Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on skin sensitising substances

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About this report

The preparation of this restriction proposal on skin sensitising substances in textile, leather, fur and hide was initiated on the basis of Article 69(1) of the REACH Regulation.

The proposal consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of Annexes with more detailed information, analysis and references underpinning the report.

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Swedish Chemicals Agency (hereafter referred to as the Dossier Submitter) would like to thank the numerous stakeholders that made contributions to the call for evidence, the questionnaire and from bilateral discussions leading to the development of this report.

This report has been reviewed for confidential information and any such information has been redacted.

Version 1.0 of this document was published on ECHA:s website on 2019-04-25. Version 1.1 of this document was published on 2019-05-28 and includes minor revisions related to references. Additional editorial revisions were also made to improve the overall readability and clarity of the restriction proposal. Version 1.2 of the document was published on 2019-06-19, at the start of the public consultation, and includes minor editorial revisions to improve clarity and readability of the restriction proposal.

Table 1: Glossary Table with definitions of terms used in the context of this restriction proposal

Term	Definition in the context of this restriction proposal
'Consecutive patients'	Means the enrollment into a study of all patients for a particular diagnosis during a defined period of time. The term conveys that selection bias did not affect the decision of which patients to include.
'Footwear'	As defined in accordance with Directive 94/11/EC *on labelling of materials used in the main components of footwear for sale to the consumer* (called Footwear Directive), means all articles with applied soles designed to protect or cover the foot, including parts marketed separately such as: o 'upper' is the outer face of the structural element which is attached to the outer sole o 'lining and sock' are the lining of the upper and the insole, constituting the inside of the footwear article o 'outer sole' is the bottom part of the footwear article, which is subjected to abrasive wear and attached to the upper. Footwear in accordance with Directive 94/11/EC includes outer sole, lining and sock, insole, and upper. It excludes second-hand, worn footwear, protective footwear covered by Directive 89/686/EEC and toy footwear.
'Lifetime prevalence'	Measure of prevalence estimated over lifetime.
'Patch test'	A diagnostic medical test normally used to assess evidence of skin sensitisation in humans.
'Prevalence'	Measure of a health state of one population (general population for example), providing the number of cases of diseases at one given time (one year for example) or short period (5 years for example) and for one given place (one country for example).
'Sensitisation', 'skin sensitisation'	The definition of sensitisation and skin sensitisation herein is taken from Regulation (EU) No 1272/2008 (CLP) where it is stated that the development of skin sensitisation includes two phases. First, an allergenic substance primes the immune system (induction). The second phase (elicitation), takes place after re-exposure to the allergen and is associated with the manifestation of allergy, i.e. the allergic contact dermatitis (ACD). The induction phase is without visible symptoms and is irreversible. Usually, for both skin and respiratory sensitisation, lower levels are necessary for elicitation than are required for induction.
'Skin sensitiser'	Means a substance that will lead to an allergic response following skin contact, as defined in Regulation (EU) No 1272/2008 (CLP).
'w/w'	Weight/weight, means the proportion of a chemical substance in the textile or leather matrix, as measured by weight or mass (for instance mg chemical substance per kg matrix).

Summary

Brief title: Restriction on skin sensitising substances in clothing and footwear and other articles with similar skin contact

This restriction proposal aims at reducing the risk for the general public to become sensitised via the skin to chemical substances in finished clothing, footwear, other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather and disposable articles that are placed on the market for the first time[1].

There is a growing concern at European level and worldwide about skin sensitisation of the general population due to exposure to chemicals in textile and leather articles. The number of individuals already sensitised to chemical substances present in finished textile and leather articles in the EEA31[2] general population is estimated by the Dossier Submitter to be between 4 and 5 million, which corresponds to 0.8%-1% of the general population in the EEA31[3]. The number of new (incident) cases of sensitisation to chemicals present in textile and leather are estimated by the Dossier Submitter to be between 45 000 and 180 000 per year, corresponding to 0.01%-0.04 % of the general EEA31 population annually[4].

Skin sensitisation is a health effect which leads to a lifelong sensitivity to a specific allergen. Also cross-reactivity to other allergens can occur. The definition of skin sensitisation in this proposal is taken from Regulation (EU) No 1272/2008 (CLP), where it is stated that the development of skin sensitisation includes two phases. First, an allergenic substance primes the immune system. This induction phase is without visible symptoms and is irreversible, and is thus responsible for the lifelong sensitivity to the allergen. The second phase, the elicitation phase, takes place after re-exposure to the allergen and is associated with the manifestation of the allergy, the so-called allergic contact dermatitis (ACD). The ACD is reversible, given that the exposure is avoided. It is generally considered that a lower level of exposure to the allergen is required for elicitation than for induction. Currently, the only detectable and measurable health effect of skin sensitisation in humans is the elicitation phase, or the ACD. Measures of prevalence and incidence are therefore related to the manifestation of ACD.

Once a person is sensitised to an allergen, he or she must avoid exposure to the allergen for the rest of their life in order to prevent allergic reactions. Data show that there is no difference in the prevalence of contact allergy between children and adults. This means that sensitisation can occur at a very young age. A factor contributing to the problem with skin sensitising substances in textile and leather article specifically, is the difficulty to avoid exposure, as clothes and footwear must be worn on a daily basis over the whole lifetime. This may be particularly problematic if the sensitised individual is unaware of which allergen he or she is reacting to.

The Dossier Submitter concludes that the risk with skin sensitising substances in clothing, footwear and other articles with similar skin contact is currently not adequately controlled. An analysis of several risk management options (RMOs) is therefore conducted in order to identify

[2] The 31 states of the European Economical Area, i.e. the 28 EU Member States plus Iceland, Lichtenstein and Norway. According to Eurostat, the EEA31 counted 518 061 408 inhabitants on 01/01/2018.

[3] These estimates of prevalent cases are based on scientific literature, presented in section 2.4.2 and in more details in Annex E.5. A summary of incidence and prevalence data are provided below under section 1.1.2.

[4] Likewise, these estimates of incidence cases are based on scientific literature, presented in section 2.4.2 and in more details in Annex E.5. A summary of incidence and prevalence data are provided below under section 1.1.2.

the most appropriate measure to address the risk and to define the scope and conditions of the restriction proposal. It is concluded that restriction under REACH is the most appropriate RMO. Three restriction options are further analysed in the impact assessment. They all aim at limiting skin sensitising substances at specified concentrations in clothing, footwear and other articles with similar skin contact placed on the market for the first time, but differ in which substances are covered.

The restriction options further assessed are the following:

- Restriction option 1a (RO1a[5]): Limiting concentrations of substances with a harmonised classification as skin sensitisers in Category 1/1A/1B, as listed in Annex VI to the CLP Regulation, and of disperse dyes indicated to cause allergic contact dermatitis, but with no harmonised classification as skin sensitisers. The latter substances are listed in Table 2.
- Restriction option 2 (RO2): Limiting concentrations of substances with a harmonised classification as skin sensitisers in Category 1/1A/1B, as listed in Annex VI to the CLP Regulation only (i.e. no additional list).
- Restriction option 3 (RO3): Limiting concentrations of disperse dyes only (covering those with harmonised classification as skin sensitisers in Category 1/1A/1B, according to the CLP Regulation, as well as the disperse dyes listed in Table 2).

Restriction options RO1a and RO2 cover chemical substances with harmonised classification as skin sensitisers, as listed in Annex VI to the CLP Regulation. The Dossier Submitter considers these substances to have the potential to induce ACD if present in clothing, footwear and other articles that come in contact with the skin. Restriction options RO1a and RO2 have a dynamic link to the CLP Regulation, which means that any substance newly included in Annex VI to the CLP Regulation due to skin sensitising properties will after the entry into force also be covered by this restriction. This design will prevent from replacing one skin sensitising substance in a textile or leather article with another skin sensitising substance, and thereby both the risk reduction capacity and the associated health benefits of the restriction are expected to be higher.

In addition to disperse dyes with harmonised classifications as skin sensitisers in Category 1/1A/1B, restriction options RO1a and RO3 both also cover a list of disperse dyes considered to have skin sensitising properties but with no harmonised classification as such yet (see Table 2 and section 1.1.4.3.). These dyes have been indicated to be allergenic to skin by inclusion in voluntary schemes (OEKO-TEX, GOTS, Bluesign[6]), and the scientific literature (Malinauskiene et al., 2013; Isaksson et al., 2015) or by patch testing with patients with suspected allergy to substances in textile articles (Anses, 2018). The Dossier Submitter therefore considers these substances to have the potential to be sensitising to skin if they are present in clothing, footwear and other articles that come in contact with the skin. As a consequence, by including these substances in the scope, RO1a and RO3 will also prevent from regrettable substitution.

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[5] Another similar restriction option (RO1b) was also analysed but not taken forward in the impact assessment. More information on the restriction options analysed is found in Chapter 2.2 of this main report.

[6] https://www.oeko-tex.com/media/init_data/downloads/STANDARD%20100%20by%20OEKO-TEX%C2%AE%20%20Limit%20Values%20and%20Individual%20Substances%20According%20to%20Appendices%204%20_%205_fr.pdf
https://www.bluesign.com/industry/infocenter/downloads/BSSL_v9.0.pdf
https://www.global-standard.org/images/GOTS_Documents/GOTS_Standard_5.0_EN.pdf

More information on the RMOs and the restriction options assessed is found in Sections 2.2.1, and 2.2.4 to 2.2.7.

Proposed restriction

On the basis of an analysis of the effectiveness, proportionality, practicality and monitorability of RO1a, RO2 and RO3, and the impact assessment performed, the following restriction is proposed:

Proposed Restriction: RO1a

Substances	Conditions of the restriction
Substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in Annex VI to Regulation (EC) No 1272/2008 The substances listed in Table 2	1. Shall not be placed on the market for the general public in any of the following articles: i. Clothing and related accessories ii. Textile, leather, fur, hide and synthetic leather articles other than clothing which come into contact with the human skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing, such as: • bed linen (e.g. sheets, duvet covers, pillow cases), • blankets, throws, • upholstery (coverings on chairs, armchairs and sofas, car seats, etc.) • cushion covers, • bathrobes, towels, • re-usable nappies and re-usable sanitary towels, • napkins and table linen, • childcare and children products other than toys (valances, babies' nests, babies' deckchairs, bibs, baby car seats, etc.), • sleeping bags, • yarn and fabrics intended for use by the final consumer , • bags like handbags, backpacks, • carpets, mats and rugs, • fashion accessories (e.g. wristwatch straps, necklaces, bracelets, etc.) iii. Disposable sanitary towels, napkins, tissues and nappies

	iv. Footwear if, they contain the substances in a concentration equal to or above the concentration specified in paragraphs 2 and 3. 2. The articles listed in paragraph 1 shall not contain substances (meaning exceeding the detection limit) belonging to the group of "disperse dyes", with harmonised classification as skin sensitisers in category 1, 1A or 1B in Annex VI to Regulation (EC) No 1272/2008, or listed in Table 2. 3. The articles listed in paragraph 1, shall not contain the following substances equal to or above concentrations specified below: i. Chromium VI compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 1 mg/kg w/w for all materials specified in paragraph 1 (after extraction, expressed as Cr VI that can be extracted from the material except for leather, fur and hide where the concentration is 1 mg/kg (0,0001 % by weight) of the total dry weight of the leather, fur or hide) ii. Formaldehyde in concentration greater than 30 mg/kg w/w for all materials specified in paragraph 1 iii. 1,4 paraphenylene diamine in concentration greater than 250 mg/kg w/w in textile and 80 mg/kg in leather, hides and furs iv. Nickel compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 120 mg/kg w/w in textile and 40 mg/kg in leather, hides and furs (after extraction, expressed as Ni metal that can be extracted from the material) v. Cobalt compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B

	listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 70 mg/kg w/w in textile and 20 mg/kg w/w in leather, hides and furs (after extraction, expressed as Co metal that can be extracted from the material) vi. Substances not covered by paragraph 3 i-v and with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008, in individual concentration greater than 130 mg/kg in textile and 40 mg/kg in leather, hides and furs. 4. Paragraphs 1 to 3 shall apply without prejudice to the application of any stricter restrictions or existing regulations. 5. Paragraphs 1 to 3 shall not apply to i. Clothing, related accessories, textile, leather, fur, hide or synthetic leather articles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**) ii. Substances that are used as active ingredients in biocidal products within the scope of Regulation (EU) 528/2012. iii. The placing on the market of second-hand clothing, related accessories, textile, leather, fur hide and synthetic leather articles other than clothing, or footwear which were in end-use in the Union before 31 January 2023. 6. When existing, the standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 to 3. (*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and

	repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51) (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'

Table 2: List of additional substances of concern

Substance name	CAS No.	EC No.
CI Disperse Blue 3	2475-46-9	219-604-2
CI Disperse Blue 7	3179-90-6	221-666-0
CI Disperse Blue 26	3860-63-7	223-373-3
CI Disperse Blue 35	12222-75-2	602-260-6
CI Disperse Blue 102	12222-97-8	602-282-6
Ci Disperse Blue 106[7]	68516-81-4	271-183-4
CI Disperse Blue 124[8]	15141-18-1	239-206-6
CI Disperse Blue 291	56548-64-2	260-255-0
CI Disperse Brown 1	23355-64-8	245-604-7
CI Disperse Orange 1	2581-69-3	219-954-6
CI Disperse Orange 3	730-40-5	211-984-8
CI Disperse Orange 37 /59/76	13301-61-6 12223-33-5 51811-42-8	236-325-1 602-312-8
CI Disperse Red 1	2872-52-8	220-704-3
CI Disperse Red 11	2872-48-2	220-703-8
CI Disperse Red 17	3179-89-3	221-665-5
CI Disperse Yellow 1	119-15-3	204-300-4
CI Disperse Yellow 9	6373-73-5	228-919-4
CI Disperse Yellow 23	6250-23-3	228-370-0
CI Disperse Yellow 39	12236-29-2	602-641-7
CI Disperse Yellow 49	54824-37-2	611-202-9
CI Disperse Yellow 64	10319-14-9	233-701-7
CI Disperse Orange 149	85136-74-9	400-340-3
CI Disperse Violet 1	128-95-0	204-922-6
CI Disperse Violet 93	268221-71-2	-

A transitional period of 36 months after its entry into force is proposed.

Summary of the justifications:

The restriction proposal is based on the following considerations:

- Substances whose hazard profile suggests that exposure lead to skin sensitisation should not be present in clothing, footwear and other articles in skin contact made of

[7] The former CAS/EC numbers for the CI Disperse Blue 106 are 12223-01-7/602-285-2
[8] The former CAS/EC numbers for the CI Disperse Blue 124 are 61951-51-7/612-788-9. In September 2019, German authority BAuA submitted a proposal for harmonised classification of C.I. Disperse Blue 124 as Skin Sens. 1A with a SCL of 0.001%.

textile, leather, fur, hide and synthetic leather placed on the market for the general public.

- The quantitative risk assessments of substances that can be found in clothing, footwear and other articles in close skin contact made of textile and leather articles, on the basis of reasonable exposure estimates, demonstrate the need to take action.
- The risk identified for disperse dyes is preferably managed by a total ban (not exceeding the detection limit), since the derived concentration limits are below the current quantification limit for disperse dyes (30-50 mg/kg) and their substitution is technically feasible at low cost.
- The risk identified for skin sensitisation to substances other than disperse dyes is preferably managed by setting concentration limits, since a total ban may hamper the production of clothing, footwear and other articles in close skin contact made of textile and leather articles.
- The concentration limits should aim at preventing elicitation reactions. The threshold dose of elicitation reactions is lower than that of induction. This means that a concentration limit in clothing, footwear and other articles in close skin contact made of textile and leather which is derived to protect already sensitised individuals from manifestation of the ACD (elicitation) also will protect naïve individuals from induction.

Identified hazard and risk

The chemical substances within the scope of this restriction proposal have the potential to cause allergic contact dermatitis in individuals exposed to the substances via the skin, since the substances either have harmonised classifications as skin sensitisers or are indicated to have skin sensitising properties (by inclusion in voluntary schemes (OEKO-TEX, GOTS, Bluesign), and in the scientific literature (Malinauskiene et al., 2013; Isaksson et al., 2015) or by patch testing with patients with suspected allergy to substances in textile articles (Anses, 2018), although not having a harmonised classification as such (i.e. the disperse dyes listed in Table 2).

Elicitation threshold doses are used as reference values from which concentration limits for chemical substances in textile and leather are derived. The risk is assessed by using a semi-quantitative approach.

The amount of available information for risk assessment varies among the skin sensitising substances in the scope of the proposed restriction (RO1a). Based on the availability of substance-specific data, the derivation of concentration limits in textile and leather for the sensitising substances in the scope is divided into three approaches (see also Table 10, Section 1.2.5):

I. Quantitative, substance-specific approach: substances or groups of substances for which substance specific information for risk assessment are available.

II. Quantitative, substance semi-specific approach: substances or groups of substances for which some substance-specific information for risk assessment are available.

III. Quantitative default approach: for substances for which no substance specific information for risk assessment was found. Scientifically justified default values were used.

The resulting proposed concentration limits are shown in the table below. More information and details on hazard, exposure and risk assessments are found in section 1.2.5 and Annex B.

Table 3: Proposed concentration limits

Substance/group of substances	Quantitative risk assessment approach	Proposed concentration limit (mg/kg)	
		Textile[1]	Leather[2]
Disperse dyes	I	Ban[3]	Ban[3]
Chromium VI compounds	I	1[4]	1
Nickel and its compounds	II	120	40
Cobalt and its compounds	II	70	20
Formaldehyde	II	30	30
1,4 paraphenylene diamine	II	250	80
Other substances in scope	III	130	40

[1]Any concentration limit proposed for textile also applies for materials such as synthetic leather, rubber materials and polymer materials, prints and coatings included in the scope coming into contact with the skin to an extent similar to clothing. The concentration limits applies also to disposable sanitary towels, napkins, tissues and nappies.

[2]Any concentration limit proposed for leather also applies for hides and furs.

[3] The ban refers to the limit of detection (that should be below the calculated concentration limits of 0.1 mg/kg in textile and 0.03 mg/kg in leather).

[4] The existing concentration limit in entry 72 of REACH Annex XVII, is assumed to also protect from skin sensitisation from substances in textile in the present restriction proposal. Hence, for regulatory consistency, no concentration limit is proposed in this restriction proposal. Instead the lowest concentration limit applies which currently is 1 mg/kg for chromium VI compounds .

For most of the assessed skin sensitising substances in the scope of this restriction proposal that may be present in finished clothing, footwear and other articles with similar skin contact made of textile and leather , the concentration limits proposed are far below the highest approximated concentrations in the articles placed on the market. Hence, lowering the concentrations of these skin sensitising substances in clothing, footwear and other articles with similar skin contact made of textile and leather to the ones proposed above, is considered to significantly reduce the risk of skin sensitisation in the general population. However, there are skin sensitising substances in the scope of this restriction proposal that currently are not used in the manufacturing and processing of clothing, footwear and other articles with similar skin contact made of textile and leather , but without this restriction they could be in the future. Therefore, in order to avoid regrettable substitution, the Dossier Submitter also included these substances in the scope. In conclusion, the proposed concentration limits are considered to adequately protect the general population against the risk for skin sensitisation from exposure to chemicals in clothing, footwear and other articles with similar skin contact made of textile and leather .

It is acknowledged that the restriction proposal calls for a revision of the following existing REACH Annex XVII restrictions:

- Current restriction limits on chromium VI compounds in leather (amendment of entry 47 of Annex XVII of the REACH regulation).
- Current restriction for the Disperse Blue 1 in textile (CAS 2475-45-8, EC 219-603-7) (amendment of entry 72 of REACH Annex XVII).
- Current entry 43 of REACH Annex XVII for the mixture disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-

oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-) (CAS 118685-33-9, EC 405-665-4).

Justification that action is required on a Union-wide basis

The risks associated with EU manufactured or imported textile and leather articles containing skin sensitising substances need to be addressed on a Union-wide basis for two reasons:

a) exposure takes place in all Member States, and
b) to ensure the free movement of goods within the Union.

Effectiveness of the proposed restriction in reducing the identified risks

The proposed restriction is effective because it is targeted to the exposure that causes the risk, it is capable of reducing the identified risk in a reasonable period of time, and it is considered to be proportionate to the risk. The proposed restriction will reduce the risks to human health to an acceptable level from 2023.

Proportionality of the proposed restriction to the risks

The expected benefits (quantified and monetised) from the proposed restriction are considered substantial and the costs of compliance (partially quantified) are considered affordable to industry.

The total annual human health benefits expected from the restriction proposal is estimated between 7 and 50 billion € from 2023, with a "reasonable" estimate[9] between 10.5 and 33.4 billion €.

Costs associated to the exposure avoidance from individuals that are diagnosed with ACD acquired from textile or leather articles (search and purchase of e.g. allergens-free clothes and shoes) would also be circumvented thanks to the restriction proposed and should be part of the benefits. These costs were however not quantified.

The information needed to quantify the expected costs from this restriction proposal was not easily available to the Dossier Submitter in spite of the efforts carried out to collect it (see Annex G). A qualitative assessment in combination with a quantitative approach has been made to reflect the information at hand (see Table 17 under section 2.4.1.1). The assessment showed that the costs of compliance to the restriction are expected to be affordable to industry due to very low costs of substitution for some substances (disperse dyes in particular), ongoing substitution for others and given the fact that moving towards best practice would

[9] The annual human benefits were discounted over 80 years (2023-2103) for new ACD cases and over 30 years (2023-2053) for current cases; at 2.5% per year over 30 years, then 0.5%. For more details, please see section 2.4.2.3 and Annex E.5

contribute also to solve the issue. Enforcement costs were estimated to be higher than for an average restriction since it includes far more substances than on average.

For the skin sensitising substances used in clothing, footwear and other articles with similar skin contact made of textile and leather, and for which alternatives are identified and price and volume data exist, a total cost of substitution has been calculated. The assessment gives a total cost of substitution for all of the chemicals where cost data exists for both the substances used and the proposed substitute at around - € 25 million per year (if rosins are substituted with acrylics) or 3 million € per year (if rosins are substituted with PUR). The negative cost of € -25 million may be anticipated to be an underestimation of the cost of substitution connected to this restriction proposal. Excluding the negative costs gives a total cost of around €0.1 million per year (if rosins are substituted with acrylics) or €24 million per year (if rosins are substituted with PUR). Furthermore, the Dossier Submitter estimates that one-time costs due to reformulation of rubber accelerators are approximately € 13.3 million. Reformulation needs related to other substances have not been identified. In addition to this, testing costs due to enforcement activities have been estimated to be less than € 0.1 million per year. It has to be noted that this assessment is highly uncertain. For more details, see section 2.4.1 and Annexes E.2 and E.4.

As a consequence, the restriction proposed is considered to be proportionate to the risk. More information and details on the proportionality of RO1a is found in section 2.4.5.

Practicality and monitorability

The proposed restriction (RO1a) is considered as practicable because it is implementable, enforceable and manageable. It is also possible to monitor.

Existing national regulations on clothing, footwear and other articles with similar skin contact made of textile and leather as well as already existing restriction under REACH (on azodyes, chromium VI compounds and the recently adopted entry 72 of REACH Annex XVII) show that the clothing, footwear, textile and leather articles industry can comply with risk management based on concentration limitations. Moreover, some methods are available already for industry to test the articles to assure their compliance. For the substances for which no method is available, methods should be developed, and ideally standardised. The Dossier Submitter considers that a transitional period of 36 months will provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction since substitution is already ongoing.

The Dossier Submitter has developed a list of chemical substances used today in textile and leather articles (see Annex E, Table 20). This list can be used by enforcement authorities and industry to identify which substances to focus on in the enforcement and compliance activities.

The proposed restriction can be monitored by Member States surveillance programs and compliance controls (including RAPEX) as well as by manufacturers, importers and distributors of clothing, footwear, textile and leather articles who will have the obligation to place on the market compliant articles.

The table below presents the comparison of restriction options assessed in this restriction proposal.

Table 4 : Comparison of restriction options

	Risk reduction capacity	Proportionality	Practicality	Monitorability
Restriction Option 1a (restriction proposed)	+ + +	+ +	+ +	+ +
Restriction Option 2 (no additional list of substances of concern)	+ / + +	+	+ +	+ +
Restriction Option 3 (disperse dyes only)	+ / + +	+ +	+ + +	+ + +

Restriction options RO2 and RO3 are also considered to be proportionate to the risk; RO1a and RO3 likely to be more proportionate than RO2, such as indicated in Table 4 (for more details see section 2.7). RO3 appears to be more desirable than RO1a in terms of practicality and monitorability and it may have a better cost/benefit ratio (not quantified). Nevertheless, RO1a is the preferred option by the Dossier Submitter based on its higher risk reduction capacity. Indeed, RO1a shows the best capacity of mitigating the risk targeted in this restriction proposal, by covering a much higher number of sensitising substances and being dynamically linked to the CLP regulation (for more details on this comparative assessment, see section 2.7). Due to the higher risk reduction capacity, RO1a is expected to have a higher net benefit than RO3.

Report

1. The problem identified

1.1. Scope and general information

1.1.1. Introduction

There is a growing concern at the EU level and worldwide about skin sensitisation of the general population from exposure to chemicals in textile and leather articles, such as clothes and footwear (Lisi et al 2014; Seidenari et al, 2002). The number of individuals sensitised to chemical substances in textile and leather in the EEA31 population is estimated by the Dossier Submitter to be between 4 and 5 million, which corresponds to 0.8%-1 % of the EEA31 population[10]. The number of new (incident) cases of sensitisation to chemicals in textile and leather are estimated by the Dossier Submitter to be between 45 000 and 180 000 per year, which corresponds to 0.01%-0.04 % of the EU-28 general population annually[11]. Once a person is sensitised to an allergen, they must avoid exposure to the allergen for the rest of their life in order to prevent allergic reactions. Furthermore, data show that there is no difference in the prevalence of contact allergy between children and adults. This means that a person can get sensitised at a very young age and can be affected during their entire life. Another factor contributing to the severity of the problem is the fact that people cannot easily avoid exposure; clothes and footwear must in practice be worn on a daily basis over the whole lifetime.

It is important to note that incidences of sensitisation are likely to be underestimated because of underdiagnosis, underreporting and lack of registration for milder cases of ACD. Also, the prevalence of ACD related to chemicals in textiles and leather is reported as increasing, probably because of changed textile manufacturing techniques, due to, for instance, the use of new substances (with unknown chemical compositions) which are continuously introduced to the textile industry to meet the demands of consumers or to supply new fashionable colours, shapes and fabrics (Lisi et al 2014; Seidenari et al, 2002).

The severity of skin sensitisation may differ significantly in the affected population, ranging from situations where individuals do not suffer any symptoms to situations where medical treatment is necessary. At first, the ACD may be hardly noticeable or even recognized as an allergy, since the allergic reaction do not occur immediately upon exposure. The ACD can progress to more severe stages, particularly if the exposure is prolonged, repeated and difficult to avoid. Although the ACD subsides once the exposure is avoided, the induction is irreversible and cannot be cured, possibly leading to health effects upon every next contact with the allergen (ECHA, 2016).

Although skin sensitisation is not life-threatening, it can be very limiting for persons suffering from it. Depending on the part of the body affected and the severity of the symptoms, ACD may significantly impair the quality of life of the person, sometimes preventing him or her from working or even living normally.

[10] These estimates of prevalent cases are based on scientific literature, presented in section 2.4.2 and in more details in Annex E.5. A summary of incidence and prevalence data are provided below under section 1.1.2.
[11] Likewise, these estimates of incidence cases are based on scientific literature, presented in section 2.4.2 and in more details in Annex E.5. A summary of incidence and prevalence data are provided below under section 1.1.2.

Several reports have been published by European government authorities, e.g. the Swedish Chemicals Agency, the Danish EPA, ANSES and the BfR, which pointed out the concern and risks of hazardous substances in textiles and leather articles and made recommendations for risk reducing measures surveys (RIVM, 2010; RIVM, 2014; BfR, 2012;KemI, 2013, KemI, 2014; KemI, 2016; ANSES, 2018). These reports identified chemicals that need to be regulated, such as azo dyes, organo-tin compounds, amines, and chromium compounds. They add evidence to the available literature regarding prevalence information on skin sensitisation from allergens in textiles and footwear (more details are available in Annex A.2.1.4).

The Rapid Alert System (RAPEX)[12] weekly reports overviews of the alerts that include information on the dangerous products found, the risks identified and the measures taken in the notifying country. More precisely, this system provides information about which substance can be found in clothing, footwear and other articles with similar skin contact made of textiles, leather, fur, hide and synthetic leather and at which concentrations.

Moreover, several cases of ACD likely to be related to textile clothing or footwear have been reported by the DGCCRF[13] in France in recent years. These cases may be due to:

- Chemical substances used in the manufacture of textile articles and footwear.
- Chemical substances used during the life cycle of textile articles and footwear, particularly during shipment and for their preservation and maintenance.
- Many other factors involved when these articles are used by the general population (mechanical, physical, co-exposure to various other products).

In order to address the increasing concern for skin sensitisation in the general population, the aim of this restriction proposal is to reduce the risk for sensitisation to chemical substances in finished clothing, footwear and other articles with similar skin contact made of textile and leather, as well as in hides, furs and synthetic leather, placed on the market for the first time.

This restriction proposal does not cover skin allergy caused by the fibres themselves.

1.1.2. Background information

Information on skin sensitising substances in clothing, footwear and other articles with similar skin contact made of textile and leather[14]

In the RMOA of skin sensitising substances in textile articles on the EU market, performed by the Swedish Chemicals Agency (KemI, 2016), it was concluded that a restriction under REACH for substances with a harmonised classification as skin sensitisers in Category 1/1A/1B was

[12] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=en

[13] The Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF)

[14] In this restriction proposal, other articles made of textile and leather also include synthetic leather, fur and hides, unless specifically specified. The restriction proposal also covers disposable sanitary towels, napkins, tissues and nappies.

the most efficient option to manage the risk in the EEA31 of allergic contact dermatitis caused by skin sensitising substances in textile.

In November 2014, ANSES received a formal request from the Directorate General for Health (DGS) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) to assess the safety of footwear and textile clothing because several cases of skin allergy and/or irritation a priori relating to textile clothing or footwear had been reported by the DGCCRF[15] in recent years. The aims of this work were:

- To identify any skin irritant or sensitising chemicals liable to be found in footwear and textile articles. If other relevant chemicals are identified, other than skin irritant or sensitising substances were identified, they were also to be included in the review of knowledge;
- To conduct a review of knowledge on the risks of the substances identified. The review should comprise:
    - a review of the existing literature in order to identify the relevant routes of exposure and existing toxicity reference values relevant to consumer exposure,
    - an assessment of the prevalence of allergic phenomena attributed to the presence of these substances in textile clothing and footwear.
- To make recommendations regarding manufacture and, if applicable, preservation during shipment, with particular focus on the final consumer;
- To issue an opinion on the advisability of limiting the use of some of the substances identified;
- To propose a methodology for investigating cases of skin allergy or intolerance reported by specialist physicians, in order to gain further knowledge about the substances in question.

In 2018, ANSES published a report on safety of footwear and textile clothing. A list of 35 chemicals with known toxicity (CMR effects, skin irritation or sensitisation according to the CLP regulation or IARC classification) or with potential toxicity (skin irritation or sensitisation) was drawn up. In addition, a protocol involving a network of dermatologist-allergists and two chemical analysis laboratories was established by ANSES to identify substances responsible for cases of skin sensitisation or irritation reported by patients to physicians after wearing clothing articles or footwear (biomedical study). The implementation of the first phase of the study confirmed the occurrence of cases of contact dermatitis (allergic or irritant) in consumers after wearing of textile clothing or footwear. The analysis of each case of the first phase of the biomedical study shows that some of the cases of dermatitis can be explained by exposure to the following two groups of chemical substances:

- Substances identified in the CLP regulation (meaning with a harmonised classification) as skin irritants or sensitisers (for example 4-tert-butylphenol, formaldehyde resin, chromium VI – even at concentrations that comply with the current regulations, rosin and nickel),

- Substances without harmonised classification as skin sensitisers or irritants under the CLP regulation (for example aromatic amines).

[15] DGCCRF surveys

Those data led ANSES' experts to advice for an Annex XVII-restriction under REACH in order to reduce the use of such substances in textiles and footwear (ANSES, 2018).

Information on incidence and prevalence of ACD from clothing, footwear and other articles with similar skin contact made of textile and leather

As already mentioned, incidences of ACD are likely to be underestimated. Also, the exact incidence of ACD from substances in clothing, footwear and textile or leather articles with similar skin contact is unknown because of the lack of controlled epidemiological studies. All the information gathered from literature reviews and expert judgements (dermatologists in particular) during the elaboration of this restriction proposal on incidence and prevalence is presented in detail in Annex E.5.

From the literature and from the dermatologists consulted during the preparation of this restriction proposal:

- The prevalence of ACD in the general population (all causes) range from 4.4 % to 18.4 %, with a lifetime prevalence[16] of around 15-20 %[17].
- Annual incidence rates (new cases) of ACD in the general population (all causes) are between 0.17 % and 0.7 % per year[18].
- Prevalence studies (frequency) of positive patch tests[19] from testing with chemicals in finished textile and leather articles in adults range from 0.4 % to 17 %[20], with an average calculated by the Dossier Submitter around 5 % (more details are provided in Annex E.5).
- Based on these data, the prevalence of ACD caused by chemical substances in textile and leather articles in the general population is around 0.8-1 % (such as calculated by the Dossier Submitter; the detailed calculation is provided in Annex E.5).
- Based on these data, the incidence of ACD caused by chemical substances in textile and leather in the general population is around 0.01 % and 0.04 % per year (such as calculated by the Dossier Submitter; the detailed calculation is provided in Annex E.5).
- There seems to be no significant difference in the prevalence of ACD caused by chemical substances in textile and leather (based on allergenic disperse dyes testing in particular) between children and adults.

The Dossier Submitter does not have available information regarding prevalence and incidence of ACD triggered by substances in articles made of hides or furs specifically.

[16] Prevalence is the measure of a health state of one population (general population for example), providing the number of cases of diseases at one given time (one year for example) or short period (5 years for example) and for one given place (one country for example). Lifetime prevalence is the measure of prevalence estimated over lifetime.
[17] Based on Hermann-Kunz, 2000; Alinaghi et al, 2018; Schnuch et al., 2002; Bfr, 2006; RIVM, 2008; Thyssen, 2007; Mortz et al, 2002.
[18] Based on Schnuch et al., 2002 et Saetterstrom et al, 2014.
[19] Prevalence studies of positive patch tests mean in those studies the frequency of positive patch tests used to detect contact allergies from substances contained in textile and footwear among a population.
[20] Based on Ryberg et al, 2011; KemI 2016 RMOA (KemI, 2016a); Zug et al, 2008; Ryberg et al, 2014; Lazarov, 2004; Slodownik et al, 2011; Isaksson et al, 2015a; Bourrain, 2016; Geier et al, 2000; Nardelli et al, 2005; Hunasehally et al, 2010; KemI, 2016b; Heratizadeh et al, 2017; Lejding et al., 2016; Manzini et al, 1991; Seidenari et al, 1991; the highest values from Lisi et al (2014) and Wentworth et al (2012) being considered as outliers, as explained in Annex E.5.

However, in case hides or furs articles, such as specified in paragraph 1 of the restriction proposal entry, would contain one or more substances covered by the scope, the Dossier Submitter considers it plausible that skin sensitisation may occur. As a consequence, the prevalence and incidence data presented above also apply for hides and furs articles.

1.1.3. Chemical substances used in textile and leather articles

Clothes and shoes have been used by humans since the end of the Paleolithic to protect bodies and feet from environmental injuries and various weather conditions. In the last decades, clothes and shoes have acquired new roles and are part of the most varied fashion styles. There are different designs of clothes and shoes for different activities, for instance for sports, work and safety purposes.

Large quantities of chemical substances are used in the manufacture of clothing, footwear ,textile- and leather articles with similar skin contact. An overview of the textile production process and the kinds of substances that are used in the different steps is illustrated in Figure 1, and has been described in several other reports (FIH, 2011; KemI, 2013; Salute, 2012). A detailed overview of textile and leather manufacturing processes is provided in Annex A to this restriction proposal.

Importantly, chemical substances are used in all steps of the clothing, footwear, textile and leather processing, from the manufacture of the fibre to the finished product. Some are used upstream in the manufacturing process, such as catalysts, lubricants or detergents. These substances are not intended to remain in the articles available on the market at point of sale, but may still present as residuals or unreacted monomers. Other chemical substances are used to give the finished article a certain property, such as dyes and coatings. These are designed to remain in the article.

Chemical substances that may be present in the finished textiles articles can be divided into the following categories:

- Functional (or effect) chemicals: Intended to remain in the finished article to give the article certain properties, e.g. dyestuffs and crease resisting agents.
- Auxiliary (or process) chemicals: Not intended to remain in the finished article but may remain as an impurity. These substances are necessary for the production process to work, e.g. solvents and softeners.
- Degradation products: No function in the finished article or in the production process but present as residues or degradation products, e.g. formaldehyde released from certain resins and arylamines from certain azo dyes.

Figure 1. Overview of the textile production process and the types of chemicals used in the different steps (Roos, 2015) (© Swerea IVF)

In Figure 1 also chemical issues related to effects to the environment are indicated, such as chemical oxygen demand (COD), air emissions and fuel combustion. These chemical issues are not within the scope of this restriction proposal.

For a detailed description of each step of the processing as well as volumes of textile and leather articles and chemicals used in those, see Annex A.

1.1.4. Scope of the restriction

The intention of this restriction is to minimise the risk to the general population from skin sensitising substances in clothing, footwear and other articles with similar skin contact made of textiles, leather, fur, hide and synthetic leather.

1.1.4.1. Articles covered by the restriction

This restriction proposal covers finished clothing, footwear and articles with similar skin contact made of textile, leather, synthetic leather, hides or furs, and which are placed on the market for the first time for the general public.

Definitions deemed useful by the Dossier Submitter for the understanding of this restriction proposal are provided in the Glossary (Table 1), in the beginning of the report.

The articles covered by this restriction proposal are essentially the same as the articles covered by the recently adopted entry 72 restriction on CMR substances[21], with some additions and amendments. The list below is not an exclusive list of the articles covered.

Articles covered by the restriction proposal are the following:

- Clothing and related accessories, such as:
  - tops, shirts, blouses,
  - underwear,
  - nightwear,
  - hosiery (e.g. socks, pantyhose, stockings, leggings),
  - trousers, pants,
  - jackets, coats, rain coats, capes,
  - dresses, skirts,
  - suits,
  - sportswear (including sports equipment)*,
  - swimwear (e.g. swimsuits, bikinis, swimming trunks),
  - gloves (including latex gloves not covered by Regulation (EU) 2016/425 of the European Parliament and of the Council on Personal Protective Equipment or Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices), mittens, muffs,
  - scarves, shawls, stoles,
  - ties, cravats,
  - hats, caps, bonnets, veils,
  - fancy dress and disguise costumes (carnival costumes), other than those already regulated by Directive on Toys Safety No 2009/48/EC[22]
  - cosmetic textiles or cosmetotextiles**.

*The entry 72 of REACH Annex XVII covers “sportswear” without any more specifications. It may be common understanding that sports equipment in contact with the skin (e.g. a ski mask) are included within the “sportswear” category, together with sports clothing. Therefore, in order to avoid any misinterpretation, the Dossier Submitter believes that sports equipment in contact with the skin must be explicitly mentioned in the inclusive list of articles covered by this restriction proposal.

**Cosmetic textiles or cosmetotextiles, with microencapsulated solids or liquids intended to be released over time when the garment is in direct contact with the skin to give functions

[21] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:256:FULL&from=EN

[22] According to the Guidance document N°17 “on the application of the Directive on the safety of toys”, the TSD (Toys Safety Directive) shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age ("toys"). Carnival costumes (fancy dress and disguise costumes) are not explicitly mentioned within the TSD and they are not toys to which the TSD does not apply nor not considered as toys within the meaning of Annex I of the TSD. Carnival costumes are products used to disguise and most children also use them to play the corresponding character (e.g. cowboy, policeman, princess and witch). If they are products designed or intended, whether or not exclusively, for use in play by children under 14 years of age they should be classified as toys - of course only if they are of a size which is suitable for children under 14 years. Carnival costumes for adults are no toys in the sense of the TSD. Therefore, toy carnival costumes for children have to comply with all requirements of the TSD. These toys are covered in particular by standard EN 71-2 (partly in chapters 4.2 and 4.3). This guidance document is available at: https://ec.europa.eu/docsroom/documents/5853.

like fragrance or moisturiser, unless the microencapsulated solids or liquids are already covered by the ongoing restriction on microplastics.

- Footwear (including inner soles**)
- Textile, leather, fur, hide and synthetic leather articles other than clothing that come into contact with the skin under normal or reasonably foreseeable condition of use to an extent similar to clothing, such as:
  - bed linen (e.g. sheets, duvet covers, pillow cases),
  - blankets, throws,
  - upholstery* (fabric covering chairs, armchairs and sofas, car seats, etc.)
  - cushion covers,
  - bathrobes, towels,
  - re-usable nappies and sanitary towels,
  - re-usable napkins and table linen**,
  - childcare and children products other than toys (valances, babies' nests, babies' deckchairs, bibs, etc.)**,
  - sleeping bags,
  - yarn and fabrics intended for use by the final consumer ,
  - bags, like handbags, backpacks, briefcases,
  - carpets, mats and rugs**,
  - Fashion accessories (e.g. wristwatch straps, necklaces, bracelets, etc.)**.

*Upholstery covers several kinds of articles such as fabric covering chairs, armchairs and sofas, car seats, including those for private use and those in public facilities (hospitals, etc.) or public transportation (bus or train seats, etc.).

** Articles covered by this restriction proposal but not by entry 72 of REACH Annex XVII for the following reasons:

- Fashion accessories (e.g. wristwatch straps, bands, neck straps, etc.): entry 72 of REACH Annex XVII includes wristwatch straps in its inclusive list of articles (under clothing and related accessories). However, including wristwatch straps only might be too restrictive in terms of health protection. In the REACH restriction for Cr (VI) in leather (entry 47 of Annex XV of REACH), articles which are expected to come into prolonged contact with skin also cover other articles used in similar ways as wristwatch straps, such as wrist bands and braces. In line with restriction entry 47, wristwatch straps and similar articles (straps/bands/braces), as well as neck laces/straps/bands are included in the scope of this restriction proposal. Herein, these articles are gathered under "fashion accessories" category. These articles are accessories and fashion jewellery articles which are not made with precious metals such as "precious jewellery". Consistently with the scope of this proposal, these articles can be made of textile, leather, synthetic leather, fur or hide.

- Childcare articles other than toys (valances, babies' nests, babies' deckchairs, bibs, etc.): there is no European legislation regulating childcare articles made of textile and possible associated risks. Toys are regulated under the Toys Safety Directive 2009/48/EC which covers only products "for use in play". In the General Product Safety

Directive, there is a general obligation to place only safe products on the market-place, but for childcare articles there are no further European legislative requirements. There are some voluntary European standards dealing with the construction of furniture and childcare products (seats, chairs, etc.) but they do not address chemicals hazards. However, under the REACH Regulation, restrictions entries 51 (on DEHP, DBP and BBP) and 52 (on DIDP, DINP, DNOP) of Annex XVII define childcare articles as *"any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children"*. Consequently, childcare articles, such as defined in the REACH restriction entries 51 and 52, are covered by this restriction proposal.

- Re-usable napkin and table linen can under normal and foreseeable conditions of use be in contact with human skin. Consequently, the Dossier Submitter proposes that these articles are included in this the scope of this restriction proposal.

- Carpets, mats and rugs: these articles are not covered by entry 72 of REACH Annex XVII. Harmonised conditions for the marketing of construction products are laid down by the Construction Products Regulation (CPR) 305/2011[23]. These conditions do however not prevent restriction of carpets, mats and rugs in REACH, as the CPR does not regulate with regard to the used material. The CPR provides a common technical language to assess the performance of construction products and ensures that reliable information is available to professionals, public authorities, and consumers, so they can compare products from different manufacturers in different countries[24]. As carpets, mats and rugs, under normal and foreseeable conditions of use may lead to direct contact with the skin and adverse exposure (e.g. babies who may play on carpets for long time periods) this restriction proposal intends to cover also these articles.

- Inner soles that can be purchased separately from shoes are covered by the restriction proposal.

Futher specification on the materials and articles covered:

Prints and coatings applied directly on textile or leather article surfaces (such as decorations or logos) are covered by the restriction proposal. In the Explanatory guide to entry 72 (endorsed by CARACAL on 27 June 2018 [CA/44/2018]), it is stated that "Prints and coatings applied directly on textile article surfaces (such as decorations or logos) are covered by the restriction". To harmonise with entry 72, prints and coatings applied directly on article surfaces (such as decorations or logos) are covered by the present restriction proposal.

Articles made of synthetic leather: synthetic leather is made of non woven synthetic fibers (most often in polyamide, but also, cotton, nylon or rayon) and then captured in a resin

[23] Construction product means any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works.
[24] It does not imply approval of products and does not impose any requirements on the finished construction work. The latter is regulated in each Member State's national law.

(commonly polyurethane). This can resemble a textile surface being coated, similarily to prints and coatings described above. Synthetic leather is a common material in clothing, footwear and other articles that may come into contact with the human skin (e.g. upholstery, bags and fashion accessories). It does not contain animal fibers. These articles are included in the scope of the restriction proposal.

Articles made of neoprene, other rubber materials or other polymer materials: These materials are commonly used in clothing and footwear. To harmonise with entry 72, skin sensitising substances (e.g. plasticisers and rubber accelerators) in clothing and footwear made of these materials are covered by the present restriction proposal.

Disposable sanitary towels, napkins, tissues and nappies: 'Disposable articles' means articles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose. These articles are not covered by entry 72 of REACH Annex XVII. However, under normal and foreseeable conditions of use, these articles may be in contact with human skin and may be of concern in similar way as re-usable articles. Disposable sanitary towels, napkins, tissues and nappies are made of fibres (synthetic, paper, cellulose, etc.) and sometimes they are coloured (especially napkins). Consequently, the Dossier Submitter proposes that these articles are included in this the scope of this restriction proposal.

1.1.4.2. Articles not covered by the restriction

Articles not covered by the current restriction proposal are essentially the same as the articles not covered by the recently adopted entry 72 of REACH Annex XVII, with the exception of the articles cited above. However, one notable difference is that entry 72 of REACH Annex XVII explicitly does not cover *"clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide"*, articles which are included in the scope of the current restriction proposal.

The articles not covered by the restriction proposal are the following:

- precious jewellery,
- glasses and sunglasses,
- curtains,
- textile lampshades and wall decorations,
- filling materials in chairs, armchairs and sofas
- second-hand articles (see further explanation below),
- articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment,
- articles within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices,
- parts of footwear that do not come into contact with the human skin under normal or reasonably foreseeable conditions of use, such as underside of footwear.

Second-hand articles

According to a note on second-hand articles recently published by ECHA[25], the term 'second hand articles' refers to articles that have already been sold to an end user in the EU but are subsequently transferred to another actor in the supply chain, e.g. through selling or disposal. Second hand articles may constitute a source of exposure, but enforcement of prohibitions on placing on the market is difficult where the goods are being re-sold by consumers. Since the second-hand market for clothing and footwear is significant, such enforcement is expected to be complex, in terms identification of second-hand articles and tests of these articles. Moreover, enforcement costs are therefore expected to be high.

Second hand clothing is becoming increasingly popular (through second hand shops, second hand clothing sale online, etc.), fed by economic drivers and a growing awareness concerning sustainable consumption. For example, the sale in Sweden of second hand of textiles and clothing increased with 16 % between 2011 and 2013 (about 0.9 kg/person in 2013) (SMED, 2014). During the same period, the consumption of new textiles decreased with 9 % (about 12.5 kg/person). A 2014 report from SMED (Svenska Miljöemissionsdata) shows that about 23 400 tonnes of textiles where collected and reused between 2011 and 2013 in Sweden. During the same period the internet sale of clothing increased with 33 %. The Swedish national goal is that by 2020, 40 % of the textiles put on the marked should be reused (SMED, 2014).

The ECHA note on second-hand articles recommends the Dossier Submitter to evaluate the need to allow second hand articles to continue to be used and placed on the market against the need to protect human health and the environment by banning their placing on the market from the date of application of the restriction. Dossier Submitter is recommended to assess:

• The likelihood and scale of resale, including that by consumers, where appropriate.

• If available, quantitative information on costs of not allowing such a resale or for second hand shops to comply with the conditions of the restriction.

In this case, the Dossier Submitter does not have enough information at hand for such assessment and quantification. It is acknowledged that in principle, a second hand article placed on the market after the entry into force of the restriction may contain substances that have been restricted and may not have the same level of safety as compared to new (compliant) articles. However, the Dossier Submitter considers that used textile articles entering the second-hand market could be assumed to have been washed for several times. Also, normal wear or use of textile and leather articles is assumed to lower the content of some skin sensitising substances, particularly those with high migration rate. Thus, the concentration of some sensitising substances in second-hand articles is expected to be below the limit value established in this restriction proposal. Taking this into account, the proposed restriction is not assumed to imply any consequences for the sale of textile articles on the second-hand market. This is why the Dossier Submitter does not include the second-hand market in the scope of the restriction proposal. Nevertheless, the actual implications of including or excluding the second-hand articles from the scope of this restriction proposal have not been investigated in-depth due to a lack of data, and are thus uncertain. The public

[25] https://www.echa.europa.eu/documents/10162/13641/stocks_2nd_hand_goods_en.pdf/7cf76c3d-4e3a-a048-1233-8b3b9248b3df

consultation may provide additional information on these aspects that could help getting a better overview of the issue.

1.1.4.3. Chemical substances covered by the restriction proposal

The aim of this restriction proposal is to reduce the risk for skin sensitisation to chemical substances in finished clothing, footwear and textile, leather, fur, hide and synthetic leather articles with similar skin contact. This restriction proposal therefore covers chemical substances that either:

1) have harmonised classification as skin sensitisitisers in Category 1/1A/1B according to the CLP Regulation, or

2) are indicated to have skin sensitising properties as they are listed by voluntary schemes, please see Table 2.

The Dossier Submitter's definition of skin sensitisation and skin sensitiser is explained in Table 1.

In total more than 1 000 substances fall within the scope of the restriction proposal, see Table 5.

Table 5 : Number of substances with a harmonised classification as skin sensitisers (including biocidal substances) or with skin sensitising concern

Substance category	Number of substances
Harmonised classification as Skin Sens. 1	1 030
Harmonised classification as Skin Sens. 1A	11
Harmonised classification as Skin Sens. 1B	9
Substances without harmonised classification but with skin sensitising properties (included in list of concern)	24
Total	1 074

Justification for inclusion of substances with harmonised classification as skin sensitisers

A large number of chemical substances are used intentionally, or are generated unintentionally during articleprocessing (please see Annex A for more information). The available data concerning which substances can be found in the articles at point of sale is not considered sufficiently reliable and comprehensive to base a restriction in terms of individual substances. The number of substances used in the manufacturing of the articles is high, many of them are unknown and the substance(s) used may change with time. An approach that would list and restrict individual substances would therefore have the disadvantage of not capturing all skin sensitising substances (including substances that may act as replacements) and hence, it would not fulfil the objective of this restriction proposal. This more limited approach could thus lead to regrettable substitution and a reduced risk reduction capacity.

Therefore, similar to the approach adopted in the restriction proposal for tattoo inks and permanent make-up, this restriction proposal intends to restrict all substances with skin sensitising properties, so that they no longer will be present above a proposed concentration

limit in the articles, based on the argumentation that this hazard is severe enough to justify the proposal. Consequently, this restriction proposal covers all substances with harmonised classification as skin sensitisers in Category 1/1A/1B listed in Annex VI to the CLP regulation. By this dynamic relationship to the CLP regulation, substitution from one skin sensitising substance in articles covered by the restriction to another skin sensitising substance will be prevented, and thereby a high risk reduction potential of the restriction will be maintained.

Justification for inclusion of substances of skin sensitising concern

The restriction proposal intends to cover substances with harmonised classifications as skin sensitisers in Category 1/1A/1B according the CLP regulation. It is important to bear in mind that skin sensitisation is not a prioritised hazard category for harmonised classification under CLP (please see Article 36 of CLP regulation) and therefore, many chemical substances with allergenic properties will not (yet) have harmonised classifications as skin sensitisers. To limit the restriction to substances with harmonised classifications may therefore be insufficient to significantly reduce the risk of skin sensitising substances in articles covered by the restriction proposal. The Dossier Submitter therefore suggests to include also disperse dyes indicated to cause ACD when present in articles in scope of the restriction proposal (see Table 2). These dyes are included in voluntary labelling schemes, such as the OEKO-TEX standard, Bluesign, Global Organic Textile Standard, EU Ecolabel and Nordic Swan Ecolabel, and on (manufacturing) restricted substances lists ((M)RSL), such as Zero Discharge of Hazardous Chemicals, because of their skin sensitising properties.

Two of the dyes in the table, Disperse Yellow 23 and Disperse Orange 37/59/76, were also identified by ANSES in a study linking the presence of chemicals in clothes and footwear to ACD reaction in patients (ANSES, 2018). This finding confirms that these specific substances are of concern and that they may be present in clothing and footwear at point of sale.

List of substances used in clothing, footwear and textile, leather, fur, hides, synthetic leather articles

It is acknowledged that not all chemical substances within the scope of this restriction proposal will be used in the production of clothing, footwear and textile, fur, hides, synthetic leather articles with similar skin contact, and not all will be present in the finished article at point of sale. In order to identify which substances are used in clothing, footwear and textile, fur, hides, synthetic leather articles with similar skin contact today, the Dossier Submitter screened chemical databases for substances with any possible indication that they may be used in textile and leather applications. Thereafter, a consultancy study was initiated with the purpose to confirm these indications of use and refine the list as far as possible (KemI, 2019). In the consultancy study the worst-case concentration of the substances in the finished articles was also estimated (for details about this consultation, please see Annex G).

The final list of substances with skin sensitising properties that may be present in finished articles at point of sale was developed by the Dossier Submitter. It includes in total 94 substances, of which 70 have harmonised classifications as skin sensitisers in Category 1/1A/1B, and 24 are on the list of concern (Table 2). This final list is called the Master List

and compiles the information the Dossier Submitter has for each chemical or group of chemicals, such as CAS numbers, expected concentration in articles at point of sale, proposed concentration limits and availability of alternatives and analysis methods. The Master List is found in Table 20 in Annex E2.

Rational for substances with parallel regulations

Some of the substances in the scope have additional harmonised classifications as carcinogenic, mutagenic and/or toxic to reproduction, and may thus be covered by the restriction of CMR substances in textile (Entry 72 of the Annex XVII of REACH). Moreover, some of the substances with harmonised classification as skin sensitisers in Category 1/1A/1B are already restricted within REACH or by other sectorial regulations such as the Biocidal Products Regulation. The chemical substance formaldehyde is also the subject of a recent restriction proposal by ECHA[26], which suggests an emission limit for substances in several article types, including textiles. ECHA's proposal is targeted at the carcinogenic properties of formaldehyde, and the current restriction proposal would thus complement ECHA's.

In case there are coexisting parallel regulations for the same substance and application, the Dossier Submitter proposes that the regulation with the stricter concentration limit applies. The route to follow is described in Figure 2.

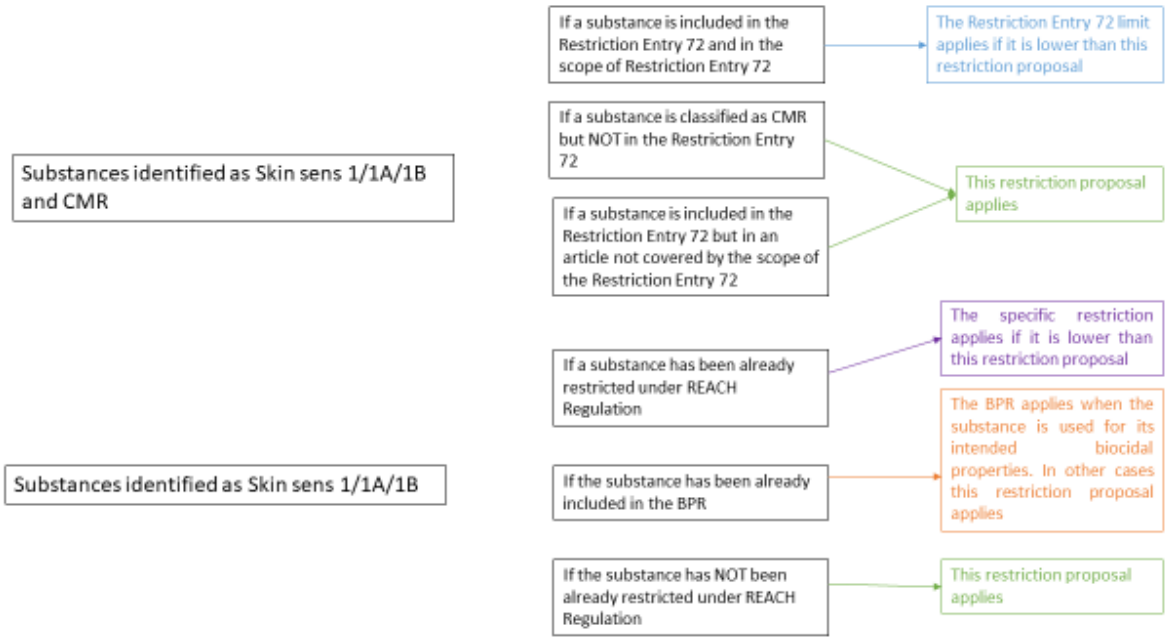


Figure 2. Route followed for substances with parallel regulations

For example, the new entry 72 of REACH Annex XVII covers 33 CMR substances, of which four substances are also within the scope of this restriction proposal. These substances are

[26] https://echa.europa.eu/registry-of-restriction-intentions/dislist/details/0b0236e182439477

formaldehyde, CI Disperse Blue 1, benzo(def)chrysene and chromium VI compounds. For these substances, in case the concentrations in the new entry 72 of REACH Annex XVII are stricter than the ones proposed herein, those concentration limits would apply (for more details see section 1.4).

A dynamic link between the Cosmetic Product Regulation Annex II was not proposed by the Dossier Submitter because the entries in Annex II of the CPR are only specified with a hazard concern for CMR substances. Consequently, a direct dynamic link targeting only skin sensitisers in Annex II of CPR is currently not feasible. To discriminate the hazard concern of skin sensitisation, there is a need for an official instance to corroborate if the substance would be in scope of the present restriction proposal by screening the SCCS opinions.

1.1.4.4. Chemical substances not covered by the restriction proposal

Substances used as biocides within the scope of Regulation (EU) 528/2012

Biocidal products can be used directly during manufacture of textile and leather articles or as in-can preservatives added to the formulations that are used during the manufacture of the articles. Biocidal products can also be used to treat the finished articles before placing them on market, in order to give them a specific biocidal function, for instance odour control or insect-repelling properties, or to preserve the articles during storing or transport (e.g. shipping).

Substances used as active ingredients in biocidal products are regulated under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) (in addition to REACH and the CLP regulation). This regulation also sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products.

According to the BPR it is after 1 March 2017 no longer possible to place on the EU market articles treated with a biocidal product containing an active substance that is not already approved under BPR, listed in Annex I to BPR, or under assessment for the relevant product type under the BPR. The biocidal product may only be used for the relevant product-type and conditions or restrictions specified in the approvals must be met.

The BPR requires manufacturers and importers of treated articles to label the articles when:

1. a claim that the treated article has biocidal properties is made, or
2. it is required in the conditions of the approval of the active substance contained in the biocidal product used to treat the article.

The labels need to be easily understandable and visible for consumers.

These rules also apply to articles manufactured outside the EEA and which then are imported to the EEA. This means that articles treated with biocidal products outside the EEA may only be placed on the EEA market if the active substance is approved, or under assessment, under the BPR for the relevant product-type and use.

The BPR provides the possibility to regulate biocides substance by substance. The decision of approval of an active substance could thus include treatment of articles or introduce specific

conditions for treatment of articles for a particular substance. However, this is a practice that has not yet been fully implemented (except the labelling requirement of treated articles).

Since biocidal substances that are used during the manufacture of clothing, footwear and textile, leather, fur, hide and synthetic leather articles or for treatment of finished articles are within the scope of the BPR, any risks connected to those uses are expected to be covered by that regulation. Therefore, the Dossier Submitter proposes that biocidal substances are not included in the current restriction. This would, however, be valid only for any substance used only for its intended biocidal properties. If the substance is used for other biocidal purposes than those approved under the BPR, or for non-biocidal purposes, the substance is covered by the present restriction proposal.

Residual biocidal substances in articles at point of sale, may be of concern to the consumer. The Dossier Submitter therefore strongly advices the Rapporteur Member State and the Biocidal Product Committee to take skin sensitising properties and potential uses related to manufacture of articles or to treatment of finished articles into account in the assessment and approval of biocidal active substances.

Each Rapporteur Member State responsible for the assessment of a biocidal active substance must complete a dossier for harmonised classification, which subsequently is scrutinised by RAC. It is therefore expected that all biocidal active substances with skin sensitisation properties are harmonised classified within a few years. However, if the implementation of the BPR regulation proves to be failing as regards risk management of clothing, footwear and textile and leather articles treated with skin sensitising biocidal products, it might be necessary to propose an update of the current restriction proposal in a few years.

Substances of concern outside the scope of this restriction proposal

The Dossier Submitter has identified substances that do not presently have a harmonised classifications as skin sensitisers according to the CLP Regulation, but which according to findings in a recent study by ANSES (ANSES, 2018), may be of concern. In the study the substances were identified multiple times in clothing and footwear, but since a firm link between the presence of the substance in the article and the reaction in the patient could not be established, these substances are not in the scope of this restriction proposal. Nevertheless, the Dossier Submitter would like to raise attention to four of these substances and encourage the Member States to oversee the possibility to propose harmonised classification according to the CLP Regulation for them. The substances are:

- Benzyl benzoate (CAS: 120-51-4/ EC 204-402-9)
- Butyl hydroxyl toluene (CAS: 128-37-0/EC 204-881-4)
- 2-phenoxyethanol (CAS: 122-99-6/EC 204-589-7)
- Para tertbutyl phenol (CAS: 98-54-4/EC 202-679-0)

For more details, please see Annex B.

In addition, the Dossier Submitter has identified chromium III substances that do not presently have harmonised classifications as skin sensitisers according to the CLP

Regulation, but that may be of concern according to a consulted leather expert [27] . The concern and relevance of chromium III compounds causing skin sensitisation was also brought forward by a respondant in the Public Consultation. Several scientific publications were referenced in the comment, including a recent experimental study showing release of Cr (III) from chromium-tanned leather eliciting allergic contact dermatitis (Hedberg, Y., et al., Chromium(III) release from chromium-tanned leather elicits allergic contact dermatitis: a use test study. Contact Dermatitis, 2018. 78(5): p. 307-314), a recent screening of several leathers that suggested that there was no correlation between extractable Cr(VI) and Cr(III) (Hedberg, Y.S., Z. Wei, and F. Moncada, Chromium(III), chromium(VI), and cobalt release from leathers produced in Nicaragua. Contact Dermatitis, 2019. 80(3): p. 149-155.) and a long-term study (8 months) on release from leather showing that Cr(VI) could be formed repeatedly and be released (Hedberg, Y.S. and C. Lidén, Chromium(III) and chromium(VI) release from leather during 8 months simulated use. Contact Dermatitis, 2016. 75(2): p. 82-88). Overall, the information received indicate that CrIII may be released from leather articles to an extent that may cause allergic responses. The Dossier Submitter would like to raise attention to these substances and encourage the Member States to oversee the possibility to propose harmonised classification according to the CLP regulation.

In the Public Consultation, a stakeholder pointed to other categories of dyestuffs beside disperse dyes that currently do not have harmonised classification as skin sensitisers in Category 1/1A/1B according to the CLP Regulation, but are reported as skin sensitisers in the scientific literature. These were acid dyes: Acid Yellow 61, Acid Red 118 and Acid Red 359, basic dyes: Basic Black 1, Basic Brown 1, Basic Red 22 and Basic Red 46 and direct dyes: Direct Orange 34 (Ryberg et al, 2009). The Dossier Submitter notes that these substances are currently not included in any voluntary schemes, which was the main criteria for inclusion in the list of concern (Table 2). However, they are highlighted here to raise awarness.

1.2. Hazard, exposure/emissions and risk

1.2.1. Identity of the substance(s), physical and chemical properties

Please see section 1.1 and Annex B for identity of the substances. Physical and chemical properties are not included in this restriction proposal due to the high number of substances included in the scope, except for the substances on the list of concern (see Annex B.1.3).

1.2.2. Classification and labelling

The majority of the chemical substances in the scope of the proposed restriction have harmonised classifications as skin sensitisers in Category 1, 1A or 1B. Evidence that a substance can cause sensitisation by skin contact in either humans or animals will normally justify classification as a skin sensitiser. Sub-categorisation into category 1A (strong and extreme skin sensitisers) and 1B (medium or weak skin sensitisers) is made based on sufficient evidence of potency. Most substances included in the scope of this restriction proposal lack sub-categorisation according to potency. Harmonised classification was in many cases decided upon prior to the introduction of the CLP-legislation, i.e. according to the

[27] Dossier submitter's personal communication 2019

Dangerous Substance Directive (67/548/EEC) which did not include potency evaluation for skin sensitisation. It should be noted that articles, such as clothes and footwear are not covered by CLP, and therefore do not require labelling according to chemical content.

1.2.3. Hazard assessment

For this restriction proposal, information on hazard properties was retrieved from published literature, reports and REACH registrations (in accordance with ECHA guidance on information gathering ECHA, 2011).

The chemical substances in the scope of the proposed restriction either have harmonised classifications as skin sensitisers in Category 1/1A/1B according to the CLP Regulation or have been indicated to have skin allergenic properties. These substances are included in the list of concern (see Table 2 and section 1.1.4.). The substances with harmonised classifications as skin sensitisers in Category 1/1A/1B have the potential to cause allergic contact dermatitis in individuals that are exposed to the substances via the skin. The chemical substances in the list of concern are considered to have skin sensitising properties, although not having a harmonised classification as such[28]. They have been indicated to be allergenic to skin by inclusion in voluntary schemes (OEKO-TEX, GOTS, Bluesign[29]), and highlighted in the scientific literature or implicated by patch testing with patients with suspected textile allergy (Anses, 2018). For disperse dyes, there are substance specific data on elicitation thresholds in combination with specific prevalence data, supporting the argument of the Dossier Submitter that there is a cause for concern of the general population (more detail in Annex B.5.4.2.). This reasoning is expanded to the other substances in the scope of this restriction proposal.

General information on the hazard of skin sensitising substances

The definition of sensitisation and skin sensitisation herein is taken from the CLP Regulation where it is stated that the development of skin sensitisation includes two phases. First, an allergenic substance primes the immune system and induces an allergy (induction). This phase is without visible symptoms and is irreversible. The entire process of the induction phase requires ca. 10 days to several weeks/months or even years. The second phase (elicitation) takes place after re-exposure to the substance and is associated with the manifestation of allergy, i.e. the allergic contact dermatitis (ACD). It is generally considered that a lower dose is required for elicitation than for induction. An elicitation phase reaction typically develops within 1–2 days from re-exposure and is reversible given that all exposure to the allergen is eliminated (more detail in Annex B.5.3.).

<u>Symptoms of ACD</u>

ACD is manifested as an inflammation of the skin typically characterised by redness, blisters, itchiness, rash and oedematous and/or scaly skin lesions (Salute, 2012). ACD from exposure

[28] In September 2019, German authority BAuA submitted a proposal for harmonised classification of Disperse Blue 124 as Skin Sens. 1A with a SCL of 0.001%.

[29] https://www.oeko-tex.com/media/init_data/downloads/STANDARD%20100%20by%20OEKO-TEX%C2%AE%20%20Limit%20Values%20and%20Individual%20Substances%20According%20to%20Appendices%204%20_%205_fr.pdf; https://www.roadmaptozero.com/mrsl_online; https://www.bluesign.com/industry/infocenter/downloads/downloadFile/94/indrsl/bluesign_RSL_v8.0.pdf; https://www.global-standard.org/images/GOTS_Documents/GOTS_Standard_5.0_EN.pdf

to substances in textile is primarily located on the chest, abdomen and thighs but can involve other parts of the body.

Diagnosis of ACD

The diagnosis of ACD is made through patch testing. It involves standardised application of small doses of a set of potential or individually suspected skin sensitisers for a period of 1-2 days (normally, a standard set of allergens are used). In the following days the exposed skin sites are checked for the occurrence of allergic reactions. International guidelines for the application, reading and interpretation of the patch test exist (SCCS, 2012).

Prevention

Primary prevention aims at preventing induction, whereas secondary and tertiary prevention deals with avoiding elicitation (the manifestation of ACD).

The dose-response relationship of skin sensitisers

Induction and elicitation are generally regarded to be threshold phenomena (i.e. there is an exposure threshold, $\mu g/cm^2$, below which the events either does not occur or is not observed clinically). However, the dose-response relationship between skin contact with sensitisers and the actual induction and/or elicitation event is complex and the thresholds are therefore often difficult to identify. It has been found that the risk for skin sensitisation is not only dependent on the dose of allergen per unit area of skin but also on the number of exposures, or accumulated dose (SCCS, 2012). Other important factors are the duration of skin exposure, presence of skin irritants and/or of other sensitisers (combination effects), the anatomical sites of exposure, condition of the skin, level of occlusion and the susceptibility of the individual.

The threshold dose of elicitation reactions is usually lower than that of induction. This means that in general, a dose per skin area derived to protect already sensitised individuals from manifestation of the ACD (elicitation) also will protect naïve subjects from induction, but not the reverse. Based on the experience of the nickel regulation, it has been shown that the dose that elicits ACD in 10% of already sensitised individuals will not only protect 90% from developing ACD, but will also prevent induction of skin sensitisation and thus decrease the incidence of allergy globally (Jensen et al., 2002; Johansen et al. 2000; Schnuch and Uter, 2003).

In order to protect the general population from the manifestation of allergy, the ACD, as well as from induction of skin sensitisation, the Dossier Submitter proposes to use the elicitation threshold dose as a reference value from which concentration limits for chemical substances in textile and leather are derived.

Elicitation threshold doses may originate from patch testing with dilution series of skin sensitisers or from repeated open application tests (ROAT). The ROAT mimics day-to-day exposure conditions to the specific product containing the allergen, and typically uses single dosings which are a small fraction of the patch test dose (SCCS, 2012). Therefore, the elicitation limits derived from ROATs will be dependent on the specific exposure scenario and may not be directly applicable to a textile exposure scenario. The Dossier Submitter has therefore chosen to use elicitation threshold doses originating from standardised patch testing with dilution series as reference values. From such patch tests, the elicitation threshold dose that represents the concentration at which 10% of sensitised individuals elicit a reaction (ED10 or $MET_{10\%}$) may be identified. It can be interpreted as the dose on skin that protects

90% of the sensitised individuals from the manifestation of allergy. Such values have previously been used to set limit values in various products in order to protect the general population. However, dose-response studies of elicitation of ACD to determine reliable threshold doses are rare (NEG, 2018).

MET (Minimal Elicitation Threshold): The $MET_{10\%}$ value represents the concentration at which 10% of sensitised individuals elicit a reaction. The $MET_{10\%}$ is derived from one occluded exposure to a dose of allergen at 0.5 cm^2 area for 48 hours. (Johansen *et al.*, 2011).

ED (Elicitation Dose): The ED10 is the dose required to elicit a reaction in 10% of sensitised individuals. Values available in the literature are not necessarily derived from occluded patch testing and therefore may differ from $MET_{10\%}$ values. However, the ED10 values given in the present restriction proposal are all derived from patch testing with dilution series, under occlusion during 48 hours.

Since the ED10 or MET10% refer to a dose that is assumed to protect 90% of the sensitised individuals from the manifestations of allergy, the Dossier Submitter has not applied any assessment factor to the value in order to compensate for intraspecies differences in sensitivity. Hence, the ED10 or $MET_{10\%}$ values found in the literature for substances in the scope are used directly in the calculations of concentration limits.

Elicitation threshold doses for substances in the scope

To efficiently and effectively deal with the large number of substances with harmonised classifications as skin sensitisers included in the scope, the Dossier Submitter used the Master list (see Annex E) as a starting point for information searches. The Master list contains a number of substances that potentially are used in the production of textile and leather. Of the substances in the Master list, a number of substances were further targeted based on a criteria defined by the Dossier Submitter.

Attempts to find elicitation threshold doses (ED10 or $MET_{10\%}$ values) were hence made for the following substances or groups of substances:

I. Groups of chemical substances with a structural similarity or same toxic entity (e.g. diisocyanates, (meth)acrylates, chromium VI compounds)
II. Substances for which there is potential for high exposure (deliberate use in textile or leather, substance intended to stay in article and high levels[30] of substance in textile or leather), and
III. Substances that are well-known skin sensitisers (e.g. rosin, formaldehyde, nickel and cobalt compounds)

In addition, the substances in the list of concern (Table 2) were specifically targeted for information searches.

[30] The term high level refer to assumptions and estimated amounts in the consultancy report (KemI, 2019) where "high" corresponded to ≥10 000 ppm or 30% (DCHP).

The available information on elicitation threshold doses is summarised in the table below (Table 6). For more detail, please see Annex B.5.4.2

Table 6: Groups of substances or substances which were targeted for information searches.

Group/Substance	Group or substance specific elicitation threshold dose (ED10 or $MET_{10\%}$)	Reference
Diisocyanates	-	-
(Meth)acrylates	-	-
Chromium VI compounds	0.02 µg/cm^2	ECHA, 2012b
Nickel compounds	0.74 µg/cm^2	Fischer et al. 2011
Direct dyes	-	-
Acid dyes	-	-
Disperse dyes[31]	0.0003 µg/cm^2	Ryberg et al. 2009
Dicyclohexyl phthalate (DCHP)	-	-
Rosin	-	-
Formaldehyde	20.1 µg/cm^2	Flyvholm et al. 1997 as reviewed in Fischer et al. 2011
Cobalt compounds	0.44 µg/cm^2	Fischer et al. 2011
1,4 paraphenylene diamine	1.5 µg/cm^2	Sosted et al 2006
Glutaraldehyde	-	-

For most substances, the elicitation threshold doses were used for risk characterisation as reported in the referenced publications. However, for disperse dyes, nickel and the other substances in the scope, for which information searches were not performed, additional assumptions had to be made by the Dossier Submitter. These are explained below.

Elicitation threshold dose for allergenic disperse dyes

The elicitation threshold dose proposed for allergenic disperse dyes is based on patch testing with dilution series with the purified dyes Disperse Blue 106 and 124. Two out of 21 patients (10%) tested positively to concentrations corresponding to 0.00030 µg/cm^2 (lowest dose tested) of the purified Disperse Blue 106, and one of them also to the corresponding dose per square centimeter of the purified Disperse Blue 124 (Ryberg and al., 2009). Disperse Orange 1 has also been indicated to have the same low threshold as Disperse Blue 106 and Disperse Blue 124 (Malinauskiene et al., 2011). The Dossier Submitter assumes that this elicitation threshold dose is relevant for all allergenic disperse dyes in the scope.

Elicitation threshold dose for nickel compounds

5 different ED10-values for nickel were reported in Fischer and al., 2011. The lowest value of 0.74 µg/cm^2 was selected.

Default elicitation threshold dose

A default elicitation threshold dose of 0.8 µg/cm^2 was assumed for the targeted substances for which no data on elicitation was found in the literature, as well as for the substances in the scope which were not targeted for information searches. The (default) elicitation threshold dose of 0.8 µg/cm^2 was proposed by Fischer and al. (2011) and is based on a meta-analysis

[31] The disperse dyes with harmonised classifications as skin sensitisers were assessed as members of the larger group of disperse dyes included in the list of concern.

of data from 16 patch test dose-elicitation studies with eight well known skin sensitisers (i.e. methylchloroisothiazolinone/ methylisothiazolinone, formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde, and methyldibromo glutaronitrile). The data was used to fit dose-response curves to identify the doses that elicit allergic responses in 10% of allergic individuals under the patch test conditions (ED10-values). The median ED10-value was 0.8 µg/cm^2. The authors found a rather small variation in the ED10-value between the various allergens (within a factor of 7 from the lowest to the highest value, leaving out three outliers). These results stimulated thoughts on the possibility of introducing a generic limit in exposure to allergens for regulatory purposes, in cases when there is a lack of data for establishing chemical specific thresholds. For example, the generic elicitation threshold dose has previously been used to derive the 0.01% (100 ppm) limit for potent fragrance allergens in cosmetic products indicative for safe use (SCCS, 2012). It has also been considered by the Risk Assessment Committee (RAC), in the the restriction of tattoo inks and permanent make-up restriction proposal.

In the Public Consultation, different views were presented on the relevance of the selected default and substance-specific elicitation threshold doses. Some stakeholders offered their support, while others pointed to limitations and uncertainties in the design of the studies on which the Dossier Submitter based reference values, such as possible issues with test substance identity, a limited study base and general lack of controls. It was also stressed that a limited number of substances were included in the derivation of the default elicitation threshold dose in the Fisher *et al.* study (2011). Stakeholders also pointed out that there might be differences in potency between member of a group that would affect the threshold dose, and that one single reference dose may not fit all substances (e.g disperse dyes). Several stakeholders requested that substance-specific data should be used. No new data was however submitted in the Public Consultation.

1.2.4. Exposure assessment

The use of textile articles is particularly difficult to avoid in modern society. Leather is also a common material in articles that are used close to skin. The frequent everyday use may lead to exposure of individuals of all ages to skin sensitisers. The level of exposure varies however according to the end-use of the materials. This means that uses with close bodily contact such as clothes, shoes and bed linen will lead to the highest exposures (Danish EPA, 2003). Most of these articles are also used for prolonged periods of time and exposure may occur under occlusion, which increases the likelihood for substances to deposit on skin and trigger ACD. Exposure from articles not used in direct contact with the skin, or for shorter periods of time, is estimated by the Dossier Submitter to be lower.

Two exposure scenarios were developed by the Dossier Submitter. The first scenario is exploring the exposure to skin sensitising substances migrating from textile. Similarily, the second scenario is exploring the exposure from leather. Hence, information on exposure parameters used for the risk assessment decribed below are given for textile and leather, respectively.

Other articles and/or materials included in the scope coming into contact with the skin to an extent similar to clothing are assimilated to the textile exposure scenario for risk assessment purposes, the reason being that these articles are typically made of materials either resembling a textile material, and/or that they have similar use patterns as textiles.

As described in section 1.1.4.1. on articles covered by the restriction, latex, rubber, neoprene, synthetic leather, prints, coatings and disposable articles (napkins, tissues and nappies) are included in the scope of the restriction. These articles, coming into close skin contact, are assimilated to textile for risk assessment purposes. Synthetic leather is produced by applying a polymer coating, for example polyurethane or polyvinyl chloride (with protective stabilizers, softening plasticizers and lubricants), to a textile base material (e.g. polyester, cotton, nylon or rayon). Rubber materials can contain rubber vulcanization accelerators and antioxidant agents (e.g. thiurams, carbamates, mercaptobenzothiazoles) or other additives (e.g. para-tert-butylphenol-formaldehyde), raising a concern for these articles. Articles made of other polymer materials can also include skin sensitising plasticisers (e.g. DCHP or (meth)acrylates). Disposable articles, like nappies or sanitary towels may be treated during the manufacturing with for example dyes, solvents or softeners. Therefore, the risk related to skin sensitising substances in such articles cannot be excluded. Prolonged skin contact with disposable sanitary towels or nappies is expected over the day. In addition, direct contact with damaged skin may increase the skin sensitisation concern. Migration of skin sensitising substances from inner layers to outer parts of such articles cannot be formally excluded. In addition, a tearing of the outer parts of the nappies may occur, leading to skin contact with the inner parts of the article. Regarding disposable napkins or tissues, a prolonged exposure is unlikely. A single short exposure is expected but repeated exposures to the similar article may occur over the day. In conclusion, the risk related to sensitising chemical substances in such materials cannot be excluded.

Hazardous chemical substances can intentionally or unintentionally remain in the final product following the manufacture and finishing of textile and leather articles. They can be released through several mechanisms, resulting in exposure of the general population: from direct release of the substance from the articles, or from fibres released from textile during normal wear and tear.

The most relevant exposure pathway in the context of skin sensitisation is direct release of substances to skin by migration from textile or leather articles. Hence, the assessment of the exposure to chemical substances released from the material would ideally be based on presence in textiles and leather articles and information on migration of the skin sensitising substance to skin during use. However, for most substances included in the scope of the restriction proposal such information is not available. According to REACH Annex I section 1.1.2 and ECHA Guidance R.8 (ECHA, 2012a), when no reliable dose descriptor can be set for a given endpoint, a qualitative approach should be taken. The Dossier Submitter has therefore, for the majority of the substances in the scope made qualitative exposure assessments based on justified assumptions on the presence of the skin sensitiser in textile and/or leather and migration of the substance from the material to skin. Semi-quantitative assessments have been attempted for a limited number of substances for which sufficient information was available to the Dossier Submitter.

Due to the large number of substances included in the scope, the Dossier Submitter targeted a subset of substances for information retrieval according to a pre-defined criteria identical to the one described in section 1.2.3. For these substances, information on exposure was researched in the literature (for details, see Annex B.9.).

Levels of skin sensitising substances in textile and leather

The Dossier Submitter has not found much published data on measured levels of skin sensitising substances in textile and leather for the targeted substances. Valuable information has been received through experts via the Call for evidence, a questionnaire, a consultancy study (KemI, 2019) and the Anses opinion collective expert appraisal report (Anses, 2018). The available information on approximate levels of the targeted skin sensitising substances in textile and leather is summarised in the table below (Table 7).

Table 7: Approximate (measured or estimated[32]) levels of targeted substances in textile and leather.

Group/Substance	Approximate levels in textile/leather	Reference
Allergenic disperse dyes	Estimated levels in certain textiles around 10 000 mg/kg (KemI, 2019). Measured levels range between 1 and 10% (10 000-100 000 mg/kg) in textile.	Dossier Submitter's personal communication, 2018; KemI, 2019
Chromium VI compounds	Estimated amount are some hundred mg/kg in textile and leather (KemI, 2019). Measured amounts in leather articles are between 1-7 mg/kg (Anses 2018).	KemI, 2019; Anses, 2018
Diisocyanates	Estimated levels above 1000 mg/kg in textile and leather. It is unclear if this number refers to cured or uncured forms.	KemI, 2019
(Meth)acrylates	Estimated levels are up to 10 mg/kg in textile and leather.	KemI, 2019
Formaldehyde	Estimated levels between 100 and 1000 mg/kg and around 75 mg/kg on unwashed easy care/non-iron resins and other finishes in textile and leather (Kemi 2019). In a study carried out by Anses (2018) levels between 6 and 160 mg/kg were reported.	KemI, 2019; Anses 2018
Nickel compunds	Nickel was quantified in four textile articles in a study at concentrations between 2.3 and 23.5 mg/kg, in the non-metal parts of the textile articles.	Anses, 2018
Cobalt compounds	Levels of cobalt compounds in textile are estimated to be 100 mg/kg (KemI, 2019). In leather, levels >50 000 mg/kg were reported (Hamann, 2018).	KemI, 2019; Hamann, 2018
Direct dyes	Estimated to be applied in textiles at 0 - 4% (40 000 mg/kg).	KemI, 2019

[32] The estimated amount in textile and leather presented in KemI (2019), is a worst case scenario which is largely the consultants' educated guesswork unless there is knowledge of Restricted Substance List test data (e.g. chromium VI, isocyanates etc).

Acid dyes	Estimated to be applied in textiles and leather at 0 - 6% (60 000 mg/kg)	KemI, 2019
Rosin	The estimated amount on textile and leather articles is 1 000 mg/kg (KemI, 2019). In the 2018 Anses study, rosin has been qualitatively detected in leather footwear.	KemI, 2019; Anses, 2018
Dicyclohexyl phthalate (DCHP)	The estimated amount in for example plastisol prints[33] on textile articles is 30% (300 000 mg/kg).	KemI, 2019
1,4 paraphenylene diamine	Quantified in textile articles at concentrations between 16 and 40 mg/kg.	Anses, 2018

It should be noted that the information on the levels of skin sensitising substances in textile and leather are approximations based on either amount applied, or on few measurements of finished articles, and was therefore not considered appropriate for use in calculations of exposure levels. In the Public Consultation, some stakeholder provided comments indicating an estimated amount of chromium VI in leather below 10 mg/kg. Stakeholders stated estimated amounts of diisocyanates below 10 mg/kg. Four stakeholders submitted information about concentration levels of glutaraldehyde in leather articles. All of them indicate concentration levels below 20 ppm, and three of them indicate levels well below 10 ppm.

Migration of skin sensitising substances from textile and leather

The level of exposure that the general population will be subjected to from chemicals in textiles or leather depends on the amount of the substance that will migrate from the material and deposit on skin.

Migration may occur to the moisture on skin or sweat and to the sebum - the oily or waxy matter that lubricate and waterproofs the skin. Migration to oil-based leave on cosmetics products may also be relevant. Direct release and migration of chemical substances from textile are dependent on a number of factors (KemI, 2014, BfR 2012):

- the inherent chemical/physical properties of the substance
- how the substance is incorporated into the textile
- the type of fibre the substance is incorporated in
- the handling of the textile (by the consumer)
- the quality of the manufacturing process

[33] As in line with entry 72 of REACH Annex XVII and the Explanatory guide to the entry (endorsed by CARACAL on 27 June 2018 [CA/44/2018]), where it is stated that “Prints and coatings applied directly on article surfaces (such as decorations or logos) are covered by the restriction”. See also explanation in section 1.1.4.1.

The available migration data is typically expressed as a percentage of the total content of the substance in the tested textile or leather (migration factor). As migration to artificial sweat is normally measured over only a few hours, the Dossier Submitter interprets these numbers as the amount of chemical that can be released to sweat during the first use of the article. Washing and/or wear and tear will reduce the amount of some chemical released from the textile or leather over time, thus the exposure assessment performed below is based on first use.

Overall, the available information on migration of substances from textile and leather is very scarce. There are limited information related to the substances (Table 7) targeted for information searches, namely for dyes from textile and chromium VI from leather. For remaining targeted substances, no information was found in the scientific literature.

Based on studies cited in the BfR report (2012), migration of dyes to artificial sweat from textiles dyed according to "state of art" was up to 0.18% of the total of the dye content in the textile. If the latest technologies have not been used, e.g. over-dyeing, using the wrong textile substrate or incomplete removal of the carriers, it was stated that exposures may be considerably higher. Furthermore, that the mechanical effects that result from the wearing of garments were not considered. In studies including simulated wear and washing also cited in BfR (2012), the highest factor was 0.42%. In their report, the BfR recommended that a migration factor of 0.5 should be used as a default worst-case assumption in the risk assessment of all dyes migrating from textiles. The voluntary scheme Bluesign's risk assessment approach for chronic dermal exposure[34] including colorants with allergenic potential, uses a default migration factor of 1-5% seemingly taking additional uncertainty into account as compared to BfR (2012). However, the basis and the assumptions underlying the Bluesign range are not available to the Dossier Submitter. The actual value used in the calculations is according to Bluesign influenced by the usage range (e.g. use next to skin and baby articles, occasional or no skin contact) and the usage during wearing of an article (e.g. sweat management).

A migration study on disperse dyes was submitted in the Public Consultation, reporting values below 0.0005% wt for most disperse dyes. The Dossier Submitter notes that these migration factors are well below those previously reported by BfR (2012). In addition, that the degree of coloration in the study (is in the lower range of the reported levels in textile (1 to 10%, see Table 7: Approximate (measured or estimated) levels of targeted substances in textile and leather.) and that the study uses the latest techniques for dyeing. In the Public Consultation, another stakeholder states that the migration of disperse dyes from textile with a high fastness seem to be very low (<<0.1%), based on own measurements.

As discussed by the BfR (2012), the conditions of use and the manufacturing techniques may influence the migration of dyes, leading to uncertainties about the real release of dyes from textile to the skin. In addition, some dyes (e.g. disperse dyes) are lipophilic substances (BfR, 2012, KemI, 2017), and migration to sebum or other oil-based matter on the skin may be higher that what has been reported using artificial sweat extraction tests. Taking into consideration the availability of poor quality (low fastness) textile products on the market, the Dossier Submitter proposes a migration factor of 10% for dyes in general in textile.

[34] https://www.bluesign.com/downloads/criteria/bluesign_criteria_for_chemical_assessment_homologation_v2_0.pdf

Information on disperse dyes submitted in the Public Consultation indicate low migration for disperse dyes, thus the Dossier Submitter consider 5% to be sufficient to cover the uncertainties described above. As no information on migration of dyes from leather was available in the literature, the Dossier Submitter proposes to use the same migration factor for dyes from textiles and leather, i.e. 5% for disperse dyes and 10 % for other dyes.

A migration factor of 30% for chromium VI was reported as the highest measured value (pH 5.5) and was applied in the restriction of Chromium VI in leather (ECHA, 2012b). A comment provided in the Public Consultation considers the value of 30% for migration of chromium VI to be an extreme worst-case assumption since the test conditions applied in the laboratory does not apply to a real-life exposure scenario. Confidential data on experimental release of chromium from tanned leather, using a method that was developed to be comparable to real life exposure conditions was provided in the Public Consultation. This study reported no release of CrVI after 6h Given the uncertainties regarding the test conditions in the new study compared to the previous one, the Dossier submitter proposes to use a migration factor of 30% for chromium VI from leather. No information was available in the literature on migration of chromium VI from textile, and the Dossier Submitter therefore suggests to apply the same migration factor of 30% from leather as well as from textile.

Default migration factor

Since many unknown factors collectively contribute to the migration of chemical substances from textile and leather, the Dossier Submitter uses a precautionary approach. It is assumed that substances in the scope for which migration information is lacking have the potential to migrate from textile and leather to skin if the substance is present in the material. Hence, for the targeted substances which lack information on migration from textile and/or leather, as well as for the substances in the scope which were not targeted for information searches, a default migration factor of 10% was assumed. This value is in the upper range of the migration factor values found in the literature, which range between 0.5-30%. For more detail, see Annex B.9.

Several comments received in the Public Consultation did not support the use of 10% as a default migration factor given that the previous studies summarised by the BfR (2012) indicated values between 0.5 and 2%. It should however be noted that the Dossier Submitter has included additional values of migration for other substances than dyes compared to the recommendation from BfR, to derive the default value proposed herein. Comments was also received in the Public Consultation that supported the precautionary approach taken by the Dossier Submitter.

Contact between textile/leather and skin

The dose per skin surface area is considered to be the most relevant dose metric for risk assessment of skin sensitisers. Therefore, the area of the exposed skin is typically an important parameter to consider in such calculations. However, in a textile or leather exposure scenario the relationship between the textile or leather surface and surface of the exposed skin is 1:1, i.e. the exposed skin area is 100% covered by the material. The exposure assessment can therefore be performed per surface area of skin, and the overall exposed skin area could be neglected.

Exposure duration

It is generally agreed that it is not only the dose per skin area that is the determinant of elicitation of skin allergy but also that the duration of the exposure, i.e. the accumulated dose per skin area is important. 24 hours was selected as an appropriate time frame for accumulated dose given that once an individual is induced, manifestations of allergy normally develop within 1-2 days after (re-) exposure to the allergen. Indeed, derivations of safe levels of allergens in cosmetics are typically made based on a 24-hour basis when repeated applications are assumed (SCCS, 2012).

Exposure frequency

Textile that come into close contact with skin may be changed 3 times per 24 hours, i.e. clothes may change into leisure- or sportswear and finally into night wear and/or contact with bedding textiles. This means that re-exposure to the same substance *via* newly purchased textile may occur up to 3 times per day.

For leather, the frequency of exposure was considered to be smaller compared to textiles. Exposure was assumed to occur at most 2 times in 24 hours (leisure footwear may change into sports shoes).

During Public Consultation, stakeholders expressed that the Dossier Submitter assumptions on use frequency per day are very conservative. One stakeholder proposed that a reasonable worst case for textile would be 1 new garment in any 24-hour period since most regular exposure will be to repeatedly laundered textiles.

Surface weights

The level of chemical content in textile or leather is typically expressed as substance weight in grams per kilogram article. However, the thickness of the material will have a large influence on how much of the chemical is deposited on the skin. Assuming that the chemical is evenly distributed in the article, the thicker the article the more chemical is contained per surface area.

The surface weight of textiles range between approximately 0.07 kg/m^2 (silk) to 0.4 kg/m^2 (blanket)[35]. A surface weight of 0.1 kg/m^2 has been used in the BfR report (2012) for risk assessment purposes. In the present restriction proposal, a value of 0.2 kg/m^2 was chosen as a reasonable worst case for textile used close to skin.

For leather, the surface weight of leather used in the restriction on chromium (VI) compounds in leather was (1.5 kg/m^2) was initially used in the present restriction proposal as a reasonable worst case for leather. During the Public Consultation, stakeholders submitted information regarding density, thickness and surface weight of different leather articles. Based on the submitted data, the range for leather surface weight is estimated to be 0.4-1 kg/m^2 for footwear, 0.3-0.8 kg/m^2 for garments and gloves, 0.6-0.9 kg/m^2 for upholstery and 0.6-1.2 kg/m^2 for automotive. A value of 0.9 kg/m^2 (corresponding to the surface weight of the most representative type of leather used in contact with the skin, i.e. bovine leather for footwear, leather goods and furniture with a thickness of 1.2 mm) was chosen for risk assessment purposes. For more detail, please see Annex B.9.

[35] Dossier Submitter's personal communication, 2018

Exposure scenario

Two worst-case exposure scenario describing exposure to skin sensitising substances via textile and leather articles respectively, have been developed in the present restriction proposal. They describe the potential exposure of consumers to chemical substances from textile and leather articles that are used close to skin.

The exposure scenario are considered relevant for all substances in the scope which are present in textile or leather, given that they have the potential to migrate.

General exposure scenario – summary
In the tables below (Table 8 and Table 9) the assumptions for the exposure scenario have been summarised. Justifications and uncertainties are also presented briefly. More detail is given in Annex B.9 (exposure assessment) and F (uncertainty analysis).

Table 8: Parameters to be applied for exposure assessment of chemical substances in textile

Parameter	Assumption	Explanation
Exposure duration (h)	24	The dose on skin is assumed to accumulate for 24 hours.
Exposure frequency (n)	3	Overall, 3 changes to occur during 24 hours (e.g. sleep wear, clothes, workout wear)
Surface weight (kg/m^2)	0.2	Higher range value in the range of textile surface weights, 0.07 kg/m^2 (silk) to 0.4 kg/m^2 (blanket).
Surface contact	1	A 1:1 contact surface between the textile and skin is assumed

Table 9: Parameters to be applied for exposure assessment of chemical substances in leather

Parameter	Assumption	Explanation
Exposure duration (h)	24	The dose on skin is assumed to accumulate for 24 h
Exposure frequency (n)	2	Overall, 2 changes to occur during 24 hours (e.g. leisure shoes and sports shoes)
Surface weight (kg/m^2)	0.9	The surface weight of the most representative type of leather (ie bovine leather for footwear, leather goods and furniture with a thickness of 1.2 mm), with a typical leather surface weight of 0.4-1 kg/m^2 for footwear, 0.3-0.8 kg/m^2 for garments and gloves, 0.6-0.9 kg/m^2 for upholstery and 0.6-1.2 kg/m^2 for automotive.
Contact surface	1	A 1:1 contact between leather and skin is assumed

Several comments made in the Public Consultation on the overall exposure assessment expressed concerns related to the use of several precautionary assumptions in combination, which may over-estimate the potential exposure of the consumers.

Conclusion on exposure to skin sensitisers in textile and leather

Dermal exposure can be assessed by actual measurements of the chemical deposited onto the skin or by using various exposure models and algorithms. This exposure concentration is then compared to a presumed safe exposure level (reference dose, derived no effect level, DNEL) to conclude on the risk.

For most substances in the scope of this restriction proposal, information on migration factors and specific concentrations in textile and leather is lacking. This makes it difficult to perform quantitative substance-specific exposure assessments.

A precautionary qualitative approach for exposure assessment is thus proposed in the present restriction proposal, where exposure of the skin is assumed to occur if the skin sensitising substance is present in the textile or leather article and if it has the potential to migrate.

For some substances in the scope, information on migration factors and other exposure parameters are available, and for the other substances in the scope it has not been possible to draw conclusions on the *absence* of migration in any event. Thus in the restriction proposal, unless there is specific migration data showing no migration or a valid scientific justification as to why migration does not occur, the Dossier Submitter assumes that substances in the scope that are present in textile or leather have the potential to migrate from the material.

1.2.5. Risk characterisation

The Dossier Submitter proposes that skin sensitising substances should be restricted in clothing, footwear and other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather based on the risk from exposure to substances classified with regard to skin sensitisation, or to substances that have been indicated to cause allergic contact dermatitis, with consideration to the exposure assessment as described in 1.2.4 and Annex B.9. Given that most of the approximated levels (indicated in table 7) are above the calculated limits for elicitation, the Dossier Submitter concludes that the risk for skin sensitisation from the substances in scope of the restriction is not adequately controlled.

The purpose of the risk characterisation is to assess the likelihood that elicitation of skin allergy is avoided when wearing or using clothing, footwear and other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather.

The RMOA finalised by KemI in 2016, concluded that an EU-wide ban of placing textile articles that contain skin sensitising substances on the market was the most appropriate RMO. A total ban of sensitising substances in textiles is not realistic, as this would seriously hamper the production of textile and leather articles. Instead, the risk is proposed to be managed by setting concentration limits for the skin sensitising chemicals in textile and leather articles. However, a detailed proposal on concentration limits was not provided in the RMOA as available analytical methods and appropriate concentration limits were considered needing further investigation. Hence, the output of the (semi-)quantitative exposure and hazard assessment is a proposal for setting concentration limits for skin sensitisers in textile and leather.

Skin sensitisation is regarded as a threshold effect (Kimber and al., 1999, Robinson and al., 2000). This, in principle, enables a quantitative approach for the risk assessment. Such an approach, based on induction thresholds, has been developed for fragrance ingredients in consumer products (Api and al. 2008), but can also be applied to other substances. Moreover, the risk assessment for the restriction of chromium in leather articles (ECHA, 2012b) and substances in tattoo inks and permanent make-up was based on elicitation thresholds.

The lack of substance specific exposure information makes it difficult to perform quantitative exposure assessments and risk characterisation ratios are difficult to calculate. The Dossier

Submitter has instead used the elicitation threshold dose as a reference dose, and combined it with available information and/or justified assumptions on exposure and migration, to derive concentration limits of skin sensitisers in textile and leather considered to be safe as regards skin sensitisation. If the level of the skin sensitising substance in the textile and/or leather at point of sale exceeds the derived concentration limit it may be of concern and should be lowered. Approximations of the concentrations of the skin sensitisers targeted for information search that may be present in textile and leather at point of sale are given in Table 7 (section 1.2.4.).

The amount of available information on elicitation threshold doses (ED10 or $MET_{10\%}$) and migration factors varies among the sensitising substances in the scope. Risk characterisation based on such data will therefore be associated with various levels of uncertainty. The Dossier Submitter approach is to use the available data as broadly as possible, but at the same time be transparent about the uncertainty. To reflect the various levels of uncertainty, and to enable the incorporation of substance specific information if such becomes available during the public consultation, the derivation of concentration limits in textile and leather for the sensitising substances in the scope is divided in three sections (see also Table 10 below);

I. Quantitative, substance specific approach. Substances or groups of substances for which substance specific elicitation threshold doses and migration data are available. The level of certainty regarding the derived concentration limits in textile and leather is considered higher as compared to section II and III.

II. Quantitative, substance semi-specific approach. Substances or groups of substances for which substance specific migration data or substance specific elicitation threshold doses are available. Medium certainty.

III. Quantitative default approach. For substances for which no substance specific migration factor or elicitation threshold dose were found. The use of generic values is associated with considerable uncertainty.

When the concentration of skin sensitising substances in textile and leather is below the proposed concentration limits (described below), the risk from the exposure as described in the exposure scenario for textile and leather is considered to be controlled for.

Table 10: The risk assessment approach.

Available substance specific migration data for the material	Available substance specific elicitation threshold doses	I) Substance specific concentration limit	II) Substance semi-specific concentration limit	III) Generic concentration limit
Yes	Yes	X	-	-
Yes	No	-	X	-
No	Yes	-	X	-
No	No	-	-	X

Equations to derive concentration limits in textile and leather

To reduce the risk for the general population from exposure to skin sensitising substances in textiles or leather, the exposure to a chemical substance migrated from the material should not exceed the elicitation threshold dose (ED10 or $MET_{10\%}$), considered as the safe dose on skin accumulated over 24 hours.

The limit in textile or leather per surface area was calculated using the following equation:

*Limit in textile or leather (µg/cm²) = elicitation threshold dose/(migration factor * contact surface * frequency of exposure)*

To convert the concentration limit in textile or leather per surface area to mg/kg the following equation was used:

*Limit in textile or leather (mg/kg) = Limit in textile or leather (µg/cm²)*10 000 (conversion factor cm² to m²) /(1 000 (conversion factor µg to mg)* surface weight)*

Derivation of concentration limits for substances in the scope

I. Concentration limits for substances with substance specific information on elicitation threshold doses and migration:

Allergenic disperse dyes

Disperse dyes are used to dye synthetic textile materials and leather. An elicitation threshold dose of 0.0003 µg/cm² (Ryberg et al., 2009) was used in combination with a substance specific migration factor of 5% and the exposure scenario for textile and leather, respectively (section 1.2.3 and Annex B.9) to derive a concentration limit for allergenic disperse dyes in textile and leather.

The concentration limit of allergenic disperse dyes in textiles ensuring that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 0.0003/(0.05*1*3) = 0.002*
*Limit in textile (mg/kg) = 0.002*10 000/(1 000*0.2) = 0.1 mg/kg*

The limit of allergenic disperse dyes in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm²) = 0.0003/(0.05*1*2) = 0.003*
*Limit in leather (mg/kg) = 0.003*10 000/(1 000*0.9) = 0.03 mg/kg*

The Dossier Submitter would like to point out, that the concentration limits are relevant for all disperse dyes included in the scope, regardless of whether the substance have a harmonised classification as a skin sensitiser according to the CLP regulation or is included in the scope through the list of concern (Table 2). Since the derived limits are below the current quantification limit for disperse dyes (30-50 mg/kg), the Dossier Submitter propose a ban of allergenic disperse dyes in textile and leather. By proposing a ban, the

Dossier Submitter intends a limit not exceeding the limit of detection (that should be below the calculated concentration limits of 0.1 mg/kg in textile and 0.03 mg/kg in leather). This restriction proposal calls for a revision of the current restriction (entry 72 of REACH Annex XVII) for the Disperse Blue 1.

Chromium VI compounds

Chromium VI is restricted to 1 mg/kg in textile articles due to CMR properties (entry 72 of REACH Annex XVII) and to 3 mg/kg in leather articles (entry 47 of REACH Annex XVII) due to its allergenic properties. In the present proposal, an elicitation threshold dose of 0.02 µg/cm^2 and a migration factor of 30% (ECHA 2012b) was used in the calculations, assuming that the amount of chromium which migrate from leather is similar to migration from textile. This information was used in combination with the exposure scenario for textile and leather, respectively to derive concentration limits.

The limit of chromium VI in textile articles to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm^2) = 0.02/(0.30 *1*3) = 0.02*
*Limit in textile (mg/kg) = 0.02*10 000/(1 000*0.2) = 1.1 mg/kg*

Since 1.1 mg/kg is higher than the concentration limit for chromium VI of 1 mg/kg in entry 72 of REACH Annex XVII, the existing concentration limit is assumed to also protect from elicitation of allergic contact dermatitis by chromium in textile. Hence, for regulatory consistency, the lowest concentration limit for chromium VI compounds in textile applies. The proposed concentration limit is expressed as CrVI that can be extracted from the material.

The limit of chromium VI compounds in leather to ensure that the elicitation threshold dose on skin is not exceeded is:

*Limit in leather (µg/cm^2) = 0.02/(0.30*1*2) = 0.03*
*Limit in leather (mg/kg) = 0.03*10 000/(1 000*0.9) = 0.37 mg/kg*

The calculated concentration limit of 0.37 mg/kg is stricter than the concentration limit for chromium VI of 3 mg/kg in entry 47 of REACH Annex XVII. Allergic reactions to levels of chromium VI below 3 mg/kg was reported in a report from ANSES (2018). One reason for setting a 3 mg/kg limit in the agreed chromium VI restriction was that it was the lowest possible detection limit with existing analytical testing methods. According to various stakeholders, the challenge of proposing a concentration limit at 1 mg/kg is related to the lack of reliability of the available analytical methods. Technological advances in test methods does however make it possible to detect even 1 mg/kg of chromium VI today. The present restriction proposal therefore argues for a lower concentration limit for chromium VI at 1 mg/kg and calls a revision of current entry 47 of Annex XVII of the REACH Regulation. The proposed concentration limit refer the total dry weight of the leather part.

II. Concentration limits for substances/groups of substances for which substance specific information on elicitation threshold doses or migration from textile or leather has been found.

Formaldehyde

Formaldehyde is included in entry 72 of REACH Annex XVII with a 75 mg/kg concentration limit for textiles, based on its CMR properties. The restriction proposal for formaldehyde, submitted by ECHA in January 2019, proposes an emission limit of 0.124 mg/m^3 in the air of a test chamber used under the conditions prescribed in EN 717-1. In November 2019, Commission Directive (EU) 2019/1929 amending Appendix C to Annex II to Directive 2009/48/EC (the Toy Safety Directive), adopting the specific limit values for formaldehyde of 30 mg/kg (content limit) in textile toy material and 30 mg/kg (content limit) in leather toy material, among other limit values. Defining a concentration limit in the article is considered more relevant to the present restriction proposal compared to the emission limit to air.

An ED10-value of 20.1 µg/cm^2 (Fischer *et al.*, 2011) was used to calculate the limit concentration in textile articles for formaldehyde. No information on migration/emission from textile or leather have been found in the literature. Hence, the Dossier Submitter use the default migration factor of 10% and the exposure scenario for textile and leather, respectively to derive concentration limits.

The limit in textile and leather, to ensure that the elicitation threshold dose is not exceeded would then be:

*Limit in textile (µg/cm^2) = 20.1/(0.1*1*3) = 67*
*Limit in textile (mg/kg) = 67*10 000/(1 000*0.2) = 3 350 mg/kg*

*Limit in leather (µg/cm^2) = 20.1/(0.1*1*2) = 100.5*
*Limit in leather (mg/kg) = 100.5*10 000/(1 000*0.9) = 1117 mg/kg*

The Dossier Submitter's derived concentration limits of 3350 mg/kg and 1117 mg/kg is higher than the concentration limits of 30 mg/kg for formaldehyde in textile toy material and leather toy material, as stated in Appendix C to Annex II to the Toy Safety Directive. Since the concentration limits in the Toy Safey Directive are based on risk for contact allergy, the Dossier Submitter proposes to align the concentration limit with the Toy Safety Directive. Thus, concentration limits of 30 mg/kg for formaldehyde in textile and leather is proposed.

Nickel compounds

Nickel is used in some dye chromophores (KemI, 2019). Nickel can also be present in metallic parts such as buttons and zippers but such non-textile parts are not intended to be covered by the restriction proposal. These articles are covered by entry 27 of Annex XVII of the REACH Regulation. An ED10 value of 0.74 µg/cm^2, the lowest of 5 ED10-values reported in Fischer et al. (2011) was used in combination with the default migration factor of 10% and the exposure scenario for textile and leather, respectively to derive concentration limits.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm^2) = 0.74/(0.1*1*3) = 2.47*
*Limit in textile (mg/kg) = 2.47*10 000/(1 000*0.2) = 123 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 120 mg/kg for nickel in textile.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm²) = 0.74/(0.1*1*2) = 3.7*
*Limit in leather (mg/kg) = 3.7*10 000/(1 000*0.9) = 41 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 40 mg/kg for nickel in leather.

The concentration limits for nickel in textile and leather are proposed to cover both nickel and the nickel compounds which are in the scope. The concentration limits are expressed as nickel metal that can be extracted from the material.

Cobalt compounds
Cobalt is used in some dye chromophores, to dye nylon and wool (KemI, 2019). Cobalt has also been found in leather furniture upholstery, shoes and gloves (Hamann et al., 2018). An ED10-value of 0.44 µg/cm² (Fischer and al. 2011), the default migration factor of 10% and the exposure scenario for textile and leather, respectively have been applied in the calculations.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 0.44/(0.1*1*3) = 1.47*
*Limit in textile (mg/kg) = 1.47*10 000/(1 000*0.2) = 73 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 70 mg/kg for cobalt in textile.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm²) = 0.44/(0.1*1*2) = 2.2*
*Limit in leather (mg/kg) = 2.2*10 000/(1 000*0.9) = 24 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 20 mg/kg for cobalt in leather.

The concentration limits for cobalt in textile and leather are proposed to cover both cobalt and the cobalt compounds which are in the scope. The concentration limits are expressed as cobalt metal that can be extracted from the material.

1,4 paraphenylene diamine
1,4 paraphenylene diamine is used as a textile dye or in azo dyes manufacturing. An ED10 value of 1.5 µg/cm² (Sosted and al., 2006) and the default migration factor of 10%, in combination with the exposure scenario for textile and leather, respectively have been used in the calculations.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 1.5/(0.1*1*3) = 5*

*Limit in textile (mg/kg) = 5*10 000/(1 000*0.2) = 250 mg/kg*

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm² article) = 1.5/(0.1*1*2) = 7.5*
*Limit in leather (mg/kg article) = 7.5*10 000/(1 000*0.9) = 83 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 80 mg/kg for 1,4 paraphenylene diamine in leather.

Is it noted that hair dyes and products intended for coloring eyelashes must not contain 1,4 paraphenylene diamine, as specified in Annex III to the Cosmetics Product Regulation. Additionally, in the Public Consultation, one stakeholder proposed a concentration limit of 20 mg/kg. The stakeholder brought forwardfrequent reports of cross-reactions with 1,4-phenylene diamine and other dyes as an argument, however, the basis for the proposal was not further explained. The Dossier Submitter acknowledge that 1,4 paraphenylene diamine is an extreme sensitiser and the risk of allergy for consumers should be taken seriously. Nevertheless, the Dossier Submitter has not been able to find further scientific data to propose a concentration limit derived quantitativley using a relevant elicitation threshold dose.

III. Concentration limits for substances/groups of substances for which no substance specific information on elicitation threshold doses or migration from textile or leather is available.

The default elicitation threshold dose of 0.8 µg/cm² skin and the default migration factor of 10% was used in combination with the exposure scenario for textile and leather, respectively, to derive concentration limits.

The limit in textile to ensure that the elicitation threshold dose is not exceeded is then:

*Limit in textile (µg/cm²) = 0.8/(0.1*1*3) = 2.66*
*Limit in textile (mg/kg) = 2.66*10 000/(1 000*0.2) = 133 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 130 mg/kg for these substances in textile.

The limit in leather to ensure that the elicitation threshold dose is not exceeded is:

*Limit in leather (µg/cm²) = 0.8/(0.1*1*2) = 4*
*Limit in leather (mg/kg) = 4*10 000/(1 000*0.9) = 44 mg/kg*

For simplicity, the Dossier Submitter proposes a concentration limit of 40 mg/kg for these substances in leather.

The calculated limits in textile and leatherare proposed for all substances in the scope which are not specifically mentioned in section I and II above.

Table 11: Proposed concentration limits for the substances in the restriction scope

Substance/group of substances	Proposed concentration limit (mg/kg)	
	Textile[1]	Leather[2]
Disperse dyes	Ban[3]	Ban[3]
Chromium VI compounds	1[4]	1
Nickel compounds	120	40
Cobaltcompounds	70	20
Formaldehyde	30	30
1,4 paraphenylene diamine	250	80
Other substances in scope	130	40

[1]Any concentration limit proposed for textile also applies for materials such as synthetic leather, rubber materials and polymer materials, prints and coatings included in the scope coming into contact with the skin to an extent similar to clothing. The concentration limits applies also to disposable sanitary towels, napkins, tissues and nappies.

[2]Any concentration limit proposed for leather also applies for hides and furs.

[3] The ban refers to the limit of detection (that should be below the calculated concentration limits of 0.1 mg/kg in textile and 0.03 mg/kg in leather).

[4] The existing concentration limit in entry 72 of REACH Annex XVII, is assumed to also protect from skin sensitisation from substances in textile in the present restriction proposal. Hence, for regulatory consistency, no concentration limit is proposed in this restriction proposal. Instead the lowest concentration limit applies which currently is 1 mg/kg for chromium VI compounds.

Voluntary labelling schemes and/or standards (such as Oeko Tex, BlueSign, etc) may have established more restrictive concentration limits for some of the substances covered by the present restriction proposal. However, the scientific basis and assumptions underlying the values are not available to the Dossier Submitter. They were therefore not taken into consideration.

An uncertainty analysis has been performed in Annex B.10.1.6 (textile) and B.10.2.6. (leather). In addition, an uncertainty analysis has been included in Annex F. This analysis shows that by increasing one parameter at a time (migration factor, frequency of exposure or surface weight), the concentration limit in leather or textile will decrease. Conversely, an increase of the elicitation threshold dose will result in an increase of the concentration limit. By using a range of values for each parameter, the analysis shows that the elicitation threshold dose is the most sensitive parameter, i.e. affecting the resulting concentration limit the most, followed by the migration factor. There is a lack of information regarding both of these factors, for most of the targeted substances in the scope.

Conclusion on the risk

For most of the targeted skin sensitisers in the scope of the restriction proposal, the concentration limits based on elicitation threshold doses, suggested in Table 11, are far below the highest approximated concentrations in textile and leather at point of sale (as indicated by Table 7, section 1.2.4.). Therefore, the risks from these substances are not adequately controlled for these uses. The Dossier Submitter assumes the reasoning can be extended to all skin sensitising substances in the scope. Hence, lowering the concentrations of the skin sensitising substances in clothing, footwear and other articles with similar skin contact made of textile, leather, fur, hide and synthetic leather to the ones proposed above, is considered to significantly reduce the risk for skin sensitisation in the general population. The

concentration limits proposed are thus considered to adequately protect consumers against skin sensitisation.

1.3. Justification for an EU-wide restriction measure

One of the primary reasons to act on a Union-wide basis is the cross-boundary human health problem: a risk from exposure exists in all Member States and because trans-boundary trade between Member States exists.

A Union-wide regulatory measure would also ensure a harmonised high level of protection for human health across the Union.

Most of the textiles used and put on the EU market have been produced in Asia. The Asian market does not have the same restrictions and control systems in place as applied for the EU market (often stricter than Asian rules). This results in for instance many RAPEX errands. The proposed restriction will provide actors with further tools and support of their work to implement more stringent specifications and requirements when purchasing textiles.

A Union-wide action to address the risks associated with textiles and leather containing skin sensitising substances is needed to ensure the free movement of goods within the EU. The fact that textiles and leather, imported as well as manufactured in the EU, need to circulate freely once on the EU market, stresses the importance of an EU-wide action rather than action by individual Member States, as these actions could differ significantly from Member State to Member State. In addition, a Union-wide action would eliminate the distortion of competition on the European market between markets with and without national legislation on the chemical composition of textiles/fur/hides/leather.

More details are available in Annex C.

1.4. Baseline

This restriction covers substances classified as skin sensitisers in Category 1, 1A or 1B under the CLP Regulation, as well as a list of substances of concern, as listed in Table 2, that may be present in articles or part of articles made of textile, leather, hides and furs at points of sale within EEA31. A list of articles relevant for the scope is provided in section 1.1.4.

The baseline, the “business as usual” scenario, is defined as the current and predicted future use of these substances in the articles covered without the proposed restriction and is described as follows:

- The geographical boundaries for the assessment are the countries of EEA31
- Regarding pending legislative changes of relevance, and as already mentioned above: Formaldehyde is also the subject of a restriction proposal from ECHA[36], which suggests an emission limit for several article types including textiles. ECHA’s proposal is targeted at the carcinogenic properties of formaldehyde and the proposal in this Annex XV

[36] https://echa.europa.eu/registry-of-restriction-intentions/dislist/details/0b0236e182439477

dossier complements the other proposal. In case certain textiles cannot meet the emission limit proposed in ECHA's restriction on formaldehyde, they would be taken off the market even if they comply with this restriction on skin sensitising substances (and vice versa). Some impacts for these textiles may thus occur. However, at this stage, it is difficult to predict them. Moreover, the recent adoption of the already-mentioned restriction entry 72 of REACH Annex XVII[37] may have some concurrent favourable effect with this restriction proposal. Such as indicated in section 1.1.4, entry 72 of REACH Annex XVII covers 33 CMR substances among which 4 substances (CLH Skin Sens.) are covered by the scope of this restriction proposal. For these substances, in case the concentrations imposed by the new entry 72 of REACH Annex XVII are stricter than the one proposed herein, the stricter limit would apply for protection purposes and in order to avoid any regulatory inconsistencies. That is the case for the substances listed in Table 12 below.

Table 12 : List of substances restricted under Entry 72 of REACH Annex XVII also covered by the scope of this restriction proposal

Substance name	CAS number	EC number	Concentration limit by weight in the CMR entry 72 restriction	Concentration limit by weight proposed in the present restriction proposal[38]
Formaldehyde	50-00-0	200-001-8	75 mg/kg	30 mg/kg
CI Disperse Blue 1	2475-45-8	219-603-7	50 mg/kg	Ban[39]
Benzo(def)chrysene	50-32-8	200-028-5	1 mg/kg	130 mg/kg[40]
Chromium VI and its compounds	-	-	1 mg/kg after extraction (expressed as CrVI that can be extracted from the material)	1 mg/kg[41]

As a result, additionally to this restriction proposal, the concurrent new entry 72 of REACH Annex XVII is expected to avoid substitution of CMR compounds by non-CMR but sensitising substances in textile articles (at least those which are CMRs and/or skin sensitisers) and to

[37] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:256:FULL&from=EN

[38] For articles which are covered by the present restriction proposal but not covered by entry 72.

[39] The ban refers to the limit of detection (that should be below the calculated concentration limits of 0.1 mg/kg in textile).

[40] Since a substance-specific risk assessment has not been performed by the Dossier Submitter, the benzo(def)chrysene will fall under the default approach with the general concentration limit. For regulatory consistency, no concentration limit is proposed in this restriction proposal for articles covered by entry 72 of REACH Annex XVII. Instead the lowest concentration limit applies which currently is 1 mg/kg for benzo(def)chrysene for articles covered by entry 72 of REACH Annex XVII.

[41] The existing concentration limit in entry 72 of REACH Annex XVII, are assumed to also protect from skin sensitisation from substances in textile in the present restriction proposal. Hence, for regulatory consistency, no concentration limit is proposed in this restriction proposal. Instead the lowest concentration limit applies which currently is 1 mg/kg for chromium VI compounds.

overall increase the protection of the general population to the exposure to these chemicals from November 2020 (the date of entry into force of new entry 72 of REACH Annex XVII).

In addition, the 2009 existing restriction on carcinogenic azo-colorants and azo-dyes in textile and leather articles (Annex XVII of REACH, entry 43) covers 9 substances in the scope of this restriction proposal and proposes a stricter limit at 30 mg/kg for 8 of them and 1 000 ppm for one mixture, as indicated in the table below.

Table 13 : List of substances restricted under Entry 43 of REACH Annex XVII also covered by the scope of this restriction proposal

Substance name	CAS number	EC number	Concentration limit by weight in the Entry 43 of REACH Annex XVII
o-aminoazotoluene	97-56-3	202-591-2	30 mg/kg
4-chloroaniline	106-47-8	203-401-0	
4,4'diaminodiphenylmethane 4,4'-methylenedianiline	101-77-9	202-974-4	
3,3'-dichlorobenzidine 3,3'-dichlorobiphenyl-4,4'-ylenediamine	91-94-1	202-109-0	
4,4'-methylenedi-o-toluidine	838-88-0	212-658-8	
4,4'-oxydianiline and its salts p-aminophenyl ether	101-80-4	202-977-0	
4-methyl-m-phenylenediamine 2,4-toluenediamine	95-80-7	202-453-1	
4-aminoazobenzene 4-phenylazoaniline	60-09-3	200-453-6	
A mixture of: disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-)	118685-33-9	405-665-4	1 000 mg/kg

Likewise, the stricter limit of 30 mg/kg would thus apply to these 8 ‘double-covered’ substances for protection purposes and in order to avoid regulatory inconsistencies. However, this concurrent existing restriction is not expected to have any additional positive impact on human health since it is already implemented and textiles and footwear end products are supposed to already comply with. This proposal however calls a revision of the current restriction (entry 43 of REACH Annex XVII) for the mixture indicated in the table above.

- Concurrently, voluntary actions from textile industry as well as textile labels exist. These schemes are part of the baseline. As explained in section 2.2., if properly implemented and monitored, voluntary agreements can be effective and businesses can help to achieve public policy aims. Since they are not regulatory schemes, their

efficiency is however difficult to measure. Nevertheless, these actions demonstrate that textile industry is willing to improve their processes and end products and have already implemented actions for these purposes.

- As shown in Annex A, the textiles and clothing consumption in the EU has constantly grown since the 1980s and has rapidly increased during the last decade where the majority (about 80%) was imported from outside the EU. Based on EU statistics more than 80% of the textile production involving chemical substances occurs outside the EU. Based on these trends, it is assumed that the production of textile and leather articles will keep on growing in the future, and the part of manufacturing occurring outside EU is assumed to remain predominant, encouraged by low-paid workforce and less stringent workers regulation in the field of textiles in particular.

- The baseline is also defined based on the current and predicted future trends in textile/leather contact allergy cases. As reported in the literature, the ACD cases in general such as textile ACDs are under-reported and under-diagnosed (see section 2.4.1 for more details) even though more and more studies document and report cases in Europe and at international level as diagnosis practices improve and patients are better informed. As documented in detail in Annex E.5 and in section 2.4.2 below:

    - The number of individuals sensitised to chemical substances in textile and leather in the EEA31 population at the time of the elaboration of this restriction proposal (2019) is estimated between 3.9 and 5 million (based on a calculated prevalence by the Dossier Submitter of 0.8%-1% of EEA31 population). According to the baseline scenarios developed in Annex D and as represented in Figure 3 below (and as shown in Table 14), these figures in 2023 are expected to be between 4 and 6 million in EEA31. These individuals are already sensitised and a significant proportion are expected to be protected from developing ACD with the adoption of this restriction since skin sensitising substances (with harmonised classification under CLP or in the list of concern) will no longer be used in textiles and footwear or will be used at a concentration considered as safe. The proportion of the already sensitised individuals that would be protected is estimated at least at 70%, due to the proposed ban of allergenic disperse dyes and due to the restriction of additional allergenic substances at low or very low levels considered as safe and up to 90% is considered to be protected by additional restriction of remaining substances in the scope (for more details, please see section 2.4.2.2 below and Annex E.5). As shown in Table 14 below, 70% of the sensitised individuals that would be protected from 2023 corresponds to 2.5-4.1 million cases; 90% corresponds to 3.6-5.3 million cases. These assumptions are based on the following:
        - Literature reports that around 2/3 (e.g. 70%) of all textile related cases of ACD are attributed to disperse dyes (reported in Bfr (2006); RIVM (2008) and RIVM (2014), based on Hatch and Maibach (1995; 2000) and Lazarov (2004)). The estimate of this proportion covers a certain degree of uncertainty[42] since it is based on the frequency of positivity of

[42] Moreover, Disperse Dyes are used only in some materials and not in all the ones covered by this restriction proposal.

patch tests performed on patients and not on an overall and comprehensive prevalence study of textile and leather ACD in the EU general population (which, as already explained, does not exist to date). Given the fact that current textile-specific patch test series, such as *Textile Colours & Finish Series TF-1000* (see Table 30 in Annex E.5) mainly contain dyes and disperse dyes and that the Textile Dye mix (TDM) (Mx30, see Table 32 Annex E5) only contain disperse dyes, these substances are currently some of the most investigated: as a consequence, the frequency of positivity of patch tests in patients to disperse dyes may not be fully representative of most of the actual cases of ACD and the proportion of 2/3 reported in the literature may be somehow biased and overestimated. Nevertheless, this information from the literature still gives an indication that a significant proportion of ACD cases may be due to disperse dyes (being 70% or lower) which is valuable information to be used.

- For the other substances of the scope, the attribution of textile and leather ACD to specific substances cannot be estimated precisely since no specific information is available. As a result, although the exact proportion of ACD cases attributed to these substances cannot be quantified, the Dossier Submitter considers that additional current cases would be protected by this restriction proposal:
    - For the substances for which a concentration limit (considered as safe) has been derived from substance-specific elicitation threshold doses, it is considered that the already sensitised individuals will be protected.
    - For the other substances for which a generic concentration limit has been proposed due to lack of data on elicitation threshold doses and/or migration factors, it is assumed that some proportion of the attributed cases will be protected.
    - The individuals who are already sensitised to substances in the scope may still suffer from them due to other sources of exposure but these sources are out of the scope of this restriction proposal and cannot be included in the human health impact assessment.
- As a whole, the proportion of individuals already sensitised to substances in the scope that would be protected by the restriction proposal is estimated to be at least 70%, due to the proposed ban of allergenic disperse dyes and due to the restriction of additional allergenic substances at low or very low levels considered as safe and up to 90% is considered to be protected by additional restriction of remaining substances in the scope. The remaining 10% of individuals potentially not protected reflect uncertainties due to the proportion of susceptible individuals in which an allergic reaction may be triggered by exposure levels below the concentration limits proposed by the Dossier Submitter and due to uncertainties that some people may still react to the substances falling under the 'generic approach' (concentration limits being 110 mg/kg in leather or 130 mg/kg in textile, see above section 1.2.5).

o Moreover, the number of new cases of sensitisation to substances in textile and leather articles in EEA31 is estimated to be in the range of 45 000-180 000 per year (based on a calculated incidence by the Dossier Submitter of 0.01%-

0.04% of EEA31 population per year). For the same reasons as above, the proportion of new cases that would be prevented is estimated to be between 70% and 90%. It has to be noted however that the Dossier Submitter expects that this proportion would be even larger, since the doses needed for induction are higher than for elicitation. Using 70% - 90% may thus be a conservative assumption here (and a potential source of underestimation of the benefits) (for more details, please see section 2.4.2.2 below and Annex E.5). As shown in Table 15 below, 70% of cases that would be avoided corresponds to 30 000-125 000 new cases per year; 90% corresponds to 40 000-160 000 new cases per year.

- The overall number of textile and leather ACD (prevalence+incidence) is thus expected to increase over time under the baseline.
- This trend is also confirmed by the literature reporting that the prevalence of textile and leather ACD seems to be increasing, probably because of changed textile manufacturing techniques (Lisi and al 2014). For instance, new substances (with unknown chemical compositions) are continuously introduced into textile industry to meet consumers demand or to supply new fashionable colours, shapes and fabrics (Seidenari and al, 2002). Without further regulation, the cases of textile and leather ACD may thus increase due to the new substances regularly used in the manufacturing processes. However, this restriction proposal may not capture the potential hazards of these new substances (such as their sensitising properties) since they are not known and have no harmonised classification under the CLP Regulation yet (nor listed in the Dossier Submitter's list of substances of concern). Nevertheless, in case these new substances would harmonised as skin sensitisers under the CLP Regulation, they would then fall into the scope of this restriction. It is however difficult to predict how many substances would be concerned. This is a source of uncertainty that cannot be addressed by the restriction at the time of its elaboration.
- Concurrently, as mentioned above, the recent adoption of entry 72 of REACH Annex XVII may help decrease the prevalence of ACD caused by substances in textile and leather. Nevertheless, entry 72 of REACH Annex XVII only covers 4 substances in the scope of this restriction proposal; therefore its relative impact is not expected to be significant.

The number of individuals already sensitised to substances in textile and leather articles and the number of cases expected to be avoided by this restriction within the EEA31 population are summarised in the Tables below.

Table 14 : Number of individuals already sensitised to substances in textile and leather articles and the number of individuals expected to be protected by the restriction (in million)

	Min	Max	Average
Number of individuals already sensitised to substances in textile and leather articles in 2019 (0.8-1% of EEA31 population) – based on prevalence	3.9	5	4.5
Number of individuals already sensitised to substances in textile and leather articles in 2023 – based on prevalence in 2019 and expected new cases 2019-2023	4	6	5
Number of individuals already sensitised to substances in textile and leather articles, that would be protected by this restriction from 2023 (assuming 70% of individuals protected)	2.8	4.1	3.5
Number of individuals already sensitised to substances in textile and leather articles, that would be protected by this restriction from 2023 (assuming 90% of individuals protected)	3.6	5.3	4.5

Table 15 : Number of annual new textile and leather ACD cases and the number of cases expected to be avoided by the restriction

	Min	Max	Average
Number of new cases per year (0.01-0.04% of EEA31 population/year) – based on incidence	45 000	180 000	113 000
Number of new cases, that would be avoided by this restriction (assuming 70% of 2019 cases avoided)	30 000	125 000	80 000
Number of new cases, that would be avoided by this restriction (assuming 90% of 2019 cases avoided)	40 000	160 000	100 000

- As a result of these simultaneous trends, it is assumed that textile and leather ACD will steadily increase over time under the baseline such as indicated in the graph below (for more details, please see Annex D).

This graph is built on 5 baseline scenarios corresponding to the min, max and average values of the number of current (prevalent cases) and new (incident) cases of textile and leather ACD from 2023, such as presented in Table 14 and Table 15 as well as in Annex D. The 5 baseline scenarios are built as follows:

- baseline scenario 1 corresponds to the combination of the min value of prevalent cases in 2019 (3.9 million in Table 14) and the min value of incident cases (45 000 in Table 15) of textile and leather ACD
- baseline scenario 2 corresponds to the combination of the max value of prevalent cases in 2019 (5 million in Table 14) and the max value of incident cases (180 000 in Table 15) of textile and leather ACD

- baseline scenario 3 corresponds to the combination of the min value of prevalent cases in 2019 (3.9 million in Table 14) and the max value of incident cases (180 000 in Table 15) of textile and leather ACD
- baseline scenario 4 corresponds to the combination of the max value of prevalent cases in 2019 (5 million in Table 14) and the min value of incident cases (45 000 in Table 15) of textile and leather ACD
- baseline scenario 5 corresponds to the combination of the average value of prevalent cases in 2019 (4.5 million in Table 14) and the average value of incident cases (113 000 in Table 15) of textile and leather ACD

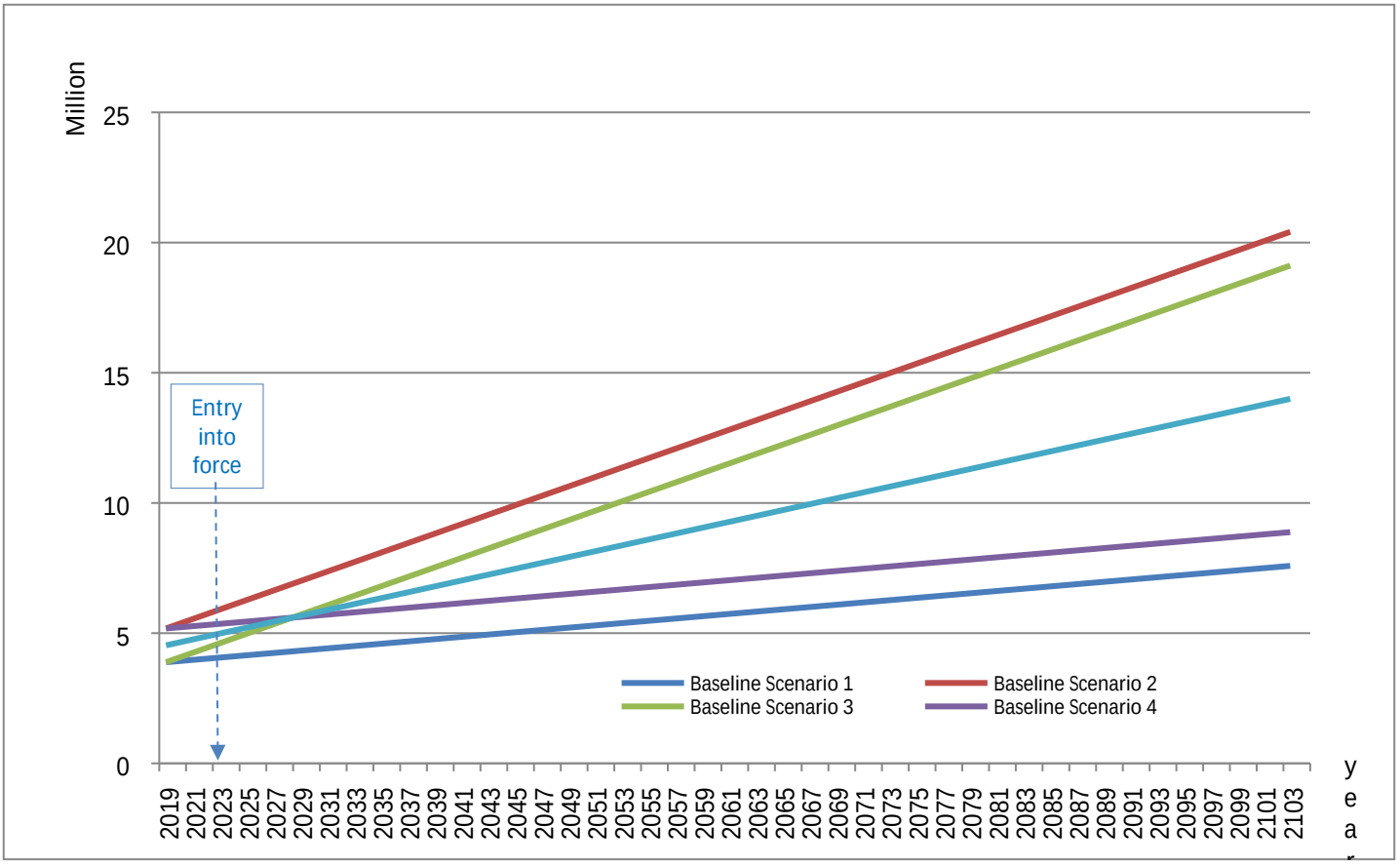


Figure 3. Projected number of total textile and leather ACD in EEA31 over time under the baseline

The baseline is based on assumptions that include some degree of uncertainty. The sources of uncertainties are presented in Annex F.

2. Impact assessment

2.1. Introduction

The Dossier Submitter evaluated a number of other EU-wide and national legislative and voluntary measures. Following an assessment of the current Member States' national legislation and an assessment of the substances in textile and leather articles that can present a risk to human health, one restriction option (RO) is proposed, although three are in total more comprehensively analysed later in the dossier (see sections 2.2.1 and sections 2.4 to 2.7). The impacts of the restriction proposed were assessed and (when possible) monetised (please see section 2.4).

2.2. Risk management options

For the purposes of this restriction proposal, several risk management options (RMOs) for the regulation of skin sensitising substances in textile and leather articles have been identified and analysed. It was concluded that none of these RMOs was appropriate to control the risk (see sections 2.2.2 to 2.2.8, and Annex E.1). Therefore several restriction options under REACH were explored: in total eight restriction options were analysed (see section 2.2.1 below).

2.2.1. REACH Restriction options according to REACH Article 69

Substances for which the manufacture, use or release on the market cause an unacceptable risk at the EU level can be restricted and included in Annex XVII of REACH. A restriction may apply to a substance as such or to one included in a mixture or an article. The restriction may also apply to substances in imported goods. Since imported textile articles constitute at least 80 % of all textile goods on the EU market (EC, 2014) and that leather articles are mainly imported from countries outside the EU market (Cr(VI) restriction, 2012), restriction has the potential to significantly reduce the risks for skin sensitisation to substances in textile and leather in the EEA31 population. Restriction also enables regulation of groups of substances, e.g. the existing restriction of certain azo dyes in textile and leather articles (entry of 43 of REACH Annex XVII), and may therefore represent an efficient RMO to regulate the risks caused by skin sensitising substances in textile and leather articles as a group (at least for those which are -and will be- harmonised as such under the CLP Regulation). Restrictions under REACH may be designed in different ways in order to reach the highest possible risk-reducing effect while having a proportionate economic impact on the EU market.

An overview of eight restriction options (RO) that have been considered are presented in Table 16 below, including a brief description of the option and the Dossier Submitter's considerations with respect to risk reducing capacity, proportionality to the risk and practicability.

Restriction Options RO1a, RO2 and RO3 have been further considered in the Impact Assessment and elaborated evaluation of the risk reduction capacity, proportionality and practicability of these ROs are given in the following sections.

Table 16 : Overview of possible restriction options (ROs).

Restriction option	Description	Considerations with respect to risk reduction capacity, proportionality to the risk and practicability
RO1a	In this RO, all substances which are classified as Skin Sens. 1/1A/1B in Annex VI to Regulation (EC) No 1272/2008, as well as a list of disperse dyes without harmonised classification but with skin sensitising properties, are covered. Concentration limits based on a combination of data-driven and preventive-driven approaches are set.	This option is assessed further in the impact assessment section, defined as RO1a. This is the proposed restriction option. It is considered as efficient in reducing the risk, as well as proportionate, monitorable and enforceable.
RO1b	Comparable to RO1a, however it includes additional conditions of labelling requirements. Regarding textile and leather, labelling requirements could be the following: *The person responsible for the placing on the market of a textile or footwear article or part of particle shall ensure that the label provides, in addition to that required by Regulation (EC) No 1272/2008, the following information: The name of all substances covered by the restriction proposal that are present in the article or part of article at a lower concentration limit than the proposed one(s);* • *The labelling shall be clearly visible, easily legible and appropriately durable; The label shall be written in the official language(s) of the Member State(s) where the substance is placed on the market, unless the Member State(s) concerned provide(s) otherwise.*	A restriction such as RO1a combined with labelling requirements would increase information to the general public about allergens contained in the textile and leather articles they may be exposed to. However, the level of additional protection of the general population such a labelling requirement would provide compared to RO1a is uncertain. The risk assessment carried out for RO1a and the concentration limits set are considered as protective for the general population. Nevertheless, it cannot be excluded that some additional benefits for human health could be expected for the general population for the substances falling under the risk assessment 'default' quantitative approach (see section 1.2 and Annex B for more details), for which there is a lack of information on the elicitation threshold and/or migration data. Labelling requirements may also cause costs for industry, given the number of substances used and the amount of articles to be labelled. These costs could not be quantified by the Dossier Submitter. The public consultation may provide additional data on these costs, and more generally on the feasibility and practicality of RO1b combined with RO1a. This restriction option is not considered further by the Dossier Submitter.
RO2	This RO covers all substances which are classified as Skin Sens. Category 1/1A/1B in Annex VI to Regulation (EC) No 1272/2008, but without a list of additional disperse dye substances of concern. The conditions of the restriction and concentration limits are unchanged compared to RO1a.	This option is further assessed in the impact assessment section, defined as RO2. This RO is expected to provide a lower risk reduction capacity compared to RO1a (lower human health benefits) since disperse dyes known to cause allergy to the consumer, but that are not classified as Skin Sens. under the CLP Regulation are not included. Furthermore, in the CLP regulation, skin sensitisation is not a prioritised endpoint, so the classification of some substances may take a long time, or not occur at all. It would result in lower prevention for general population.
RO3	This RO covers a narrow list of substances, including disperse dyes only (with harmonised classification as Skin Sens. according to the CLP regulation as well as the ones listed in the list of substances of concern provided in Table 2). The conditions of the restriction and concentration limits are unchanged compared to RO1a.	This option is further assessed in the impact assessment section, defined as RO3. This RO would cover substances that are already included in different voluntary schemes, indicating that substitution, enforcement and compliance are possible.

		The substitution costs are considered very low. However, the risk reduction capacity compared to RO1a will be lower (40% lower human health benefits).
RO4	This RO has a broader scope than RO1a. It covers substances harmonised classified either as Skin Sens. Category 1/1A/1B, Skin Irrit. 2 or Skin Corr. 1A/1B/1C in Annex VI to Regulation (EC) No 1272/2008. The conditions of the restriction and concentration limits are unchanged compared to RO1a.	In principle, this restriction option would be more protective than RO1 since it would also prevent general population from adverse skin effects associated with irritant and corrosive properties of substances present in textile and leather articles. The associated benefits for human health are expected to be higher. However, these skin effects are considered less severe in that they are reversible (compared to an ACD caused by a skin sensitising substance). Furthermore, for these substances, the threshold of the induction of the adverse effect (corrosion or irritation) is not available in the open literature, making it difficult to carry out a qualitative or a quantitative health risk assessment. Also, the Dossier Submitter finds it unlikely that these substances would be present in articles at such high concentrations that would cause harm to persons wearing the articles. This restriction option is not considered further by the Dossier Submitter. It is however noted that many of the substances covered by the proposed restriction (RO1a) also have harmonised classification as skin irritants or corrosive substances. With RO1a, adverse skin effects related to skin irritation or corrosion of these substances will also be prevented.
RO5	In this RO, the scope is identical to RO1a, but migration limits are proposed instead of concentration limits.	Migration better relates to the actual risk and therefore a migration limit may be preferred. However, the concentration limits proposed in this restriction proposal accounts for migration and therefore is deemed sufficient. Migration limit is also expected to be less practical and enforceable. This restriction option is not considered further by the Dossier Submitter.
RO6	In this RO, the scope is identical to RO1a, but aims at a total ban of skin sensitising substances in textile and leather articles placed on the EU market, based on the lowest concentration limits as possible, either 0 or limits based on the limits of detection.	With this RO the benefits for human health would probably be the highest. A total ban of placing textile and leather articles containing skin sensitising substances on the EU market has the potential to increase the quality of life among allergic individuals and can prevent new cases to occur. However, from a risk-based perspective, banning all substances of the scope is not justified because, except for disperse dyes, these substances are considered as safe provided they are present in the finished article (or part of article) below a certain concentration limit. Moreover, the costs associated with the implementation are expected to be the highest and may not be proportionate (100

		% substitution for the whole group of substances of the scope with safer alternatives, costs of compliance and control by importers and retailers, and authority enforcement costs). These costs will be a burden primarily for the textile and leather sector (producers, importers and retailers), but the size of this burden and the proportionality of RO6 is difficult to estimate without further investigation. These costs couldn't be quantified by the Dossier Submitter. Some practicality and monitorability issues could be also expected for industry and authorities for the substances with LoD far above the set concentration limit. In fact its enforcement for concentration limit will be easier to follow than for LoD due to the fact that LoD depends on the method and the equipment. LoD limits will imply an important work of standard harmonisation. The public consultation may provide information on the overall costs associated to RO6, and more generally on the feasibility and practicality of this restriction option. This restriction option is not considered further by the Dossier Submitter.
RO7	In this RO, the scope is broader than the scope of RO1a and includes self-classified substances.	Although self-classification of substances is based on the criteria specified in the CLP Regulation, notifiers could differ in their assessment of these criteria, resulting in different conclusions on the need for self-classification for skin sensitisation of the same substance. Contradicting self-classifications could cause issues for the practicality and monitorability for industry and authorities. This restriction option is not considered further by the Dossier Submitter.

2.2.2. Introduction of labelling requirements for textile and leather articles containing skin sensitising substances on the EU market without any restriction

In order to inform the general population about skin sensitisers in the textile and footwear articles they may purchase, the introduction of labelling requirements for the articles containing the substances targeted herein is considered as a desirable RMO. Similar requirements are already in place for skin sensitising substances in chemical mixtures under the CLP regulation.

Several labels on textile and leather (but not covering all the substances of the proposed scope) exist and are presented in detail in Annex B.9.1.2.

Today, labels on textile and leather articles do not provide any information about chemical content. It is therefore not possible for consumers to make informed choices and to avoid articles that may cause skin sensitisation. This is in particular an issue for those who already suffer from ACD to substances in textile/leather but also for the average consumer (Mobolaji-Lawal & Nedorost, 2015). Labelling requirements for textiles and leather articles that contain

skin sensitising substances have the potential to significantly increase the quality of life for people who suffer from ACD. It will make it easier for those affected to avoid articles that may elicit an allergic reaction, without needing to take precautionary measures that implies large restrictions on their daily life.

Both the costs and the benefits from labelling requirements are probably smaller relative to a total ban or a restriction under REACH limiting the concentration of sensitising substances in these articles, such as proposed in this restriction proposal. Labelling of textile/leather articles could make it possible for the average consumer to avoid articles with substances that may cause ACD, but it is not considered that it would reduce the risk to the same degree as a total ban or a restriction. This RMO would probably need to be accompanied with information campaigns, primarily directed towards sensitised individuals but potentially also to consumers in general, to have any real risk reduction effects.

The main costs caused by the implementation of a labelling restriction would be:

- labelling costs,
- information campaign costs,
- costs of compliance and control by importers and retailers, and
- authority enforcement costs.

Since labelling does not force companies to replace skin sensitising substances, it is likely to have a smaller economic impact on the EU textile and leather sector, in comparison to a total ban or a REACH restriction limiting the concentration. This relative cost reduction may be partially offset by the costs of labelling and information. The costs of compliance and control within the textile and leather articles supply chains and the authority enforcement costs are likely to be similar to the costs in the ban alternative.

2.2.3. Identification as SVHC according to REACH Article 57 and subsequent authorisation

Skin sensitising substances may be identified as SVHC according to REACH article 57(f) and put on the candidate list. The substances can then be included in REACH Annex XIV, which means that they may not be used or placed on the market without authorisation. ECHA will consider whether substances that are on the Authorisation list, when used in articles, pose a risk to human health or the environment according to REACH article 69.2. In the case of skin sensitising substances, identification of SVHC requires evidence that the substance is of equivalent level of concern to CMR substances. For a major part of skin sensitising substances found in textile and leather articles it is not likely that such evidence is available.

The requirements for authorisation only apply to articles produced in the EU. Since at least 80 % of all textile and leather articles on the EU market are imported from outside the EU, identifying textile and leather related skin sensitising substances as SVHC will likely have minor risk reducing effects on allergic textile/leather dermatitis. In addition, SVHC identification and the authorisation system are designed for risk management of one substance at a time and it would be a very time consuming and inefficient process to regulate the risks with skin sensitising substances in textile and leather articles.

Identification of substances as SVHC may, however, to some extent lead to an improved consumer information as it entails information requirements under REACH Article 33. On request from the consumers, the supplier of the article has to provide information if the article contain more than 0.1 % of an SVHC substance. However, this concentration would not help preventing from elicitation reactions (which is the aim of this restriction proposal).

2.2.4. Harmonised classification of substances under CLP (EC) No 1272/2008

Harmonised classification of substances according to the CLP regulation entails requirements, such as labelling. However, these requirements only cover chemical substances and mixtures and would not apply to hazardous substances in textile and leather articles.

In the case of risk management of skin sensitising substances in textile and leather articles, harmonised classification of substances may aid the implementation of other regulations. A harmonised classification can for example form the grounds to define which substances that should be covered by a possible restriction proposal (see next section).

2.2.5. Other legislations

The Textile Fibre Labelling Regulation (EU) No 1007/2011

The textile fibre labelling regulation contains provisions on labelling of the fibre composition in textile products. In a previous report, the Swedish Chemicals Agency proposed an expansion of the Fibre Labelling Regulation to cover also hazardous chemicals as a possible option for regulation of chemicals in textiles (KemI, 2013). The European Commission stated in their overview of the textile fibre labelling regulation in 2013 that regulation of hazardous substances in textile articles is of interest for the consumers (EC, 2013a). However, they also argued that the issue do not need to be addressed in the textile fibre labelling regulation and that EU chemicals legislations, such as REACH, may be better suited.

The General Product Safety Directive (GPSD) (EC) No 2001/95

The GPSD requires all consumer products to be safe when placed on the European market. The GPSD sets a number of requirements that needs to be met by producers (and importers) and distributors in order to secure consumer safety, including taking appropriate action to avoid risks, e.g. by withdrawing a dangerous product from the market or warning the consumers of a specific danger concerning a certain product. However, the regulation concerns actions made towards specific products that unexpectedly pose at risk under normal or reasonably foreseeable conditions of use and not towards a more general hazard. Consumer products that pose an acute health risk in various Member States, e.g. because of a specific chemical substance, may become temporarily restricted by a Commission Decision (rapid intervention). This type of restriction, however, provides only short-term solutions that apply one year at a time awaiting permanent regulations. It does not directly apply in EU Member States, but must be implemented through national legislation, and does thus not mean a full harmonisation. This type of procedure does not happen very often. It was applied for the highly allergenic chemical substance dimethyl fumarate (DMF), which is now regulated under REACH Annex XVII.

Development of a specific EU product legislation covering textiles and leather

There may also be a need for a specific EU product legislation concerning textiles (KemI, 2013, 2016). Today, the regulation of hazardous substances in textiles is fragmented and a specific textile product act would impose uniform requirements on chemicals in textiles and on the development and dissemination of relevant information in the supply chain. However, the development of a specific textile regulation is only possible in the long term. Given the current conditions, the risks with hazardous substances in textiles can be addressed under existing chemical legislations. If a specific textile regulation is developed in the future, existing restrictions may be integrated in that legal act.

2.2.6. Voluntary actions

A recent review of 47 studies on voluntary agreements between governments or government bodies and individual businesses or industry groups concluded that, if properly implemented and monitored, voluntary agreements can be effective and businesses can help to achieve public policy aims (Bryden and al., 2013). The most important characteristics of effective voluntary agreements are that: a credible threat of legislation exists; there are substantial and financially important incentives and sanctions for non-participation or nonfulfillment of targets; the targets of the agreement are distinct and monitorable. None of the characteristics highlighted by Bryden et. al. (2013) would be fulfilled in the absence of other policy actions. Furthermore, the effectiveness of voluntary agreements is highly uncertain. This is primarily an effect of the lack of enforcement mechanisms. This lack of effectiveness makes this option non-feasible in terms of risk management.

Several voluntary initiatives in the form of different labelling schemes exist. These textile labels are guides for consumers and industry. In the textile field, there are several ecolabels, which involve certification of industrial companies that meet these labels' criteria: Global Organic Textile Standard (GOTS), Nordic Eco-Label, EU Ecolabel, OEKO-TEX, Blue Sign and Nordic Swan. These initiatives have established lists of substances with concentration limits that must not be exceeded by industry in order to obtain the right to claim that its article meets the criteria of the so called label.

2.2.7. Economic policy instruments

A fee or a tax could be introduced on textile articles containing skin sensitising substances. In order for such an instrument to be economically motivated, the external effect has to be clarified. External effects are uncompensated impacts on other individuals' welfare caused by actions by one individual or firm. These effects can be positive or negative.

In the case investigated here, use of skin sensitising substances by producers of textile articles may lead to negative impacts on the welfare of the consumers in terms of reduced quality of life and increased health care costs. These impacts can be considered external, unless the consumers are informed about them in such a way that they can take these impacts into account when making their consumption decisions. The external effects can be internalised by introducing a fee or a tax that forces the producer to take the welfare losses

of consumers into account, when choosing whether to use skin sensitising substances in the production process, or not.

Two alternative economic policy instrument options have been identified:

i. a fee or a tax on its own, or
ii. a fee or a tax in combination with a labelling requirement.

Option i) internalises the external effects related to elicitation of those who are already sensitised as well as new cases of sensitisation. In option ii), the external effect relating to those who are already sensitised is assumed to be largely internalised by the labelling requirement, whereas the economic policy instrument (fee or tax) internalises the external effect related to new cases of sensitisation. Thus option ii) takes into account that the labelling requirement is targeted towards those consumers who are already sensitised, while other consumers will be less likely to change their consumption due to labelling, even though they face the risk of sensitisation.

The unanimity requirement in the tax area means that the possibility of using taxation as a Union-wide instrument is limited (EC, 2007). These economic instruments would therefore have to be considered at the national level. National taxes would however create an uneven playing field for market actors, especially as the e-commerce market for textile articles is likely to grow in importance. An EU-wide instrument is preferable, therefore the tax options have not been analysed further in this report.

2.2.8. Conclusion on the most appropriate risk management option

The alternative RMOs presented above have been discussed at the Risk Management Expert Meeting (RiME) in 2016 after the publication of the Swedish Chemicals Agency's RMOA, and then carefully considered by the Dossier Submitter. Given current conditions, the Dossier Submitter believes that the most efficient way to regulate skin sensitising substances in textile and leather articles is to address them as a group and using relevant legal instruments available in REACH. EU-wide legally binding regulatory measures in REACH will impose equal conditions for the entire EU market and will make it easier for the companies to set demands on the suppliers. In the long term, it is considered that development of a specific EU product legislation covering textiles, in which existing provisions on hazardous chemicals in textiles could be integrated, would be a good way forward.

The Dossier Submitter considers restriction under REACH Article 69.1 as the most appropriate RMO. Restriction enables regulation of groups of substances, may apply to imported articles (which stand for 80 % of textile and leather articles in the EU) and may cover all types of hazard endpoints. It is also in line with available and proposed regulatory measures for hazardous substances in textile articles. Some carcinogenic azo-dyes are already restricted in textile articles under REACH (Annex XVII, entry 43) and the recently adopted entry 72 of REACH Annex XVII covers 33 CMR substances in textile articles, under REACH Article 68.2[43].

[43] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2018:256:FULL&from=EN

Eight restriction options were analysed in the framework of the elaboration of this restriction proposal and the option RO1a, such as described above, is considered as the most appropriate option to mitigate the risk in a proportionate way. This option has been further assessed in the impact assessment section against options RO2 and RO3.

2.3. Response to Restriction scenario(s)

In response to the proposed restriction option (RO1a), actors in the supply chain and society as a whole are expected to react as follows:

- Manufacturers of chemicals in the EEA31 and worldwide will react by producing more of the chemicals, which are proposed as substitutes and less of the chemicals, which are restricted (all else equal).

- Manufacturers of textile and leather articles in the EEA31 and worldwide will in some cases incur increased costs due to this restriction (compliance costs) and depending on the price elasticity of demand of the textile buyers (the manufacturers of apparel and footwear), it can be anticipated that they may push some of these costs down the supply chain to the distributors and finally to the consumers. Price changes (if any) are not expected to be equal for all textile and leather articles due to the fact that all chemicals are not used in the production of all textiles and do not have the same function for all textile and leather articles. The exact reaction to the anticipated price increase (if any) on textiles cannot be predicted with certainty since price/demand elasticities for all textiles and countries are not available. Nevertheless, the Dossier Submitter assumes that this potential increase (if any) would likely be negligible given the very high volume of textile and leather articles marketed within EEA31. The Dossier Submitter considers that, even though extra costs would be borne by textile and leather industry due to the restriction, these extra costs would not necessarily be passed on in the supply chain and finally on the end consumers. Instead these extra costs could be absorbed by the upstream supply chain, due to i) the high level of competition of textile and leather markets, inside and outside EEA31 and ii) the fact that costs for production and raw materials is generally one small component of the consumer price of this type of article (for more details, see section 2.4.4).

- The actors in the supply chain (including distributors) in the EEA31 to deplete textile and leather articles in stock prior to the entry into force of the restriction. This can induce a forced sale, but it can be anticipated that this can be combined with already planned sales. The way existing stocks would be depleted in the supply chain (gradually – business as usual speed - , depletion of stock until the entry into force of this restriction or forced sale) depends on the capacity of the transitional period to allow such a depletion. The Dossier Submitter considers that the proposed transitional period of 36 months would provide sufficient time to the supply chain to adapt and to gradually deplete existing stocks.

- The proposed restriction might influence the use of about 43% of substances (about 40 out of 94 substances identified as possibly being currently used in textile and leather (not exhaustive though) and that would not be compliant with the concentrations limits proposed by the Dossier Submitter (see section 2.4.1 and Annex E.2).

- The impact assessment performed shows that technically and economically feasible alternatives with similar or better hazard and risk profiles exist for disperse dyes which are proposed to be banned. Difficulties are however expected from a technical and/or economical standpoint regarding the replacement of other substances such as for example intermediates, plasticiser for neoprene, cobalt and rosins. Nevertheless, for most of them switching to best practices in the manufacturing process of textile and leather articles may solve the issue, according to the information gathered by the Dossier Submitter from stakeholders consulted. The transition to alternative chemicals and or improved processes is expected to increase costs during the transition period as well as the first couple of years after the entry into force due to processes adaptations and testing costs. These costs are presented and discussed in section 2.4.1 below.

- Enforcement authorities in the EU Member States, currently without national legislation, to put the necessary measures for control in place and those Member States with national legislation to amend current national regulation. This would also include the development of standardised testing methods for key groups of substances, where they do not already exist. (In the table 20 in Annex E.2. there are a number of substances, where information on testing methods are not available. This can be due to the fact that they do not exist, but information can also be lacking. This needs to be confirmed during the public consultation process).

2.4. Assessment of restriction option RO1a (the proposed restriction)

2.4.1. Economic impacts

2.4.1.1. Substitution costs

Substitution costs include the cost related to complying with the limits set for the finished article at point of sale. It includes the replacement of skin sensitising chemicals with alternatives without skin sensitising properties (and ideally with general better hazards profile for human health and environment). It also includes changes/improvements in the production process, both for the recipe and the formulation of the chemicals as well as in the curing steps and inclusion of potential extra-washing steps before articles reach point of sale. Another cost of substitution which has been identified for some chemicals is reformulation costs. All these types of costs are more extensively discussed in Annex E.2.2 and E.2.3. They are however for the convenience of the reader also summarised here.

2.4.1.1.1. *Costs of substituting to alternative chemical substances*

The Dossier Submitter's analysis of the cost of substitution to alternative, non-skin sensitising, substances indicates that they will, in the cases where substitutes have been identified, not be an not insurmountable economic burden for the industry as a whole. This can be seen in Table 17 below for the different substances, where it is shown that the cost/weight unit for the alternatives is lower or similar to the cost/weight unit for the substances used today (and targeted to be restricted). The economic and technical feasibility of the different substances

are also analysed and described per substance (or substance group) in more detail in Annex E.2.3. For the purposes of the identification and the analysis of alternatives, KemI (2019) proceeded in grouping the substances when feasible and when relevant (again, more details are provided in Annex E.2).

A total cost assessment is also made for the substances where data availability makes that possible (as well as a sensitivity analysis for total reformulation costs) please see section 2.4.1.4. below.

Table 17 : Information about technical and economic feasibility of the substitution of the substances in the scope, according to the industry consulted (KemI, 2019)

Substance/ group	Cost of the substance restricted (€/metric ton)	Substitute	Technical feasibility	Cost of substitute* /economic feasibility, (€/metric ton)	volume textile (metric ton)	volume leather (metric ton)	Impact of substitution on the cost effectiveness of the process
Benzenamine (aniline) (Indigo)	€1300-1400 per metric tons.	Regarding substitution for indigo, there are a couple of replacements but these are not feasible given the size of the denim industry. Natural indigo grown in the US, China and India. Fermented Indigo made from bacteria and a sugar source. The issue is low yield, water use and competing for arable land (Corn is the typical feedstock and it is needed in large quantities). Some sulfur dyes can mimic indigo but these have not gained any momentum in the industry since their introduction a few year ago. They are claimed to be all significantly more expensive than indigo. Indigo can be made without using aniline but aniline is a building block chemical for many other dyes If it is restricted, these colours/dyes simply will not be available (KemI, 2019)	If restricted colour will not be available.	Not assessed.	180	18	Decreased
Chromium III compounds		According to the chromium VI (2012) restriction proposal the following substitutes to chromium III exist: Glutaraldehyde, mineral tannages (aluminium, titanium, zirconium salts), oil tannage, synthetic tannage (resin –syntans) and vegetable tanning.	According to the chromium VI restriction proposal, the substitutes do not result in leather with the same quality properties as chromium tanned leather. They are therefore note	With regard to substitution aldehydes such as glutaraldehyde cost €1600 per metric ton	36 metric ton (for group)	70 400 metric ton (for group).	Decreased.

Substance/ group	Cost of the substance restricted (€/metric ton)	Substitute	Technical feasibility	Cost of substitute* /economic feasibility, (€/metric ton)	volume textile (metric ton)	volume leather (metric ton)	Impact of substitution on the cost effectiveness of the process
		It is however indicated that the industry can comply with the proposed lower concentration limit. In that case no need to substitute and no cost of substitution.	equivalent. Based on an overall comparison, the chromium VI (2012) restriction proposal states that aldehyde (glutaraldehyde) is the main substitute to chromium VI. For more details we refer to the chromium VI restriction.				
Dyes	Depend on the type of dye.	Substitutes exist	OK according to KemI (2019)	Should not differ much.	9 944	465	Unchanged
Formaldehyde	€400 - €600 per metric ton at 37% purity	Polycarboxylic Acid Superplasticizer 40% (not assessed for leather hides and fur)	No explicit substitute found for leather. The included substitute is used in textile as substitute, may be good substitute for leather as well, but this needs industry feedback.	€700-1100/ metric ton	288	28	Decreased
Intermediates	€900 - €1300 per metric ton is estimated for 1,3-	Na	Not technical feasible to substitute due to its many uses	Na	540	53	Na

Substance/ group	Cost of the substance restricted (€/metric ton)	Substitute	Technical feasibility	Cost of substitute* /economic feasibility, (€/metric ton)	volume textile (metric ton)	volume leather (metric ton)	Impact of substitution on the cost effectiveness of the process
	Isobenzofurandione [phthalic anhydride]		according to KemI, 2019.				
Metals (cobalt), inorganic compounds	Na	Na	Na	Na	11	0	Na
Phthalate	€3 600 -€5 400 /metric ton.	A plasticizer Acetyl Tri-butyl Citrate ATBC has been identified as a possible substitute.	Some concern about regrettable substitution from industry for some endpoints, but better overall.	€900-€2 600/metric ton	4 050	792	Improved
Plasticiser for neoprene	€86 000/metric ton	Dioctyl sebacate	May be regrettable substitution in one way or another, according to industry.	€900- € 89 200 per metric ton.	180	0	Cost of substitute lower, quality differences not clear.
Rosins	€1 300-€1 800 per metric ton	Polyurethaneadhesive/polyurethane and Adhesion styrene Acrylic emulsion binder	Acrylics may be regrettable substitutes.	€3 100-€4 400/per metric ton. and €900– €1 300/metric ton.	10 800	0	Decreased if substituted with acrylics. Increased otherwise.

Substance/ group	Cost of the substance restricted (€/metric ton)	Substitute	Technical feasibility	Cost of substitute* /economic feasibility, (€/metric ton)	volume textile (metric ton)	volume leather (metric ton)	Impact of substitution on the cost effectiveness of the process
Rubber accelerators	€900- €89 200 /metric ton (depending on which accelerator)	Reformulation is needed	Uncertain since reformulation is needed.	Should not differ much according to rubber expert, (large cost for reformulation possible) €13 300/ reformulation is estimated.	378	37	Unchanged
Solvents	Depending on which type of solvent (intermediate) the price per ton range from € 900/ton to €44 500/ton.	Best practice?	No substitutes identified. Best practice can possible be a way forward.	Na	7 261	335	Na

Na: not available

* When not provided by industry in Kemi (2019), the costs of substitutes have been searched for in Alibaba (converted from US $ to €)

Regarding glutaraldehyde, this substance is the most common alternative to chromium tanning for a range of leathers. At the same time, glutaraldehyde is a known as a potent skin sensitiser, with a harmonised classification as Skin Sens. 1A under the CLP regulation. According to information in the background document for the REACH restriction for chromium VI substances, there are no reports of shoe dermatitis developing from glutaraldehyde-tanned leather shoes. The authors of the background document refers to a study by Nardelli et al. (2005), where the relation between the localisation of foot dermatitis and the causative allergens in shoes were analysed. The result of patch testing in 1 168 patients with foot dermatitis did not record any patients with a positive reaction to glutaraldehyde (2% in petrolatum). The authors of the background document also refers to NICHAS (1995), and say that in leather, glutaraldehyde is bound irreversibly to the collagen molecule and severe acid hydrolysis is required to release it by breaking the peptide bonds within the collagen rather than the actual glutaraldehyde binding site. Based on this information, a derogation for glutaraldehyde could have be considered by the Dossier Submitter for this restriction proposal. However, since glutaraldehyde is a potent skin sensitiser, the Dossier Submitter proposes to not derogate glutaraldehyde from the current restriction proposal. If new information arrives during the public consultation process, the Dossier Submitter may reconsider this decision. Moreover, a restriction on the use of glutaraldehyde might induce high costs on for example the car industry since the substance is used for tanning leather in car seats. The magnitude of this impact is however uncertain since it has not been investigated further by the Dossier Submitter and since the concentration in articles at point of sale is not known.

2.4.1.1.2 *Costs related to reformulation, research and development*

At the moment, needs for reformulation have been identified for a number of rubber accelerators. To assess these costs, a rubber expert connected to the consultant firm “Lysmask Innovation AB” has been involved in the review of these substances.

According to the rubber expert, substitution should be no problem, but it will be hard to say beforehand which the substitutes will be and if they will be less problematic from a skin sensitising perspective. This follows from the fact that a reformulation process will be needed for substitution. Moreover, several of the identified substances are also the cause of work-related exposure and it is therefore suspected that a substitution process is already ongoing, primarily to reduce occupational exposure. Work-related hazards are not covered in this restriction proposal, but reducing such problems is of course a bonus, all else equal.

According to the rubber expert, the cost of the substitutes in €/kg will not be a big issue since they will be a very small share of the total cost of production. The expert estimates that they may be less than 1% of the material costs. The material cost is in itself estimated to be a small cost of the total production cost.

The larger cost will instead, be the reformulation costs. Reformulation can be both quite easy and also relatively hard. For the easy cases the rubber expert estimates a couple of days of work in the lab (with for example a chemical engineer) and then some simple tests in the factory. For the very difficult reformulation cases one year work cost and then substantial changes in processes in the factory can be expected followed by certification and other quality

related costs. The reformulations connected to textile applications are expected to be the easiest kind (since for example certification costs do not exist).

In order to calculate the additional reformulation cost that would be borne by industry, the current cost per reformulation as well as the number of reformulations due to this restriction proposal are needed. In addition to the business as usual reformulations, these data are also needed in order to estimate what the additional burden of reformulation will be due to this restriction as compared to the reformulations that the industry plan to conduct regardless of this restriction proposal.

It is here assumed that the reformulation will be of the easier type, which the rubber expert defines as a couple of days, or more (the Dossier Submitter here assumes four weeks) for reformulation in laboratories. This assumption may change if better information arrives in the public consultation process.

The Dossier Submitter is assuming that the labour cost is 50 €/hour, which is about twice the average labour cost in EEA31, according to Eurostat, and is approximately what a chemical engineer earns in Sweden. This is motivated since the personal working on reformulation will be experienced and with an above average salary. For the laboratory cost estimates, the Dossier Submitter is assuming that 60 % of the total reformulation cost is labour cost and that the remaining 40 % is the cost of using the laboratory itself. This is based on (COLA, 2015) where labour cost is estimated to be 50-70 % of the total clinical laboratory cost. This gives the following “on the back of an envelope”- calculations based on an additional assumption of one month full time work for one person;

- 40 hours per week, for four weeks gives 160 hours work in total. Labour cost is € 8 000 per month (based on € 50/hour for 160 hours). Laboratory costs are estimated to be 40 % of total reformulation costs (and 60 % labour cost). This gives that total reformulation cost is approx. € 13 300 /reformulation, with laboratory costs of € 5 300 /reformulation and labour cost of € 8 000/reformulation.

This is however an estimate based a number of assumptions and best available data and the Dossier Submitter has not been able to get this information at first hand from the industry. Improvements with better data in the public consultation process may therefore improve the quantitative assessment.

The number of products which will be in need of reformulation due to this restriction proposal has not been possible to estimate at this stage, but the Dossier Submitter hopes to improve on this information gap as well in the public consultation. However, in order to discuss and problematise on the total cost of reformulation, a sensitivity analysis based on assumed number of reformulations required due to this restriction proposal is conducted in Annex E.4.1.6. A summary of the results is presented below in section 2.4.1.4.

It is further assumed that the industry under a business as usual scenario would regularly reformulate products even without a restriction proposal with some frequency. It is however clear that reformulation frequency can differ a lot depending on company strategy and products. For some mature products, a new reformulation is not done during the products life range. For other companies (and other product types) both regulatory driven and cost driven reformulations are business as usual practice. Regarding the product type in question for reformulation due to this restriction, “accelerators for vulcanized rubber”, the rubber expert states that reformulation will not be done without external demands in a business as usual

case. Therefore the Dossier Submitter has to assume that the companies are bearing the full cost of reformulation due to this restriction proposal and that reformulation would not have been done in a long time span without this restriction proposal.

It is however not possible to know on beforehand if the reformulated substitutes would be better for consumers with regard to skin sensitisation or other human health endpoints, according to the consulted rubber expert. Reformulation costs can therefore turn out to be sunk costs with some unknown probability.

Reformulation might also be needed for other substances, but that has not been clarified at this stage.

2.4.1.1.3. *Production process changes incurred when moving towards best practice (including possible investment costs for new machinery)*

KemI (2019) indicates that diisocyanates may be present in consumer articles in concentrations up to 1000 ppm. According to comments received during the public consultation on this restriction proposal, this statement is based on results from the use of inappropriate analytical techniques. The actual concentration levels in articles within the scope of the proposed restriction are claimed to be considerably lower than 1000 ppm, and should not be found in concentrations above 10 ppm. The Dossier submitter does not have information to further challenge these comments. In case new information that challenges the comments received during the public consultation emerges, then a move to best practice would be needed to ensure compliance to the proposed restriction.

According to the information collected, no substitutes exist for diisocyanates. However if best practice is used, with correct amount of ingredients, catalysts, high enough curing temperatures and potential washing afterwards, the chemicals should not be present in articles at point of sale (KemI, 2019). As discussed in Annex E.2.2.9. it is assumed that most companies follow subnormal, normal or good practice and only a minority follows best practice. It has not been possible to get data on the cost of moving towards best practice for diisocyanates despite both a questionnaire contact and consultants' enquiries (see Annex G for a detailed description on the efforts made).

Indications from ECHA suggest that similar best practice improvements might be a way forwards for solvents. This has however not been confirmed by industry or any other available information.

2.4.1.2. Testing and enforcement costs

In this section, the associated administrative costs for testing and enforcement that will be incurred by industry and enforcement authorities in order to ensure compliance with the restriction are assessed.

Initially it has to be noted that there are many uncertainties related to testing costs. The most important ones identified by the Dossier submitter are:

- the costs per test,
- the number of articles on the EEA market to be tested,

- the frequency of test required from companies to establish compliance,
- which chemicals of the scope are already tested routinely by companies, either due to existing regulations or due to various voluntary schemes, and
- how many of the affected companies are already testing substances in the scope proposed restriction.

The Dossier submitter has not obtained this information in the consultation and research carried out in the preparation phase of the restriction proposal. The Dossier submitter has assessed the costs per test (see section E.4.2) and made some assumptions on the number of additional tests that will be performed annually. These assumptions are however very uncertain.

The public consultation brought very limited quantitative information. Information on the costs per test provided in the public consultation are in line with the Dossier submitters assessment. The public consultation does however indicate that other assumptions made by the Dossier submitter leads to an underestimation of the total testing costs.

Overall, the very limited information at hand does not allow for a proper assessment of testing costs. More information would be needed.

The testing costs presented below are indicative costs to individual enforcement authorities and to individual companies and do not represent the aggregated EU-wide costs for all substances within the scope of this restriction proposal. The testing costs per material, when available, are provided for indicative purposes since the overall testing cost will be determined by the number of tests to be conducted on all the articles of concern and this overall cost couldn't be assessed. According to the Dossier Submitter's personal communication with a chemist and researcher at RISE (Research Institutes of Sweden), it is not possible to come up with the total testing costs for companies or authorities per year for testing all the substances within the scope of this restriction proposal. There are a number of uncertainties and reason for why the total testing costs cannot be provided. The costs for testing depend on how the tests are set up and if substances have to be extracted from the materials (which is almost always the case). In many cases the leather material is more time demanding to test compared to textile material. Another reason is that various test labs have very different price levels for testing. For instance the testing costs vary a lot between laboratories in the EU and in Asia.

What can be said with some certainty is that there will be an increased cost for verifying the compliance with the new regulation and that the companies will increase the number of tests conducted during the first years after the new restriction has been implemented in order to ensure compliance. The number of tests conducted in order to ensure compliance will then after a few years however decrease over time, as in the case of implementing other restriction proposal. How much these costs will increase during the first years depends on how many different materials are to be tested, how many different suppliers each company has and how many batches that will be run or tested each year etc. It also depends on their suppliers understanding and compliance of the new regulation.

The overall experience of testing laboratories show that companies in general try to reduce the number of suppliers of chemical substances used as well as the number of risky or risk-related materials in order to gain a good overview and to reduce the costs for testing and compliance. Another component that reduces the number of tests performed each year is the profits of each article, as tests will not be conducted for smaller collections. The reliability of

the supplier and the level of risk for each material are two of the drivers/steering factors for conducting tests of chemical substances.[44]

An assessment of costs per test is provided in Annex E.4.2.

It is foreseen that the enforcement costs for authorities could be higher than for the concerned companies. For enforcement authorities, testing costs might therefore be of higher importance. A higher burden and cost for testing of compliance could result in that less enforcement activities and controls are in fact conducted. Many of the substances within this restriction proposal are already being analysed and tested with regard to the criteria for labelling such as for instance with the OEKO-TEX label. For the companies that already have such labelling systems implemented in their business the testing costs are not expected to increase due to this proposed restriction. These companies already have a cost for the certification and testing of the textiles that is not an impact of this restriction proposal.

For companies that do not have labelling or certification systems implemented, there can be an additional cost for testing. Based on the price information from consulted laboratories on the substances within the scope of this restriction, the total testing and enforcement costs are estimated initially to be somewhat higher than an average for a REACH restriction since the number of substances required to be tested are much higher than for a regular restriction.

In comparison with the restriction proposal for tattoo inks and permanent make-up the total annual testing costs for compliant tattoo inks were reported up to €80 000 for the 4 130 substances within the scope. If that value would be transferred to this restriction proposal for textile and leather articles, all else equal, with about 1000 substances within the scope, the total annual testing costs for compliant textiles would be €19 200 (24% of €80 000). And the annual average incremental costs for testing for EEA22[45] would be about €48 000 (24% of €200 000). An extrapolation to EEA31 can be found in Annex E.4.2. In the tattoo inks and permanent make-up restriction it was assumed that the member states with national legislation would continue sending the same amount for analytical testing to ensure compliance as before the proposed restriction was put in force. This is however not the case for the restriction proposal for textile and leather articles where members states are anticipated to have incremental testing costs during the first couple of years after the restriction has entered into force.

Based on the available information about testing costs for phthalates, formaldehyde, disperse dyes, cobalt and chromium, the Dossier Submitter has calculated the annual testing costs during the first couple of years to €82 800 (in the best estimate scenario). For further information on these calculated annual costs for testing, please see Table 30 in Annex E.4.2. This calculation does not take into account that:

- some of the substances assessed are to some extent already covered by regulations and will be tested anyway,

[44] Dossier submitter's personal communication with chemist and researcher at RISE, March 2019

[45] The geographical boundaries for the assessment applied in the tattoo ink restriction dossier were EEA31. But the presented selected statistics were for the Members States that at the time did not have any national legislative measures implemented for tattoo inks.

- a number of affected companies are already carrying out tests under various certification and labelling systems,
- laboratories offer discounts when testing multiple substances and/or materials.

As a result of the proposed restriction both industry and enforcement authorities will need to perform additional testing in order to ensure the compliance with the restriction. The extent of these additional required testing that needs to be performed compared to the testing already undertaken is not known. For industry it is however assumed that overall, these costs would not outweigh possible gains due to surplus from marketing alternative substances. To some extent the already existing quality control and testing performed by the concerned companies may already provide the necessary information.

In general, companies would commission standard laboratories for testing the levels of the concerned substances. It is assumed that only a minority of companies would invest money in in-house laboratory devices. According to the Dossier Submitter's information standard laboratories are already equipped with suitable devices for testing most of these substances and prices are not expected to change as a result of this restriction proposal.

Overall, the very limited information at hand does not allow for a proper assessment of testing costs. More information would be needed.

2.4.1.3. Other costs

Some of the other costs that industry may face due to this restriction could be the cost associated with transportation, packaging and dispatch from one country to another. These costs are however not expected to be changed as a result of this restriction proposal and are therefore not assessed in this restriction report.

2.4.1.4. Total cost of substitution

Total cost of substitution has been calculated only for the cases where price information is available for both the substance used (restricted) and for the alternative, as indicated in Table 17 above. Details are provided in Annex E.4.1.5.

The assessment gives a total cost of substitution for all of the chemicals where cost data exists for both the substances used and the proposed substitute at around - € 25 million per year (if rosins are substituted with acrylics) or 3 million € per year (if rosins are substituted with PUR). Excluding the negative costs gives a total cost of around €0.1 million per year (if rosins are substituted with acrylics) or €24 million per year (if rosins are substituted with PUR). From this, the total overall annual substitution cost with regard to the price difference between the substance restricted and the alternative (assuming no difference in quality, volume or other factors) may be negative. This follows from the fact that the cost of the alternative for phthalate is lower and so is the cost of the alternatives for plasticisers for neoprene and rosins. Discrepancies exist in the substitution costs between the substance groups. Moreover, it is important to recognise that hidden costs related to quality differences and other aspects not known to the Dossier Submitter may exist. Thus, this negative cost

may be considered to result from some underestimation of the costs (see Annex E.4.1.5 for a more detailed discussion).

The total annual costs estimated are presented in Table 18 below. They are annual costs (not discounted).

Table 18: Total annual cost estimates of substitution between restricted substances and alternatives

Substance group	Cost of substance used	Cost of Substitute*	Cost difference per weight unit on average	Volume used (ton)	Total cost difference with regard to chemicals restricted
Phthalate	€ 3 600 -€ 5 400 / metric ton.	€ 900-€ 2 600 / metric ton	€ -2 750	4 842	€ -13 315 500
Dyes	Depend on the type of dye.	Should not differ much.	0	10 409	0
Rubber accelerators	€ 900- € 89 200 / metric ton (depending on which accelerator)	Should not differ much according to rubber expert, (large cost for reformulation possible) € 13 300/reformulation is estimated.	Should not differ much according to rubber expert, (large cost for reformulation possible) € 13 300/reformulation is estimated.	415	0
Rosins	€ 1300-€ 1800 per metric ton	€ 900-€ 1 300 / per metric ton if substitution with acrylic binders Potential regrettable substitution.	€ -450	10 800	€ -5 000 000
Rosins	€ 1300-€ 1800 per metric ton	€ 3100-€ 4 400 / per metric ton if substitution with polyurethane binders	€2 200	10 800	23 760 000€
Formaldehyde	€ 400-€ 600 per metric ton at 37% purity	Polycarboxylic Acid Superplasticizer 40%. € 700- € 1100 / metric ton.	€ 400	288 in textiles and 28 in leather	€126 400

Plasticiser for neoprene	€ 86 000/ metric ton	€ 900 -€ 89 200 per metric ton.	-40 950	180	€-7 371 000
Sum of total annual substitution cost (if rosins substituted with acrylics)					€-25 420 100
Sum of total annual substitution cost (if rosins substituted with PUR)					€3 084 700
Sum of total annual substitution cost (excluding negative costs) (if rosins substituted with acrylics)					€ 11 200
Sum of total annual substitution cost (excluding negative costs) (if rosins substituted with PUR)					€23 771 200

*The cost of the substitute is based on a low-high interval including all identified substitutes.

Regarding rosins, during the public consultation, one stakeholder confirmed that polyurethane binders may also be suitable but are known to be more expensive than acrylic ones. If both substitutes are suitable, the dossier submitter would expect that the industry would rather replace rosins by acrylics binders than with PUR (all else equal).

For the rubber accelerators, as mentioned above in section 2.4.1.1.2, the costs per reformulation is estimated to amount to €13 300. However, it should be noted that the lack of information on the number of reformulations required make calculating the total cost of reformulation difficult. Therefore, sensitivity analysis was performed, where different numbers of reformulations in a low (100 reformulations), medium (1000 reformulations) and high (10 000 reformulations) scenario was used. Assuming that the medium scenario is most likely, the total cost of reformulation would amount to approximately € 13.3 million (one time cost). The industry needs to give feedback during the public consultation on the assumption regarding the number of reformulations in order to improve this estimation, see Table 29 in Annex E.4.1.5.

2.4.2. Human health impacts

As described in detail in Annex E.5, contact with textile and leather articles may result in contact dermatitis such as urticaria, irritant contact dermatitis (ICD) and ACD. This restriction proposal does not cover the allergies due to the fibres themselves.

Chronic urticaria can be allergic or not and may be associated with contact with textiles mainly due to proteins such as latex- or silk-proteins. Chemical-induced (not protein-based) urticaria exists but there is little information on the association between urticaria and contact with products containing skin sensitising substances and no information about reported cases. Therefore, the quantitative part of the human health impacts assessment performed in this restriction proposal does not include the prevented urticaria cases and may be underestimated.

Textile and leather articles are reported, among other consumer products, to be causing ICD. Depending on the article and the irritant of concern, ICD can cause minor to mild effects, it is reversible and not permanent. For the reasons explained above, irritants are out of the scope of the restriction. Therefore, ICDs cases are not considered for the human health impact

assessment of this restriction proposal. Nevertheless, it cannot be excluded that some irritation cases may be the preliminary signs of future sensitisation and that those cases may actually reflect symptoms of future skin allergy. However, there is no medical information available that would allow assessment of the proportion of irritation cases (when diagnosed) that would lead to allergies.

The human health impacts assessment performed herein focuses on ACD. The association between ACD and contact with sensitising substances is proved and ACD is a largely reported effect in the literature. Such as described in sections 1.2.4 above and B.5.5 of the Annexes, allergic contact allergy or ACD is caused by chemical substances that penetrate the skin. As already explained, sensitisation is a two-step process in which a substance first primes the immune system and induces an allergy (induction). This step is without visible symptoms and is irreversible. The second step (elicitation) takes place after re-exposure to the allergen and is associated with the manifestation of allergy, i.e. ACD. It is generally considered that a lower dose per skin area is required for elicitation to occur than for induction. According to the WHO International Classification of Diseases, “allergic contact dermatitis” is defined as an eczematous response provoked by a Type IV delayed immune reaction in the skin to a substance or substances to which the individual has previously been induced. The allergic contact dermatitis is a subcategory of category 14 - Diseases of the skin / Dermatitis due to exogenous factors and is classified as category EK00 in the 2018 WHO ICD-11 classification of diseases[46]. The category EK00.0 is specific to *Allergic contact dermatitis due to clothing or footwear*.

ACD is characterised by rash, erythema, oedema, and the skin can become dry, shift and fissures develops. Symptoms associated with ACD[47]:

- dry, scaly, flaky skin
- hives
- oozing blisters
- skin redness
- skin that appears darkened or leathery
- skin that burns
- extreme itching
- sun sensitivity
- swelling, especially in the eyes, face, or groin areas

As explained by ECHA (2014), the severity of the health effects of skin sensitisers may differ significantly in the affected population, ranging from situations where subjects sometimes do not even notice any symptoms to situations where medical treatment is necessary. At first, sensitisation effects may be hardly noticeable or even recognized as ACD, since the symptoms often do not occur immediately. Due to a lack of awareness, the effects may progress to more severe effects if the exposure is prolonged or repeated. Although health effects subside once exposure has ceased, the induction is irreversible; possibly leading to health effects upon every next contact.

The rash can be very uncomfortable in some cases. Depending on the part of the body and the severity of the symptoms, ACD may be very invalidating for people that suffer from it,

[46] https://icd.who.int/browse11/l-m/en
[47] https://www.healthline.com/health/contact-dermatitis#symptoms

preventing them sometimes from living normally or even working, therefore impacting their quality of life.

Footwear dermatitis primarily involves the feet, but sometimes spreads to other areas. A combination of occlusion, with resultant heat and sweating, friction and pressure within footwear, in the presence of multiple allergens, may trigger an episode of footwear dermatitis (Saha, 1993). Chronic foot dermatitis can be disabling. It can result in painful fissuring, often with secondary infection and can lead to inability to walk.

When the skin sensitising substance is identified and the exposure is avoided, the symptoms usually subside in a few weeks. However, since textile and leather articles are of concern in this case, avoiding the exposure (i.e. avoiding being in contact with clothing or shoes) might be extremely difficult for patients, even impossible, for obvious social and practical reasons.

2.4.2.1. Prevalence and incidence data: the population of concern under the baseline

Prevalence data on ACD used for the human health impact assessment are summarised in section 1.1.2 above and detailed in Annex E.5. The Dossier Submitter collected information and data on prevalence and incidence of ACD in the general population (all causes) as well as prevalence of positive patch tests from skin sensitisers in textile and leather (i.e. frequency of positivity of patch tests used to detect contact allergy from substances contained in textile and leather).

From the literature and from the dermatologists consulted during the preparation of this restriction proposal:

- The prevalence of ACD in the general population (all causes) ranges from 4.4% to 18.4% with a lifetime prevalence[48] around 15%-20%.
- Annual incidence rates (new cases) for ACD in the general population (all causes) are between 0.17% and 0.7% per year.
- Prevalence studies (frequency) of positive patch tests from testing with chemical substances contained in textile and leather in adults tested range from 0.4% to 17% with an average calculated by the Dossier Submitter 5%.
- Based on these data, the calculated prevalence of ACD caused by substances in textile and leather in the general population is thus around 0.8% - 1% (such as calculated by the Dossier Submitter, see Annex E.5).
- Based on these data, the calculated incidence of ACD in the general population to skin sensitising substances in textile and leather is thus around 0.01% and 0.04% per year (such as calculated by the Dossier Submitter).
- There seems to be no significant difference in prevalence of ACD from sensitising substances in textile and leather (based on testing with allergenic disperse dyes in particular) between children and adults.

For more details, please see Annex E.5.

[48] Prevalence is the measure of a health state of one population (general population for example), providing the number of cases of diseases at one given time (one year for example) or short period (5 years for example) and for one given place (one country for example). Lifetime prevalence is the measure of prevalence estimated over lifetime.

These data are used in the human health impact assessment to estimate the number of textile ACD cases that would be prevented in the EEA31 population by the restriction proposed (see further below for details as well as Baseline section 1.4 above and Annex E.5).

2.4.2.2. The number of estimated cases of sensitisation that are considered to be prevented by the restriction proposal

As explained in the Baseline section 1.4 and as detailed in Annex E.5, the population of concern includes individuals that are already sensitised to chemicals in textiles and leather (proportion measured from prevalence data) and individuals that are likely to be newly sensitised (proportion measured from incidence data). Based on the EEA31 population (around 518 million individuals[49]) and the prevalence and incidence data presented above, it is estimated by the Dossier Submitter that:

- The number of individuals already sensitised to chemical substances contained in textile and leather articles in EEA31 general population is estimated to be between 4 and 6 million (average 5 million) in 2023. This corresponds to 0.8% - 1% of the EEA31 population in 2019 plus the expected number of new cases from 2019 to 2023.

- The number of new cases of sensitisation to chemical substances in textile and leather articles are estimated to be between 45 000-180 000 per year (average 113 000) which corresponds to 0.01% and 0.04% of the 2019 EEA31 population.

These intervals of prevalence and incidence have been used by the Dossier Submitter to build projections of allergy to skin sensitising substances in textile and leather under the baseline (i.e. without the restriction) based on 5 baseline scenarios in order to assess what would be the human health positive effects expected from the restriction, from its date of entry into force (2023). The baseline scenarios correspond to all possible combinations of min, max and average values of the number of prevalent cases and new (incident) cases of ACD caused by exposure to skin sensitising substances in textile and leather articles from 2023. The projections based on these scenarios are presented in Figure 3 in section 1.4 and Annex D.

The proposed restriction is expected to:

- Protect a significant proportion (70% - 90%) of the already sensitised population from developing ACD from exposure to skin sensitisers in textile and leather articles. Skin sensitising substances (with harmonised classification under the CLP regulation or in the list of concern) will no longer be used in textiles or will be used at concentrations in textile and leather that are considered safe. At least 70% of the already sensitised population is considered to be protected from developing ACD due to the proposed ban of allergenic disperse dyes and due to the restriction of additional allergenic substances at low or very low levels considered as safe, and up to 90% is

[49] According to Eurostat, the EEA31 counted 518 061 408 inhabitants on 01/01/2018.

considered to be protected by additional restriction of remaining substances in the scope. The remaining 10% of the individuals potentially not protected reflect uncertainties due to the proportion of susceptible individuals that may react to exposure levels below the concentration limits proposed by the Dossier Submitter and due to uncertainties that some people may still react to the substances falling under the 'generic approach' (concentration limits being 110 ppm in leather or 130 ppm in textile, see above Table 10). For more details, please see the Baseline section 1.4 above and Annex E.5.

- Prevent the occurrence of new cases of sensitisation to chemical substances in textile and leather articles. Since the induction of sensitisation occurs at higher doses than elicitation, a large proportion of the naïve population (not yet sensitised) will also be protected by the proposed restriction. For the same reasons as above, it is assumed that between 70% and 90% of new cases would be avoided. It has to be noted however that the Dossier Submitter expects that this proportion would be even larger, since the doses needed for induction are higher than for elicitation. Using 70% - 90% may thus be a conservative assumption here (and a potential source of underestimation of the benefits). For more details, please see the Baseline section 1.4 above and Annex E.5.

2.4.2.3. The valuation of disease burden

Disease course

Such as described in CowI (2004) and detailed in Annex E.5, the contact allergy course can be divided into 3 states: diagnosis, daily treatment and acute care.

Diagnosis is the state where the patient exhibits allergic reactions and where the diagnosis of allergy is being settled. Regarding ACDs, diagnosis is often complex due to several reasons related to the patient's willingness to consult a specialist and the identification of the disease and the substance of concern by medical practitioners. Further details are provided in Annex E.5.

Daily treatment for contact allergy is the everyday coping with contact allergy. This may include daily treatment with topical agents, moistures and avoidance of certain chemicals. This treatment is opposed to acute care. Further details are provided in Annex E.5.

Acute care is when the patient is having an allergic reaction which requires specific treatment that is not included in the long term management of the disease; i.e. additional treatment due to an acute allergic reaction. Further details are provided in Annex E.5.

Valuation of health impacts and benefits assessment

The valuation of the health impacts includes the following cost elements:

- Direct costs: treatment related costs can become very high as the health effects are incurable and treatment is only palliative (symptom based). Daily treatment for ACD includes all activities related to managing the disease when the diagnosis is settled. This is the daily routine treatment of the disease. This may include medication, routine

visits to GP (General Practitioner), medical specialists, ambulatory services, hospital services, etc. This may also include acute care.

- Indirect costs: ACD may hamper persons in their daily activities, cause inconveniences, and may also lead to absence from work because of the recurring effects. Indirect costs may also thus be borne by patients due to the loss of working days in case of invalidating symptoms and sick leaves. The indirect costs are usually assessed based on production losses (costs of lost working days).

- Welfare (intangible) costs: depending on the severity of the contact allergy, the quality of life may be more or less affected. In that case, the loss of quality of life can be assessed.

For this purpose, the benefits assessment developed for this restriction proposal is based on 4 studies: Saetterstrom and al (2014), the Chromium VI restriction proposal (2012) and ECHA 2014 and 2016 reports.

Saetterstrom and al (2014) assessed direct and indirect costs of contact dermatitis. They investigated the effects of contact dermatitis in terms of healthcare costs and production loss in 21 441 patients tested in hospital or clinics (over 2004-2009) in Denmark including children (0-15 years), occupational contact dermatitis (16-65 years) and non-occupational dermatitis (≥ 16 years). Controls were randomly selected in the population.

The Chromium VI proposal (2012) assessed the direct, indirect and intangible costs of contact allergies to chromium VI containing in leather articles. Their analysis is mainly based on CowI (2004) with some updates and amendments.

ECHA (2014) and ECHA (2016) assess the willingness to pay of contact allergies that can be used as reference values for restriction dossiers.

Table 19 : Economic values available to assess the disease burden of contact allergies

Source	Annual Direct costs / case (healthcare costs)	Annual Indirect cost/ case (productivity loss)	Annual Intangible cost / case (welfare loss)
Saetterstrom et al (2014)	€360 (adult)	€ 615 (adult) (long-term sick leaves; € 280.5/day – DK data)	-
Restriction proposal on Chromium VI in leather	€ 472 (after diagnosis) (€ 9 650 over lifetime)	€ 1 190 (18 590€ over lifetime) (7 working days lost; € 170/day – EU27 data)	€ 1 875 (€ 37 850 over lifetime) (125 symptom days; € 15/day)
ECHA (2014 & 2016)	-	-	€ 2 000-€ 12 000 (severe, chronic sensitisation)

From this, as explained in Annex E.5, the economic values used in this evaluation are the following:

- Direct costs: € 400- € 500 annual per case (based on the restriction on chromium VI and Saetterstrom et al., 2014)
- Indirect costs: € 1 400 annual per case (based on the restriction on chromium VI, adjusted with EU 28 2017 hourly labour cost)
- Intangible costs: € 2 000-€ 12 000 annual per case (based on ECHA (2016 report) and similar value for the lower bound from the restriction on chromium VI)
- This leads to a total annual costs per new case between € 3 800 and € 13 900
- Regarding direct costs borne by already sensitised individuals, they are expected to be lower than the direct costs borne by new ACD cases since one can reasonably expect that the diagnosis has already been done and the disease better managed (at least for those who have consulted a specialist). The Dossier Submitter thus applied a decrease of 20% on the direct costs for the already sensitised individuals, leading to a total annual costs per prevalent case between € 3 700 and € 13 800.

Based on the economic values assessed in these studies, the estimation performed herein includes the following types of benefits:

- The benefits (cost savings) expected from the restriction due to 70%-90% avoided new sensitisation cases (constant number per year of avoided new cases which leads to increased accumulated cost savings): to this number of new cases (70% standing for 30 000-125 000 new cases avoided; 90% standing for 40 000-160 000 new cases avoided, as shown in Table 14) are applied the costs per case such as selected above (and summarised in the following table). These benefits are calculated over 2023+80 years, taken as the average life expectancy in the EE31[50].

- The benefits (cost savings) expected from the restriction due to the protection of a significant proportion of already sensitised individuals who currently suffer from textile and leather allergies), estimated between 70% and 90% (70% standing for 2.8-3.6 million cases protected; 90% standing for 4.1-5.3 million cases protected, as shown in Table 15). These benefits are calculated over 2023+30 years, considered by the Dossier Submitter as a reasonable approximation of the average remaining lifetime of already sensitised people from 2023 (including young people, middle-aged people as well as elder people).

It has to be noted that the number of prevalent and incident cases prevented such as calculated above are, strictly speaking, “sensitisation” cases and not “ACD” cases, since some individuals may not have shown clinical symptoms of ACD (if no exposure subsequent to the induction to the allergens has occurred). For those who may not have shown clinical symptoms, costs shouldn’t be applied in principle since these people may not have borne any costs. Nevertheless, the Dossier Submitter considers that, as already mentioned, regarding textile and leather, exposure cannot be avoided and sooner or later the individual with an induced allergy to chemicals in textile and leather will show symptoms and will bear the costs. For the present assessment, it is thus assumed that induction and manifestation of allergy

[50] According to Eurostat, the average life expectancy in the EEA31 was 78.3 years for men and 83.6 years for women in 2017.

are concomitant or at least, very close in time. As a result, the costs associated to ACDs are applied to all sensitised individuals.

Table 20 : Summary of the number of ACD cases and economic values used for the HHIA

	Total annual costs per sensitisation case (for new cases)	Number of annual new sensitised cases prevented from 2023 (between 70%-90%)	Total annual costs per sensitisation case (for current cases)	Number of current sensitised cases protected from 2023 (between 70%-90%)
Min values	€ 3 800	30 000-125 000	€ 3 700	2.8-3.6 million
Max values	€ 13 900	40 000-160 000	€ 13 800	4.1-5.3 million

Human health benefits: results

Based on the above, the annual benefits expected from the restriction have been assessed with 4 sensitivity scenarios (detailed in Annex E.5), discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5% - for more details, please see Annex E.5). These sensitivity scenarios are all possible combinations of the number of new and current cases of ACDs and the associated annual costs per case, such as:

- When assuming 70% of prevalent and new cases prevented:
  - Sensitivity scenario 1 corresponds to the combination of the min values of prevalent and new cases of textile and leather ACD (respectively 2.8 million and 30 000) and the associated min values of cost per case (€3 700 and €3 800 respectively)
  - Sensitivity scenario 2 corresponds to the combination of the min values of prevalent and new cases of textile and leather ACD (respectively 2.8 million and 30 000) and the associated max values of cost per case (€13 800 and €13 900 respectively)
  - Sensitivity scenario 3 corresponds to the combination of the max values of prevalent and new cases of textile and leather ACD (respectively 3.6 million and 125 000) and the associated min values of cost per case (€3 700 and €3 800 respectively)
  - Sensitivity scenario 4 corresponds to the combination of the max values of prevalent and new cases of textile and leather ACD (respectively 3.6 million and 125 000) and the associated max values of cost per case (€13 800 and €13 900 respectively)
  - The results are presented in Table 21.

Table 21 : Total annual human health benefits expected from the restriction: assuming 70% of current and new cases protected).

	Total annual benefits associated to new sensitisation cases avoided (in million €)	Total annual benefits associated to current sensitised cases protected (in million €)	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €, rounded up)
Sensitivity Scenario 1: Min; Min	83	7 004	7087
Sensitivity Scenario 2: Min; Max	310	25 980	26 290
Sensitivity Scenario 3: Max; Min	340	10 190	10 530
Sensitivity Scenario 4: Max; Max	1 200	37 800	39 000

Values discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%)

- When assuming 90% of current and new cases prevented:
  - Sensitivity scenario 1 corresponds to the combination of the min values of prevalent and new cases of textile and leather ACD (respectively 4.1 million and 40 000) and the associated min values of cost per case (€3 700 and €3 800 respectively)
  - Sensitivity scenario 2 corresponds to the combination of the min values of prevalent and new cases of textile and leather ACD (respectively 4.1 million and 40 000) and the associated max values of cost per case (€13 800 and €13 900 respectively)
  - Sensitivity scenario 3 corresponds to the combination of the max values of prevalent and new cases of textile and leather ACD (respectively 5.3 million and 160 000) and the associated min values of cost per case (€3 700 and €3 800 respectively)
  - Sensitivity scenario 4 corresponds to the combination of the max values of prevalent and new cases of textile and leather ACD (respectively 5.3 million and 160 000) and the associated max values of cost per case (€13 800 and €13 900 respectively)
  - The results are presented in
  - Table 22.

Table 22 : Total annual human health benefits expected from the restriction: assuming 90% of current and new cases protected)

	Total annual benefits associated to new cases avoided (in million €)	Total annual benefits associated to current cases protected (in million €)	Total annual human health benefits expected from the restriction proposed (RO1a) (in million €, rounded up)
Sensitivity Scenario 1: Min; Min	100	9 000	9 100
Sensitivity Scenario 2: Min; Max	400	33 000	33 400
Sensitivity Scenario 3: Max; Min	450	13 000	13 450
Sensitivity Scenario 4: Max; Max	1 600	48 600	50 200

Values discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%)

In conclusion, the total annual human health benefits expected from the restriction amount between 7 and 50 billion € from 2023 with "reasonable" estimate (based on scenarios 2 and 3, considered as "reasonable" compared to the extreme scenarios 1 and 4) between 10.5 and 33.4 billion € (discounted over 80 years from 2023 and 2103 for the new cases and over 30 years from 2023 and 2053 for the current cases; at 2.5% over 2023-2053, then 0.5%).

Uncertainties surrounding these estimates are presented in Annex F. A further sensitivity analysis (SA) has been performed on several parameters: the prevalence of patch tests positivity to textiles, the prevalence of contact dermatitis in the general population (all causes) and the proportion of current cases of textile and leather ACD protected. Please see Annex E.5.1.5 for further details.

Moreover, another benefit that should be taken into account in the overall benefits expected from the restriction proposed is the avoided costs associated with the exposure avoidance from people that are already sensitised with clinical symptoms of ACD. These people may want to avoid the exposure to allergens in textile and leather by purchasing allergens-free apparel and footwear (when available and affordable to them). The costs for these expenditures would be avoided with the proposed restriction. These allergens-free textile and leather articles are not available all over Europe (they are mainly supplied in big cities) and are generally more expensive (most of the time far more expensive) than regular textile and leather articles. These costs are difficult to quantify but to the Dossier Submitter's knowledge, allergens-free clothes and shoes exist, e.g. chromium-free shoes, supplied by specialized shops and sometimes even tailored on demand[51]. The current difference in prices between e.g. chromium-free shoes or disperse dyes-free clothes and regular shoes and clothes would be a good indication and example of such costs. Nevertheless, depending on the burden of the substitution cost on industry and whether they may pass the extra costs on the consumers or not (see section 2.4.4 for this discussion), it may be expected that after the entry into

[51] For example, La Botte Gardiane with 100% chromium-free vegetal tanning http://www.labottegardiane.com/fr/cuir-sans-chrome/157-tannage-vegetal.html; Elnaturalista https://www.elnaturalista.com/en/chrome-free or https://www.cottonique.com/

force of the restriction proposed, the current difference in prices may be reduced between allergens-free and regular (compliant) textile and leather articles. This difference will depend on the reason for the allergen-free textile and leather articles being more expensive than regular ones today. Competition can be lower for this segment, but production cost can also be higher, or "worse" scale effect, with smaller series of articles produced. There are thus uncertainties as to how a stricter concentration limits for the substances within the scope of this restriction as well as how other factors will affect the prices. Nevertheless, since skin sensitising substances in the scope would no longer be used after the entry into force of this restriction proposal (or to concentration limits considered as mostly safe), the Dossier Submitter is of the opinion that the allergens-free textile and leather markets will expand so that the prices will be significantly reduced compared to the current ones. As a consequence, the people that are already sensitised will be protected from developing ACD and they would additionally no longer bear the costs of search and purchase of these low-available and expensive allergens-free apparel and footwear. These costs will most definitely be reduced when all textile and leather articles are restricted.

2.4.3. Environmental impacts

As the rationale for this restriction proposal is human health, the environmental impacts arising from substances in textile and leather articles, and their comparison with those of the alternatives, are not discussed further.

2.4.4. Practicability, monitorability and distributional impacts

The restriction proposed (RO1a) is considered to be practical and monitorable.

Practicality

Practicality in the context of an Annex XV restriction dossier under REACH is defined in terms of three criteria: implementability, enforceability and manageability. Overall, the restriction proposed (RO1a) is considered practical, more information is given below.

Implementability

Existing national regulations on textile and leather as well as already existing restriction under REACH (on azodyes, chromium VI compounds and the recently adopted entry 72 of REACH Annex XVII) show that industry can in principle comply with risk management based on concentration limitations.

The transitional period of 36 months, as proposed by the Dossier Submitter, appears reasonable for the following practical reasons:

- A transitional period of 36 months will provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction. Substitution is already ongoing for some of the substances within the scope

of this proposed restriction (for example for several disperse dyes voluntary schemes are in place). Substitution of a chemical substance is, according to the consulted actors, possible when the chemical itself is used intentionally (can change from the intended use of a toxic solvent to a non-toxic). Substitution of substances that exist as impurities can take longer time. The ongoing substitution efforts (of specific chemicals) are driven by pressure from already adopted legislations for some of these substances as well as voluntary schemes (such as ecolabels that point out hazardous chemicals in textile and leather).

- The transitional period will allow development of additional test methods required for the restriction.
- For the restriction on CMR substances in textile (entry 72 of REACH Annex XVII), the transitional period is 24 months (corresponding to year 2020). Thus this transitional period was found by the Commission as practicable for the textile and leather industry. Formaldehyde is in this restriction derogated until 2023. To avoid any inconsistencies in the implementation of these two restriction, the Dossier Submitter thus proposes that this restriction is implemented in year 2023. This equals to a transitional period of 36 months.

Enforceability

Enforcement of national legislation (in Germany for example) or alert systems (such as the RAPEX system or national poison information centers like the French poison center) are already in place to monitor compliance and to share information on non-compliant products. Member States that do not have national legislations or such alert systems in place could build on this experience.

To assist compliance, the Dossier Submitter has developed a list of chemical substances that may be present today in textile and leather articles (see Annex E, Table 20). This list can be used by enforcement authorities and industry to identify which substances to focus on in their enforcement and compliance activities.

Moreover, some methods are available already for industry and enforcement authorities to test the articles to check for compliance (for further details, please see Table 25 in Annex E). For the substances for which no method is available, methods should be developed, and ideally harmonised. Industry can also use contractual agreements to ensure that the substances within the scope of the restriction are not used in articles above the recommended concentration limits.

Manageability

Given the similarity with existing measures (other restrictions on textiles or leather articles for example) and that the stakeholders' raised awareness on the issue (driven by already enforced regulations but also by voluntary schemes and labels), the proposed restriction should be clear and understandable to all the actors involved.

It is noted that additional chemical substances with sensitising properties will be harmonised classified as Skins Sens. 1/1A/1B under the CLP regulation in the future and they will be automatically included in the scope of this restriction, once the amendment to the CLP enters into force. For these substances, there will be no opportunity to assess specific concentration

limits (they may fall under the 'generic' concentration limits such as set in section 1.2.5) or any issues regarding substitution.

Monitorability

Again, existing national regulations on textile and leather as well as already existing restrictions under REACH (on azo dyes, chromium VI compounds and the recently adopted entry 72 of REACH Annex XVII) show that industry can in principle comply with such risk management option based on concentration limitations.

Moreover, as already explained, the Dossier Submitter has developed a list of chemical substances that may be present today in textile and leather articles (see Annex E, Table 20). This list can be used by enforcement authorities and industry to identify which substances to focus on in their enforcement and compliance activities.

The possibilities to monitor the results of the implementation of the proposed restriction, could be through patch tests with the textile dyes mix and other relevant test series. However, only a few substances are covered by those series compared to the scope of the restriction proposal. In addition, patients may react to substances included in the scope but from other sources than textile or leather articles, which will make it difficult to monitor the restriction. There are recurring public health studies, such as the Swedish Environmental health report where respondents are asked to assess if they have allergic reactions and to what. The outcome of these studies could be a way to monitor the effect of the restriction. Lastly, enforcement reports and market surveillance could show if the concentration of skin sensitising substances present in the articles are lowered.

Finally, some methods are available for authorities to test and control the articles to check for their compliance. The methods available are presented in Table 20 in Annex E.2. It is therefore expected that enforcement authorities can efficiently monitor compliance with the proposed restriction for the substances that have appropriate testing methods available. For substances without any available testing method, methods should be developed (and ideally harmonised) during the transitional period. CEN TC248/WG26 that develops EN testing methods for the EC restricted substances in textiles has been given a mandate by the EU commission to develop EN methods for all the textile related chemicals that are restricted under REACH and other related EU regulations. Some of the available testing methods listed in Table 19 are not EN methods. Some are developed from OEKO-TEX and confidential and therefore not applicable for enforcement purposes as they are not transparent or correlate to an EN method commissioned by the EU commission. With regard to the total ban of disperse dyes, enforcement authorities will however be able to measure for any concentrations in the article. For direct and acid dyes the following methods are available, established and used by various labs; ISO 16373-1:2015, ISO 16373-2:2014 and DIN 54231. Some of these dyes are however unknown to the consulted laboratories and some are out of their capability. For some of the listed dyes it is not possible to test salts. For disperse dyes the OEKO-TEX method/LoQ 50mg/kg is developed and applied.[52]

[52] Dossier Submitter's personal communication with chemist and researcher at RISE, March 2019

Other impacts – distributional impacts

The Dossier Submitter anticipates that distributional effects may occur after the entry into force of the restriction. Firstly, the cost of the restriction may be shared by the different actors in the supply chain and the consumers inside the EEA31 (as discussed in section 2.3). Secondly, the costs of the restriction may be borne differently by industry inside EEA31 and industry outside EEA31.

Regarding the impacts on consumers, the Dossier Submitter anticipates that the extra costs due to compliance (substitution and testing costs) likely to be borne by producers, importers and distributors of textile and leather articles may be passed on to the consumers by increasing the consumer price of these articles. As a consequence, one may expect some increase of consumer prices after the entry into force of the restriction. Nevertheless, the Dossier Submitter is of the view that this potential increase (if any) would likely be negligible due to several reasons:

i) Most of the market for textile and leather articles is highly competitive (put aside some luxury niche apparel markets) and the price competition is rough, especially on clothing and footwear articles, outside and inside the EEA31;

ii) The production and raw materials cost is generally one small component of the final consumption price of this type of article: this is particularly the case for textile articles such as ordinary clothing and footwear (and to a lesser extent for leather, hides and furs articles for which the raw materials are generally more costly). The final consumption price of textile articles is influenced by far more by other components, such as brand, advertisement, reputation, etc. The final price is to a relatively small extent connected to the production and raw materials cost. The illustrations in Figure 4 provide examples where the raw material costs make up around 10-15% of the retail price, and cost of chemical inputs is only one component of the raw material costs.

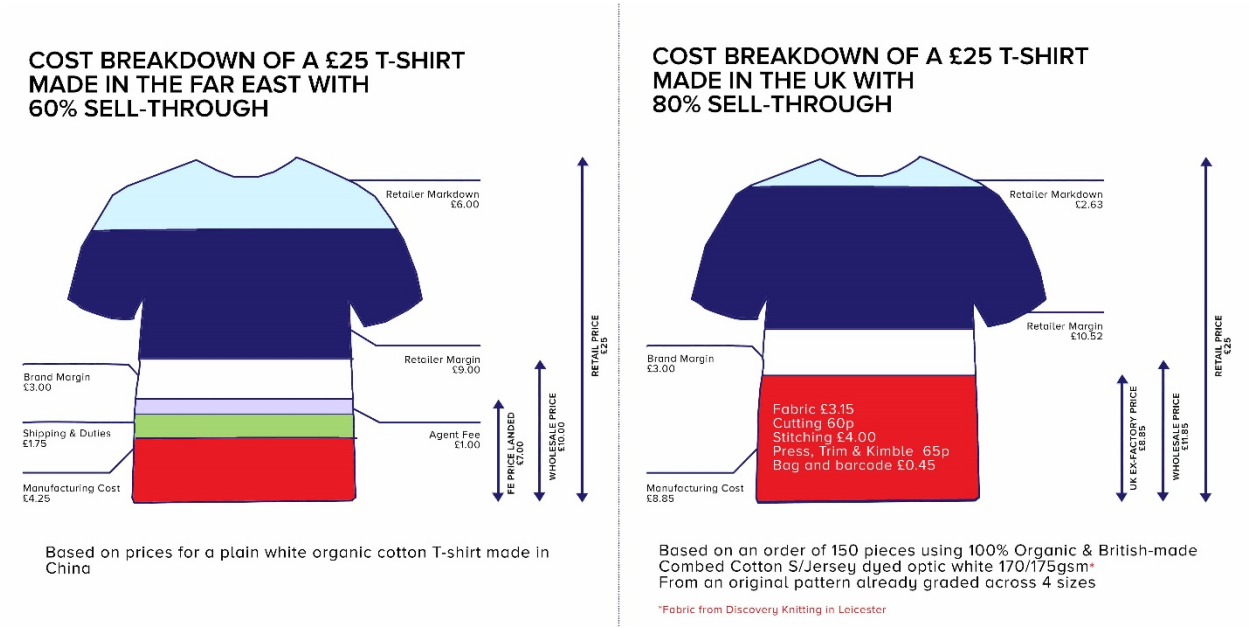
iii) The total annual production value in the sectors mainly affected by this restriction is around €197 billion, while the annual value added[53] is around €57 billion (Table 23). The estimated compliance costs of this restriction is only a small fraction of this. The compliance costs have been quantified to around €12 million in annual substitution and testing costs, and a one-off cost (due to reformulation of rubber accelerators) of approximately €13 million, see section 2.4.1. These costs are only around 0.02% of the value added and less than 0.01% of the production value.

[53] Value added represents the difference between the value of what is produced and intermediate consumption (including e.g. raw materials and labor) entering the production, less subsidies on production and costs, taxes and levies.

Table 23. Structural Business Statistics – Value added for manufacture of textile, wearing apparel and leather and related products in 2015 for EEA[54] (Eurostat, 2019)

2015 (million €)	Manufacture of textiles	Manufacture of wearing apparel	Manufacture of leather and related products	Total
Production value	80 535	66 310	50 760	197 604
Value added	23 216	19 431	14 190	56 836

Figure 4 : Examples of cost breakdowns of clothing articles



[54] EEA31 excluding Liechtenstein.

As a result, the Dossier Submitter considers that, even though extra costs would have been borne by industry due to the restriction, these extra costs would not necessarily be passed on to the EEA31 consumers but could be absorbed by the upstream supply chain instead, in order to maintain its competitiveness level.

With this restriction, one could also to some extent expect positive income effects felt by low income consumers in EEA31, due to the fact that these low income consumers cannot afford to substitute allergenic apparel and footwear to allergen-free apparel and footwear (which are usually far more expensive) today in order to prevent their symptoms (for those who are already sensitised) or to avoid sensitisation (for those who are not yet sensitised).

Moreover, distributional economic impacts may occur between outside EEA31 industry and inside EEA31 industry. Since 80% of textile and leather are imported from outside, the Dossier Submitter expects that the substitution costs and best practice associated costs would mainly impact outside EU industry of textile and leather. EEA31 industry will have to comply to the restriction too (please see reactions expected from the restriction in section 2.3 above) but it is expected that impacts may be more significant outside EEA31.

2.4.5. Proportionality

Given that the approach performed in this restriction proposal to assess impacts follows a semi-quantitative cost-benefit approach, the proportionality of the restriction proposed is assessed by comparing the expected costs and the benefits, when quantified.

Summary of the costs (substitution and enforcement)

Information is not available to quantify the costs of substitution for all substances, but a qualitative assessment in combination with a quantitative approach have been made where possible (See section 2.4.1 above).

In summary for substitution, where the Dossier Submitter has identified substitutes and collected cost information, the cost/ton of the substitute is estimated of the same magnitude overall as the substances up for restriction. However, between the substance groups there are some discrepancies and uncertainties:

- The substitution cost for disperse dyes is very low, which makes the substitution economically feasible (and with better hazards profile).

- For some of the substances evaluated, the proposed alternatives are much cheaper in price per metric ton. This leads to a situation where the total substitution cost with regard to the price difference between the substances used and the alternatives proposed may be negative (-€25 million per year, assuming all other aspects constant, such as quality aspects and volumes used and assuming that rosins are substituted with acrylics). This may indicate that the costs are underestimated, since it is unlikely that the industry would not have chosen the cheaper alternative if there were no hidden cost (see sections 2.4.1.4 and Annex E.4.1.5 for additional discussion on these total costs). This is however only speculation and the industry needs to give feedback on the negative costs in the public consultation. The total substitution cost is estimated

at €3 million otherwise (assuming all other aspects constant, such as quality aspects and volumes used and assuming that rosins are substituted with PUR).

- The substitution cost for formaldehyde and rosins are positive, with highest costs for rosins at €23 million per year if substituted with PUR, and €11,200 per year for formaldehyde.

- For some of the substances evaluated, regrettable substitution may occur since the identified substitutes do not have a better risk profile.

Moreover, for some of the evaluated substances, there is a lack of data needed to assess the cost of substitution (e.g. for solvents, glutaraldehyde and metals).

For diisocyanates and solvents (see annexes E.2 and E.3) a change in manufacturing and processing practice from subnormal, normal or good practice towards best practice might be needed to comply with the proposed concentration limits. The cost of moving towards best practice has not been estimated due to lack of data.

For a number of rubber accelerators, reformulation has been identified as necessary. The cost of a single reformulation is on average estimated to be €13 300/reformulation (see Annex E for details). The total number of articles in need of reformulation is however not estimated due to lack of data. In section 2.4.1.4 and Annex E.4.1.5 a simple sensitivity analysis is conducted. In that sensitivity analysis a low (100 reformulation), medium (1000 reformulation) and a high (10 000 reformulation) scenario is calculated based on assumptions regarding the number of reformulations. If it is assumed that the most likely scenario is the medium (1000 reformulations) scenario, then the total cost of reformulation is €13.3 million (this is a onetime cost). Reformulation may be needed for other substances as well if new information arrives in the public consultation, but at time of writing the restriction proposal only rubber accelerators have been indicated.

It is foreseen that the enforcement costs for authorities could be higher than for the concerned companies. The total enforcement costs are estimated to be higher than average for a REACH restrictions since the number of substances required to be tested are much higher than on average.

A consequence of the proposed restriction would be that both industry and enforcement authorities would need to perform additional testing in order to ensure the compliance. The extent of these additional required testing that needs to be performed compared to the testing already undertaken is not known. For industry it is however assumed that these costs would not outweigh possible gains due to surplus from marketing alternative substances. To some extent, the already existing quality control testing performed by the concerned companies may provide the necessary information.

In general, companies would commission standard laboratories for testing the levels of the concerned substances. It is assumed that only a minority of companies would invest money in in-house laboratory devices. According to the Dossier Submitter's information standard laboratories are already equipped with suitable devices for testing most of these substances and prices are not expected to change as a result of this restriction proposal. It is therefore assumed that the additional costs for testing are most probably to be affordable and of minor importance to the concerned actors compared to the overall costs of the restriction.

For enforcement authorities, a higher burden and cost for testing of compliance could result in that less enforcement activities and controls are in fact conducted.

Based on the price information from consulted laboratories on the substances within the scope of this restriction proposal the cost of testing is estimated to be somewhat higher than for an average restriction since it includes far more substances than on average. This has however not been quantified in detail due to lack of data.

The costs assessment includes some degree of uncertainty that is addressed in Annexes E.2 and F.

Summary of the benefits (human health)

As shown in section 2.4.2.1, the total annual human health benefits expected from the restriction proposal amount between 7 and 50 billion € from 2023 with “reasonable” estimate between 10.5 and 33.4 billion € (based on scenarios 2 and 3, considered as “reasonable” compared to the extreme scenarios 1 and 4). These benefits have been discounted over 80 years (2023-2103) for the new cases and over 30 years (2023-2053) for the current cases; at 2.5% over 2023-2053, then 0.5% . These ranges include some degree of uncertainty that is addressed in Annexes E.5 and F.

As explained above in section 2.4.4, the costs associated to the exposure avoidance from people that are already sensitised today with clinical symptoms of ACD (search and purchase of e.g. allergens-free cloths and shoes) would also be avoided thanks to the restriction proposed and should be part of the benefits (not quantified).

Comparison of the costs and the benefits

The costs and benefits expected from the restriction proposed (restriction option RO1a) are summarised and compared in the following table.

Table 24 : Comparison of costs and benefits expected from the restriction proposed (RO1a)

<table>
<tr><th>Costs expected from the restriction proposed (RO1a)</th><th>Total human health benefits expected from the restriction proposed (RO1a) (in million €)</th></tr>
<tr><td>Substitution costs<table><tr><td>Diisocyanates</td><td>Na. A move towards best practice might be required. The cost of moving towards best practice has not been estimated due to lack of data.</td></tr><tr><td>Dyes</td><td>Very low costs (considered close to zero)</td></tr></table></td><td>7 087-9 100 (least conservative bounds)</td></tr>
</table>

Formaldehyde	Total cost of substitution is estimated to be € 11,200 per year (for leather).	39 000-50 200 (most conservative bounds) + avoided costs associated to the exposure avoidance (search and purchase of e.g. allergens-free cloths and shoes)
Glutaraldehyde	Cost of substitution could not be investigated in detail but considered as +2-6% more expensive (main substitute to chromium III)	
Chromium III	Costs may be realised by the stricter concentration limit from 3 ppm to 1ppm in leather, but this remains a factor of uncertainty. One consulted leather expert indicate no additional cost to comply with 1ppm.	
Intermediates	Na (expected to be difficult to substitute)	
Metals (cobalt), inorganic compounds	Na	
Phenol, 4-(1,1-dimethylethyl)-Plasticiser	Na	
Phthalate	Total substitution cost is - € 13.3 million per year (cheaper alternative). Uncertainty remains with regard to quality changes, so the substitution cost may be to some extent underestimated.	
Plasticiser for neoprene (only one)	Total substitution cost is - € 7.4 million per year (much cheaper alternatives). Uncertainty remains with regard to quality changes, so the substitution cost may be to some extent underestimated.	
Rosins	Total substitution costs estimated to be €-5 million per year (if substituted with acrylics) or €23 million with PUR.	
Rubber accelerators	€13 300 /reformulation. Total cost of reformulation is €13.3 million (onetime cost), assuming 1000 reformulations needed.	
Solvents	Na, but costs will be incurred for moving towards best practice (not estimated due to lack of data)	

Overall, the cost of substitution is low or even negative for some substances, but lack of

information makes general quantification for all substances difficult at this point.	
Enforcement costs: Based on the price information from consulted laboratories on the substances within the scope of this restriction the cost of testing is estimated to be somewhat higher than for an average restriction since it includes far more substances than on average. This has however not fully been quantified in detail due to lack of data.	

Na; not available.

Overall, the Dossier Submitter considers that the expected benefits from the proposed restriction are substantial and the costs of compliance may be affordable to industry. Despite some discrepancies within the substance groups evaluated, the costs are deemed overall not disproportionate for the substances within the scope of the proposed restriction due to very low costs of substitution for some substances, ongoing substitution for others and given the fact that moving towards best practice would contribute also to solve the issue. As already mentioned, it is also expected that the EEA31 industry of textile and leather would be less impacted in absolute terms compared to industry outside EEA31, since 80% of textile and leather are imported from outside the EEA31. It is also expected that the EEA31 industry potentially has already implemented better substitutes and practice to a higher degree than outside EEA31 industry, so that the former would also be less impacted in relative terms.

Uncertainty remains due to lack of data for some substances and despite all the efforts made by the Dossiers Submitter to collect information on substitution. The Dossier Submitter hopes that this will be improved during the public consultation. Moreover, as already mentioned, it is not expected by the Dossier Submitter that the extra costs of compliance borne by industry (outside and inside EEA31) would significantly impact the final consumer price of restricted textile and leather articles due to:

i) the high level of competition of textile and leather markets, inside and outside EEA31 and
ii) the fact that production and raw materials cost is generally one small component of the final consumption price of this type of article (for more details, please see section 2.4.4 above).

Finally, the Dossier Submitter considers that the restriction proposal may be particularly beneficial for low income consumers into the EEA31: some positive income effect may be observed due to the fact that these low income consumers cannot afford to substitute allergenic apparel and footwear to allergens-free apparel and footwear (which are usually far

more expensive) in order to avoid symptoms (for those who are already sensitised) or to avoid induction of the allergy (for those who are not yet sensitised) today.

In conclusion, taking into account all these distributional effects, the restriction proposal is considered as affordable, proportionate and socially desirable.

2.5. Assessment of restriction option 2

Restriction Option 2 (no list of substances of concern)

This RO covers all substances which are classified as Skin Sens. Category 1/1A/1B in Annex VI to Regulation (EC) No 1272/2008, but without a list of additional substances of concern. The conditions of the restriction and concentration limits are unchanged compared to RO1a.

The enforcement costs from RO2 are expected to be similar or slightly lower than RO1a due to the fact that a lower number of substances would have to be tested and monitored (not quantified).

This RO is expected to provide a lower risk reduction capacity compared to RO1a (lower human health benefits) since some substances known to cause allergy to the general population, but that not already have a harmonised classification under the CLP regulation, will not be included (disperse dyes that do not have harmonised classification as skin sensitisers under the CLP Regulation). Furthermore, in the CLP regulation, skin sensitisation is not a prioritized endpoint for harmonised classification, so the classification of some substances may take a long time, or not occur at all. It would result in a lower prevention for general population.

The associated exact human health benefits could not be quantified by the Dossiers Submitter since the proportion of allergy cases attributed to the substances in the list of concern is not known. However, all of these substances are disperse dyes (see the list in Table 2) and as already mentioned, disperse dyes seem to contribute significantly to the overall contact allergies from textile and leather (even though their exact contribution is uncertain). As explained in section 2.4.2 and Annex E.5, literature reports show that around 2/3 of all textile related cases of allergy may be attributed to disperse dyes[55] (reported in Bfr (2006); RIVM (2008) and RIVM (2014), based on Hatch and Maibach (1995; 2000) and Lazarov (2004)). With RO2, some disperse dyes would be covered (the ones with harmonised classification) but others would not be (those in the list of concern with no harmonised classification). It is impossible to say how much of these 2/3 of textile related cases are attributable to the classified disperse dyes and how much is attributable to those which are not yet classified. Nevertheless, the Dossier Submitter considers that if removing all the disperse dyes on the list of concern from the scope would result in substantially lower benefits than RO1a, mainly driven by the fact that regrettable substitution from one disperse dye (covered by RO2) to another (not covered by RO2) may occur.

[55] This proportion covers a certain degree of uncertainty which is discussed above in the Baseline section 1.4.

Regarding the expected costs from RO2, due to the lack of data to develop a robust quantitative costs assessment, the costs of compliance specifically associated to the substances in the list of concern could not be assessed. Nevertheless, since all of these substances are disperse dyes, the substitution of disperse dyes is considered to be feasible technically and economically with very low costs, as shown in section 2.4.1 and Annex E.2. As a result, the costs of a risk option without the list of concern would be lower (probably slightly lower) than RO1a.

Overall, benefits associated with RO2 are expected to be significantly lower than RO1a with probably slightly lower costs. RO2 is thus considered as less proportionate compared to RO1a.

Practicality and monitorability are not expected to be very different from RO1a.

Table 25 : Comparison of costs and benefits expected from the restriction option 2 (RO2)

Costs expected from the restriction the restriction option RO2	Total human health benefits expected from the restriction option RO2 (in million €)
Substitution costs: Similar or slightly lower than RO1a	<<7 087-9 100 (least conservative bounds) <<39 000-50 200 (most conservative bounds)
Enforcement costs: Similar or slightly lower than RO1a	+ costs associated to the exposure avoidance (search and purchase of e.g. allergens-free cloths and shoes)

2.6. Assessment of restriction option 3

Restriction Option 3 (disperse dyes only, with and without harmonised classification as skin sensitisers in category 1/1B/1A)

This RO covers a narrow list of substances, including disperse dyes only (with harmonised classifications as skin sensitisers according to the CLP regulation, as well as the ones without harmonised classification included in the list of concern, see Table 26 below). The conditions of the restriction and concentration limits are unchanged compared to RO1a.

Table 26. Substances covered by the scope of Restriction Option 3 (disperse dyes only, with and without harmonised classification as skin sensitisers in category 1/1A/1B

Substance name	CAS number	EC number	Harmonised classification as Skin Sens. 1/1A/1B, or in the list of concern (Table 2)
CI Disperse Blue 1	2475-45-8	219-603-7	Harmonised classified
CI Disperse Yellow 3	2832-40-8	220-600-8	
CI Disperse Blue 3	2475-46-9	219-604-2	Listed in Table 2
CI Disperse Blue 7	3179-90-6	221-666-0	
CI Disperse Blue 26	3860-63-7	223-373-3	
CI Disperse Blue 35	12222-75-2	602-260-6	
CI Disperse Blue 102	12222-97-8	602-282-6	
Ci Disperse Blue 106	68516-81-4	271-183-4	
CI Disperse Blue 124	15141-18-1	239-203-6	

CI Disperse Blue 291	56548-64-2	260-255-0	
CI Disperse Brown 1	23355-64-8	245-604-7	
CI Disperse Orange 1	2581-69-3	219-954-6	
CI Disperse Orange 3	730-40-5	211-984-8	
CI Disperse Orange 37 /59/76	13301-61-6 12223-33-5 51811-42-8	236-325-1 602-312-8	
CI Disperse Red 1	2872-52-8	220-704-3	
CI Disperse Red 11	2872-48-2	220-703-8	
CI Disperse Red 17	3179-89-3	221-665-5	
CI Disperse Yellow 1	119-15-3	204-300-4	
CI Disperse Yellow 9	6373-73-5	228-919-4	
CI Disperse Yellow 23	6250-23-3	228-370-0	
CI Disperse Yellow 39	12236-29-2	602-641-7	
Ci Disperse Yellow 49	54824-37-2	611-202-9	
CI Disperse Yellow 64	10319-14-9	233-701-7	
CI Disperse Orange 149	85136-74-9	400-340-3	
CI Disperse Violet 1	128-95-0	204-922-6	
CI Disperse Violet 93	268221-71-2	-	

This RO would cover substances that are already included in different voluntary schemes, indicating that substitution, enforcement and compliance are possible. Moreover, as already mentioned and shown in section 2.4.1 and Annex E.2, the substitution costs associated to the replacement of disperse dyes are considered very low. The costs of this restriction is thus expected not to be a major issue.

The enforcement costs from RO3 are expected to be lower than RO1a due to the fact that a much lower number of substances would have to be tested and monitored (not quantified).

However, the risk reduction capacity of RO3 compared to RO1a will be lower with lower associated human health benefits, since the substances restricted are fewer. The assessment of the benefits that would only be attributed to the ban of disperse dyes is however not easy. As explained in section 2.4.2 and Annex E.5, it is reported in literature that around 2/3 of all textile related cases of allergy may be attributed to disperse dyes (reported in Bfr (2006); RIVM (2008) and RIVM (2014), based on Hatch and Maibach (1995; 2000) and Lazarov (2004)). The estimate of this proportion covers a certain degree of uncertainty since it is based on the frequency of the positivity of patch tests performed on patients and not on an overall and comprehensive prevalence study of textile and leather ACD in the EU general population (which, as already explained, does not exist to date). Given the fact that current textile-specific patch tests, such as *Textile Colours & Finish Series TF-1000* (see Table 33 in Annex E.5) mainly contain dyes and disperse dyes and that the Textile Dye mix (TDM) (Mx30, see Table 35 in Annex E.5) only contain disperse dyes, these substances are currently the most investigated. As a consequence, the frequency of positivity of patch tests in patients due to disperse dyes may not be representative of most of the actual cases of ACD and the proportion of 2/3 reported in the literature may be biased and overestimated. Nevertheless, this literature information still gives an indication that a significant proportion of ACD may be due to disperse dyes (being 70% or lower), which is valuable information to be used.

In order to assess the benefits associated with RO1a (the restriction proposed), the Dossier Submitter assumed that at least 70% of current and new textile and leather ACD cases would

be protected due to the ban of disperse dyes and due to the restriction of additional allergenic substances at low or very low levels considered as safe. With RO3, under which only disperse dyes would be restricted and banned, the number of ACD cases and the associated benefits, are expected to be lower than with RO1a. Although the exact proportion of ACD attributed to disperse dyes is uncertain, the Dossier Submitter attempted to estimate the benefits that would be due to the ban of disperse dyes only, based on the same method as used for RO1a, but taking into account the studies reporting frequency of positive patch tests data focusing on disperse dyes only. From the literature overview provided in Annex E.5, and as reported in the KemI 2016 RMOA, the prevalence of allergic textile dermatitis to disperse dyes among consecutive patients at dermatology clinics is typically around 3% (Isaksson et al., 2015a; Isaksson et al, 2015b; Ryberg et al., 2006, 2010, 2011, 2014; Hatch et al., 2000; Malinauskiene et. al., 2012; Kemi, 2016_ENREF_39). More information on prevalence data can be found in detail in Annex E.5.

As a result, depending on the proportion of ACD attributed to disperse dyes (70% or lower), the benefits associated to RO3 will vary. For illustrative purposes and in order to compare RO3 with RO1a and RO2, the Dossier Submitter used 50% and 70% as (arbitrary) values for this proportion. The human health benefits associated with RO3 are thus estimated between 3 and 16.7 billion € based on a frequency of positivity of patch tests of 3% and a proportion of 50% of current and new cases protected and estimated between 4.2 and 23.4 billion € based on a frequency of positivity of patch tests of 3% and a proportion of 70% of current and new cases protected (see Table below), with an 'reasonable' estimate of 4.5-11.2 billion € and 6.3-15.7 billion € respectively.

Due to the fact that the costs associated with RO3 would be very low and the benefits relatively high (but 40% lower than RO1a), RO3 is considered to be proportionate.

Practicality and monitorability is expected to be higher than RO1a due to the fact that a much lower number of substances would have to be tested and monitored and there are analytical methods available for all disperse dyes.

Table 27 : Comparison of costs and benefits expected from the restriction option 3 (RO3)

Costs expected from the restriction option RO3	Total human health benefits expected from the restriction option RO3 (in million €)
Substitution costs: very low	3 000-4 200 (least conservative bounds) 16 700-23 400 (most conservative bounds)
Enforcement costs: Lower than RO1a	+ costs associated to the exposure avoidance (search and purchase of e.g. disperse dyes-free cloths and shoes)

2.7. Comparison of restriction options

The restriction option RO1a would be the most efficient in terms of risk reduction capacity.

Table 28 : Comparison of restriction options

	Risk reduction capacity	Proportionality	Practicality	Monitorability
Restriction Option 1a (restriction proposed)	+ + +	+ +	+ +	+ +
Restriction Option 2 (no additional list of substances of concern)	+ / + +	+	+ +	+ +
Restriction Option 3 (disperse dyes only)	+ / + +	+ +	+ + +	+ + +

Overall, the 3 restriction options further assessed are considered to be proportionate by the Dossiers Submitters; RO1a and RO3 likely to be more proportionate than RO2.

RO3 appears to be more desirable than RO1a in terms of practicality and monitorability and it may have a better cost/benefit ratio (not quantified). However, RO1a is the preferred option by the Dossiers Submitters based of its higher risk reduction capacity. Indeed, RO1a shows the best capacity of mitigating the risk targeted in this restriction proposal, by covering a much higher number of sensitising substances and being dynamically linked to CLP regulation. It is considered that RO1a would allow protecting at least 70%-90% of current and new cases of sensitisation within the EEA31 (with associated benefits 40% higher than RO3). As explained above, substitution of some substances covered by RO1a may be an issue today but safer chemical and/or technical solutions are already being searched for and some of them are already implemented by industry. Substitution is therefore considered by the Dossier Submitter as being an issue only about a matter of time and not being technically insurmountable for industry. Regarding the higher costs of substitution associated to RO1a, the Dossier Submitter considers that the marginal effort to be made by industry and the actors of the supply chain to comply with the restriction and replacement of more substances, compared to RO3, is possible to overcome and would be highly beneficial from a protection and society standpoint. To this respect, the transitional period of 36 months proposed for RO1a is considered to be fit for purpose.

3. Assumptions, uncertainties and sensitivities

Please see Annex F.

4. Conclusion

There is a growing concern at European level and worldwide about skin sensitisation of the general population due to exposure to chemicals in textile and leather. Therefore, the Dossier Submitter proposes that skin sensitising substances should be restricted in these materials. The Dossier Submitter bases the restriction proposal on the risk from exposure to substances

with a harmonised classification with regard to skin sensitisation, or on substances that that have been indicated to cause allergic contact dermatitis, but does not yet have harmonised classification. These latter substances are shown on a list of concern (see Table 2). The identified risks need to be addressed on a Union-wide basis to achieve a harmonised high level of protection of human health and free movement of goods within the Union.

The risk management option analysis (RMOA), finalised by KemI in 2016, concluded that an community-wide ban of placing textile articles that contain skin sensitising substances on the market, based on harmonised classification, was the most appropriate RMO. A total ban of sensitising substances in textiles is not realistic, as this would seriously hamper the production of textile and leather articles. The risk is proposed to be managed by setting concentration limits for the skin sensitising chemicals in textile and leather. As the amount of available information on elicitation threshold doses and migration factors vary among the sensitising substances in the scope, the Dossier Submitter sets the concentration limits using a quantitative approach, either a substance-specific, a semi-substance specific or a default approach. The proposed concentration limits are shown in Table 29 below.

Table 29 : Proposed concentration limits for the substances in the restriction scope

Substance/group of substances	Proposed concentration limit (*mg/kg*)	
	Textile[1]	Leather[1]
Disperse dyes	Ban[2]	Ban[2]
Chromium VI compounds	1[3]	1
Nickel compounds	120	40
Cobalt compounds	70	20
Formaldehyde	30	30
1,4 paraphenylene diamine	250	80
Other substances in scope	130	40

[1]Any concentration limit proposed for textile also applies for materials such as synthetic leather, rubber materials and polymer materials, prints and coatings included in the scope coming into contact with the skin to an extent similar to clothing. The concentration limits applies also to disposable sanitary towels, napkins, tissues and nappies.

[2]Any concentration limit proposed for leather also applies for hides and furs.

[3] The ban refers to the limit of detection (that should be below the calculated concentration limits of 0.1 mg/kg in textile and 0.03 mg/kg in leather).

[4] The existing concentration limit in entry 72 of REACH Annex XVII, is assumed to also protect from skin sensitisation from substances in textile in the present restriction proposal. Hence, for regulatory consistency, no concentration limit is proposed in this restriction proposal. Instead the lowest concentration limit applies which currently is 1 mg/kg for chromium VI compounds .

It is acknowledged that not all substances covered by the scope are used in textile and leather today. However, for substances that the Dossier Submitter considers as relevant for textile and leather (based on the information available to the Dossier Submitter, please see Table 7), the suggested concentration limits are far below the highest approximated concentrations in the materials at point of sale. Hence, lowering the concentrations of the skin sensitising substance in textile and leather to the ones proposed, is considered to significantly reduce the risk for skin sensitisation in the general population. The concentration limits proposed are thus considered to adequately protect consumers against skin sensitisation.

As a consequence of the concentration limits proposed here above, this restriction proposal calls for a revision of the following existing REACH Annex XVII restrictions:

- revision of the current restriction limits on chromium compounds in leather (amendment of entry 47 of Annex XVII of the REACH regulation).
- revision of the current restriction for the Disperse Blue 1 in textile (CAS 2475-45-8, EC 219-603-7) (amendment of entry 72 of REACH Annex XVII)
- revision of entry 43 of REACH Annex XVII for the mixture disodium (6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)(1-(5-chloro-2-oxidophenylazo)-2-naphtholato)chromate(1-); trisodium bis(6-(4-anisidino)-3-sulfonato-2-(3,5-dinitro-2-oxidophenylazo)-1-naphtholato)chromate(1-) (CAS 118685-33-9, EC 405-665-4)

To identify the most appropriate measure to address the risk targeted here, three restriction options under REACH were assessed (the restriction proposed, RO1a, and two other restriction options, RO2 and RO3). To decide which one of these options that is the most beneficial from a societal perspective, RO1a, RO2 and RO3 were assessed against the criteria of risk reduction capacity, proportionality, practicality and monitorability. The conclusions of this assessment are the following:

Risk reduction capacity

RO1a (the proposed restriction covering all substances with a harmonised classification as Skin Sens 1, 1A or 1B and the list of substances of concern) is considered to be the most efficient restriction option in terms of risk reduction capacity since it covers a much higher number of sensitising substances. The combination of the dynamic link to the CLP regulation, which will prevent that one skin sensitising substance is replaced with another substance with a harmonised classification today or in the future, and the list of disperse dyes already included in voluntary schemes, will assure a high risk reducing potential of the restriction. The concentration limits proposed are deemed to adequately protect general population against skin sensitisation. It is considered that RO1a would protect at least 70%-90% of current and new cases of sensitisation within the EEA31. Regrettable substitution of some substances covered by RO1a may be an issue. However, safer chemical and/or technical solutions are already being searched for by industry and some of them are already implemented, also driven by the existing voluntary schemes.

In comparison, RO2 (covering harmonised classified substances, but not the additional list of substances of concern) would provide a lower risk reduction capacity since some substances known to cause allergy to the general population, but that are not already harmonised classified through CLP regulation, will not be included. In the CLP regulation, skin sensitisation is not a prioritised endpoint for harmonised classification, so the harmonisation of some substances may take a long time, or not occur at all. RO2 would therefore result in lower prevention of the general population.

Likewise, the risk reduction capacity of RO3 compared to RO1a will be lower since the restricted substances (disperse dyes only) are fewer. For the same reasons as for RO2, RO3 would result in lower prevention for general population.

Proportionality

The three restriction options assessed are considered to be proportionate by the Dossier Submitter. RO1a and RO3 are likely to be more proportionate than RO2.

Regarding RO1a (the proposed restriction), the Dossier Submitter considers that the expected benefits are substantial and the highest compared to RO2 and RO3. The associated costs of compliance are affordable to industry and not disproportionate for the substances within the scope: because of very low costs for substitution for some substances, ongoing substitution for others and given the fact that moving towards best practice would contribute also to solve the issue. Uncertainty remains due to lack of data on substitution for some substances and despite all the efforts made by the Dossier Submitter to collect information on substitution. Nevertheless, substitution is considered by the Dossier Submitter as mainly a matter of time and does not seem technically insurmountable for industry to achieve.

Based on the price information from consulted laboratories on the substances within the scope of this restriction, the cost of testing of RO1a is estimated to be somewhat higher than for an average restriction since it includes far more substances than on average (and the cost is expected to be higher for authorities than for companies). This has however not been quantified in detail due to lack of data. Both industry and enforcement authorities will need to perform additional testing, compared to those already undertaken for their products, in order to ensure further compliance. The extent of the required additional testing is not known. Moreover, it is not expected that the extra costs for compliance borne by industry (outside and inside EEA31) would significantly impact the final consumer price of restricted textile and leather articles. Finally, some distributional effects would also be observed. It is expected that the impacts for industry of textile and leather within EEA31 would be lower (in terms of substitution at least) compared to those for industry outside EEA31, since 80% of textile and leather are imported from outside the EEA31. RO1a may therefore be particularly beneficial for low income consumers in the EEA31.

The total annual human health benefits expected from the restriction amount between 7 and 50 billion € from 2023 with “reasonable” estimate (based on scenarios 2 and 3, considered as “reasonable” compared to the extreme scenarios 1 and 4) between 10.5 and 33.4 billion € (discounted over 80 years from 2023 and 2103 for the new cases and over 30 years from 2023 and 2053 for the current cases ; at 2.5% over 2023-2053, then 0.5%).

The total costs of substitution for RO1a (based on the price difference between chemical used and alternative proposed), estimated with the available data, indicates a total cost of substitution for all of the chemicals where cost data exists for both the substances used and the proposed substitute at around - € 25 million per year (if rosins are substituted with acrylics) or 3 million € per year (if rosins are substituted with PUR). The negative cost of € -25 million may be anticipated to be an underestimation of the cost of substitution connected to this restriction proposal. Excluding the negative costs gives a total cost of around €11 200 per year (if rosins are substituted with acrylics) or €23 million per year (if rosins are substituted with PUR). This estimation is based on a simplified analysis, assuming that the volume used, quality aspects and all other factors of importance, are held constant. In section 2.4.1.4 above and in Annex E.4.1.5 it can be seen that these negative costs are driven by cheaper alternatives for rosins, phthalates and plasticisers for neoprene. The Dossier Submitter sees this as an underestimation of the total costs and without the negative costs the total annual costs are estimated to be 11.9 million per year. Apart from these annual costs, the cost for reformulation (rubber accelerators) has also been estimated. Based on a

calculated cost per reformulation of €13,300 and an assumption that 1000 reformulations are needed due to this restriction proposal, a total one-time cost of reformulation of €13.3 million is estimated.

The benefits (not quantified) of RO2 are expected to be significantly lower than for RO1a, since the substances excluded (i.e. the substances on the additional list) are disperse dyes that seem to contribute significantly to the overall contact allergies from textile and leather. Moreover, the associated costs are expected to be slightly lower than for RO1a since substitution of disperse dyes is considered technically and economically feasible with associated costs that are very low. The enforcement costs for RO2 are expected to be similar or slightly lower than for RO1a due to the fact that a lower number of substances would have to be tested and monitored (not quantified). As a result, the costs of RO2 would be lower (probably slightly lower), but with significantly lower benefits. RO2 is thus considered to be less proportionate compared to RO1a.

An attempt of assessing the benefits of RO3 has been performed by the Dossier Submitter with some degree of uncertainty. The estimated benefits are relatively high, though 40% lower than the benefits expected for RO1a. RO3 covers substances that are already included in different voluntary schemes, indicating that substitution, enforcement and compliance are possible. Again, the substitution costs for replacement of disperse dyes are considered very low. Moreover, the enforcement costs are expected to be lower than for RO1a because a much lower number of substances would have to be tested and monitored (not quantified). As a result, the costs associated to RO3 are expected not to be a major issue. Therefore, RO3 is considered proportionate.

Practicality and monitorability

RO1a is considered overall practicable and monitorable. Existing national regulations on textile and leather as well as already existing restriction under REACH (on azodyes, chromium compounds and the recently adopted entry 72 of REACH Annex XVII) show that industry can comply with a risk management based on concentration limitations. Moreover, some methods are already available for industry to test the articles to assure their compliance. For the substances for which no methods are available, methods should be developed and ideally harmonised. The Dossier Submitter believes that a transitional period of 36 months will provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction since substitution is already ongoing. Moreover, the Dossier Submitter has developed a list of chemical substances used today in textile and leather, to be used for enforcement and compliance purposes. Overall, RO1a is thus considered implementable, enforceable and manageable.

RO1a can be monitored by Member State surveillance programs and compliance controls (including RAPEX) as well as manufacturers, importers and distributors of textile and leather articles who will have the obligation to place compliant articles on the market.

Practicality and monitorability of RO2 are expected to be similar to RO1a, whereas for RO3 they are expected to be higher than of RO1a. The reason is that for RO3, a much lower number of substances would have to be tested and monitored and that there are analytical methods available for all disperse dyes.

Overall conclusion

In conclusion, being effective (proportionate and showing the highest risk reduction capacity), practical and monitorable, RO1a is considered to be the most appropriate RMO to address the risk for human health from exposure to skin sensitising substances in textile and leather on a Union-wide basis.