternatives

Section A: Contact details

Name:

Organisation Name:

Address:

Country:

Telephone number:

Fax number:

E-mail:

Section B: National market of cellulose wadding insulation materials with ammonium salt adjuvants

Question 1.	
Where known to you, could you kindly provide the following information:	
The number (or approximate number) of manufacturers of cellulose insulation in your country	
The number (or approximate number) of importers of cellulose insulation in your country	
The amount (or approximate amount) of cellulose insulation placed on the market	(please precise the unit)
The amount (or approximate amount) of ammonium salts used as an adjuvant of cellulose insulation	(please precise the unit)
The proportion (%) of cellulose insulation in your country that may ammonium salts? Please also indicate the basis of this percentage (guess, estimate or market data).	

Question 2
Where known to you, could you kindly provide price of ammonium salts per kg:

Question 3
Where known to you, could you kindly provide the names of relevant industry associations of cellulose insulation in your country:

Section C: Information on exposure / risk related to ammonia emissions

Question 4.
Have you any idea of consumer complaints related to ammonia emission (odour...)? **Do irritative / respiratory symptoms have been diagnosed, following consumer complaints?** ☐**Yes** ☐**No** **If yes, please specify:** **- The number and the description of the different types of complaints / symptoms observed** **- The duration of work stoppage /hospitalization (number of days, if severe cases)**

Question 5.
Are there some campaigns to measure ammonia levels in indoor airs in your country, following consumer complaints? ☐**Yes** ☐**No** **If yes, please specify below what is the results of these campaigns (including analytical methods used and unit of ammonia)**

Section D: National regulation / ammonium salts alternatives

Question 6.		
Is there currently a national legislation which bans, restricts or controls the production, import, use and/or marketing of cellulose wadding insulation materials with ammonium salt adjuvants? ☐**Yes. Please provide the relevant information below** ☐**No**		
Materials/Substances regulated	**Limit concentration of the substance (if relevant)**	**Legal reference**

Question 7.	
Are there currently non-regulatory actions aiming at banning, restricting or controlling the production, import, use and/or marketing of cellulose wadding insulation materials with ammonium salt adjuvants? ☐**Yes. Please provide the relevant information below** ☐**No**	
Materials/Substances considered	**Type of non-regulatory actions and actors involved (year)**

Question 8.
Do you have any information of alternatives used as flame retardant in cellulose wadding insulation materials (e.g. borates)? Advantages and drawbacks compared to ammonium salts? ☐**Yes. Please provide details below** ☐**No**
Efficacity *Price...*

Question 9.
Are there substitution measures currently under development but not yet on the market?

Advantages and drawbacks compared to ammonium salts? ☐**Yes. Please provide details below** ☐**No**
Method of impregnation of cellulose wadding insulation materials *Efficacity* *Price...*

Question 10.
Do you have any information on alternatives of cellulose wadding (hemp / excelsior insulation materials)? **Advantages and drawbacks compared to cellulose wadding?** **Which adjuvant is employed (ammonium salts?)**
Please specifiy: *Method of impregnation* *Efficacity* *Price...*

***

Please also indicate below other relevant national bodies (and their contact information) which could assist us in this study:

Feel free to add any comments on issues raised by this questionnaire in the space below:

We thank you very much for participating to this study

Please return your completed questionnaire by <u>September 20th 2013</u> to:

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If you need additional time to complete the questionnaire, please let us know as soon as possible.