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)]

Agreed

11 June 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 VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**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 consultation on the Annex XV dossier 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 **19/06/2019**. Interested parties were invited to submit comments and contributions by **19/12/2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Julie SEBA*

Co-rapporteur, appointed by RAC: *Miguel 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 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 artictextile 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	236-325-1

[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%.

	12223-33-5 51811-42-8	602-312-8
CI Disperse Red 1	2872-52-8	220-704-3
CI Disperse Red 11	2872-48-2	220-703-8
CI Disperse Red 17	3179-89-3	221-665-5
CI Disperse Yellow 1	119-15-3	204-300-4
CI Disperse Yellow 9	6373-73-5	228-919-4
CI Disperse Yellow 23	6250-23-3	228-370-0
CI Disperse Yellow 39	12236-29-2	602-641-7
CI Disperse Yellow 49	54824-37-2	611-202-9
CI Disperse Yellow 64	10319-14-9	233-701-7
CI Disperse Orange 149	85136-74-9	400-340-3
CI Disperse Violet 1	128-95-0	204-922-6
CI Disperse Violet 93	268221-71-2	-

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

THE OPINION OF RAC

See the opinion of RAC.

THE OPINION OF SEAC

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

The conditions of the restriction proposed by SEAC 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 limit is 3 mg/kg (0,0003 % 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) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**) ii. Substances that are used as active ingredients in biocidal products within the scope of Regulation (EU) 528/2012. iii. The placing on the market of second-hand clothing, related accessories, textile, leather, fur, hide and synthetic leather articles other than clothing, or footwear which were in end-use in the Union before 31 January 2023. 6. When existing, the standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 to 3.

	(*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51) (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'

Table 2: List of additional substances of concern

Substance name	CAS No.	EC No.
CI Disperse Blue 3	2475-46-9	219-604-2
CI Disperse Blue 7	3179-90-6	221-666-0
CI Disperse Blue 26	3860-63-7	223-373-3
CI Disperse Blue 35	12222-75-2	602-260-6
CI Disperse Blue 102	12222-97-8	602-282-6
Ci Disperse Blue 106[4]	68516-81-4	271-183-4
CI Disperse Blue 124[5]	15141-18-1	239-206-6
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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
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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
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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	-

[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 hazard(s) and exposure/emissions) (scope)

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

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

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Uncertainties in the risk characterisation

See the opinion of RAC.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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 to the general public associated with exposure to skin sensitising substances contained in clothing, footwear, textile-based disposables and textile, leather, fur, hide and synthetic leather articles other than clothing with similar potential of human skin contact is needed to ensure the free movement of goods within the EU. The severity of the possible health risk and the extent of the risk as children and adults are in daily contact with the articles targeted by the proposed restriction that may contain skin sensitising substances call for a Union-wide restriction. The lifetime prevalence of allergic contact dermatitis from textile and leather in the EEA31 general population is estimated by the Dossier Submitter to be around 0.8 to 1%. 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 the materials and articles targeted by the proposed restriction.

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 to the general public associated with the presence of skin sensitising substances[6] in clothing and related accessories, footwear, textile-based disposable articles and textile, leather, hide, fur or synthetic leather articles other than clothing with similar potential of human skin contact (in this opinion referred to as “articles targeted by the proposed restriction”) should be implemented in all Member States.

Key elements underpinning the SEAC and RAC conclusions:

SEAC considers that the proposed restriction targets the presence of skin sensitising substances in a wide range of EU-manufactured and imported articles that are categorised into four groups as (1) clothing and related accessories, (2) footwear, (3) disposable sanitary towels, napkins, tissues and nappies and (4) textile, leather, fur, hide and synthetic leather articles other than clothing with similar potential of human skin contact. These articles have in common that they are partly or exclusively made of textile, leather, hide or fur but may also be partly or in some cases exclusively made of other materials such as non-fibre polymers or rubbers. These articles are available to the general public and are freely moved within the Union. In addition, the Dossier Submitter has provided evidence supporting a risk of allergic contact dermatitis in the general population caused by the targeted skin sensitising substances and an associated human health impact due to a lifetime prevalence of allergic contact dermatitis caused by textile and leather of up to 1% in the EEA31 general population.

[6] Substances with a harmonised classification as Skin Sens. Cat 1, 1A or 1B and disperse dyes listed in Table 2 of the proposal

SEAC considers that the free movement of goods is an important factor for the functioning of the internal EU market and therefore considers that any measure taken to reduce the human health impact of skin sensitising substances should be taken on an EU-wide basis. SEAC considers an EU-wide measure to mitigate the risks, unlike measures at Member State level, will not negatively influence the free trade of the affected articles on the internal market and will provide a harmonised level of protection of the general population across the Union. The articles included in the scope of the restriction proposal are available to and used by all consumers across the Union.

SEAC furthermore considers that a Union-wide restriction on skin sensitisers in articles targeted by the proposed restriction would have a level of consistency with the existing Union-wide REACH restriction (entry 72 of Annex XVII) restricting the presence of 33 CMR substances in clothing, footwear and related textile articles with similar potential of human skin contact. SEAC notes that some other aspects of the current proposal are different in comparison with the entry 72 restriction, such as the coverage of natural leather and textile-based disposable articles. Where relevant such differences are discussed later in this opinion. A large majority of respondents in the consultation on the Annex XV dossier supported the need for a Union-wide measure to control the risks of the general public resulting from exposure to skin allergens in articles targeted by the restriction. The focus of the responses was primarily on textile and leather.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Justification for the opinion of SEAC

Summary of proposal:

The proposed scope of the restriction aims at preventing the placing on the market for the general public of clothing and related accessories, footwear, textile-based disposables and textile, leather, hide, fur and synthetic leather articles other than clothing with similar potential of human skin contact 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 articles targeted by the proposed restriction or for the 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 (PPE), 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 a high migration rate.

The following three REACH restriction options to regulate skin sensitising substances in textile and leather articles were identified and discussed by the Dossier Submitter in the restriction dossier:

- Restriction on **harmonised Skin Sens. 1/1A/1B substances and disperse dyes** in articles targeted by the proposal (Restriction option (RO) 1a):

  This is the proposed restriction, which is concluded to be effective in reducing the risk, proportionate, monitorable and enforceable. This option includes 24 disperse dyes that

do not (yet) have a harmonised classification for skin sensitisation. Concentration limits are based on a combination of data-driven and preventive-driven approaches.

- Restriction on **harmonised Skin Sens. 1/1A/1B substances only** (RO2).

  This restriction option is the same as RO1a but without the inclusion of the list of disperse dyes. Compared to RO1a this option has lower human health benefits and slightly lower costs. RO2 is thus considered to be less proportionate compared to RO1a.

- Restriction on **disperse dyes only** (RO3)

  This restriction option includes only disperse dyes, either with harmonised classification as Skin Sens. 1/1A/1B (2 disperse dyes) or without harmonised classification (the 24 disperse dyes included in RO1a). The Dossier Submitter concludes this option to be proportionate as costs would be very low and benefits high. Benefits are estimated to be approximately 40% lower compared to RO1a, which is therefore taken forward as the proposed restriction.

The following restriction options were briefly considered, but not assessed further by the Dossier Submitter:

- Restriction as RO1a with **additional labelling requirements** (RO1b); would increase information to the general public about allergens contained in the textile and leather articles they may be exposed to, but the level of additional protection offered is uncertain.

- Restriction as RO1a but including also substances with **harmonised classification Skin Irr.2 or Skin Corr.1A/1B/1C** (RO4); this option would provide more protection than RO1a however the presence of irritant or corrosive substances at sufficiently high levels in textile and leather is considered unlikely.

- Restriction as RO1a but with **migration limits** instead of concentration limits (RO5); not considered further as concentration limits under RO1a cover for migration factors. Furthermore, migration limits are less practical and enforceable.

- Restriction as RO1a but with **concentration limits at level of detection or zero** (RO6); this option is not further assessed as total ban has no basis in risk assessment and would incur high costs on the sector.

- Restriction as RO1a but including also **self-classified Skin Sens. 1/1A/1B** substances (RO7); this option is not further assessed as contradicting self-classifications could cause issues for the practicality and monitorability for industry and authorities.

The following regulatory management options other than restrictions were briefly considered, but not assessed further by the Dossier Submitter:

- **Labelling requirements** for textile and leather articles with skin sensitisers; the

Dossier Submitter concludes both costs and benefits of such RMO to be lower compared to a ban or concentration limits on sensitisers.

- SVHC identification followed by REACH **authorisation**; not further considered as authorisation would apply only to SVHC incorporated into textile and leather articles in the EU and hence would not be effective for 80% imported articles.

- **Harmonised classification** under CLP; is only applicable to substances and mixtures not to articles.

- **Other legislations**

    - **Textile Fibre Labelling Regulation** (EU) No 1007/2011; the Dossier Submitter presents the option of expansion of the Textile Fibre Labelling Regulation as a less preferred option compared to using existing chemicals Regulation such as REACH based on an analysis made in 2013 by the European Commission.

    - The **General Product Safety Directive** (GPSD) (EC) No 2001/95; the GSPD requires all consumer products to be safe when placed on the European market but the measure is analysed to be more appropriate for specific interventions on products rather than more general hazards. Rapid interventions by the Commission are possible (e.g. on acute health risks caused by chemicals) but would need to be implemented in Member States and therefore not constitute a fully harmonised measure at EU level.

    - Development of a **specific EU product legislation** covering textiles and leather; according to the Dossier Submitter a specific textile and leather Regulation is only possible in the long term and existing chemicals legislations can currently be used to manage risks.

- **Voluntary actions**; the Dossier Submitter considers the effectiveness of voluntary agreements highly uncertain because of a lack of enforcement mechanisms. Furthermore, this option lacks proper incentives, targets and sanctions.

- **Economic policy instruments**; because of the unanimity requirement economic instruments such as taxation would have to be considered at Member State level. National taxes would however create an uneven playing field for market actors.

SEAC conclusions:

In general, SEAC concludes that amongst the different restriction options and other risk management options described by the Dossier Submitter, a REACH restriction according to **RO1a is the most appropriate measure** to manage the risks to the general public arising from the use of skin sensitising substances in the articles targeted by the proposed restriction.

SEAC concludes the other REACH **restriction options and other RMOs to be less appropriate measures** to address the risks of the general public caused by skin sensitisers in the targeted articles because these measures provide less or uncertain (additional) human

health benefits, are poorly enforceable, would incur high costs for the affected sectors or create an uneven playing field.

SEAC **supports the approach targeting clothing and related accessories, footwear, textile-based disposables, and textile, leather, hide, fur and synthetic leather articles other than clothing with similar potential of human skin contact containing skin sensitisers placed on the market for the general public** as it resembles a level of consistency with existing entry 72 of Annex XVII on CMR substances in similar articles. SEAC considers consistent elements across both related restrictions to be important for the practical implementation and ease of compliance and enforcement of the proposed skin sensitiser restriction. In this respect, SEAC specifically notes that RO1a also contains elements that are diverging from entry 72 of Annex XVII which deserves attention in the decision-making phase or at the level of communication and guidance for companies and enforcement bodies.

SEAC supports the **concentration limits** amended by RAC and recommends making some modifications based on technical feasibility considerations (chromium VI, disperse dyes, nickel and cobalt). As regards the late proposed lowering of the proposed formaldehyde concentration limit from 75 mg/kg to 30 mg/kg following recent changes in the Toys Safety Directive SEAC cannot yet conclude pending comments from stakeholders to be solicited during the consultation on the SEAC draft opinion.

SEAC supports the proposed derogations for personal protective equipment, medical devices, second hand articles and substances used as Active Substances in biocidal products under the BPR. However, SEAC does provide some additional recommendations for implementation.

SEACs supports the proposed 36 months **transitional period.**

SEAC supports a **dynamic link with Annex VI of CLP** and recommends investigating the possibilities for semi-dynamic linking[7] at the implementation phase allowing adoption of transitional periods before newly harmonised skin sensitisers will be banned in the articles as proposed by this restriction. SEAC has insufficient information to advise on the costs, benefits, proportionality and practicality of an additional (dynamic) **link with skin sensitisers in the CPR**.

Key elements underpinning the SEAC conclusions:

In general, SEAC concludes that amongst the different restriction options described by the Dossier Submitter, a REACH restriction according to RO1a is the most appropriate measure to manage the risks to the general public arising from the use of skin sensitising substances in the targeted articles. SEAC compared RO1a, RO2 and RO3 with respect to their costs, benefits, proportionality and practicality.

<u>Other restriction options considered</u>

In SEAC's view RO1b would most likely be a less appropriate restriction option as it is the

[7] e.g. comparable with the insertion of newly identified CMR Cat 1A, 1B or 2 substances in the relevant appendices of Annex XVII entries 28-30 of REACH.

same as RO1a and the additional labelling requirement is proposed only for skin sensitising substances that are in the scope of the proposed restriction, and present in the targeted articles at concentrations below the limit value of the proposed restriction. SEAC considers the Dossier Submitter presented RO1b as an option to make more safety information readily available to the general public purchasing the targeted articles but without justification based on possible additional human health benefits and scrutiny of additional costs. SEAC considers additional health benefits of this labelling provision uncertain in addition to the health benefits offered by RO1a which are substantiated by risk assessment. SEAC concurs with the analysis by the Dossier Submitter concluding not to take forward restriction options RO4 to RO7 because they would provide no or very limited additional human health benefits (RO4), be less practical and enforceable (RO5 and RO7) or result in high costs for the sectors involved (RO6). None of these additional options were analysed in detail in the Background Document.

Other RMOs considered

SEAC concurs with the analysis by the Dossier Submitter that textile and leather labelling would be a less appropriate risk management measure compared to the proposed restriction (RO1a). Costs of labelling may be lower as labelling does not force companies to replace skin sensitising substances (which reduces compliance costs and reformulation costs) but also the human health benefits would be less certain and most likely lower. Labelling of textile/leather articles could make it possible for the average consumer to avoid buying and using articles containing substances that may cause allergic contact dermatitis, but it is not considered that it would reduce the risk to the same degree as a restriction on the placing of the market of such articles. During the consultation on the Annex XV dossier one Member State pointed at the importance of labelling to protect already sensitised people. They argued that this would be the only option allowing consumers to avoid using articles containing skin sensitisers and stated that a simple way would be the use of QR codes on existing labels. A fragrances association in the consultation on the Annex XV dossier (#2414) argued that given the low prevalence of allergic contact dermatitis in the general population, prevention of induction would be the most rational way forward and hence they stated that adequate consumer information through labelling would be more appropriate than the proposed restriction, which is targeted at preventing elicitation of already sensitised individuals in the general population. An NGO stressed the need for a restriction on skin sensitisers to provide clarity over an abundance of already existing labelling schemes.

SVHC identification on a substance by substance basis and subsequent authorisation and harmonised classification is considered by SEAC an inappropriate RMO to manage the identified risks. The main reason for this is that the authorisation requirements only apply to articles produced in the EU where skin sensitisers would be incorporated in such articles. Hence, the majority of articles targeted by the proposed restriction on the EU market would not be covered (e.g. for textile the Background Dossier clarifies 80% of the articles placed on the market in the EU are imported).SEAC also concurs with the analyses by the Dossier Submitter disregarding the risk management options of amending the Textile Fibre Regulation, using the General Product Safety Directive or implementing a specific EU product legislation covering textiles and leather. SEAC concurs with the arguments provided by the Dossier Submitter for not taking forward these options. It is noted that the argumentation provided focusses on textile articles only while the article scope of the restriction proposal is much broader. Typically, coverage of a relative broad chemical scope and broad range of uses

of such chemicals in textiles, leather and other materials in order to control an identified risk is well captured under REACH where the alternative RMOs discussed here would provide only partial solutions. No comments on these options were provided in the consultation on the Annex XV dossier. In general, the idea of legislative measures trough REACH was supported.

As regards voluntary actions by industry, SEAC notes that some information is available in the Background Document. A range of existing textile labelling schemes, such as the European ecolabel for textiles and footwear, Global Organic Textile Standard (GOTS), Nordic Eco-Label, OEKO-TEX, Blue Sign and Nordic Swan (See Annex E.1.3) include to some extent criteria on the use of harmful substances. These textile labels primarily function as guides for consumers and industry and are expected by SEAC to deliver some substitution pressure for skin sensitising substances. However, no information is available on the effectiveness of these specific labelling schemes with respect to substitution of skin sensitisers and associated health benefits. A meta-analysis of research undertaken on the effectiveness of labels on hazardous chemicals and other products[8] suggests that several factors influence whether a user who reads a product label will follow the instructions on that label. The factor that seems to have the largest influence on behaviour is familiarity with the product – users familiar with a product are less likely to notice the label, believe the information on it and comply with the instructions. Several stakeholders (e.g. #2426) from the textile industry stated a preference for self-regulation measures such as widely used certificate systems like Oeko-Tex® Standard, brand restricted substances list (RSL) and Manufacturing Restricted Substances List (MRSL) and ZDHC. SEAC considers that these existing schemes have added value in terms of quality certification and consumer awareness but are uncertain with respect to their human health benefits in terms of preventing induction and elicitation of allergic contact dermatitis. Therefore, SEAC concurs with the analysis by the Dossier Submitter that voluntary actions are not an appropriate EU-wide measure to address the identified risks. Finally, SEAC agrees with the Dossier Submitter that economic policy instruments such as fees or taxation (in combination with labelling) are not likely to be appropriate measures because such measures would have to be taken at Member State level creating an uneven playing field for market actors.

Scope: articles placed on the market for the general public

The proposed restriction targets only articles placed on the market for supply to consumers (i.e. 'the general public'). This aspect of the proposal is consistent with entry 72 of Annex XVII for CMR substances in clothing or related accessories, other textile articles likely to come into contact with human skin and footwear. SEAC concurs with this approach but notes that the limitations that the Commission applied on the CMR restriction targeting only the general public had a legal basis in REACH article 68.2 which only allows a restriction targeted at consumer uses. SEAC notes that the Dossier Submitter, whilst not having such legal restrictions under REACH article 69.4, could have included placing on the market for uses by professionals or in industrial settings, but has opted not to include such uses in the proposed scope. SEAC supports this approach as it considers that legal consistency with entry 72 of

[8] U.S. Environmental Protection Agency (2016). The Effectiveness of Labelling on Hazardous Chemicals and Other Products [RIN 2070-AK07]. Office of Chemical Safety and Pollution Prevention. March 2016. Available at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0247

Annex XVII is important for the practical implementation and enforcement of the restriction. No comments were received on this aspect during the consultation on the Annex XV dossier and in the Forum advice.

Scope: clothing and related accessories and footwear

SEAC notes that the restriction targets clothing and related accessories and footwear comparable with REACH Annex XVII entry 72. The differences may be summarised as follows:

- Unlike entry 72 the proposed restriction specifically includes (parts of) articles made from natural leather, fur and hide;
- Unlike entry 72 the proposed restriction contains no specific exemption for non-textile fasteners and decorative attachments;

Unlike entry 72, the proposed restriction exempts parts of footwear (such as the underside) that do not come into contact with the human skin under normal or reasonably foreseeable conditions of use. SEAC has taken note of these differences and largely concurs with the choice of scope by the Dossier Submitter which is based on human health risk- and impact assessment. SEAC considers the broader material scope of the restriction proposal covering besides textile also other materials (as in entry 72) but also natural leather, fur and hide justified as the Background Document contains evidence that these materials may contain skin sensitisers. Clothing, related accessories and footwear in practice are assembled articles containing textile, leather, fur, hide and other materials such as a wide range of polymers and rubbers. It is the intention of the Dossier Submitter to cover also these materials in the scope of the restriction and SEAC agrees with this approach since it is consistent with entry 72 and it is likely to have a positive effect on the human health benefits of the restriction. [SEAC notes RAC supports the inclusion of these materials based on risk considerations].

Considering the articles in scope SEAC agrees with including clothing and related accessories and footwear based on the socio-economic arguments provided in the Background Document. There is however a need to clarify how the 'clothing related accessories' are defined and how such articles relate to the other articles covered by the restriction in paragraph 1.ii for which a non-exhaustive list of examples is taken up in the proposal. SEAC notes that recital 4 of Commission Regulation 2018/1513 states '… related accessories (including, inter alia, sportswear and bags) …'. Hence, SEAC sees a possible overlap between paragraph 1.i and 1.ii as regards the clothing related accessories and this should be clarified.

SEAC notes that the Dossier Submitter proposes no exemption for (non-textile) fasteners and decorative attachments however the Background Document contains some ambiguous information on this issue. Metal parts, such as buttons and zippers, are stated to be exempt. SEAC notes that there may be sensitising metals such as nickel in metal parts such as zippers, buttons and decorative attachments. These articles are however covered by entry 27 of Annex XVII of the REACH Regulation restricting nickel content. The dossier does cover also cobalt in its scope, but the dossier does not contain any information on the use of cobalt in metallic parts. SEAC sees a need to clarify and justify any need for exempting specific fasteners and decorative attachments.

The Dossier Submitter proposes an exemption specifically for 'those parts of footwear that do not come into contact with the human skin' (the underside is given as an example). Although SEAC understands the 'lack of risk' consideration underpinning such exemption, SEAC has

concerns with such exemption as is not included in entry 72 and introducing it would thus be another point of divergence between the two restrictions and cause confusion for industry and enforcement. SEAC advises to align the restrictions at this point. SEAC agrees with the Dossier Submitter that it is sensible to cover inner soles which may be purchased separately from shoes.

Scope: textile, leather, fur, hide and synthetic leather articles with similar skin contact

SEAC notes that the restriction targets articles with 'clothing-like' human skin contact in a comparable way as REACH Annex XVII entry 72. The differences are that the proposed restriction besides textile articles also covers leather, fur, hide and synthetic leather. SEAC supports the inclusion of such materials based on the arguments given in the paragraph above. Unlike entry 72, the proposed restriction does not exempt carpets for indoor use, rugs and runners. Furthermore, the proposal includes a non-exhaustive list of example articles that according to the Dossier Submitter fall under this category.

As regards the inclusion of re-useable textile articles, such as table linen and napkins and carpets, mats and rugs, in the scope, SEAC notes that the Dossier Submitter justified this approach based on exposure and risk considerations. The Commission for entry 72 temporarily excludes wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners due to potential regulatory overlap and because other substances may be relevant for them. This exemption will be reviewed. No information on these uses was submitted in the consultation on the Annex XV dossier. No socio-economic arguments are provided and hence SEAC concurs with the inclusion of these articles as proposed by the Dossier Submitter.

The inclusion of wristwatch straps as a fashion accessory is broadened to cover also similar articles, such as wrist braces and bands and necklaces, straps and bands. SEAC agrees with this specification. SEAC concurs with the choice of article scope based on health impact considerations although it should be noted that information on specific (additional) human health benefits of inclusion of articles such as carpets, mats, rugs and runners is not available in the Background Document. SEAC supports non-exhaustive listing of specific example articles that are included in the scope in the legal text or guidance to facilitate compliance and enforcement. Finally, SEAC sees a need to clarify how some articles within this category of articles relate to the clothing related accessories as included in paragraph 1.i of the proposal (See above).

SEAC notes that the Dossier Submitter also intends to include the category of childcare articles other than toys, such as valances, babies' nests, deckchairs, seats etc. The Dossier Submitter refers to REACH Annex XVII entries 51 and 52 for the definition being "any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children". SEAC notes that the dossier contains no information on the costs of restricting such specific uses in textile, leather, hide and fur for these childcare applications and no information was submitted in the consultation on the Annex XV dossier. SEAC considers nevertheless that the information available for the textile and leather industry cover also costs for this sector.

Scope: disposable sanitary towels, napkins, tissues and nappies

SEAC notes that disposable sanitary towels, napkins, tissues and nappies are included in the proposed scope. The Dossier Submitter considers that under normal and foreseeable conditions of use, these articles may be in contact with human skin and may be of concern in a similar way as re-usable textiles and some disposables may be coloured. SEAC notes that at this point the restriction proposal diverges from entry 72, which in paragraph 5 specifically

exempts 'disposable textiles' from the restriction. The Dossier Submitter in paragraph 1.iii of the proposal includes these articles as a separate category, which represents primarily so-called non-woven textiles. Some articles in this category such as nappies and sanitary towels are multi-layered and may contain materials other than textiles. SEAC takes note of four comments received during the consultation on the Annex XV dossier all disagreeing with the inclusion of these articles (#2397, 2411, 2426, 2788) based on differences in the exposure scenarios. SEAC takes note of RAC's support of including such articles based on risk considerations and agrees with the inclusion as socio-economic reasoning for exclusion is lacking. However, SEAC also notes that articles falling under the scope of the Regulation on food contact materials (Commission Regulation (EC) No 1935/2004) should be exempted from the restriction.

Concentration limits

For the substances covered in RO1a the Dossier Submitter proposed concentration limits based on quantitative risk assessment approaches (either substance-specific, semi-specific or default). Based on information provided during the consultation on the Annex XV dossier and discussions during the RAC and SEAC opinion development, the Dossier Submitter made changes to the proposed limits in the background document. These changes are shown in Table 1. For leather the concentration limits were reduced by approximately a factor of 3 for nickel- and cobalt compounds, 1,4 paraphenylene diamine and other substances in scope of the restriction based on slight changes made in the risk assessment such as the use of a higher density of leather as input parameter. Also, for nickel in textile some slight adjustment was made resulting in a concentration limit changing from 130 to 120 mg/kg. For disperse dyes the Dossier Submitter adopted changes in the limit of detection based on information provided in the consultation on the Annex XV dossier affecting the risk assessment resulting in the concentration limit in textile changing from 0.05 mg/kg to 0.1 mg/kg and for leather changing from 0.04 mg/kg to 0.03 mg/kg. For formaldehyde the Dossier Submitter changed the limit value in all materials in the final Background document from 75 to 30 mg/kg based on consistency with recent changes in the Toys Safety Directive.

Based on further changes made in the risk assessment RAC arrived at slightly different concentration limits for nickel and its compounds in textile (125 mg/kg) and for nickel and its compounds(25 mg/kg), cobalt and its compounds (15 mg/kg), 1,4 paraphenylene diamine (50 mg/kg) and other substances (30 mg/kg) in leather. The RAC proposed concentration limits are presented in Table 1 in bold.

Table 1: Concentration limits (from Table 3 of the Background Document and RAC opinion). Figures in bold are taken from the RAC opinion.

Substance / group of substances	Proposed concentration limit (mg/kg)	
	Textile and other materials	Leather, fur and hide
Disperse dyes	Ban[1]	Ban[1]
Chromium VI compounds	1[2]	1
Nickel and its compounds	120 **125**	40 **25**
Cobalt and its compounds	70	20 **15**
Formaldehyde	30	30
1,4 paraphenylene diamine	250	80 **50**
Other substances in scope	130	40 **30**

[1] 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. RAC applies the same concentration limit for textile and 0.02 mg/kg for leather.

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

According to the Dossier Submitter, the risk of the group of allergenic disperse dyes (24 without harmonised classification included in Table 2 of the Background Document plus eight disperse dyes, with harmonised classification as Skin Sens. Category 1) should be managed by a total ban (not exceeding the detection limit (LOD)), since the derived concentration limits are below the current quantification limit for disperse dyes (10-50 mg/kg) and their substitution is technically feasible at low cost. 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). As regards technical and economic feasibility of the proposed LOD concentration limit for this group of substances SEAC considers that the information in the Background Document is very limited.

SEAC considers that the proposed LOD as a concentration limit effectively means a complete ban on the use of these dyes. Hence, information on technically and economically feasible substitutes is essential for an evaluation of the proposal by SEAC. For two acid dyes (acid red 447 and acid yellow E JD 3442) and two direct dyes (Direct Blue 301 and Direct Yellow 162) and eight disperse dyes with harmonised classification (See Table 26 in Annex E.2.2.2.), the Dossier Submitter states that the AFIRM industry expert group (apparel and footwear) confirms that adequate substitutes exist at the same cost. It should be noted that the two acid dyes and the two direct dyes are proposed to be restricted according to the generic concentration limits (RAC recommends 130 mg/kg for textile and 30 mg/kg for leather) since they are not disperse dyes.

On the 24 additional disperse dyes no good information on substitution possibilities is available. Despite a lack of information for the 24 disperse dyes, the Dossier Submitter concludes that substitutes exist for the total group of dyes (Table 18 of section 2.4.1.1.1. of the Background Document). In the consultation on the Annex XV dossier the same sector group (#2413) provided arguments against the low generic concentration limits for disperse dyes. According to them no pure reference standards are commercially available for these dyes, so analysis would need to be performed with technical grade dyes containing an unknown concentration of the active ingredients as a comparison point. To achieve and reliably test to these low limits in products would require the use of pharmaceutical grade dye formulations, which would largely increase their cost and also the costs to the final consumer. They propose restricting the group of disperse dyes to the Oeko-Tex limit of 50 mg/kg each, which is claimed to be industry best practice since the 1990s. Another stakeholder from the textile industry (#2384) states that there are currently no analytical methods that could enforce at levels (as initially proposed) of 0.05 mg/kg in textile and 0.04 mg/kg in leather. They refer to their own certification scheme in which a usage ban is set with a limit of detection of 20 mg/kg for listed disperse dyes. According to them 20 mg/kg is a globally acknowledged limit that is also feasible for testing labs. They further state that with this limit, intentional use of banned disperse dyes in articles can be avoided. According to another stakeholder (#2409) a limit of 0.05 mg/kg in textile is not realistic and they state that with the DIN 54231 method a lowest limit of quantification would be around 15 mg/kg.

One stakeholder (#2493) states that disperse dyes should be regulated on a per substance risk bases. They state that dyes like Disperse Blue 291, Disperse Violet 93 and Disperse Yellow 64 are common dyes that have been distributed around the world for a long time and for dyeing industries, the dyes are key substances that are difficult to substitute and costs for industry would be high if restricted. Another stakeholder (#2795) opposes a ban on Disperse Blue 291:1 Cl/Br (EC 287-466-0, CAS 85508-41-4 and EC 257-486-4, CAS 51868-46-3), Disperse Blue 291 (EC 279-131-2, CAS 79295-99-1) and Disperse Violet 93:1 Cl/Br (EC 266-405-1, CAS 66557-45-7 and EC 258-110-1, CAS 52697-38-8) as these are wide-used components of commercial products. They estimate an EU tonnage of over 500 tons/year for these dyes. The colorants are components of at least 50% of all disperse dyes preparations covering the Navy Blue/black shades both in European as well as imported articles. These numbers correspond to ca. 40% in volume of all Navy Blue/black preparations in the EU. The importance of DB 291 and DV 93 mostly for use in black dyes is affirmed by another stakeholder (#2801). They state that it is impossible to dye synthetic fibres without these dyes. No information was submitted to verify the importance of specific dyes for the textile industry and SEAC notes that none of the dyes Disperse Blue 291:1 Cl/Br, Disperse Blue 291 and Disperse Violet 93:1 Cl/Br mentioned above are in the scope of the proposed restriction.

Based on the information obtained in the consultation on the Annex XV dossier SEAC concludes that the low generic limit values for the group of 24 disperse dyes will cause challenges for the involved industries as analytical standards of sufficient purity are lacking. Hence, SEAC recommends in addition to the LOD, the lowest of the quantification limits currently applied in certification schemes such as BlueSign and Oekotex could be used for compliance testing. According to information provided a quantification limit of 15-20 mg/kg would be feasible and in line with current practice together with an appropriate and lower limit of detection.

The Dossier Submitter proposes to manage the risks identified for skin sensitising substances other than disperse dyes by setting concentration limits, since a total ban may hamper the production of textile and leather articles. SEAC concurs with this general principle and assesses the proposed concentration limits based on technical and economic feasibility information as follows:

Chromium VI compounds: The proposed concentration limit of 1 mg/kg in textile and leather are based on a quantitative substance-specific approach and in the Background Document limited information is available on the technical and economic feasibility of the limits. SEAC notes that the proposed limit of 1 mg/kg for textiles is the same as in entry 72 of Annex XVII and it is supported by RAC. Therefore, it may be considered technically and economically feasible also for the proposed restriction for its skin sensitising properties. The respondents in the consultation on the Annex XV dossier did not object the 1 mg/kg limit for chromium VI in textile.

For leather, hide and fur, the Dossier Submitter arrived at a concentration limit of 1 mg/kg which is lower than the existing 3 mg/kg concentration limit in entry 47 of Annex XVII for chromium (VI) in leather. SEAC takes note of RAC's risk-based recommendation for a limit in leather of 1 mg/kg and RAC's consideration to align this value to the standardised quantification limit of chromium (VI) in leather (3 mg/kg) for enforcement reasons. SEAC considers that the technical and economic feasibility of the 1 mg/kg limit value for leather might be challenging based on information in the 2013 consolidated RAC-SEAC opinion on the

Danish 'Annex XV dossier proposing restrictions on chromium (VI) compounds in leather articles'. RAC, in its opinion, stated that the limit of 3 mg/kg '*represents the quantitative limit of the analytical method used to determine the content of hexavalent chromium in leather in its current state. The method is the international standard EN ISO 17075:2007'*. In the current Background Document, no information is available to SEAC to assess the feasibility of the lower proposed limit. Some stakeholders in the consultation on the Annex XV report stated that it is possible to achieve a limit of 1 mg/kg of Cr(VI) in leather (#2368, 2379, 2391, 2394, 2423, 2427) and they referred e.g. to publications by Hedberg et al. and others[9] providing insight in how change in experimental parameters influence the outcome of ISO 17075 tests. Proper control of these parameters would allow reduction of the effective LoD and LoQ values to ca. 0.75 and 2.5 mg/kg, respectively. However, a majority of stakeholders (#2366, #2393, #2398, #2403, #2405, #2407, #2409, #2413, #2417, #2795 and others) from the leather industry responded negatively to the proposed 1 mg/kg limit value, stating that it would not be possible to enforce a level below 3 mg/kg with current analytical methods. Also, the Forum advice argues against a 1 mg/kg limit value for chromium VI in leather, as its members are not aware of any method which would reliably measure levels below 3 mg/kg. The 1 mg/kg limit is regarded as not technically feasible as the currently applied standard for sampling and analyses EN ISO 17075 does not support reliable quantification lower than 3 mg/kg. In addition, the instability of hexavalent chromium in leather is related to environmental conditions, in particular during storage before testing. This instability associated with the heterogeneous distribution of hexavalent chromium in leather does not allow a precise and reliable detection of hexavalent chromium below 3 mg/kg. One consultant (#2394) provides information on measures to take in order to reduce the chromium VI content in leather formed during storage and refers to some international commercial labs having reported LOQ of 0.5 mg/kg for their in-house methods. One stakeholder (#2423 and #2427) suggests CEN could be required to re-evaluate if it is possible to lower the detection limit to 1 mg/kg. However, the detection limit has to be correct from an analytical point of view. Several stakeholders (e.g. #2390, #2449, #2872, #2874, #2876, #2796) from the leather industry explained that chromium VI, unlike what was communicated in the Annex XV dossier, itself is not used as a tanning agent in leather manufacture. The Background Document was updated to modify the incorrect description of the leather processing. Chromium III compounds are used for 85% of the volume of leather placed on the EU market and chromium VI may be formed in chromium-tanned leather during processing, storage and service life. Further it was explained that vegetable tanning (as alternative to chromium and glutaraldehyde tanning) is not technically feasible and not available in sufficient volumes. According to one respondent (#2796) the process time for vegetable tanning is much longer (up to 1 year instead of 5 days) and because of this the market would lack capacity to substitute chromium tanning. In addition, the limited availability of vegetable tanning chemicals and the finding that vegetable tanning cannot be performed with the same equipment as regular tanning were brought forward as

[9] Hedberg Y. S. et al. (2015) Chromium released from leather – I: exposure conditions that govern the release of chromium(III) and chromium(VI), Contact Dermatitis, 72, 206-215
Mathiason, F., C. Lidén, and Y. Hedberg, Chromium released from leather – II: The importance of environmental parameters. Contact Dermatitis, 2015. 72(5): p. 275–285.
Hedberg, Y.S. and C. Lidén, Chromium(III) and chromium(VI) release from leather during 8 months simulated use. Contact Dermatitis, 2016. 75(2): p. 82-88.
Hedberg, Y., C. Lidén, and I. Odnevall Wallinder, Correlation between bulk- and surface chemistry of Cr-tanned leather and the release of Cr(III) and Cr(VI). Journal of Hazardous Materials, 2014. 280: p. 654-661.
Anderie, I. and K. Schulte, Chromate Testing in Leather: EN ISO 17075, in Metal Allergy2018, Springer. p. 31-38.

arguments against substitution. SEAC considers that a Cr VI limit value of 3 mg/kg in leather is feasible for industry and enforcement bodies against no costs as it is already in place in the existing entry 47 in Annex XVII. SEAC concludes that evidence available shows that a 1 mg/kg limit value is not likely to be technically feasible. SEAC has no information on the share of Cr III tanned leather placed on the EU market that would be affected by the restriction. The lack of information is largely due to the broadly stated lack of technical feasibility of reliable analyses < 3mg/kg and the consequential lack of reported lower concentrations. Considering that a lower limit of 1 mg/kg cannot be complied with due to these analytical limitations, implementing such concentration limit would effectively constitute a ban on Cr III tanning. Considering that leather based on glutaraldehyde tanning may be 2-6% more expensive than chrome tanned finished leather[10] and the 85% market share of Cr III tanned leather currently on the EU market, SEAC considers the impacts of a 1 mg/kg concentration limit on the involved sector could be substantial.

SEAC concludes that considering the large market share of chromium tanned leather on the EU market, the limited possibilities to substitute chromium-based tanning techniques and the evidence that application of EN ISO 17075-1 currently is not able to provide reliable chromium VI concentrations below 3 mg/kg, the limit value should be set at that level accordingly. SEAC notes that RAC recommends a risk-based limit value of 1 mg/kg and that a risk of chromium (VI) induced allergic contact dermatitis cannot be ruled out if compliance with the restriction would be proven with a 3 mg/kg limit value. SEAC therefore recommends the 3 mg/kg concentration limit to have a temporary nature and advises that the consultation of the SEAC draft opinion is used to gather information on the time window and practical needs to achieve a reliable 1 mg/kg detection limit for Cr (VI) in leather.

Nickel, cobalt and compounds: The proposed concentration limits of 120 mg/kg and 40 mg/kg for nickel and its compounds in textile and leather respectively are based on a quantitative substance semi-specific approach and no specific information is available in the Background Document on technical and economic feasibility of these limits. RAC recommends 125 mg/kg in textile and 25 in leather, hide and fur. The proposed concentration limits of 70 mg/kg and 20 mg/kg for cobalt and its compounds in textile and leather respectively are based on a quantitative substance semi-specific approach and no specific information is available in the Background Document on the technical and economic feasibility of these limits. RAC recommends 70 mg/kg for textile and 15 mg/kg for leather.

According to the Forum advice the nickel and cobalt limit values need further refinement, but it is not clear what is meant. It seems that Forum sees a lack of clarity whether the limits refer to specific nickel and cobalt compounds or to the metal. During the consultation on the Annex XV dossier some stakeholders from the leather industry (#2393, #2403) stated not to be aware of an intentional use of these two metals. They expect the substances to be detected at low concentrations in a few leather materials. They could potentially be associated with dyes used in the leather production process. Furthermore, they state that limiting the presence of these substances in leather could have an impact as many chemical products used for leather dyeing would have to be substituted with difficult to evaluate economic impact. A Member State (#2784) confirmed that the presence of cobalt (and not likely nickel) in textiles and leather articles can originate from metal-complex dyes, which typically have

[10] According to a 2011 report from TEGEWA referenced in the background documents for this restriction proposal and for the current chromium VI restriction in leather

strong metal-ligand binding. As skin sensitising properties are mainly related to the free metals, they note that the restriction as well as a quantification method should differentiate between the occurrences of these metals as dye-complex or released ions. Other stakeholders (#2793, 2879) stated that the limit value should be applied only to inorganic cobalt compounds, some of which are well-known skin sensitisers and other cobalt compounds such as organic Cobalt complex dyes should be excluded from the restriction. They recommended that the term “cobalt compounds” should be replaced by “inorganic cobalt compounds”. In addition, each affected compound should be identified individually with its CAS or EC numbers.

Taking account of information provided in the consultation on the Annex XV dossier SEAC concludes that the originally proposed concentration limits for cobalt and its compounds and nickel and its compounds are technically and economically feasible because analytical methods are available and, except for use in metal-complex dyes, the use of both metals and their inorganic compounds in textile, leather and other materials in scope of the restriction is expected to be limited. SEAC recommends that the consultation on the draft SEAC opinion is used to request information from stakeholders on the feasibility of the lower concentration limit values in leather, hide and fur proposed by RAC of 25 mg/kg for nickel and its compounds and 15 for cobalt and its compounds.

Formaldehyde: The initially proposed limit value of 75 mg/kg in textile and leather in line with entry 72 of Annex XVII (based on the carcinogenic properties of the substance) was supported in the consultation on the Annex XV dossier and in the Forum advice although some stakeholders (#2384) pointed at potential double regulation to be an issue possibly introducing a lack of clarity for companies. Another stakeholder (#2906) challenged the 75 mg/kg limit as too low for upholstery, coats and jackets and for workwear and PPE as higher formaldehyde levels (300 mg/kg) would be required ascertaining e.g. flame retardant properties. SEAC takes note of this information, which was the basis for extending a temporary higher limit value in entry 72 for formaldehyde. SEAC notes that PPE and workwear are outside the scope of the current restriction proposal.

After the consultation on the Annex XV dossier, the Background Document was updated changing the formaldehyde concentration limits in all materials to 30 mg/kg on the basis of consistency with a recent change in Appendix C to Annex II to Directive 2009/48/EC (the Toy Safety Directive), adopting the specific limit values for formaldehyde of 30 mg/kg (content limit) in textile toy material and 30 mg/kg (content limit) in leather toy material based on allergic contact dermatitis. SEAC recommends that the consultation on the draft SEAC opinion is used to solicit information from stakeholders on the feasibility of a limit value of 30 mg/kg. Specific responses should be requested from sectors that requested and were granted an extended transitional period introducing the lowering of the concentration limit from 300 mg/kg to 75 mg/kg in entry 72 for upholstery, coats and jackets based on feasibility considerations. Finally, SEAC takes note of a currently processed separate REACH Restriction proposal for formaldehyde and formaldehyde releasers in articles and considers that the article/material scope of this restriction proposal could be partly overlapping with the proposal by France and Sweden. However, both restriction proposals cover different exposure scenarios, risks and a different restriction approach and therefore should be considered separately.

1,4 paraphenylene diamine: The proposed concentration limits of 250 mg/kg and 80 mg/kg for 1,4 paraphenylene diamine in textile and leather respectively are based on a quantitative

substance semi-specific approach and no specific information is available in the Background Document on the technical and economic feasibility of these limits. RAC recommends 250 mg/kg for textile and 50 mg/kg for leather. In the Forum advice, the Forum requests a limit value of 30 mg/kg without further justification. In the consultation on the Annex XV dossier two stakeholders of the textile industry (#2384, 2791) suggest a limit value of 20 mg/kg as an appropriate consumer safety limit without further justification apart from the fact that this is the limit applied by them in their textile quality certification scheme (https://www.bluesign.com/downloads/bssl/bssl-v10.0.pdf). They mention 1,4 paraphenylene diamine might be present as an impurity but is not intentionally used in auxiliaries and dyes in textile industry. Based on the information in the Background Document and responses in the consultation on the Annex XV dossier SEAC concludes that there are no feasibility issues with the proposed limits in textile, leather and other materials.

Other substances in scope: The proposed generic concentration limits of 130 mg/kg and 40 mg/kg for the other substances in the scope of the proposed restriction in textile and leather respectively are based on quantitative default approach and no specific information is available in the Background Document on the technical and economic feasibility of these limits. RAC recommends 130 mg/kg for textile and 30 mg/kg for leather. Some stakeholders from the leather industry (#2366, #2393, #2403) noted that generic limits proposed are much lower than the thresholds normally applicable to skin sensitisers in the safety datasheets. Hence, information in the supply chain would be limited or not available. SEAC notes that the generic concentration limits are for skin sensitisers in textile and leather material and not for chemicals or chemical products formulations for which a safety datasheet requirement applies. Hence, the comment is considered not relevant. No further information was received on the feasibility of the generic concentration limits. Based on the information in the Background Document and responses in the consultation on the Annex XV dossier SEAC concludes that there are no feasibility issues with the proposed limits for other substances in scope of the proposal in textile, and leather and other materials.

Derogations for personal protective equipment (PPE) and medical devices

SEAC concurs with the proposal by the Dossier Submitter to derogate uses in personal protective equipment and medical devices falling under the scope of Regulation (EU) 2016/425 and Regulation (EU) 2017/745 respectively. Although the Dossier Submitter provides no detailed justification SEAC supports both derogations, as they are consistent with the derogation in entry 72 of Annex XVII, which was based on the need for such equipment and devices to fulfil specific requirements in terms of safety and functionality. One NGO in the consultation on the Annex XV dossier argued that PPE should not be exempted as according to them recent scientific evidence shows that exposure to sensitisers while using PPE may have an important impact on workers' health. The article reports on a study carried out in the UK that shows that "Clothing, footwear, facemasks and headgear need to be recognized as causes of dermatoses occurring at body sites less commonly associated with occupational skin disease". In the UK dermatoses associated with non-glove PPE account for 0.84% of occupational skin disease. They further state that hazards coming from the PPE are not specifically included in the scope of Regulation (EU) 2016/425. SEAC considers that the PPE Regulation applies to PPE intended for use by consumers and other end-users (i.e. professional and industrial workers). Detailed analyses of the PPE Regulation shows that the legal provisions are largely targeted towards safety and design characteristics, usability and efficacy. However, in Annex II (essential health and safety requirements), section 1.2.1.1. also requirements are included ascertaining chemical risks are minimised. The materials of which the PPE are made, including any of their possible decomposition products, must not adversely affect the health or safety of users. Based on the above considerations SEAC currently supports the exemption of PPE and will use the consultation of the SEAC draft opinion to request the affected sectors for information on the impacts on a REACH restriction on skin sensitising chemicals in PPE. On the medical device exemption no further information has been received and SEAC concurs with the proposal of the Dossier Submitter.

Derogation for substances used in biocidal products

SEAC agrees with the Dossier Submitter that substances that are used as active ingredients in biocidal products used in the EU in the manufacture of textile and leather articles or for the treatment of finished articles are within the scope of the BPR and any risks connected to those uses are covered by that regulation. Based on a need to prevent double regulation SEAC considers an exemption for active substances in biocidal products in the proposed restriction to be justified. SEAC notes RAC's conclusion that residual biocidal substances in textile and leather articles at point of sale are a source of concern. SEAC considers that skin sensitising substances used in textile and leather as biocidal active substance and at the same time for providing other functionalities may be a challenge as these substances will probably not be taken into account by enforcement.

However, SEAC notes that the BPR requires importers of such treated articles to label the articles if a claim that the article has biocidal property is made or if such label is required under the approval of the active substance contained in the biocidal product used to treat the article. SEAC considers that there may be imported textile and leather articles containing skin sensitising biocidal active substances for which no biocidal property claim is made on the label and questions the enforceability of this aspect. In the consultation on the Annex XV dossier several stakeholders agreed on exempting biocidal active substances regulated under the BPR to prevent double regulation (#2425, #2426, #2409, #2394). Some mentioned to be worried

about substances with multiple uses, biocidal and others, which could lead to conflicting regulation. A Member State (#2420) argued against the biocide exemption and stated preference for a scope including articles treated with biocidal products that have a harmonized classification as skin sensitiser. Finally, one stakeholder from the leather industry (#2413) pointed at the finding that several biocides that are critical for the preservation of leather against mould are included in the restriction proposal with a generic 110 mg/kg limit (newly proposed limit by RAC 30 mg/kg) for non-biocidal uses. As they are worried about a risk of mould, they propose removing the below listed substances from the proposal or else restricting them to the below limits to maintain safe control of mould:

- TCMTB – 500 mg/kg
- 4-chloro-3-methyl phenol – 600 mg/kg
- 2-octylisothiazol-3(2H)-one – 250 mg/kg

SEAC concludes the exemption for biocides and biocide treated articles is justified although not consistent with entry 72 for which no such exemption was introduced. For skin sensitising biocidal substances that also have other functionalities in textile leather or other articles that are in the scope of the restriction proposal SEAC recommends applying the applicable concentration limit (e.g. generic limit) laid down in the proposed restriction since at point of sale enforcement bodies will not be able to distinguish the uses.

Derogation for second hand articles

Although supporting information in the Background Document is limited, SEAC concurs with the analysis by the Dossier Submitter that the second-hand consumer market for textile and leather articles is likely to be relatively large and complex. Thus, it will be difficult and expensive to enforce a restriction on skin sensitisers in these articles. More importantly, SEAC considers enforcement on compliance of second-hand articles is much less cost-effective compared to the enforcement of new articles on the market since a single inspection on the latter would cover a whole batch or brand or article type while compliance control on second hand articles would affect no more than the one single article inspected.

SEAC notes that the Dossier Submitter argues that, due to normal wear and washing, the concentration of sensitising chemicals in second hand articles is likely to be reduced. SEAC takes note of RAC's agreement to derogate such articles for practicality reasons although acknowledging that second-hand articles may constitute a source of exposure for skin sensitising substances in footwear. SEAC considers that additional health benefits of including second hand articles in the scope are likely to be limited. Based on the argument of complexity to control, monitor and enforce compliance of the proposed restriction in a relatively large second-hand market and the limited expected additional human health benefits of including the second hand market in the scope of the restriction, SEAC agrees with the derogation of second hand textile and leather articles.

No comments on this exemption were received in the consultation on the Annex XV dossier. The Forum supports the exemption.

Transitional period

The Dossier Submitter proposes a transitional period of 36 months after entry into force as it will provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of the restriction (e.g. to deplete existing stocks) since

substitution is already ongoing. The period is also needed for the development of additional test methods.

SEAC considers that the Background Document contains minimal information justifying a specific transitional period of 36 months with respect to stock depletion, reformulation (impurity and intentionally used skin sensitisers) and the influence of the fact that for some chemicals substitution is already ongoing.

SEAC further considers that for compliance testing and enforcement of the proposed restriction, it would be important that EU harmonised analytical methods are available. Based on information presented in Table 19 in Annex E.2 of the Background Document it is clear that, for a range of skin sensitisers, analytical methods are either not available or are not yet standardised. Hence, there is a need to develop testing methods for a range of skin sensitisers in textile and leather. SEAC notes that CEN TC248/WG26 has been tasked by the Commission to develop such methods.

Dynamic link with CLP Annex VI

The Dossier Submitter under RO1a proposes to restrict all skin sensitising substances using a dynamic link between the restriction in Annex XVII of REACH and substances classified as skin sensitisers in Annex VI of the CLP Regulation. SEAC notes that a dynamic link with harmonised skin sensitisers in Annex VI of CLP is an integral part of the restriction proposed (both in RO1a and RO2) and as such a justification for the dynamic link or comparison with other options of regulating harmonised skin sensitisers has not been provided by the Dossier Submitter.

SEAC notes that there is no exhaustive list of substances used in the manufacturing processes of the articles covered by this restriction proposal. The Dossier Submitter has developed a list of chemical substances that may be present today in textile and leather articles (Table 19 in Annex E of the Background Document). 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, as well as 24 disperse dyes. However, SEAC notes that this list is indicative and not exhaustive. For example, ECHA undertook a search of REACH registration dossiers for 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 categorised as either: dyes, plasticisers, acrylates or diisocyanates. This search yielded 243 registered substances. ECHA analysed the overlap between the original list of 176 relevant substances assessed by the Dossier Submitter as a starting point for the IN-list (for more information, see Annex A.2.2 in the Background Document) with the 243 substances identified by ECHA and found 15 substances were present in both lists. In SEAC's view, this gives an indication that more substances than those on the IN-list may be used in the EU in the manufacturing of textiles and leather and other articles in the scope of the proposed restriction. SEAC considers likewise this would apply to articles manufactured outside the EU. Furthermore, SEAC notes that the dynamic link with CLP could prevent regrettable substitution.

SEAC notes that RAC supports the dynamic link with CLP based on risk management considerations. In the consultation on the Annex XV dossier one Member State and an NGO stated explicitly to be in support of this approach (#2379, 2850). Other respondents stated to disagree with such approach as it would not take into account the potential exposure level for each substance. They requested a refocus of the restriction on substances for which there is a proven risk of allergic contact dermatitis related to an exposure to textile and leather

articles (#2366, 2384, 2413, 2423 and others). Another respondent (#2906) requested a semi-dynamic link with CLP with a three-year transitional time for every restriction change adding chemicals based on risk considerations. One Member State (#2784) flagged the need for a semi-dynamic link through a separate appendix updating the restriction in Annex XVII with new relevant skin sensitisers through the appropriate legislative process.

Taking into account all information available SEAC supports a dynamic link with CLP Annex VI and recommends the Commission to consider the options for a semi-dynamic linking[11] in the implementation phase allowing adoption of transitional periods before newly harmonised skin sensitisers will be banned in the articles as proposed by this restriction.

Possible link with the Cosmetic Products Regulation

During the RAC and SEAC opinion development the question was raised why the Dossier Submitter did not consider a dynamic link with skin sensitising substances in the Cosmetic Products Regulation (CPR; EC Regulation 1223/2009). SEAC considers that the Dossier Submitter did not include in their proposal any link with the CPR. SEAC considers that for the skin sensitisers with a CLP harmonised classification currently listed in CPR and for any future amendments of CPR as regards harmonised skin sensitisers there is no added value of a dynamic link as such substances are already in scope of the proposal through the proposed dynamic link with CLP Annex VI. SEAC notes that CPR may indeed contain skin allergens that do not have a CLP harmonised classification for this property and such substances may also be newly added in the future. Since the Dossier Submitter did not consider a link with CPR SEAC has no information on the number of chemicals this would cover in addition to RO1a and to assess the costs, benefits, proportionality and practicality of adding such dynamic link.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Socio-economic impact

Justification for the opinion of SEAC

[11] E.g. comparable with the insertion of newly identified CMR Cat 1A, 1B or 2 substances in the relevant appendices of Annex XVII entries 28-30 of REACH.

Costs

Summary of proposal:

For the skin sensitising substances used in textile and leather articles, and for which alternatives are identified and price and volume data exist, the total cost of substitution has been calculated. The estimated costs are outlined below.

Costs of substituting to alternative chemical substances: Based on the available data on cost differences per unit used for groups of skin sensitisers and substitutes, the Dossier Submitter has estimated an overall total cost of -€25 million per year (if rosins are substituted with acrylics) or €3 million per year (if rosins are substituted with polyurethane binders). The Dossier Submitter has taken both scenarios forward, as it is not clear whether both acrylic and polyurethane binders are suitable alternatives to rosins. In addition to the possible negative cost for rosins (if they are substituted with acrylics binders), there are also negative substitution costs for phthalates and neoprene plasticisers. The Dossier Submitter regards this as an underestimation of the total costs due to some degree of uncertainty of the collected cost data as well as the fact that, for some substances, data is missing. Without the negative costs, the total annual costs are estimated to be from €0.01 million to €23.8 million depending on the selected rosins substitutes. More details appear in the table below.

Reformulation costs: The need for reformulation has been identified for a number of rubber accelerators. Based on consultations with a rubber expert, the Dossier Submitter estimates that the reformulation labour cost would be €8 000 per reformulation (€50/hour for 160 hours). Assuming that the laboratory costs would be 40% of the total reformulation cost gives a total cost of €13 300 per reformulation. Based on the assumption that 1 000 reformulations would be needed, the Dossier Submitter estimates that the total one-time cost for reformulating rubber accelerators would be €13.3 million. It should be noted that this one-off cost is additional to the annual substitution costs outlined in the table below.

Cost of switching to best practice: For diisocyanates (and possibly solvents), a change in manufacturing and processing practice can lead to a situation where the substances are not present above the proposed concentration limits in articles placed on the market for the general public. The cost of moving towards best practice has not been estimated due to lack of data.

Enforcement costs: Both industry and enforcement authorities will need to perform additional testing in order to ensure compliance with the restriction. Based on the available information about testing costs for phthalates esters, formaldehyde, disperse dyes, cobalt and chromium, the Dossier Submitter estimates that the annual testing costs during the first couple of years would be €82 800. However, the Dossier Submitter notes that there are many uncertainties related to testing costs and that the limited information at hand does not allow for a proper assessment of these costs.

Table 2: Summary of the total annual substitution costs provided by the Dossier Submitter

Substance group	Cost of substance used	Cost of Substitute	Cost difference per weight unit on average	Volume used (ton)	Total cost difference with regard to chemicals restricted
Phthalate	€ 3 600 -€ 5 400 / metric ton.	€ 900-€ 2 600 / metric ton	€ -2 750	4 842	€ -13 315 500
Dyes	Depend on the type of dye.	Should not differ much.	0	10 409	0
Rubber accelerators	€ 900- € 89 200 / metric ton (depending on which accelerator)	Should not differ much according to rubber expert, (large cost for reformulation possible, €13 300/reformulation is estimated separately).	Should not differ much according to rubber expert, (large cost for reformulation possible, €13 300/reformulation is estimated separately).	415	0 (the one-off reformulation cost is not included here)
Rosins	€ 1300-€ 1800 per metric ton	€ 900-€ 1 300 / per metric ton if substitution with acrylic binders Potential regrettable substitution.	€ -450	10 800	€ -5 000 000
Rosins	€ 1300-€ 1800 per metric ton	€ 3100-€ 4 400 / per metric ton if substitution with polyurethane binders	€2 200	10 800	23 760 000€
Formaldehyde	€ 400-€ 600 per metric ton at 37% purity	Polycarboxylic Acid Superplasticizer 40%. € 700-€ 1100 / metric ton.	€ 400	288 in textiles and 28 in leather	€126 400
Plasticiser for neoprene	€ 86 000/ metric ton	€ 900 -€ 89 200 per metric ton.	-40 950	180	€-7 371 000

Sum of total annual substitution cost (if rosins substituted with acrylics)	**€-25 420 100**
Sum of total annual substitution cost (if rosins substituted with PUR)	**€3 084 700**
Sum of total annual substitution cost (excluding negative costs) (if rosins substituted with acrylics)	**€ 11 200**
Sum of total annual substitution cost (excluding negative costs) (if rosins substituted with PUR)	**€23 771 200**

SEAC conclusions:

SEAC agrees with the cost assessment performed by the Dossier Submitter as an appropriate method to assess the economic impacts of the proposed restriction on the skin sensitising substances used in textile and leather articles. Overall, SEAC agrees that the proposed estimates provide an indication of the order of magnitude of the costs, with possible underestimation due to the lack of data.

SEAC considers that the differences in substitution and enforcement costs across Restriction options RO1a, RO2 are not significant. Because of the inclusion of only a limited list of skin sensitizers (disperse dyes) of which some have been voluntary phased out by industry, RO3 is concluded to be the lowest cost option.

Key elements underpinning the SEAC conclusions:

Availability of alternatives

SEAC reviewed the analysis provided by the Dossier Submitter regarding the existence and availability of alternatives for the skin sensitizing substances used in textile and leather articles that do not comply with the proposed limits at point of sale. Based on expert consultations, questionnaires, KemI (2019) and the information provided in the consultation on the Annex XV dossier, the Dossier Submitter concludes that there are technically and economically feasible alternatives available for most of the concerned skin sensitizing substances used in textile and leather articles. Specifically for the group of diisocyanates, the Dossier Submitter concludes that no alternatives are available and therefore compliance can only be achieved by reverting to best practices to reduce the point of sale levels of residual diisocyantes in textile articles. Based on a comment provided in the consultation on the Annex XV dossier (#2874) diisocyanates have a high degree of reactivity and therefore the presence of residue concentrations in the articles is unlikely.

Reformulation needs have been identified for a number of rubber accelerators. While a consulted rubber expert confirmed that substitution is possible, it is not clear what the substitutes will be and if they will be less problematic from a skin sensitizing perspective. SEAC rapporteurs lack information related to the substitution process and potential substitutes.

For a number of substances the identified substitutes are considered as regrettable in one aspect or another by the industry consulted. For rosins, phthalate esters, plasticisers for neoprene, for instance, there is uncertainty as to whether or not substitutes exist with a better

health/risk profile. For a number of substances, there is also a lack of information on alternatives.

For cobalt there is a lack of information on all parameters. For the intermediates and the solvents, substitution has been considered to be technically not possible due to their many uses, but there are indications that the substances will not be present at point of sale. For chromium VI, as an oxidation product of chromium III tanning, it is indicated that a stricter limit could be a problem. Glutaraldehyde has been identified as a substitute, but several comments in the consultation on the Annex XV dossier indicate that it is not a feasible alternative to chromium in all applications. According to the pubic consultation, the concentration of glutaraldehyde in leather articles at point of sale could comply with the proposed concentration limit for glutaraldehyde in leather. For Benzenamine (aniline) the information is inadequate since it was recognized very late in the process by industry. But according to KemI (2019), Benzenamine (used for synthetic indigo) is hard to substitute and no possible alternative is identified that can be used for the large volumes needed.

Substitution costs

SEAC reviewed the analysis provided by the Dossier Submitter on the substitution costs regarding the availability and costs of alternatives for the skin sensitising substances used in textile and leather articles that do not comply with the proposed limits at point of sale.

Raw materials costs

The Dossier Submitter estimates the raw material costs of substitution to alternative non-skin sensitising chemicals based on cost per weight unit data for the substances known to be used today (and targeted to be restricted) and identified alternatives. The Dossier Submitter presents the overall annual substitution cost based on the price difference, which for some substances is a negative value. The Dossier Submitter notes that large discrepancies exist in the costs between the groups of substances analysed and considers that the negative costs for some substances may have been the result of an under-estimation of the costs. SEAC considers the analysis of raw material substitution costs in the Background Document highly uncertain as it is only based on six (groups of) substance(s) (i.e. phthalate, dyes, rubber accelerators, rosins, formaldehyde and neoprene plasticisers). For phthalate and neoprene plasticisers, and one of the potential substitutes for rosins (acrylic binders) negative costs are estimated based on an average lower price of the alternative compared to the skin sensitising substance to be replaced. The ranges presented are broad and therefore SEAC considers the use of average values debatable. Furthermore, SEAC argues that it is very unlikely that costs in reality are negative because industry would probably already have substituted the skin sensitising plasticisers concerned. SEAC considers that there may be differences in quality, efficacy (volumes to be applied) and other feasibility considerations that play a role here that are not known and are not included in the costs assessment. This was also highlighted by several industry comments to the consultation on the Annex XV report (e.g. #2817-2825, 2827-2830, 2832-2835 etc.), who stated that the substitution cost did not consider the need of changing processes (R&D costs, machinery, etc.). At the same time, these industry comments did not provide specific data, which would allow SEAC to estimate the costs of such process changes. European Plasticisers (#2892) referred to an IHS report published in May 2018, according to which alternatives to phthalates are more likely to result in higher prices.

Based on the comments provided by EEB in the consultation on the Annex XV dossier (#2379) for plasticisers it is possible to find alternatives via reformulation testing and use technically suitable, non-hazardous substances instead of substitution with other phthalate esters. However, this statement is not supported with any economic values and it was therefore not possible for SEAC to evaluate quantitatively the suggested alternatives.

Based on a comment (#2379) provided by EEB in the consultation on the Annex XV dossier two suitable alternatives for rosins are available: acrylic binders and polyurethane binders. The polyurethane binders are known to be more expensive than acrylic ones. Replacing the rosin-based glues by acrylic-based ones would result in savings of €5 million for industry, however some technical issues are possible. Substitution of rosins by polyurethane binders would generate additional costs for the industry of €23.8 million. For formaldehyde, the figures presented seem to give more certainty but only a small volume is used in leather only. For dyes and rubber accelerators, zero raw material costs are estimated based on expert statements from stakeholders that prices “should not differ much”.

Overall, SEAC concludes based on the information available in the Background Document and the information submitted to the consultation on the Annex XV report that raw material substitution costs as a result of the proposed restriction remain uncertain. While the impact on specific sectors is not quantified due to lack of information and may vary from significant to no impacts on their business, for industry as a whole, raw material substitution costs may be expected to not be significant.

Reformulation costs

The Dossier Submitter reports that because of the proposed restriction reformulation might be needed for the rubber accelerators, as well as potentially for other substances. SEAC notes that the reformulation cost is provided only for the rubber accelerators where the cost of €13 300 per reformulation is estimated in a sensitivity analysis, providing a total cost of €13.3 million based on an assumption of 1000 reformulations. SEAC agrees with the principle that the best available data has been used by the Dossier Submitter however SEAC considers the sensitivity analysis uncertain since it is based on assumptions regarding the number of reformulations. The European Rubber Chemicals Association (#2894) criticised the estimates for being based on the expertise of a single expert and for lacking transparency but did not provide any other cost data. It is not possible with the information at hand to know the relative magnitudes of possible overestimation and underestimation for unit reformulation cost, and SEAC agrees to use the estimates proposed by the Dossier Submitter, having not enough evidence to conclude if they are overestimated or underestimated.

Moving to the Best practice

According to information in the Background Document no substitutes exist for diisocyanates but compliance with the restriction can be achieved by ascertaining best practices by textile and leather manufacturers (KemI, 2019). SEAC has concerns related to the costs of introducing best practices, which are currently not estimated due to the lack of information (including from the consultation on the Annex XV report). Based on the comment provided in the consultation on the Annex XV dossier (#2874, Stazione , Italy), diisocyanates have a high degree of reactivity and therefore the presence of residue concentrations in the articles is

unlikely and analytical determination is complicated thus the differences between these types of industrial practices are difficult to assess.

Total substitution costs

The total substitution costs are calculated with regard to the cost difference between the skin sensitising chemical used and its alternative. All other factors, i.e. volume used and quality aspects, are assumed to be held constant (due to the lack of data discussed above). The Dossier Submitters provided estimates of the total cost of substitution at around - € 25.4 million per year (if rosins are substituted with acrylics) or 3 million € per year (if rosins are substituted with polyurethane). Excluding the negative costs gives a total cost of around €0.01 million per year (if rosins are substituted with acrylics) or €23.4 million per year (if rosins are substituted with\ polyurethane). SEAC has concerns regarding the negative substitution costs reported by the Dossier Submitter for the plasticiser neoprene, for phthalate and for rosins (if replaced with acryl-based glue). It seems unlikely that the market would not have chosen the cheapest substitute unless there is some hidden cost, related to quality differences and other aspects not known to the Dossier Submitter (which may be the reason why industry is using the seemingly more expensive chemical). SEAC considers that further consideration is needed of the suggestion by one stakeholder in the consultation on the Annex XV dossier on reformulation testing to find technically suitable, non-hazardous substances instead of substitution with phthalate.

SEAC highlights the limited data as a source of uncertainty that may results in under- or overestimates of the total substitution costs. SEAC agrees with the Dossier Submitter that unless better data is provided, it is difficult to assess the total substitution costs.

Comparison of substitution costs for the three Restriction options RO1a, RO2 and RO3 assessed by the Dossier Submitter

The substitution costs slightly vary across the three restriction options. The above presented costs focus on the substances listed in RO1a. The costs of RO2 (without the additional list of substances of concern) are expected to be slightly lower than RO1a due to its smaller chemical scope. RO3 focuses on a limited number of substances, including only disperse dyes, of which some have been voluntarily phased out and KemI (2019) and experts consulted by the Dossier Submitter have indicated that some have economically feasible alternatives. RO3 is hence considered by the Dossier Submitter to be technically feasible and implementable at very low costs for industry. While SEAC highlights the limited data on substitutes for some disperse dyes (as discussed in the section on scope, including derogations), it agrees with the Dossier Submitter that RO3 will have significantly lower substitution costs compared with RO1a and RO2.

Enforcement costs

The Dossier Submitter semi-quantitatively assesses enforcement costs. SEAC notes that the Dossier Submitter did however not include the enforcement costs in the total cost estimations. The total enforcement costs are estimated to be higher than average for REACH restrictions since the number of substances required to be tested are much higher than for a regular restriction. SEAC agrees that considering the multitude of substances covered by the

proposal, compliance testing and enforcement is likely more resource intensive than for a restriction covering a single chemical or relatively small group of chemicals.

The Dossier Submitter has assessed the substance-specific costs per test and made some assumptions on the number of additional tests that will be performed annually but acknowledged that there are many uncertainties related to testing costs such as the costs per test, the number of articles on the EEA market to be tested, the frequency of test required from companies to establish compliance etc. SEAC acknowledges that the limited available information does not allow for a proper assessment of testing costs. Based on the comments provided by the labs on the testing cost the Dossier Submitter concludes that the kind of substance that needs to be tested may have a higher impact on the testing and enforcement costs than the actual number of substances that needs to be tested as the cost for testing/material vary. Due to the lack of data the Dossier Submitter was not be able to estimate the administrative costs. The Forum advice contains no information on costs but states in general that the large number of chemicals will be a challenge from an enforcement perspective. Forum mentions furthermore some specific analytical challenges but in general sampling and analyses of these types of materials is well known by inspectors and the Forum does not make any reference to costs. To address this gap the Dossier Submitter used the estimation on administrative costs from the restriction dossier for tattoo inks. In the restriction proposal for tattoo inks and permanent make-up the total annual testing costs for compliant tattoo inks were reported to be up to €80 000 for the 4 130 substances within the scope. The Dossier Submitter transferred this value to the restriction proposal for skin sensitisers, all else equal, with about 1000 substances within the scope. They estimated the total annual testing costs for compliant textiles at €19 200 (24% of €80 000). And the annual average incremental costs for testing for EEA22 at about €48 000 (24% of €200 000). Furthermore they extrapolated to EEA31 (assuming that the costs per Member State would be the same) and estimated the costs for testing for compliance per year at €27 055. SEAC agrees that in absence of data this method is a reasonable way to provide some indication of the testing costs but considers that there is uncertainty related to the extrapolations.

Several comments to the consultation on the Annex XV report (e.g. #2791, 2817-2825, 2827-2830, 2874, 2894) stated that the restriction proposal would force industry to run more testing and verification procedure, with additional costs. One comment stated that the compliance testing cost estimates for textile sector in the background document are significantly underestimated. They provided some limited data (claimed confidential) indicating that the testing costs for industry may by far exceed the estimates in the Background Document. The comment indicated that there is a high number of textile manufacturing companies in the EU. However, it is not clear to what extent the large number of textile manufacturing companies mentioned in the comment would need to perform additional testing. SEAC notes that there may be many companies covered by the EU statistics in the Textile Manufacture category for which compliance control with the proposed restriction would not be relevant as they have a different role in the supply chain (e.g. companies that only perform spinning or weaving without any handling of chemicals or textile article manufacturers that have a role in assembling articles). Furthermore, it can be assumed that the companies affected by the skin sensitiser restriction already undertake routine testing for chemicals and SEAC notes that it is unclear what share of any testing costs would be incremental to the proposed restriction. In addition, the costs would in practice depend on

enforcement requirements, such as whether companies would need to demonstrate compliance by testing or whether supply chain communication alone might be considered sufficient. The consultation on the SEAC final draft opinion should be used to gather more specific information about testing costs.

Comparison of enforcement costs for the three Restriction options RO1a, RO2 and RO3 assessed by the Dossier Submitter

SEAC notes that the Dossier Submitter did not provide a quantitative assessment of the total enforcement costs for the three restriction options RO1a, RO2 and RO3 separately. Since these costs to some extent are connected with the number of substances that would have to be tested for compliance control, the enforcement costs for RO2 and RO3 should be lower than RO1a. Since the RO3 focuses only on disperse dyes it is expected to have the lowest enforcement costs of the three restriction options analysed.

Other costs

Some of the other costs that industry may face if this restriction is implemented could be the cost associated with transportation, packaging and dispatch from one country to another. These costs are however not expected to be significantly changed as a result of this restriction proposal and are therefore not assessed in this restriction report. SEAC agrees with the Dossier Submitter that these costs are not significant in this case.

Benefits

Summary of proposal:

The human health impacts assessment focuses on allergic contact dermatitis because it is associated with contact with sensitising substances and is largely reported in the literature. A restriction of skin sensitising substances in textiles and leather articles should also prevent some irritant contact dermatitis (ICD) and urticarial cases but there is little information on the association between these cases and contact with articles containing skin sensitising substances. Therefore, the Dossier Submitter notes that the assessed health benefits of the restriction may be underestimated.

The Dossier Submitter has collected information and data on the prevalence and incidence of allergic contact dermatitis in the general population (all causes) as well as the prevalence of positive patch tests from skin sensitisers in textile and leather (i.e. frequency of positivity of patch tests used to detect contact allergy from substances contained in textile and leather). Based on these data, the calculated prevalence of allergic contact dermatitis caused by substances in textile and leather in the general population is around 0.8% - 1% (giving 4 - 6 million individuals already sensitised in the EEA31). The calculated incidence of allergic contact dermatitis in the general population to skin sensitising substances in textile and leather is around 0.01% and 0.04% per year (giving 45 000 – 180 000 new cases in the EEA31 per year).

The restriction is expected to protect 70% - 90% of the already sensitised population from developing allergic contact dermatitis from the exposure to skin sensitisers in textile and leather articles. It is also expected to prevent the occurrence of at least 70 - 90% of new cases of sensitisation to chemical substances in textile and leather articles.

Based on a review of four studies, the Dossier Submitter used the following economic values and assumptions for the valuation of the health impacts:

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

For avoided new sensitisation cases, the benefits are calculated over 2023+80 years, taken as the average life expectancy in the EEA31. For the protection of already sensitised people, the benefits are calculated over 2023+30 years, considered by the Dossier Submitter as a reasonable approximation of the average remaining lifetime of already sensitised people. The annual benefits expected from the restriction have been assessed using four sensitivity scenarios, discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%). The sensitivity scenarios are all possible combinations of the number of new and current cases of allergic contact dermatitis and the associated annual costs per case.

The total annual human health benefit expected from the restriction is €7 - €50 billion with a most "reasonable" estimate of €10.3 - €33.4 billion.

SEAC conclusions:

SEAC concludes that the proposed restriction would result in benefits to society in terms of avoidance of new cases of allergic contact dermatitis and prevention of sensitised individuals from elicitation of effects. The proposed restriction is also expected to prevent some irritant contact dermatitis and urticarial cases. However, due to lack of data for these cases, the associated benefits to society cannot be quantified. Additional social benefits that have not been monetised include avoided costs associated with the exposure avoidance search and purchase of e.g. allergens-free cloths and shoes.

SEAC agrees with the Dossier Submitter's analysis on the health benefits of the proposed restriction and finds the approach taken by the Dossier Submitter to focus on prevalence and avoidance of new cases of allergic contact dermatitis for the quantification of benefits justified and reasonable. The estimated economic value of human health impacts of allergic contact dermatitis considers a lower and higher value of the prevalence and avoidance of new cases. SEAC concurs with the range of values of the social costs and the human health benefits given by the Dossier Submitter.

SEAC concludes that the expected benefits of the RO1a will be larger in comparison to RO2

and RO3 due to the higher prevalence and avoidance of new cases potentially associated with the scope of the ROs.

Key elements underpinning the SEAC conclusions:

Prevalence and incidence data

Prevalence data on allergic contact dermatitis used by the Dossier Submitter for the human health impact assessment are from the literature and from the dermatologists consulted during the preparation of this restriction proposal. In the Background Document, the Dossier Submitter explained that depending on the purposes of the study and the data available, prevalence may be calculated over a short period of time (one year) or a medium period of time (10 years) or over lifetime. Lifetime prevalence data are usually considered as the most representative measure of the prevalence of a health state of the general population. Therefore, the Dossier Submitter decided to use lifetime period. The prevalence data included: the range of the prevalence of allergic contact dermatitis in the general population (4.4% to 18.4% with a lifetime prevalence of 15%-20%); Annual incidence rates for allergic contact dermatitis in the general population (0.17% - 0.7%); Frequency of positive patch tests from testing with chemical substances contained in textile and leather in adults tested (0.4% to 17% with an average calculated by the Dossier Submitter 5%).

Based on these data, the Dossier Submitter calculated a prevalence (0.8% - 1%) and an incidence (0.01% and 0.04%) of allergic contact dermatitis caused by substances in textile and leather in the general population, as well as the number of textile allergic contact dermatitis cases that would be prevented in the EEA31 population by the restriction proposed. The Dossier Submitter did not find significant differences in prevalence of allergic contact dermatitis from sensitising substances in textile and leather (based on testing with allergenic disperse dyes in particular) between children and adults. Several stakeholders in the consultation on the Annex XV dossier specifically challenged the prevalence figures (#2414, #2781, #2784, # 2788, #2795, #2816, #2845, #2783). Some of them (#2783, 2784, 2788) highlighted that the estimates in the Background Document are based on patch tests, which are generally conducted on individuals who are experiencing allergic contact dermatitis and don't represent a cross-section of the whole population. Comment #2783 submitted by a member of the Information Network of Departments of Dermatology (http://www.ivdk.org/en) considered the prevalence data provided by the Dossier Submitter "...dramatically over-estimated" and provided alternative values of a 1-year prevalence of 0.003% (3 / 100.000) and a 8-year prevalence (for the study period of 8 years, an approximation of life time prevalence) of 0.02% (24 / 100.000), which is much lower than the prevalence figure calculated in the Background Document. The comment did not provide any incidences values. SEAC notes that the figures provided by the Dossier Submitter are calculated using different initial data and methods and consider different time periods related to the representative prevalence interpretation which may result in the significant differences in their figures. However, SEAC agrees that the possible overestimation of prevalence may impact substantially the values of human health benefits. To address the uncertainties related to the prevalence values and the potential over-estimation of benefits, the Dossier Submitter provided an additional sensitivity analysis using a patch tests positive frequency of 0.5% instead of 5% such as assumed in the dossier (annex E.5 of the BD). The results from the sensitivity analysis indicates that if lower patch tests positive frequency of 0.5% is used, the monetized value of health benefits will decrease but remain significant. More details on the

results of the sensitivity analysis are presented in the section below. SEAC considers the approach taken by the Dossier Submitter appropriate.

Furthermore, comment #2784 pointed out some misinterpretation of the data from the Bfr 2006 value of 1%-2% (being the positive reaction from patch tests in clinics and not the prevalence of textile-allergic contact dermatitis in the general population) which may cause overestimation of the benefits. The Dossier Submitter updated the Background Document and clarified that the Bfr value of 1-2% has been used as a benchmark in the dossier but not in the assessment and therefore it has no impact on the benefits figures. SEAC concurs with this clarification.

Benefits for human health

SEAC concurs with the Dossier Submitter's approach to estimate the human health benefits of the proposed restriction based on prevalence and incidence data of allergic contact dermatitis (number of current and new cases) and costs. The valuation of the health impacts includes the direct costs or treatment-related costs, indirect costs or costs of lost working days, and welfare (intangible) costs. The input data comes from four studies (Saetterstrom and al (2014), the Chromium VI restriction proposal (2012) and the ECHA 2014 and 2016 reports on willingness-to-pay).

Saetterstrom and al (2014) assessed direct and indirect costs of contact dermatitis in terms of healthcare costs and production loss. The Chromium VI proposal (2012) assessed the direct, indirect and intangible costs of contact allergies to chromium VI contained in leather articles. ECHA (2014) and ECHA (2016) assess the willingness to pay of contact allergies that can be used as reference values for restriction dossiers. In their assessment ECHA (2016) provides reference values of dermatitis with a central value of €250 for acute or mild cases, and a range of €2 000 - €12 000 for 'severe, chronic dermatitis'. In their estimates on human health benefits, the Dossier Submitter adopted the ECHA estimates for 'severe, chronic dermatitis' because the profile of this health effect fits best to the contact allergies due to textile and leather. The Dossier Submitter considers that even though all contact allergies to textile and leather may not be severe, this profile fits best to the proposed restriction because identifying the exact piece of clothing or footwear or other article responsible of the allergy may be very complex since textiles and footwear articles often contain a high number of various chemicals that may be found in most of the articles in contact with the skin; in those circumstances, the exposure avoidance is difficult or even impossible in some cases and in the meantime, the patients' quality of life may be heavily affected. SEAC considers these arguments reasonable, although it recognises that the severity of symptoms is not affected by the possibilities to avoid symptoms.

SEAC has scrutinised the sources used for the estimated values and concludes that the figures provided by these studies are relevant for the benefits assessment in the proposed restriction.

Based on the above, the annual benefits expected from the restriction have been assessed with four scenarios, discounted over 2023-2103 for the new cases and over 2023-2053 for the current cases (at 2.5% over 2023-2053, then 0.5%). These scenarios are all possible combinations of the number of new and current cases of allergic contact dermatitis and the associated annual costs per case. SEAC agrees with the approach to perform a scenario analysis on the possible human health benefits including different combinations of the number of new and current cases of allergic contact dermatitis and the associated annual costs per case for 70 and 90 percent prevalence and avoidance of allergic contact dermatitis.

In order to address uncertainties related to human health benefits, including those raised by stakeholders in the consultation on the Annex XV dossier, the Dossier Submitter provided sensitivity analyses on the following parameters: the prevalence of patch tests positivity to textiles, the prevalence of contact dermatitis in the general population (all causes), the proportion of current and new cases of textile and leather allergic contact dermatitis prevented and the assessment periods. Furthermore, while SEAC agrees with the Dossier Submitter that the category of 'severe, chronic dermatitis' in the ECHA (2016) study fits best to contact allergies due to textile and leather, it has decided to do a sensitivity analysis of what the total benefits would be if the lower value for intangible costs was based on the €250 value for 'mild, acute dermatitis'. Considering all these sensitivity analyses, the lowest bound of the annual human health benefits would be €708 million (assuming that the average prevalence/frequency of positivity patch tests to textiles is 0.5%), while the highest bound would be €78 billion (assuming that the average prevalence/frequency of positivity patch tests to textiles is 10% and 70% of current and new cases protected). The results from the sensitivity analyses are presented in the table below.

Table 3. Total annual human health benefits under different scenarios- sensitivity analysis

Sensitivity Scenarios	**Total annual human health benefits expected from the restriction proposed (RO1a) (in million €)**						
	10% frequency of positivity patch tests	0.5% frequency of positivity patch tests	8%-12% the prevalence of ACD in the general population	0.8%-2% the prevalence of ACD in the general population	For 30 years assessment period	For 10 years assessment period	€250/case as the lower intangible cost
Min; Min	14 000	708	3 900	7087	7 081	9 450	3 745
Min; Max	53 000	2 629	14 600	26 290	26 260	35000	26 290
Max; Min	21 000	1 053	6 900	19 500	10 504	14 000	5 579
Max; Max	78 000	3 900	27 500	72 200	38 950	51 900	39 042

SEAC concurs with the sensitivity analyses. The results from the sensitivity analysis indicates that while the values of annual human health benefits may be much lower than the estimate provided by the Dossier submitter they are still significant.

Overall, SEAC agrees with the range of values provided by the Dossier Submitter on the monetary values, numbers of cases of allergic contact dermatitis and the human health benefits. If the lower values on prevalence proposed in the consultation on the Annex XV dossier are considered the values of human health benefits will be substantially reduced but the expected human health benefits from the proposed restriction will remain significant. The proposed restriction is also expected to prevent some irritant contact dermatitis and urticarial cases and in addition. However, due to lack of data for these cases, these benefits to society

cannot be quantified. Additional social benefits will be generated from avoided costs associated with the exposure avoidance (search and purchase of e.g. allergen-free clothes and shoes). However, SEAC does not have the required data to quantify and monetise these benefits.

Comparison of benefits for the three Restriction options RO1a, RO2 and RO3 assessed by the Dossier Submitter

Based on the estimation provided by the Dossier Submitter in the Background Document the total annual human health benefits expected from the proposed restriction RO1a are estimated to be €7 - €50 billion with a "reasonable" estimate between 10.5 and 33.4 billion (but they may be between €708 million and €78 billion when considering the uncertainties assessed in the sensitivity analysis). In addition, the Dossier Submitter notes that there may be additional benefits in terms of avoided costs associated with exposure avoidance (e.g. the search and purchase of allergen-free clothes and shoes), which are currently not quantified. Overall benefits associated with RO2 are expected to be significantly lower than RO1a. SEAC notes that the Dossiers Submitter does not provide estimates on the expected benefits under RO2. In the Background Document the Dossier Submitter explains that around 2/3 of all textile related cases of allergy seem to be attributed to disperse dyes according to the literature (Bfr (2006); RIVM (2008) and RIVM (2014)), however, it is not clear which of these substances are on the list of concern. Therefore it is not possible to estimate a monetised value of benefits for RO2.

The human health benefits associated with RO3 are 40% lower than RO1a. They are estimated to be €3 - 14.7 billion based on a frequency of positivity of patch tests of 3% and a proportion of 50% of current and new cases protected and €4 - 20.6 billion based on a frequency of positivity of patch tests of 3% and a proportion of 70% of current and new cases protected. The Dossier Submitter considers a 'reasonable' estimate to be €3.9-10.7 billion and €5.6-15 billion respectively.

SEAC takes note of RAC's considerations of the risk reduction capacity and the scope of the substances of the three options. Therefore, SEAC concludes that the expected benefits of RO1a, followed by the RO2 will be larger due to their higher risk reduction potential associated with the scope of substances in comparison to RO3.

Other impacts

Summary of proposal:

The Dossier Submitter anticipates that distributional effects may occur after the entry into force of the restriction. The compliance costs borne by producers, importers and distributors of articles may be passed on to the consumers by increasing the consumer price of these articles. Nevertheless, the Dossier Submitter is of the view that this potential increase would likely be negligible since most of the market for textile and leather articles is highly competitive and the production and raw materials cost is generally a small component of the final consumption price of this type of article.

There may also be some positive income effects to low income consumers in EEA31, due to the fact that these consumers cannot afford to substitute allergenic apparel and footwear to allergen-free apparel and footwear (which are usually far more expensive) today in order to prevent their symptoms or to avoid sensitisation.

Moreover, distributional economic impacts may occur between outside EEA31 industry and inside EEA31 industry. Since 80% of textile and leather are imported from outside, the Dossier Submitter expects that the substitution costs and best practice associated costs would mainly impact the industry outside the EEA.

SEAC conclusions:

SEAC concludes that the restriction proposal is likely to result in some redistribution of costs and benefits. All EU consumers will benefit from the restriction through reduced incidence of allergic contact dermatitis due to the presence of skin sensitisers in textiles and leather articles. Allergen-free materials are expected to become mainstream because of the restriction, thereby removing costs currently incurred by some consumers wishing to revert to such materials without the restriction in place. SEAC concludes that, as a consequence of the competitive market (depending largely on import) and due to the small contribution of production and raw material costs on retail prices, a cost distribution from manufacturers down the supply chain towards consumers is likely to be minimal.

Key elements underpinning the SEAC conclusions:

SEAC agrees with the Dossier Submitter that the restriction may result in some consumer price increase of textile and leather articles due to industry passing on compliance costs. The Dossier Submitter considers the price increase to be negligible because of the mostly highly competitive market for textiles and leather and the finding that production and raw material costs make up a small fraction of the consumer prices, which was exemplified in the Background Document at SEAC's request.

SEAC concurs with the finding of the Dossier Submitter that the restriction may have some positive income effect on consumers. Safety aware consumers suffering from allergic contact dermatitis or wanting to prevent exposure to allergens in the first place would in theory no longer have to revert to more expensive allergen-free textiles and leather articles after entry into effect of the proposed restriction. Hence, for these consumers the restriction would have a positive income effect without any further improvement as regards to their health situation. For the majority of consumers who either are less aware of skin sensitisers in textile and leather articles or who are aware but have insufficient income to buy allergen-free textile and leather articles, the restriction will provide health benefits due to improved access to allergen-free textile and leather articles at affordable price. As regards the market for textile and leather articles, SEAC notes that the EU market depends largely on import (80% for textiles). Therefore, SEAC considers it likely that the majority of testing and compliance and substitution costs are incurred by non-EU companies.

<u>Overall proportionality</u>

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 (even if the lower prevalence values and smaller portion of the prevalence incidents on overall population are considered) 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 low costs of substitution for some substances, ongoing substitution for others and given that for some it is expected 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 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:

SEAC concludes that the proposed restriction is proportionate to the risk because: the expected benefits to society (i.e., prevented current and avoided new cases of allergic contact dermatitis, irritation contact dermatitis and urticarial cases) are higher than the compliance costs for industry. It is based on a grouping approach addressing all skin sensitising substances (to the extent possible given the available information), therefore minimising the risks of regrettable substitution. Finally, the proposed restriction may be particularly beneficial for low income consumers into the EEA31 due to the access to allergen-free textile and leather articles at affordable price. SEAC considers that all three ROs are proportional to the risk. RO1a and RO3 are likely to be more proportionate than RO2. RO3 appears to be more implementable than RO1a in terms of practicality and monitorability but has lower risk reduction capacity compare to RO1a**.**

Key elements underpinning the RAC and SEAC conclusions:

SEAC has reviewed and agrees with the semi quantitative cost-benefit assessments conducted by the Dossier Submitter. Based on the figures provided by the Dossier Submitter, SEAC concludes that the proposed restriction is proportionate. The expected benefits from the proposed restriction are significant and the costs of compliance are expected to be affordable to industry.

SEAC notes that uncertainty related to the cost estimates remains due to lack of data for some substances. However SEAC agrees with the Dossier Submitter that the extra costs of compliance borne by industry (outside and inside EEA31) would not impact significantly the final consumer price of textile and leather articles because of the high level of market competition for these articles, and the fact that production and raw materials cost is generally one small component of the final price of this type of articles.

Since 80% of textile and leather articles are imported from outside the EEA31, the impact on the EEA31 textile and leather industry would be lower compared to industry outside the EEA31.

SEAC acknowledges that there are uncertainties related to the use of prevalence data of allergic contact dermatitis and hence of the benefits estimates due to the quality of the data available. However, SEAC agrees with the sensitivity analysis performed by the Dossier

Submitter showing that the expected human health benefits from the proposed restriction will remain significant in case lower prevalence assumptions are used (i.e. as proposed in the consultation on the Annex XV dossier in comment#2783).

SEAC concurs with the Dossier Submitter that the proposed restriction may generate some positive income effect for low income consumers in the EEA31: due to the fact that these low income consumers may currently not be able to afford to substitute allergenic apparel and footwear to allergen-free apparel and footwear (which are usually far more expensive) in order to avoid symptoms (for those who are already sensitised) or induction of the allergy (for those who are not yet sensitised).

Furthermore, the proposed restriction has the additional benefit of avoiding regrettable substitution. Targeting in a single restriction proposal all classified skin sensitiser substances in textile and leather products should reduce the risk of regrettable substitution taking place, even if the actual magnitude of costs and benefits remains uncertain. Replacement of restricted chemicals by not yet classified chemicals is possible, but industry is expected to try to use long-term alternatives to avoid further substitution costs later on.

While there are uncertainties related to both the costs and the benefits, based on the available information and the sensitivity analyses undertaken, SEAC concludes that these uncertainties are not large enough to undermine the conclusion that the proposed restriction is proportionate.

Comparison of restriction options

Overall, SEAC agrees with the Dossier Submitter's assessment and concludes that the three restriction options are proportionate; RO1a and RO3 are likely to be more proportionate than RO2. Table 4 provides a comparison of the costs and benefits of the proposed restriction options. As explained, there is uncertainty regarding the different cost elements for which the consultation on the SEAC final draft opinion may still provide further information.

Table 4: Comparison of costs and benefits of the restriction options

Costs expected for the restriction proposed	Total human health benefits expected of the restriction proposed
RO1a	**RO1a**
Substitution costs: **Raw material costs** Considering also negative costs: -€25 million per year (if rosins are substituted with acrylics) or €3 million per year (if rosins are substituted with polyurethane binders) Without the negative costs: €0.01 million or €23.8 million per year **Reformulation costs** (based on rubber accelerators), cost €13.1 million **Enforcement costs for industry and authorities:** €0.082 million	€7 - €50 billion with a "reasonable" estimate between 10.5 and 33.4 billion (but they may be between €708 million and €78 billion when considering the uncertainties assessed in the sensitivity analysis) + avoided costs associated to the exposure avoidance (search and purchase of e.g. allergens-free cloths and shoes)
RO2	**RO2**
Substitution costs: Similar or slightly lower than RO1a **Enforcement costs:** Similar or slightly lower than RO1a	**<<(LESS THAN)** €7 087 - 9 100 million (least conservative bounds) **<<(LESS THAN)** €39 000 - 50 200 million (most conservative bounds) + costs associated to the exposure avoidance (search and purchase of e.g. allergens-free cloths and shoes)
RO3	
Substitution costs: very low **Enforcement costs:** Lower than RO1a	€3 000- 4 200 million (least conservative bounds) €16 700- 23 400 million (most conservative bounds) + costs associated to the exposure avoidance (search and purchase of e.g. disperse dyes-free cloths and shoes)

The cost/benefit ratio is not quantified by the Dossier Submitter and it was not possible for SEAC to compare quantitatively the ROs.

The benefits associated with RO2 are expected to be significantly lower than RO1a, since disperse dyes are known to cause allergy to the general population, but those that do not

already have a harmonised classification are not in the scope of RO2. SEAC recognises that the associated exact human health benefits could not be quantified by the Dossiers Submitter since the proportion of allergy cases attributed to the substances in the list of concern is not known. However, all of these substances are disperse dyes and the literature review still gives an indication that a significant proportion of allergic contact dermatitis may be due to disperse dyes contributing significantly to the overall contact allergies from textile and leather. The costs, practicality and monitorability of RO2 are not expected to differ significantly from RO1a. Therefore, RO2 is expected to provide a lower risk reduction capacity and is less proportionate compared to RO1a.

RO3 appears to be more desirable than RO1a as it may have a better cost/benefit ratio (not quantified) due to the fact that the costs associated with RO3 would be very low (only disperse dyes are considered) and the benefits relatively high (but approximately 40% lower than RO1a). However, SEAC concurs with the Dossier Submitter that RO1a shows the best capacity of mitigating the risk targeted in this restriction proposal, by covering a much higher number of sensitising substances and being dynamically linked to the CLP regulation. It is expected that RO1a would allow protecting at least 70%-90% of current and new cases of sensitisation within the EEA31.

Uncertainties in the proportionality section

There are uncertainties related to the methodological approach which is used to include or exclude substances for the socio-economic assessment in the proposed restriction. Firstly, substances may have been missed in the original search done by the Dossier Submitter. As previously explained, ECHA undertook a search of REACH registration dossiers for 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. This search yielded 243 registered substances which passed the aforementioned search filters, giving an indication that more substances than the 94 substances on the IN-list may be used in the EU in the manufacturing of textiles and leather and other articles in the scope of the proposed restriction. SEAC considers likewise this would apply to articles manufactured outside the EU. Since the cost assessment is based on the substances on the IN-list, there may be additional costs related to substances excluded from that list. Secondly the estimation of the mg/kg limits done by KemI (2019) can be an over- or underestimation since it is based on assumptions and best available knowledge. Uncertainties also follow due to the lack of adequate information. For the cases where substitution costs have not been assessed due to information gaps, there is a substantial risk that there are some important substitution costs, which have not been assessed properly and this will affect the total cost. Uncertainties related to the costs, benefits, and proportionality to risk of the proposed restriction options are discussed in the preceding sections.

Uncertainty related to the negative price of some alternatives compared to the skin sensitising substances to be replaced is reported. SEAC considers it very unlikely that costs in reality are negative because industry would probably already have substituted the skin sensitising substances of concern. SEAC considers that there may be differences in quality, efficacy (volumes to be applied) and other feasibility considerations that play a role in the substitution that are not included in the costs assessment due to lack of information.

As a result of the proposed restriction both industry and enforcement authorities will need to

perform additional testing in order to ensure compliance. The extent of these additional required testing that needs to be performed compared to the testing already undertaken is not known. For industry it is however assumed that these costs would not outweigh possible gains for alternative suppliers due to increased sales of alternative substances. To some extent the already existing quality control testing performed by the concerned companies may already provide the necessary information. In general, the costs are not expected to outweigh the overall societal gains.

Uncertainties related to the human health impact assessment. SEAC acknowledges that there are uncertainties related to the prevalence and associated human health benefits estimates due to the quality of the data available. Furthermore the socio-economic assessment is based on allergic contact dermatitis cases. Occupational contact dermatitis and urticarial cases are not taken into account due to information gaps and thus may be a source of underestimation of benefits.

The calculated prevalence of textile and leather allergic contact dermatitis is based on diagnosed sensitisation from positive patch tests but sensitisation is known to be under-diagnosed and under-reported therefore there may be a source of underestimation of benefits. Furthermore, the number of new textile and leather allergic contact dermatitis prevented each year is assumed to be constant over time until 2103 - this may be a source of underestimation of benefits since the EEA31 population increases over time (and so does the number of individuals exposed to allergens contained in textile and leather under the baseline). The assumption that 70%-90% of new cases of textile and leather allergic contact dermatitis would be avoided may thus be a conservative assumption and a source of underestimation of the benefits. Another source of underestimation may be the lack of information on allergic contact dermatitis cases caused by exposure to skin sensitisers contained in other materials that are in the scope of the proposed restriction (such as synthetic leather and non-fibrous polymers used in the targeted consumer articles. In addition the healthcare costs are partly assessed from Saetterstrom et al (2014). However, healthcare provision (primary and secondary care) in Denmark is to a great extent publicly funded (85% of healthcare costs are financed through taxes), so the healthcare costs may be somehow underestimated. The selected intangible cost from ECHA (2016) corresponds to the range of values for chronic dermatitis, where the lower value of the willingness to pay starts at €2 000 per case thus the intangible cost may be overestimated. Prevalence of contact dermatitis in the general population is estimated to be between 15%-20%. These data are considered robust since they are taken from the literature from thorough studies. However, the Dossier Submitter acknowledges that this prevalence may be decreasing due to the regulations adopted since the past few years on different skin allergens such as nickel and chromium. Moreover, the prevalence of contact dermatitis in the general population may differ from one country to another within the EEA31 due to e.g. cultural clothing habits or local fashions, etc. The Dossier Submitter however couldn't assess whether these potential differences would be a source of underestimation or overestimation.

In addition to this, there is an uncertainty as to how the dynamic connection with CLP will evolve. In cases where newly (after restriction implementation) identified substances (with a harmonised classification as skin sensitizer and with mg/kg level for articles at point of sale, above the allowed), do not coincide with the groups and substances analysed in the SEA, the benefit cost ratio might very well be different from what is assessed. It is difficult to assess

the impact on the proportionality to the risk of the restriction, because it depends on the (unknown) significance of the possible underestimation of the cost of compliance. Therefore, this is regarded by SEAC as the main source of uncertainty in its assessment.

When comparing the costs and benefits, it should be noted that the cost assessment is based on the substances on the IN-list, while the benefit assessment is done based on overall (not-substance specific) prevalence and incidence data for allergic contact dermatitis. The consultation on the Annex XV report did not yield much new data on costs, apart from some information that testing costs will be higher for a restriction with many substances in the scope. The benefits assessment, on the other hand, is based on overall (not-substance specific) prevalence and incidence data for allergic contact dermatitis. Therefore, it is not possible to determine the share of total benefits associated with e.g. the substances on the IN-list. While there are uncertainties related to both the costs and the benefits, based on the available information and the sensitivity analyses undertaken, SEAC concludes that the magnitude of these uncertainties does not undermine the conclusion that the proposed restriction is proportionate.

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 Safety Gate system (EU rapid alert system for dangerous non-food products formerly known as RAPEX) 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:

Based on the information available in the Background Document, advice from Forum and comments provided in the consultation on the Annex XV dossier SEAC concurs with the findings by the Dossier Submitter that the restriction proposed is practical and can be enforced.

Key elements underpinning the RAC and SEAC conclusions:

SEAC has taken note of the Forum advice stating enforcement could be challenging due to the numerous substances in the scope of the proposed restriction. For some substances the methodology for sampling, sample preparation and analysis are not yet established which will result in difficulties for enforcement. The many substances covered by the restriction proposal will make it impossible for authorities to check on all of them. A reduction of the scope or a master list of the most important ones would help to achieve the goal of the proposal. SEAC notes such master list is available in the Background Document (the IN-list in Table 19 in Annex E).

SEAC considers that from an enforcement and practicality perspective it is important the Dossier Submitter aimed to seek consistency between the proposed restriction and the existing entry 72 on 33 CMR substances in clothing and related accessories, footwear and related textile articles. However, there are also a range of differences which may be confusing for enforcement and necessitate for guidance and explanation. Important differences noted by SEAC are:

- entry 72 contains a closed list of chemicals whereas the proposed skin sensitiser restriction contains both a closed list and a dynamic link with Annex VI of CLP;
- The proposed skin sensitiser restriction includes natural leather where entry 72 does not;
- The proposed skin sensitiser restriction exempts biocides where entry 72 does not;
- The proposed skin sensitiser restriction contains an exemption for parts of footwear with no skin contact where entry 72 does not have such exemption;
- The proposed skin sensitiser restriction covers textile, leather, fur and hide and synthetic leather articles that may come into contact with the human skin comparable with clothing, where entry 72 only covers such articles made of textile;
- The proposed restriction covers single use textiles such as tissues and nappies where entry 72 does not.

SEAC has no information on the feasibility of the 36 months transitional period from enforcement perspective.

Comparison of RO1a, RO2 and RO3:

SEAC considers the practicality and enforceability to be different based on the differences in chemical scope. The ease of enforcement would be highest for RO3 because of its limited chemical scope. Both RO1a and RO2 would require more effort due to their linkage with CLP Annex VI and the need to prioritise relevant chemicals (i.e. from a masterlist as presented in Table 19 of the Background Document) for inspection purposes.

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.

The possibilities to monitor the results of the implementation of the proposed restriction through allergenic patch testing with the textile dyes mix and other relevant test series could be limited due to the large chemical scope and confounding factors such as other sources of exposure. The use of recurring public health studies, such as the Swedish Environmental health report could be another way to monitor the effect of the restriction. Lastly, enforcement reports and market surveillance could show if the concentration of skin sensitising substances present in the articles are lowered.

RAC and SEAC conclusions:

SEAC concurs with the findings by the Dossier Submitter that the restriction proposed is monitorable but also identifies there are uncertainties.

Key elements underpinning the RAC and SEAC conclusions:

Little information is available in the Background Dossier on the monitorability of the restriction proposal. The Forum provided no advice on this aspect and in the consultation on the Annex XV dossier no information was obtained. SEAC considers patch testing of individuals not an effective means to monitor the effectiveness of the restriction given the uncertainties around possible other exposures and the large and possibly expanding chemical scope of the restriction. SEAC considers public health studies could provide some indications on changes in incidences of allergic contact dermatitis among the EU population but also such studies would have high uncertainty as regards the question which part of the reported allergic contact dermatitis cases would be attributable to skin sensitisers in the articles targeted by the restriction. Moreover, since the article scope is much broader than only clothing and footwear it will be very difficult for consumers to understand when to link a allergic contact dermatitis case to exposure to a ‘relevant’ article. SEAC considers enforcement reports (i.e. through international REACH enforcement projects) and use of market surveillance systems the best options ensuring valuable effectiveness monitoring data on the proposed restriction.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

SEAC

Summary of proposal:

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

- **Scope**: Irritant, 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. Also, 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.

- **Analysis of alternatives**: substances may have been missed in the original search

- **Economic impacts/substitution costs**: lack of adequate information, among others, on: the use of some substances (including intermediates and solvents), their requirement in the process, their potential substitute that still persist in certain areas, regrettable substitution, etc.

- **Total substitution costs**: that the total cost calculations are based on the price difference of the substance used and the alternative assuming that all factors (for example volume and quality) are held constant.

- **Human health impact assessment**: A sensitivity analysis has been performed on several parameters: the prevalence of patch tests positivity to textiles, the prevalence of contact dermatitis in the general population (all causes) and the proportion of current cases of textile and leather allergic contact dermatitis protected.

Others: there is an uncertainty as to how the dynamic connection with CLP will evolve.

SEAC conclusions:

SEAC's analyses of uncertainties in the conclusions and corresponding justifications is given in the respective sections of this opinion. In summary, SEAC notes the following:

- Costs of the proposed restriction: based on the assessment provided by the Dossier Submitter and on information submitted during the consultation on the Annex XV dossier, SEAC concludes that the estimation of costs of the proposed restriction is associated with uncertainty following the lack of adequate information for many substances in the scope. Due to information gaps, there is a substantial risk that there are some important substitution costs, which have not been assessed properly and this will affect the total costs. Some information submitted in the consultation on the Annex XV dossier points at possible underestimation of testing and compliance costs for the textile sector.
- Benefits of the proposed restriction: based on the assessment provided by the Dossier Submitter and on information submitted during the consultation on the Annex XV dossier, SEAC concludes the human health benefits may have been underestimated or overestimated in the impact assessment. Underestimation could be due to only accounting for allergic contact dermatitis and no other related effects, due to underreporting or diagnosis of positive patch testing, population increase not accounted for in the 80 year assessment period, a conservative assumption on the percentage of new allergic contact dermatitis cases avoided and lack of information on allergic contact dermatitis cases caused by exposure to skin sensitisers contained in other materials that are in the scope of the proposed restriction (such as synthetic leather and non-fibrous polymers used in the targeted consumer articles). In addition, health care costs may have been underestimated for the EU as these were partly based on a Danish source including a large proportion of public funding which does not apply in other EU countries. On the other hand, the allergic contact dermatitis prevalence in the general population caused by textile and leather allergens may be overestimated and there may be a bias in the patch testing results due to the repeated presence of certain well-known allergens. Also, prevalence may have decreased in recent years due to the regulations adopted on different skin allergens such as nickel and chromium. SEAC notes that the Dossier Submitter has undertaken additional sensitivity analyses to address most of these uncertainties. In addition to this, there is an uncertainty as to how the dynamic connection with CLP will evolve. In cases where newly (after restriction implementation) identified substances (with a harmonised classification as skin sensitizer and with a mg/kg level for articles at point of sale, above the allowed), do not coincide with the groups and substances analysed in the SEA, the benefit cost ratio might very well be different from what is assessed.
- Restriction being the most appropriate RMO: SEAC considers uncertainties in the conclusion on RO1a being the most appropriate RMO in comparison with RO2 and RO3 limited. However, based on information in the Background Document and provided in

the consultation on the Annex XV dossier SEAC notes the practical implementability of the proposed restriction and associated uncertainties in the compliance and enforcement costs are high. SEAC has taken note of the fact that many stakeholders argued against the practical implementation of an all-in restriction covering many skin sensitising chemicals of which only a limited number is used in the articles targeted by the proposal and state to be in favour of a closed list.

Key elements underpinning the SEAC conclusions:

Further information on SEAC's justification is provided in the respective sections of this opinion.