Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Skin sensitising substances

ECHA/RAC/RES-O-0000006785-62-01/F
ECHA/SEAC/[Opinion N°(same as opinion number)

Adopted

12 March 2020

12 March 2020

ECHA/RAC/RES-O-0000006785-62-01/F

11 June 2020

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s):	**Skin sensitising substances**
EC No.:	**-**
CAS No.:	**-**

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

PROCESS FOR ADOPTION OF THE OPINIONS

France and Sweden have submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on **19 June 2019**. Interested parties were invited to submit comments and contributions by **19 December 2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: ***Julie SEBA***

Co-rapporteur, appointed by RAC: ***Miguel A. SOGORB***

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **12 March 2020**.

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Richard LUIT***

Co-rapporteur, appointed by SEAC: ***Nikolinka SHAKHRAMANYAN***

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **11 June 2020.**

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

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

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration. Interested parties were invited to submit comments on the draft opinion by **24 August 2020**.

The opinion of SEAC

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

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted **by [consensus.][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

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 1	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: a. bed linen (e.g. sheets, duvet covers, pillow cases), b. blankets, throws, c. upholstery (coverings on chairs, armchairs and sofas, car seats, etc.) d. cushion covers, e. bathrobes, towels, f. re-usable nappies and re-usable sanitary towels, g. napkins and table linen, h. childcare and children products other than toys (valances, babies' nests, babies' deckchairs, bibs, baby car seats, etc.), i. sleeping bags, j. yarn and fabrics intended for use by the final consumer , k. bags like handbags, backpacks, l. carpets, mats and rugs, m. 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 1. 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 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 1: 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[2]	68516-81-4	271-183-4
CI Disperse Blue 124[3]	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

[2] The former CAS/EC numbers for the CI Disperse Blue 106 are 12223-01-7/602-285-2

[3] 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%.

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.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **skin sensitising substances** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the scope and conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

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 1	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: a. bed linen (e.g. sheets, duvet covers, pillow cases), b. blankets, throws, c. upholstery (coverings on chairs, armchairs and sofas, car seats, etc.) d. cushion covers, e. bathrobes, towels, f. re-usable nappies and re-usable sanitary towels, g. napkins and table linen, h. childcare and children products other than toys (valances, babies' nests, babies' deckchairs, bibs, baby car seats, etc.), i. sleeping bags, j. yarn and fabrics intended for use by the final consumer , k. bags like handbags, backpacks, l. carpets, mats and rugs, m. 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 1. 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 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 50 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 125 mg/kg w/w in textile and 25 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 15 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 30 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) 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[4]	68516-81-4	271-183-4
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CI Disperse Yellow 9	6373-73-5	228-919-4
CI Disperse Yellow 23	6250-23-3	228-370-0
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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	-

THE OPINION OF SEAC

See the opinion of SEAC.

[4] The former CAS/EC numbers for the CI Disperse Blue 106 are 12223-01-7/602-285-2

[5] 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%.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

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

Summary of proposal:

A large number of chemical substances covered by this restriction are used intentionally, or are generated unintentionally during processing of textiles, leather and other materials; furthermore, many of them are unknown and may change with time, e.g. due to modifications in industrial processes.

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. It is generally considered that a lower level of exposure is required for elicitation than for induction to occur.

The restriction proposal intends to cover substances with harmonised classifications as skin sensitisers in Category 1/1A/1B according to the CLP regulation. Skin sensitisation is not a prioritised hazard category for harmonised classification under CLP and therefore, many chemical substances with allergenic properties will not (yet) have harmonised classifications as skin sensitisers. To limit this restriction to substances with harmonised classifications may therefore be insufficient to significantly reduce the risk from skin sensitising substances. The restriction proposal therefore also covers a specific list of 24 disperse dyes which have been indicated to have skin allergenic properties (cf. Table 2) when present in textile or leather articles.

In total, more than 1 000 substances fall within the scope of the restriction proposal. However, it is acknowledged that not all chemical substances within the scope will be used in the production of textile and leather articles, and not all will be present in the finished article at the point of sale. A list of substances with skin sensitising properties that may be present in finished textile and leather articles was developed by the Dossier Submitter and 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 (disperse dyes referred to above). This list is called the IN-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 IN-List is indicative and not exhaustive. It cannot be excluded that other substances with harmonised classifications as skin sensitisers will also be present in the articles covered by the restriction proposal.

This restriction proposal covers clothing, footwear and articles with similar skin contact made of textile, leather, synthetic leather, hides or furs, as well as disposable sanitary towels, napkins, tissues and nappies and which are placed on the market for the first time for the general public.

The articles covered by this restriction proposal are essentially the same as the articles covered by the recently adopted entry 72 restriction of Annex XVII of REACH on CMR substances[6], with some additions and amendments. For example, articles made of leather, fur and hide are included in this restriction proposal but specifically excluded from entry 72.

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

While wristwatch straps are explicitly listed in the explanatory guide on entry 72, in the proposed restriction the Dossier Submitter has covered fashion articles more broadly (mentioning e.g. wrist bands, braces, neck laces, straps and bands). The restriction proposal covers childcare articles other than toys (valances, babies' nests, babies' deckchairs, bibs, etc.) which are not explicitly mentioned in entry 72[7]. Napkins and table linen (that are re-usable), carpets, mats and rugs are also covered by the proposed restriction but not by entry 72. The proposed restriction contains an exemption for parts of footwear with no skin contact where entry 72 does not have such an exemption.

Further specification on the materials and articles covered: prints and coatings, articles made of synthetic leather, articles made of neoprene, other rubber materials or other polymer materials, disposable textile such as disposable napkins, tissues, sanitary towels and nappies.

RAC conclusions:

RAC is of the opinion that substances which are known to have intrinsic properties as skin sensitisers, therefore increasing the risk of skin sensitisation, should be restricted in finished clothing, footwear and articles made of textile, leather, hides or furs that are expected to come into contact with the skin under normal or reasonably foreseeable conditions of use as well as disposable sanitary towels, napkins, tissues and nappies.

The skin sensitisation hazard is indicated by:

- A harmonised EU classification as a skin sensitiser in Category 1/1A/1B according to the CLP regulation;
- An additional list of substances having a concern for skin sensitisation but without harmonised classification as Skin Sens. 1/1A/1B.

The articles covered by the scope of the restriction are the following:

- Articles of clothing and related accessories;
- Footwear;
- 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;
- Disposable sanitary towels, napkins, tissues and nappies.

Only the finished articles listed above, placed on the market for the first time, are targeted by the proposed restriction.

Key elements underpinning the RAC conclusions:

RAC agrees with the Dossier Submitter that sensitising substances in clothing, footwear and other related articles can induce allergic contact dermatitis. Reports have shown that skin sensitising chemicals are found in clothing or footwear and allergic contact dermatitis from clothing or footwear, as well as other related articles, has been described and reviewed in many scientific publications and authority reports. The Dossier Submitter estimated the number of individuals presenting allergic contact dermatitis caused by chemical substances in textile and leather to be around 5 million persons in the EEA31 population.

Sensitisation to a chemical is irreversible and constrains the affected person to avoid exposure to the allergen for life. Exposure to chemicals in clothes and footwear, in particular, begins from early life and is inevitable. The purpose of this restriction is therefore to reduce the risk for sensitisation to chemical substances in clothing, footwear, other articles made of textile, leather, hides, furs and synthetic leather as well as disposables sanitary towels, napkins, tissues and nappies that are placed on the market for the first time.

[7] It should be noted that neither in the proposed restriction nor in the explanatory guide on entry 72, the lists of articles covered in the scope are exhaustive.

1. Articles covered by the restriction proposal

The scope of the restriction includes clothing and footwear made of any material. In addition, textile, leather, hides, furs, and synthetic leather articles that come into contact with the skin under normal or reasonably foreseeable condition of use to an extent similar to clothing (defined as "other related articles" in the present opinion) are also included in the scope of the restriction. Disposable sanitary towels, napkins, tissues and nappies are also included. RAC supports the proposal to harmonise the articles covered by this restriction with those included within the scope of entry 72 of REACH Annex XVII with some additional articles and amendments.

For clothing and footwear, RAC supports the inclusion of any material, including coatings (e.g. prints), synthetic leather, latex gloves, neoprene or other polymer materials.

The Dossier Submitter clarified that clothing or footwear made of natural latex or rubber materials (e.g. latex gloves, rubber boots or raincoats), synthetic rubber materials (e.g. neoprene diving suits) or other polymer materials (e.g. footwear) are in the scope of the proposal. Cases of allergic contact dermatitis due to skin sensitising additives, such as rubber vulcanization accelerators and antioxidant agents (e.g. thiurams, carbamates, mercaptobenzothiazoles,) or other additives (e.g. para-tert-butylphenol-formaldehyde) raised a concern for these articles. Articles made of other polymer materials can also include sensitising plasticisers (e.g. DCHP or (meth)acrylates). Therefore, the risk related to sensitising chemicals in such materials cannot be excluded.

Clothing, footwear and other related articles made of synthetic leather are also targeted by the restriction proposal. Synthetic leather is usually found in clothing, home furnishing, shoes and bags. Mock leather is made by applying a polymer coating, for example polyurethane (different kinds of synthetic materials coated with PU) or polyvinyl chloride (with protective stabilisers, softening plasticisers and lubricants), to a textile base material (e.g. polyester, cotton, nylon or rayon) or in sheets. Such articles can therefore be seen as coated textiles. RAC supports the inclusion of clothing, footwear or other related articles made of synthetic leather that come into contact with the skin to an extent similar to clothing into the scope of the restriction.

Furthermore, the Dossier Submitter did not define in their proposal the concept of "*an extent similar to clothing".* Repeated short contact times may cause allergic response as easily as a few longer contact periods. RAC is therefore of the opinion that to adequately address the concern related to skin sensitisers in textiles or leather, the use of the phrase 'to an extent similar to clothing' should be interpreted as prolonged and/or repeated contact with the skin over the day.

1.1 Clothing and related accessories

This restriction proposal targets clothing and related accessories, including single-use clothing. This includes day clothes, suits and ties, underwear, nightwear and hosiery. Outerwear, including coats and jackets as well as scarf, shawls, hats, gloves are also covered. Considering that dermal contact with sensitising substances in textile and leather articles can induce contact allergic dermatitis, RAC is of the opinion that including all articles of clothing and related accessories in the scope of the restriction is appropriate.

RAC agrees with the Dossier Submitter that fancy dress and disguise costumes that are not covered by the Directive on Toys Safety No 2009/48/EC should be included in the scope of the restriction. Further clarification is given in the related section of the present opinion (section 1.5).

Sportswear and swimwear are included in the scope of the restriction, similarly to entry 72 of REACH Annex XVII. The Dossier Submitter, however, intends to also include sports equipment

in contact with the skin. “Sport equipment” should be understood as only articles that can be interpreted as clothing. This would include, for example, shin pads or ski masks and exclude other articles such as balls or rackets. RAC is of the opinion that sports equipment made of textile or leather should be included with sportswear in the context of the present restriction. RAC also notes that the perspiration induced by sporting activities might increase the concern related to skin sensitisation. RAC therefore supports the inclusion of swimwear, sportswear and sports equipment in contact with the skin on the scope of the restriction.

Finally, the Dossier Submitter proposed to include cosmetic textiles with microencapsulated solids or liquids intended to be released over time when the garment is in direct contact with the skin to give cosmetic functions, unless the microencapsulated solids or liquids are already covered by the ongoing restriction on microplastics. Microencapsulation involves encapsulating liquid or solid substances in micro- or nanosized thin-walled natural or synthetic bubbles. The mechanical rubbing caused by the use of the textile ruptures the membrane over time, allowing a gradual release of the active agents from the microspheres. RAC notes that the microencapsulated mixtures intended to be released on the skin and with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition fall into the scope of the Cosmetic Products Regulations No 1223/2009 (CPR). The risk related to such substances is therefore expected to be covered by the CPR. However, textile-based materials, as well as the capsule itself, are not covered by the Cosmetic Product Regulation. The inclusion of cosmeto-textiles in the scope of the restriction is therefore supported.

1.2 Footwear

The Dossier Submitter aligned their definition of footwear with Directive 94/11/EC on labelling of materials used in the main components of footwear for sale to consumers. This definition includes outer sole, lining and sock, insole and upper. Accordingly, footwear is described as all articles with applied soles designed to protect or cover the foot, including parts marketed separately.

RAC agrees with the Dossier Submitter that all footwear, as defined by the Directive 94/11/EC, should be included in the scope of the restriction. Although direct contact with the skin when wearing footwear might be reduced by the use of textile barriers (e.g. socks) in some cases, exposure to sensitising chemicals present in footwear can lead to acute contact dermatitis. The inclusion of footwear in the scope is therefore appropriate.

The proposal further includes in the scope inner soles that can be purchased separately from shoes. Considering that a prolonged skin contact with textile or leather might occur during the use of inner soles, their inclusion in the scope of the restriction is supported by RAC.

1.3 Other articles that come into contact with the skin under normal or reasonably foreseeable condition of use to an extent similar to clothing

Similarly to the entry 72 of REACH Annex XVII, **RAC agrees to include in the scope of the restriction proposal other textile, leather, fur, hide or synthetic leather articles that are expected to come into contact with the skin under normal or reasonably foreseeable condition of use to an extent similar to clothing**. They include re-usable home and hygiene articles, such as towels and bathrobes, sanitary towels, re-usable nappies, bed linen, blankets which are assimilated to the textile exposure scenario for risk assessment purposes. Upholstery, such as fabric covering chairs, armchairs and sofa and car upholstery are included in the scope, including those in public facilities or on public transportation. Travel and bag articles, for example sleeping bags, handbags, backpacks or briefcases, as well as yarn and fabrics intended for use by the final consumer are also targeted.

Childcare articles are defined as “*any products intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of the children*” based on restriction

entries 51 (DEHP, DBP and BBP) and 52 (DIDP, DINP and DNOP) of Annex XVII. They comprise for example valances, babies' nests or babies' deckchairs. Such articles that were not designed "for use in play", are not covered by the EU Toys Safety Directive No 2009/48/EC. There is to date no specific European legislation regulating the skin sensitisation concern related to childcare articles made of textile fibres or leather. RAC therefore supports the inclusion of childcare articles in the scope of the present restriction.

Entry 72 of REACH Annex XVII limits fashion accessories to wristwatch straps. The Dossier Submitter is of the view that this might be insufficient in terms of health protection and therefore proposes that the scope includes other fashion accessories, for example wrist bands and laces, necklaces, straps and bands or bracelets. RAC agrees that prolonged and/or repeated skin contact with fashion accessories made of textile or leather might lead to skin sensitisation in consumers and is therefore of concern. RAC however notes that jewellery is outside the scope of the restriction proposal. The distinction between fashion accessory and jewellery might be difficult, potentially leading to enforcement issues. **RAC is therefore of the view that the articles targeted as fashion accessories should be carefully defined within the scope of the present restriction.**

In addition, fashion accessories for children which are not for use in play are not considered as toys within the meaning of the Toys Safety Directive No 2009/48/EC. These articles are therefore considered to fall within the scope of the present restriction if they are made exclusively or partly of textile, leather, fur or hide.

The Dossier Submitter proposed re-usable napkins and table linen to be included in the scope. Although a prolonged exposure seems unexpected under normal or reasonably foreseeable conditions of use, repeated exposure to re-usable napkins and table linen are likely to happen over the day. RAC therefore agrees with the Dossier Submitter to include re-usable napkins and table linen in the scope of the present restriction.

The restriction proposal also includes carpets, mats and rugs. RAC notes that some carpets, especially wall-to-wall carpets, cannot be easily washed in order to reduce exposure to some chemicals and can cover extended surfaces. Wall-to-wall carpets are regulated by the Construction Products Regulation 305/2011, which does not impose any requirements to protect consumers against a risk related to chemicals skin sensitisers present in such articles. Repeated and/or prolonged exposure to sensitising substances can occur under normal or reasonably foreseeable conditions of use, especially for children. RAC therefore supports the inclusion of carpets, mats and rugs in the scope of the restriction.

1.4 Disposable sanitary towels, napkins, tissues and nappies

Finally, the proposal includes disposable sanitary towels, napkins, tissues, or nappies. RAC notes that such articles may be impregnated with substances with a view exclusively or mainly to cleaning the external parts of the human body, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. Such substances could therefore be interpreted as cosmetic products and the related skin sensitisation concern would, in principle, be regulated according to the EU Cosmetic Products Regulation No 1223/2009. In contrast, such articles are also expected to be possibly treated during manufacturing with chemicals for other purposes than a cosmetic function, for example dye, solvent, softener or even as residual substances. Therefore, the risk related to sensitising chemicals in such articles cannot be excluded. Prolonged skin contact with disposable sanitary towels or nappies is expected over the day. RAC also notes that a direct contact with damaged skin may increase the skin sensitisation concern. 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. **RAC therefore supports the inclusion of disposable sanitary towels, napkins, tissues and nappies in the scope of the restriction.**

Several materials, including cellulose, polypropylene, polyethylene or polyester may enter in the composition of sanitary towels or nappies. However, sanitary towels and nappies are made of multilayer materials of which some layers are not expected to come into direct contact with the skin. The proposal of the Dossier Submitter is to include all parts of these articles, including inner and outer parts. RAC concurs with the Dossier Submitter that a migration from inner layers to outer parts of such articles cannot be excluded. In addition, tearing of the outer parts of the nappies may occur, leading to skin contact with the inner parts of the article, especially for nappies, although the exposure to chemicals from the inner part of the nappy cannot be the same as the external one. Finally, the inclusion of only some layers of the articles in the scope of the proposal may lead to enforcement issues. **RAC is therefore of the opinion that all layers of disposable nappies and sanitary towels should be considered in the scope of the restriction.**

RAC notes that some articles, for example disposable napkins, are covered by the Food Contact Material Regulation N° 1935/2004, which explicitly aims to secure a high level of health protection. **To avoid double regulation, the inclusion of articles covered by the Food Contact Material Regulation N° 1935/2004 is not supported by RAC.**

1.5 Articles not covered by the restriction proposal

Specific articles not covered by the scope of the restriction
The Dossier Submitter provided a list of several articles that are especially not covered by the scope of this restriction:

- jewellery;
- glasses and sunglasses;
- curtains;
- textile lampshades and wall decorations;
- filling materials in chairs, armchairs and sofas;
- and 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
The restriction proposal only targets textile and leather finished articles that are placed on the EU market for the first time. Second-hand articles, defined as articles that have already been sold to an end user in the EU but are subsequently transferred to another actor in the supply chain, are outside the scope of the restriction. The decision of the Dossier Submitter to exclude second-hand articles is mainly based on complexity and cost of enforcement. In addition, the Dossier Submitter argues that the washing and normal use of clothes would lower the content of some skin sensitising substances.

Articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment
All textile or leather articles of clothing, footwear that come into contact with the skin under normal or reasonably foreseeable condition of use which are covered by the EU Regulation 2016/425 on personal protective equipment are outside the scope of the present restriction.

Articles within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
All textile or leather articles of clothing, footwear that come into contact with the skin under normal or reasonably foreseeable condition of use which are covered by the EU Regulation 2017/745 on medical devices are outside the scope of the present restriction.

Articles within the scope of Directive on Toys Safety No 2009/48/EC
The Toy Safety Directive 2009/48/EC defines the safety criteria that toys must meet before they can be marketed in the EU. The articles targeted by this Directive are therefore excluded from the scope of the present restriction. Nevertheless, the Annex I of the Directive on Toys Safety presents a list of products that, in particular, are not considered as toys within the

meaning of this Directive. This list includes in particular fashion accessories for children which are not for use in play. These articles are therefore considered to fall within the scope of the present restriction if they are made of textile, leather, fur or hide.

In addition, childcare products made of textile or leather, such as valances, bibs, babies' nest or babies' deckchairs that were not designed "for use in play" do not need to meet the Toys Safety Directive requirements. These products are therefore interpreted to fall within the scope of the present restriction.

Regarding carnival costumes, the Guidance document n°17 "*on the application of the Directive on the safety of toys"* states that the Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age. Carnival costumes, fancy dresses and disguise costumes that are designed or intended, whether or not exclusively, for use in play by children under 14 years are therefore covered by the Toys Safety Directive. In contrast, carnival costumes for adults or teenagers from the age of 14 years and above are not considered as toys and are targeted by the present restriction.

2. Substances covered by the restriction proposal

During all steps of textile and leather manufacturing, chemicals are used and may still be present in finished products. The functional chemicals, for example dyes and coating, are intended to remain in the finished article to provide certain properties. In contrast, other chemicals found in textiles and leathers are not intended to remain in the finished article. These substances may be auxiliary chemicals, such as solvents and softeners,
or remaining degradation products, including for example formaldehyde and degradation products of azo dyes. All these chemicals are covered by the restriction proposal independently of whether they intend to remain in the finished article or not, as there is a possibility that they end up in the finished article.

2.1 Chemical substances having a harmonised classification as skin sensitisers in Category 1 / 1A / 1B according to the CLP Regulation

The scope of this restriction proposal covers substances with harmonised classifications as skin sensitisers in Category 1/1A/1B according to the CLP regulation, which currently represents more than 1 000 substances. This number is expected to increase with time although skin sensitisation is not a prioritised hazard category for harmonised classification under CLP.

Skin sensitization is widespread in the human population and can be a severe condition, thus justifying the proposal Sensitising substances present in clothing, footwear or related articles can induce contact dermatitis allergy and the sensitisation to a chemical is irreversible. After sensitisation to an allergen, there is a need to avoid exposure for life whereas skin contact with clothes and footwear is inevitable from early life.

To date, there is no exhaustive list of substances used in the manufacturing processes of clothing and footwear. The Dossier Submitter presented a list of substances with skin sensitising properties that are expected to be present in clothing or footwear at point of sale (Table 19 in Annex E of the BD). This list is referred to as the 'IN-list' and includes in total 70 substances having a harmonised classification as Skin Sens. 1/1A/1B. According to this database, RAC acknowledges that most chemicals having a harmonized classification as skin sensitisers were not found in clothing, footwear or other related articles. However, this list of substances was concluded of limited reliability by the DS and only targeted clothing and footwear articles. It cannot be excluded that other skin sensitising substances might be present in finished articles included in the scope of the proposal but were not highlighted during the consultancy study.

A large number of substances may be involved during the manufacture of clothing or footwear. For example, ECHA has carried out an exercise in relation to searching REACH's registration database to detect how many substances with harmonised classification under CLP as skin sensitisers 1/1A/1B, which have service life uses related to textiles and/or leather and which are categorized as either: dyes, plasticisers, acrylates or diisocyanates are registered. This search yielded 243 substances which passed the aforementioned search filters, this clearly exceeds the (master) IN-list elaborated by the dossier submitter which contains 94 substances (70 of them which have harmonised classifications as skin sensitisers in Category 1/1A/1B). Numerous manufacturing processes can be involved and such processes may vary with time. Overall, the available database presented in the restriction proposal is considered of limited reliability and does not allow drawing a complete picture of the skin sensitising chemicals present in clothing, footwear or related articles.

Considering the lack of reliable overview on the skin sensitising substances used in such manufacturing processes or present in clothing, footwear or related articles in the scope of the restriction, RAC is of the view that the proposal to include all substances with a harmonised classification as skin sensitisers is more appropriate than a narrow list of substances that might be present in clothing or footwear. RAC also notes that this approach will allow to prevent regrettable substitution of the restricted substances. **In conclusion, RAC agrees with the approach taken by the Dossier Submitter to include all substances classified as Skin Sens. 1/1A/1B in the scope of the restriction**.

A dynamic linkage referring directly to the harmonised classification under the CLP regulation is proposed by the Dossier Submitter. RAC supports this proposal and considers that a dynamic link with CLP allows a better protection of human health from skin sensitising risks related to textile or leather exposure. This option also allows a faster regulation of hazardous substances with a harmonised classification as Skin Sens. 1/1A/1B and contributes to prevent regrettable substitution better than an approach based on a narrower closed list of substances

In relation to the suggestion to link this restriction to the EU Cosmetic Products Regulation N°1223/2009 (CPR), RAC notes that such an approach could be justified in some cases, for instance the tattoo inks restriction because all hazards were targeted. However, RAC does not support the same approach in the current restriction proposal because the Annexes of the CPR comprise a list of prohibited substances in cosmetics (Annex II), substances which must not be contained except subject to the restrictions laid down (Annex III) or colourants allowed in cosmetics (Annex IV), and because all the substances in the annexes do not have a clear link to hazard data (sometimes only a related opinion of the Scientific Committee on Consumer Safety (SCCS) can be found). Therefore, based on the CPR Annexes, it is not possible to distinguish sensitising substances as such, without a cross-reference to Annex VI of the CLH regulation, from other substances which might have been included based on a different hazard profile than the skin sensitising one strictly speaking, for example CMR substances.

2.2 Chemical substances without harmonised classification as skin sensitisers but with skin sensitising concern

The Dossier Submitter proposes to include in the scope of the restriction an additional list of chemicals (Table 2 in the Annex XV report). Although they do not have a harmonised classification as Skin Sens. 1/1A/1B, these substances have a concern of skin sensitisation. This list comprises 24 selected disperse dyes.

According to Article 36 of the EU 1272/2008 Regulation, skin sensitisation is not a prioritized hazard category under CLP. Many sensitising chemicals do not have a harmonised classification at the moment. Consequently, **RAC agrees that skin sensitising substances without harmonised classification can be present in textiles or leather finished articles. An additional list of appropriate substances of concern is therefore considered relevant to adequately protect consumers against skin sensitisation** and

at the same time to prevent regrettable substitution of substances already classified as skin sensitisers.

The disperse dyes presented in Table 2 were included in voluntary schemes because of their skin sensitising properties. These schemes include Oeko-tex standard, Bluesign, Global Organic Textile Standard, EU Ecolabel and Nordic Swan Ecolabel as well as (manufacturing) restricted substances lists ((M)RSL) such as Zero Discharge of Hazardous Chemicals. In addition, two of the dyes, Disperse Yellow 23 and Disperse 37/59/76 were detected by ANSES in clothes and footwear. This study indicated that these disperse dyes were linked to allergic contact dermatitis reaction in patients (ANSES, 2018).

2.3 Chemical substances with biocidal properties

The Dossier Submitter proposed to not include biocidal active ingredients in the scope of this restriction. The Biocidal Products Regulation (BPR, Regulation EU 528/2012) regulates substances used as active ingredients in biocidal products as well as articles treated with, or intentionally incorporating biocidal products. The risk related to exposure to skin sensitisation after exposure to biocidal active ingredients as well as biocidal products intentionally incorporated in textile or leather finished articles is therefore expected to be covered by the BPR since 1 March 2017. According to the Regulation, articles can only be treated with biocidal products containing active substances approved in the EU. In addition, articles treated with one or more biocidal products, that are manufactured or imported in the EU need to present an easily understandable and visible labelling for consumers when:

- A claim that the treated article has biocidal properties is made;
- It is required in the conditions of the approval of the active substance contained in the biocidal product used to treat the article.

In conclusion, RAC supports the Dossier Submitter's proposal to not include within the scope of the current restriction biocidal substances authorised by the BPR since the risk of skin sensitisation is already covered by this regulation. This would be valid only for substances used for its biocidal properties covered by the BPR; whereas if the substance is used for other biocidal purposes than those approved under the BPR, or for non-biocidal purposes, the substance would be covered by the present restriction proposal.

2.4 Substances of concern outside the scope of this restriction proposal

Some substances were highlighted by the Dossier Submitter to be of concern regarding skin sensitisation but remained outside the scope of this restriction proposal. The four following chemicals were not concluded to be the ones that triggered sensitisation on the patients when they were quantified in articles in the ANSES study (2018) and were therefore not included in the proposal. Detailed information on the studies can be found in Annex I to this opinion. In addition, the Dossier Submitter pointed out a potential concern for chromium (III). For the substances that are known skin sensitisers but do not yet have a related harmonised classification, RAC recommends (for example to Member State competent authorities or industry) to consider a proposal for harmonised classification regarding skin sensitization so that these substances will be classified and hence ensure a higher level of protection to consumers.

Benzyl benzoate
Based on the SCCS analysis, RAC acknowledges that benzyl benzoate is a contact allergen in humans. The ANSES study also demonstrated that benzyl benzoate can be present in clothes and footwear articles. RAC therefore considers that skin sensitisation caused by an exposure to benzyl benzoate in clothes and footwear might be a concern although no clear risk was established in the ANSES study.

*Butyl hydroxyl toluene (*CAS 128-37-0, EC 204-881-4)
RAC agrees that there is a concern regarding the skin sensitisation hazard of butyl hydroxyl

toluene. The ANSES study also confirms that BHT is present in textile and footwear finished articles.

2-phenoxyethanol (CAS 122-99-6, EC 204-589-7)
Overall, although 2-phenoxyethanol has a concern of skin irritation, no clear dataset demonstrating skin sensitisation is available for this substance. RAC however agrees that 2-phenoxyethanol can be present in textile and leather finished articles.

Para tertbutyl phenol (4-tert-butylphenol CAS 98-54-4, EC 202-679-0)
Scientific evidence suggests that para-tert-butylphenol (ptBP) has a low sensitisation capacity by itself. Nevertheless, exposure to p-tert-butylcatechol might lead to cross-reactions with p-tert-butylphenol. Formaldehyde has a harmonised classification as Skin Sens. 1 and is therefore in the scope of the restriction proposal. The concern related to ptBP formaldehyde resin is therefore expected to be covered by the present restriction.

Chromium (III)
Chromium (VI) has a harmonised classification within Annex VI of CLP regulation and therefore is included within the scope of the restriction but Cr (III) does not have such a harmonised classification and therefore is outside the scope of the restriction. Some concerns have been raised by the Dossier Submitter and in the consultation (comments 2368 and 2379) regarding the skin sensitisation potential of Cr (III) in leather and leather articles. It is also known that Cr (III) is a poorer protein binder than Cr (VI) and can leach out of leather gaining contact with skin, especially when inadequate tanning or inappropriate washing of leather has not removed the unbound Cr (III).

RAC noted several studies showing that Cr (III) is able to induce allergic contact dermatitis in Cr (VI)-sensitised individuals, although the elicitation threshold of Cr (III) seems to be clearly higher than the elicitation threshold of Cr(VI). Therefore, **based on the scientific evidences, RAC concludes that there is a concern for the sensitising properties of chromium III and it should be looked into further, in the future.**

Other dyes
In the 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 noted 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). Nevertheless, RAC (in this draft opinion) and the Dossier Submitter (in their background document) highlight this to raise awareness.

3. Information gathering and search strategy for hazard and exposure assessment of substances

In order to perform the risk assessment, the Dossier Submitter needed specific information on hazard and exposure of substances that are present in textile and articles. Such information was, therefore, used to make general assumptions on all substances within the scope of the proposal. The identification of relevant chemicals in finished textile and leather products was based on a first screening of chemical databases for substances with any possible indication that they may have been used in textile and leather applications. A consultancy study was afterwards initiated to confirm the indications of uses (Kemi, 2019) and estimate the concentrations of substances in the finished articles. The resulting substances were included in the IN list.

Of the substances on the IN-list, a number of substances were further targeted for information searches based on the following criteria:

- Groups of chemicals with a structural similarity or same toxic entity;
- Substances for which there is potential for high exposure (deliberate use in textile or leather, substance intended to stay on article and high levels of substance in textile or leather);
- Substances that are well-known skin sensitisers.

In addition, the substances on the list of concern (Table 2) were specifically targeted for information searches together with other disperse dyes having a harmonised classification as skin sensitiser.

The substances or group of substances targeted for the information retrieval on hazard and exposure assessment were the following: allergenic disperse dyes, chromium (VI) compounds, diisocyanates, (meth)acrylates, formaldehyde, nickel compounds, cobalt compounds, direct dyes, acid dyes, rosin, dicyclohexyl phthalate (DCHP), 1,4-paraphenylene diamine and glutaraldehyde.

Allergenic disperse dyes

Disperse dyes are water-insoluble dyes introduced to allow the dyeing of synthetic fibres, including nylon, polyester or acrylic and to colour leather. Although they seem to be less used in the production of textile and textile articles, these dyes still can be contained in textile articles. In addition to the list of concern, at least six disperse dyes having a harmonised classification as Skin Sens. 1 were identified on the IN-list.

- *Disperse Blue 1* (1,4,5,8-tetraaminoanthraquinone, CAS 2475-45-8, EC 219-603-7)
- *Disperse Yellow 3* (Acetamide, N-[4-[2-(2-hydroxy-5-methylphenyl)diazenyl]phenyl]-, CAS 2832-40-8, EC 220-600-8);
- *Disperse Blue 370* (Propanamide, N-[2-[(2-cyano-4,6-dinitrophenyl)azo]-5-(dipropylamino)phenyl]-, CAS 106359-94-8, EC 430-010-7);
- *Disperse Red 282* (L-Alanine,N-[4-[(2-chloro-4-nitrophenyl)azo]-3-[(1-oxopropyl)amino]phenyl]-, methyl ester, CAS 155522-12-6, EC 416-240-8);
- *Disperse Yellow 236* (3-Pyridinecarbonitrile, 1-butyl-5-[(2-chloro-4-nitrophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-, CAS 75511-91-0, EC 407-970-8);
- *Terasil Red WRS* (Glycine, N-[3-(acetylamino)phenyl]-N-(carboxymethyl)-, CAS 188070-47-5, EC 424-290-7).

Chromium (VI) compounds

In leather, hexavalent chromium may be unintentionally formed during the manufacturing process. Chromium salts are also used as a catalyst in the manufacturing process for textiles and as a chrome dye for wool.
Chromium compounds on the IN-list comprise:

- *Ammonium dichromate* (CAS 7789-09-5, EC 232-140-5)
- *Potassium chromate* (CAS 7789-00-6, EC 232-140-5)
- *Sodium chromate* (CAS 7775-11-3, EC 231-889-5)
- *Chromium trioxide* (CAS 1333-82-0, EC 215-607-8)
- *Chromyl dichloride* (CAS 14977-61-8, EC 239-056-8)
- *Dichromium tris(chromate)* (CAS 24613-89-6, EC 246-356-2)
- *Potassium dichromate* (CAS 7778-50-9, EC 231-906-6)

Diisocyanates

Diisocyanates can be used in coated textiles and pigment printed textiles, as well as in adhesives or mock leather. At least seven diisocyanates having a harmonised classification as skin sensitisers were identified likely to be used in the production of textile and leather (KemI, 2019).

- *4,4'-methylenediphenyl diisocyanate* (MDI) (CAS 101-68-8, EC 202-966-0)
- *m-tolylidene diisocyanate* (TDI) (CAS 26471-62-5, EC 247-722-4)
- *3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (*IPDI) (CAS 4098-71-9, EC 223-861-6)
- *4-methyl-m-phenylene diisocyanate* (CAS 584-84-9, EC 229-54-5)

- *o-(p-isocyanatobenzyl)phenyl isocyanate* (CAS 5873-54-1, EC 227-534-9)
- *Hexamethylene diisocyanate* (HDI) (CAS 822-06-0, EC 212-485-8)
- *2-methyl-m-phenylene diisocyanate* (CAS 91-08-7, EC 202-039-0)

Meth(acrylates)

Residues of (meth)acrylates can be present in acrylic binders or coating. In addition, (meth)acrylates may be used for impregnation of textiles or adhesive application. They can be found in coated and pigment printed textile and leather articles. At least 3 (meth)acrylates having a harmonised classification as skin sensitisers were identified likely to be used in the production of textile and leather (KemI, 2019).

- *2,3-epoxypropyl methacrylate* (CAS 106-91-2, EC 203-441-9)
- *2-dimethylaminoethyl methacrylate* (CAS 2867-47-2, EC 220-688-8)
- *Butyl methacrylate* (CAS 97-88-1, EC 202-615-1)

Formaldehyde

The use of formaldehyde in easy care/non-iron products allows various properties such as shrinkage resistance, wrinkle-resistance or dirt-repellence antistatic function. In addition, formaldehyde can be found in articles with coated, laminated pigment printed or in leather tanning (KemI, 2019).

Nickel (CAS 7440-02-0, EC 231-111-4)

Nickel can be used in dye chromophores and was detected in non-metal parts of textile articles in the Anses study (2018). Nickel can also be present in metallic parts of clothing articles and footwear such as rivet buttons, tighteners, rivets, zippers and metal marks, but these articles are not covered by the present Restriction proposal.

Cobalt (CAS 7440-48-4, EC 231-158-0)

Cobalt can be present as an impurity in dyestuffs. In addition, the substance can be used in colorants for textile and leather articles. In particular, some pre-metallised dyes contain cobalt. The substance has been found in nylon, wool and leather (KemI, 2019; Hamann et al., 2018).

Direct dyes

Direct dyes are used to dye various cellulose fibres, including cotton, linen, viscose, lyocell, polyamide, silk or wool. These substances have high water solubility and are held on the fibre by weak forces. Direct dyes are usually considered as low fastness dyes. Therefore, loose, unfixed direct dye may be present in the article. At least two acid dyes were identified with a high probability for exposure in the KemI study (2019).

- *Direct Blue 301* (CAS 124605-82-9, EC 408-210-8)
- *Direct Yellow 162* (CAS 81898-60-4, EC 400-010-9)

Acid dyes

Acid dyes include azo and anthraquinone compounds and are used to colour textile materials polyamide, silk, wool and leather. The substances have high water solubility and are held on the fibre by electrostatic interaction. Loose, unfixed dye has been detected in fabrics at low concentrations. At least two acid dyes were identified with a high probability for exposure in the KemI study (2019).

- *Acid Rec 447* (CAS 141880-36-6, EC 410-070-8)
- *Acid Dye "Yellow E-JD 3442"* (CAS 147703-65-9, EC 410-150-2)

Rosin

Rosins are mixtures of natural substances that can be used as an ingredient in the finishing stage of leather production. In addition, rosins can be used in printing inks and coatings as well as in the finishing stage of leather production (KemI, 2019). At least two skin sensitising rosins were identified with a high probability for exposure in the KemI study (2019).

- *Tall-oil rosin* (CAS 8052-10-16, EC 232-484-6)

- *Rosin* (CAS 8050-09-7, EC 232-475-7)

Dicyclohexyl phthalate (DCHP, CAS 84-61-7, EC 201-545-9)
Dicyclohexyl phthalate is used as a plasticiser in the coating of textiles and other articles such as luggage and sport equipment. DCHP can also be present in pigment printed textiles (KemI, 2019).

1,4-paraphenylene diamine (CAS 106-50-3, EC 203-404-7)
Para-phenylenediamine is used in dark dyes in leather or textile or in azo dyes manufacturing.

Glutaraldehyde (Pentanedial, CAS 111-30-8, EC 203-856-5)
Glutaraldehyde is reported as a reactive tanning agent in the chromium-free tanning process of leather (KemI, 2019). In leather, glutaraldehyde is bound irreversibly to the collagen molecule. However, exposure to unwashed residues cannot be completely ruled out. In textiles, glutaraldehyde has been evaluated and found suitable as a substituent of formaldehyde in press finish for cotton fabrics (Yarn et al. 2000).

RAC agrees that due to the large number of substances included in the scope, there is a need to target a subset of substances for information retrieval on hazard and exposure according to pre-defined criteria. The IN-list and the choice of the criteria is considered appropriate to refine the final list of targeted substances. The use of specific information on targeted substances to make general assumptions on all the substances in the scope of the restriction is also supported.

Description of the risks addressed by the proposed restriction

Information on hazards

Summary of proposal:

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 according to the CLP regulation or have been indicated to have skin allergenic properties. 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. Information on hazard properties was retrieved from published literature, reports and REACH registrations (in accordance with ECHA guidance on information gathering ECHA, 2011). 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.

Evidence that a substance can cause sensitisation by skin contact in either humans or animals will normally justify classification as a skin sensitiser.

RAC conclusions:

Although skin sensitisation is not life-threatening, it is a non-reversible process that can be very incapacitating for persons suffering from it. 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. Depending on the part of the body affected and the severity of the symptoms, the allergic contact dermatitis derived from skin sensitisation may significantly impair the quality of life of the person, sometimes preventing him or her from working or even living normally.

RAC is of the opinion that substances with a harmonised classification as skin sensitisers as well as substances which are known to have intrinsic properties (for example from the published literature and unpublished reports,) leading to skin

sensitisation should be restricted in clothing and related accessories, footwear and 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.

Key elements underpinning the RAC conclusions:

A skin sensitiser is a substance that will lead to an allergic response following skin contact. Sensitisation includes two phases: the first phase is induction of specialised immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e. production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitised individual to an allergen. This elicitation is associated with the manifestation of allergy, i.e. the allergic contact dermatitis. The clinical features of allergic contact dermatitis include eczema, oedema, rash and itching, pruritis and vesicles. Symptoms can range from mild to severe, and they can appear within a few hours up to 10 days after the moment of contact with the allergen. The inflammatory response typically develops at the site of allergen contact. Symptoms are maximal within 2–3 days and, without further exposure to the allergen, they decline.

The Dossier Submitter proposes the restriction of more than 1 000 substances according to two different groups: i) Substances with harmonised classification in the Classification, Labelling and Packaging Regulation (EC) n° 1272/2008 as Skin sensitiser 1,1A, 1B; which would include more than 1 000 substances (1030 Skin Sens 1, 11 Skin Sens 1A and 9 Skin Sens 1B); ii) Substances without an harmonised classification but of skin sensitising concern; which would include up to 24 disperse dyes shown in Table 2.

1. **Substances with harmonised classification in the Classification, Labelling and Packaging Regulation (EC) n° 1272/2008**

Substances classified as skin sensitisers (Category 1/1A/1B) were those for which there is evidence in humans that the substance can lead to sensitisation by skin contact in a substantial number of persons; or for which there are positive results from an appropriate animal test. The information used for the assessment was retrieved from published literature, databases and REACH registrations in accordance with ECHA guidance on information gathering. RAC notes that the placing on the market for use by the general public of the substances with harmonised classification as Skin Sens. 1/1A/1B is already limited by the CLP Regulation, which indicates that hazards posed by these substances have already been assessed to a great extent. RAC therefore concludes that the skin sensitisation hazard of substances classified as skin sensitisers (Category 1/1A/1B) is acknowledged, independently of the potency. RAC concurs with the Dossier Submitter and considers that substances with harmonised classification in Regulation (EC) n° 1272/2008 should be within the scope of the restriction.

2. **Substances without an harmonised classification but of skin sensitising concern: disperse dyes**

RAC bears in mind that skin sensitisation is not a prioritised hazard category under CLP and, therefore, many chemical substances with allergenic properties will not yet have harmonised classifications as skin sensitisers. Hence, to limit the restriction to substances with harmonised classifications is judged insufficient by RAC to significantly reduce the risk of skin sensitising substances in finished clothing, footwear, other articles with similar skin contact made of textile, leather, fur, hide and artificial leather articles and disposable textiles that are placed on the market for the first time.

The Dossier Submitter suggested adding disperse dyes shown in Table 2 to the scope of the restriction since these disperse dyes have a capability of inducing skin sensitisation when present in textile or leather articles. Most of the disperse dyes are azo dyes, but some are anthraquinones (Morgardt-Ryberg, 2009). Disperse dyes are mainly used for dyeing textiles

(not only clothes, but also furnishing fabrics, car interiors and sports equipment), fur (in leather processing) and plastics (Morgardt-Ryberg, 2009).

Due to the lack of harmonised classification for these disperse dyes RAC considers that a case-by-case approach is needed in order to determine whether the concern regarding the capability of these substances to induce skin sensitisation is supported by experimental evidences or not.

The disperse dyes presented in Table 2 comprise azo, anthraquinone, nitro, quinoline and methine dyes.

2.1 RAC conclusion about azo disperse dyes

A total of 13 azo dyes were proposed in the scope of this restriction. Robust evidences of skin sensitisation in animals or human patch tests were found for 9 of them during the evaluation of the hazard by RAC (Disperse Blue 106, 124 and 102, Disperse Brown 1, Disperse Orange 1, 3 and 37/59/76, Disperse Red 1 and 17). However, no literature related to the skin sensitisation of the 4 remaining azo dyes was found (Disperse Blue 291, Disperse Orange 149, Disperse Yellow 23 and Disperse Violet 93).

Many azo dyes are known to be skin sensitisers. In Europe, the routine textile dye mix used in patch testing includes among others Disperse Blue 106 and 124, Disperse Orange 1 and 3 and Disperse Red 1 and 17, supporting the scientific evidences presented above.

As was commented above, the process of skin sensitisation is mechanistically divided in two stages. The first one is the induction (in which the immune system is primed) and the second one the elicitation. Two conditions are needed for induction, the first one is that the chemical must necessarily be able to penetrate the skin and the second one is that once the skin barrier has been crossed the substance must binds to proteins forming haptens. The haptens are further recognized and processed by Langerhans cells that migrate to the draining lymph nodes where T-cells are activated and start to proliferate and generate so-called memory T-cells that will further cause a rapid release of cytokines and other inflammatory mediators if a second dermal exposure (elicitation) with the sensitising substance takes place.

RAC notes that the chemical structure of the 13 azo-dyes displayed in Table 2 is quite similar. The chemical structure of all of them includes the azo bond with aromatic rings which have polar groups as nitro or hydroxyl groups at the edges of the molecule. It suggests that, despite no evidence of the capability of acting as skin sensitisers were found for some of them, all the substances of the family might potentially be able to cross the skin barrier and react with protein in the inner milieu due to their comparable chemical structure. In addition, other azo disperse dyes were listed in the IN list and are in the scope of the restriction due to their harmonised classification as Skin Sens 1/1A/1B:

- Disperse Yellow 3 (Acetamide, N-[4-[2-(2-hydroxy-5-methylphenyl)diazenyl]phenyl]-, CAS 2832-40-8, EC 220-600-8);
- Disperse Blue 370 (Propanamide, N-[2-[(2-cyano-4,6-dinitrophenyl)azo]-5-(dipropylamino)phenyl]-, CAS 106359-94-8, EC 430-010-7);
- Disperse Red 282 (L-Alanine,N-[4-[(2-chloro-4-nitrophenyl)azo]-3-[(1-oxopropyl)amino]phenyl]-, methyl ester, CAS 155522-12-6, EC 416-240-8);
- Disperse Yellow 236 (3-Pyridinecarbonitrile, 1-butyl-5-[(2-chloro-4-nitrophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-, CAS 75511-91-0, EC 407-970-8);
- Terasil Red WRS (Glycine, N-[3-(acetylamino)phenyl]-N-(carboxymethyl)-, CAS 188070-47-5, EC 424-290-7).

Overall, **RAC supports grouping all the azo-dyes reported in Table 2 and the inclusion of all these disperse azo dyes within the scope of this restriction.** See the Annex in support of hazard identification for detailed information.

2.2 RAC conclusion about anthraquinone dyes

A total of six anthraquinone dyes were proposed in the scope of this restriction: Disperse Blue 3, 7, 26 and 35, Disperse Red 11 and Disperse Violet 1. Robust or sufficient evidences of skin sensitisation in humans were available for all anthraquinone dyes. RAC also notes that Disperse Blue 1 (CAS 2475-45-8, EC 219-603-7), included in the IN-list, is an anthraquinone dye with harmonised classification as Skin Sens. 1. **RAC is therefore of the opinion that the skin sensitisation hazard related to those substances supports the inclusion of the 6 anthraquinone dyes in the scope of the restriction.** See Annex II to this opinion in support of hazard identification for detailed information.

2.3 RAC conclusion about nitro dyes

Two nitro dyes, Disperse Yellow 1 and Disperse Yellow 9, were included in the scope of the restriction proposal. Evidence of skin sensitisation in humans were available for these substances. **RAC is therefore of the opinion that the skin sensitisation hazard related to those substances supports the inclusion of the two identified nitro dyes in the scope of the restriction.** See Annex II to this opinion in support of hazard identification for detailed information.

2.4 RAC conclusion about methine dyes

Two methine dyes, Disperse Yellow 39 and Disperse Yellow 49 were included in the scope of the restriction proposal. No evidence of skin sensitisation were found for the two substances. The available studies in animal or human showed an absence of skin sensitisation potential for Disperse Yellow 39. **In the absence of evidence of skin sensitisation potential, RAC does not support the inclusion of Disperse Yellow 39 and 49 in the scope of this restriction.** See the Annex II to this opinion on hazard identification for detailed information.

2.5 RAC conclusion about quinoline dyes

Finally, one quinoline dye, Disperse Yellow 64, was proposed to be included in the scope of the restriction. One study showed some evidence of contact allergy after exposure to Disperse Yellow 64. **RAC therefore supports the inclusion of Disperse Yellow 64 in the scope of this restriction.** See the Annex to this opinion in support of hazard identification for detailed information.

1. The dose-response relationship of skin sensitisers

1.1 Use of elicitation threshold doses as a reference value for risk assessment of skin sensitisers

As was stated above, skin sensitisation is mechanistically divided in two different stages, induction and elicitation. The induction and elicitation of skin sensitisation in humans are generally regarded to be threshold phenomena (i.e. there is an exposure threshold, µg/cm^2, below which sensitisation 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 is complex and the thresholds are therefore often difficult to identify, in particular at a population level because the risk for skin sensitisation depends not only of the dose of allergen per unit area of skin but also other factors, such as the number of exposures, accumulated dose (SCCS, 2012), duration of skin exposure, the presence of skin irritants and/or of other sensitisers, the anatomical sites of exposure, condition of the skin, the level of occlusion and individual susceptibility.

The sensitisation or induction thresholds

The sensitisation or induction thresholds are determined by the potency of the chemical.

Potency can be defined as the relative ability of a chemical to induce sensitisation. Potency determination is typically based on results from animal studies, such as the local lymph node assay (LLNA), in which chemicals are tested in mice in order to define the sensitisation potential. It may also be inferred from historical data from Human Repeated Insult Patch Test (HRIPT). The sensitisation threshold may be used to set limits in products that may prevent individuals from becoming sensitised to skin allergens (primary prevention).

The elicitation threshold

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 allergic contact dermatitis (elicitation) will also 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 allergic contact dermatitis in 10% of already sensitised individuals will not only protect 90% from developing allergic contact dermatitis, 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, allergic contact dermatitis, as well as from induction of skin sensitisation, the Dossier Submitter proposed to use the elicitation threshold dose as a reference value from which concentration limits for chemical substances in textile and leather are derived.

The elicitation threshold dose can be identified by experimental dose-response studies performed on allergic individuals. This dose is likely to be lower than the threshold dose for the induction of sensitisation (Allenby et al., 1989, 1993; Andersen et al., 2001; Frosch et al., 1995; Johansen et al., 1996; McFadden et al., 1998; Menné, 1994).

Studies in human volunteers have demonstrated that an inverse relationship exists between the strength of sensitisation and the elicitation threshold dose (Boukhman et al., 2001; Friedmann, 2007; Friedmann et al., 1983). This means that at a higher sensitisation dose, a lower dose is needed for elicitation responses (Scott et al., 2002).

Elicitation threshold doses may originate from patch testing with dilution series of skin sensitisers or from repeated open application tests (ROAT). From these two types of studies, the dose that gives reactions in 10 % of the most sensitive individuals (ED_{10} or MET10%) may be identified.

MET (Minimal Elicitation Threshold) 10% value represents the concentration at which 10% of sensitised individuals elicit a reaction.

ED (Elicitation Dose)$_{10}$ is the dose required to elicit a reaction in 10% of sensitised individuals. The ED_{10} values given in the present restriction proposal are all derived from patch testing with dilution series, under occlusion during 48 hours.

RAC conclusion

RAC concurs with the Dossier Submitter that: i) induction and elicitation in skin sensitisation are threshold phenomena; ii) elicitation thresholds are lower than induction thresholds and protect against both elicitation and sensitisation processes. Therefore, **the approach used by the Dossier Submitter for risk assessment based on elicitation threshold derivation is supported by RAC since this will protect against allergic contact dermatitis to non-sensitised and already sensitised citizens.**

1.2 Derivation of elicitation thresholds for substances in the scope

Elicitation threshold doses (ED_{10} or MET10%-values) were searched for by the Dossier

Submitter in the literature for the following substances: diisocyanates, (meth)acrylates, chromium (VI) compounds, nickel compounds, selected dyes, DCHP, rosin, formaldehyde, cobalt compounds, 1,4-paraphenylenediamine and glutaraldehyde. The selection of the substances was based on the information retrieval strategy as detailed in section 3.

In general, the Dossier Submitter had difficulties to find public data on elicitation threshold doses for most chemicals. The Dossier Submitter search strategy included mainly the Internet and the search engine PubMed. Search terms used were chemical names, CAS numbers and chemical group names. Furthermore, the Dossier Submitter looked for information in the Call for Evidence responses and via personal communication with researchers in the field.

The available information on elicitation threshold doses is summarised in the table below (Table 3). For some targeted substances/groups of substances such as allergenic disperse dyes, chromium and formaldehyde, sparse data was found (Table 3).

Table 3: Groups of substances or substances which were targeted for hazard information searches

Group / Substance	Number of substances	Group or substance specific elicitation threshold dose (ED_{10} or MET10 %)	Source of the ED_{10} or MET 10 %
Diisocyanates	7	-	-
(Meth)acrylates	4	-	-
Chromium (VI) compounds	8	0.02 µg/cm^2	Cr (VI) restriction proposal, 2012
Nickel compounds	1	0.74 µg/cm^2	Fischer et al. 2011
Dyes	2 direct dyes	-	-
	2 acid dyes	-	-
	8 disperse dyes	0.0003 µg/cm^2	Ryberg et al., 2009
DCHP	1	-	-
Rosin	2	-	-
Formaldehyde	1	20.1 µg/cm^2	Flyvholm et al. 1997 as reviewed in Fischer et al. 2011
Cobalt compounds	1	0.44 µg/cm^2	Fischer et al. 2011
1,4 paraphenylene diamine	1	1.5 µg/cm^2	Sosted et al. 2006
Glutaraldehyde	1	-	-

Hazard information related to targeted substances or groups of substances

Allergenic disperse dyes

Eight disperse dyes are included within the list of substances with harmonised classification as Skin Sens 1 according to CLP, likely to be present in textiles (KemI, 2019) and 24 disperse dyes are additional included in the scope via the list of concern.

Disperse dyes have been linked to textile-induced contact allergies (see for example Brookstein 2009; Mobolaji-Lawal and Nedorost 2015). Patients that seek medical care for contact allergy are diagnosed with the use of patch tests containing a series of allergenic substances. More information on prevalence data on disperse dyes can be found in detail in Annex E.5.

The relative importance of individual dyes within the group of allergenic disperse dyes as culprit agents of allergic contact dermatitis is difficult to assess since only a few of them has been examined by epicuteaneous testing in clinical trials. In addition, there are frequent

reports of cross-reactions with other dyes and with 1,4-phenylene diamine.

The sensitising potential of some disperse dyes has been investigated in mice using the local lymph node assay (LLNA). Disperse Blue 106 and Disperse Blue 124 have been identified as strong allergens in several studies (Seidenari et al. 1991; Betts et al. 2005; Kimber et al. 2005). The sensitisation potential of Disperse Blue 106 (the lowest EC_3 value was 0.003% for disperse Blue 124, which corresponds to an area dose of 0.75 µg/cm^2) was estimated as being similar to 2,4-dinitrochloro-benzene (Betts et al, 2005). Other disperse dyes have been found to have a higher sensitisation threshold. The suggested relative variation in induction potency between different disperse dyes are depicted in Figure 1.

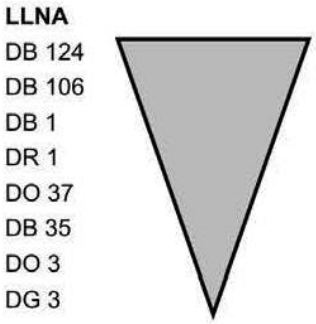

Figure 1: Variation in induction potency between different disperse dyes. DB refers to Disperse Blue, DR to Disperse Red, DO denotes Disperse Orange and DG refers to Disperse Green (results from *in vitro* tests excluded) (BfR, 2012).

Elicitation threshold doses based on patch testing with dilution series have been studied with 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). This skin area dose is comparable to the lowest doses reported to give positive reactions in sensitised subjects, such as some phenol formaldehyde resins (Bruze et al, 1986; Zimmerson et al., 2000) and the perfume contact allergen chloroatranol (Johansen et al, 2003), all regarded as very potent sensitisers. Disperse Orange 1 have also been indicated to have the same low threshold as Disperse Blue 106 and Disperse Blue 124 (Malinauskiene et al., 2011).
The value of 0.0003 µg/cm^2 was proposed by DS as a threshold dose to calculate concentration limits in textiles and leather for all allergenic disperse dyes included in the scope.

Chromium (VI) compounds
The estimated minimal elicitation threshold for 10% of sensitised individuals, MET10% values have been reported to be between 0.02-0.9 µg/cm^2. In the restriction dossier for chromium (VI) compounds in leather (ECHA 2012b), the lower value was used in the overall risk assessment. This value of 0.02 µg/cm^2 was used by the DS as the reference dose in the present restriction proposal.

Diisocyanates
No information on elicitation threshold doses for diisocyanates has been found by the DS.

(Meth)acrylates
Although skin allergy to (meth)acrylates seems to be an overall increasing problem in society, no information on elicitation thresholds doses have been found by the Dossier Submitter in

the literature.

Formaldehyde
An ED_{10} of 20.1 µg/cm^2 was reported in Fischer et al., 2011. This value of 20.1 µg/cm^2 was used by the Dossier Submitter as the reference dose in this restriction proposal to calculate the concentration limit in textile and leather articles for formaldehyde.

Nickel compounds
Five different ED_{10} for nickel were reported in Fischer et al., 2011. The median value of 0.82 µg/cm^2 was used by the Dossier Submitter as the reference dose in this restriction proposal to calculate the concentration limit in textile and leather articles for nickel.

Cobalt compounds
An ED_{10} of 0.44 µg/cm^2 was reported in Fischer et al., 2011. This value of 0.44 µg/cm^2 was used by the Dossier Submitter as the reference dose in this restriction proposal to calculate the concentration limit in textile and leather articles.

1,4-paraphenylene diamine
An ED_{10} value of 1.5 µg/cm^2 was reported in Sosted et al., 2006. This value of 1.5 µg/cm^2 was used by the Dossier Submitter as the reference dose in this restriction proposal to calculate the concentration limit for 1,4-paraphenylene diamine in textile and leather articles.

Direct dyes
No ED_{10} or Met10% value has been found by the Dossier Submitter in the literature.

Acid dyes
No ED_{10} or Met10% value has been found by the Dossier Submitter in the literature.

Rosin
No ED_{10} or Met10% value has been found by the Dossier Submitter in the literature.

DCHP
No ED_{10} or Met10% values has been found by the Dossier Submitter in the literature.

Glutaraldehyde
No ED_{10} or Met10% value has been found by the Dossier Submitter in the literature.

Default elicitation threshold dose

Fischer et al. (2011) gathered 16 patch test dose-elicitation studies for eight well known skin sensitisers (i.e. methylchloroisothiazolinone/ methylisothiazolinone, formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde, and methyldibromo glutaronitrile) from the scientific literature, according to pre-determined quality criteria. The quality criteria for the studies to be included in the Fisher et al (2011) meta-analysis were: i) substances should be dosed in water or alcohol-based vehicles; ii) the methodology should include the use of Finn Chambers method iii) the study should consider at least four patch test dilutions and include 10 participants; iv) the information provided in the paper should allow to estimate the dose in µg/cm^2; and, v) dose-response should be included in the study. The data was used to fit dose-response curves to identify the doses that will elicit an allergic response in 10% of allergic individuals under patch test conditions (ED_{10}) for the different allergens (Figure 2). The median ED_{10} value was 0.835 µg/cm^2. The authors found a rather small variation in the ED_{10} value between the various allergens (within a factor of seven from the lowest to the highest value, leaving out three outliers).

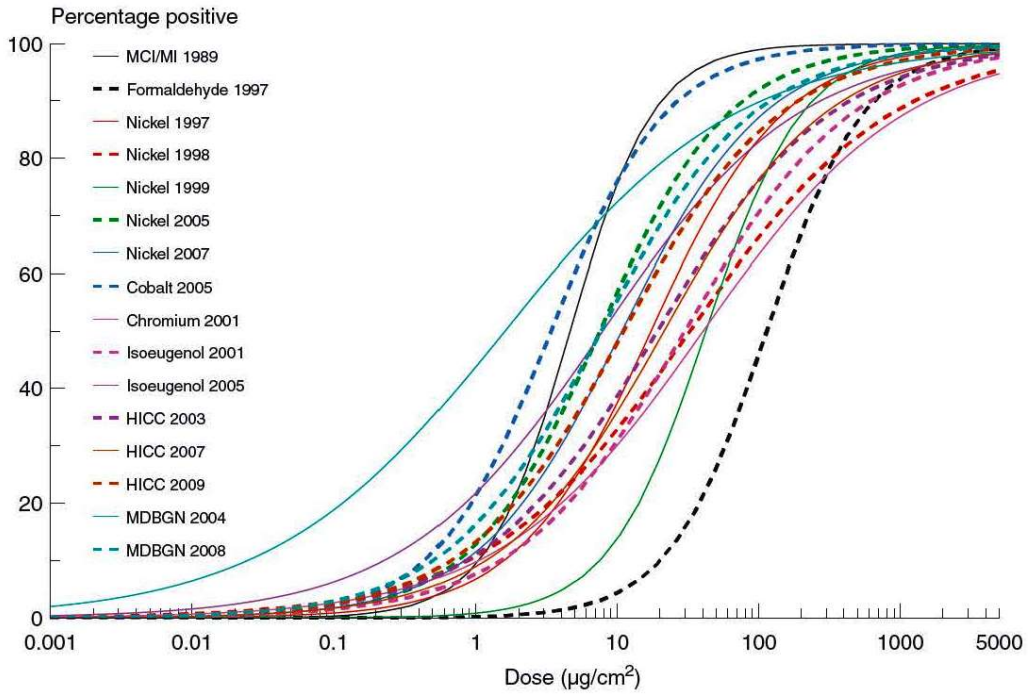

Figure 2: Logistic dose–response curve for 16 patch test elicitation dose–response studies with methylchloroisothiazolinone/methylisothiazolinone (MCI/MI), formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) (Fischer et al., 2011).

The results from the Fischer et al. (2011) study 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, a generic elicitation limit of 0.8 µg/cm^2 has been used to derive the 0.01% (100 mg/kg) limit for potent fragrance allergens in cosmetic products indicative for safe use (SCCS, 2012). The SCCS comments that the suggested limit value may hold for weak to strong allergens, but that some strong and extreme sensitisers may require lower individual thresholds. On the other hand, for very weak sensitisers, this generic threshold may be overly conservative. An elicitation threshold dose of 0.8 µg/cm^2 has also been proposed by the Risk Assessment Committee (RAC), as the reference dose for skin sensitisation in the evaluation of the restriction of tattoo inks and permanent make-up restriction proposal.

In the Consultation, some stakeholders offered their support to the use of a generic elicitation threshold, while others pointed to limitations and uncertainties in the design of the studies on which the Dossier Submitter based their 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. Stakeholders also pointed out that there might be differences in potency between members of a group that would affect the threshold dose, and that one single reference dose may not fit all substances within said group, for example disperse dyes. Several stakeholders requested that substance-specific data should be used. Overall, no new data was however submitted in the Public Consultation.

RAC conclusion on reference doses

RAC notes that elicitation thresholds are derived from studies with a relatively low number of participants (5 for chromium VI, 21 for disperse dyes, 15 for 1,4-paraphenylenediamine, 20 for formaldehyde, 11 for cobalt and 13 for nickel). RAC has also examined the CLH-dossier for disperse blue 124 (the most potent disperse dye sensitiser) finding no information that

allows the discrimination of elicitation threshold with lower levels of uncertainty. RAC also notes that other approaches, as the use of specific concentration limits for classification and labelling of mixtures should not be necessarily more protective than the derived elicitation thresholds since such concentration limits were derived for induction, a less sensitive phenomenon.

Finally, RAC also notes that in the past, a study with only five patients published in the scientific open literature was considered valid for setting elicitation threshold of chromium VI and that this value was also proposed by the Dossier Submitter. Thus, since all other elicitation thresholds were derived using studies with higher number of patients than in the case of chromium VI and were also published in open scientific literature, it seems logical that these elicitation threshold were adopted by RAC.

In conclusion, RAC considers that, despite the aforementioned uncertainties, to the best available knowledge, elicitation thresholds can be applied as follows:

- 0.0003 µg/cm^2 for all allergenic disperse dyes included in the scope
- 0.02 µg/cm^2 for chromium (VI)
- 20.1 µg/cm^2 for formaldehyde
- 0.44 µg/cm^2 for cobalt compounds
- 1.5 µg/cm^2 for 1,4 paraphenylene diamine
- 0.74 µg/cm^2 for nickel compounds
- 0.8 µg/cm^2 for those substances for which no specific elicitation threshold dose has been found.

RAC notes that the Dossier Submitter proposed a reference dose of 0.82 µg/cm^2 for nickel as the median value of the five ED_{10} reported by Fisher et al (2011). However, RAC also notes that the five individual values reported by Fisher et al were 1.58, 0.8, 7.49, 0.74 and 0.82 µg/cm^2. RAC considers that it would be more appropriate to consider the lowest of these values as a reference value, in a similar approach to the methodology used for setting the reference value for chromium (VI), where the lowest available value was taken. Thus, **RAC supports 0.74 µg/cm^2 as the reference value for nickel and nickel compounds.**

RAC notes an uncertainty related to compounds for which no elicitation threshold could be found. RAC also notes that a possible DNEL based on animal data probably exists, and would probably be more relevant than a default elicitation threshold. However, it should be stressed that during their determination of the median ED_{10} value, the Dossier Submitter highlighted a rather small variation in the ED_{10} value between the various allergens.

Overall, RAC agrees with the Dossier Submitter's approach to use a default elicitation threshold dose of 0.8 µg/cm^2 based on Fischer et al. (2011) for those substances for which no specific elicitation threshold dose is available.

Information on emissions and exposures

Summary of proposal:

The frequent everyday use of textiles 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 textile or leather articles. This means that uses with close bodily contact such as clothes, shoes and bed linen will lead to the highest exposures. Most of the articles referenced above are also used for prolonged periods of time and exposure occurs under occlusion, which increases the likelihood for substances to deposit on skin and trigger allergic contact dermatitis. Exposure from textile and leather articles not used in direct contact with 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**

explores *the exposure to skin sensitising substances migrating from textiles*. Other articles and/or materials (e.g. latex, rubber, neoprene, synthetic leather, prints, coatings and disposable articles as napkins, tissues and nappies) that are included in the scope on the basis of 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 having similar use patterns as textiles. **The second scenario explores** *exposure from leather.*

The most relevant exposure pathway in the context of skin sensitisation is direct release of substances to skin by migration from clothing, footwear and other articles with similar skin contact. Hence, the assessment of the exposure to chemical substances released from the material would, ideally, be based on their presence in the article and information on migration of the skin sensitising substances 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 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.

The available information on approximate levels of the targeted skin sensitising substances in textile and leather articles is summarised in the table below.

Table 4: Approximate (measured or estimated) 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 compounds	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
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 10 footwear.	KemI, 2019; Anses, 2018
Dicyclohexyl phthalate (DCHP)	The estimated amount in for example plastisol prints 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

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.

The available migration data is typically expressed as a percentage of the total content of the substance in the tested textile or leather article (migration factor). Many unknown factors collectively contribute to the migration of chemical substances from textile and leather articles; hence, the Dossier Submitter uses a default approach. It is assumed that substances in the scope for which migration information is lacking, have the potential to migrate from the materials to skin if the substance is present in textile or leather. **Hence, for the targeted substances, which lack information on migration from textile and/or leather articles, as well as for the substances in the scope, which were not targeted for information searches, a default migration factor of 10% was assumed. For chromium (VI) compounds, a migration factor of 30%** was considered (as this value has been measured and reported in the literature). For disperse dyes, the Dossier Submitter originally proposed to use a migration factor of 10%, although lower values had been reported. During the consultation, it was stressed that a migration factor of 10% was an overestimation based on previously researched migration rates (0.5-2%). Therefore, a **migration factor value of 5% for disperse dyes in textile and leather** is considered sufficient to cover any uncertainties.

For exposure, the following worst-case scenarios are proposed by the Dossier Submitter:

Table 5: Parameters to be applied for exposure assessment of chemical substances in textiles

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	The mean value in the range of textile surface weights, 0.07 kg/m² (silk) to 0.4 kg/m² (blanket).
Surface contact	1	A 1:1 contact surface between the textile and skin is assumed

Table 6: 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. work/leisure shoes and sports shoes)
Surface weight (kg/m^2)	0.9	The surface weight of the most representative type of leather (i.e. 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

RAC conclusions:

RAC supports an exposure assessment based on two worst-case scenarios for textile and leather articles, respectively and is of the view that other materials and articles are assumed to be covered in the exposure scenario related to textile. RAC also agrees that the available information on the level of skin sensitising substances is of limited reliability and therefore not taken into consideration in the calculation of exposure levels.

The parameters considered in the exposure assessment for each use are the contact surface between the article and the skin, the duration and frequency of exposure and the amount of substance that will come into contact with the skin. The last parameter is dependent on the migration factor of the substance from textile or leather and the surface weight of the material. RAC agrees to apply the following assumptions for exposure assessment of skin sensitising substances in textile or leather:

Parameter	Assumption in textile	Assumption in leather
Exposure duration (h)	24	24
Exposure frequency (n)	3	2

Surface weight (kg/m^2)	0.2	1.5
Contact surface	1	1

Migration factors from textile or leather were searched for by the Dossier Submitter in the literature according to the information retrieval strategy as discussed in section 3. When specific data on migration is lacking for substances, **RAC supports the use of a default migration factor, assuming that the substances concerned have the potential to migrate. RAC agrees to apply the following migration factors for exposure assessment of skin sensitising substances in textile or leather**:

Substance	Migration factor in textile (%)	Migration factor in leather (%)
Disperse dyes	5	5
Chromium (VI) compounds	30	30
Other substances in the scope	10	10

Key elements underpinning the RAC conclusions:

The basis for the assessment of exposure to clothing, footwear and related articles is the migration potential of the substance from the material. Secondly, data on the skin absorption of the substance involved is also necessary. Other parameters which can influence the exposure to skin sensitisers from clothing, footwear and related articles are the area weight of the textile, the contact surface of the exposed skin area as well as the duration/frequency of exposure. However, parameters directly related to the consumer (e.g. skin absorption) have a direct influence on the outcome of the patch-test results and are therefore not further developed in the exposure assessment as they are assumed to be covered by the ED_{10} values.

RAC agrees that the most relevant exposure pathway for skin sensitisation after the use of clothing, footwear and related articles is a direct release of substances by migration from the article, leading to a skin contact between the sensitising chemical and the skin. The updated exposure scenario as proposed by the Dossier Submitter was divided into two different uses based on the material of the article: clothing, based on textiles, and footwear, assuming leather as the main material. No detailed exposure scenario was provided for other related articles (paragraphs 1.ii and 1.iii of the proposed restriction) which are treated similar to clothing in the exposure assessment.

Nevertheless, RAC notes that some clothing can be made of leather whereas textile-based footwear are not uncommon. In addition, as described in section 1 of the present opinion, articles not made of textile or leather are included in the scope of the restriction (e.g. articles made of latex, rubber, neoprene, synthetic leather, other polymers, prints/coatings or nappies). No specific exposure assessment was developed by the Dossier Submitter for these materials, but are assumed to be covered by the exposure assessment for clothing (textiles). RAC is of the view that an exposure assessment of such materials using textiles as a proxy might be appropriate for risk assessment purposes. However, RAC acknowledges that this approach is linked with a higher level of uncertainty.

In conclusion, RAC supports an assessment based on two worst-case exposure scenarios. The

first exposure scenario includes textiles and other materials and uses a textile-made clothing as a basis for the evaluation. The second scenario includes leather, fur and hides and uses leather-made footwear as a typical article for the assessment.

1. Level of skin sensitising substances in textiles and leather

The assessment of the exposure to chemical substances released from the material would ideally be based on presence in clothing or footwear. Nevertheless, the information available on the levels of skin sensitising substances in textile and leather were concluded to be of limited reliability due to approximations based on amount applied or few measurements of finished articles. RAC therefore supports the approach of the Dossier Submitter not to use the levels of skin sensitising substances in textile and leather in the calculations of exposure levels.

Allergenic disperse dyes
The measured and estimated levels of allergenic disperse dyes ranged between 10 000 and 100 000 mg/kg in textile. (Kemi, 2019, Dossier Submitter's communication, 2018). No information on level of allergenic disperse dyes in leather was available.

Chromium (VI) compounds
The Dossier Submitter estimated the amounts of chromium (VI) compound in textile and leather to some hundred mg/kg. Available data indicated measured amounts of chromium (VI) in leather between 1 and 7 mg/kg (KemI, 2019; Anses, 2018).

Diisocyanates
The KemI study (2019) estimated the levels of diisocyanates in textile and leather to be above 1000 mg/kg. It remained unclear whether this estimation related to cured or uncured forms.

(Meth)acrylates
(Meth)acrylates were reported at levels around 10 mg/kg in textile and leather (KemI, 2019).

Formaldehyde
Formaldehyde was reported at levels between 6 and 160 mg/kg in textiles and between 3 and 400 mg/kg in leather (Anses, 2018). The KemI (2019) study approximated formaldehyde amounts to 75 mg/kg in unwashed easy care / non-iron resins and other finishes as well as in leather.

Nickel
Nickel was detected in non-metal parts of the textile articles at levels between 2.3 and 23.5 mg/kg (Anses, 2018). No information on nickel levels in leather was available.

Cobalt
Levels of cobalt were found to be around 100 mg/kg in textiles (KemI, 2019). In leather, amounts of >400 mg/kg and >50 000 mg/kg have been reported (Hamann, 2018).

Direct dyes
Direct dyes are considered to be typically applied at amounts up to 40 000 mg/kg in textiles (KemI, 2019). No information on direct dyes levels in leather was available.

Acid dyes
Acid dyes are considered to be typically applied at amounts up to 60 000 mg/kg in textiles and leather (KemI, 2019).

Rosin
The estimated amounts of rosin in textile and leather articles are 1 000 mg/kg (KemI, 2019). In the Anses study (2018), rosin has been qualitatively detected in textile and leather footwear.

1,4 paraphenylediamine
1,4-paraphenylene diamine was detected in textile articles at concentration ranging between 16 and 40 mg/kg (Anses, 2018). No information on 1,4-paraphenylenediamine levels in leather was available.

Dicyclohexyl phthalate (DCHP)
The KemI study (2019) estimated amounts of DCHP in plastic prints on textile articles to 30%. No information on DCHP levels in leather was available.

Glutaraldehyde
No information on glutaraldehyde amounts in leather or textile was available.

2. Migration factor

The level of exposure that the consumer will be subjected to depends on the amount of substance that will migrate from the material. The amount of substance that will be released is expressed as a percentage of the total content of the substance in the tested material (reported as migration factor). Both material (fibre type, manufacturing techniques), substance (physico-chemical properties, amount incorporated, chemical bonding to the material) and conditions of use (frequency, friction, skin sweat and moisture, presence of oil-based leave-on cosmetics) can influence the migration of substances from an article to the skin.

RAC supports an exposure assessment based on the 'first use' of the textile or leather article as second-hand articles are excluded from the scope of the restriction. However, several shortcomings on the specific and default migration values are related to the normal and foreseeable use of leather and textile articles. It is acknowledged that the migration of substances can be influenced by washing and wear and tear (friction for example). Leather articles are unlikely to be washed to a similar extent to textile articles. However, such articles can get wet when worn, for example by the rain, potentially increasing the migration factor of water-soluble chemicals. Moreover, the migration of a substance from textile or leather is usually measured to artificial sweat over a few hours. Migration data therefore does not take into consideration prolonged exposure throughout the day. In addition, other types of vehicles, for example sebum and leave-on cosmetics are few studied to date. Such vehicles might increase the migration factor of lipophilic chemicals.

Migration factors were searched for by the Dossier Submitter in the literature according to the information retrieval strategy as detailed in section 3. When specific data on migration was lacking, the Dossier Submitter proposed to use a default migration factor.

No information on migration from textile or leather has been found for diisocyanates, meth(acrylates), rosin, dicyclohexyl phthalate, 1,4 paraphenylene diamine or glutaraldehyde. RAC therefore agrees to use a default migration factor.

Formaldehyde, direct dyes and acid dyes have high water solubility, indicating a high ability of this substance to migrate and be dissolved from the article by sweat or saliva. However, no specific migration data from textile or leather articles was available for these substances. The use of a default migration factor in the risk assessment is thus supported.

2.1 Migration factor for cobalt and nickel compounds

Metallic cobalt and nickel have low water solubility and have been reported by KemI to be "tied in" when used in textiles, indicating low potential to migrate from the article via sweat. The Dossier Submitter, however, concluded that migration could not be ruled out in any event. No specific migration data from textile or leather articles was available for these two

compounds and the default migration factor was therefore retained by the Dossier Submitter for cobalt compounds and nickel compounds.

In textiles, metallic cobalt can be used in some dye chromophores, to dye nylon and wool and can also be found as an impurity in dyes and pigments (KemI, 2017; KemI, 2019). The substance could then be present up to 100 mg/kg. Cobalt is also used in the pre-metallized dyeing of leather products and has been found in leather furniture upholstery, shoes and gloves at levels >400 mg/kg and >50 000 mg/kg (Hamann et al., 2018).

Nardelli *et al.* (2005) conducted a retrospective study in Belgium in 1 168 patients suspected of footwear-induced contact dermatitis. The most frequent allergens detected in patients with foot dermatitis were potassium dichromate and cobalt chloride (concomitant to the chromium). In addition, Hedberg et al (2019) studied the chromium and cobalt releases of coloured Cr-tanned leather samples from two Nicaraguan tanneries. Cr, Cr(VI) and Co were extracted in phosphate buffer for 3 hours at 25°C. Results showed cobalt releases comprised between 0.84 and 4.7 mg/kg. The authors suggested that it was originated from cobalt-containing dyes. Allergic contact dermatitis caused by cobalt in leather have also been reported in clinical cases (Bregnbak et al. 2017). These evidences suggest that cobalt has the capacity to migrate from leather and to induce allergic contact dermatitis in patients wearing footwear. However, measured cobalt releases available from the Hedberd study are considered of limited relevance to define a migration factor because they were limited to samples from two tanneries only and a standard analytical solution not resembling to sweat was used for the extraction procedure.

Nickel compounds are other metal compounds for which concern regarding skin sensitising properties is high. There is no indication of use of metallic nickel in textiles but nickel salts may be used in dye chromophores and pigments. It is estimated that nickel is used at a low or even zero level in textiles according to KemI (2019). Nevertheless, 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).

RAC concurs with the Dossier Submitter that migration could not be ruled out in any event. No specific migration data from clothing or footwear was available for these two compounds. RAC therefore agrees to use a default migration factor of 10 % for cobalt compounds and nickel compounds for all articles within the scope of this restriction proposal, with consideration to the exposure assessment described in the previous section. The risk characterisation aims at assessing the likelihood that elicitation of skin allergy is avoided during the use of textile or leather articles in close contact with skin.

The approach in the restriction proposal is, in principle, based on a quantitative assessment of substances as skin sensitisation is regarded as a threshold effect. The elicitation threshold dose (ED_{10} or MET10%), used as a reference dose, is combined with justified assumptions on exposure and migration to derive concentration limits in clothing and footwear which are considered to be safe as regards to skin sensitisation. This quantitative approach was initially developed for fragrance ingredients in consumers products and can be used for other substances (Api and al., 2008). Although the general approach is based on a quantitative assessment, RAC is of the view that this risk characterisation can be considered as qualitative due to the related considerable uncertainties.

To reduce the risk for the general population, the exposure to a skin sensitising chemical substance migrated from clothing or footwear should not exceed the elicitation threshold dose, considered as the safe dose on skin over 24 hours.

The equations proposed by the Dossier Submitter to derive the concentration limits in clothing or footwear are the following:

Limit in clothing or footwear ***($\mu g/cm^2$)*** *= elicitation threshold dose/(migration factor * contact surface * frequency of exposure)*

To convert the limit in clothing or footwear per surface area to mg/kg, the following equation is used:

Concentration limit in clothing or footwear *(**mg/kg**) = Limit in* clothing or footwear *(µg/cm²) * Conversion factor cm² to m² / Conversion factor µg to mg * Surface weight in kg/m²*

RAC agrees to use elicitation thresholds as a reference dose for the risk assessment of skin sensitising substances, similarly to the risk characterisation approach applied in the restrictions on chromium VI in leather articles and substances in tattoo inks and permanent make-up.

Overall, the assessment of the reference-doses and the exposure scenarios have demonstrated important limitations, in particular related to the migration factors, the ED_{10} and the materials other than textile or leather. [In the previous version of the opinion, the different options for the derivation of the concentration limits are explained by RAC)

For harmonisation reasons, RAC considers that a stricter concentration limit should apply in case of coexisting regulations for the same substance and application. In particular, some of the substances in the scope of the restriction are also covered by the entry 72 of the Annex XVII of REACH, including formaldehyde, CI Disperse Blue 1, benzo(def)chrysene and chromium (VI) compounds.

Therefore, RAC supports the following 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	125	25
Cobalt compounds	70	15
Formaldehyde	30	30
1,4 paraphenylene diamine	250	50
Other substances in scope	130	30

[1]Any concentration limit proposed for textiles also applies to 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 to 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.

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

Furthermore, information on elicitation threshold doses (ED_{10} or MET10%) and/or migration factors was only retrieved for specific substances targeted in the information retrieval strategy (see section 3). For some of these substances as well as for the other substances in the scope, specific data on elicitation threshold and/or migration factor were not always available. In that event, a default migration factor and/or a default elicitation threshold was applied.

1. **Substance specific approach (RAC supported values for textile and other materials and leather, hides and furs)**

Allergenic disperse dyes

RAC agreed to use an **elicitation threshold of 0.0003 µg/cm²** and a **migration factor of 5%** to derive a concentration limit for allergenic disperse dyes in textile and leather articles.

The concentration limit of allergenic disperse dyes in textile articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in textile and other materials = $\frac{0.0003}{0.05*1*3}$ = 0.002 µg/cm² article

Concentration limit in textile and other materials = $\frac{0.002*10\,000}{1000*0.2}$ = **0.1 mg/kg**

The concentration limit of allergenic disperse dyes in leather articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in leather= $\frac{0.0003}{0.05*1*2}$ = 0.003 µg/cm² article

Concentration limit in leather, fur and hides = $\frac{0.003*10\,000}{1000*1.5}$ = **0.02 mg/kg**

The concentration limits for allergenic disperse dyes in textile or leather apply for both disperse dyes with a harmonised classification and for disperse dyes included in the scope through the list of concern.

Disperse dyes were measured and estimated in textile and leather at levels comprised between 10 000 and 100 000 mg/kg. Such values are coherent with the dyeing function of these substances in textile and leather. Concentration limits of ≤ 0.1 mg/kg in textile and ≤ 0.02 mg/kg in leather would therefore correspond to a practical ban of the allergenic disperse dyes.

RAC also notes that the derived limits of 0.1 mg/kg in textile and 0.02 mg/kg in leather are below the current restriction of 50 mg/kg for Disperse Blue 1 in textile (entry 72 of REACH Annex XVII).

The Dossier Submitter proposed a ban since the derived limits are below the current quantification limit for disperse dyes (30-50 mg/kg) based on test method ISO 16373-1:2015 for dyestuffs in textiles. The ban has to be interpreted as a limit not exceeding the limit of detection. According to the opinion of the Forum on the present restriction, a ban without associated value could lead to enforceability issues. If no limit value is set, non-compliance depends on the limit of detection of the available method.

The Forum advice concluded that based on the absence of analytical standards of the required purity, laboratories were not able to confirm the non-detection of many of disperse dyes. RAC, however, notes that the current available quantification limit is 300 to 2 500 times higher than the calculated concentrations leading to risks for skin sensitisation of disperse dyes in textile and leather. In addition, RAC cannot exclude a revision of the standardised test method that could lead to lower quantification limits for disperse dyes. Therefore, RAC does not recommend practical limit values for disperse dyes that would be aligned on the actual current quantification limits. **RAC concurs with the Dossier Submitter to propose a ban for disperse dyes in textile and other materials as well as in leather, fur and hides. This limit would be interpreted as a limit not exceeding the current limit of detection.**

Chromium (VI) compounds

RAC agreed to use an **elicitation threshold of 0.02 µg/cm²** and a **migration factor of**

30 % to derive a concentration limit for chromium (VI) compounds in textile and leather articles.

The concentration limit of chromium (VI) compounds in textile articles, ensuring that the elicitation threshold is not exceeded, is:

$$\text{Limit in textile} = \frac{0.02}{0.3*1*3} = 0.02\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in textile and other materials} = \frac{0.02*10\,000}{1000*0.2} = \textbf{1.1 mg/kg} \approx \textbf{1 mg/kg}$$

The entry 72 of REACH Annex XVII restricts chromium (VI) compounds (listed in Annex XVII, Entry 28, 29, 30, Appendices 1-6 of REACH) with a concentration limit of 1 mg/kg in textile after extraction (expressed as Cr VI that can be extracted from the material) due to their carcinogenic properties. **RAC therefore agrees to use a concentration limit of 1 mg/kg chromium (VI) in textile and other materials in the present restriction for regulatory consistency with the entry 72 of REACH Annex XVII.**

The concentration limit of chromium (VI) compounds in leather articles, ensuring that the elicitation threshold is not exceeded, is:

$$\text{Limit in leather} = \frac{0.02}{0.3*1*2} = 0.03\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in leather, fur and hides} = \frac{0.03*10\,000}{1000*1.5} = \textbf{0.2 mg/kg}$$

The entry 47 of REACH Annex XVII already restricts chromium (VI) with a concentration limit of 3 mg/kg in leather articles due to its allergenic properties. In this restriction, the value of 3 mg/kg is based on the quantitative limit of the analytical method used to determine the content of hexavalent chromium in leather (ISO 17075:2007). An illustrative risk assessment was available in the Background Document. However, the risk characterisation was mainly based on prevalence of chromium (VI) allergy in the general population. In particular, RAC highlighted in their opinion that the estimation of 45% of newly chromium allergy cases caused by leather or leather articles was possibly an under-estimation. Patch testing results from Leuven in Belgium concluded that 86% of patients with a contact allergy to potassium dichromate were considered to have been due to exposure via footwear (ECHA, 2012b)

However, the new Anses study (2018) revealed allergic reactions to levels of chromium below 3 mg/kg, indicating that the current concentration limit of 3 mg/kg chromium (VI) in leather might not be sufficient to protect against skin sensitisation. In the course of the biomedical study, chromium (VI) was quantified in 14 samples of leather footwear at concentrations ranging between 0.25 and 19.7 mg/kg. In one case, a link was demonstrated between the presence of chromium VI in the article at a concentration below the regulatory limit (measured concentration of 1.8 mg/kg), the positivity of the patch test, and the clinical symptoms. The methods used in the quantitative analysis of chromium (VI) in footwear were CTC-C-CG-01 or EN ISO 17075 (Annex IX, ANSES 2018).

The Dossier Submitter therefore proposed to use a practical limit value of 1 mg chromium (VI)/kg in leather because allergic reactions to levels of chromium below 3 mg/kg was reported in the Anses (2018) study.

During the consultation, it was raised that achieving a limit value of 1 mg/kg chromium (VI) did not raise any major technological issue during the tanning process of leather (Comment 2423, Nordic Leather Research Council; comment 2796, Leather UK). However, the setting of a limit value of 1 mg/kg Cr (VI) in leather was identified as a potential limitation by several stakeholders.

The actual reference methods for quantification of chromium (VI) in leather is ISO 17075-2:2017 (chromatographic method). This test method is suitable to quantify the chromium (VI) content in leathers down to 3 mg/kg. Another standardised method is based on colorimetry (ISO 17075-1:2017) with the same limit of quantification. However, some colour dyes used in leather may interfere with the colorimetric method. For that reason, the ISO 17075-1:2017 specifies a solid-phase extraction procedure to remove the dyes from the extraction fluid. Due to hexavalent chromium instability and oxidization of trivalent chromium, a standardized method to analytically measure chromium (VI) in leather is crucial in order to provide reliable results.

In their advice, the Forum stated that there is no analytical method that can reliably measure below 3 mg/kg to date. They clarified that "*the FCPSA (Dutch Authority) has tried LC-ICP-MS in collaboration with experts from America. This has not provided a reliable method and therefore the FCPSA uses ISO 17075 that is specially made for Chromium (VI) in leather.*" The Forum also noted that *"there is already experience in the EU in enforcing the Chromium VI in leather compounds and no issue has been brought so far to the attention of the Forum on this matter to our knowledge."*

During the consultation, in-house methods with lower quantification limits than 3 mg/kg were described, some of them with an LOQ of 0.5 mg/kg Cr (VI). The Dossier Submitter concluded that technological advances in test methods make it possible to detect even 1 mg/kg of chromium VI today and proposed a practical concentration limit of 1 mg/kg for Cr VI in leather in order to prevent skin contact dermatitis. However, the Forum was not aware that anything was done, after that restriction on chromium (VI) in leather came into force, to improve the reliability around the limit value of the restriction. Therefore, according to the Forum, a measurement of 1 mg/kg of chromium (VI) extracted from leather cannot currently be guaranteed with current methods.

RAC is of the opinion that, based on the calculated risk of skin sensitisation in leather footwear, a concentration limit of 0.2 mg chromium (VI)/kg in leather, fur and hides should be recommended to avoid elicitation. Nevertheless, RAC agrees with the Dossier Submitter to use a concentration limit of 1 mg chromium (VI)/kg leather. The proposed concentration limit refers to the total dry weight of the leather part. RAC acknowledges that to date there is no standardised method available to achieve this concentration limit. However, the proposed implementation period (36 months from the publication of the decision) could allow the development of additional test methods required for the restriction. This new concentration limit would imply a revision of entry 47 in Annex XVII in REACH.

2. Substance semi-specific approach (RAC supported values for textile and other materials and leather, hides and furs)

<u>Formaldehyde</u>
RAC agrees to use an **elicitation threshold of 20.1 µg/cm²** and a **default migration factor of 10 %** to derive a concentration limit for formaldehyde in textile and leather articles.

The concentration limit of formaldehyde in textile articles ensuring that the elicitation threshold is not exceeding is:

$$\text{Limit in textile} = \frac{20.1}{0.1*1*3} = 67\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in textile and other materials} = \frac{67*10\,000}{1000*0.2} = \textbf{3350 mg/kg}$$

The concentration limit of formaldehyde compounds in leather articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in leather= $\frac{20.1}{0.1*1*2}$ = 101 µg/cm² article

Concentration limit in leather, fur and hides = $\frac{100.5*10\,000}{1000*1.5}$ = **670 mg/kg**

In entry 72 of REACH Annex XVII, the concentration limit of formaldehyde in textile is 75 mg/kg based on the carcinogenic properties of the substance. In addition, in the Commission Directive (EU) 2019/1929 of 19 November 2019, amending Appendix C to Annex II to Directive 2009/48/EC (the Toy Safety Directive) of the European Parliament and of the Council for the purpose of adopting specific limit values for chemicals used in certain toys, as regards formaldehyde, the concentration limit for formaldehyde in textile and leather toy materials is 30 mg/kg; which is lower than the derived concentration limits for skin sensitising properties of formaldehyde. The existing concentration limit of 30 mg/kg in the Toy Safety Directive is assumed to also protect from allergic contact dermatitis by formaldehyde because this limit value is based on skin sensitisation. **RAC therefore recommends to apply a concentration limit of 30 mg/kg for formaldehyde in textile and other materials as well as in leather, fur and hides.**

Nickel compounds

RAC agreed to use an **elicitation threshold of 0.74 µg/cm²** and a **default migration factor of 10%** to derive a concentration limit for nickel in textile and leather articles.

The concentration limit of nickel in textile articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in textile = $\frac{0.74}{0.1*1*3}$ = 2.5 µg/cm² article

Concentration limit in textile or other materials = $\frac{2.5*10\,000}{1000*0.2}$ = **125 mg/kg**

The concentration limit of nickel in leather articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in leather= $\frac{0.74}{0.1*1*2}$ = 3.7 µg/cm² article

Concentration limit in leather, fur and hides = $\frac{3.7*10\,000}{1000*1.5}$ = **25 mg/kg**

During the consultation, several stakeholders, however, suggested to ban or restrict nickel compounds to extraction limits (comments 2413, 2401, 2405). In addition, one stakeholder recommended applying not a total extraction approach but an extraction with artificial sweat solution such as DIN EN 16711-2 for textile articles and ISO 17072-1 for leather articles (comment 2384). Finally, it was also raised that the definition “nickel compounds” is very generic and that the actual compounds which are banned as sensitisers should be either identified by their CAS/EC number or linked to a reference which provides this identification (comments 2401, 2405).

The Forum concluded that no problem was expected with the measurement of nickel at the limits proposed by RAC or the Dossier Submitter when extracted from textiles and possibly from leather. In addition, the Forum recommended to express the condition of concentration limit as follows or along this line: “x mg/l (i.e. expressed as Ni, metal that can be extracted from the material)“RAC agrees that the concentration limits for nickel in textile and leather articles apply to both nickel and nickel compounds that are in the scope of this restriction.

RAC is of the opinion that limit values of 125 and 25 mg/kg should be retained for nickel in textile and other materials or leather, fur and hides, respectively.

(expressed as Ni metal that can be extracted from the textile and leather material respectively)

Cobalt compounds

RAC agreed to use an **elicitation threshold of 0.44 µg/cm²** and a **default migration factor of 10 %** to derive a concentration limit for cobalt in textile and leather articles.

The concentration limit of cobalt in textile articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in textile = $\frac{0.44}{0.1*1*3}$ = 1.47 µg/cm² article

Concentration limit in textile and other materials = $\frac{1.47*10\,000}{1000*0.2}$ = **73 mg/kg ≈ 70 mg/kg**

The concentration limit of cobalt in leather articles, ensuring that the elicitation threshold is not exceeded, is:

Limit in leather = $\frac{0.44}{0.1*1*2}$ = 2.2 µg/cm² article

Concentration limit in leather, fur and hides = $\frac{2.2*10\,000}{1000*1.5}$ =**15 mg/kg**

During the consultation, several stakeholders recommended, however, to ban or restrict cobalt compounds to extraction limits (comments 2413, 2401, 2405). In addition, one stakeholder recommended applying not a total extraction approach but an extraction with artificial sweat solution such as DIN EN 16711-2 for textile articles and ISO 17072-1 for leather articles (comment 2384, Bluesign). Finally, it was also raised that the definition "cobalt compounds" is very generic and that the actual compounds which are banned as sensitisers should be either identified by their CAS/EC number or linked to a reference which provides this identification (comment 2401, 2405).

The Forum concluded that no problem was expected with the measurement of cobalt at the limits proposed by RAC or the Dossier Submitter when extracted from textiles and possibly from leather. In addition, the Forum recommended to express the condition of concentration limit as follows or along this line: "x mg/l (i.e. expressed as Co, metal that can be extracted from the material)".

i.e. Cobalt and its compound

Substance	**Concentration limit by weight in textiles**
Cobalt and its compounds	**70 mg/kg (expressed as Co metal that can be extracted from the textile material)**

RAC agrees that the concentration limits for cobalt in textile and leather articles apply to both cobalt and cobalt compounds that are in the scope of this restriction. **RAC supports the use of 70 mg/kg as a concentration limit for cobalt in textile and other materials. RAC also supports the use of a limit value of 15 mg/kg for cobalt compounds in leather, fur and hide articles (both limits expressed as Co metal that can be extracted from materials).**

1.4-paraphenylene diamine

RAC agreed to use an **elicitation threshold of 1.5 µg/cm²** and a **default migration factor of 10 %** to derive a concentration limit for 1.4-paraphenylene diamine in textile and leather articles.

The concentration limit of 1.4-paraphenylene diamine in textile articles, ensuring that the elicitation threshold is not exceeded, is:

$$\text{Limit in textile} = \frac{1.5}{0.1*1*3} = 5\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in textile and other materials} = \frac{5*10\,000}{1000*0.2} = \textbf{250 mg/kg}$$

The concentration limit of 1.4-paraphenylene diamine in leather articles, ensuring that the elicitation threshold is not exceeded, is:

$$\text{Limit in leather} = \frac{1.5}{0.1*1*2} = 7.5\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in leather, fur and hides} = \frac{7.5*10\,000}{1000*1.5} = \textbf{50 mg/kg}$$

Based on the calculated risk of elicitation caused by 1,4-paraphenylene diamine, **RAC agrees to retain limits values of 250 and 50 mg/kg for 1.4-paraphenylene diamine in textile and other materials or leather, fur and hides articles respectively.** RAC however notes that cross-sensitization of 1,4-paraphenylene diamine may occur with other compounds that also contain an amine group in their benzene ring at the para position. In particular, cross-sensitisation to 1,4-paraphenylene diamine is known to happen in azo-dye-sensitive subjects (Seidenari et al. 2006). **The derived limit values of 250 and 50 mg/kg for 1,4-paraphenylene diamine might therefore not be sufficient to prevent cross-reactions between 1.4-paraphenylene diamine and azo-dyes.**

3. **Qualitative default approach (RAC supported values for textile and other materials and leather, hides and furs)**

RAC agreed to use a **default elicitation threshold of 0.8 µg/cm²** and a **default migration factor of 10 %** to derive a concentration limit in textile and leather articles for other chemicals in the scope of the restriction.

The default concentration limit in textile articles ensuring that the elicitation threshold is not exceeding is:

$$\text{Limit in textile} = \frac{0.8}{0.1*1*3} = 2.7\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in textile and other materials} = \frac{2.7*10\,000}{1000*0.2} = \textbf{133 mg/kg} \approx \textbf{130 mg/kg}$$

The default concentration limit in leather articles, ensuring that the elicitation threshold is not exceeded, is:

$$\text{Limit in leather} = \frac{0.8}{0.1*1*2} = 4.0\ \mu g/cm^2 \text{ article}$$

$$\textbf{Concentration limit in leather, fur and hides} = \frac{4.0*10\,000}{1000*1.5} = \textbf{27 mg/kg} \approx \textbf{30 mg/kg}$$

RAC supports the use of default limits values of 130 and 30 mg/kg in textile and other materials or leather, furs and hides articles respectively.

Uncertainties in the risk characterisation

First, risk assessment is usually based on the actual exposure to the substances. In clothing, footwear and related articles, no exhaustive overview of the identity and amount of skin

sensitising substances used in the manufacturing processes is available. The Dossier Submitter described a list of substances likely to be present in clothing or footwear associated with amount estimations. This database was however concluded of insufficient reliability to allow a proper risk assessment. In this view, the risk-assessment was based on an alternative quantitative approach, using elicitation threshold dose as a reference dose combined with justified assumptions on exposure and migration to derive concentration limits in articles, which are considered to be safe as regards to skin sensitisation.

Depending on the availability of scientific information related to ED_{10} or migration factors (MF), quantitative (substance-specific ED_{10} and MF available), semi-quantitative (substance-specific ED_{10} available and default MF assumed) or qualitative risk characterisation (default ED_{10} and MF assumed) were proposed. For all three approaches, the risk characterisation is linked with several uncertainties related to both ED_{10} dose-reference and exposure assessment, including migration factors and variety of materials.

Regarding dose-reference, RAC notes that the literature is limited for targeted substances. ED_{10} were identified for chromium VI compounds, nickel, disperse dyes, formaldehyde, cobalt and 1,4-paraphenylene diamine. For each of these targeted substances, ED_{10} were derived based on single studies with dilution series (e.g. disperse dyes) or presenting different ED_{10} values (e.g. nickel). Some studies were also based on a limited number of patients and may therefore not adequately reflect intraspecies variation.

For all other 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, a default elicitation threshold dose was assumed. This value is based on a meta-analysis from 16 patch-test dose-elicitation studies using eight well-known sensitisers. A rather small variation between the available values was pointed out by the DS. RAC however considers that this default value is associated with a high level of uncertainty due to the high number of substances in the scope for which this default value would apply and the absence of consideration of skin sensitisation potency. The limited number of patients may also not adequately reflect intraspecies variations, including children exposure or skin absorption.

Literature related to migration factors of substances from textile or leather is even scarcer. Scientific justification for targeted-substances migration factors were only identified for disperse dyes in textiles and chromium in leather. For these two groups of substances, migration factors for other materials were based on assumption. For all other substances in the scope, a default migration factor was assumed based on limited information available for a limited number of substances. In general, measured migration factors are based on *in vitro* studies using preferably a solution resembling to sweat. It is acknowledged that such experimentation does not take adequately into consideration the conditions of use (frequency, friction, skin sweat and moisture, presence of oil-based leave-on cosmetics). In addition, other parameters influencing migration factors and related to the material (fibre type, manufacturing techniques) or the substance itself (physico-chemical properties, amount incorporated, chemical bonding to the material) are not adequately reflected in the use of a default migration factor.

The scope of the restriction includes other materials than textile or leather, for example synthetic leather, latex, rubber or polymers. Due to the absence of appropriate data migration of skin sensitisers from these articles, a reliable exposure assessment could not been performed. Such materials were therefore assimilated to textile in the exposure assessment. Similarly, no reliable exposure assessment of targeted or non-targeted skin sensitising substances in the scope of the restriction was available for multilayer disposable articles, neither in the main proposal nor in the public consultation and such articles were therefore included, as a whole, within the exposure assessment of textiles.

Finally, RAC also highlights as an additional uncertainty the possible additive, synergistic or cross-sensitising effects of different sensitising and even irritant substances found in the

articles within the scope of this restriction proposal.

Overall, RAC is of the opinion that the assumptions in the risk assessment are conservative and that the uncertainty is towards overestimation of the risk and not towards underestimation.

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

Summary of proposal:

For most of the targeted skin sensitisers in the scope of this restriction proposal, the concentration limits, are far below the highest approximated concentrations in textile and leather at point of sale. 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 substance in textile and leather articles to the ones proposed above, is considered to significantly reduce the risk for skin sensitisation in the general population.

RAC conclusions:

RAC agrees with the Dossier Submitter that, in the current situation, the risk of sensitisation through dermal exposure to skin sensitising substances in clothing, footwear and other articles with similar skin contact made of textiles, leather, fur, hide and synthetic leather is not adequately controlled.

Key elements underpinning the RAC conclusions:

Table 4 shows approximate (measured or estimated) levels of targeted substances in textile and leather. It can be concluded that in most of the cases the concentration is higher than the concentration limit proposed in this restriction. Thus, the limits proposed in this restriction will notable reduce exposure and therefore it is expected that the incidence of skin sensitisation would also notable reduced.

Evidence if the existing regulatory risk management instruments are not sufficient.

Summary of proposal:

Several risk management options (RMOs) for the regulation of skin sensitising substances in textile and leather articles have been identified and analysed (existing regulations on leather, existing EU and national restrictions, labelling schemes), however it was concluded that none of these RMOs was appropriate to control the risk. The Dossier Submitter considers restriction under REACH Article 69.1 as the most appropriate risk management option

RAC conclusions:

RAC agrees with the Dossier Submitter in the consideration that restriction under REACH Article 69.1 is the most appropriate risk management option.

Key elements underpinning the RAC conclusions:

Several options might indeed be applied for risk management as:

Introduction of labelling requirements for textile and leather articles containing skin sensitising substances on the EU market without any restriction. RAC considers that labels on textile and leather articles might not be informative enough for the general consumer and would not force manufacturers to reduce the concentration of sensitising chemicals in the products and therefore would not reduce the incidence of allergic contact dermatitis. Moreover, labelling might be useful only for those already sensitised citizens that were aware about which specific chemical is causing their allergy, but not for sensitised individuals who ignore the chemical responsible of their allergy. Therefore, RAC considers that labelling would not, in practice, avoid new cases of sensitisation

Identification as SVHC according to REACH Article 57 and subsequent authorisation. The Authorisation process only applies to the use in EU of a chemical during its incorporation into an article. 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 with subsequent authorisation by RAC, would likely have a minor risk reducing effects on allergic textile/leather dermatitis.

Harmonised classification of substances under CLP (EC) No 1272/2008. The CLP regulation is based on hazard identification and not on risk assessment. Thus, RAC noted that a harmonised classification of a substances might aid to identify which substances will have to be subjected to other, more restrictive, regulations, like, for example, the present restriction. Furthermore, since the restriction is based on a dynamic link to Annex VI of CLP regulation, it will allow the scope of the restriction to be kept permanently updated whether in case new chemicals are classified as skin sensitisers whilst avoiding regrettable substitution.

Other legislations. RAC notes that there are legislations such as the Textile Fibre Labelling Regulation (EU) No 1007/2011 or the General Product Safety Directive (EC) No 2001/95 that might contribute to address the problem only partially or temporally. Thus, a specific textile regulation is lacking and possible in the long term and in the meanwhile restriction is a better option to tackle the problem.

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 (Bryden and al., 2013). However, RAC considers that the effectiveness of voluntary agreements is highly uncertain and therefore this option, in absence of complementary legislation, is non-feasible in terms of risk management.

Economic policy instruments. A fee or a tax could be introduced on textile articles containing skin sensitising substances. RAC does not consider this possibility a risk management measure as such because it does not rely on scientific criteria and might even cause a reduction of citizenship welfare.

Overall, RAC supports that the use of restriction under REACH Article 69.1 is the most efficient way to reduce the cases of allergic contact dermatitis caused as a consequence of the exposure to sensitising substances present in clothing, footwear and other articles with similar skin contact made of textiles, leather, fur, hide and synthetic leather as well as disposable sanitary towels, napkins, tissues and nappies.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

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, leather, hide and fur, 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.

SEAC and RAC conclusions:

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with skin sensitisation in clothing, footwear and other related articles should be implemented in all MS.

Key elements underpinning the SEAC and RAC conclusions:

EU wide measure is expected to harmonise level of protection across the EU. In addition, some of the articles within the scope of the proposed restriction are imported and a restriction applies to imported products. Textile and leather articles that are imported can be distributed freely in the EU, therefore harmonised measures are needed to ensure same protection level in the EU.

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

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

The proposed scope of the restriction aims at preventing the placing on the market for the general public of clothing, footwear (and other articles which come into contact with human skin similar to clothing) that contain skin sensitisers. The proposed restriction covers substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in Annex (VI) to Regulation (EC) No 1272/2008, as well as 24 disperse dyes that are indicated to have skin sensitising properties.

Active ingredients in biocidal products are not covered by the proposed restriction since any risks connected to the use of biocidal substances during the manufacture of textile and leather articles or for treatment of finished articles are expected to be covered by the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012). The restriction would not apply to personal protective equipment, medical devices and second-hand articles. While second-hand articles may constitute a source of exposure, the enforcement of re-sold articles is expected to be complex and costly. Furthermore, it is assumed that second-hand articles have been washed several times and that normal wear or use of these articles would have lowered the content of some skin sensitising substances, particularly those with high migration rate.

RAC conclusions:

RAC agrees that the suggested restriction option is the most appropriate EU wide measure.

RAC agrees to derogate the following articles from the present restriction proposal:

- Substances that are used as active ingredients in biocidal products within the scope of Regulation (EU) 528/2012;
- Second-hand clothing, related accessories, articles other than clothing, or footwear, which were in end-use in the Union before 31 January 2023;
- Medical devices according to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

However, RAC does not support the proposal of the Dossier Submitter to derogate 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 of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

Key elements underpinning the RAC conclusions:

The proposed scope of the restriction aims at preventing the placing on the market for the general public of clothing, footwear (and other articles which come into contact with human skin similar to clothing) that contain skin sensitisers. The proposed restriction covers substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in Annex (VI) to Regulation (EC) No 1272/2008, as well as 24 disperse dyes that are indicated to have skin sensitising properties.

The Dossier Submitter detailed in the Table 17 of the main report six other possible restriction options with a modified scope. Restriction options RO2 (no additional list of disperse dyes)

and RO3 (narrow list of substances) are considered by RAC to result in lower risk reduction against skin sensitisation for general population, as well as to prevent regrettable substitution.

Restriction option RO4 covers substances harmonised classified either as Skin Sens. Category 1/1A/1B, Skin Irrit. 2 or Skin Corr. 1A/1B/1C. This restriction option is considered inappropriate due to the absence of demonstrated risk related to skin irritation or skin corrosion induced by the normal or foreseeable use of clothing or footwear.

In the restriction option RO5, the scope was identical to that of 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. Moreover, a migration limit is also expected to be less practical and enforceable.

In the restriction option RO6 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 possible concentration limits, either zero or based on the limits of detection. RAC notes that with RO6 the benefits for human health would probably be the highest. However, RAC also notes that from a risk-based perspective, banning all substances within the scope is not justified because, except for disperse dyes, these substances are considered as safe provided they are present in the finished article below a certain concentration limit.

RO7 includes, in addition, substances self-classified as skin sensitisers. This restriction option would therefore increase the risk reduction against skin sensitisation for general population. Nevertheless, RAC concurs with the DS that notifiers could differ in their assessment of the criteria, leading to contradicting self-classification and potential practicality/monitorability issues.

Therefore, RAC agrees that the REACH Restriction option RO1a is the most appropriate EU wide measure. The scope of this proposal includes derogation regarding active ingredients in biocidal products, second-hand articles, medical devices and personal protective equipment.

1. Active ingredients in biocidal products according to EU Regulation 528/2012

The Dossier Submitter proposed to derogate biocidal active ingredients from the scope of the restriction. The risk related to exposure to skin sensitisation after exposure to biocidal active ingredients as well as biocidal products in textile or leather finished articles is expected to be covered by the Biocidal Product Regulation EU 528/2012 since 1 March 2017. **RAC therefore agrees with the Dossier Submitter that active ingredients in biocidal products that adequately meet the requirement of the EU Biocidal Product Regulation No 528/2012 can be derogated.**

2. Second-hand articles

The restriction proposal only targets textile and leather finished articles that are placed on the EU market for the first time. Second-hand articles, defined as articles that have already been sold to an end user in the EU but are subsequently transferred to another actor in the supply chain, are outside the scope of the restriction. The decision of the Dossier Submitter to exclude second-hand articles is mainly based on complexity and cost of enforcement. In addition, the Dossier Submitter argues that the washing and normal use of clothes would lower the content of some skin sensitising substances.

RAC acknowledges that second-hand articles may constitute a source of exposure for skin sensitising substances in footwear, clothing or related articles. RAC notes that although the washing of clothes is expected to lower the content of some skin sensitisers, it cannot be excluded that the friction of fibres and leather induced by normal wear and use might increase

the release of such substances. **However, RAC agrees to derogate second-hand articles from the scope for ensuring the practicality and proportionality of the proposed restriction.**

3. Articles within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

All clothing, footwear or other related articles that come into contact with the skin under normal or reasonably foreseeable condition of use which are covered by the EU Regulation 2017/745 on medical devices are outside the scope of the present restriction.

Medical devices made of textile are quite varied and include for example hygiene textile (surgical gowns, drapes, sterilisation wraps, staff uniform, facemasks, bedding), but also implantable material (artificial tendon/ligament, vascular grafts/heart valves) and wound or orthopaedic dressing. With the exception of the adhesive part of plasters, no strong evidence of skin allergy induced by medical devices made of textile or leather was found. **RAC therefore agrees to derogate articles within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices from the present restriction.**

4. Articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment

Clothing, related accessories, articles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council from the present restriction proposal are proposed to be derogated from the present Restriction.

EU Regulation 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment aims to ensure common standards for personal protective equipment (PPE) in all Member States in terms of protection of health and the safety of users. Article 4 of this Regulation states that "*PPE shall only be made available on the market if, where properly maintained and used for its intended purpose, it complies with this Regulation and does not endanger the health or safety of persons, domestic animals or property*".

Annex II of the EU Regulation 2016/425 also add that "*PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use*" (Annex II: 1.2.1) and that "*the materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users*" (Annex II 12.1.1).

In addition, the Council Directive of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace states in article 4.1 that "*All personal protective equipment must: (a) be appropriate for the risks involved, without itself leading to any increased risk*".

However, the European Agency for Safety and Health at Work acknowledged that some personal protective equipment can induce allergies themselves. The Agency highlighted in particular protective gloves and boots made of latex rubber or leather tanned with chromium-containing substances (OSHA Factsheet 40).

Occupational allergies induced by latex rubber-made personal protective equipment used in Europe are well demonstrated in recent scientific literature. For example, Hamnerius et al. demonstrated that contact allergy to rubber additives in medical gloves was the most common cause of occupational allergic contact dermatitis in healthcare workers (2018, Sweden). Another study showed that the use of accelerator-free medical gloves was effective to reduce allergic symptoms in healthcare workers after a diagnosis of allergic contact dermatitis caused by rubber accelerators (Crepy et al., 2018, France). A Danish retrospective matched case-

control study also concluded that contact allergy to thiuram mix was more common in healthcare workers (Schwensen et al., 2016).

In addition, a review of non-glove PPE-related occupational dermatoses reported to EPIDERM between 1993 and 2013 showed that of all the PPE-related cases, 9.2% were attributable to non-glove PPE (clothing, footwear, facemasks/safety glasses and headgear). Allergic contact dermatitis was diagnosed for 47.4% of the non-glove PPE-related dermatoses, footwear and clothing being the most common causes of non-glove PPE-related allergic contact dermatitis. Allergens associated with personal protective footwear and clothing related allergic contact dermatitis included thiuram, mercapto mix and carba mix in rubber, azo dyes in textiles, formaldehyde resins in fabric finish, chromate in leather, and nickel in the toecaps of protective boots. Two cases of allergic contact dermatitis induced by diethylthiourea were reported in people wearing neoprene wet suits as part of their occupation whereas the allergens associated with facemask contact allergy were IPPD and nickel. (Bhoyrul et al., 2018, UK).

Overall, based on the available literature showing a concern related to PPE-induced allergic contact dermatitis, RAC does not support the proposal of the Dossier Submitter to derogate from the restriction proposal clothing, footwear and related accessories made of textile or leather that are within the scope of the 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).

Justification for the opinion of SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

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. 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).

The proposed restriction is expected to protect a significant proportion (70% - 90%) of the already sensitised population from developing allergic contact dermatitis from exposure to skin sensitisers in textile and leather articles. At least 70% of the already sensitised population is considered to be protected from developing allergic contact dermatitis 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. In addition, up to 90% of the population is 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. Furthermore, this proposed restriction is expected also to prevent the occurrence of new cases of sensitisation to chemical substances in textile and leather articles (it is assumed that between 70% and 90% of the new cases will be avoided).

RAC conclusions:

RAC agrees with the Dossier Submitter that the proposed restriction option is expected to reduce skin sensitisation and elicitation posed by chemicals present in textile or leather articles.

RAC considers that a dynamic link of the restriction proposal to the CLP harmonised classification is expected to increase the restriction's effectiveness.

Key elements underpinning the RAC conclusions:

The incidence of allergic contact dermatitis caused by sensitising substances contained in textile and leather articles is quite high, which suggests that elicitation and sensitisation thresholds are reached during exposure of skin to these articles. Thus, a reduction in the level of the exposure to these sensitising chemicals would, in principle, reduce the incidence of the allergic contact dermal cases.

The risk characterisation in this restriction was performed by targeting elicitation thresholds instead of sensitisation thresholds and therefore, since elicitation thresholds are lower than sensitisation thresholds, already sensitised members of the public will be also covered by this restriction proposal.

The end-point of the risk characterisation was an ED_{10}; which means that the limit values would prevent 90% of the non-sensitised population from elicitation and 100% of the already sensitised population. 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 in the restriction.

Finally, the restriction is based on a dynamic link to Annex VI of CLP regulation. It will allow the scope of the restriction to be kept permanently updated in case new chemicals are classified as skin sensitisers but it will also avoid regrettable substitution. This will contribute to increase this restriction's effectiveness.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Benefits

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Other impacts

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

Overall proportionality

Summary of proposal:

The restriction proposal's impact assessment is based on a semi-quantitative cost-benefit approach, where the proportionality of the proposed restriction is assessed by comparing the expected costs and the benefits, when quantified.

Overall, the Dossier Submitter considers that the expected benefits from the proposed restriction are substantial and that 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. This is due to very low costs of substitution for some substances, ongoing substitution for others and given the fact that moving towards best practice is expected to mean that the substances are not present above the proposed concentration limits in the articles placed on the market for the general public. 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. Finally, the Dossier Submitter considers that the restriction proposal may be particularly beneficial for low income consumers in the EEA31 who currently cannot afford to substitute allergenic apparel and footwear to allergens-free ones.

Taking into account all the impacts, the Dossier Submitter concludes that the restriction proposal is affordable, proportionate and socially desirable.

RAC and SEAC conclusions:

RAC considers that a decrease in the adverse effects due to the incidence of skin sensitisers in textiles is expected, taking into account the broad scope of the restriction and the proposed CLs.

Key elements underpinning the RAC and SEAC conclusions:

This restriction proposal shows the best capacity of mitigating the risk by covering a rather high number of sensitising substances and being dynamically linked to CLP regulation. It is considered that this restriction proposal would allow protecting at least 70%-90% of current and new cases of sensitisation within the EEA31.The substitution of some substances covered by this restriction 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.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Overall, the Dossier Submitter concludes that the restriction proposed is considered practical. Existing national regulations on textile and leather as well as already existing restrictions under REACH show that industry can in principle comply with risk management based on concentration limits. A transitional period of 36 months is proposed by the Dossier Submitter for the following reasons:

- To provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction.
- To allow the development of additional test methods required for the restriction.
- To avoid any inconsistencies in the implementation of the restriction on CMR substances in textile and its derogation of formaldehyde until 2023, the Dossier Submitter proposes that this restriction is implemented in 2023. This equals to a transitional period of 36 months.

Enforcement of national legislation (in Germany for example) or alert systems (such as the RAPEX system or national poison information centres like the French poison centre) are already in place to monitor compliance and to share information on non-compliant products. The Dossier Submitter has developed a list of chemical substances that may be present today in textile and leather articles. 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 the substances for which no method is available, testing methods should be developed.

RAC and SEAC conclusions:

RAC notes that, although some obstacles still have to be overcome (like, for instance the development of additional test methods with a sufficiently low limit of quantification to ensure an efficient enforcement), the restriction proposed (RO1a) would be practical and monitorable after the transitional period.

Key elements underpinning the RAC and SEAC conclusions:

RAC

Enforceability

According to the Forum, the enforcement of this restriction could be challenging with regard to the numerous substances within its scope. Especially, problems involving sampling, sample preparation and analytical methods may result in increased difficulties for its proper enforcement. However, RAC considers that the transition period should be long enough for the development of the needed analytical methodologies that would provide a sufficient level of protection for consumers. Indeed, the Forum informed of attempts at developing analytical methodologies (using LC-ICP-MS techniques) with a view to reduce the limit of detection of Cr (VI) from the currently established standard of 3 mg/kg to 1 mg/kg. However, this has not led to a reliable analytical method, this has been strongly supported by industry respondents throughout the public consultation who share the Forum's view that no such methods are currently available.

The Forum has also provided several recommendations regarding terminology and wording. Some of these recommendations were adopted by the Dossier Submitter in the last version of the Background Document and others, such as the term "contact with human skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing" or "related accessories" were largely illustrated with examples; which in the opinion of RAC, helps enforceability by reducing the possibility of borderline situations.

Another point that raised the Forum's concerns for effective enforceability, is the large number of theoretically restricted substances (1050 included in the Annex VI of CLP regulation plus 24 in the list of concern) and suggested the Dossier Submitter to, either, reduce the scope of this restriction or to produce a list of the most important substances targeted by this restriction. RAC notes that such a list already exists (Table 19 in Annex E of the Background Document) and has been elaborated by the dossier submitter with the 94 substances relevant for the scope of the current restriction proposal, using chemicals likely to be found today in textile and leather articles' manufacturing processes. Therefore, RAC notes that this list will also support the enforceability of the restriction because it could be used by enforcement authorities and industry to identify which substances to focus on in their enforcement and compliance activities.

Overall, **RAC notes that in order to reach full enforcement, analytical methods with an appropriate limit of detection should be developed and, ideally, harmonised for those substances for which appropriate methodology is still not available.**

Implementability

RAC considers that the restriction is implementable based on the following reasons:

1 A transition period of 36 months from entry into force would provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction. These requirements would initially be: i) development of additional test methods required for the restriction; and, ii) substitution of certain chemicals already in use, which should be relatively easy for when the chemical is intentionally used but can take longer time for substances found in the articles as impurities of other chemicals.

2 RAC notes that some substances will also need to comply with the restriction on CMR substances in textile (entry 72 of REACH Annex XVII), for which the transitional period is 24 months from entry into force, corresponding to year 2020. This transitional period was found by the Commission as practicable for the textile and leather industry. However for the CMRs for which there are new concentration limits, once this skin sensitisers restriction comes into effect, RAC is of the opinion that the transitional period should be 36 months, similarly to the other substances in the scope of the present restriction.

3 The existence of national regulations on textile and leather, as well as already existing restrictions under REACH (on azodyes, chromium VI compounds and the entry 72 of REACH Annex XVII) suggest that industry, in principle, comply with risk management based on concentration limitations.

Overall, **RAC supports the transitional period of 36 months from entry into force in order to allow all actors involved in this restriction the adoption of all needed actions to meet this restriction requirements. RAC also supports the transitional period of 36 month from entry into force for the new concentration limit related to CMR chemicals**.

Manageability

It is noted that additional chemical substances with sensitising properties will be harmonised and 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. The dossier submitter proposed to consider the substances that might be included in Annex VI of CLP regulation after this restriction come into force within the group of "other substances"

RAC supports the Dossier Submitter's proposal for including substances classified in the future as skin sensitisers within the group of other substances (concentration limits of 130 and 40 mg/kg; respectively for textile and leather) since there will be no opportunity to assess specific concentration limits.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

The Dossier Submitter has developed a list of chemical substances that may be present today in textile and leather articles. This list can be used by enforcement authorities and industry to identify which substances to focus on in their enforcement and compliance activities. Some methods are available for authorities to test and control the articles to check for their compliance. 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.

RAC and SEAC conclusions:

RAC notes that the restriction should be monitorable if appropriate analytical methodologies are developed during the transition period.

Key elements underpinning the RAC and SEAC conclusions:

RAC

The master list created by the Dossier Submitter should be a very useful tool for monitoring the restriction since it would allow the enforcement authorities to focus on substances of real concern instead of focusing on the whole list of substances classified as sensitisers.

The Forum has raised a concern regarding the unavailability of analytical methodologies for monitoring sensitising substances at the limits proposed in the restriction. RAC insists on highlighting the necessity to use the transitional period for developing such methodologies.

RAC also notes that, according to the Dossier Submitter, OEKO-TEX has developed analytical methods able to meet the needed requirements for some substances. These methods are confidential and do not correlate with EN methods and therefore cannot be used in enforcement, so far. However, it suggests to RAC that the analytical detection of the proposed limits should be technically viable with proper developmental work and further harmonisation of appropriate testing methods. This is relevant, especially considering that, according to the dossier submitter, CEN TC248/WG26, which 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.

Overall, **RAC considers that the restriction would be monitorable and encourages the European Commission and other involved actors to develop appropriate methodologies for such purpose.**

RAC notes that the alternative proposed by the Dossier Submitter for monitoring the restriction based on patch tests with the textile dyes mix is of lower reliability and applicability than the chemical determination of the restricted substances in the articles. RAC bases this opinion on the following premises: i) path tests address only a few of the restricted substances; and ii) further epidemiological studies would be needed among the subjects in order to determine whether they have allergic reactions and to what specific chemicals.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

The Dossier Submitter has listed and described a number of uncertainties. These can be categorised as follows:

- **Scope**: Irritant, and non-classified (if they are not in the list of concern) substances not included in the scope
- **Risk Management**:
  - The Dossier Submitter has assumed that migration takes place for all substances in the scope. In addition, the exact relation between content and migration potential is uncertain.
  - The Dossier Submitter assumes there is potential for exposure to all substances in the scope, if present in the textile or leather.
  - There is a lack of data regarding use patterns for different textile and leather articles.
  - The range of elicitation doses was 0.025–20.1 µg/cm2, indicating differences depending on the substance. The median value, 0.8 µg/cm2, has been used as a generic elicitation.
  - The calculations to generate concentration limits in textile and leather are based on worst-case scenarios for migration and exposure frequency.

RAC conclusions:

RAC recognises the existence of uncertainties that might hinder the implementation of the proposed restriction, but on the other hand, these uncertainties should act as an important incentive for scientific and regulatory community to fill existing knowledge gaps.

Key elements underpinning the RAC conclusions:

RAC

See above the section *"Uncertainties in the risk characterisation".*

SEAC

Summary of proposal:

See the opinion of SEAC.

SEAC conclusion(s):

See the opinion of SEAC.

Key elements underpinning the SEAC conclusion(s):

See the opinion of SEAC.

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