Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Formaldehyde and formaldehyde releasers

ECHA/RAC/RES-O-0000006740-76-01/F

ECHA/SEAC/[SEAC opinion number]

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 13 March 2020) and SEAC's opinion (adopted [Date])

Draft date: 13 March 2020

13 March 2020

ECHA/RAC/RES-O-0000006740-76-01/F

12 March 2020

ECHA/SEAC/[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Formaldehyde and formaldehyde releasers**
EC No.:	**-**
CAS No.:	**-**

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/restrictions-under-consideration on **20 March 2019**. Interested parties were invited to submit comments and contributions by **20 September 2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Agnes SCHULTE

Co-rapporteur, appointed by RAC: Ruth MOELLER

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **13 March 2020**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Luisa CAVALIERI

Co-rapporteur, appointed by SEAC: Klaus URBAN

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **12 March 2020**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22919/term on **25 March 2020**. Interested parties were invited to submit comments on the draft opinion by **25 May 2020**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and] 71(1) of the REACH Regulation.] [No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and] 71(1)].

The opinion of SEAC was adopted **by [consensus.][a simple majority]** of all members having the right to vote.] [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]

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OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Formaldehyde EC No 200-001-8 CAS No 50-00-0	1. Articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture, shall not be placed on the market if the formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X. Road vehicles and aeroplanes produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 as measured in accordance with the conditions specified in Appendix X. 2. Paragraph 1 shall apply 12 months from the entry into force of the restriction. 3. By way of derogation, paragraph 1 shall not apply to articles that are only for outdoor use under reasonably foreseeable conditions. 4. By way of derogation, paragraph 1 shall not apply to articles exclusively for industrial and professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use. 5. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2018/1513. 6. By way of derogation, paragraph 1 shall not apply to the use of formaldehyde and formaldehyde releasers as biocide subject to Regulation (EU) 528/2012. 7. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2017/745. 8. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2016/425. 9. By way of derogation, paragraph 1 shall not apply to articles subject to Regulation (EU) 2011/10. 10. By way of derogation, paragraph 1 shall not apply to articles subject to Directive 2009/48/EC. 11. By way of derogation, paragraph 1 shall not apply to second-hand articles.

THE OPINION OF RAC

See RAC opinion.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on **formaldehyde and formaldehyde releasers** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs as demonstrated in the justification supporting this opinion.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Summary of proposal:

The Dossier Submitter's proposal is to restrict the placing on the market of articles intended for indoor use that release formaldehyde under reasonably foreseeable conditions resulting in consumer exposure. The restriction establishes a maximum emission limit value for articles of 0.124 mg/m^3 in a test chamber (as measured in accordance with the conditions specified in Appendix X to the restriction proposal). Articles that are exclusively used in outdoor environments are not intended to be included within the scope of the proposal. The proposal is intended to cover articles where formaldehyde or formaldehyde releasing substances (also termed formaldehyde releasers) are used in their production (either as such or in mixtures) and where formaldehyde releases occur during use as a result of either the "off-gassing" of residual formaldehyde or from the degradation and chemical reactions of other substances used in the production. The proposal is not intended to cover articles produced without using formaldehyde or formaldehyde releasing substances. In such articles formaldehyde is either not released (because it is not present in the article, e.g. glass articles) or it can be only released by the decomposition of substances naturally present in the materials used to produce the article (e.g. lignin degradation in solid wood) or as a result of combustion.

As well as in the interiors of buildings, the proposal aims also to reduce consumer exposure to formaldehyde in the interiors of vehicles (road, rail, air and water vehicles). In the specific case of road vehicles (e.g. cars, trucks, vans, buses and motor-homes) and aeroplanes the proposal is intended to restrict the placing on the market of articles where the interior concentration of formaldehyde exceeds 0.1 mg/m^3 under reasonably foreseeable conditions of use. For articles used in rail and water vehicles, the same requirements as for other articles apply as the interior can be reasonably assumed to be similar to living environment in homes and building apartments.

Articles subject to the existing restriction on CMR substances in clothing and footwear (entry 72 of Annex XVII of REACH) , articles subject to Regulation (EU) 2017/745 on medical devices, articles subject to Regulation (EU) 2016/425 on personal protective equipment (PPE), articles subject to Regulation 2011/10 on food contact materials, articles subject to Directive 2009/48/ EC on toy safety, articles exclusively for industrial and professional use, second-hand articles as well as the use of formaldehyde and formaldehyde releasers as a biocide are intended to be exempted from the proposed restriction.

The restriction proposal considers the risks to human health of exposure to formaldehyde from articles regardless of its original source. Thus, both formaldehyde and formaldehyde releasers are within the scope of the proposal and considered together.

Regarding articles used in construction (e.g. wood-based panels, laminate flooring, wallpapers), the Dossier Submitter notes that, although formaldehyde emissions from these articles affect the general population, they are mostly used by workers and professionals operating in the construction sector. In order to protect consumers from risks related to formaldehyde exposure, the Dossier Submitter considers limiting formaldehyde emissions from these articles at the time when they are placed on the market. For this reason, the restriction proposal is not limited to articles intended for consumer use but relates more broadly to articles through which consumers can become exposed to formaldehyde.

The Dossier Submitter has concluded that formaldehyde release from the consumer use of mixtures for non-biocidal use is adequately controlled and the use of formaldehyde in mixtures for consumer use in concentration ≥ 0.1% is prohibited according to Commission Regulation (EU) 2018/675.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion:

See RAC opinion.

Description of the risk(s) addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

Formaldehyde is a highly reactive, acutely toxic substance leading to skin and respiratory tract irritation and corrosion, skin sensitisation, genotoxicity (such as DNA-protein cross links and DNA adducts) and carcinogenicity. Nasal tumours were observed mainly in rats and mice following inhalation exposure of 6 ppm (7.4 mg/m^3) formaldehyde and higher.

Even if formaldehyde is a genotoxic carcinogen, SCOEL (2016) considered that a mode-of-action based limit value can be derived. SCOEL considers that tumour induction in the nasal mucosa of rats and mice is the result of chronic proliferative processes caused by the cytotoxic effects of the substance in combination with DNA alterations by endogenous and exogenous formaldehyde.

The most sensitive effect of formaldehyde in humans is sensory irritation. Those effects were the basis for the OEL of 0.3 ppm (0.369 mg/m^3) for workers proposed by SCOEL (2016) and for the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m^3 (WHO, 2010).

It is the Dossier Submitter's opinion that the inhalation cancer risks opposed by formaldehyde in the air at the OEL for workers of 0.3 ppm (0.369 mg/m^3) as recommended by SCOEL and at the WHO Guideline for Indoor Air Quality for formaldehyde of 0.1 mg/m^3 (0.08 ppm) can be considered negligible. Risks associated with consumer exposure to formaldehyde from inhalation are therefore assessed against the WHO guideline value of 0.1 mg/m^3.

Other risks from formaldehyde have been considered but the Dossier Submitter has concluded that the risks from inhalation of formaldehyde are the most significant.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Information on emissions and exposures

Summary of proposal:

Formaldehyde is a high-production volume chemical predominantly used as a chemical intermediate for the synthesis of formaldehyde-based resins and other chemicals. Formaldehyde-based resins are widely used in the production of articles which, as a result,

may release formaldehyde during use. The primary use of formaldehyde-based resins is in the manufacturing of wood-based panels, where they act as a bonding agent for wood particles. Such resins are also used in the production of other wood-based products (e.g. furniture and flooring) and for wallpapers, foams, parts for vehicles and aeroplanes, textile and leather products etc.

The Dossier Submitter considers formaldehyde released from articles into indoor air as the primary route for consumer exposure. The exposure assessment therefore focuses on inhalation exposure from articles and consists of three elements:

1. Based on a literature review, relevant formaldehyde emission sources in indoor air have been identified, including solid wood, wood-based panels, furniture, wallcoverings, paints, mineral wool, foams, and textiles (curtains and carpets). The Dossier Submitter concludes that wood-based panels (or rather urea formaldehyde resins used in these panels) and other wood-based articles made from such panels (e.g. furniture) are the main (permanent) formaldehyde emission sources in indoor air. Temporary emission sources, including various combustion sources (e.g. wood burning, smoking, candle burning, cooking, ethanol fireplaces), have also been identified as having the potential to lead to high formaldehyde concentrations in indoor environments. Temporary combustion sources are however outside the scope of the proposed restriction.

2. On the basis of a review of the literature on measured formaldehyde concentrations in indoor air in the EU, the Dossier Submitter concludes that formaldehyde levels do not exceed the WHO Guideline for Indoor Air for formaldehyde in the majority of cases.

3. Formaldehyde concentrations have been estimated for an exposure scenario (consisting of three sub-scenarios) that assumes the conservative case of newly built homes where wood-based panels are used as construction material and where other typical formaldehyde emitting sources, such as furniture made from wood-based material or textiles, are present. The assumption of newly built homes means that estimations are based on data derived from newly produced materials. Formaldehyde release is higher when materials are new and declines over time as formaldehyde is off-gassed. No decrease in formaldehyde emissions due to ageing of materials has been assumed by the Dossier Submitter in its estimations. Based on the results of the estimations, the Dossier Submitter concludes that the WHO guideline value could be exceeded under specific circumstances, such as the use of high emitting materials in large quantities.

Other exposure routes and sources, in particular dermal exposure and inhalation exposure from mixtures, have also been addressed but these were not further considered as the Dossier Submitter concluded that risks from inhalation of formaldehyde released from articles are the most significant.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Characterisation of risk(s)

Summary of proposal:

The conclusion of the Dossier Submitter's risk assessment is that human health risks from formaldehyde release from consumer articles are not adequately controlled in all scenarios.

Even though a review of the literature on measured formaldehyde concentrations in indoor air in the EU shows that formaldehyde levels do not exceed the WHO Guideline for Indoor Air for formaldehyde in the majority of cases, estimations by the Dossier Submitter suggest this guideline can be exceeded under certain circumstances (new homes, use of high emitting materials in large quantities).

With regard to formaldehyde release from mixtures for consumer use, the Dossier Submitter concludes that risks to human health seem adequately controlled. This conclusion is based on available literature information and the outcome of an exposure estimation using ConsExpo.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Uncertainties in the risk characterisation

See RAC opinion.

Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

European manufacturers of wood-based panels adopted a voluntary industry agreement in 2007 to produce only panels complying with the formaldehyde emission class E1 as defined in the harmonised European Standard EN 13986 and to no longer place higher formaldehyde emitting class E2 panels on the EU market. The E1 emission class sets a limit on the release of formaldehyde from wood-based panels at a concentration of 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in the European Standard EN 717-1. Wood-based panels with formaldehyde releases above 0.124 mg/m^3 fall into emission class E2. Voluntary agreements or commitments with respect to limiting formaldehyde emissions exist also in the European furniture and automotive industries.

Articles that are not compliant with the voluntary agreements can however still be placed on the EU market, due to non-compliant EU producers and/or extra-EU imports. For wood-based panels, the Dossier Submitter estimates that higher formaldehyde emitting class E2 panels account for about 6.5 % of all wood-based panels consumed in the EU in 2016. Such high formaldehyde emitting articles could potentially contribute to indoor air formaldehyde concentrations that exceed the WHO guideline value under specific circumstances.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

The Dossier Submitter identified a number of regulatory measures – both at the European and the national level – that aim at limiting formaldehyde emissions from articles in indoor environments:

- The Construction Products Regulation (EU) No 305/2011 (CPR) sets out harmonised rules for the marketing of construction products in the EU. The CPR requires a CE marking for construction products before they are placed on the internal market. Construction products for which a harmonised European standard exists must comply with the relevant standard to obtain the required CE marking. While the harmonised standard for wood-based panels (EN 13986) defines two formaldehyde emission classes – E1 and E2 – it does not restrict the placing on the market of higher formaldehyde emitting class E2 wood-based panels.

- Currently, eight Member States have adopted national legislation to limit formaldehyde emissions from wood-based panels. These legally binding emission limits generally correspond to the E1 emission class. However, despite these initiatives, to date no EU-wide harmonised regulation of formaldehyde emissions from articles exist. According to the Dossier Submitter, this results in different levels of risk reduction across the EU and the potential for consumer exposure to formaldehyde levels above the WHO guideline value persists in indoor environments under certain circumstances.

The Dossier Submitter also examined other possible Union-wide risk management options but concluded that these measures were assessed as inappropriate to address all of the sectors and products contributing to risk.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

JUSTIFICATION IF ACTION IS REQUIRED ON A UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter states that risks associated with articles that may release formaldehyde in indoor environments need to be addressed on a Union-wide basis because of the following factors:

- Exposure takes place in all Member States from articles produced in the EU as well as from imported articles manufactured with the addition of formaldehyde or formaldehyde releasing substances and these goods are free to move within the Union.

- A number of Member States have established legislation to prevent or reduce the risk associated with indoor consumer exposure to formaldehyde from articles (in particular wood-based products). However, to date no EU-wide harmonised regulation of formaldehyde emissions from articles exists.

- Voluntary agreements to self-restrict formaldehyde emissions are in place in major EU industry sectors. European manufacturers of wood-based panels adopted a voluntary industry agreement to produce only panels complying with the formaldehyde emission class E1 as defined in the harmonised European Standard EN 13986. The voluntary emission limit adopted by European manufacturers of wood-based panels is also supported by the European furniture industry. Non-compliant articles can however still be placed on the EU market, due to manufacturers that have not subscribed to such voluntary agreements and/or extra-EU imports. A voluntary agreement is also in place by the automotive industry to limit the formaldehyde concentration in the interior of road vehicles to a maximum of 0.1 mg/m^3.

- The risks of health issues for consumers exposed to formaldehyde released from articles in indoor environments are considered not adequately controlled EU-wide.

SEAC and RAC conclusion(s):

SEAC and RAC agree that the **health risks for consumers** exposed to formaldehyde released from articles should be controlled on an EU-wide basis.

Based on the key principles of ensuring a consistent level of protection of human health across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that risks associated with formaldehyde should be addressed in all Member States.

Key elements underpinning the SEAC and RAC conclusion(s):

SEAC

The potential for consumer exposure to formaldehyde levels above the WHO guideline value persists in indoor environments under certain circumstances.

In the absence of a legally binding EU-wide measure, voluntary agreements to self-restrict formaldehyde emissions from articles might not be able to prevent producers who have not subscribed to such voluntary agreements and importers of articles produced outside the EU from placing high formaldehyde releasing materials on the EU market.

Moreover, at present, the existing national legislations can prevent only at national level the placing on the market of non-compliant wood-based panels releasing formaldehyde. These disparities may result in different levels of risk reduction across the EU.

RAC

See RAC opinion.

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

Non-REACH legislation and other measures have not been considered suitable by the Dossier Submitter for managing the identified risks. For this reason, a number of potential restriction options under REACH have been considered:

- **RO1 – Full ban of formaldehyde releasing articles and mixtures**: RO1 is disregarded by the Dossier Submitter as this option is considered neither consistent with the risk assessment nor proportionate to the risk.

- **RO2 – Concentration limit for formaldehyde or specific formaldehyde releasing substances in articles and mixtures:** RO2 is disregarded by the Dossier Submitter due to a number of uncertainties that make it difficult to link a concentration limit for formaldehyde and known (to date) formaldehyde releasers to formaldehyde emissions. In addition, an emission limit is considered more closely linked to inhalation exposure and hence to the actual risk.

- **RO3 – Emission limit for wood-based panels consistent with formaldehyde emission class E1:** The Dossier Submitter considers RO3 consistent with the risk assessment as wood-based panels are the major (permanent) source of formaldehyde emissions to indoor air and it would effectively reduce risks by preventing that high formaldehyde emitting class E2 wood-based panels are placed on the EU market. RO3 is considered proportionate, implementable and manageable. The Dossier Submitter states that while RO3 would ensure that only class E1 panels are used for the manufacturing of finished products such as furniture or laminate flooring in the EU, high formaldehyde emitting articles made from non-compliant panels could still be imported from outside the EU. RO3 is therefore disregarded in favour of RO4.

- **RO4 – Emission limit for articles consistent with formaldehyde emission class E1**: RO4 extends the emission limit described in RO3 to other articles (including, but not limited to, wood-based panels) as a further precaution against producing and importing additional formaldehyde emitting articles, in particular wood-based products such as furniture and laminate flooring.

Under both options, RO3 and RO4, the Dossier Submitter considers an emission limit lower than the one defined by the E1 emission class as not consistent with the risk assessment, because indoor air formaldehyde concentrations measured in the EU are in the majority of cases below the WHO guideline value (0.1 mg/m^3). The Dossier Submitter concludes that, compared to the E1 emission limit, a lower emission limit would also not be supported by the available information from a proportionality point of view.

The proposal covers consumer articles that are used in indoor environments[1] as well as articles for both indoor and outdoor use (e.g. wood-based panels). Articles that are only meant to be used in outdoor environments are not included in the restriction proposal. The proposal covers articles where formaldehyde or formaldehyde releasing substances (formaldehyde releasers) are used in their production (either as such or in mixtures) and

[1] Indoor environments are not limited to buildings but also include other environments such as cars, trucks, buses, trains, aeroplanes, mobile homes, or container homes.

where formaldehyde is released during use as a result of either the “off-gassing” of residual formaldehyde or from the degradation and chemical reactions of other substances used in the production. The proposal does not cover articles produced without the use of formaldehyde or formaldehyde releasing substances. In such articles formaldehyde is either not released (because it is not present in the article, e.g. glass articles) or it can be only released by decomposition of substances that are naturally present in the material of the article (e.g. lignin degradation in solid wood) or as a result of combustion.

As well as in the interiors of buildings, the proposal aims also to reduce consumer exposure to formaldehyde in the interiors of vehicles (road, rail, air and water vehicles). In the specific case of road vehicles (e.g. cars, trucks, vans, buses and motor-homes) and aeroplanes the proposal is intended to restrict the placing on the market of articles where the interior concentration of formaldehyde exceeds 0.1 mg/m^3 under reasonably foreseeable conditions of use.

Formaldehyde concentrations in textiles worn on or near the skin are already limited by the restriction on CMR substances in clothing and footwear, i.e. Regulation (EU) 2018/1513 (implemented as entry 72 of Annex XVII of REACH). The Dossier Submitter therefore proposes to exempt articles subject to entry 72 of Annex XVII of REACH from the current restriction proposal. Articles not subject to the restriction on CMR substances in clothing and footwear, such as wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners, would however fall into the scope of the proposed restriction.

The Dossier Submitter also proposes an exemption for substances used as biocides under the Biocidal Products Regulation (BPR), i.e. Regulation (EU) 528/2012, because the Commission is already developing regulatory activities under BPR. BPR does however not apply to imported articles (even if treated with biocides) and to articles releasing formaldehyde from the use of substances for other purposes than biocide. Such articles would therefore be in the scope of the proposed restriction.

Based on the information received from stakeholders during the consultation and further advice from ECHA’s Forum for Exchange of Information on Enforcement (Forum), the Dossier Submitter proposes additional derogations for articles subject to Regulation (EU) 2017/745 on medical devices, articles subject to Regulation (EU) 2016/425 on personal protective equipment (PPE), articles subject to Regulation 2011/10 on food contact materials, articles subject to Directive 2009/48/EC on toy safety, articles exclusively for industrial and professional use, as well as second-hand articles.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Justification for the opinion of SEAC

Summary of proposal:

See summary of proposal by RAC.

SEAC conclusion(s) on *risk management options*:

SEAC considers that, among the Union-wide risk management options analysed by the Dossier Submitter, the proposed restriction under REACH (referred to as **RO4**) seems to be the most practical, effective and efficient option to prevent consumer exposure to formaldehyde from high formaldehyde emitting articles.

SEAC agrees that a full ban of formaldehyde releasing articles and mixtures (RO1) would have substantial economic impacts, which would be disproportionate to the resulting benefits.

Similarly, SEAC agrees that setting a concentration limit for formaldehyde releasing substances in articles and mixtures (RO2) would not be effective in order to control emissions.

RO3 and RO4 appear to be similar options since they both propose an emission limit consistent with formaldehyde emission class E1 and since wood-based panels seem to be the main permanent sources of formaldehyde emissions.

However, SEAC considers RO4 including not only wood-based panels more protective for human health than RO3.

In SEAC's view, taking into consideration the flexibility introduced by the Appendix X of the proposed restriction on the use of testing methods, RO4 can be considered as a proportionate risk management option.

Key elements underpinning the SEAC conclusion(s) *on risk management options*:

SEAC considers that measures to limit consumer exposure to formaldehyde, such as voluntary agreements and national regulations in some Member States, already exist and that formaldehyde concentrations measured in indoor environments in the EU are, in most cases, below the WHO Guideline for Indoor Air Quality (2010) of 0.1 mg/m^3. However, SEAC recognises that, in some Member States, consumers may still be exposed to formaldehyde concentrations exceeding the WHO guideline value because the placing on the market of high formaldehyde emitting materials, such as class E2 wood-based panels used in construction (e.g. in ceilings and walls) or finished articles (e.g. furniture) is still allowed.

SEAC recognises that the proposed restriction is intended as a preventive measure which would lead to the harmonisation of national risk management measures related to the formaldehyde release from articles (mainly wood-based panels) across the EU.

After assessing all possible **risk management options**, SEAC considers RO1 (full ban of formaldehyde releasing articles and mixtures) not to be consistent with the risk assessment and substitutes for all uses are not available.

In SEAC's view, RO2 (concentration limit for formaldehyde or specific formaldehyde releasing substances in articles and mixtures) would not be effective to control emissions due to the uncertain link between formaldehyde emissions and a concentration limit.

RO3 (emission limit for wood-based panels consistent with formaldehyde emission class E1) leaves a regulatory gap for high formaldehyde emitting articles made from non-compliant wood-based panels imported from outside the EU (e.g. imported furniture) and non-wood-based articles in general. RO3 is therefore disregarded in favour of RO4.

SEAC conclusion(s) on *scope* of the restriction proposed by the Dossier Submitter:

SEAC agrees with the Dossier Submitter's revised and clarified text of the **scope** as defined in the Background Document, in which:

- only articles where formaldehyde releasing substances have been intentionally added in their production process are restricted;
- the "use" of articles exceeding the emission limit is not restricted anymore due to the complexity of enforcement in line with the Forum advice;
- articles that are only for outdoor use are derogated;

- articles exclusively for industrial and professional use, if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use, is derogated;

- road vehicles and aeroplanes produced with the intentional addition of formaldehyde or formaldehyde releasing substances, where exposure to consumers can occur in their interior, shall not be placed on the market if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 as measured in accordance with the conditions specified in Appendix X;

- **Appendix X** on testing methods has been added;

- **second-hand articles** are exempted;

- **articles already regulated** under other EU regulations are exempted.

Key elements underpinning the SEAC conclusion(s) on *scope* of the restriction proposed by the Dossier Submitter:

SEAC notes that while the **scope** of the restriction, as originally proposed, was somewhat ambiguous, revisions and clarifications in the Background Document have made it clear which articles are in and out of scope.

Articles in scope

SEAC agrees that the scope includes articles produced using formaldehyde or formaldehyde releasing substances as such or in a mixture if the formaldehyde released from them exceeds a concentration of 0.124 mg/m^3 as measured in accordance with the conditions specified in Appendix X.

SEAC agrees that the proposal should cover only articles in which formaldehyde or formaldehyde releasing substances have been intentionally added in their production process and where releases may occur as a result of off-gassing of residual formaldehyde present in the article or from degradation of the substances used in the production process.

Concerning road vehicles and aeroplanes, SEAC notes that the scope includes the placing onto the market of such vehicles produced with the intentional addition of formaldehyde or formaldehyde releasing substances where exposure to consumers can occur in their interior if the formaldehyde in their interior exceeds a concentration of 0.1 mg/m^3 (i.e. the WHO guideline value) as measured in accordance with the conditions specified in Appendix X.

The proposed restriction affects in particular the following industry sectors:

- sector of **wood-based panels** (e.g. plywood, particleboard, oriented strand board (OSB), medium density fibreboard (MDF)) and their downstream users, such as:

- **furniture** sector;

- **construction** sector.

Different sectors manufacturing other articles are concerned by the scope of the proposed restriction. These include:

- **automotive** sector, for example due to polyoxymethylene (POM) based articles in car interiors;

- manufacturers of **complex articles** and foams made of MDI/pMDI;

- **textile** sector (clothing, carpets, curtains, carpet flooring or wallcovering);
- **non-textile accessories**, closures and trim elements.

Derogations and articles out of scope

Articles produced without the addition of formaldehyde or formaldehyde releasing substances

SEAC agrees that articles produced without the **addition of formaldehyde** or formaldehyde releasing substances are out of the scope. Such articles either do not release formaldehyde (because it is not present in the article, e.g. metals, minerals, polymers (PE, PP, PVC, PET), glass, ceramics etc.) or formaldehyde can be released by decomposition of substances naturally present in them (e.g. lignin degradation in grown solid wood) or as a result of burning processes.

Articles exclusively used outdoor

SEAC agrees with the exclusion from the scope of articles **exclusively used in outdoor** environments as they do not contribute to formaldehyde exposure in indoor air. The following non-exhaustive list are examples, which in SEAC's understanding, constitute articles exclusively for outdoor use: trellises, pagodas, wooden play equipment, car ports, equipment sheds, etc.

Articles for industrial and professional use

SEAC supports the derogation for articles **exclusively for industrial and professional use**, if formaldehyde released from them does not generate exposure to consumers (paragraph 4 of the proposed restriction). In SEAC's understanding this derogation also covers articles which undergo further processing before being sold to industrial/professional end users, e.g. articles for the core of sealed doors for fire-protection, noise reduction and anti-burglar resistance, as well as for packaging, transportation and shielding/formwork of construction sites.

Certified doors for fire-protection, noise reduction and anti-burglar resistance may not be drilled into or mechanically altered or else there is a threat of losing the certificate. This ensures permanent sealing against possible formaldehyde emissions. In contrast to the exemption for such gas-tight sealed articles, SEAC considers that the core boards of laminated/coated boards for furniture and carpenter use should already be of E1 quality. This is important in view of the fact that, often, during the further processing of such articles to furniture and/or fixed wood-based installations in apartments (e.g. walk-in cupboards), the surface is opened by drilling holes in the panels to allow more flexibility in affixing fasteners in consumer use.

SEAC welcomes this derogation also with regard to the packaging industry. Valuable and/or fragile cargo is often packed in large plywood or OSB boxes. There are also certified plywood/OSB boxes for the transport of dangerous goods which have to pass several tests to be granted a certification. Essential cornerstones of the testing and approval requirements for wooden packaging are contained in the regulations of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Volume II, Appendix A, Part 6. The test requirements for rail, sea and air transport do not differ significantly. These packaging materials are intended for the industrial sector and not for individual end users. The function of maintaining safety/security outweighs the risk of exposure to formaldehyde. There should also be no exposure for customers to formaldehyde in the intended use.

A comparable industrial/professional application without consumer exposure is the provision of wood-based materials (plywood, OSB, chipboard) for transportation. EURO pallets are standardised equipment for handling a vast range of products and consist of boards made of

grown, natural softwood and spacers between the boards. These spacers are made of composite materials consisting of pressed wood sawdust and a binder/glue.

The situation is similar when using e.g. OSB, plywood and chipboard for shielding of outdoor construction sites. This is also an industrial application without consumer exposure to formaldehyde. The application for construction sites is in the temporary protection of neighbouring areas against dust and noise as well as to restrict access. In the same way, large plywood boards are used as a basis for the labelling/explanation of construction site projects. In addition, formwork for concrete construction is often also made of various wood-based materials.

Exemption for second-hand articles

SEAC supports the derogations proposed by the Dossier Submitter relating to second-hand articles and for articles subject to other European regulations.

For **second-hand articles**, available information from stakeholders indicates that:

- **used wood-based panels and construction materials**, for instance after demolition, are unlikely to be placed on the second-hand market,
- **furniture** is more likely to be placed on the second-hand market via Internet or in specialised shops,
- in most cases, formaldehyde emissions from **other types of articles** are below the limit of the restriction proposal already when they are first placed on the market.

In the majority of cases, for articles sold (or transferred) as second-hand articles, it has to be considered that formaldehyde releases decrease over time (as off-gassing of residual formaldehyde occurs) and that the remaining releases are expected to be very limited.

In addition, based on advice received from ECHA's Forum for Exchange of Information on Enforcement (Forum), the enforcement of second-hand articles seems extremely problematic.

For these reasons, SEAC supports the exemption of second-hand articles from the proposed restriction even though, based on the available information, it has not been possible for the Dossier Submitter to perform a quantitative assessment of the risks posed by second-hand articles.

Exemptions for articles already regulated under other regulations

Issues concerning potential **double regulation** have been raised during the consultation in particular for toys (see comment 2002), construction materials (comments 2081 and 2207), food contact materials, medical devices and personal protective equipment (see comments 2173, 2444).

By introducing some exemptions, the Dossier Submitter clarified in the Background Document which articles are already subject to other regulations and thus do not fall under the scope of the proposed restriction.

The proposed exemptions concern the following articles:

- Articles subject to Regulation (EU) 2017/745 on **medical devices** because such devices have to fulfil specific requirements in terms of safety and functionality.
- Articles subject to Regulation (EU) 2016/425 on **personal protective equipment** (PPE), because such equipment needs to fulfil specific safety requirements and to ensure their functionality.

- Articles in the scope of Regulation 2011/10 on **food contact materials**, as emitting substances used in food contact materials (mostly MF plastics) are expected to have a very low potential of releasing formaldehyde in indoor environments and it can be reasonably assumed that their use by consumers will be limited to short periods. During cooking, there could be a risk of formaldehyde migration from food contact materials to food. Regulation 2011/10 establishes a migration limit for formaldehyde of 15 mg of substance per kg of food. However, food cooking, is considered a temporary source hence not covered by the restriction proposal.

- Articles subject to Directive 2009/48/EC on **toy safety**, provided that the Commission, in amending Appendix C to Annex II, will establish the same or more stringent limit values for formaldehyde in toy materials compared to the limits proposed in this restriction. The emission limit in resin-bonded wooden toy materials coincides with the emission limit of the current restriction proposal.

- Articles subject to the existing restriction on **CMR substances in clothing and footwear** (Entry 72 of Annex XVII of REACH implementing the Regulation (EU) 2018/1513). In fact, entry 72 already established limits on formaldehyde concentrations in textiles worn on or near the skin. As formaldehyde is very unlikely to cause cancer through dermal exposure unless present at very high concentrations, the limits established by Regulation (EU) 2018/1513 are considered to be protective enough. These articles are significantly below the concentration of 0.2 % for skin sensitisation. In addition, the contribution of articles subject to entry 72, is unlikely to significantly contribute to inhalation exposure. Textile articles (such as wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners) not subject to Regulation (EU) 2018/1513 will be subject to this current restriction proposal and they will have to comply with the emission limit proposed.

- Substances used as biocides under the Regulation (EU) 528/2012 (BPR) on **Biocidal Products** because the Commission is already developing regulatory activities. Specifically, formaldehyde is listed in Annex II to the Review Programme Regulation to be evaluated by Germany for the disinfectants and algaecides not intended for direct application to humans or animals, veterinary hygiene, and embalming and taxidermist fluids. However, are included in the scope of the current restriction proposal articles to which BPR doesn't apply such as imported articles treated with biocides and articles releasing formaldehyde from the use of substances for other purposes than biocide.

The European Commission provided comments on the fourth version of the RAC and SEAC draft opinions (i.e. the draft opinions presented at RAC-52 and SEAC-46, respectively) which, among others, included also comments on the derogation of PPE, food contact materials and articles for outdoor use.

In response to the Commission's comments, SEAC notes that for PPE potentially there could be inhalation exposure of individual consumers. However, as pointed out by the Dossier Submitter in the Background Document, SEAC considers that such equipment needs to fulfil specific safety requirements to ensure protection of EU workers.

As far as food contact materials are concerned, SEAC notes that in the Background Document the derogation is proposed by the Dossier Submitter because food contact materials are considered unlikely to significantly contribute to the formaldehyde concentration in indoor environments. This is due to the low release potential of the formaldehyde emitting substances used in food contact materials (mostly MF plastics) and it can be reasonably assumed that use by consumers is not continuous and limited to short periods.

SEAC actually understands outdoor use to mean objects for use in the garden or in parks, such as trellises, pagodas, wooden play equipment, car ports, equipment sheds, etc. These items clearly intended for outdoor use can be exempted from the planned restriction as they do not contribute to formaldehyde exposure in indoor environments.

In conclusion, SEAC welcomes the above-mentioned derogations for articles subject to other EU regulations.

Exclusion of temporary sources

SEAC acknowledges that formaldehyde emissions from temporary combustion sources, such as cooking, smoking, burning wax or incense candles and ethanol fireplaces, cannot be addressed by an emission limit on articles. However, SEAC notes that temporary formaldehyde emission sources which are outside the scope of this restriction proposal further increase formaldehyde concentrations in indoor air, at least temporarily.

Exclusion of consumer mixtures

SEAC notes that formaldehyde can also be released from **consumer mixtures** such as resins, glues, adhesive, fillers, stabilizers, foaming agents, paints, etc. However, mixtures for consumer use are not in the scope of the proposal because a concentration limit of 0.1 % already applies to mixtures due to formaldehyde's classification as Carc. 1B and its inclusion in entry 28 of REACH Annex XVII. Moreover, SEAC notes that the Dossier Submitter's assessment shows that risk from consumer mixtures is adequately controlled at such a concentration limit.

SEAC conclusion(s) on *transition period* of the restriction proposed by the Dossier Submitter:

For a restriction with the limit values proposed by the Dossier Submitter, SEAC notes a transition period of 12 months after the entry into force is sufficient to ensure compliance without imposing major costs to the industry.

SEAC conclusion(s) on *transition period* of a restriction with lower limit values:

SEAC notes that RAC indicates that a transition period of 24 months for all articles and interiors of road vehicles would be enough for the industry to comply with the lower limit values proposed.

SEAC notes that in case industry would have to comply with limit values lower than proposed by the Dossier Submitter, a transition period longer than 12 months after entry into force of would be needed.

SEAC notes that, during the consultation, the affected industrial sectors claimed that with a lower limit value there would be a need of a transition period much longer than 12 months after the entry into force of the proposed restriction. It was explained by the industry that such additional time would be justified by the need of availability on the market of higher volumes of alternative resins (namely MDI- and pMDI-based resins), as well as the glues and binders to be used, by the technical production changes to be made and, for some specific products, by the requirements of new safety certifications. SEAC notes that for the wood-based panels industry, a minimum transition period of 24 months after entry into force of the restriction with the limit values proposed by RAC was suggested by the European Chemical Industry Council (CEFIC).

SEAC notes that additional information would be needed for SEAC to make sector specific considerations on the transition period needed to comply with the limit values proposed by RAC. Therefore, SEAC calls for the submission of such information during the consultation on this SEAC draft opinion.

SEAC conclusion(s) on *limit values* of the restriction proposed by the Dossier Submitter:

SEAC agrees with the limit values set by the Dossier Submitter at the level of **0.124 mg/m³**

for articles in the scope of the proposed restriction and at the level of **0.1 mg/m³** for interiors of road vehicles and aeroplanes considering that, in general, complying with such limit values is technically and economically feasible for the industry.

Key elements underpinning the SEAC conclusion(s) on *limit values* of the restriction proposed by the Dossier Submitter:

SEAC notes that the WHO Guideline for Indoor Air Quality for formaldehyde, which was adopted by the Dossier Submitter as a DNEL in the proposed restriction, sets an exposure limit to 0.1 mg/m³ (0.08 ppm) for all indoor environments.

SEAC conclusion(s) on *limit values* proposed by RAC:

SEAC recognises the higher protective potential of the limit values set by the RAC at the level of **0.05 mg/m³** for articles included in the scope of the proposed restriction and for interiors of road vehicles. However, SEAC currently lack sufficient information on the technical feasibility, costs and benefits of setting the limit values at the level proposed by RAC.

Key elements underpinning SEAC conclusion(s) on *limit values* proposed by RAC:

SEAC takes note that RAC does not agree with the Dossier Submitter that the WHO guideline value is sufficiently protective for the general population. Instead RAC derived a **DNEL** of **0.05 mg/m³** (0.04 ppm; relevant equally for all indoor environments) for use in its evaluation. On this basis, RAC proposes limiting emissions exceeding 0.05 mg/m³ in the air of a test chamber used under the conditions specified in Appendix X for articles in scope and a concentration limit of 0.05 mg/m³ for road vehicle cabin interiors.

SEAC notes that RAC carried out an extensive overview at global level of the currently existing mandatory and voluntary formaldehyde emission limits as well as voluntary certification labels and markings for wood-based construction materials, furniture and for other products (see Table 19 of RAC opinion).

SEAC agrees with RAC that some EU (and non-EU) countries have already in place **mandatory formaldehyde emission limits** for wood-based panels that are slightly lower than the E1 standard. However, SEAC notes that no European nor extra-European country imposes formaldehyde emission limit values as stringent as the limit proposed by RAC.

Moreover, SEAC acknowledges that, for enhancing the emissions reduction, countries such as France and Japan require information on formaldehyde emissions on the labels of wood-based panels. However, SEAC notes that these requirements can be considered as a **labelling** rewarding lower emissions and not as a ban on emissions beyond the E1 threshold.

Moreover, around the world, there are many different **voluntary agreements and multiple forms of eco-labelling** certifying lower formaldehyde emissions compared to E1. In SEAC's opinion, indeed voluntary certification labels and markings represent an additional way, on the one hand, to make consumers care about the indoor air quality at home and become more aware of their choices and, on the other hand, for providing incentives to companies to differentiate their products from those of competitors by reaching lower emission levels.

In agreement with RAC, SEAC acknowledges that in the EU only few panels with emissions higher than the E1 standard are produced. SEAC notes that this fact further indicates that the production and use of wood-based panels with formaldehyde emission lower than E1 (e.g. ½ E1, ⅓ E1) seems feasible and it is becoming more and more common on a voluntary basis.

Based on the results of the consultation, SEAC notes that, in most cases, the main issue for the industry to comply with a lower limit value, as proposed by RAC, seems to be mainly the economic feasibility and much less the technical feasibility. The related economic consequences of a change of limit value are discussed in detail below in the section on costs.

In conclusion, even if lower emission limit values than the existing E1 class proposed by the Dossier Submitter have already been reached by part of the industry in some cases, SEAC considers that a limit value set at the level of **0.05 mg/m³** for both articles in scope and road vehicle cabin interiors is not feasible in all applications/sectors, either technically or economically. In this respect, SEAC notes that such a limit is met mainly by special niche applications such as for instance equipment of retirement homes with almost 100 % indoors exposure of patients, kindergartens, schools, energy saving buildings with poor ventilation (ACH < 0.5 h^{-1}).

SEAC conclusion(s) on *testing methods and Appendix X*:

SEAC considers that Appendix X ensures the enforceability of the proposed restriction and allows industry to reduce the costs of compliance by using all suitable **test methods**, provided that results can be correlated to the reference conditions specified in Appendix X.

SEAC also welcomes the clarification added by the Dossier Submitter in the Background Document of the proposed restriction concerning the **testing of complex articles**.

Key elements underpinning the SEAC conclusion(s) on *testing methods and Appendix X*:

As confirmed by a large number of comments received during the consultation, for many industry sectors testing methods are considered by the industry to be the most critical issue of the restriction proposal (see, for example, comments 2002, , 2023,2050, 2055, 2060, 2071, 2090, 2099, 2114, 2159, 2173, 2178, 2198, , 2214, 2217, 2275, 2334, 2349, 2350, 2444, 2494,2483, 2569,2570, 2583, 2604, 2615, 2622, 2644, 2657, 2665, 2677).

SEAC notes that, among all these comments, some were in favour of the use of other methods than EN 717-1, which was specifically referred to by the Dossier Submitter in the original proposed wording of the restriction entry (see comments 2002, 2060, 2206), a number of comments suggested the use of EN 16516 (see comments 2023, 2071, 2114, 2604, 2615, 2622, 2644, 2665, 2677), a number of comments suggested the use of EN 16516 (see comments 2217, 2275, 2334, 2349, 2350, 2494, 2569), others proposed to allow to continue using current methods for different sectors such as automobile (comments 2067, 2083, 2133, 2136), leather (comments 2133, 2136), office furniture as well as for the flexible polyurethane foam industry (comment 2211).

SEAC agrees with the Dossier Submitter that, taking into consideration the comments received during the consultation, Appendix X on testing methods introduces flexibility for industry hence reducing the additional costs of the proposed restriction.

According to **Appendix X**, emissions from articles in the restriction proposal refer to a concentration in the air of an emission test chamber (expressed in mg/m^3). The test chamber is the reference method and Appendix X defines the conditions (temperature, relative humidity, air exchange rate, loading factor, etc.) for the test chamber. Analytical methods and sampling methods used to determine the formaldehyde concentration are defined in specific test standards. Therefore, other standard test methods (e.g. gas analysis) or non-standard test methods can be performed if a reliable correlation to the reference test chamber can be established.

In the case of road vehicles for the transportation of people and passenger aeroplanes, Appendix X considers that testing of formaldehyde concentrations in the interior of the vehicle or aeroplane is acceptable to guarantee compliance with the current restriction proposal. Therefore, in such a case, the concentration of formaldehyde in a vehicle or aeroplane interiors, measured in accordance with the conditions specified in Appendix X, shall not exceed 0.1 mg/m^3.

It seems essential to SEAC that the methods are in accordance with Quality Management

(QM) in general:

- The reference test chamber measurements will be done at certified/accredited test laboratories (e.g. GLP/EN 17025).
- Other (not reference chamber testing) standard test methods (e.g. gas analysis, perforator) are used routinely by the producers for daily production checks. Such kind of self-control needs a traceable QM and if required a certification/accreditation too.
- The operators of factory test methods should be responsible for validated correlation to the chamber test methods for the articles concerned.
- In cooperation with Forum, responsible actors should be assigned for those cases where there are questions.

In conclusion, SEAC considers that the proposed **limit value** of 0.124 mg/m^3, as measured in accordance with the conditions specified in Appendix X, ensures the enforceability of the proposed restriction, allowing the industry to reduce the costs of compliance by using all suitable **test methods**, provided that results can be correlated to the reference conditions specified in Appendix X.

Testing complex articles

Many comments submitted in the consultation expressed concern about the need to test complex big articles like furniture, which indeed are produced in such a large variety that testing all of them would be extremely expensive.

Taking into consideration these challenges, SEAC agrees with the clarification made by the Dossier Submitter in Section 2.2.2.2 of the Background Document that testing of complex articles (e.g. pieces of furniture) is not needed if their components do not contain formaldehyde or formaldehyde releasing substances or if formaldehyde emissions of individual components are within the limit established by the current proposal. However, when formaldehyde or formaldehyde releasing substances or mixtures (e.g. lacquers or glues) are added during the production process of complex articles, testing is required.

Testing small articles made of POM

Articles made of POM, engineering thermoplastic used in precision parts requiring high stiffness, low friction, and excellent dimensional stability, are used in a wide range of industrial and automotive applications, inside homes, offices and vehicles.

SEAC takes note that, during the consultation, some comments (see comments 2083, 2214, 2731) raised the issue of and requested a derogation for small articles made of POM mainly due to high testing costs. In fact, POM articles are claimed by the industry to be low formaldehyde releasing materials and to have a low loading factor.

Based on the information provided in the consultation, these articles seem to be already in compliance with the proposed restriction because their emission is recorded integrally with the total emission of the vehicle interior air.

Moreover, POM parts such as fittings on furniture are unlikely to play a role in the overall formaldehyde concentration of a building's interior air, because these appear to be associated with very low formaldehyde emissions. POM articles are not derogated *per se*.

SEAC conclusion(s) on *alternatives*:

SEAC notes that several **formaldehyde-based and formaldehyde-free resins** could be used in substitution of UF resins, namely for reducing formaldehyde emissions from some

articles other than wood-based panels.

Key elements underpinning the SEAC conclusion(s) on *alternatives*:

In general, at least for **wood-based panels**, SEAC does not see the need for switching to **formaldehyde-free alternatives** as a longer curing time of UF resins should be enough to reduce formaldehyde emissions in indoor air. The commitment of the European wood-based panels industry to only produce class E1 panels by continuing using UF resins demonstrates the technical and economic feasibility of the use of UF resins in such a way to be in line with the proposed restriction. Therefore, at least for the wood-based panels, SEAC sees no need for a major transition away from UF resins towards alternative resins necessary to achieve the aim of this restriction proposal.

Formaldehyde-based resins

Urea formaldehyde (UF) resins

SEAC notes that currently the most used resins in the production of wood-based panels and of other articles concerned by this restriction are urea formaldehyde (UF) resins.

As stated in Annex D.4 of the Background Document, UF resins are very economical and fast curing but are not suitable for damp conditions and are typically used for panels intended for non-structural use such as particleboard and hardwood plywood. UF resins are also non-staining and therefore do not blemish the high-quality expensive face veneers used for hardwood panels for interior finish applications. Because the formaldehyde component of UF resins is not completely chemically fixed by the urea, some formaldehyde is free to dissipate and, as such, UF resins are associated with the highest releases of formaldehyde when compared with other formaldehyde-based resins.

Other formaldehyde-based resins

Other formaldehyde-based resins such as phenol formaldehyde (PF), melamine formaldehyde (MF), melamine urea formaldehyde (MUF), resorcinol formaldehyde (RF), and phenol resorcinol formaldehyde (PRF) resins release little to no formaldehyde from the cured product and can be considered as substitutes for UF resins. However, each of these resins has some shortcomings:

- **PF** resins show low or no formaldehyde emissions form the cured product but there may be a concern for worker health due to the use of phenol. There are environmental concerns when using phenol too. PF resins require high temperature for curing and long press times and are 2-3 times more expensive than UF resins but cheaper than other formaldehyde-based resins like RF and PRF resins. PF resins have a wide application beyond their use in the wood-working industry. A comment submitted in the consultation (comment 2483) shows other uses in different industry sectors. SEAC notes that PF resins can only be used in limited cases as a replacement for UF resins due to their 2-3 times higher price and its dark colour. SEAC has no information whether the availability on the market is sufficient to cover a larger demand for PF resins.

- **MF and MUF** resins have a comparably good weather and water resistance like PF resins. MF resins are up to 3 times more expensive than UF resins. MUF resins are cheaper than MF resins but more expensive than UF resins too. Melamine capacity to meet demand of the wood-based panels industry is uncertain. MF and MUF resins belong to the class of resins with low/no formaldehyde emissions from cured products.

- **RF and PRF** resins have a comparably good weather and water resistance but a very dark (dark brown to black) colour. According to Annex D.4 of the Background Document, RF and PRF resins have around four times the price of UF resins and the

supplies of resorcinol may not be sufficient to meet the needs of the wood-based panels industry. Worker health concerns regarding both phenol and resorcinol should be comparable to PF resins.

Formaldehyde-free alternatives – isocyanate resins

Based on some comments received in the consultation (see comments 2037, 2206), SEAC takes note that both monomeric **methylene diphenyl diisocyanate (MDI)** and **polymeric methylene diphenyl diisocyanate (pMDI)** resins could in principle be used as a substitute to UF resins.

SEAC notes that:

- **MDI** resins could be used as a substitute to UF resins **in MDF/particleboard** and in **Composite Wood Products** (CWP) in buildings. Based on the available information, as alternative to UF resins, in general, MDI resins seem to be technically suitable (nearly drop-in) and economically feasible (only slightly more expensive).

- **pMDI** have lower hazard concerns, which could be addressed by the foreseen restriction on diisocyanates and by proper risk management measures (RMM). However, SEAC notes that technical and economic considerations have to be made in order to be considered as a suitable substitute to UF resins.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter expects the proposed restriction to be an effective measure for addressing the identified risks, in particular with regard to new articles imported into the EU. The overall risk reduction potential is however expected to be limited given that the measured indoor air formaldehyde concentrations in the EU are already today below the WHO guideline value in the majority of cases.

The exposure reduction expected from the proposed restriction is assessed quantitatively in the dossier. This assessment is based on the estimations of formaldehyde concentrations in indoor air which the Dossier Submitter performed as part of the exposure assessment. The conclusions from the Dossier Submitter were that formaldehyde concentrations in indoor environments can exceed the WHO guideline value if high emitting articles, such as class E2 wood-based panels, are used in large quantities but that such exceedances could be avoided if emissions from panels and other articles do not exceed the proposed emission limit of 0.124 mg/m^3.

The Dossier Submitter also states that formaldehyde emissions decline over time and that formaldehyde concentrations are typically found to be higher in new homes. The analysis presented in the proposal only focuses on newly built homes. It is therefore expected that, with the passing of time, formaldehyde concentrations in homes above the WHO guideline value fall below the guideline value simply as a result of formaldehyde decay. Even if this is the case, the proposed restriction could help to avoid periods in the order of up to several months in which people in newly built homes are exposed to formaldehyde concentrations above the WHO guideline value.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

Although all consumer articles for indoor or indoor/outdoor use in which formaldehyde or formaldehyde releasing substances have been used in their production process would fall under the scope of the proposed restriction, the impact assessment carried out by the Dossier Submitter focuses on wood-based panels. This is because wood-based panels used in both construction and finished articles have been identified as the main permanent formaldehyde emission sources in indoor air; hence they are expected to be the class of articles most affected by the proposed restriction.

The economic impact of the proposed restriction is expected to be limited, given that a voluntary agreement is in place in the EU's wood-based panels industry to only produce panels with formaldehyde emissions complying with the restriction proposal. Since the proposed emission limit is already legally binding in a number of Member States for wood-based panels,

additional enforcement costs are only expected for authorities in Member States without national regulations to ensure compliance with the restriction and the imposed emission limit. Investment costs and additional testing costs are expected to be negligible and were not estimated by the Dossier Submitter. For the reference year 2016 costs to EU society are estimated to be in the order of €28 million (central estimate).

SEAC conclusion(s) on *costs* associated with the restriction proposed by the Dossier Submitter:

Considering the **limit value proposed by the Dossier Submitter**, in line with the comments received during the consultation, SEAC agrees with the Dossier Submitter that costs are expected to be limited both for the European wood-based panels and for the furniture sectors.

Overall, SEAC concludes that the restriction proposed by the Dossier Submitter entails additional costs for the EU society in terms of production, sampling, testing and enforcement costs in the order of some tens of millions of euros. Additional costs to EU consumers will depend on the extent to which non-EU manufacturers are able to pass through production cost increases in the form of higher prices.

Based on the additional information gathered from the industry during the consultation, SEAC notes that if a **lower limit value** was established, the socio-economic costs to comply with the proposed restriction would impose higher costs on the concerned industry sectors and may affect the production of certain wood-based panel products. In addition, in case of a lower emission limit, an increasing effort on the part of the enforcement authorities in the Member States would have to be expected.

Key elements underpinning the SEAC conclusion(s) on *costs* associated with the restriction proposed by the Dossier Submitter:

As confirmed by the consultation, SEAC notes that the sectors most concerned by this restriction are the wood-based panels industry and their downstream users such as, for instance, furniture producers and the construction sector.

SEAC notes that economic impacts on the sectors of other articles emitting formaldehyde were not further assessed by the Dossier Submitter as such impacts are assumed to be negligible compared to those related to wood-based panels which represent the articles most affected by the proposed restriction.

SEAC further notes that its evaluation of the various cost elements is based on the evaluation of the Dossier Submitter's assessment on costs of substitution, investment, production, sampling, testing and for enforcement calculated using the limit value of the restriction proposal.

SEAC considers that industry sectors producing other articles in the scope of the proposed restriction such as curtains, carpets and interior furnishings of road vehicles would not bear significant socio-economic impacts, given that these industry sectors will be able to continue using their current testing methods as foreseen by Appendix X.

Overall, SEAC agrees with the conclusions of the socio-economic assessment carried out by the Dossier Submitter for the proposed restriction.

SEAC's conclusion on the costs associated with a lower limit value is based on information received in the consultation, as described at the end of this section on costs.

<u>Compliance costs associated with the restriction proposed by the Dossier Submitter</u>

For the EU actors in the supply chain of class E2 wood-based panels as well as for EU importers of class E2 wood-based panels, if they do not want to lose their market, the proposed

restriction is expected to increase production costs to reach the class E1 emission level or, even more, in order to achieve the European Low Emission Standard (E.LES)[2].

In terms of compliance costs, the main impacts are expected for the wood-based panels industry, but other industry sectors (e.g. furniture, construction textile and automotive industry) might also have to bear additional costs to comply with the proposed restriction.

Substitution costs associated with the restriction proposed by the Dossier Submitter

SEAC agrees with the Dossier Submitter that, to comply with the proposed restriction, no major substitution of formaldehyde is expected due to the specific technical properties and economic aspects related to each formaldehyde and formaldehyde-based resin as well as formaldehyde-free resins as described further above in the opinion.

Moreover, SEAC notes that according to the furniture industry, the demand for wood-based panels could not be met if all manufacturers would switch from the use of UF resins to that of isocyanate resins for the production of boards.

However, due to limited information on availability, cost and performance of formaldehyde-free products as alternatives to UF resins, uncertainties remain concerning the cost of substitution.

Investment and production costs associated with the restriction proposed by the Dossier Submitter

SEAC considers that the proposed restriction could entail only very limited (if any) new investments.

SEAC based its conclusion on **investment costs** on the fact that at least for wood-based panels no or only very limited changes in technology, new machinery or modification of existing equipment seem to be necessary to switch from the production of class E2 to that of class E1 panels. For other articles concerned by the proposed restriction, SEAC cannot exclude some minor investment costs.

However, SEAC considers that there could be an increase of **production costs** for those EU companies still producing class E2 panels as well as for non-EU manufacturers producing class E2 panels for the EU market.

In fact, producing class E1 panels is more expensive than producing class E2 panels because it implies the use of lower quantities of UF resins or the use of resins with a lower content of formaldehyde, entailing longer curing time and higher costs than the relatively inexpensive and fast curing UF resins used in the production of class E2 panels. This also means that, when switching to the production of class E1 panels, the production volume will shrink Compared to the production of class E2 panels this will further increase production costs. This increase in production costs has been estimated by the Dossier Submitter on the basis of information provided by the European Panel Federation (EPF). According to EPF, the production costs of E.LES wood-based panels would be 10-15 % higher than those for class E1 panels[3]. As the exact difference in production costs between class E1 and E2 panels is not known, this range was used by the Dossier Submitter as an approximation for the difference in production costs between E1 and E2 panels. The lower end of this range (10 %) was used

[2] In December 2016, EPF announced the so called (**E.LES**), which sets different emission limits for different product groups. Under E.LES the formaldehyde emission limit for fibreboard and OSB is consistent with E1 (= 0.1 ppm or 0.124 mg/m^3) but is set to a lower value of 0.065 ppm (= 0.08 mg/m^3) for particleboard and plywood. E.LES is available to all EPF members for use but without any form of obligation (EPF, 2017).

[3] According to EPF, the price difference depends on the panel characteristics, with the price difference being smaller for standard grade boards and higher for boards that need high mechanical performance and/or strong resistance to humidity.

by the Dossier Submitter in the calculation.

Costs of changing EU production of wood-based panels from class E2 to class E1 wood-based panels will be borne by EU society, either by EU manufacturers or by EU consumers, depending on the extent to which EU manufacturers will be able to pass through these costs. SEAC considers the impact of higher production costs on EU manufacturers of wood-based panels to be minimal as the vast majority of them already produce E1 panels. In fact, for the EU manufacturers of wood-based panels, who have already subscribed to a voluntary agreement to only produce class E1 panels, no negative impacts are expected in terms production costs due to the proposed restriction.

For non-EU-manufactured wood-based panels which are placed on the EU market, the costs associated with a switch from class E2 to class E1 panels will depend on their ability to pass through increased production costs to the EU consumers. The part of extra costs that non-EU manufacturers are able to pass through to EU consumers represents a cost to EU society. However, in case a pass through is not possible, the extra costs are borne by non-EU manufacturers. SEAC notes that the Dossier Submitter considers a pass through of costs as not very likely since non-EU manufacturers are assumed to compete on price.

Anyway, even if there is a strong price competition in the wood-based panels sector, SEAC considers that it cannot be excluded that non-EU manufacturers would pass through some of these extra costs to EU consumers.

Sampling and testing costs associated with the restriction proposed by the Dossier Submitter

SEAC considers that for the wood-based panels sector additional sampling and testing costs are likely to be limited since formaldehyde emissions testing is already part of routine production control.

Concerning sampling costs of wood-based panels, the Swedish Chemical Agency (KEMI) underlined that sampling using EN 717-1 (or EN 14080 for glue laminated timber and glued solid timber) and sampling preparation according to EN 326-1 are quite complicated as several fresh samples (5) are needed and several pieces from the board have to be tested. The samples should be wrapped up and hermetically sealed until being tested by specialists.

As far as **testing costs of wood-based panels** are concerned, in order to comply with national regulations with respect to formaldehyde emissions, the industry already developed reliable chamber test methods for formaldehyde and other compounds using large (up to 48 m^3) or smaller chambers (0.225 m^3 and 1 m^3). In addition, wood-based panel producers control formaldehyde emissions during production via smaller scale derived test methods, in accordance with quality control limits based on correlations with chamber test methods.

Taking into consideration the information gathered during the consultation on **other articles**, SEAC considers that, given the flexibility with regard to test methods introduced in the Background Document through Appendix X of the restriction proposal, testing the compliance with the proposed formaldehyde emission limit would imply minor additional costs for manufacturers of these articles.

SEAC notes that such additional sampling and testing costs would depend on the type and number of articles that will have to be tested (which should be limited as only articles where formaldehyde or formaldehyde releasing substances have been intentionally added are within the scope of the proposed restriction), as well as on the testing methods and testing conditions used. Even though SEAC concurs with the Dossier Submitter's assessment that additional testing costs would be limited, SEAC also considers that, at least initial phase after entry into force of the proposed restriction, there will be additional costs related to the need to establish correlations between testing methods in order to keep using the testing methods already in place.

SEAC does not anticipate sampling and testing costs additional to those currently incurred by the industry in the following cases:

- Companies producing materials as well as their downstream users manufacturing consumer articles in which formaldehyde or formaldehyde releasing substances were not intentionally added during the production processes, as defined in the scope. Only in cases of doubt downstream users will afford costs to check the formaldehyde emissions in accordance with the conditions specified in Appendix X (see below).

- Sectors with established pre-testing or factory standard testing methods. The requirements for routine checks to ensure a reliable correlation between the used in-house testing methods and testing in accordance with the conditions specified in Appendix X remain unchanged.

SEAC anticipates some additional sampling and testing costs in the following cases:

- Industries without sector-specific testing methods in place for formaldehyde emissions will have to develop specific methods and to establish the correlation with the conditions specified in Appendix X.

- Companies in doubt about whether their suppliers could have used formaldehyde or formaldehyde releasers in their production processes would have to test if formaldehyde can be released from their articles.

- Industry still making use of very old correlations of some derived test methods (e.g. EN 120 and WKI flask method) which are probably not valid anymore and need to be re-evaluated on the basis of the conditions specified in Appendix X.

However, based on the information available, SEAC doesn't have sufficient data to quantify any of these sampling and testing costs nor for assessing the need for specific derogations.

SEAC notes that, in general, regardless of the level of the emission limit (either the level proposed by the Dossier Submitter or the value recommended by RAC), costs for testing should be the same. However, in some cases, a lower limit value could potentially lead to higher sampling and testing costs for industry since the lowered emission limit could partly undermine the voluntary agreements of industry. In this context of self-commitment by the industry, there could be a need to increase the controls of suspected cases of companies breaching the agreement by producing articles exceeding the emission limit.

Enforcement costs associated with the restriction proposed by the Dossier Submitter

Regarding **enforcement**, SEAC considers that some **costs** can be expected for the National Enforcement Authorities.

Considering the Forum advice, based on information provided by KEMI on the costs of sampling, sampling preparation and testing by the enforcement authorities and taking into consideration that the Dossier Submitter's analysis does not include articles other than wood-based panels, SEAC considers that the generic value for enforcement costs of €60 000 per year, suggested by the Dossier Submitter, could be considered as an underestimation of the administrative costs incurred by Member State authorities to ensure compliance with the emission limit of the proposed restriction.

However, SEAC notes that enforcement costs in those Member States already enforcing national regulations for wood-based panels cannot be considered as additional costs of the proposed restriction since they are already incurred in the baseline scenario.

Taking into consideration both these arguments, overall, SEAC concludes that the generic order of magnitude estimate of around €60 000 per year, could be a good indication of the

enforcement costs also for this restriction.

SEAC conclusion(s) on *costs* associated with limit values proposed by RAC:

Based on the information provided by stakeholders during the consultation, SEAC concludes that the limit values proposed by RAC (0.05 mg/m^3 both for articles and for interiors of road vehicles) might entail significant negative socio-economic impacts on the whole supply chain of the wood industry, as well as on other industry sectors affected by this restriction.

Key elements underpinning the SEAC conclusion(s) on *costs* associated with limit values proposed by RAC:

SEAC takes note that RAC does not agree with the Dossier Submitter that the WHO Guideline for Indoor Air Quality for formaldehyde, which sets an exposure limit to 0.1 mg/m^3, is considered protective for the general population. Instead RAC derived a DNEL of 0.05 mg/m^3 (relevant equally for all indoor environments) for use in its evaluation.

The ECHA Secretariat, on behalf of SEAC, invited industry stakeholders (email sent on 2 September 2019) to submit in the consultation information about the possible impacts of an emission limit lower than the value proposed by the Dossier Submitter should RAC propose a lower limit value following its derivation of a lower DNEL.

In response to this invitation, different companies and sector associations claimed that, in case a lower emission limit value would be set, several negative impacts can be expected. Such socio-economic costs would include increased production and investment costs, revenue and job losses, reduced technical performances, loss of competitiveness on extra EU markets, negative impacts on the circular economy and even, in some cases, shutdowns.

SEAC considers that all comments provided by the industry, as described below, are valuable to understand impacts on the wood-based panels sector and the woodworking industries. However, SEAC considers that the costs provided by industry represent an overestimation of the negative impacts of a lower limit value since this information was provided before the introduction of the Appendix X (hence does not take into account the increased flexibility with regard to testing) and of the exemption for industrial and professional uses.

Furthermore, not all impacts reported in the comments received from industry precisely refer to the specific limit value proposed by RAC. This is because the exact limit value proposed by RAC following its derivation of a lower DNEL was not yet known at the time when industry stakeholder were invited to submit information on the possible impacts of a lower limit value. In addition, RAC also proposes a lower limit value of 0.05 mg/m^3 for formaldehyde concentrations in the interior of road vehicles. This is likely to lead to additional costs to the automotive industries. However, no further information on the order of magnitude of such costs has been received during the consultation.

Moreover, many of the comments were claimed confidential therefore, in order to provide some examples of the claims from the industry, only non-confidential comments are reported below.

Therefore, SEAC invites industry, Member States, NGOs and any other stakeholder to provide (possibly in a non-confidential manner), during the consultation on this SEAC draft opinion, any specific qualitative and quantitative information available on socio-economic impacts related to production changes, substitutions of resins, sampling and testing and enforcement of a restriction with the limit value proposed by RAC. This information is needed in order to enable SEAC's assessment of the proportionality of a potential restriction that would have the same scope (including derogations) proposed by the Dossier Submitter but with the limit value proposed by RAC.

Furthermore, during the consultation on this draft opinion, SEAC invites stakeholders to

provide information on what transition period would be needed to comply with the limit values proposed by the Dossier Submitter and the limit values proposed by RAC.

Comments received in the consultation on the Annex XV report from the wood-based panels and woodworking industries on a lower limit value

For wood-based panels, **EPF**, the European Panel Federation (comment 2620), considers that the limit value of 0.124 mg/m³, proposed by the Dossier Submitter, is the most appropriate and proportionate value to guarantee safety to the European citizens while minimizing the costs for the industry.

In the opinion of EPF, a limit value corresponding to half the level proposed by the Dossier Submitter, i.e. a limit of **0.062 mg/m³** (or half the level associated with formaldehyde emission class E1) would bring only negligible additional benefits in terms of protection for EU citizens, but at a cost close to €500 million.

According to EPF, costs would rise exponentially for emission limits lower than 0.062 mg/m^3 and would already be in the order of billions of euros for an emission limit of **0.05 mg/m³**. EPF stated that even though this emission limit can be achieved by extremely advanced non formaldehyde-based resins, the availability of these resins is very limited and few resin suppliers have the necessary technology and recipes. Furthermore, according to EPF, upscaling the production and use of these resins will be a long and slow process with supply bottlenecks that will also lead to likely substantial shortages of essential additives that are required for these advanced resins, in particular melamine.

SEAC notes that a **limit of 0.025 mg/m³** (i.e. 20 % of the limit value proposed by the Dossier Submitter) is considered by EPF to be completely disproportionate, industry threating and society harming. In fact, such a limit value would imply major investments to radically change all adhesive systems currently used in the wood-based panels industry entailing an estimated cost of around €20 billion, which would put the majority of the companies producing wood-based panels out of business, threatening approximately 1.2 million jobs across the EU. However, SEAC notes that these impacts refer to a limit value which is half of the limit proposed by RAC.

Fedustria, the Belgian Federation of the Woodworking, Furniture and Textile Industries (comment 2597) provided information according to which a lower emission limit could have substantial impacts on the wood-based panels and woodworking industries and their supply chains. The industry association identifies serious impacts in the following industry/product sectors: wood-recycling, wood bending and furniture sector, production and use of plywood as packaging, possible outsourcing of floor and wall coverings outside the EU, expensive re-testing of fire doors, anti-theft or sound proof doors (€5 000-10 000 per test depending on the article tested) for a new certificate in consequence of a new production process and the use of particleboard or wood-based panels as a major component in timber frame construction of houses.

Confindustria, the Italian industrial confederation, on the behalf of the Italian wood-based industry indicates that, by lowering the emission limit, there would be a serious **cost increase** (comment 2677). For instance, for the Italian industry alone, the half E1 scenario (i.e. 0.062 mg/m^3 according to EN 717-1) would imply an estimated increase of costs of around €32 million for particleboard, around €15 million for MDF and more than €10 million for plywood. Overall, it was underlined that the cost for the Italian particleboard industry alone would translate into an increase of more than €125 million compared to the cost under E1 limit value. Moreover, the increase in the cost of the chipboard alone would result in a cost increase for the furniture sector, which would seriously impact the competitiveness of Italian furniture exports.

In addition to the comments made by the wood-based panels and woodworking sector, information on the impacts of a lower limit value was also received from a number of

companies of other sectors. The information provided in these submissions appears to be broadly in line with the information provided by EPF, Fedustria and Confindustria, with impacts ranging from increased production and investment costs to production shutdowns, depending on the level of a lower emission limit.

Comments received in the consultation on the Annex XV report by other sectors on a lower limit value (sorted by impact categories)

Some of the publicly disclosed information received during the consultation is indicated below, sorted by different impact categories.

Substitution and production costs in case of a lower limit value

Concerning the **potential switch to MDI/pMDI** resins (comments 2597 and 2620), it was reported by the industry that the current OEL of 5 ppb for the use of diisocyanates implies a total compartmentation of the gluing and press areas using MDI by sealing these off and putting them in suppression. Furthermore, it was underlined that the curing of MDI glues is slower than UF glues resulting in a 10 % production capacity loss. However, a complete substitution would have to face a serious lack of availability of pMDI (comments 2622, 2627 and 2677). Therefore, according to the comments received, there would be a need to build new production plants, requiring a considerable amount of time (8 years) and investment. Furthermore, the comments received during the consultation indicate that, contrary to formaldehyde-based resins, most of the MDI production occurs outside the EEA, meaning that the resin supply would mostly come from outside the EEA (from Chinese and other global players).

Concerning the impacts on **technical performance of articles**, one comment received during the consultation (comment 2604) indicates that, if the composition of the used materials changes, for fire protection doors, anti-theft or sound proof doors currently produced with wood-based panels, new tests would be necessary to get new certifications. The company indicates that fire tests, smoke tests, destruction tests and sound tests are very expensive (€5 000-€10 000 per test depending on the article tested). For one producer, switching to pMDI glues would entail about €1 million of extra cost for testing (comments 2597 and 2627). Even a limit value of half E1 (0.062 mg/m^3) would no longer guarantee technical safety to produce with condensation resins, also due to fluctuations and required safety distances.

In this context, SEAC stresses the importance of the exception in paragraph 4 of the proposed restriction to articles exclusively for industrial and professional use if formaldehyde released from them does not generate exposure to consumers under foreseeable conditions of use. Such applications (e.g. articles for the core of sealed doors for fire-protection, noise reduction and anti-burglar resistance) could be considered as articles which undergo further processing before being sold to industrial/professional end users. Such certified doors may not be drilled into or mechanically altered if there is a threat of losing the certificate. This ensures permanent sealing against possible formaldehyde emissions.

Wider economic impacts on the circular economy in case of a lower limit value

Several stakeholders (comments 2597, 2627 and 2677) highlighted the negative effects of lower limit values on the **circular economy**. Such limit values would reduce the ability to use recycled wooden material streams, thus increasing the use of virgin wood. As a consequence, wooden materials that were previously recycled would be landfilled or burned with associated emissions. Formaldehyde scavengers are needed when recycling wood-based panels which is a well-known best practice in the circular economy, namely for the Italian and Belgian wood industry. The use of a formaldehyde-free resins may not allow to reach the required values. Lower limits would also increase the use of plastics instead of wood-based products. In fact, a big market for plywood is packaging and transportation and if the price for plywood would increase plastic packaging will gain the market (comment 2597).

Benefits

Summary of proposal:

The Dossier Submitter states that the proposed restriction would limit exposure to formaldehyde in indoor environments by restricting the placing on the market of high formaldehyde releasing articles, including from imports. This would contribute to keeping indoor air formaldehyde concentrations below the WHO guideline value and would help to prevent detrimental health effects linked to formaldehyde inhalation exposure.

While the Dossier Submitter expects the proposed restriction to be an effective measure for addressing the identified risks, in particular with regard to new articles imported into the EU, the overall risk reduction potential, and hence the benefits of the proposal, are expected to be limited, given that the formaldehyde concentrations measured in indoor air environments in the EU are already below the WHO guideline value in the majority of cases.

For a reference year, 2016, the Dossier Submitter estimates that around 300 000 homes or 690 000 individuals could potentially benefit from reductions in formaldehyde concentration to values below the WHO guideline value as a result of the proposed restriction. In addition, the proposed restriction would serve as a preventative measure that bans high formaldehyde emitting articles from being placed on the EU market and it would harmonise the existing rules on formaldehyde emissions for the entire Union.

SEAC conclusion(s) on *benefits* associated with the restriction proposed by the Dossier Submitter:

SEAC considers that benefits of this restriction will derive from reducing the exposure to formaldehyde in indoor environments. Adverse health effects from indoor exposure to formaldehyde relate to irritation of the eyes, upper airways and nasal cancer.

SEAC agrees with the Dossier Submitter that benefits will mainly come from the reduction of exposure to formaldehyde from wood-based panels (and articles made from them, such as furniture), which are the main consumer articles releasing formaldehyde.

SEAC notes that the benefits, assessed by the Dossier Submitter in terms of number of homes and individuals for which formaldehyde exposure could potentially be brought below the WHO guideline value, mainly concern the wood-based panels (and articles made from them, such as furniture) installed in new dwellings.

Therefore, SEAC considers that the benefits of the proposed restriction could be higher than assessed by the Dossier Submitter since it also reduces formaldehyde releases from articles other than wood-based panels.

Key elements underpinning the SEAC conclusion(s) on *benefits* associated with the restriction proposed by the Dossier Submitter:

SEAC based its conclusions on benefits on the following considerations:

- Even if the exposure from other permanent sources has been considered as a background exposure, the analysis of the benefits carried out for this restriction only focuses on class E2 wood-based panels assumed to be installed in new homes without considering that such panels could be installed in old homes being renovated. However, SEAC recognises that such an assumption does not affect SEAC's conclusion on benefits.

- Additional benefits, which were not included in the assessment made by the Dossier Submitter, could come from avoiding the exposure resulting from other consumer articles releasing formaldehyde in indoor air.

- Benefits were not monetized in the Background Document by, for instance, calculating the avoided costs of illness related to the main endpoints (skin and eyes irritations) or by using estimates of willingness-to-pay for formaldehyde emission reduction.

Overall, SEAC considers that all these remarks do not affect SEAC's conclusion on benefits.

SEAC conclusion(s) on *benefits* associated with limit values proposed by RAC:

SEAC takes note of the RAC proposal to reduce the limit values proposed by the Dossier Submitter from 0.124 mg/m^3 for articles in scope and from 0.1 mg/m^3 for vehicle cabin interiors to an overall value of 0.05 mg/m^3.

SEAC acknowledges the potential additional benefits arising from the RAC proposal in terms of reduced exposure and associated reduction in the risk of eyes and upper airways irritations that may lead to nasal cancers. SEAC notes, however, that the risk reduction was not quantified and that the magnitude of any additional benefits is currently not known.

Key elements underpinning the SEAC conclusion(s) on *benefits* associated with limit values proposed by RAC:

SEAC considers that the lower limit value proposed by RAC implies an additional reduction of consumer exposure to formaldehyde which in turn a further reduction in the risk of eyes and upper airways irritations that may lead to nasal cancers. SEAC notes that the additional human health benefits from the lower limit value proposed by RAC currently remain unquantified as the reduction in risk associated with lowering the limit value was neither quantified by RAC nor by the Dossier Submitter. Therefore, SEAC does not have sufficient information to assess the magnitude of the additional human health benefits associated with the limit value proposed by RAC.

Therefore, also for the benefits, SEAC invites Member States, NGOs and any other stakeholder to submit, during the consultation on this SEAC draft opinion, any available information on additional benefits that would arise from a potential restriction with the limit value proposed by RAC. Gathering this information would facilitate SEAC's assessment of the proportionality of the RAC proposal.

Other impacts of the restriction proposed by the Dossier Submitter

Summary of proposal:

Social impacts: Although the proposed restriction applies to all articles that may release formaldehyde in indoor environments, the Dossier Submitter has limited the assessment of potential impacts of the proposed restriction to various relevant actors in the supply chain of wood-based panels. This choice is justified by the fact that this is expected to be the sector most affected by the proposed restriction. Relevant impacts are identified for both EU and non-EU manufacturers of non-compliant wood-based panels as well as downstream users of panels. To the extent that impacts on these actors lead to costs for EU society, they are considered as economic impacts. Other actors discussed are producers of formaldehyde and formaldehyde-based resins, exporters of wood-based panels and SMEs. Any effect of the proposed restriction on these actors are however expected to be limited.

Wider economic impacts: According to the Dossier Submitter, the proposed restriction would have minor impacts on article prices of class E1 wood-based panels. As such, international trade flows are likely to remain unchanged and no substantial wider economic impacts are expected as a result of the restriction. No wider impacts on the economic growth or development, changes to competition with the EU or direct impacts on the macroeconomic stabilisation have been identified by the Dossier Submitter for the case that the proposed restriction was implemented.

Distributional impacts: The Dossier Submitter expects any negative impacts on manufacturers and importers of class E2 wood-based panels to be offset by gains by manufacturers and importers of class E1 wood-based panels. As the vast majority of wood-based panels placed on the EU market already complies with the formaldehyde emission class E1 and therefore with the proposed restriction, these distributional impacts are expected to be limited.

SEAC conclusion(s) on *other impacts* of the restriction proposed by the Dossier Submitter:

SEAC notes that from the proposed restriction only limited **social impacts** can be expected, namely for the actors of the wood-based panels industry.

SEAC considers that only minor **wider economic impacts** on the macroeconomic stability and growth and on the international and European competition (limited changes on article prices as well as on trade flows) can be expected from the proposed restriction.

SEAC considers that **distributional impacts** can be expected to be limited with some negative impacts on manufacturers and importers of class E2 wood-based panels and some positive impacts on manufacturers and importers of class E1 panels. SEAC notes that the proposed restriction is expected to have limited impacts on small and medium-sized enterprises as most wood-based panels producers in the EU already subscribed to the voluntary industry agreement of producing only class E1 panels.

Therefore, overall, SEAC concludes that social, distributional and wider economic impacts of the restriction as proposed by the Dossier Submitter are negligible.

Key elements underpinning the SEAC conclusion(s) on *other impacts* of the restriction proposed by the Dossier Submitter:

Concerning **social impacts**, SEAC conclusions are based on the fact that the proposed restriction mainly affects actors in the supply chain of wood-based panels as this sector is the most affected. No unemployment effects are expected as a result of the proposed restriction, because it is assumed that wood-based panel factories will continue their activity by putting their production in conformity with the proposed limit. Accordingly, the supply chain should not be affected by any social consequence in terms of unemployment. The consultation did not contradict this view.

The **economic impacts** for the EU associated with the switch from class E2 to class E1 panel production will depend on the capacity of non-EU manufacturers to pass through increased production costs down to EU consumers. Only the part of the extra costs passed through to EU consumers represents a cost to EU society. However, even if the distribution of these costs between non-EU manufacturers and EU consumers is not known, most probably, due to international competition, extra costs of imported articles would be mainly borne by non-EU manufacturers rather than EU consumers.

Moreover, the economic impacts of the proposed restriction are not of such a magnitude to imply **wider economic impacts** in terms of article prices, as well as on international trade and on macroeconomic stability and growth.

Concerning **distributional impacts** for the wood-based panels industry, SEAC conclusions are based on the fact that most wood-based panels placed on the EU market already comply with the emission limit of the proposed restriction since a vast majority are already class E1 panels. For manufacturers and importers of class E1 panels some positive impacts are to be expected as they have already consolidated markets in terms of, for instance, clients, point of sales, marketing activities, etc.

As far as downstream users of class E2 wood-based panels, such as construction industry, furniture manufacturers, producers of laminate flooring, and consumers are concerned, some

higher costs are expected for purchasing more expensive class E1 panels, as reflected in the estimate of production costs by the Dossier Submitter.

Overall proportionality

Summary of proposal:

The Dossier Submitter considers the proposed restriction as proportionate to the risk. This conclusion is based on an examination of the proposed restriction's cost-effectiveness, which compares compliance costs with the number of homes or individuals in the EU that could potentially benefit from formaldehyde concentrations below the WHO guideline value. For a reference year, 2016, the resulting costs of achieving formaldehyde concentrations below the WHO guideline value – €93 per affected home and €41 per affected individual (central estimates) – are considered marginal compared to the costs of a new dwelling.

RAC and SEAC conclusion(s):

RAC

See RAC opinion.

SEAC

Proportionality of the restriction proposed by the Dossier Submitter

Based on the assessment carried out by the Dossier Submitter in the Background Document for the proposed restriction, SEAC considers that the benefits deriving from limiting formaldehyde emissions from consumer articles can be achieved at limited costs for EU society, taking into consideration the addition of the Appendix X on testing conditions which minimises the potential additional costs for industries other than the wood-based panels industry. Therefore, SEAC agrees with the Dossier Submitter that the proposed restriction, is proportionate to the risk.

Proportionality of the restriction with the limit value proposed by RAC

SEAC cannot currently conclude on the proportionality of the RAC proposal due to information gaps, in particular with regard to the additional human health benefits associated with the limit value proposed by RAC.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC

See RAC opinion.

SEAC

Proportionality of the restriction proposed by the Dossier Submitter

SEAC based its conclusions on the fact that from the restriction as proposed by the Dossier Submitter only limited costs are expected for the EU society to get the benefits (even if limited) associated with the proposed restriction due to the following considerations:

- The vast majority of the European industries of wood-based panels and furniture are already complying with the E1 limit value proposed in the restriction due to the existence of several national regulations and self-commitments.

- Only few other consumer articles on the EU market would release formaldehyde over

the proposed limit value and their contribution to the overall emissions in indoor environments is expected to be minor.

- The automotive sector has already voluntary agreements and stringent standards in place which are in line with the Dossier Submitter's proposal.

- Other categories of articles are expected to have limited impacts, if any, as either formaldehyde-based substances are not added in the production process or because they already comply with the E1 limit value proposed by the restriction.

Proportionality of the restriction with the limit value proposed by RAC

SEAC acknowledges that a restriction with a lower limit value would potentially entail higher benefits. SEAC also notes that, from the comments received in the consultation, significant socio-economic impacts are anticipated by the industry to attain the limit value of 0.05 mg/m^3.

In order to compare the costs and benefits of a restriction at a limit value of 0.05 mg/m^3 as proposed by RAC with those of the restriction proposed by the Dossier Submitter in the Background Document, SEAC compiled Table 1 below. Table 1 provides an overview of the current quantitative and qualitative information available and underlines the remaining information gaps. As mentioned above, SEAC would like to remind interested parties that further information can be submitted during the consultation on the SEAC draft opinion.

Table 1: Costs and benefits for the RAC proposal and the Dossier Submitter proposal

	Restriction proposed by DS (limit value 0.124 mg/m³ for articles in scope and 0.1 mg/m³ for interiors of road vehicles and aeroplanes)	**Restriction proposed by RAC (limit value 0.05 mg/m³ both for articles in scope and interiors of road vehicles)**
Costs	**€93**/new dwelling (i.e. **€41**/individual) Order of magnitude **millions**	Higher production and investment costs (investments in new production processes and equipment, decrease in production and higher prices for alternatives) Testing costs for new certifications In some cases production shutdowns associated with revenue and job losses Negative impacts on wood recycling and the environment Precise quantitative information for all affected sectors is missing but order of magnitude **billions** (according to information provided by industry in the consultation)
Benefits	300 000 dwellings (690 000 individuals) per year could benefit from exposure reductions to values below the WHO guideline value which can help to avoid irritation of eyes and upper airways and (in case of very high exposure) nasal cancer	Potentially additional benefits in terms of reduced exposure and associated reduction in the risk of eyes and upper airways irritations that may lead to nasal cancers but not quantified **Information gap**
Proportionality	Proportionate	Cannot currently conclude due to information gaps, in particular on benefits

Uncertainties on proportionality

RAC

See RAC opinion.

SEAC

Uncertainties on proportionality of the restriction proposed by the Dossier Submitter

SEAC considers that several uncertainties are present in the socio-economic assessment (see dedicated paragraph on uncertainties below), nevertheless they do not challenge the overall conclusion on costs, benefits and proportionality of the proposed restriction.

SEAC acknowledges that, in order to reduce the level of the existing uncertainties, in the development of this restriction proposal, both for the exposure and the assessment of socio-economic impacts related to wood-based articles, the Dossier Submitter made several plausible assumptions.

However, SEAC considers that, overall, the socio-economic impacts, which were calculated by the Dossier Submitter only for the wood-based panels, could be slightly underestimated

because the proposed restriction also affects industries manufacturing or importing articles other than wood-based panels emitting formaldehyde above the proposed limit. However, SEAC notes that costs could also be underestimated as they only refer to wood-based panels.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter considers the proposed restriction practical, because it is implementable, manageable and enforceable.

The restriction proposal is considered implementable (within the timeframe of 12 months) and manageable because the measures proposed are, to a large extent, already applied in the EU as a result of voluntary agreements in specific industry sectors and national legislation in a number Member States that is broadly in line with the restriction proposal.

It is considered enforceable because some Member States (e.g. Austria, Denmark, Germany, Italy and Sweden) have already implemented or are planning to implement legislation to limit formaldehyde emissions from specific categories of articles, in particular wood-based products. Formaldehyde emission limits are therefore already enforced in a number of Member States and chamber tests (performed in accordance with EN 717-1 or under similar conditions) are prescribed to enforce the legislative requirements. Chamber tests as well as other test methods exist to monitor the release of formaldehyde from articles and enforcement authorities have already experience in applying them. Enforcement authorities of other Member States can therefore set up an efficient supervision mechanism to monitor compliance with the proposed restriction.

RAC and SEAC conclusion(s):

RAC and SEAC consider that **enforcement** authorities of Member States without national regulations in place to limit formaldehyde emissions from articles can monitor compliance with the proposed restriction in the same way as Member States already having such national regulations in place by know-how transfer.

RAC

See RAC opinion.

SEAC

Implementability and enforceability of the restriction proposed by the Dossier Submitter

Supported by the absence of comments in the consultation, SEAC considers that for the wood-based panels industry, the emission limit proposed by the Dossier Submitter (0.124 mg/m^3) is implementable within the timeframe of 12 months after entry into force of the proposed restriction giving sufficient time for the market to comply. Moreover, SEAC considers that compliance with the proposed restriction will be manageable also by the other main European industry sectors affected by the proposed restriction.

For the **enforceability** of the limit of the proposed restriction for the **wood-based panels,** SEAC concludes that enforcement authorities of other Member States will also be able to enforce.

In line with the Forum advice, SEAC considers that **enforceability for other** types of **articles** is possible considering that the introduction of Appendix X provides enough flexibility with regards to testing by allowing different suitable test methods and correlating them to the

reference conditions.

SEAC considers that, after initial efforts to establish suitable correlations, the restriction will be practicable without major negative long-term impacts on industry.

Key elements underpinning the RAC and SEAC conclusion(s):

RAC

See RAC opinion.

SEAC

Implementability and enforceability of the restriction proposed by the Dossier Submitter

SEAC based its conclusions on the **compliance** with the proposed transition period and on the **manageability** of the proposed restriction on the following elements:

- Large part of the wood-based panels industry is already in compliance due to the fact that voluntary agreements and national legislations already exist.
- Other relevant industry sectors such as furniture and automotive have already signed voluntary agreements to reduce formaldehyde emissions.
- If not challenged by the consultation, for articles other than wood-based panels for which no voluntary agreements nor national regulations are in place, formaldehyde emissions can be expected to be already below the proposed emission.

For **wood-based panels** and for other categories of articles, SEAC based its conclusions on the **enforceability** of the proposed limit value by EU enforcement authorities on the fact that eight Member States, having national regulations in place, are already enforcing similar limit values by using already existing test methods such as chamber tests and other testing methods in accordance with EN 717-1 or under similar conditions. Therefore, SEAC is of the opinion that for such articles National Enforcement Authorities of other Member States will also be able to enforce this restriction.

In line with the Forum advice on **sampling and sampling preparation**, SEAC based its conclusions on the **enforceability** of the proposed restriction **for articles other than wood-based panels** on the following elements:

- EN 717-1 is a complicated and expensive method and for the enforcement authorities not suitable for every article, because it is specifically designed for wood-based panels.
- For sampling and preparation, EN 326-1 referred to by EN 717-1 is adapted to wood-based panels (or at least flat samples).
- EN 14080 is a sampling method available for glulam beams, nevertheless no further standards are established for sampling other articles.
- For specific purpose sampling and testing for other types of articles, for instance articles with large dimensions/very small pieces, it seems important to set up technical rules how to get representative samples from these articles.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

According to the Dossier Submitter, the effectiveness of the proposed restriction could be monitored by quantifying, over time, the amount of EU-manufactured and imported articles with compliant formaldehyde emissions compared to the current situation.

RAC and SEAC conclusion(s) on monitorability:

Based on the information provided in the Background Document as well as on the information gathered during the consultation, RAC and SEAC agree that **monitoring** compliance of **wood-based panels**, furniture and other EU-manufactured and imported articles with the formaldehyde emission limit as set in paragraph 1 of the restriction entry can be done over time by using test methods in accordance with the conditions specified in Appendix X.

Key elements underpinning the RAC and SEAC conclusion(s) on monitorability:

RAC

See RAC opinion.

SEAC

Monitorability of the restriction proposed by the Dossier Submitter

For wood-based panels, and consequently for wood-based furniture, SEAC conclusions are mainly based on the fact that, at present, the limit of this restriction is already monitored due to the existing national regulations and testing standards.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter identified a number of uncertainties in the exposure assessment. On the one hand, these uncertainties relate to the assumptions made in setting up the exposure scenario, in particular assumptions regarding loading factors, emission reductions from covering materials and climatic conditions. On the other hand, they concern the scoping choices made, particularly with regard to the non-consideration of temporary emission sources and mixtures.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

Justification for the opinion of SEAC

Summary of proposal:

Uncertainties in the impact assessment, as identified by the Dossier Submitter, mainly relate to the lack of information about class E2 wood-based panels in terms of market volume, emissions and productions costs. Other sources of uncertainty concern the ability of non-EU manufacturers to pass through costs to EU consumers, testing costs, as well as the extent to which class E2 panels are concentrated in a number of homes. The Dossier Submitter also recognises that the focus of the impact assessment on wood-based panels, despite the wider scope of the restriction proposal, introduces some relevant uncertainties.

SEAC conclusion(s):

SEAC considers that some of the uncertainties associated with the restriction proposed by the Dossier Submitter were clarified during the consultation, namely on the (minor) impacts on industries manufacturing or importing articles other than wood-based panels.

SEAC considers that the remaining uncertainties do not challenge the overall conclusion on costs, benefits and proportionality of the restriction as proposed in the Background Document.

As far as a potential restriction with a limit value of 0.05 mg/m^3 (both for articles in scope and for interiors of road vehicles) as proposed by RAC is concerned, SEAC considers that the main uncertainty relates to the lack of information with regard to the level of risk reduction capacity of such a limit which determines the benefits of this measure. This uncertainty is of such a magnitude that it makes it impossible to conclude on the proportionality of the RAC proposal.

Key elements underpinning the SEAC conclusion(s):

The uncertainties related to the socio-economic assessment carried out by the Dossier Submitter concern the extent to which:

- the assumption made by the Dossier Submitter in terms of emissions and production costs on the EU total market volume of manufactured and/or imported class E2 panels is reliable in the absence of exact information.

- the assumption made by the Dossier Submitter on production costs difference of 10 % between E1 and E2 panels is a reliable figure in the absence of market information for class E2 panels. To quantify the production cost, the Dossier Submitter made an approximation based on industry information that class E1 panels are 10-15 % cheaper in production than lower emitting E.LES panels. In the absence of more precise information on this difference, the Dossier Submitter assumes it to be 10 %. SEAC concludes that it is reasonable to assume that the 10 % cost difference is an upper bound and hence it represents a conservative estimate of economic impacts as an emission reduction from E2 level to E1 level is more easily achievable than from E1 level to the even lower E.LES level.

- non-EU manufacturers will pass through the additional costs to EU consumers. Even if it seems reasonable to consider that, due to price competition, non-EU manufacturers will not be able to pass through any additional costs to EU consumers, SEAC notes that this possibility cannot be excluded. To address this uncertainty, the Dossier Submitter carried out a sensitivity analysis for the estimation of economic impacts assuming different shares of extra costs passed through to EU consumers (50 % or 100 %) which brings the estimation of economic impact amounts to €53 million and €79 million, respectively. The costs per home to ensure the WHO guideline value would be €178 (50 % pass through) and €263 (100 % pass through). These values are still considered marginal relative to the costs of a new dwelling.

- all the class E2 wood-based panels are used only in indoor building and construction and not outdoor.

- the entire volume of class E2 panels for building and construction purposes is concentrated in a number of new houses as assumed by the Dossier Submitter. However, even if the installation of a mixture of E1 and E2 panels for construction purposes cannot be excluded, usually panels can be expected to be bought in batches.

- the class E2 panels would be installed only in newly built homes and not in the recent renovation of ancient houses. This would result in a different stock of dwelling to be taken as a basis for the calculations.

- the assumption made by the Dossier Submitter that costs and benefits for producers and extra-EU importers of wood-based panels for the reference year 2016 would be representative for impacts occurring in future years taking into consideration that trends in the construction sector might change quite quickly.