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/RES-O-0000006913-69-01/F

17 September 2020

12 March 2020

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

17 September 2020

ECHA/SEAC/RES-O-0000006913-69-01/F

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 17 September 2020.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted by consensus. of all members having the right to vote.

Contents

A. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Designation of the substance, of the group of substances or of the mixture	Conditions of 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[1] 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

[1] It should be noted that while the entry text proposed by the Dossier Submitter refers to "footwear" as a whole, the Dossier Submitter has in the Background Document clarified that its intention was to exempt 'those parts of footwear that do not come into contact with the human skin' (the underside is given as an example). This exemption is explained in section 1.1.4.2. Articles not covered by the restriction of the Background Document.

	category 1, 1A or 1B in Annex VI to Regulation (EC) No 1272/2008, or listed in Table 1. 3. The articles listed in paragraph 1, shall not contain the following substances equal to or above concentrations specified below: i. Chromium VI compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 1 mg/kg w/w for materials specified in paragraph 1 (after extraction, expressed as Cr VI that can be extracted from the material except for leather, fur and hide where the concentration is 1 mg/kg (0,0001 % by weight) of the total dry weight of the leather, fur or hide) ii. Formaldehyde in concentration greater than 30 mg/kg w/w for all materials specified in paragraph 1 iii. 1,4 paraphenylene diamine in concentration greater than 250 mg/kg w/w in textile and 80 mg/kg in leather, hides and furs iv. Nickel compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 120 mg/kg w/w in textile and 40 mg/kg in leather, hides and furs (after extraction, expressed as Ni metal that can be extracted from the material) v. Cobalt compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 70 mg/kg w/w in textile and 20 mg/kg w/w in leather, hides and furs (after extraction, expressed as Co metal that can be extracted from the material) vi. Substances not covered by paragraph 3 i-v and with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008, in individual concentration greater than 130 mg/kg in textile and 40 mg/kg in leather, hides and furs 4. Paragraphs 1 to 3 shall apply without prejudice to the application of any stricter restrictions or existing regulations. 5. Paragraphs 1 to 3 shall not apply to i. Clothing, related accessories, textile, leather, fur, hide or synthetic leather articles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (**) ii. Substances that are used as active ingredients in biocidal products within the scope of Regulation (EU) 528/2012. iii. The placing on the market of second-hand clothing, related accessories, textile, leather, fur, hide and synthetic leather

	articles other than clothing, or footwear which were in end-use in the Union before 31 January 2023. 6. When existing, the standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 to 3. (*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51) (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'

Table 1: List of additional substances of concern (Dossier Submitter)

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

[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%.

Substance name	CAS No.	EC No.
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.

A.1. THE OPINION OF RAC

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

The conditions of the restriction proposed by RAC are:

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
Substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in Annex VI to Regulation (EC) No 1272/2008 The substances listed in Table 2	1. Shall not be placed on the market for the general public in any of the following articles: i. Clothing and related accessories ii. Textile, leather, fur, hide and synthetic leather articles other than clothing which come into contact with the human skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing, such as: 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 2. 3. The articles listed in paragraph 1, shall not contain the following substances equal to or above concentrations specified below: i. Chromium VI compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 1 mg/kg w/w for materials specified in paragraph 1 (after extraction, expressed as Cr VI that can be extracted from the material except for leather, fur and hide where the concentration is 1 mg/kg (0,0001 % by weight) of the total dry weight of the leather, fur or hide) ii. Formaldehyde in concentration greater than 30 mg/kg w/w for all materials specified in paragraph 1 iii. 1,4 paraphenylene diamine in concentration greater than 250 mg/kg w/w in textile and 50 mg/kg in leather, hides and furs iv. Nickel compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 125 mg/kg w/w in textile and 25 mg/kg in leather, hides and furs (after extraction, expressed as Ni metal that can be extracted from the material) v. Cobalt compounds with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008 in individual concentration greater than 70 mg/kg w/w in textile and 15 mg/kg w/w in leather, hides and furs (after extraction, expressed as Co metal that can be extracted from the material) vi. Substances not covered by paragraph 3 i-v and with harmonised classification as skin sensitisers in category 1, 1A or 1B listed in Annex VI to Regulation (EC) No 1272/2008, in individual concentration greater than

	130 mg/kg in textile and 30 mg/kg in leather, hides and furs 4. Paragraphs 1 to 3 shall apply without prejudice to the application of any stricter restrictions or existing regulations. 5. Paragraphs 1 to 3 shall not apply to i. Clothing, related accessories, textile, leather, fur, hide or synthetic leather articles other than clothing, or footwear within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council (**) ii. Substances that are used as active ingredients in biocidal products within the scope of Regulation (EU) 528/2012. iii. The placing on the market of second-hand clothing, related accessories, textile, leather, fur, hide and synthetic leather articles other than clothing, or footwear which were in end-use in the Union before 31 January 2023. 6. When existing, the standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 to 3. (*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51) (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).'

Table 2 List of additional substances of concern (RAC)

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

[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%.

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

* Substances, not supported by RAC, to be included in the scope of the proposed restriction

A.2. 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 and SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
Substances with harmonised classification as skin sensitisers in Category 1 or 1A or 1B in	1. Shall not be placed on the market for the general public in any of the following articles: i. Clothing and related accessories

Annex VI to Regulation (EC) No 1272/2008 The substances listed in Table 3	ii. Textile, leather, fur, hide and synthetic leather articles other than clothing which come into contact with 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's 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 3. 3. The articles listed in paragraph 1 shall not contain the following substances equal to or above the concentrations specified below: i. Chromium VI compounds in individual concentration greater than 1 mg/kg w/w in textile and 3 mg/kg in leather, fur or hide (after extraction, expressed as Cr VI that can be extracted from the material) ii. Formaldehyde in concentration greater than 75 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 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 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 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. iv. Metallic parts of articles 6. Paragraphs 1 to 3 shall come into effect three years after entry into force of the restriction, with the following exceptions: i. The chromium VI concentration limit in leather, fur and hides as specified in paragraph 3.i shall decrease from 3 mg/kg to 1 mg/kg five years after entry into force ii. For nickel compounds as specified in paragraph 3.iv paragraphs 1 to 3 shall come into effect five years after entry into force iii. For cobalt compounds as specified in paragraph 3.v paragraphs 1 to 3 shall come into effect five years after entry into force 7. For substances that are classified as skin sensitisers in category 1, 1A or 1B in Annex VI to Regulation (EC) No 1272/2008 following the entry into force of this restriction, a 3-year transitional period shall apply before inclusion in the restriction entry. 8. 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 3: List of additional substances of concern (SEAC)

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[6]	68516-81-4	271-183-4
CI Disperse Blue 124[7]	15141-18-1	239-206-6
~~CI Disperse Blue 291*~~	~~56548-64-2~~	~~260-255-0~~
CI Disperse Brown 1	23355-64-8	245-604-7
CI Disperse Orange 1	2581-69-3	219-954-6
CI Disperse Orange 3	730-40-5	211-984-8
CI Disperse Orange 37/59/76	13301-61-6 12223-33-5 51811-42-8	236-325-1 602-312-8
CI Disperse Red 1	2872-52-8	220-704-3
CI Disperse Red 11	2872-48-2	220-703-8
CI Disperse Red 17	3179-89-3	221-665-5
CI Disperse Yellow 1	119-15-3	204-300-4
CI Disperse Yellow 9	6373-73-5	228-919-4
CI Disperse Yellow 23	6250-23-3	228-370-0
CI Disperse Yellow 39	12236-29-2	602-641-7
CI Disperse Yellow 49	54824-37-2	611-202-9
~~CI Disperse Yellow 64*~~	~~10319-14-9~~	~~233-701-7~~
CI Disperse Orange 149	85136-74-9	400-340-3
CI Disperse Violet 1	128-95-0	204-922-6
~~CI Disperse Violet 93*~~	~~268221-71-2~~	-

* Substances, not supported by SEAC, to be included in the scope of the proposed restriction

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

[7] 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%.

B. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

B.1. RISK ASSESSMENT

Justification for the opinion of RAC

B.1.1. Grouping and targeting

B.1.1.1. Summary of Dossier Submitter's proposal:

Skin sensitisation includes two phases. First, an allergenic substance primes the immune system (induction). The second phase (elicitation) takes place after re-exposure to the allergen and is associated with the manifestation of allergy, i.e. the allergic contact dermatitis. A lower level of exposure is generally considered to be required for elicitation than for induction to occur.

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

In total, more than a thousand substances fall within the scope of the restriction proposal. However, it is acknowledged that not all chemical substances within the scope will be used in the production of textile and leather articles, and not all will be present in the finished article placed on the market. A list of substances with skin sensitising properties that may be present in finished textile and leather articles was developed by the Dossier Submitter and it includes in total 94 substances, of which 70 have harmonised classifications as skin sensitisers in Category 1/1A/1B, and 24 are on the list of concern (the disperse dyes referred to above). This list is called the IN-List and compiles the information the Dossier Submitter has for each chemical or group of chemicals, such as CAS numbers, expected concentration in articles at point of sale, proposed concentration limits and availability of alternatives and analysis methods. The IN-List is indicative and not exhaustive. It cannot be excluded that other substances with harmonised classifications as skin sensitisers will also be present in the articles covered by the restriction proposal.

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

The articles covered by this restriction proposal are essentially the same as the articles covered by the recently adopted entry 72 restriction of Annex XVII of REACH on CMR

substances[8], with some additions and amendments. For example, articles made of leather, fur and hide are included in this restriction proposal but specifically excluded from entry 72. While wristwatch straps are explicitly listed in the explanatory guide on entry 72, in the proposed restriction the Dossier Submitter has covered fashion articles more broadly (mentioning e.g. wrist bands, braces, neck laces, straps and bands). The restriction proposal covers childcare articles other than toys (valances, baby 'nests', baby chairs, bibs, etc.) which are not explicitly mentioned in entry 72[9]. Napkins and table linen (that are re-usable), carpets, mats and rugs are also covered by the proposed restriction but not by entry 72. The proposed restriction contains an exemption for parts of footwear with no skin contact where entry 72 does not have such an exemption.

The Dossier Submitter has also specified that the following materials and articles are covered: prints and coatings, articles made of synthetic leather, articles made of neoprene, other rubber materials or other polymer materials, and disposable sanitary towels, napkins, tissues and nappies.

B.1.1.2. RAC conclusion(s)

RAC is of the opinion that substances known to have intrinsic properties as skin sensitisers should be restricted in (i) clothing and related accessories, (ii) footwear (iii) articles with similar skin contact made of either textile, leather, synthetic leather, hides or furs, as well as (iv) disposable sanitary towels, napkins, tissues and nappies.

The skin sensitisation hazard is indicated by:

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

B.1.1.3. Key elements underpinning the RAC conclusion

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

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

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

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

B.1.1.3.1. Articles covered by the restriction proposal

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

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

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

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

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

B.1.1.3.1.1. Clothing and related accessories

This restriction proposal targets clothing and related accessories, including single-use clothing. This includes day clothes, suits and ties, underwear, nightwear and hosiery. Outerwear, including coats and jackets as well as scarves, shawls, hats, gloves are also covered. Considering that dermal contact with sensitising substances in textile and leather

articles can induce contact allergic dermatitis, RAC is of the opinion that including all articles of clothing and related accessories in the scope of the restriction is appropriate.

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

Sportswear and swimwear are included in the scope of the restriction, similarly to entry 72 of REACH Annex XVII. The Dossier Submitter, however, intends to also include sports equipment in contact with the skin. “Sport equipment” should be understood as only articles that can be interpreted as clothing. This would include, for example, shin pads or ski masks and exclude other articles such as balls or rackets. RAC is of the opinion that sports equipment made of textile or leather, with the clarifications made above, should be included in the proposed restriction. RAC also notes that the perspiration induced by sporting activities might increase the concern related to skin sensitisation. RAC therefore supports the inclusion of swimwear, sportswear and sports equipment in contact with the skin in the scope of the restriction.

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

B.1.1.3.1.2. Footwear

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

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

The proposal further includes in the scope inner soles that can be purchased separately from

shoes. Considering that a prolonged skin contact with textile or leather might occur during the use of inner soles, their inclusion in the scope of the restriction is supported by RAC.

It should be noted that 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). This exemption is not specified in the entry text proposed by the Dossier Submitter but is instead presented only in the Background Document (section 1.1.4.2. Articles not covered by the restriction).

B.1.1.3.1.3. Other articles that come into contact with the skin under normal or reasonably foreseeable condition of use to an extent similar to clothing

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

Childcare articles are defined as "*any products intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of the children*" based on restriction entries 51 (DEHP, DBP and BBP) and 52 (DIDP, DINP and DNOP) of Annex XVII. They comprise for example valances, baby 'nests' and baby chairs. Such articles that were not designed "for use in play", are not covered by the EU Toys Safety Directive No 2009/48/EC. There is to date no specific European legislation regulating the skin sensitisation concern related to childcare articles made of textile fibres or leather. RAC therefore supports the inclusion of childcare articles in the scope of the present restriction.

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

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

The Dossier Submitter proposed re-usable napkins and table linen to be included in the scope.

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

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

B.1.1.3.1.4. Disposable sanitary towels, napkins, tissues and nappies

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

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

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

B.1.1.3.2. Articles not covered by the restriction proposal

B.1.1.3.2.1. Specific articles not covered by the scope of the restriction

The Dossier Submitter provided a list of several articles that are not intended to be covered by the scope of the proposed restriction:

- jewellery;
- glasses and sunglasses;
- curtains;
- textile lampshades and wall decorations;
- filling materials in chairs, armchairs and sofas;
- and parts of footwear that do not come into contact with the human skin under normal or reasonably foreseeable conditions of use, such as the underside of footwear.

B.1.1.3.2.2. Second-hand articles

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

B.1.1.3.2.3. Articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment

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

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

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

B.1.1.3.2.4. Articles within the scope of Directive on Toys Safety No 2009/48/EC

The Toy Safety Directive 2009/48/EC defines the safety criteria that toys must meet before they can be marketed in the EU. The articles targeted by this Directive are therefore excluded from the scope of the present restriction. Nevertheless, the Annex I of the Toy Safety Directive presents a list of products that, in particular, are not considered as toys within the meaning of the Directive. This list includes, in particular, fashion accessories for children which are not for use in play. These articles are therefore considered to fall within the scope of the present restriction if they are made of textile, leather, synthetic leather, fur or hide.

In addition, childcare products made of textile, leather, synthetic leather, fur or hide, such as valances, bibs, baby ‘nests’ or baby chairs that were not designed “for use in play” do not need to meet the Toys Safety Directive requirements. These products are therefore interpreted to fall within the scope of the proposed restriction.

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

B.1.1.3.3. Substances covered by the restriction proposal

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

B.1.1.3.3.1. Chemical substances having a harmonised classification as skin sensitisers in Category 1/1A/1B according to the CLP Regulation

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

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

To date, there is no exhaustive list of substances used in the manufacturing processes of the articles within the scope of the restriction. The Dossier Submitter presented a list of substances with skin sensitising properties that are expected to be found in the manufacturing process of textile and leather articles (Table 19 in Annex E of the Background Document). This list is referred to by the Dossier Submitter as the ‘IN-list’ and includes in total 70 substances having a harmonised classification as Skin Sens. 1/1A/1B. According to this list, RAC acknowledges that most chemicals having a harmonized classification as skin sensitisers are not found in clothing, footwear or other related articles. However, this list of substances was concluded to be of limited reliability by the Dossier Submitter and only targeted clothing and footwear articles. It cannot be excluded that other skin sensitising substances might be

present in finished articles included in the scope of the proposal but were not highlighted during the consultancy study.

A large number of substances may be involved during the manufacture of articles within the scope of the restriction. For example, ECHA searched REACH registration data to find out how many registered substances with harmonised classification under CLP as skin sensitisers 1/1A/1B have service life uses related to textiles and/or leather and which are categorised as either: dyes, plasticisers, acrylates or diisocyanates. This search identified 243 substances, clearly exceeding the IN-list collated by the Dossier Submitter which contains 94 substances (70 of them with harmonised classifications as skin sensitisers in Category 1/1A/1B). Numerous manufacturing processes can be involved, and such processes may vary with time. Overall, the available data presented in the restriction proposal is considered of limited reliability and does not allow a complete picture of the skin sensitising chemicals present in articles within the scope of the restriction to be understood.

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

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

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

B.1.1.3.3.2. Chemical substances without harmonised classification as skin sensitisers but with skin sensitising concern

The Dossier Submitter proposes to include in the scope of the restriction an additional list of substances (Table 1). Although they do not have a harmonised classification as Skin Sens.

1/1A/1B, these substances have skin sensitising properties. This list comprises 24 disperse dyes.

According to Article 36 of the CLP Regulation, skin sensitisation is not a prioritised hazard category. Many sensitising chemicals do not have a harmonised classification at the moment. Consequently, RAC agrees that skin sensitising substances without harmonised classification can be present in textiles or finished leather articles. Inclusion of an additional list of substances of concern but without a harmonised skin sensitising classification is therefore considered appropriate to adequately protect consumers against skin sensitisation and at the same time to prevent regrettable substitution of substances already classified as skin sensitisers.

The disperse dyes presented in Table 1 were included in voluntary schemes because of their skin sensitising properties. These schemes include the Oeko-tex standard, Bluesign, Global Organic Textile Standard, EU Ecolabel and Nordic Swan Ecolabel, as well as (manufacturing) restricted substances lists ((M)RSL), such as Zero Discharge of Hazardous Chemicals. In addition, two of the dyes, Disperse Yellow 23 and Disperse 37/59/76, were detected by ANSES in clothing and footwear. This study indicated that these disperse dyes were linked to allergic contact dermatitis reaction in patients (ANSES, 2018).

B.1.1.3.3.3. Chemical substances with biocidal properties

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

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

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

B.1.1.3.4. Substances of concern outside the scope of this restriction proposal

Some substances were highlighted by the Dossier Submitter to be of concern regarding skin sensitisation but remained outside the scope of this restriction proposal. The four following substances were concluded not to have triggered sensitisation in patients despite being

quantified in articles in the ANSES (2018) study.

Detailed information on the studies can be found in Annex I to this opinion. In addition, the Dossier Submitter pointed out a potential concern for chromium (III). For the substances that are known skin sensitisers but do not yet have a related harmonised classification, RAC recommends (for example to Member State competent authorities or industry) to consider a proposal for harmonised classification regarding skin sensitisation so that these substances will be classified and hence ensure a higher level of protection to consumers.

B.1.1.3.4.1. Benzyl benzoate

Based on an analysis by SCCS, RAC acknowledges that benzyl benzoate is a contact allergen in humans. The ANSES (2018) study also demonstrated that benzyl benzoate can be present in clothes and footwear articles. RAC therefore considers that skin sensitisation caused by an exposure to benzyl benzoate in clothes and footwear might be a concern although no clear risk was established in the ANSES (2018) study.

B.1.1.3.4.2. Butyl hydroxyl toluene (CAS 128-37-0, EC 204-881-4)

RAC agrees that there is a concern regarding the skin sensitisation hazard of butyl hydroxyl toluene. The ANSES (2018) study also confirms that butyl hydroxyl toluene is present in textile and footwear finished articles. RAC therefore considers that skin sensitisation caused by an exposure to benzyl benzoate in clothes and footwear might be a concern, however a firm link between the presence of the substance in the article and an adverse reaction in the consumer could not be established in the ANSES (2018) study.

B.1.1.3.4.3. 2-phenoxyethanol (CAS 122-99-6, EC 204-589-7)

Overall, although 2-phenoxyethanol has a concern of skin irritation, no clear dataset demonstrating skin sensitisation is available for this substance. RAC however agrees that 2-phenoxyethanol can be present in articles within the scope of the restriction.

B.1.1.3.4.4. Para tertbutyl phenol (4-tert-butylphenol CAS 98-54-4, EC 202-679-0)

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

B.1.1.3.4.5. Chromium (III)

Chromium (VI) has a harmonised classification as Skin Sens. 1 within Annex VI of the CLP regulation and therefore is included within the scope of the restriction but Cr(III) does not have such a harmonised classification and therefore is outside the scope of the restriction. Some concerns were raised by the Dossier Submitter and in the consultation on the Annex XV report (#2368 and 2379) regarding the skin sensitisation potential of Cr(III) in leather and leather articles. It is also known that Cr (III) is a poorer protein binder than Cr(VI) and can leach out of leather gaining contact with skin, especially when inadequate tanning or inappropriate washing of leather has not removed any unbound Cr(III).

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

B.1.1.3.4.6. Other dyes

In the consultation on the Annex XV report, a stakeholder pointed to other categories of dyestuffs beside disperse dyes that currently do not have harmonised classification as skin sensitisers in Category 1/1A/1B according to the CLP Regulation, but are reported as skin sensitisers in the scientific literature. These were acid dyes: Acid Yellow 61, Acid Red 118 and Acid Red 359, basic dyes: Basic Black 1, Basic Brown 1, Basic Red 22 and Basic Red 46 and direct dyes: Direct Orange 34 (Ryberg et al, 2009). The Dossier Submitter noted that these substances are currently not included in any voluntary schemes, which was the main criteria for inclusion in the list of concern (Table 1). Nevertheless, RAC (in this opinion) and the Dossier Submitter (in the Background Document) highlight this to raise awareness, as these dyes could be considered for inclusion in voluntary schemes or a Member State could propose a harmonised classification.

B.1.1.3.5. Information gathering and search strategy for hazard and exposure assessment of substances

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

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

In addition, the substances on the list of concern (Table 1) were specifically targeted for information searches together with other disperse dyes having a harmonised classification as skin sensitiser.

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

exposure can be found in Annex III to this opinion.

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

B.1.2. Information on hazards

B.1.2.1. Summary of Dossier Submitter's proposal:

All the chemical substances in the scope of the proposed restriction have harmonised classifications as skin sensitisers in Category 1, 1A or 1B according to the CLP regulation or have been indicated to have skin sensitising properties. Sub-categorisation into category 1A (strong and extreme skin sensitisers) and 1B (medium or weak skin sensitisers) is made based on sufficient evidence of potency. Most substances included in the scope of this restriction proposal lack sub-categorisation according to potency. Information on hazard properties was retrieved from published literature, reports and REACH registrations (in accordance with ECHA guidance on information gathering ECHA, 2011). It should be noted that articles, such as clothes and footwear are not covered by CLP, and therefore do not require labelling according to chemical content.

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

B.1.2.2. RAC conclusion(s)

Although skin sensitisation is not life-threatening, it is a non-reversible process that can be very incapacitating for persons suffering from it. The severity of skin sensitisation may differ significantly in the affected population, ranging from situations where individuals do not suffer from any symptoms to situations where medical treatment is necessary. Depending on the part of the body affected and the severity of the symptoms, the allergic contact dermatitis derived from skin sensitisation may significantly impair the quality of life of the person, sometimes preventing them from working or even living normally.

RAC is of the opinion that substances with a harmonised classification as a skin sensitiser as well as substances which are known to have intrinsic properties (for example from the published literature) leading to skin sensitisation should be restricted in clothing and related accessories, footwear and articles other than clothing which come into contact with the human skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing.

B.1.2.3. Key elements underpinning the RAC conclusion(s)

A skin sensitiser is a substance that will lead to an allergic response following skin contact. Sensitisation includes two phases: the first phase is induction of the specialised immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e. production of a cell-mediated or antibody-mediated allergic response by

exposure of a sensitised individual to an allergen. This elicitation is associated with the manifestation of allergy, i.e. allergic contact dermatitis. The clinical features of allergic contact dermatitis include eczema, oedema, rash and itching, pruritus and vesicles. Symptoms can range from mild to severe, and they can appear within a few hours up to 10 days after the moment of contact with the allergen. The inflammatory response typically develops at the site of allergen contact. Symptoms are maximal within 2–3 days and, without further exposure to the allergen, they decline.

The Dossier Submitter proposes the restriction of more than 1 000 substances according to two different groups: i) Substances with harmonised classification in the Classification, Labelling and Packaging Regulation (EC) n° 1272/2008 as Skin sensitiser 1, 1A, 1B; which would include more than 1 000 substances (1 030 Skin Sens 1, 11 Skin Sens 1A and 9 Skin Sens 1B); ii) Substances without an harmonised classification but of skin sensitising concern; which would include up to 24 disperse dyes shown in Table 1 (Table 2 in the Background Document).

B.1.2.3.1. Substances with harmonised classification in the Classification, Labelling and Packaging Regulation (EC) n° 1272/2008

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

B.1.2.3.2. Substances without a harmonised classification but of skin sensitising concern: disperse dyes

RAC acknowledges that skin sensitisation is not a prioritised hazard category under CLP and, therefore, many chemical substances with allergenic properties will not yet have harmonised classifications as skin sensitisers. Hence, to limit the restriction to substances with harmonised classifications is judged insufficient by RAC to significantly reduce the risk of skin sensitising substances in the articles intended be within the scope of the proposed restriction.

The Dossier Submitter suggested adding the disperse dyes shown in Table 1 to the scope of the restriction since these have a capability of inducing skin sensitisation when present in the articles within the scope of the restriction. Most of the disperse dyes are azo dyes, but some are anthraquinones (Morgardt-Ryberg, 2009). Disperse dyes are mainly used for dyeing textiles (not only clothes, but also furnishing fabrics, car interiors and sports equipment), fur (in leather processing) and plastics (Morgardt-Ryberg, 2009).

Due to the lack of harmonised classification for these disperse dyes, RAC considers that a case-by-case approach is needed in order to determine whether the concern regarding the

capability of these substances to induce skin sensitisation is supported by experimental evidence or not.

The disperse dyes presented in Table 1 comprise azo, anthraquinone, nitro, quinoline and methine dyes.

RAC conclusion about azo disperse dyes

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

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

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

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

Overall, RAC supports grouping all the azo dyes reported in Table 1 and the inclusion of all these disperse azo dyes within the scope of this restriction. See Annex II in support of hazard identification for detailed information.

RAC conclusion about anthraquinone dyes

A total of six anthraquinone dyes were proposed in the scope of this restriction: Disperse Blue 3, 7, 26 and 35, Disperse Red 11 and Disperse Violet 1. Robust or sufficient evidence of skin sensitisation in humans was available for all anthraquinone dyes. RAC also notes that Disperse

Blue 1 (CAS 2475-45-8, EC 219-603-7), included in the IN-list, is an anthraquinone dye with harmonised classification as Skin Sens. 1. RAC is therefore of the opinion that the skin sensitisation hazard related to those substances supports the inclusion of the 6 anthraquinone dyes in the scope of the restriction. See Annex II to this opinion in support of hazard identification for detailed information.

RAC conclusion about nitro dyes

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

RAC conclusion about methine dyes

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

RAC conclusion about quinoline dyes

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

B.1.2.3.3. The dose-response relationship of skin sensitisers

B.1.2.3.3.1. Use of elicitation threshold doses as a reference value for risk assessment of skin sensitisers

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

The sensitisation or induction thresholds

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

The elicitation threshold

The threshold dose of elicitation reactions is usually lower than that of induction. This means that in general, a dose per skin area derived to protect already sensitised individuals from manifestation of allergic contact dermatitis (elicitation) will also protect naïve subjects from induction, but not the reverse. Based on the experience of the nickel regulation (Directive 94/27/EC), it has been shown that the dose that elicits allergic contact dermatitis in 10% of already sensitised individuals will not only protect 90% from developing allergic contact dermatitis, but will also prevent induction of skin sensitisation and thus decrease the incidence of allergy globally (Jensen et al., 2002; Johansen et al. 2000; Schnuch and Uter, 2003).

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

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

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

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

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

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

RAC conclusion

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

B.1.2.3.3.2. Derivation of elicitation thresholds for substances in the scope

Elicitation threshold doses (ED_{10} or MET10%-values) were searched for by the Dossier Submitter in the literature for the following substances: diisocyanates, (meth)acrylates, chromium (VI) compounds, nickel compounds, selected dyes, DCHP, rosin, formaldehyde, cobalt compounds, 1,4-paraphenylenediamine and glutaraldehyde. The selection of the substances was based on the information retrieval strategy as detailed in sub-section 3 of the "Key elements underpinning the RAC conclusion" section of this opinion.

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

The available information on elicitation threshold doses is summarised in the table below (Table 4). For some targeted substances/groups of substances such as allergenic disperse dyes, chromium and formaldehyde, sparse data was found (Table 4).

Table 4 Groups of substances or substances which were targeted for hazard information searches

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

			as reviewed in Fischer et al. 2011
Cobalt compounds	1	0.44 µg/cm^2	Fischer et al. 2011
1,4 paraphenylene diamine	1	1.5 µg/cm^2	Sosted et al. 2006
Glutaraldehyde	1	-	-

Hazard information related to targeted substances or groups of substances

Allergenic disperse dyes

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

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

The relative importance of individual dyes within the group of allergenic disperse dyes as culprit agents of allergic contact dermatitis is difficult to assess since only a few of them have been examined by epicuteaneous testing in clinical trials. In addition, there are frequent reports of cross-reactions with other dyes and with 1,4-phenylene diamine.

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

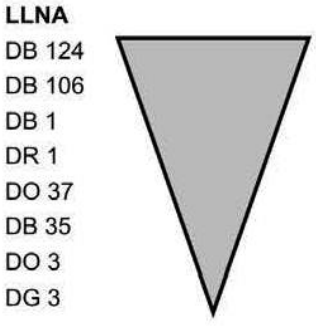

Figure 1: Variation in induction potency between different disperse dyes. DB refers to Disperse Blue, DR to Disperse Red, DO denotes Disperse Orange and DG refers to Disperse

Green (results from *in vitro* tests excluded) (BfR, 2012).

Elicitation threshold doses based on patch testing with dilution series have been studied with purified dyes Disperse Blue 106 and 124. Two out of 21 patients (10%) tested positively to concentrations corresponding to 0.00030 µg/cm^2 (lowest dose tested) of the purified Disperse Blue 106, and one of them also to the corresponding dose per square centimetre of the purified Disperse Blue 124 (Ryberg and al., 2009). This skin area dose is comparable to the lowest doses reported to give positive reactions in sensitised subjects, such as some phenol formaldehyde resins (Bruze et al, 1986; Zimmerson et al., 2000) and the perfume contact allergen chloroatranol (Johansen et al, 2003), all regarded as very potent sensitisers. Disperse Orange 1 has also been indicated to have the same low thresholds as Disperse Blue 106 and Disperse Blue 124 (Malinauskiene et al., 2011).
The value of 0.0003 µg/cm^2 was proposed by the Dossier Submitter as a threshold dose to calculate concentration limits in textiles and leather for all allergenic disperse dyes included in the scope.

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

Diisocyanates
No information on elicitation threshold doses for diisocyanates was found by the Dossier Submitter.

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

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

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

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

1,4-paraphenylene diamine

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

Direct dyes

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

Acid dyes

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

Rosin

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

DCHP

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

Glutaraldehyde

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

Default elicitation threshold dose

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

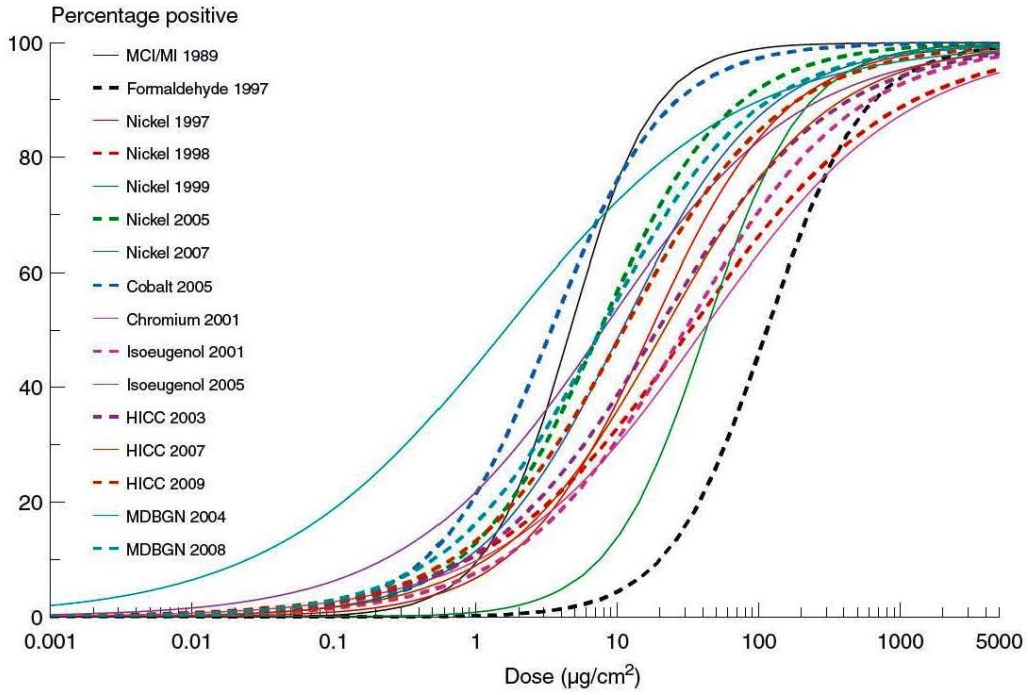

Figure 2: Logistic dose–response curve for 16 patch test elicitation dose–response studies with methylchloroisothiazolinone/methylisothiazolinone (MCI/MI), formaldehyde, nickel, cobalt, chromium, isoeugenol, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) (Fischer et al., 2011).

The results from the Fischer et al. (2011) study introduce the possibility of introducing a generic (default) elicitation concentration for regulatory risk assessment, in cases when there is a lack of data for establishing chemical specific thresholds. For example, a generic elicitation limit of 0.8 µg/cm^2 was used to derive the 0.01% (100 mg/kg) limit for potent fragrance allergens in cosmetic products indicative for safe use (SCCS, 2012). The SCCS comments that the suggested limit value is appropriate for weak to strong allergens, but that some strong and extreme sensitisers may require lower individual thresholds. On the other hand, for very weak sensitisers, this generic threshold may be overly conservative. An elicitation threshold dose of 0.8 µg/cm^2 has also been proposed by RAC, as the reference dose for skin sensitisation in the evaluation of the proposed restriction of tattoo inks and permanent make-up.

In the consultation on the Annex XV report, some stakeholders offered their support to the use of a generic elicitation threshold, while others pointed to limitations and uncertainties in the design of the studies on which the Dossier Submitter based their reference values, such as possible issues with test substance identity, a limited study base, and general lack of controls. It was also stressed that a limited number of substances were included in the derivation of the default elicitation threshold dose. Stakeholders also pointed out that there might be differences in potency between members of a group that would affect the threshold dose, and that one single reference dose may not fit all substances within a particular group, for example disperse dyes. Several stakeholders requested that substance-specific data should be used. Overall, however, no new data was submitted in the consultation to allow such a substance-specific approach.

RAC conclusion on reference doses

RAC notes that elicitation thresholds are derived from studies with a relatively low number of participants (5 for chromium VI, 21 for disperse dyes, 15 for 1,4-paraphenylenediamine, 20 for formaldehyde, 11 for cobalt and 13 for nickel). RAC examined the CLH dossier for disperse blue 124 (the most potent disperse dye sensitiser) finding no information that would allow the discrimination of elicitation threshold with lower levels of uncertainty. RAC also notes that other approaches, such as the use of specific concentration limits for classification and labelling of mixtures, would not be necessarily more protective than the derived elicitation thresholds since such concentration limits were derived for induction, a less sensitive phenomenon.

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

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

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

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

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

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

B.1.3. Information on emissions and exposures

B.1.3.1. Summary of Dossier Submitter's proposal

The frequent everyday use of textile and leather articles may lead to exposure of individuals of all ages to skin sensitisers. The level of exposure varies however according to the type of article. This means that uses with close bodily contact such as clothes, shoes and bed linen will lead to the highest exposures. Most of the articles referenced above are also used for prolonged periods of time and exposure occurs under occlusion, which increases the likelihood for substances to deposit on skin. Exposure from textile and leather articles not used in direct contact with skin, or for shorter periods of time, is estimated by the Dossier Submitter to be lower.

Two exposure scenarios were developed by the Dossier Submitter. The first scenario explores *the exposure to skin sensitising substances migrating from textiles*. Other articles and/or materials (e.g. latex, rubber, neoprene, synthetic leather, prints, coatings and disposable articles as napkins, tissues and nappies) that are included in the scope of the restriction on the basis of coming into contact with the skin to an extent similar to clothing are assimilated into the textile exposure scenario for risk assessment purposes. The reason being that these articles are typically made of materials either resembling a textile material, and/or having similar use patterns as textiles. The second scenario explores *the exposure to skin sensitising substances migrating from leather.* Other articles and/or materials (e.g. hides and furs) that are included in the scope on the basis of coming into contact with the skin to an extent similar to clothing are assimilated to the leather exposure scenario for risk assessment purposes.

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

The available information on approximate concentrations of the targeted skin sensitising substances in textile and leather articles is summarised in Table 5 below.

Table 5 Approximate (measured or estimated) levels of targeted substances in textile and leather.

Group/Substance	Approximate concentrations in textile/leather	Reference

Allergenic disperse dyes	Estimated concentrations in certain textiles around 10 000 mg/kg (KemI, 2019). Measured levels range between 1 and 10% (10 000 - 100 000 mg/kg) in textile.	Dossier Submitter's personal communication, 2018; KemI, 2019
Chromium (VI) compounds	Estimated concentrations are some hundred mg/kg in textile and leather (KemI, 2019). Measured amounts in leather articles are between 1-7 mg/kg (Anses 2018).	KemI, 2019; Anses, 2018
Diisocyanates	Estimated concentrations above 1 000 mg/kg in textile and leather. It is unclear if this number refers to cured or uncured forms.	KemI, 2019
(Meth)acrylates	Estimated concentrations are up to 10 mg/kg in textile and leather.	KemI, 2019
Formaldehyde	Estimated concentrations between 100 and 1 000 mg/kg and around 75 mg/kg on unwashed easy care/non-iron resins and other finishes in textile and leather (Kemi 2019). In a study carried out by Anses (2018) concentrations between 6 and 160 mg/kg were reported.	KemI, 2019; Anses 2018
Nickel compounds	Nickel was quantified in four textile articles in a study at concentrations between 2.3 and 23.5 mg/kg, in the non-metal parts of the textile articles.	Anses, 2018
Cobalt compounds	Concentrations of cobalt compounds in textile are estimated to be 100 mg/kg (KemI, 2019). In leather, levels >50 000 mg/kg were reported (Hamann, 2018).	KemI, 2019; Hamann, 2018
Direct dyes	Estimated to be applied in textiles at 0 - 4% (40 000 mg/kg).	KemI, 2019
Acid dyes	Estimated to be applied in textiles and leather at 0 - 6% (60 000 mg/kg)	KemI, 2019
Rosin	The estimated amount on textile and leather articles is 1 000 mg/kg (KemI, 2019). In the 2018 Anses study, rosin has been qualitatively detected in 10 footwear.	KemI, 2019; Anses, 2018

Dicyclohexyl phthalate (DCHP)	The estimated amount in for example plastisol prints on textile articles is 30% (300 000 mg/kg).	KemI, 2019
1,4 paraphenylene diamine	Quantified in textile articles at concentrations between 16 and 40 mg/kg.	Anses, 2018

Migration of skin sensitising substances from textile and leather

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

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

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

Table 6 Parameters to be applied for exposure assessment of chemical substances in textiles

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

Table 7 Parameters to be applied for exposure assessment of chemical substances in leather

Parameter	Assumption	Explanation
Exposure duration (h)	24	The dose on skin is assumed to accumulate for 24 h
Exposure frequency (n)	2	Overall, 2 changes to occur during 24 hours (e.g. work/leisure shoes and sports shoes)
Surface weight (kg/m^2)	0.9	The surface weight of the most representative type of leather (i.e. bovine leather for footwear, leather goods and furniture with a thickness of 1.2 mm), with a typical leather surface weight of 0.4-1 kg/m2 for footwear, 0.3-0.8 kg/m2 for garments and gloves, 0.6-0.9 kg/m2 for upholstery and 0.6-1.2 kg/m2 for automotive.
Contact surface	1	A 1:1 contact between leather and skin is assumed.

B.1.3.2. RAC conclusion(s)

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

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

Parameter	Assumption in textile	Assumption in leather
Exposure duration (h)	24	24
Exposure frequency (n)	3	2
Surface weight (kg/m^2)	0.2	1.5
Contact surface	1	1

Migration factors from textile or leather were searched for by the Dossier Submitter in the literature according to the information retrieval strategy as discussed in B.1.3.3.2 of the “Key elements underpinning the RAC conclusion” section of this opinion. When specific data on

migration is lacking for substances, RAC supports the use of a default migration factor, assuming that the substances concerned have the potential to migrate. RAC agrees to apply the following migration factors for exposure assessment of skin sensitising substances in textile or leather:

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

B.1.3.3. Key elements underpinning the RAC conclusion(s)

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

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

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

In conclusion, RAC supports an assessment based on two worst-case exposure scenarios. The first exposure scenario includes textiles and other materials and uses a textile-made clothing as a basis for the evaluation. The second scenario includes leather, fur and hides and uses leather-made footwear as a typical article for the assessment.

B.1.3.3.1. Concentration of skin sensitising substances in textiles and leather

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

B.1.3.3.1.1. Allergenic disperse dyes

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

B.1.3.3.1.2. Chromium (VI) compounds

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

B.1.3.3.1.3. Diisocyanates

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

B.1.3.3.1.4. (Meth)acrylates

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

B.1.3.3.1.5. Formaldehyde

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

B.1.3.3.1.6. Nickel

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

B.1.3.3.1.7. Cobalt

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

B.1.3.3.1.8. Direct dyes

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

B.1.3.3.1.9. Acid dyes

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

B.1.3.3.1.10. Rosin

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

B.1.3.3.1.11. 1,4 paraphenylediamine

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

B.1.3.3.1.12. Dicyclohexyl phthalate (DCHP)

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

B.1.3.3.1.13. Glutaraldehyde

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

B.1.3.3.2. Migration factor

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

RAC supports an exposure assessment based on the ‘first use’ of the textile or leather article as second-hand articles are excluded from the scope of the restriction. However, several shortcomings on the specific and default migration values are related to the normal and foreseeable use of leather and textile articles. It is acknowledged that the migration of substances can be influenced by washing and wear and tear (friction for example). Leather articles are unlikely to be washed to a similar extent to textile articles. However, such articles can get wet when worn, for example by the rain, potentially increasing the migration factor of water-soluble substances. Moreover, the migration of a substance from textile or leather

is usually measured using artificial sweat over a period of a few hours. Migration data therefore does not take into consideration prolonged exposure throughout the day. In addition, other types of vehicles, for example sebum and leave-on cosmetics are poorly studied to date. Such vehicles might increase the migration factor of lipophilic chemicals.

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

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

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

B.1.3.3.2.1. Migration factor for cobalt and nickel compounds

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

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

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

Nickel compounds are also of concern regarding skin sensitising properties. There is no indication of the use of metallic nickel in textiles, but nickel salts may be used in dye

chromophores and pigments. Nickel was quantified in four textile articles in a study at concentrations between 2.3 and 23.5 mg/kg, in the non-metal parts of the textile articles (Anses, 2018).

RAC concurs with the Dossier Submitter that migration could not be ruled out in any event. No specific migration data from clothing or footwear was available for these two compounds. RAC therefore agrees to use a default migration factor of 10% for cobalt compounds and nickel compounds for all articles within the scope of the restriction proposal.

B.1.3.3.2.2. Migration factor for chromium (VI) compounds

Realistic estimates of chromium released from leather and the release rate under physiological conditions are difficult to establish. The migration factor of 30% for chromium (VI) compounds was used for exposure assessment as reported in the restriction on Chromium (VI) in leather. This value supposed that the total amount of chromium (VI) extracted from an article was representative of the total amount available for migration from leather to human skin or sweat in a worst-case scenario. However, the test method used a standard analytical solution not resembling to sweat. A study carried out by the German BGFA (*Berufsgenossenschaftliches Forschungsinstitut fur Arbeitsmedizin*) concluded that the migration was at the most 30% of the concentrations determined. The pH influences the leaching of chromium (VI) from leather into artificial sweat. RAC therefore considered in their previous opinion that a migration rate of 30% of the amount of measured chromium (VI) from leather to human skin represented a more realistic but still conservative estimation of the potential exposure (ECHA 2012b).

RAC agrees to use a migration factor of 30% for chromium (VI) compounds for leather articles, similarly to the value retained in the restriction on chromium (VI) in leather. RAC also supports the use of information on migration of chromium (VI) from leather as a proxy for migration from textile or other materials, taking into account the differences in how chromium is incorporated into the different materials and therefore also on how it is released.

B.1.3.3.2.3. Migration factor for disperse dyes

The disperse dyes with harmonised classification as skin sensitisers were assessed as member of the larger group of allergenic disperse dyes included in the list of concern. The available literature indicated that migration of eight disperse dyes from textile to artificial sweat was in the range of 0.5-2% of the total of the dye content in the material (BfR 2012). However, some uncertainties have been raised to consider a potential underestimation of the real migration rate. First, the studies were based on the latest technologies. The BfR report concluded that exposure may be higher in case of over-dyeing, use of the wrong textile substrate or incomplete removal of the carriers. The risk assessment approach of the voluntary scheme Bluesign proposed a migration factor of 5% for dermal chronic exposure under sweating conditions and a migration factor of 10% for mouthing. Furthermore, the Dossier Submitter considered that lipophilic behaviour of disperse dyes might influence the migration rate to sebum or other oil-based matter present on the skin in addition to sweat. The Dossier Submitter's proposal was to use a migration factor of 5% for disperse dyes.

During the consultation, it was stressed that a migration factor of 10% was an overestimation based on previously researched migration rates (0.5-2%). The same stakeholder also highlighted that a migration factor of 10% would lead to a completely colourless material after ten wear events (comment #2368). Other stakeholders also commented on the lipophilic behaviour of disperse dyes. With regard to the second step that comes after migration (in this case skin absorption) an *in vitro* study about the influence of artificial sebum on the dermal absorption of chemicals in excised human skin suggested an absence of influence of sebum on the penetration of toluene and ethanol in and through skin (Schneider et al, 2016). In contrast, RAC notes that the application of skin creams may increase the dermal penetration of ethanol according to this study (comments 2401, 2405).

RAC acknowledges that the conditions of use and manufacturing techniques may influence the migration factor of disperse dyes, leading to some uncertainties about the release of disperse dyes from textile articles to the skin. However, a migration factor value of 5% for disperse dyes in textile articles is considered sufficient to cover the uncertainties described above.

No information on migration factor for disperse dyes in leather was available in the literature. RAC therefore agrees to use the same migration factor of 5% for disperse dyes in leather as well as in textile and other materials.

B.1.3.3.2.4. Default migration factor

When data on migration rates from textiles was lacking and for substances not targeted for information searches, the Dossier Submitter proposed to use a default migration factor. Since many factors related to the material, the substance and the conditions of use collectively contribute to the migration of chemical substances from textiles and leather, the Dossier Submitter used a precautionary approach. It was assumed that substances in the scope for which migration information is lacking have the potential to migrate from the articles to skin if the substance is present in the textile or leather.

A general search for migration portions from textiles and/or leather indicated a range of migration factors comprised between 0.5 and 30%. The Dossier Submitter assumed a default migration factor of 10%, which is in the upper range of the available migration factors retrieved from literature.

Table 7: Measured values on migration of various chemical substances from textile or leather to artificial sweat or standard analytical solution found in the literature

Group of substance	Migration factor (%)	Material	Reference
Disperse dyes, high fastness	0.5 – 2	Garment textiles	Bfr, 2012
Hydrophilic textile auxiliaries	2	Textile	Bfr, 2012
Hydrophobic auxiliaries	0.1	Textile	Bfr, 2012
Flame retardants	1-30	Textile in car seats for children	MST, 2015

Chromium (VI)	30	Leather	ECHA, 2012b

During the consultation, Bluesign indicated the use of migration factors in their risk assessment for consumer safety limits. The migration factor used in their calculations depends on the usage range itself and the usage during wearing of an article. This migration factor for chronic dermal exposure is usually estimated to be 2% for hydrophilic agents and 5% for sweat management (comment 2368).

Considering the large number of substances included in the scope as well as the high number of factors collectively affecting the migration of substances from leather, textile or other materials, RAC agrees to adopt a conservative approach for estimating the migration of substance in the scope of the restriction. Without specific information, the assumption that the substance has the potential to migrate from the articles to skin if present in the textile or leather is supported. RAC concurs with the Dossier Submitter's proposal to apply a default migration factor of 10%.

1. Contact between textile or leather and skin

For both textile and leather, the Dossier Submitter proposed to perform an exposure assessment per surface area of skin. RAC agrees that the dose per skin surface area is the most relevant dose metric for risk assessment of skin sensitisers.

For textiles, RAC supports the proposal to consider that the exposed skin area is 100% covered by fabric (relationship 1:1).

For leather, the typical article is footwear. Although a skin barrier might be present, by wearing socks for example, many footwear can be used with a direct skin contact (summer shoes, high heel shoes, slippers). RAC therefore concurs with the Dossier Submitter to consider a 1:1 relationship between leather and skin.

2. Exposure duration

The elicitation of skin allergy is also determined by the accumulated dose per skin area, which is influenced by the duration of exposure. RAC agrees to select a time frame of 24 hours for both textile and leather similarly to the risk assessment allergens in cosmetics after repeated exposure (SCCS, 2012).

3. Exposure frequency

When changing clothes or footwear throughout the day, re-exposure to the same substance via newly purchased articles may occur. The Dossier Submitter assumed in their scenarios an exposure frequency of 3 times per day for clothing and twice per day for footwear.

During Public Consultation, stakeholders expressed that the assumptions on use frequency per day are very conservative and even one stakeholder proposed a reasonable worst case for textile with 1 new garment in any 24-hour period.

For textiles, RAC concurs with the Dossier Submitter that an exposure frequency of 3 times

per day, illustrated by the example of work wear, leisure/sportswear and night wear/bedding textile, may be considered as a worst case scenario.

Re-exposure to leather products throughout the day is considered to be smaller compared to textile. RAC agrees to use an exposure frequency of twice per day (e.g. work/leisure shoes and sports shoes) as a worst-case scenario.

4. Surface weights

Assuming that a substance is evenly distributed in the article, the thickness of the material influences the amount of chemical per surface area.

For clothing, the surface weight can vary depending on the textile fibres. The BfR report (2012) assumed a surface weight of 0.1 kg/m² for risk assessment purposes. Based on their textile laboratory, the Dossier Submitter considered that the surface weight of textiles range between approximately 0.07 kg/m² (silk) to 0.4 kg/m² for a blanket (Dossier Submitter's personal communication, 2018). They concluded that the value of 0.1 kg/m² was slightly underestimated and proposed the value of 0.2 kg/m². RAC supports the use a surface weight of 0.2 kg/m² for textiles and other materials as a reasonable worst-case scenario for most types of articles used close to the skin.

For footwear, the Dossier Submitter originally proposed to use a leather surface weight of 1.5 kg/m² based on the restriction on chromium (VI) compounds in leather (ECHA, 2012b). In the exposure scenario, the mean density of leather was assumed to be 1 500 kg/m³. RAC calculated that the weight of 1 cm² leather of 1 mm weights 0.00015 kg, translating it into a surface weight of 1.5 kg/m² as a reasonable worst-case (ECHA, 2012b).

It was however suggested by a stakeholder to consider a leather surface weight of 0.9 kg/m² based on their review of leathers currently used for the manufacture of shoes, garments and upholstery. A density of 750 kg/m³ (corresponding to 0.75 g/cm³) was proposed for calculation. An average leather thickness of 1.2 mm was assumed from the leather average thickness of modern shoes (1.0 to 1.5 mm), for furniture upholstery (0.8 to 1.2 mm) and garment (0.6 to 1.0 mm) (comments 2401 and 2405). Based on these comments, plus follow up questions to the respondents, the Dossier Submitter revised the proposal to use a surface weight of 0.9 kg/m² for leather.

However, as there is a clear precedent, RAC supports the use of a surface weight of 1.5 kg/m² for leather, as this is the value previously retained in the restriction of chromium (VI) compounds in leather.

B.1.4. Characterisation of risks

B.1.4.1. Summary of Dossier Submitter's proposal

The purpose of the risk characterisation is to assess the likelihood that elicitation of skin allergy is avoided when wearing or using clothing or footwear in close contact with skin. Skin sensitisation is regarded as a threshold effect. This, in principle, enables a quantitative approach for the risk assessment. Such an approach, based on elicitation thresholds, has

been developed for restrictions such as chromium in leather articles (ECHA, 2012b) and substances in tattoo inks and permanent make-up.

The amount of available information on elicitation threshold doses and migration factors varies among the sensitising substances in the scope of this particular restriction. Risk characterisation based on such data will therefore be associated with various levels of uncertainty (low, medium and considerable). The Dossier Submitter approach is to use the available data as broadly as possible, but at the same time be transparent about the uncertainty.

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

The limit in clothing or footwear per surface area was calculated using the following equation:

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

The Dosser Submitter divided the risk characterisation into three different approaches:

- Quantitative approach: When both a specific elicitation threshold dose and migration factor was available for substances or group of substances, a quantitative risk assessment was performed;

- Semi-quantitative approach: For several substances or group of substances, a specific elicitation threshold was available but a specific migration factor was lacking. A default migration factor was therefore applied in the quantitative equation;

- Qualitative approach: For the substances outside the scope for information retrieval strategy and for some targeted substances, no specific elicitation threshold or migration factor were available. The use of default ED_{10} and migration factor allowed the derivation of a generic value.

The proposed concentration limits for the substances in the restriction scope are compiled in the table below. This table proposes concentration limits for textiles and leather (please note that to develop the concentration limit value for leather, the Dossier Submitter has used a surface weight value of 0.9 kg/m²):

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

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

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

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

[4] The existing concentration limit in entry 72 of REACH Annex XVII, is assumed to also protect from skin sensitisation from substances in textile in the present restriction proposal. Hence, for regulatory consistency, no concentration limit is proposed in this restriction proposal.

B.1.4.2. RAC conclusion(s)

RAC supports the proposal to use elicitation thresholds as a reference dose for the risk assessment of skin sensitising substances. RAC also supports to base the risk characterisation on the derivation of concentration limits of sensitising substances in textile and leather, as proposed by the Dossier Submitter.

RAC notes that other approaches would have been possible. Indeed, the Dossier Submitter initially proposed an approach where a set of concentration limits for skin sensitising substances for clothing and related articles and another set for footwear would be derived. RAC noted that with this approach, the derived concentration limits would be independent of the material (e.g. same concentration limit for leather clothing or textile clothing) and therefore a substance present in textile-made clothing or textile-made footwear would lead to two different concentration limits depending on the type of article. An alternative approach could have been to develop concentration limits for skin sensitisers independently of the material. This would lead to single set of concentration limits regardless of the material; which would have been more coherent and easy to enforce, but might increase the overall uncertainty. Another option would have been, taking into consideration the uncertainties associated with the different materials, the high number of substances and the limitations related to the migration factors and the ED_{10}, to adopt a generic limit value for all substances and all articles based on GCLs and SCLs according to the CLP legislation. However, this approach also would raise uncertainties since GCLs and SCLs are intrinsically defined for sensitisation and not for elicitation and, therefore, the level of protection would have been considerably lower.

Overall, RAC notes that a risk assessment based on derived limit values for textiles and other materials or leather, fur and hide is the most balanced option in terms of minimisation of uncertainties.

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

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

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

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

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

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

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

Overall, the RAC's evaluation of the reference-doses and the exposure scenarios have highligted important limitations, in particular related to the migration factors, the ED_{10} and the materials other than textile or leather.

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

Therefore, RAC supports the following concentration limits for the substances in the restriction scope:

Substance/group of substances	Proposed concentration limit (mg/kg)	
	Textile[1]	Leather[2]
Disperse dyes	Ban[3]	Ban[3]
Chromium VI compounds	1[4]	1
Nickel compounds	125	25
Cobalt compounds	70	15
Formaldehyde	30	30
1,4 paraphenylene diamine	250	50
Other substances in scope	130	30

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

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

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

[4] The existing concentration limit in entry 72 of REACH Annex XVII, is assumed to also protect from skin sensitisation from substances in textiles in the present restriction proposal. Hence, for regulatory consistency, no concentration limit is proposed in this restriction proposal.

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

Furthermore, information on elicitation threshold doses (ED_{10} or MET10%) and/or migration factors was only retrieved for specific substances targeted in the information retrieval strategy (see section 3). For some of these substances as well as for the other substances in the scope, specific data on elicitation threshold and/or migration factor were not always available. In that event, a default migration factor and/or a default elicitation threshold was applied.
Annex IV to this opinion details the calculations, dossier submitter proposals and Forum advice that RAC has taken into consideration to derive their supported values for textile and other materials and leather, hides and furs respectively) according to a substance specific approach, substance semi-specific approach and qualitative default approach. This is outlined below.

B.1.4.3. Key elements underpinning RAC conclusion(s)

B.1.4.3.1. Substance specific approach (RAC supported values for textile and other materials and leather, hides and furs)

B.1.4.3.1.1. Allergenic disperse dyes

Concentration limit in textile and other materials = 0.1 mg/kg

Concentration limit in leather, fur and hides = 0.02 mg/kg

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

The Dossier Submitter proposed a ban since the derived concentration limits are below the current quantification limit for disperse dyes (30-50 mg/kg) based on test method ISO 16373-1:2015 for dyestuffs in textiles.

RAC concurs with the Dossier Submitter to propose a ban on the use of disperse dyes in textile and other materials as well as in leather, fur and hides. This limit would be interpreted as a limit not exceeding the current limit of detection.

B.1.4.3.1.2. Chromium (VI) compounds

Concentration limit in textile and other materials = 1.1 mg/kg ≈ 1 mg/kg

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

Concentration limit in leather, fur and hides = 0.2 mg/kg

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

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

B.1.4.3.2. Substance semi-specific approach (RAC supported values for textile and other materials and leather, hides and furs)

B.1.4.3.2.1. Formaldehyde

Concentration limit in textile and other materials = 3 350 mg/kg

Concentration limit in leather, fur and hides = 670 mg/kg

In entry 72 of REACH Annex XVII, the concentration limit of formaldehyde in textile is 75 mg/kg based on the carcinogenic properties of the substance. In addition, in the Commission Directive (EU) 2019/1929 of 19 November 2019, amending Appendix C to Annex

II to Directive 2009/48/EC (the Toy Safety Directive) for specific limit values for chemicals used in certain toys, the concentration limit for formaldehyde in textile and leather toy materials is 30 mg/kg; which is lower than the derived concentration limits for skin sensitising properties of formaldehyde. The existing concentration limit of 30 mg/kg in the Toy Safety Directive is assumed to also protect from allergic contact dermatitis by formaldehyde because this limit value is based on skin sensitisation. RAC therefore recommends to apply a concentration limit of 30 mg/kg for formaldehyde in textile and other materials as well as in leather, fur and hides.

B.1.4.3.2.2. Nickel compounds

Concentration limit in textile or other materials = 125 mg/kg

Concentration limit in leather, fur and hides = 25 mg/kg

The Forum concluded that no problem was expected with the measurement of nickel at the concentration limits proposed by RAC or the Dossier Submitter when extracted from textiles and possibly from leather.

RAC is of the opinion that limit values of 125 and 25 mg/kg should be retained for nickel in textile and other materials or leather, fur and hides, respectively. (expressed as Ni metal that can be extracted from the textile and leather material respectively)

B.1.4.3.2.3. Cobalt compounds

Concentration limit in textile and other materials = 73 mg/kg ≈ 70 mg/kg

Concentration limit in leather, fur and hides =15 mg/kg

As with nickel, the Forum concluded that no problem was expected with the measurement of cobalt at the limits proposed by RAC or the Dossier Submitter when extracted from textiles and possibly from leather
RAC agrees that the concentration limits for cobalt in textile and leather articles apply to both cobalt and cobalt compounds that are in the scope of this restriction. RAC supports the use of 70 mg/kg as a concentration limit for cobalt in textile and other materials. RAC also supports the use of a concentration limit value of 15 mg/kg for cobalt compounds in leather, fur and hide articles (both limits expressed as Co metal that can be extracted from materials).

B.1.4.3.2.4. 1.4-paraphenylene diamine

Concentration limit in textile and other materials = 250 mg/kg

Concentration limit in leather, fur and hides = 50 mg/kg

Based on the calculated risk of elicitation caused by 1,4-paraphenylene diamine, RAC agrees to retain concentration limits values of 250 and 50 mg/kg for 1.4-paraphenylene

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

B.1.4.3.3. Qualitative default approach (RAC supported values for textile and other materials and leather, hides and furs)

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

B.1.4.4. Uncertainties in the risk characterisation

No exhaustive overview of the identity and amount of skin sensitising substances used in the manufacturing processes of clothing, footwear and related articles is available. The Dossier Submitter described a list of substances likely to be present in clothing or footwear associated with volume estimates. These data were, however, concluded to be of insufficient reliability to allow a quantitative exposure assessment. Therefore, the risk-assessment was based on an alternative approach, using the elicitation threshold combined with justified assumptions on exposure and migration to derive concentration limits in articles, which are considered to be preventative for both the induction and elicitation of skin sensitisation.

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

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

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

Literature related to migration factors for substances in textile or leather is even scarcer.

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

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

Finally, RAC also highlights as an additional uncertainty the possible additive, synergistic or cross-sensitising effects of different sensitising and even irritant substances found in the articles within the scope of this restriction proposal.

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

B.1.5. Risk management measures and operational conditions implemented and recommended by the manufactures / importers

B.1.5.1. Summary of Dossier Submitter's proposal

For most of the targeted skin sensitisers in the scope of this restriction proposal, the concentration limits are far below the highest approximated concentrations in textile and leather at point of sale. Therefore, the risks from these substances are not adequately controlled for these uses. The Dossier Submitter assumes the reasoning can be extended to all skin sensitising substances in the scope. Hence, lowering the concentrations of the skin sensitising substance in articles within the scope of the restriction to the ones proposed above, is considered to significantly reduce the risk for skin sensitisation in the general population.

B.1.5.2. RAC conclusion(s)

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

B.1.5.3. Key elements underpinning the RAC conclusion(s)

Table 5 shows approximate (measured or estimated) levels of targeted substances in textile and leather. It can be concluded that in most of the cases the concentration is higher than the concentration limit proposed in this restriction. Thus, the limits proposed in this restriction will notably reduce exposure and therefore it is expected that the incidence of skin sensitisation would also notable reduced.

B.1.6. Existing regulatory risk management instruments

B.1.6.1. Summary of Dossier Submitter's proposal

Several risk management options (RMOs) for the regulation of skin sensitising substances in textile and leather articles were identified and analysed (existing regulations on leather, existing EU and national restrictions, labelling schemes). However, it was concluded that none of these RMOs was appropriate to control the risk. The Dossier Submitter considers restriction under REACH Article 69 (1) as the most appropriate risk management option.

B.1.6.2. RAC conclusion(s)

RAC agrees with the Dossier Submitter in the consideration that restriction under REACH Article 69(1) is the most appropriate risk management option.

B.1.6.3. Key elements underpinning the RAC conclusion(s)

Several options might indeed be considered for risk management, such as:

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

Identification as SVHC according to REACH Article 57 and subsequent authorisation. The Authorisation process only applies to the use in EU of a chemical during its incorporation into an article. Since at least 80 % of all textile and leather articles on the EU market are imported from outside the EU, identifying textile and leather related skin sensitising substances as SVHC with subsequent authorisation by RAC, would likely have a minor risk reducing effects on allergic textile/leather dermatitis.

Harmonised classification of substances under CLP (EC) No 1272/2008. The CLP regulation is based on hazard identification and not on risk assessment. Thus, RAC noted that a harmonised classification of a substances might aid to identify which substances will have to be subjected to other, more restrictive, regulations, like, for example, the present

restriction. Furthermore, since the restriction is based on a dynamic link to Annex VI of the CLP regulation, it will allow the scope of the restriction to be kept permanently updated in case new chemicals are classified as skin sensitisers whilst avoiding regrettable substitution.

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

Voluntary actions. A recent review of 47 studies on voluntary agreements between governments or government bodies and individual businesses or industry groups concluded that, if properly implemented and monitored, voluntary agreements can be effective (Bryden and al., 2013). However, RAC considers that the effectiveness of voluntary agreements is highly uncertain and therefore this option, in absence of complementary legislation, is non-feasible in terms of risk management.

Economic policy instruments. A fee or a tax could be introduced on articles containing skin sensitising substances. RAC does not consider this possibility as a risk management measure as such because it does not rely on scientific criteria.

Overall, RAC concludes that the use of a restriction under REACH Article 69(1) is the most efficient way to reduce the cases of allergic contact dermatitis caused as a consequence of the exposure to sensitising substances present in clothing and related accessories, footwear and other articles with similar skin contact made of textiles, leather, fur, hide and synthetic leather, as well as disposable sanitary towels, napkins, tissues and nappies.

B.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

B.2.1. Summary of Dossier Submitter's proposal

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

B.2.2. SEAC and RAC conclusions(s)

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[10] in the articles targeted by the proposed restriction should be implemented in all Member States.

B.2.3. Key elements underpinning the SEAC and RAC conclusion(s)

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

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:

i. clothing (and related accessories);
ii. articles other than clothing made of textile, leather, hide, fur or synthetic leather but with similar potential for human exposure to clothing;
iii. disposable sanitary towels, napkins, tissues and nappies;
iv. footwear.

These articles have in common that they are partly or exclusively made of textile, leather, synthetic 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. The Dossier Submitter provided evidence that allergic contact dermatitis in the general population can be caused by the skin sensitising substances within the scope of the proposed restriction and that the reported lifetime prevalence of allergic contact dermatitis caused by textile and leather in the EEA of

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

up to 1% is evidence of impact.

SEAC considers that the free movement of goods is an important factor for the functioning of the internal EU market and therefore concludes that any measure taken to reduce the human health impact of skin sensitising substances should be taken on an EU-wide basis. SEAC considers that 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. The articles included in the scope of the restriction proposal are available to and may be 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 be complimentary to 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 for human skin contact. SEAC notes that some aspects of the current proposal differ from the entry 72 restriction, such as the conditions for natural leather and disposable articles. Where relevant, such differences are discussed later in this opinion. A large majority of respondents to the consultation on the Annex XV report supported the need for a Union-wide measure to control the risks of the general public resulting from exposure to skin allergens in the articles targeted by the restriction. The focus of the responses was primarily on textile and leather.

B.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

B.3.1. Scope including derogations

Justification for the opinion of RAC

B.3.1.1. Summary of Dossier Submitter's 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, other articles made of textile, leather, hide, fur or synthetic leather which come into contact with human skin similar to clothing, and disposable sanitary towels, napkins, tissues and nappies 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 within the scope of the restriction or for treatment of finished articles are expected to be covered by the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012). The restriction would not apply to personal protective equipment, medical devices and second-hand articles. While second-hand articles may constitute a source of exposure, the enforcement of second-hand articles is expected to be complex and costly. Furthermore, it is assumed that second-hand articles have been washed several times and that normal wear or use of these articles would have lowered the content of some skin sensitising substances, particularly those with high migration.

B.3.1.2. RAC conclusion(s)

RAC supports the Dossier Submitter's conclusion that that the suggested restriction (RO1a) option is the most appropriate EU wide measure.

RAC supports the proposal of the Dossier Submitter to derogat the following from the proposed restriction:

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

However, RAC does not support the proposal of the Dossier Submitter to derogate articles within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council

of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

B.3.1.3. Key elements underpinning the RAC conclusion(s)

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

The Dossier Submitter detailed in Table 17 of the Background Document six other possible restriction options with a modified scope. Restriction options RO2 (no additional list of disperse dyes) and RO3 (narrow list of substances) are considered by RAC to result in lower risk reduction against skin sensitisation for general population.

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

In restriction option RO5, the scope is identical to that of RO1a, but migration limits are proposed instead of concentration limits. Migration better relates to the actual risk and, therefore, a migration limit may be preferred. However, the concentration limits proposed in this restriction proposal accounts for migration and therefore is deemed sufficient. Moreover, a migration limit is also expected to be less practical and enforceable.

In restriction option RO6 the scope is identical to RO1a but aims at a total ban of skin sensitising substances in textile and leather articles placed on the EU market, based on the lowest possible concentration limits, either zero or based on the limits of detection. RAC notes that with RO6 the benefits for human health would probably be the greatest. However, RAC also notes that from a risk-based perspective, banning the presence of all substances within the scope is not justified because, except for disperse dyes, these substances are considered as safe provided they are present in the finished article below a certain concentration limit.

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

Therefore, RAC supports the Dossier Submitter's conclusion that the REACH Restriction option RO1a is the most appropriate EU wide measure. The scope of this proposal includes derogations for active ingredients in biocidal products, second-hand articles, medical devices and personal protective equipment.

B.3.1.3.1. Active ingredients in biocidal products according to EU Regulation 528/2012

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

B.3.1.3.2. Second-hand articles

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

RAC acknowledges that second-hand articles may constitute a source of exposure for skin sensitising substances in footwear, clothing or related articles. RAC notes that although the washing of clothes is expected to lower the content of some skin sensitisers, it cannot be excluded that the friction of fibres and leather induced by normal wear and use might increase the release of such substances. However, RAC supports the conclusion of the Dossier Submitter to derogate second-hand articles from the scope to ensure the practicality and proportionality of the proposed restriction.

B.3.1.3.3. Articles within the scope of Regulation (EU) 2017/745 on medical devices

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

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

B.3.1.3.4. Articles within the scope of Regulation (EU) 2016/425 on personal protective equipment (PPE)

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

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

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

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

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

Occupational allergies induced by latex rubber-made PPE used in Europe are well demonstrated in recent scientific literature. For example, Hamnerius et al.2018, demonstrated that contact allergy to rubber additives in medical gloves was the most common cause of occupational allergic contact dermatitis in healthcare workers, according to a study carried out in Sweden . Another study showed that the use of accelerator-free medical gloves was effective to reduce allergic symptoms in healthcare workers in Franceafter a diagnosis of allergic contact dermatitis caused by rubber accelerators (Crepy et al., 2018. A Danish retrospective matched case-control study also concluded that contact allergy to thiuram mix was more common in healthcare workers (Schwensen et al., 2016).

In addition, a review of non-glove PPE-related occupational dermatoses reported to EPIDERM between 1993 and 2013 showed that of all the PPE-related cases, 9.2% were attributable to non-glove PPE (clothing, footwear, facemasks/safety glasses and headgear). Allergic contact dermatitis was diagnosed for 47.4% of the non-glove PPE-related dermatoses, footwear and clothing being the most common causes of non-glove PPE-related allergic contact dermatitis. Allergens associated with personal protective footwear and clothing related allergic contact dermatitis included thiuram, mercapto mix and carba mix in rubber, azo dyes in textiles, formaldehyde resins in fabric finish, chromate in leather, and nickel in the toecaps of protective boots. In a UK-wide surveillance scheme analysing incident case reports from dermatologists of non-glove PPE-related dermatoses between 1993 and 2013, two cases of allergic contact dermatitis induced by diethylthiourea were reported in people wearing

neoprene wet suits as part of their occupation, whereas the allergens associated with facemask contact allergy were IPPD and nickel. (Bhoyrul et al., 2018).

Overall, based on the available literature showing a concern related to PPE-induced allergic contact dermatitis, RAC does not support the proposal of the Dossier Submitter to derogate from the restriction proposal articles that are within the scope of the Regulation (EU) 2016/425on personal protective equipment.

Justification for the opinion of SEAC

B.3.1.4. Summary of Dossier Submitter's proposal

The proposed restriction affects 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, in the following articles (hereafter referred to as "articles targeted by the proposed restriction"):

i. clothing (and related accessories);
ii. articles other than clothing made of textile, leather, hide, fur or synthetic leather but with similar potential for human exposure to clothing;
iii. disposable sanitary towels, napkins, tissues and nappies;
iv. footwear.

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 the restriction in these 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:

- 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 identified 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 that this option would be proportionate as costs would be very low and benefits high. However, the estimated benefits are 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 also including substances with harmonised classification Skin Irr.2 or Skin Corr.1A/1B/1C (RO4); this option would theoretically provide greater protection than RO1a. However, the presence of irritant or corrosive substances at sufficiently high concentrations in textile and leather to result in risks is considered to be unlikely.

- Restriction as RO1a but with migration limits instead of concentration limits (RO5); not considered further as concentration limits under RO1a are derived based on 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 a total ban has no basis in risk assessment and would incur high costs on society.

- 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 (RMOs), other than restriction, were briefly considered, but not further assessed by the Dossier Submitter:

- Labelling requirements for textile and leather articles containing skin sensitisers; the Dossier Submitter concludes that both the costs and benefits of such an 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 the use of SVHC incorporated into textile and leather articles in the EU and hence would not be effective to address risks from imported

articles.

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

- Other legislation

    - 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 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 REACH can currently be used to manage risks.

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

- Economic policy instruments: economic instruments such as taxation are considered at Member State level. However, national taxes could create single market distortion.

B.3.1.5. SEAC conclusion(s)

In general, SEAC concludes that amongst the different restriction options and other RMOs described by the Dossier Submitter, a REACH restriction corresponding 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 are 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 targeting of the restriction as it resembles the existing restriction of CMR substances in similar articles (entry 72 of Annex XVII). SEAC considers consistent elements across both restrictions to be important for the practical implementation and ease of compliance and enforcement of the proposed restriction. In this respect, SEAC specifically

notes that RO1a also contains elements that diverge 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, 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 Toy Safety Directive, SEAC recommends that the initially proposed concentration limit of 75 mg/kg is maintained based on comments received 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.

SEAC supports the proposed 36-month transitional period.

SEAC supports a dynamic link between the scope of the proposed restriction and Annex VI of CLP, but recommends that a three year deferral period[11] is introduced after inclusion in Annex VI of CLP to allow sufficient time for information on alternatives, the feasibility of the generic concentration limits proposed by RAC or other considerations of relevance to be considered, as well as for the supply chain to get prepared, before inclusion in the restriction. SEAC has insufficient information to conclude on the costs, benefits, proportionality and practicality of an additional (dynamic) link with skin sensitisers in the CPR.

B.3.1.6. Key elements underpinning the SEAC conclusion(s)

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.

B.3.1.6.1. Other restriction options considered

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

[11] SEAC recommends the deferral time to start at the date of the decision to amend the CLP Regulation by including the skin sensitising substance(s) in Annex VI. The available information does not allow SEAC to provide advice on the practical and legal implementation of the proposed deferral period.

that the additional health benefits of this labelling provision in addition to the health benefits offered by RO1a are uncertain.

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.

B.3.1.6.2. 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). The 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 report 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 report (#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. On the contrary, 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 as an inappropriate RMO to manage the identified risks. The main reason for this is that the authorisation requirements only apply to articles manufactured in the EU in which skin sensitisers would be incorporated. Hence, the majority of articles targeted by the proposed restriction on the EU market would not be covered (e.g. for textile the Background Document clarifies that around 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 regulatory 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 relatively broad chemical scope and broad range of uses of such chemicals in textiles, leather and other materials is well captured under REACH, whilst the alternative RMOs would provide only partial solutions. No comments on these options were provided in the consultation on the Annex XV report. In general, the idea of legislative measures through 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[12] 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 the 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.

B.3.1.6.3. 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 opted not to include such uses in the proposed scope. SEAC supports this approach as it considers that consistency with entry 72 of Annex XVII is important for the practical implementation and enforcement of the restriction. No comments were received on this aspect during the consultations on the Annex XV dossier and the SEAC draft opinion and in the Forum advice.

[12] 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

B.3.1.6.4. 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 (this exemption is only specified in the Background Document, rather than in the entry proposed by the Dossier Submitter). 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, synthetic leather 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 that 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 did not include an exemption in the restriction entry 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 release. The scope of the proposed restriction includes cobalt, but the Background Document does not contain any information on the use of cobalt in metallic parts. SEAC considers that metal parts, such as buttons, fasteners and zippers, should be excluded from the scope of the proposed restriction due to lack of an assessment to justify their inclusion. However, SEAC notes the lack of robust justification for exempting these.

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). This exemption is not specified in the entry text proposed by the Dossier Submitter but is instead

presented only in the Background Document (section 1.1.4.2. Articles not covered by the restriction). Although SEAC understands the 'lack of risk' consideration underpinning such exemption, SEAC has concerns with such an exemption as it 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.

B.3.1.6.5. 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. 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 (in the non-exhaustive list of articles with similar exposure to potential to clothing) as a fashion accessory is expanded in the Background Document (section 1.1.4.1. Articles covered by the restriction) 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, synthetic leather, hide and fur for these childcare applications and no information was submitted in the consultation on the Annex XV report. SEAC considers nevertheless that the information available for the textile and leather industry cover also costs for this sector.

B.3.1.6.6. 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 report 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 any 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.

In the consultation on the SEAC draft opinion, some stakeholders commented that they considered the material and article scope of the restriction confusing (#590, #591). Specifically, some definitions are missing, and some categories of articles were thought to overlap (such as bags, which could be considered as 'clothing related accessories' or 'other articles with similar skin contact'). These uncertainties are stated to result in legal uncertainty. Four French industry associations (#599, #609, #622, #627) stated that there had been major changes to the proposed restriction (the wording regarding materials was changed and concentration limits were reduced for many compounds). According to them this should result in a new restriction procedure. SEAC notes that although the wording of the proposed legal text was revised during opinion making the scope of the restriction (in terms of the types of articles considered) was based on the conclusions of the risk assessment and remained the same throughout the process. In addition, the metals industry (#623) considered that the proposed restriction text was unclear with respect to the exclusion of metal parts (which are covered by entry 27 of Annex XVII). SEAC concludes that the issues raised by industry during the consultation on the SEAC draft opinion are already addressed in the opinion and SEAC provides recommendations targeted at removing these uncertainties. The conclusions and recommendations were not affected by the consultation on the SEAC draft opinion.

B.3.1.6.7. 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 report and discussions during the RAC and SEAC opinion development, the Dossier Submitter made changes to the proposed concentration limits. These changes are shown in Table 8. For leather, the concentration limits for nickel and cobalt compounds, 1,4 paraphenylene diamine and other substances in scope of the restriction were reduced by approximately a factor of three as a consequence of minor changes to the assumptions used in the risk assessment (such as the use of a higher density of leather as input parameter).The concentration limit for nickel in textiles was revised from 130 to 120 mg/kg. The Dossier Submitter revised the

concentration limits for disperse dyes in textiles from 0.05 mg/kg to 0.1 mg/kg and for leather from 0.04 mg/kg to 0.03 mg/kg based on information provided in the consultation on the Annex XV report affecting the risk assessment. For formaldehyde, the Dossier Submitter revised the concentration limit in all materials from 75 to 30 mg/kg to be consistent with recent changes in the Toys Safety Directive.

RAC agreed slightly different concentration limits for nickel and its compounds in textiles (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 8 in bold.

Table 8 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 risks posed by allergenic disperse dyes (i.e. the 24 substances 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 mean of a total ban on intentional use (i.e. concentrations not exceeding the limit of detection (LOD) in materials), since the derived risk-based concentration limits are currently below the limits of detection/quantification for disperse dyes (10-50 mg/kg) but their substitution is technically feasible at low cost. Rather than a risk-based concentration limit, the restriction refers to a limit of detection (that would ideally be below the calculated risk-based concentration limits of 0.1 mg/kg in textile and 0.03 mg/kg in leather). As regards the 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 applying an LOD as a concentration limit effectively results 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 report 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 increase their costs significantly 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 basis. They state that dyes like Disperse Blue 291, Disperse Violet 93 and Disperse Yellow 64 are in widespread use globally, 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 widely used in 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 dye preparations covering 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 Disperse Blue 291 and Disperse Violet 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.

In the consultation on the SEAC draft opinion, several stakeholders for the textile industry again requested to exempt Disperse Blue 291, Disperse Violet 93 and Disperse Yellow 64 from the restriction. The German MSCA (#521, #613) and several industry associations (#536, #552, #557 #601, #618, #620, #628) requested that the inclusion of these three disperse dyes in the restriction should be reconsidered as according to them there would be no evidence of consumer risk and the socio-economic implications would be severe. They again highlighted that these three dyes are the most frequently used disperse dyes for polyester and polyester-blend fabric dyeing. According to dye manufacturers TEGEWA and ETAD (#552, #557) more than 50% of the dye market for navy and black shades of polyester and most of the light shades with high light-fastness would be affected by a ban. With respect to

alternatives, they state in general that disperse dyes are the only class of dyes which can be used to dye polyester and potential future alternatives would be other disperse dyes, many of which with the exact same self-classification as H317. In the end they expect the restriction on harmonised skin sensitisers may negatively affect the possibility to dye polyester. The Federation of European Sporting Goods Industry (FESI, #625) added a request for explicit exemptions for these dyes unless and until proper toxicological analysis is performed on each substance individually with results indicating that further restrictions are needed. Comment #625 by FESI also request that Disperse Violet 1, which is widely used to achieve certain shades, is exempted.

SEAC recommends that further consideration is needed regarding Disperse Blue 291, Disperse Violet 93 and Disperse Yellow 64 based on the information on the likelihood of a significant impact of a ban on dye manufacturers and the textile and leather sectors. SEAC considers such impact could be significant because of the high market share of these specific dyes (i.e. 50%) on the dye market and specifically for polyester dyeing in combination with a lack of alternatives free of skin sensitising properties. While SEAC considers that the information submitted in the consultation on the SEAC draft opinion is credible and useful, it notes that no information was provided on how long industry may need to substitute these three disperse dyes. Therefore, SEAC recommends that these three dyes are instead considered for a harmonised classification through the CLP process. SEAC notes that in case Disperse Blue 291, Disperse Violet 93 are Disperse Yellow 64 are classified as skin sensitisers in category 1, 1A or 1B and the semi-dynamic link proposed by SEAC is implemented, then consideration of alternatives would be given still before their inclusion into the restriction entry.

SEAC concurs with the risk-based limit values for the group of disperse dyes proposed by RAC. Based on the information obtained in the consultation on the Annex XV report and the draft SEAC opinion, SEAC concludes that the concentration limit values may cause challenges for the involved industries as analytical standards of sufficient purity seem to be lacking for some of the dyes hampering detection at a sufficiently low detection limit. Although one comment in the consultation on the SEAC draft opinion (#601) argued that a limit of 50 mg/kg would be feasible and sufficient for the purpose of assuring that banned disperse dyes are not intentionally used, SEAC has too limited information to give specific recommendations on a limit of detection applicable to the whole group of disperse dyes. However, SEAC has received no clear information that development of proper analytical sensitivity to detect the disperse dyes included in Table 1 of the restriction proposal at a level below the risk-based limits defined by RAC would not be feasible before the end of the transitional period of the restriction. Therefore, although SEAC acknowledges that there may be technical challenges with analytical detection of the disperse dyes at levels below the limit values proposed by RAC and levels of quantification of dyes in existing certification schemes are generally much higher (e.g. 15-20 mg/kg), SEAC supports the risk-based concentration limits proposed by RAC.

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 as follows:

B.3.1.6.7.1. Chromium VI compounds:

The proposed concentration limit of 1 mg/kg in textile and leather is based on a quantitative substance-specific approach. There is limited information on the technical and economic feasibility of these limits reported in the Background Document. 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 report 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 (currently 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 proposal to restrict 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. (2015) and others[13] providing insight into how changes in experimental parameters influence the outcome of ISO 17075 tests. Proper control of these parameters would allow the 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 analysis (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

[13] 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.

(#2394) provided 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) suggested CEN could be required to re-evaluate if it is possible to lower the detection limit to 1 mg/kg. However, the detection limit must 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, contrary to what was stated in the Annex XV report, 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 lacks 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 arguments against substitution. SEAC considers that a Cr VI limit value of 3 mg/kg in leather is feasible for industry and enforcement bodies 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 currently 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 with limits of quantification < 3mg/kg and the consequential lack of reported lower concentrations. Considering that a lower limit of 1 mg/kg cannot currently be complied with due to these analytical limitations, implementing such a 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 chromium tanned finished leather[14] 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.

During the consultation on the SEAC draft opinion, information was requested on the risk-based concentration limit of 1 mg/kg for chromium VI in leather, fur and hides and specifically on when it could be achieved and what would be needed to arrive at this lower level. Several individual scientists and NGOs (#509, # 540, #564, #584, #608) supported a 1 mg/kg concentration limit. As a general line of reasoning SEAC concludes, based on these comments, that it is technically possible to analyse chromium VI as low as 1 mg/kg and that it is a matter of time and resources to be made available to arrive there. In addition, comment #509 refers to the availability of chromium free tanning which could be an alternative if that market would be expanded since the leather is comparable to chrome tanned products and the costs of reverting to such alternative processes would not be a high economic burden (i.e. as existing equipment can be used). Comment #509 further states that the alternative technology is currently being tested by one of the largest groups in the automotive sector and is proven to be applicable to all kinds of raw materials. At the same time, other comments (#521, #590,

[14] 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

#544) highlight difficulties with alternative tanning processes, stating that they are difficult to implement technically, are not available in sufficient quantities or produce leathers with different properties. SEAC notes that on the availability of alternative tanning methods to substitute chromium III-based tanning, the information available is divergent. Based on the information available it is evident that substitution of chromium III-based tanning by other tanning methods for supply of chromium VI-free leather on the EEA market will take at least some years, but SEAC has no specific information on estimated or envisaged timelines by industry. Time would be needed due to the current large market share of chromium III-based tanning on the EEA market, the limited availability of alternative tanning methods to take over the market share and possible needs to test alternatives. Stakeholders also point at weaknesses in the ISO 17075-1 guideline with respect to the definition and derivation of the LOD. The guideline has not been updated in 13 years and the derivation of the 3 mg/kg quantitation limit is in the view of these comments unclear and not verifiable. Another major level of uncertainty they state is introduced by the level of flexibility the ISO guideline introduces with respect to sample treatment and storage. Especially the humidity conditions and storage temperature may influence the measured chromium VI concentrations to a large extent. The flexibility of the guideline with respect to sampling and storage before analyses would explain the large variability in the test results. The statement in the guideline “results below 3 mg/kg show large variations and have limited reliability; therefore, the quantification limit shall be 3 mg/kg” comes without data or references. One stakeholder (#608) states that available evidence suggests that detection and quantitation limits below 3 mg/kg are feasible for the revised 2017 standard ISO 17075-2:2017, which follows a method by the US-EPA and would be capable of quantifying to at least one-half the existing limit (i.e. 1.5 mg/kg), to be confirmed still experimentally. They recommend the withdrawal of the old ISO 17075-1:2017 standard to be replaced by the ISO 17075-2:2017 standard and to conduct a study to scientifically evaluate the true quantification limit of chromium VI and they also advise to revise the standard to require modern instrumentation.

Several stakeholders from the chemical industry and leather industry in the consultation on the SEAC draft opinion (#533, #535, #536, #537, #555, #566, #552, #578, #544, #591, #592, #593, #599, #601, #603, #625), again pointed at the infeasibility of a 1 mg/kg concentration limit largely using the same arguments as provided during the consultation on the Annex XV report. In addition, also a member state representative (#521) and standardisation institute (#590) argued that currently detection of chromium VI at levels below 3 mg/kg would not be feasible, and they argue the sampling itself being the limiting factor rather than the instrumental system applied for the analyses. Several stakeholders (#536, #537, #566, #552, #578) state that recent improvements in detection technology might be used as a basis for developing a procedure to reduce the LoQ. The expected timeframe, including validation, is five years. Also, some other stakeholders point at a period of five years needed to develop the analytical guidelines for reliable detection and quantification of chromium VI as low as 1 mg/kg. The Nordic Leather Industry Council (#635) specifically recommended to request CEN TC 289/WG1 to re-evaluate the method and the possibility to lower the detection limit in the future.

Based on the information received, SEAC concludes that the scientific and industrial communities are divided about the feasibility to implement 1 mg/kg as the concentration limit for chromium VI in leather, fur and hides in the proposed restriction. It is clear, however, that it is technically possible to lower the currently applied limit of 3 mg/kg in the ISO 17075-1:2017 but there is a need for time and resources to arrive at an improved guideline. SEAC

notes especially the guidance on sampling and sample treatment and storage requires attention and should be clarified and tightened ensuring reduced variability between laboratories. 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 further notes that for substitution of chromium III tanned leather supplied on the EEA market to alternatively tanned leather, also time and resources will be needed. SEAC therefore recommends a temporary concentration limit of 3 mg/kg with a 5-year transitional period (i.e. 2 years on top of the 3-year transitional period for the restriction overall). After 5 years the lower risk-based limit value of 1 mg/kg should enter into effect.

B.3.1.6.7.2. 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 concentration limits of 125 mg/kg in textile and 25 mg/kg 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 concentration limits of 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 the 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 report 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 stated 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 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 report, 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.

During the consultation on the SEAC draft opinion, information was requested on the feasibility and impacts of the lowered concentration limits of 25 mg/kg for nickel and its compounds and 15 mg/kg for cobalt and its compounds in leather, fur and hide. A Member State (#521) argued that the limit should apply to the metal itself since if it were to refer to (a) compound(s) such would have to be specified. An industry stakeholder shared this view on a need for clarity on the nickel and cobalt compounds covered (#536). A group of stakeholders from the leather industry (#552, #566, #578, #606) stated that it would be challenging but probably manageable to meet the initially proposed limits of 110 mg/kg for nickel and 60 mg/kg for cobalt. They stated that the lower limits would make it more difficult to manufacture leather, especially chromium-free tanned leather. Other stakeholders from the leather industry (#563, #601, #625) stated that currently no feasible substitutes are available for cobalt-based dyes. They (#563) also pointed at a lack of information in safety datasheets on cobalt in dyes as concentrations are often below 0.1%, hence making it difficult for leather manufacturers to know whether nickel and cobalt are present in dyes in the supply chain. Given the technical complexity they requested a transitional period of 5 years (2 years in addition to the transitional period for the restriction proposed by the Dossier Submitter).

A stakeholder from the nickel industry (#623) stated that nickel release rather than nickel content would be the key factor to determine if there is a risk of nickel sensitisation and referred to REACH Annex XVII entry 27 restricting nickel release, to be measured in accordance with the CEN standard EN 1811. They also point at some materials containing nickel but being safe after prolonged skin contact (e.g. stainless steel). For implementation they ask for differentiating between metallic and coated articles for which entry 27 would apply and textile, leather, fur and hide materials for which the proposed concentration limits would apply to be assessed through the appropriate CEN standards.

Based on the information provided, SEAC recommends to implement the risk-based limit values for nickel (125 mg/kg in textile and other materials and 25 mg/kg in leather, fur and hides)) and cobalt (70 mg/kg for textile and other materials and 15 mg/kg for leather, fur and hides) as proposed by RAC with an additional transitional period of two years (i.e. a total transitional period of five years for nickel and cobalt) allowing industry to find alternative dyes. SEAC also supports the concentration limits to be expressed as Ni and Co metal that can be extracted from the material as according to the Forum advice such analyses are expected to be technically feasible. SEAC notes that metal parts are exempted from this restriction but covered by other restrictions.

B.3.1.6.7.3. Formaldehyde:

The initially proposed limit value of 75 mg/kg in textile and leather consistent with entry 72 of Annex XVII (based on the carcinogenic properties of the substance) was supported in the consultation on the Annex XV report and in the Forum advice although some stakeholders (#2384) considered that double regulation could be an issue. 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) can be required 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 report, the Background Document was updated revising the formaldehyde concentration limit 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. RAC estimated risk-based concentration limits for textile and other materials, and leather, fur and hides at significantly higher concentrations but recommended applying a concentration limit of 30 mg/kg to align with the Toy Safety Directive.

During the consultation on the SEAC draft opinion several industry stakeholders argued that the proposed lower concentration limit for formaldehyde in textile and leather of 30 mg/kg instead of the initially proposed 75 mg/kg would not be feasible (#536, #537, #566, #563, #599, #601, 620, #628). Several stakeholders did not support transposing the 30 mg/kg limit value for skin sensitisers in textile and leather parts of toys under the Toy Safety Directive (2009/48/EC) to the textile and leather articles (such as clothing and footwear) in the proposed restriction as many textile products need to have special technical functions or functional finishes such as flame retardancy, water or stain repellence, wash permanence and shape maintenance. Such characteristics were stated to be specifically important for personal protective equipment, upholstery, workwear, curtains, shirts, blouses, trousers, knitwear, coats, and jackets and could not be achieved with a limit for formaldehyde lower than 75 mg/kg. Hence, many articles would become non-compliant and industry argues that there are limited means to prevent such lower formaldehyde levels. The lower limit is estimated by some to have a major impact on economic operators and would lead to three times more non-compliant leather and textile articles. Compliance with a 30 mg/kg limit would require the use of more expensive low or no-formaldehyde resins, and it would likely result in the phase-out of many finishing effects in the textile sector. Another argument is that a limit of 30 mg/kg would not be consistent with other international regulations, which are based on a limit of 75 mg/kg (e.g. Chinese standard GB 20400-2006).

Based on the comments provided in the consultations SEAC recommends a 75 mg/kg concentration limit for formaldehyde in all articles and materials covered by the scope of the restriction. SEAC notes RAC's recommendation to align with the 30 mg/kg concentration limit for formaldehyde in the Toy Safety Directive despite estimating significantly higher risk-based concentration limits. SEAC has no information on any difference in human health benefits of implementing concentration limits of 30 mg/kg (aligning with the Toy Safety Directive), 75 mg/kg (as proposed by the Dossier Submitter and aligning with REACH Annex XVII entry 72 based on carcinogenic properties) or the higher risk-based concentration limits as specified in the RAC opinion (i.e. 3 350 mg/kg for textile and other materials and 670 mg/kg for leather, fur and hides). SEAC argues that the additional human health benefits of lowering the formaldehyde limit from 75 mg/kg to 30 mg/kg are uncertain while the impact, especially for the textile sector, could be significant. SEAC considers that there is no compelling need for the current restriction to be consistent with the Toys Safety Directive (2009/48/EC) as toys are different articles and the risks and impacts may have been approached differently.

B.3.1.6.7.4. 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 report 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 that 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 report, SEAC concludes that there are no feasibility issues with the proposed limits in textile, leather and other materials.

B.3.1.6.7.5. 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 not considered to be relevant.

Some stakeholders from the textile industry (#628, #536, #601, #625) noted that the dynamic link between CLP and the scope of the proposed restriction could result in frequently used dyes being restricted for which the generic 130 mg/kg limit could not be met. These comments refer in particular to Reactive Black 5, a key component in the vast majority of all reactive black dyes, for which an intention to propose it for harmonised classification as a category 1 sensitiser under the CLP Regulation has recently been communicated to ECHA. Comment #628 states that more than 90% of all black dyed cotton is dyed with reactive dyes containing Reactive Black 5. According to #601 and #625, alternatives are available but at significantly higher costs and with substantial impacts on water and energy use and performance. The comments argue that with a ban of these dyes, black and navy colours on both polyester and cellulose materials would be nearly impossible to achieve due to their market dominance. SEAC notes that Reactive Black 5 is not yet in the scope of the proposed restriction but in case it would be classified as skin sensitisers in Annex VI of the CLP Regulation in the future, the generic concentration limits for other substances would apply to it. SEAC notes that for substances classified in the future, the suggested transition time between CLP Annex VI inclusion of skin sensitisers and uptake in the restriction (also referred to as semi-dynamic linking in other parts of this opinion) could be used to consult affected stakeholders on e.g. alternatives, relevant specific concentration limits to be applied or the relevance of the substance for the sector.

During the consultation on the SEAC draft opinion information was requested on the availability of alternative dyes not containing an aniline impurity, on their health/risk profile and on the impacts of substituting to these dyes. In addition, SEAC requested information on the concentration levels at which aniline is reported to be present as 'impurity' in the dyes. Several stakeholders from the textile sector (#552, #557, #578, #606) provided

some information challenging the need to regulate aniline as according to them none of the aniline-based dyes currently on the market has ever been found responsible for textile allergies. They further provide information on average concentrations of 10-30 ppm, and in some deep dyed, non-laundered (rigid) denim jeans levels >100ppm have been found. The proposed 130mg/kg limit on aniline in textiles according to them would not present compliance problems. Several alternatives (i.e. aniline free dyes) are available to dye cotton in blue colour. However, these dyes are generally not capable of providing the unique 'washdown' effect achieved by indigo. For leather, aniline is used in black azo-dyes for which substitution is stated not to be possible yet and industry is searching for alternatives. Based on risk assessment considerations, which cannot be evaluated by SEAC, they challenge the lower concentration limit favouring the initially proposed limit for leather, fur and hides of 110 mg/kg. Also, other textile industry stakeholders (#601, #625) confirm the limit of 130 mg/kg is not likely to present compliance issues however compliance with the 30 mg/kg limit in leather, fur and hides is questionable and the search for substitution of black azo-dyes is underway but not successful yet. SEAC concludes that the information provided during the consultation on the SEAC draft opinion confirms that the limit value for aniline in textile is not likely to lead to compliance issues while the limit value for leather, hides and furs could cause some challenges for the leather sector to comply. Some information has been provided on the lack of current availability of alternatives for aniline-containing black azo-dyes for leather. However, research on substitution is underway and SEAC has no indications that substitution cannot be achieved within the timeframe of the proposed 3-year transitional period. SEAC received no further information on the health/risk profile of alternatives and on impacts of substitution. Therefore, SEAC recommends adhering to the RAC proposed risk-based concentration limits both for textile and other materials and for leather, hide and fur.

B.3.1.6.8. 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 report 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 recognised 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 stated that hazards coming from 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 analysis 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. 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.

As the RAC opinion based on risk assessment considerations does not support a derogation for PPE, the consultation on the SEAC draft opinion was used to collect information on the impacts of a restriction on skin sensitising chemicals in PPE. Very little information was provided on the impacts of affected sectors of a restriction on skin sensitisers in PPE. The majority of respondents from the chemical sector, textile sector and leather sector (#536, #537, #628, #592, #593, #599, #609, #622) supported SEAC's view in favour of the derogation as proposed by the Dossier Submitter and in aligning with the arguments that chemical safety for workers and consumers for these articles is regulated in the PPE Regulation (EU) 2016/425 and an exemption would be consistent with Annex XVII entry 72 of REACH on CMR substances in textiles. A Member State representative (#613) stated to qualitatively support the view of RAC based on risk considerations that a derogation should not be warranted as the materials used to make PPE would according to them basically be the same as for other textiles and leather articles and hence could contain similar levels of skin sensitisers. Furthermore, they argued that the exposure could be higher as the duration and frequency of wearing are longer and higher in an occupational set up than for the consumer while the wash frequency is usually lower. They stated that only in theory the PPE Regulation should deal with the fact that manufacturers should ensure the harmlessness of PPE. Another stakeholder from the textile and fashion industry (#620) opposed the inclusion of PPE in the restriction. They stated that the protective objective of regulating all skin-sensitizing chemicals in Europe, on the suspicion that individual workers could develop an allergy, would be disproportionate to the loss of environmentally friendly production of high-quality protective equipment in Europe. The production of high-quality protective equipment without the risk of qualitative fluctuations according to them must continue to be possible within the EU and they specifically referred to the Covid-19 pandemic where a need to be less dependent on the production of important protective textiles manufactured outside the EEA became apparent to guarantee a timely and sufficient supply of PPE.

SEAC concludes that the consultation on the SEAC draft opinion provided some qualitative information on possible impacts on PPE coverage in the proposed restriction on skin sensitisers. SEAC considers the restriction could have some impacts on EEA-based PPE manufacturing sector as it would have to comply with a restriction specifically for skin sensitisers. Similarly, the restriction would also apply to imported PPE. The restriction on skin sensitisers in PPE could also have some additional (though unquantified human health benefits) due to specific limitations on the use of certain skin sensitisers whereas under the PPE Regulation chemical safety for consumers and workers is only regulated at a generic level. Earlier commenters during the consultation on the Annex XV report already stated such generic safety regulation could result in unaddressed risks and hence missed benefits (examples were provided of reported worker skin allergies). SEAC concludes that the information provided during the consultation on the SEAC draft opinion was rather supportive to its considerations in the draft opinion and the weight given by SEAC to preventing double regulation and a consistent approach with earlier similar restrictions with PPE derogations remains unaltered.

B.3.1.6.9. 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 considered 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 report 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.

B.3.1.6.10. 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 during the consultation on the Annex XV report or the SEAC draft opinion. The Forum supports the exemption.

B.3.1.6.11. 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.

B.3.1.6.12. 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 proposed restriction (both in RO1a and RO2). However, 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 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 that have 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 considerations. In the consultation on the Annex XV report one Member State and an NGO stated explicitly to be in support of this approach (#2379, #2850). Other respondents did not support such an approach as it would not consider 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.

During the consultation on the SEAC draft opinion, information was requested on compliance testing costs and other costs associated with the dynamic link with Annex VI of the CLP Regulation. Almost all industry comments provided arguments against the proposed dynamic link with Annex VI of CLP, e.g. due to unclarity about substances that would be relevant for the sectors involved (i.e. those that are actually used in the materials covered by the proposal), difficulty of monitoring, expected high testing costs, legal uncertainty due to the expanding list, long development and order times, contracts, enforceability etc. Many comments requested that the restriction would focus on a smaller set of clearly identified substances to keep the restriction manageable and enforceable. The semi-dynamic linking recommendation provided in the SEAC draft opinion was by some stakeholders considered a possible solution. Several stakeholders argued for a 3-year transitional period and stated that including some kind of evaluation of newly classified substances before their inclusion in the scope of the restriction would be necessary to assess their relevance for the sector, migration, threshold, harmonised test method, etc. Some argued that a process similar to the introduction of the art 68(2) fast track restriction on 33 CMR substances in textile including consultation with industry specifically on use of substances in the materials covered by the restriction could be an option. Several comments said that without enough analytical capabilities, the proposed restriction is poorly enforceable (#590, #591, #633, #525, #552, #557, #552 and #557). It was argued that there is a lack of analytical methods for the over 1 000 substances so the need for test method development is very large. Others mentioned sufficient transitional time (e.g. 10 years) would be needed to develop all required test methods and harmonised European test standards (ISO or CEN).

Several stakeholders from the textile and leather industries provided some cost estimates for testing/compliance costs and other costs as a result of the dynamic link. This is assessed in the costs section of this opinion.

Taking into consideration all information provided in the consultations, SEAC concludes that the dynamic link of the proposed restriction with Annex VI of the CLP Regulation together with the starting point of the proposed restriction covering all currently classified skin sensitisers and 24 disperse dyes is regarded as a disproportionate measure by many stakeholders. SEAC considers that the dynamic link is an inherent part of RO1a as presented by the Dossier Submitter and as assessed by RAC and SEAC. Assessment of a static or other type of linkage between the restriction and Annex VI of the CLP Regulation was not presented as a Restriction Option in the Annex XV report and hence, cost, benefits, proportionality and practicality of such restriction option could not be scrutinised by SEAC to the full extent. Considering the many arguments provided by industry and Member States opposing a dynamic link, SEAC recommended in the draft SEAC opinion to consider options for semi-dynamic linking instead. Having considered the comments received during the consultation on the SEAC draft opinion, SEAC concludes that the combination of the broad and expanding chemical scope with the large and complex article and material scope covering various sectors of use necessitates a deferral time between Annex VI inclusion of skin sensitisers and uptake in the restriction. A deferral time of three years could be used to consult with affected stakeholders to take into account information on alternatives, the feasibility of the generic concentration limits proposed by RAC or other considerations of relevance, in case these would indicate the need for a longer transitional period or derogation. SEAC recommends organising the process in such a way that it would not in any way influence the inclusion of substances on Annex VI of the CLP Regulation. SEAC furthermore recommends the deferral time to start at the date of the decision to amend the CLP Regulation by including the skin sensitising substance(s) in Annex VI. The available information does not allow SEAC to provide advice on the practical and legal implementation of the proposed deferral period.

SEAC notes that the recommended deferral period could have some other implications such as a delay in realising the human health benefits of the restriction due to a delay of placing newly identified skin sensitisers under the scope of the restriction. The deferral period would also trigger some additional work by authorities and some additional administrative burden for relevant sectors as there would be a need to investigate and gather information on the relevant aspects before inclusion in the restriction. Costs for compliance and substitution on the other hand may also be somewhat delayed by the deferral.

B.3.1.6.13. Possible link with the Cosmetic Products Regulation

During RAC and SEAC opinion development it was questioned why the Dossier Submitter did not consider a dynamic link with the skin sensitising substances included in the Cosmetic Products Regulation (CPR; EC Regulation 1223/2009). SEAC notes 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. 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.

B.3.2. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

B.3.2.1. Summary of Dossier Submitter's proposal

The number of individuals already sensitised to chemical substances contained in textile and leather articles in EEA31 general population is estimated to be between 4 and 6 million (average 5 million) in 2023. The number of new cases of sensitisation to chemical substances in textile and leather articles are estimated to be between 45 000-180 000 per year (average 113 000).

The proposed restriction is expected to protect a significant proportion (70% - 90%) of the already sensitised population from developing allergic contact dermatitis from exposure to skin sensitisers in articles within the scope of the restriction. At least 70% of the already sensitised population is considered to be protected from developing allergic contact dermatitis due to the proposed ban of allergenic disperse dyes and due to the restriction of additional allergenic substances at low or very low levels considered as safe. In addition, up to 90% of the population is considered to be protected by the additional restriction of the remaining substances in the scope. The remaining 10% of the individuals potentially not protected reflect uncertainties due to the proportion of susceptible individuals that may react to exposure levels below the concentration limits proposed by the Dossier Submitter. Furthermore, this proposed restriction is expected also to prevent the occurrence of new cases of sensitisation to chemical substances in articles within the scope of the restriction (it is assumed that between 70% and 90% of the new cases will be avoided).

B.3.2.2. RAC conclusion(s)

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

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

B.3.2.3. Key elements underpinning the RAC conclusion(s)

The incidence of allergic contact dermatitis caused by sensitising substances contained in textile and leather articles is quite high, which suggests that elicitation and sensitisation thresholds are reached during exposure of skin to these articles. Thus, a reduction in the level of the exposure to these sensitising chemicals would, in principle, reduce the incidence of the allergic contact dermal cases.
The risk characterisation in this restriction was performed by targeting elicitation thresholds instead of sensitisation thresholds and therefore, since elicitation thresholds are lower than sensitisation thresholds, already sensitised members of the public will be also covered by this restriction proposal.
The end-point of the risk characterisation was an ED_{10}; which means that the limit values would prevent 90% of the non-sensitised population from elicitation and 100% of the already sensitised population. The remaining 10% of the individuals potentially not protected reflect

uncertainties due to the proportion of susceptible individuals that may react to exposure levels below the concentration limits proposed in the restriction.
Finally, the restriction is based on a dynamic link to Annex VI of CLP regulation. It will allow the scope of the restriction to be kept permanently updated in case new chemicals are classified as skin sensitisers but it will also avoid regrettable substitution. This will contribute to increase this restriction's effectiveness.

B.3.3. Socio-economic impact

Justification for the opinion of SEAC

B.3.3.1. Costs

B.3.3.1.1. Summary of Dossier Submitter's proposal

For the skin sensitising substances used in articles within the scope of the restriction, 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.

B.3.3.1.1.1. 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 estimated an overall total negative cost of -€25 million per year (if rosins are substituted with acrylics) or a total cost of €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 plasticisers for neoprene. 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 Table 9.

B.3.3.1.1.2. Reformulation costs:

The need for reformulation has been identified for a number of rubber accelerators. 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 Table 9.

B.3.3.1.1.3. 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. The cost of moving towards best practice has not been estimated due to lack of data.

B.3.3.1.1.4. 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 initial years after entry into force 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 9 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 (i.e. the substitute is cheaper)	4 842	€-13 315 500 (i.e. a negative cost)
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	€1 300 - €1 800 per metric ton	€900 - €1 300 / per metric ton if substitution with acrylic binders Potential regrettable substitution	€-450 (i.e. the substitute is cheaper)	10 800	€-5 000 000 (i.e. a negative cost)

Rosins	€1 300 - €1 800 per metric ton	€3 100 - €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 - €1 100 / 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 (i.e. the substitute is cheaper)	180	€-7 371 000 (i.e. a negative cost)
Sum of total annual substitution cost (if rosins substituted with acrylics)					€-25 420 100 (i.e. a negative cost)
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

B.3.3.1.2. SEAC conclusion(s)

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 in articles within the scope of the restriction. 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, in particular for the enforcement costs.

SEAC considers that the differences in substitution costs between Restriction options RO1a and RO2 are not significant. The differences in enforcement costs are more uncertain, since the available data has not allowed a full quantification of these costs. Because of the inclusion of only a limited list of skin sensitisers (disperse dyes) of which some have been voluntary phased out by industry, RO3 is concluded to be the lowest cost option.

B.3.3.1.3. Key elements underpinning the SEAC conclusion(s)

B.3.3.1.3.1. Availability of alternatives

SEAC reviewed the analysis provided by the Dossier Submitter regarding the existence and availability of alternatives for the skin sensitising substances in articles within the scope of the restriction 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 report, the Dossier Submitter concludes that there are technically and economically feasible alternatives available for most of the concerned skin sensitising substances used in articles within the scope of the restriction. 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 report (#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 the Dossier Submitter confirmed that substitution is possible, it is not clear what the substitutes will be and if they will be less problematic from a skin sensitising perspective. SEAC lacks information related to the substitution process and potential substitutes. Based on a comment provided in the consultation on the SEAC draft opinion, reformulation may be needed for other substances as well. EDANA (#600) highlighted that disposable sanitary towels and nappies have complex supply chains (often with multiple suppliers for each component) and the proposed restriction may incur reformulation of up to two years to change the production process at multiple lines and sites.

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 substitutes exist with a better health/risk profile. For several substances, there is also a lack of information on alternatives. A comment from the consultation on the SEAC draft opinion reports several studies on available alternatives for phthalates. In this comment (#613), the German competent authority states that there are a variety of plasticisers which are currently considered safer than phthalates. However, it is unknown to the German competent authority, whether these alternatives are cheaper than phthalate plasticisers and whether they can be used in textiles.

For cobalt, further information on alternatives was provided in the consultation on the SEAC draft opinion. Swiss Watches (#563), AFIRM Group (#601) and Federation of the European Sporting Goods Industry (#625) provided comments indicating that dyes containing cobalt compounds are widely used for leather, as well as to achieve certain shades for wool, polyamide, silk and cellulosic fibres. According to these comments, there are currently no identified substitutes. In relation to leather, comment #563 stated that it is difficult for tanneries to identify which dyes are concerned, as the presence of cobalt is rarely indicated in the safety data sheets of mixtures below the threshold of 0.1%. According to this comment, cobalt content of >15 mg/kg could be found in about a quarter of the leathers. In relation to textiles, comments #601 and #625 stated that cobalt-based dyes are particularly important in yellow acid dyestuffs and its blends, including brown acid dyestuff. According to these comments, these cobalt-based dyestuffs would need to be phased out from use altogether in order to comply with the proposed restriction, eliminating the ability of industry to achieve these shades for specific fibre compositions, and for which there are currently no feasible alternatives.

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 it may be difficult to reliably detect Cr(VI) below 3 mg/kg (see the discussion in the section on concentration limits for further information on this). Glutaraldehyde has been identified as a substitute, but several comments in the consultation on the Annex XV report indicate that it is not a feasible alternative to chromium in all applications. According to the consultation on the Annex XV report, the concentration of glutaraldehyde in leather articles at point of sale could comply with the proposed concentration limit for glutaraldehyde in leather. In the consultation on the SEAC draft opinion, the German competent authority (#521) stated that alternative tanning processes for tanning with chromium and glutaraldehyde are difficult to implement technically and are not available in sufficient quantities. Leather UK (#544) stated that chromium tanning is preferred due to its cost, speed of production and the properties of the leather produced. While other tanning chemistries are available, including synthetic tanning agents (syntans) and tanning with vegetable extracts (vegtan), they produce leathers with different properties and cannot necessarily be used a substitute for chromium tanning. Furthermore, #544 argues that vegetable tanning is typically a slow process, with some processes taking in excess of a year to complete. According to #544 many leather users, including those in the automotive sector, have tried other tanning chemistries for their products but have returned to chromium-tanned leather. Comments by AFIRM GROUP (#601) and the Federation of the European Sporting Goods Industry (#625) refer to a recent study[15] indicating that chromium tanning is still the most energy and water efficient leather tanning process available. The comments state that while wet-white tanning has a lower environmental impact than vegetable tanning, the large quantity of glutaraldehyde used can damage wastewater treatment systems by interfering with the microbiological degradation process. One comment from the consultation on the SEAC draft opinion (#509) highlights an available metal-free alternative based on aldehyde (not formaldehyde) tanning, which produces universally applicable hide and leather, requires no additional investments for tanneries and has a 15% shorter processing time than for chromium leather.

For formaldehyde, as explained in more detail in the section on concentration limits, several comments in the consultation on the opinion state that lowering the concentration limit would result in a loss of functionality as it would not be feasible to achieve a lower limit (#536, #537, #566, #563, #599, #601, #620, #628). While formaldehyde in itself is not used in leather processing, comments #536 and #566 state that certain condensation products of formaldehyde with melamine, urea or dicyandiamide are used to improve some technical properties/characteristics of textiles or as alternative tanning agents (synthetic aromatic and resin tanning agents). According to these comments, there are no alternatives to produce these finishes. AFIRM Group (#601) states that while they are not able to estimate the socio-economic impact of reducing the limit to 30 mg/kg, it would require the use of low or no formaldehyde resins, which are significantly more expensive, and it would likely result in the phase-out of many finishing effects unless and until suitable alternatives become available.

According to KemI (2019), Benzenamine (aniline, used for synthetic indigo) is hard to substitute and no possible alternative is identified that can be used for the large volumes needed. Several comments in the consultation on the SEAC draft opinion (#552, #557, #578,

[15] “Comparison of the Sustainability of the Vegetable, Wet-White and Chromium Tanning Processes through the Life Cycle Analysis.” A Bacardit, F Combalia, J Font, G Baquero. Journal of the American Leather Chemists Association, 115, 105-111 (2020).

#606) argue that none of the aniline-based dyes currently on the market have ever been found to be responsible for textile allergies despite their widespread use all over the world for many years. According to these comments, indigo is the only possible dyestuff to achieve the typical and requested wash-down effects required for the final denim, with the colour constantly changing over the lifetime of the product. They also state that there are several other aniline free dyes available to dye cotton in blue colour but that these are generally not able to provide the unique wash-down effects of indigo. At the same time, they state that compliance with the proposed 130mg/kg limit in textiles will not be a problem. Similar comments with regards to the proposed limits are provided also by #601 AFIRM GROUP and #625 FESI, stating that a 130 mg/kg concentration limit on aniline in textiles should not present compliance problems. They highlight that new indigo dyes for textiles with only trace or non-detectable amounts of aniline are available but cannot meet the current demand for denim in the EU. In terms of leather, several essential black azo dyes utilise aniline as a building block, and alternatives that can match the affinity for the substrate and the final performance of the dyed articles are not available.

In the consultation on the SEAC draft opinion, the German competent authority (#521, #613) and several industry associations (#536, #552, #557, #601 #618, #620, #621) request to exclude Disperse Blue 291, Disperse Violet 93 and Disperse Yellow 64 from the restriction as they argue that there is no evidence of consumer risk and that the socio-economic implications of inclusion within the restriction would be severe. They state that these three dyes are the most frequently used disperse dyes for polyester and their blended fabric dyeing. The comments argue that in general, disperse dyes are the only class of dyes which can be used to dye polyester and that there are no other dye classes that can substitute them since the others are either water soluble substances, react chemically with fibres and form different kinds of chemical bonds, or consist of molecules that are too large to be included into the fibres. According to #628, alternatives for these three dyes are significantly more expensive and may not be sufficiently available to compensate the shortage. It argues that since polyester covers 65% of the European textile market and accounts for about 80% of all synthetic fibres, banning these three dyes will result in loss of market share of synthetic fibres.

B.3.3.1.3.2. 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 in articles within the scope of the restriction that do not comply with the proposed limits at point of sale.

Raw material costs

The Dossier Submitter estimated 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 that the analysis of raw material substitution costs described in the Background

Document is highly uncertain as it is only based on six (groups of) substance(s) (i.e. phthalate, dyes, rubber accelerators, rosins, formaldehyde and plasticisers for neoprene). For phthalate and plasticisers for neoprene, 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 that the use of average values may either under- or overestimate the actual cost difference. Furthermore, SEAC argues that it is very unlikely that costs in reality are negative because industry would probably already have substituted the substances concerned. SEAC considers that there may be differences in quality, efficacy (volumes to be applied) and other feasibility considerations that play a role that are not known and are not included in the cost 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 a requirement to change 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 report (#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.

During the consultation on the SEAC draft opinion, information was requested on the availability of safer alternatives for plasticisers for neoprene, phthalates and rosins, their unique characteristics for use in clothing, footwear and other articles targeted by the proposed restriction and on the costs and other impacts associated with their substitution. Overall SEAC received very little information to answer this question. SEAC received some references by a Member State (#613) to studies on plasticisers safer than phthalates with endocrine disrupting and/or reprotoxic properties. However, the feasibility of such alternatives for the uses covered by the restriction proposal and the costs of substitution could not be scrutinised by SEAC due to lack of further information on these aspects. Some stakeholders from the textile sector (#601, #625) deferred the question to the European Plasticisers Trade Association but no further information was received from this sector group.

SEAC concludes that no new information on specific alternatives with a better safety profile and on the costs of substitution has been made available. Hence the information provided during the consultation on the SEAC draft opinion does not provide an explanation on the ‘negative’ substitution costs for plasticisers for neoprene, for phthalates and for rosins (if replaced with acryl-based glue). Therefore, SEAC’s conclusions regarding the uncertainties around the costs of substitution is not affected by the latest consultation (See section on total substitution costs).

Based on a comment (#2379) provided by EEB in the consultation on the Annex XV report 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 consultations on the Annex XV report and the SEAC draft opinion 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 rubber accelerators, as well as potentially for other substances. SEAC notes that the reformulation cost is provided only for 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 1 000 reformulations. SEAC agrees with the principle that the best available data has been used by the Dossier Submitter. However, SEAC considers the sensitivity analysis to be 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 insufficient evidence to conclude if they are overestimated or underestimated.

In the consultation on the SEAC draft opinion, EDANA (#600) provided a rough estimate of all costs associated with reformulation for larger disposable sanitary towel and nappy companies. They state that the reformulation costs depend on the material and qualification requirements and may vary from €125 000 to €320 000 per production line for manufacturers of the finished products. They estimate that all costs related to reformulation can vary from €1 million to up to €20+ million. SEAC is not able to scrutinise these values due to the limited information provided but notes that this indicates that reformulation costs may be incurred also for products other than rubber accelerators. SEAC agrees that the large costs could become business critical especially for small and medium size companies but also points out that the cost estimates provided by EDANA are based on some particular types of products with complex supply chain.

Moving to best practice

According to information in the Background Document no substitutes exist for diisocyanates but compliance with the restriction can be achieved by implementing 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 a lack of information (including from the consultations). Based on the comment provided in the consultation on the Annex XV report (#2874, Stazione , Italy), diisocyanates have a high degree of reactivity and therefore the presence of residue concentrations in articles is unlikely and analytical

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

Costs of research and development

FESI (#625) provided a comment that there are additional costs related to research and development of alternatives for the substances of concern that could be substantial and need to be considered in the assessment. However, FESI did not provide estimates for these costs. Instead, they reported that the cost for new substance registration under REACH is between USD 5 000 and USD 10 000 per tonne of substance considering the data on one substance. SEAC agrees with the comment but notes that it is not known how many new registrations would be needed in total.

A comment by I&P Europe - Imaging and Printing Association e.V (#543) stated that the costs to substitute a chemical in a product family ranges from approximately €250 000 to €800 000 (excluding any printer or hardware compatibility issue that may need to be resolved due to the chemical substitution). SEAC is not able to scrutinise these values due to the limited information but considers that the large costs could become business critical especially for small and medium size companies.

Total substitution costs

The total substitution costs are calculated based on 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 Submitter provided estimates of the total cost of substitution at a negative cost of 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). In a comment on the SEAC draft opinion, ChemSec (#540) stated that companies may try to avoid changing their established procedures (as they would need time to establish new procedures), even if alternatives are cheaper. ChemSec also pointed out that what drives substitution is mainly regulation. SEAC notes that the establishment of new procedures also implies costs but notes that the available information does not allow for a quantification of such costs.

SEAC highlights the limited data as a source of uncertainty that may results in under- or overestimates of the total substitution costs. The consultation on the Annex XV report and the SEAC draft opinion have been used to gather more information on the various cost elements. Since only limited additional data has been received, SEAC concludes that uncertainties remain regarding the total substitution costs.

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

The quantified 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) as well as the substitution challenges and associated socio-economic implications highlighted in the consultation on the SEAC draft opinion regarding Disperse Blue 291, Disperse Violet 93 and Disperse Yellow 64, it agrees with the Dossier Submitter that RO3 will have significantly lower substitution costs compared with RO1a and RO2.

B.3.3.1.3.3. Enforcement costs

The Dossier Submitter semi-quantitatively assessed 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 restriction with a more limited substance scope. 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 laboratories on the testing costs, 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 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. The Forum mentions furthermore some specific analytical challenges but notes in general that sampling and analyses of these types of materials is well known by inspectors.

To address this gap the Dossier Submitter used the estimation on administrative costs from the Annex XV report proposing restrictions on tattoo inks and permanent make-up (https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a). In the restriction proposal 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 1 000 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.

In terms of enforcement costs for industry, 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 procedures, with additional costs. One comment stated that the compliance testing cost estimates for the textile sector in the Background Document are significantly underestimated. They provided some limited data (claimed confidential) indicating that the testing costs for industry may 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.

Some comments in the consultation on the SEAC draft opinion provided estimates for the expected testing cost for industry due to the proposed restriction:

- I&P Europe (#534) stated that the restriction may require non-routine testing to determine classification status and/or compliance obligations, including local lymph node assay (LLNA), extraction testing of a final product, and human patch testing. For these kinds of tests, they reported costs of €25 000 to €45 000 (per ink family).
- TEGEWA (#552) stated that considering the > 1 000 substances currently proposed, the best-case estimation (assuming a minimum of €60 per substance or group of substances to be tested) is that testing costs would at least double if not triple for a single lot to be tested (from €6 000 to €9 000).
- The Federation of the Swiss watch industry FH (#563) estimated that based on an average analysis cost of about €150 for dispersive dyes and assuming that a manufacturer supplies 300 – 500 references per year, this would result in an annual additional average cost of €60 000. Based on their experience they estimated that the screening of skin sensitising substances category 1/1A/1B would cost around €500, meaning an annual additional average cost of €200 000 per manufacturer.
- The Confederation of the German Textile and Fashion Industry (#620) reported the results from a survey undertaken by GermanFashion on the additional expected costs if the dynamic link with CLP is implemented. Based on information about eight

companies, which would each test between 1 000 and 34 200 pieces per year at a cost of €200 per test, they derive an additional cost of €0.3 – 11.4 million per company if they would need to test each different piece due to the CLP dynamic link. The comment argued that, if the reported costs are extrapolated to the whole German textile industry, the additional testing cost would be more than €660 million/year.

- AFIRM GROUP (#601) and the Federation of the European Sporting Goods Industry (#625) estimated that with the addition of 90+ substances included in the proposal that are relevant to the apparel and footwear industry, and the additional substances restricted over time due to the dynamic link, a medium to large global brand would incur additional testing costs of millions of dollars per year, which would be double (or more) the amount of testing costs incurred today.
- EURATEX (#628) stated that a test may cost up to €200 per new substance. An individual test may be used for a group of substances; hence, its price would be lower (e.g. €60 per substance). The dynamic link would introduce new substances to be regulated, which would mean that each piece of new collection (every colour is a different lot/stock) would need to be tested for that new substance. This significantly increases the overalls costs. The lowest price of performing 100 tests for group substances (approx. €60 per test) would amount to €6 000 for one article. In case of new substances costing €200 euros per article, the overall cost can go up to €20 000 for each textile article. According to the comment, at best, maximum three pieces of textiles can be tested for new substances. They also highlight that groups of substances such as those already regulated together with new ones, can be tested together if the method is the same. Since there is no test method defined for a new substance, the first step is to identify the most suitable one.

SEAC notes that the testing costs of €60 - €200 per substance or substance group reported in the consultations are comparable with the costs per material outlined in the Background Document. However, it is not clear how many additional tests would need to be undertaken by how many companies because of the proposed restriction. While the comments received in the consultation indicate a potentially significant additional cost for industry, it is difficult for SEAC to scrutinise the estimates without further information about how the total estimates have been derived, the current testing costs incurred by the industry and how companies would change their testing practices due to the proposed restriction. For example, comment #628 in the consultation on the SEAC draft opinion stated that the dynamic link means that each piece of a new collection would need to be tested for that new substance. Similarly, comment #606 stated that an automatic inclusion of new substances via the dynamic link with CLP (even with a delay) would require the testing of all substances with new H317 harmonised classification, including those which are not used by the sector. At the same time, SEAC notes that other comments (e.g. #536 and #620 in the consultation on the SEAC draft opinion, as well as #2891 in the consultation on the Annex XV report) highlighted that many companies in the sector use contracts with references to specific legislation to guarantee legal certainty within the long lead times (stated to be 2-2.5 years from the formulation of chemicals until selling to consumers by #536 and 1 – 5 years between the development of a textile and placing it on the EU-market by #620). Similar comments were made in the consultation on the Annex XV report, with e.g. #2906 stating that many textile companies sign “Agreements for international purchase” with their customers approximately one year before the final products are placed on the market to make sure that production facilities

within and outside Europe are compliant with EU regulation including REACH. Furthermore, it should be noted that the possible total testing costs of more than €660 million/year estimated by comment #620 for the German textile industry are based on the assumption that it would not be possible to exclude new substances classified with H317 in the textile value chain with the help of the typical instruments, such as contracts. The comment in question states that the time between design, order and delivery to Europe is longer than one year, while the time for the sale is estimated at six months, or in outlet centres up to a year. However, if the semi-dynamic linking was implemented with a sufficiently long transitional period in between classification of new substances and entry into effect, then SEAC assumes that industry could continue making use of contracts, meaning that the claimed need for testing would be reduced. SEAC also notes that the estimates on the possible testing costs due to the proposed restriction do not all seem to consider the substances already tested for, which would reduce the costs.

In terms of enforcement costs for authorities, less information was provided in the consultations. Some comments on the Annex XV report (e.g. #2788, 2894) and the SEAC draft opinion (e.g. #521, 552, 557) stated that the proposed restriction would require comprehensive compliance checks activities and the development of test methods for a range of substances.

The German Institute for Standardization (DIN, #590) estimated the cost of test method development at about €50 000 per substance and the costs for standardisation work at €150 000. They expect the investment costs for laboratories carrying out tests to be €700 000 per laboratory. This applies to market surveillance laboratories and third-party contract laboratories. In addition to the investment costs, they state that annual personnel costs of at least €150 000 per laboratory per year would be incurred. Similar estimates are provided by EDANA (#600), stating that an analytical method with development work and validation to ensure repeatability and accuracy can be up to €30 000 per substance. Some substances can be grouped together or fit into existing methods. Therefore, the industry estimates an average of €6 000 – 7 000 per substance for more than 1 000 substances classified as sensitisers, summing up to €6 to 7 million. EDANA further states that subsequent product compliance testing could easily be above €10 000 per product variant. SEAC is not able to scrutinise these values due to limited information related to the data used for these estimates but considers that the cost estimates seem overall plausible. At the same time, SEAC notes that these costs may to some extent already be reflected in the previously outlined testing costs that industry would pay the laboratories for testing the samples.

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 relate to 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. It should also be noted that the dynamic link with CLP in options RO1a and RO2 would mean that new substances would be included in the scope in the future, which could increase substitution costs (if such substances are present in the articles within the scope of the restriction) and enforcement costs. While information on

such costs are not currently available, SEAC notes that information on any substitution costs could be considered before the conditions of the restriction took effect for such substances, as part of the 'semi-dynamic link' proposed by SEAC.

B.3.3.1.3.4. 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 because 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.

B.3.3.2. Benefits

B.3.3.2.1. Summary of Dossier Submitter's proposal

The human health impacts assessment focuses on allergic contact dermatitis because it is associated with contact with sensitising substances and there is more information available about this type of contact dermatitis than about other types of contact dermatitis. The proposed restriction should also prevent some irritant contact dermatitis and cases of urticaria 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 articles within the scope of the restriction. It is also expected to prevent the occurrence of at least 70 - 90% of new cases of sensitisation to chemical substances in articles within the scope of the restriction.

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 reduction 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.

B.3.3.2.2. SEAC conclusion(s)

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 cases of urticaria. 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 to be 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.

B.3.3.2.3. Key elements underpinning the SEAC conclusion(s)

B.3.3.2.3.1. 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 by the Dossier Submitter during the preparation of the 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), a medium period of time (e.g. 10 years) or over a lifetime. Lifetime prevalence data are usually considered as the most representative measure of the prevalence of a health state in the general population. Therefore, the Dossier Submitter decided to use the lifetime period. The prevalence data included: the range of the prevalence of allergic contact dermatitis in the general population (4.4% - 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% - 0.04%) of allergic contact dermatitis caused by substances in articles within the scope of the restriction 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 articles within the scope of the restriction (based on testing with allergenic disperse dyes in particular) between children and adults. Several stakeholders in the consultation on the Annex XV report 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 do not 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. Comments received during the consultation on the SEAC draft opinion by Germany (#613) and the International Fragrance Association Europe (#567) also recommend using the data provided by the member of the Information Network of Departments of Dermatology (#2783 in the consultation on the Annex XV report).

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. The alternative prevalence numbers are derived based on a method called Clinical Epidemiology – Drug utilization Research, which uses data on both the use of patch tests and annual sales data provided by the main manufacturers to determine the nation-wide use of patch tests. It was not clear to SEAC how the alternative prevalence data had been derived (in particular the 'eligible for patch testing' figures based on sales data from manufacturers).

SEAC acknowledges that the Dossier Submitter considered the alternative prevalence figures and provided to the SEAC rapporteurs estimates on the benefits using these figures with the incidence figures estimated by the Dossier Submitter. Due to the uncertainties related to the data and their interpretation, these estimates were not included in the Background Document nor in the SEAC opinion. Instead, 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% (which lowers the prevalence values to 0.08 - 0.1% and incidence values to 0.001 - 0.004%) instead of a patch tests positive frequency of 5% (with prevalence values of 0.8 - 1% and incidence values of 0.01 - 0.04%) as assumed in the main calculations (Annex E.5 of the Background Document). The 5% positive patch test used for the prevalence figures in the main calculations seemed to be a key concern in many of the comments on the prevalence figures, including comment #2783. Some of these comments said that it was not analytically justified to derive an average of 5% based on a wide variety of positive patch tests ranging from 0.4% to 17% for textiles and leather reported in the literature. The results from the sensitivity analysis indicates that if the lower patch tests positive frequency of 0.5% is used, the monetised value of health benefits will decrease to €0.7 – 3.9 billion per year. More details on the results of the sensitivity analysis are presented in Table 10 below. SEAC agrees that the possible overestimation of prevalence may impact substantially the values of human health benefits. SEAC considers the sensitivity analysis undertaken by the Dossier Submitter appropriate for addressing this uncertainty.

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 Background Document but not in the assessment and therefore it has no impact on the benefits figures. SEAC concurs with this clarification.

B.3.3.2.3.2. 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 et al., 2014, the Chromium VI restriction proposal (2012) and the ECHA 2014 and 2016 reports on willingness-to-pay).

Saetterstrom et 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. 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 articles within the scope of the restriction. The Dossier Submitter considers that even though all contact allergies to

articles within the scope of the restriction 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 chemicals; in those circumstances, exposure avoidance is difficult or even impossible in some cases and in the meantime, the affected individual's quality of life may be significantly 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 report, the Dossier Submitter provided a sensitivity analysis 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 articles within the scope of the restriction, SEAC 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 frequency of positivity patch tests to textiles is 0.5%, which lowers the prevalence values to 0.08-0.1% and the incidence values to 0.001-0.004%), while the upper 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 Table 10.

Table 10 Total annual human health benefits under different scenarios- sensitivity analyses

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	7 087	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 done by the Dossier Submitter. The results from the sensitivity analysis indicate that while the values of annual human health benefits may be much lower than the main estimate provided by the Dossier Submitter, the sensitivity analysis with the lowest values would still entail monetised health benefits of €0.7 – 3.9 billion per year.

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 (including the sensitivity analyses). The proposed restriction is also expected to prevent some irritant contact dermatitis and cases of urticaria. 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 footwear). However, SEAC does not have the required data to quantify and monetise these benefits.

B.3.3.2.3.3. 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 footwear), 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.

B.3.3.3. Other impacts

B.3.3.3.1. Summary of Dossier Submitter's 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 the articles within the scope of the restriction 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.

B.3.3.3.2. SEAC conclusion(s)

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 articles within the scope of the restriction. 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.

B.3.3.3.3. Key elements underpinning the SEAC conclusion(s)

SEAC agrees with the Dossier Submitter that the restriction may result in some consumer price increase of articles within the scope of the restriction 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 articles within the scope of the restriction or who are aware but have insufficient income to buy allergen-

free articles, the restriction will provide health benefits due to improved access to allergen-free 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 most of the testing and compliance and substitution costs are incurred by non-EU companies.

B.3.3.4. Overall proportionality

B.3.3.4.1. Summary of Dossier Submitter's 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.

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

B.3.3.4.2. RAC and SEAC conclusion(s)

RAC considers that a decrease in the adverse effects due to the incidence of skin sensitisers in textiles is expected, considering the broad scope of the restriction and the proposed concentration limits.

SEAC concludes that the proposed restriction is likely to be 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) offset more than the estimated 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 in the EEA31 due to the access to allergen-free articles at affordable price. SEAC considers that all three ROs are expected to be proportionate 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.

B.3.3.4.3. Key elements underpinning the RAC and SEAC conclusion(s)

According to RAC, this restriction proposal shows the best capacity of mitigating the risk by covering a rather high number of sensitising substances and being dynamically linked to CLP regulation. It is considered that this restriction proposal would protect at least 70%-90% of current and new cases of sensitisation within the EEA.

SEAC has reviewed and generally agrees with the semi quantitative cost-benefit assessment conducted by the Dossier Submitter. Based on the figures provided by the Dossier Submitter, SEAC concludes that the proposed restriction is likely to be proportionate. The expected benefits from the proposed restriction are expected to outweigh the costs 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 and limited information on the total testing costs that would be incremental to the proposed restriction. However, SEAC agrees with the Dossier Submitter that the extra costs of compliance borne by industry (outside and inside EEA31) would not be likely to significantly impact the final consumer price of articles within the scope of the restriction 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 be €0.7 – 3.9 billion per year in case lower prevalence assumptions are used (i.e. as proposed in the consultation on the Annex XV report 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 articles within the scope of the restriction 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, the available information demonstrates that the proposed restriction is likely to be proportionate. Nevertheless, SEAC notes that the total testing costs are particularly uncertain and that it is possible that they could exceed the lowest estimated annual benefit of €708 million (from the sensitivity analysis based on a 0.5% frequency of positivity of patch tests). As discussed in

the section on testing costs, SEAC notes that it considers it possible to reduce the total testing costs through semi-dynamic linking at the implementation phase allowing adoption of deferral periods before newly harmonised skin sensitisers will be restricted.

B.3.3.4.3.1. 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 11 provides a comparison of the costs and benefits of the proposed restriction options. As explained, there are uncertainties in the different cost elements, and these are also reflected in the comparative assessment of the proportionality of the three restriction options presented by the Dossier Submitter.

Table 11 Comparison of costs and benefits of the restriction options as quantified by the Dossier Submitter

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), one-off 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.

B.3.3.5. 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 noted elsewhere in this opinion , 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, 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 that 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 substitution costs in reality would be 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 cost assessment due to lack of information.

As a result of the proposed restriction both industry and enforcement authorities will need to perform additional testing to ensure compliance. The extent of these additional required testing that needs to be performed compared to the testing already undertaken is not known. To some extent the already existing quality control testing performed by the concerned companies may already provide the necessary information. While in general the costs are not expected to outweigh the overall societal gains, SEAC notes that the testing costs are a key uncertainty in the overall cost assessment.

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 considered 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 and therefore this 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 rather robust since they are taken from the literature from several studies.

However, the Dossier Submitter acknowledges that this prevalence may be reducing 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. SEAC took note of the comments received in the consultations on the Annex XV report and the SEAC draft opinion challenging the prevalence figures for allergic contact dermatitis used as they are based on patch tests conducted on a sub-population of individuals experiencing allergic contact dermatitis and hence could result in overestimation of the whole population's prevalence. SEAC acknowledges that the prevalence values are the key uncertainty in the human health benefits estimates, however, considers that the various sensitivity analyses undertaken in the benefits assessment sufficiently address all 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 sensitiser 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. The classification of new substances as skin sensitisers in the future could increase the human health benefits (if the substances are present in articles in the scope of the restriction), the substitution costs (if the substances are present) and the enforcement costs (as further testing by industry and authorities, as well as the development of testing methods, may be required). While information on such benefits and costs are not currently available, SEAC notes that as part of the 'semi-dynamic link' proposed by SEAC information on any substitution costs could be considered before the conditions of the restriction took effect for the substances in question. SEAC considers it unlikely that the classification of new substances in the future would affect its overall conclusion on proportionality.

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 consultations on the Annex XV report and on the SEAC draft opinion did not yield much new data on costs, but contained some information on the socio-economic implications of restricting specific dyes and on substances that do not yet have a harmonised classification but might be classified in future and thereby included in the scope of this restriction via the dynamic link to CLP (see the section on scope related to e.g. Reactive Black 5) as well as some cost estimates for testing costs. While SEAC is not able to fully scrutinise the testing cost estimates, they indicate 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, the available information demonstrates that the proposed restriction is likely to be proportional. Nevertheless, SEAC notes that the total testing costs are particularly uncertain and that it is possible that they could exceed the lowest estimated annual benefit of €708 million (from the sensitivity analysis based on a 0.5% frequency of positivity patch tests). As discussed in the section on testing costs, SEAC notes that it considers it possible to reduce

the total testing costs through semi-dynamic linking at the implementation phase allowing adoption of transitional periods before newly harmonised skin sensitisers will be restricted.

B.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

B.3.4.1. Summary of Dossier Submitter's 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 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.

B.3.4.2. RAC and SEAC conclusion(s)

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

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

B.3.4.3. Key elements underpinning the RAC and SEAC conclusion(s)

B.3.4.3.1. RAC

B.3.4.3.1.1. Enforceability

According to the Forum, the enforcement of this restriction could be challenging regarding the numerous substances within its scope. Especially, problems involving sampling, sample preparation and analytical methods may result in increased difficulties for its enforcement. However, RAC considers that the transition period should be long enough for the development of the necessary analytical methodologies that would provide a sufficient level of protection for consumers. Indeed, the Forum informed of attempts at developing analytical methodologies (using LC-ICP-MS techniques) with a view to reduce the limit of detection of Cr (VI) from the currently established standard of 3 mg/kg to 1 mg/kg. However, a reliable analytical method has not been developed yet, something which has been corroborated by industry respondents throughout the consultation on the Annex XV report.
The Forum has also provided several recommendations regarding terminology and wording. Some of these recommendations were adopted by the Dossier Submitter in the last version of the Background Document and others, such as the term “contact with human skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing” or “related accessories” were largely illustrated with examples; which in the opinion of RAC, helps enforceability by reducing the possibility of borderline situations.

Another point that raised the Forum’s concerns for effective enforceability, is the large number of theoretically restricted substances (1 050 included in the Annex VI of CLP regulation plus 24 in the list of concern) and suggested the Dossier Submitter to either reduce the scope of this restriction or to produce a list of the most important substances targeted by this restriction. RAC notes that such a list already exists (Table 19 in Annex E of the Background Document) and has been elaborated by the Dossier Submitter with the 94 substances relevant for the scope of the current restriction proposal, using chemicals likely to be found today in textile and leather articles’ manufacturing processes. Therefore, RAC notes that this list will also support the enforceability of the restriction because it could be used by enforcement authorities and industry to identify which substances to focus on in their enforcement and compliance activities.

Overall, RAC notes that to be fully enforceable, analytical methods with an appropriate limit of detection should be developed and, ideally, harmonised for those substances for which appropriate methodology is currently not available.

B.3.4.3.1.2. Implementability

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

1. A transition period of 36 months from entry into force would provide sufficient time for manufacturers and other economic operators in the supply chain to adapt to the requirements of this restriction. These requirements would initially be: i) development of additional analytical methods required for the restriction; and, ii) substitution of certain chemicals already in use, which should be relatively easy for when the chemical is intentionally used but can take longer time for substances found in the articles as impurities of other chemicals.
2. RAC notes that some substances will also need to comply with the restriction on CMR substances in textile (entry 72 of REACH Annex XVII), for which the transitional period is 24 months from entry into force, corresponding to year 2020. This transitional period was found by the Commission as practicable for the textile and leather industry. However, for the CMRs for which there are new concentration limits, once this skin sensitisers restriction comes into effect, RAC is of the opinion that the transitional period should be 36 months, similarly to the other substances in the scope of the present restriction.
3. The existence of national regulations on textile and leather, as well as already existing restrictions under REACH (on azo-dyes, chromium VI compounds and the entry 72 of REACH Annex XVII) suggest that industry, in principle, comply with risk management based on concentration limitations.

Overall, RAC supports the transitional period of 36 months from entry into force to allow all actors to meet their obligations. RAC also supports the transitional period of 36 month from entry into force for new concentration limits related to CMR substances.

B.3.4.3.1.3. Manageability

It is noted that additional chemical substances with sensitising properties will be harmonised and classified as Skins Sens. 1/1A/1B under the CLP regulation in the future, and they will be automatically included in the scope of this restriction, once the amendment to the CLP enters into force. The Dossier Submitter proposed to consider the substances that might be included in Annex VI of CLP regulation after this restriction come into force within the group of “other substances”.

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

B.3.4.3.2. SEAC

SEAC has taken note of the Forum advice stating that 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 that 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 the enforcement perspective.

B.3.4.3.2.1. 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 master list as presented in Table 19 of the Background Document) for inspection purposes.

B.3.5. Monitorability

Justification for the opinion of RAC and SEAC

B.3.5.1. Summary of Dossier Submitter's 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 possibility 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.

B.3.5.2. RAC and SEAC conclusion(s)

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

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

B.3.5.3. Key elements underpinning the RAC and SEAC conclusion(s)

B.3.5.3.1. RAC

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

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

RAC also notes that, according to the Dossier Submitter, OEKO-TEX has developed analytical methods able to meet the needed requirements for some substances. These methods are confidential and do not correlate with EN methods and therefore cannot be used in enforcement, so far. However, it suggests to RAC that the analytical detection of the proposed limits should be technically viable with proper developmental work and further harmonisation of appropriate testing methods. This is relevant, especially considering that, according to the Dossier Submitter, CEN TC248/WG26, which develops EN testing methods for the EC restricted substances in textiles, has been given a mandate by the EU commission to develop EN methods for all the textile related chemicals that are restricted under REACH and other related EU regulations.

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

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

B.3.5.3.2. SEAC

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 report 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 an 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.

B.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

B.4.1. RAC

B.4.1.1. Summary of Dossier Submitter's proposal:

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

- Scope: Irritant, and non-classified (if they are not in the list of concern) substances not included in the scope.
- Risk Management:
    - The Dossier Submitter has assumed that migration takes place for all substances in the scope. In addition, the exact relation between content and migration potential is uncertain.
    - The Dossier Submitter assumes there is potential for exposure to all substances in the scope, if present in the textile or leather.
    - There is a lack of data regarding use patterns for different textile and leather articles.
    - The range of elicitation doses was 0.025–20.1 µg/cm^2, indicating differences depending on the substance. The median value, 0.8 µg/cm^2, 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.

B.4.1.2. RAC conclusion(s)

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

B.4.1.3. Key elements underpinning the RAC conclusion(s)

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

B.4.2. SEAC

B.4.2.1. Summary of Dossier Submitter's 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.
- 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.

B.4.2.2. SEAC conclusion(s)

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 consultations on the Annex XV report and the SEAC draft opinion, 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. Information submitted in the consultations on the Annex XV report and the SEAC draft opinion points at likely underestimation of the quantified enforcement costs.
- Benefits of the proposed restriction: Based on the assessment provided by the Dossier Submitter and on information submitted during the consultations on the Annex XV report and the SEAC draft opinion, SEAC concludes that there are some uncertainties in the human health benefits, including on the positive patch test and the associated prevalence figures and the assessment period. SEAC considers that the various sensitivity analyses undertaken in the benefits assessment sufficiently address the uncertainties.
- 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 consultations on the Annex XV report and the SEAC draft opinion, SEAC notes that the practical implementability of the proposed restriction and associated uncertainties in the enforcement costs are higher for RO1a and RO2 as compared to RO3. SEAC has taken note 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 that they would be in favour of a closed list. While SEAC considers RO1a the most appropriate restriction option, it has suggested some changes to it, including the so called 'semi-dynamic' link to increase predictability for substances classified according to CLP in the future.

B.4.2.3. Key elements underpinning the SEAC conclusion(s)

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

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ANNEX I. SUBSTANCES OF CONCERN OUTSIDE THE SCOPE OF THIS RESTRICTION PROPOSAL

Benzyl benzoate

Benzyl benzoate (CAS 120-51-4, EC 204-402-9) has no harmonised or self-classification as a skin sensitiser. The REACH registration dossier only describes one negative OECD TG 429 LLNA study. Nevertheless, the SCCS established benzyl benzoate as a contact allergen in humans in their opinion on Fragrance allergens in cosmetic products (SCCS/1459/11) which therefore listed as one of the 26 allergenic fragrances according to the Cosmetic Products Regulation (CPR, Regulation EU 1223/2009).

Benzyl benzoate was quantified in the ANSES study in 21% of footwear articles at concentrations ranging from 13 to 45 mg/kg in 6 footwear articles and was also detected in textiles using thermal desorption. Allergic contact dermatitis was observed in association with the quantification. Nevertheless, no firm causality with benzyl benzoate was established. The substance seems to be used as dye accelerator or as a plasticizer for certain polymers. Benzyl benzoate also presents biocidal properties although its use as an active substance is not approved in the EU.

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

Butyl hydroxyl toluene *(*CAS 128-37-0, EC 204-881-4)

Butyl hydroxyl toluene (BHT) has a harmonised classification as Acute Tox. 4* H302 according to the previous EU Directive 67/548/EEC on classification, labelling and packaging of substances. In the REACH registration dossier, many studies were described showing conflicting results regarding skin sensitisation of BHT. A self-classification as Skin Sens. 1 was retained by 44 notifiers.

In the ANSES study, BHT was quantified in all the footwear articles at concentrations between 11 and 71 mg/kg. BHT was also thermally extracted from 15 textile articles with a maximum concentration of 165 mg/kg. Allergic contact dermatitis was observed after exposure to some of the footwear articles without firm link with BHT.

RAC agrees that there is a concern regarding the skin sensitisation hazard of butyl hydroxyl toluene. The ANSES study also confirms that BHT is present in textile and footwear finished articles.

2-phenoxyethanol (CAS 122-99-6, EC 204-589-7)

2-phenoxyethanol has a harmonised classification as Acute Tox. 4* H302 and Eye Irrit. 2 H319 according to the previous EU Directive 67/548/EEC on classification, labelling and packaging of substances. No self-classification as skin sensitiser was retained for this substance by the notifiers. Phenoxyethanol was recently the object of a RAC opinion on harmonised classification. However, skin sensitisation was not open for discussion in the CLH

proposal. No conclusion was therefore provided by RAC on the skin sensitisation potential of 2-phenoxyethanol. In addition, the SCCS did not highlight a skin sensitisation hazard of phenoxyethanol in their related opinion in 2016 (SCCS/1575/16).

Phenoxyethanol was quantified in all the footwear articles at concentrations between 11.30 and 68 mg/kg in leather. This chemical was also detected in 7 textiles using thermo-desorption at a maximum concentration of 11.30 mg/kg.

Overall, although 2-phenoxyethanol has a concern of skin irritation, no clear dataset demonstrating skin sensitisation is available for this substance. RAC however agrees that 2-phenoxyethanol can be present in textile and leather finished articles.

Para tertbutyl phenol (4-tert-butylphenol CAS 98-54-4, EC 202-679-0)
Para-tert-butylphenol (ptBP) has a harmonised classification as Skin Irrit. 2 H315, Eye Dam. 1 H318, STOT SE 3 H335 and Repr. 2 H361f. Although in their opinion (Nov 2010), RAC concluded that ptBP did not fulfil the classification criteria for skin sensitisation based on the available information, several human data in the report showed very variable picture of human sensitisation to ptBP. This chemical is restricted according to the Cosmetics Products Regulation (Annex II/340) as well as in the Toy Safety Directive (No 2009/48/EC) where it is defined as an allergenic fragrance.

The ANSES study indicated that p-tert-butylphenol was present in 12 textile and leather articles at concentrations up to 152 mg/kg. The study concluded that the presence of formaldehyde in the analyses, at concentration up to 425 mg/kg, in conjunction with ptBP, was a potential indicator of ptBP formaldehyde resin in footwear.

Overall, scientific evidence suggest that para-tert-butylphenol has a low sensitisation capacity by itself. Nevertheless, exposure to p-tert-butylcatechol might lead to cross-reactions with p-tert-butylphenol. Formaldehyde has a harmonised classification as Skin Sens. 1 and is therefore in the scope of the restriction proposal. The concern related to ptBP formaldehyde resin is therefore expected to be covered by the present restriction.

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

Hedberg and co-workers (2018) exposed 10 Cr-allergic subjects and 22 controls to patches of serial dilutions of Cr(VI) for 2 days, patches of serial dilutions of Cr(III) for 2 days, Cr-tanned leather bracelets (containing no other metal than Cr) and Cr-free tanned leather bracelets (containing no other metal than Cr). These authors found: no positive reactions in the Cr-negative controls, either in patch or bracelet tests; no positive reactions to Cr-free leather bracelets; 10 individuals reacting to Cr (VI) patches; 7 individuals reacting to Cr(III) patches and 4 individuals reacting to bracelets. Although the chromium-allergic participants

reacted positively to 10-100 fold lower concentration of Cr (III) as compared to Cr (VI) in the Hedberg study, the releases of Cr (III) at normal skin conditions or in contact with rain are expected to be 1 000 – 1 000 000 fold greater as compared to chromium (VI) (Mathiason et al, 2015).

RAC has also addressed this question with publications in the scientific open literature and has found several demonstrating the capability of Cr (III) to elicit skin sensitisation. Hasen et al (2003) tested in 18 chromium-allergic patients the capability of Cr (III) and Cr (VI) dissolved in synthetic sweat to induce allergy after 48-hours of exposure. They found dose-response positive reactions for both forms of chromium and estimated MET10 of 6 and 1 ppm for Cr(III) and Cr (VI); respectively. In a follow up study Hansen et al (2006) tested 2 211 consecutive eczema patients finding 31 positive reaction to Cr (III) among the Cr (VI) reacting patients.

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

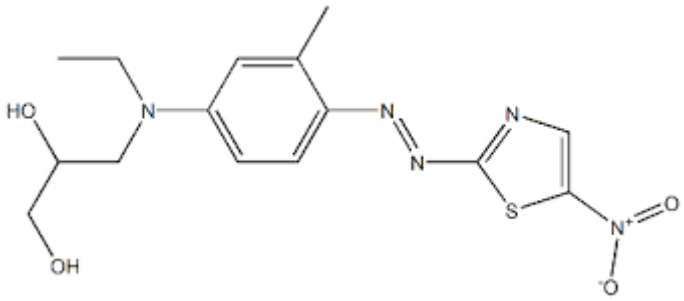
ANNEX II. IN SUPPORT OF HAZARD IDENTIFICATION

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

1.1 Azo dyes

CI Disperse Blue 102

The chemical name of this substance is 1,2-propanediol, 3-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-. The chemical structure is shown below, and its CAS number is 12222-97-8.

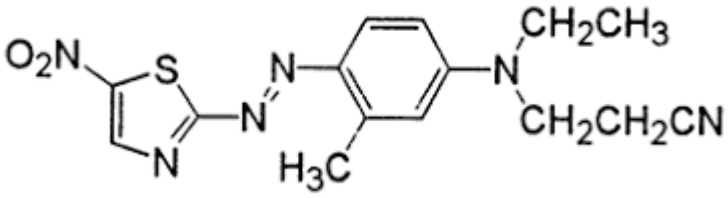


Chemical structure of CI Disperse Blue 102 (CAS number 12222-97-8)

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding lack of data on patch testing with Disperse Blue 102. No experimental evidences could be found by RAC to support a potential dermal sensitising capability of Disperse Blue 103.

CI Disperse Blue 106

The chemical name of this substance is ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-. The chemical structure is shown below, and its CAS number is 12223-01-7.



Chemical structure of CI Disperse Blue 106 (CAS number 12223-01-7)

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding 30 positive reactions (4.7%) against Disperse Blue 106.

The case of a 35-year-old man with a 2-year history of severe facial dermatitis was presented by Hansson and co-workers (1997). The patient had operated at the work an automatic colour film-developing machine for the past 5 years. After 3 years of this work, he developed strongly pruritic erythematous dermatitis on his forehead. The patient was patch tested with several allergens and gave positive against Disperse blue 106.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 44 non-occupational (28.6%) positive reaction against Disperse Blue 106.

Seidinari and co-workers (2005) patch tested with Disperse Blue 106 a total of 1094 children (509 boys and 585 girls) from 1995 to 2001 finding a positive response in 5.7% of them.

Malinauskiene and co-workers (2013) reviewed studies, reports on contact allergy to disperse dyes during the period 1990–2012 finding 16 aimed and 13 screening studies with positive results against Disperse Blue 106. The prevalence was 16.7% (342/2051) and 1.9% (639/35334) in the aimed and screening studies; respectively.

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and 5 of them showed positive answer to Disperse Blue 106. In another study only 2/60 patched patients showed positive reaction against Disperse Blue 106 (Ryberg et al., 2009).

Contact allergy to Disperse Blue 106 was tested in two different studies at the Department of Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 16/159 patients (9.8%) were positive, while in the second study 2% (10/500) was positive (Morgardt-Ryberg 2009).

The positive reactions to Disperse Blue 106 were tested in 32 German and Austrian patch test clinics between 1995 and 1999 with 1847 patients finding erythematous reaction in 34, erythema, infiltration and possibly papules in 44, erythema, infiltration and papulovesicles in 12 and erythema, infiltration and confluent papulovesicles in 8 (Uter et al., 2001).

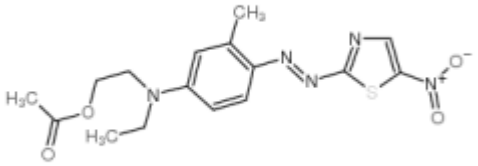
Ahuja and co-workers (2010) assessed the sensitising potential of various disperse dyes using a biphasic protocol of the local lymph node assay in mice finding that an administration of 50 µl of a 0.003, 0.03 and 0.3% solution of Disperse Blue 106 on a surface of 2 cm^2 was able to increase the cell counting in auricular lymph nodes of mice by 37, 79 and 82%; respectively. It allowed to the authors to postulate Disperse Blue 106 as a strong sensitiser.

Sonnenburg and co-workers (2012) used the so-called called loose-fit co-culture-based sensitisation assay (LCSA) based on co-culture of primary human keratinocytes and allogenic

dendritic cell-related cells for combined testing of the sensitising and irritative properties of these substances. It was found that Disperse Blue 106 was considered an extreme sensitiser with an EC_{50} of 2 µM.

CI Disperse Blue 124

The chemical name of this substance is ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-, 1-acetate. The chemical structure is shown below, and its CAS number is 61951-51-7.



Chemical structure of CI Disperse Blue 124 (CAS number 61951-51-7)

Disperse Blue 124 is self-classified by 23 notifiers as skin sensitiser category 1.

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding 34 positive reactions (5.3%) against Disperse Blue 124.

The case of a 35-year-old man with a 2-year history of severe facial dermatitis was presented by Hansson and co-workers (1997). The patient had operated at the work an automatic colour film-developing machine for the past 5 years. After 3 years of this work, he developed strongly pruritic erythematous dermatitis on his forehead. The patient was patch tested with several allergens and gave positive against Disperse blue 124.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 84 (79 non-occupational and 5 occupational) (54.5%) positive reaction against Disperse Blue 124.

Seidinari and co-workers (2005) patch tested with Disperse Blue 124 a total of 1094 children (509 boys and 585 girls) from 1995 to 2001 finding a positive response in 1.9% of them.

Malinauskiene and co-workers (2013) reviewed studies, reports on contact allergy to disperse dyes during the period 1990–2012 finding 15 aimed, and 14 screening studies with positive results against Disperse Blue 124. The prevalence was 15.5% (376/2363) and 1.7% (517/19964) in the aimed and screening studies; respectively.

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and 6 of them showed positive answer to Disperse Blue 124. In another study only

2/60 patched patients showed positive reaction against Disperse Blue 124 (Ryberg et al., 2009).

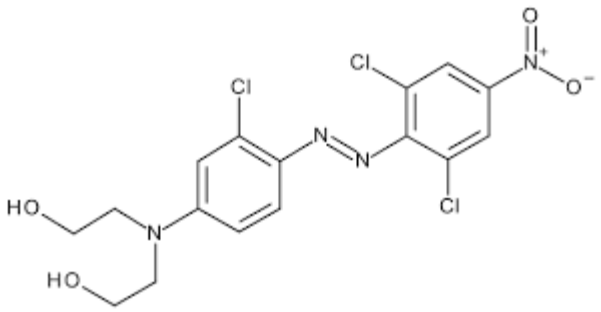
The positive reactions to Disperse Blue 106 were tested in 32 German and Austrian patch test clinics between 1995 and 1999 with 1829 patients finding erythematous reaction in 39, erythema, infiltration and possibly papules in 33, erythema, infiltration and papulovesicles in 14 and erythema, infiltration and confluent papulovesicles in 8 (Uter et al., 2001).

Contact allergy to Disperse Blue 124 was tested in 2 different studies at the Department of Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 6/159 patients (3.8%) were positive, while in the second study 1.8% (9/500) was positive (Morgardt-Ryberg 2009).

Ahuja and co-workers (2010) assessed the sensitising potential of various disperse dyes using a biphasic protocol of the local lymph node assay in mice finding that an administration of 50 µl of a 0.003 and 0.03 solution of Disperse Blue 124 on a surface of 2 cm^2 was able to increase the cell counting in auricular lymph nodes of mice by 21 and 79%; respectively. It allowed to the authors to postulate Disperse Blue 124 as a strong sensitiser.

Sonnenburg and co-workers (2012) used the LCSA for combined testing of the sensitising and irritative properties of these substances. It was found that Disperse Blue 124 was considered an extreme sensitiser with an EC_{50} of 0.25 µM.

CI Disperse Brown 1
The chemical name of this substance is 2,2'-[[3-chloro-4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]imino]bisethanol. The chemical structure is shown below, and its CAS number is 23355-64-8.



Chemical structure of CI Disperse Brown 1
(CAS number 23355-64-8)

Disperse Brown 1 is self-classified by 13 notifiers as skin sensitiser category 1; although another 33 notifiers did not self-classify the substance.

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding 1 positive reactions (0.2%) against Disperse Brown 1.

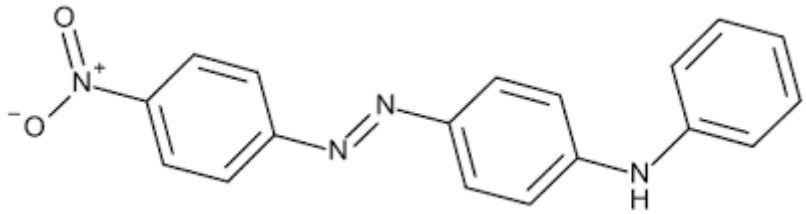
Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact

dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding three non-occupational (1.9%) positive reaction against Disperse Brown 1.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding 10 aimed and 2 screening studies with positive results against Disperse Brown 1. The prevalence was 1.5% (22/1498) and 0.1% (2/2355) in the aimed and screening studies; respectively.

CI Disperse Orange 1

The chemical name of this substance is 4-[(4-nitrophenyl)azo]-N-phenylaniline. The chemical structure is shown below, and its CAS number is 2581-69-3.



Chemical structure of CI Disperse Orange 1 (CAS number 2581-69-3)

Disperse Orange 1 is self-classified by 2 notifiers as skin sensitiser category 1.

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding 3 positive reactions (0.5%) against Disperse Orange 1.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 10 (8 non-occupational and 2 occupational) (6.5%) positive reaction against Disperse Orange 1.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding 9 aimed and 4 screening studies with positive results against Disperse Orange 1. The prevalence was 2.3% (34/498) and 0.9% (52/6184) in the aimed and screening studies; respectively.

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and 17 of them showed positive answer to Disperse Orange 1. In another study only 2/60 patched patients showed positive reaction against Disperse Orange 1 (Ryberg et al., 2009).

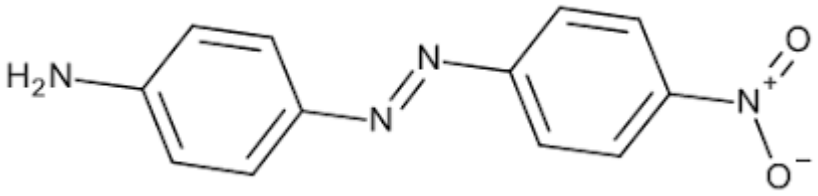
Contact allergy to Disperse Orange 1 was tested in 2 different studies at the Department of

Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 2/159 patients (1.3%) were positive, while in the second study 1.2% (6/500) was positive (Morgardt-Ryberg 2009).

A case report was found in the literature where is described as a 66-year-old male with a 2-year history of severe hand eczema (Figure 1A) progressively worsening course was positively reacted to Disperse Orange 1 patch test.

CI Disperse Orange 3

The chemical name of this substance is 4-[(4-nitrophenyl)azo]aniline . The chemical structure is shown below, and its CAS number is 730-40-5.



Chemical structure of CI Disperse Orange 3 (CAS number 730-40-5)

Disperse Orange 3 is self-classified by a total of 34 notifiers as skin sensitiser category 1; while 2 other notifiers did not self-classified Disperse Orange 3.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 9 (7 non-occupational and 2 occupational) (5.8%) positive reaction against Disperse Orange 3.

Malinauskiene and co-workers (2013) reviewed studies, reports on contact allergy to disperse dyes during the period 1990–2012 finding 17 aimed, and 12 screening studies with positive results against Disperse Orange 3. The prevalence was 10.6% (244/2256) and 1.2% (334/27899) in the aimed and screening studies; respectively.

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and 1 of them showed positive answer to Disperse Orange 1. In another study 5/60 patched patients showed positive reaction against Disperse Orange 1 (Ryberg et al., 2009).

Contact allergy to Disperse Orange 3 was tested in 2 different studies at the Department of Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 5/159 patients (3%) were positive, while in the second study 3.6% (18/500) was positive (Morgardt-Ryberg 2009).

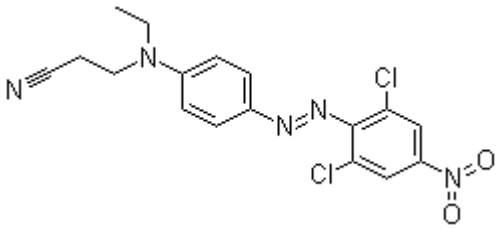
A case report was found in the literature where is described as a 66-year-old male with a 2-year history of severe hand eczema (Figure 1A) progressively worsening course was positively reacted to Disperse Orange 1 patch test.

Seidinari and co-workers (2005) patch tested with Disperse Orange 3 a total of 1094 children (509 boys and 585 girls) from 1995 to 2001 finding a positive response in 1.8% of them.
On the opposite to the above stated results, Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding no positive reactions against Disperse Orange 3.

Ahuja and co-workers (2010) assessed the sensitising potential of various disperse dyes using a biphasic protocol of the local lymph node assay in mice finding that an administration of 50 µl of a 30% solution of Disperse Orange 3 on a surface of 2 cm^2 was able to increase the cell counting in auricular lymph nodes of mice by a non-statistically significant 30%. It allowed to the authors to postulate Disperse Orange 3 as a very weak sensitiser.

Sonnenburg and co-workers (2012) used the LCSA for combined testing of the sensitising and irritative properties of these substances. It was found that Disperse Orange 3 was considered a strong sensitiser with an EC_{50} of 18 µM.

CI Disperse Orange 37/59/76
The chemical names of Disperse Orange 37 and 59 are 3-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]ethylamino]propiononitrile and propanenitrile, 3-[[4-[2-(2,6-dichloro-4-nitrophenyl)diazenyl]phenyl]ethylamino]-; respectively. The chemical structure of Disperse Orange 37 is shown below, and its CAS number is 13301-61-6. The CAS numbers for Disperse Orange 59 and 76 are 12223-33-5 and 51811-42-8; respectively.



Chemical structure of CI Disperse Orange 37 (CAS number 13301-61-6)

Disperse Orange 3 (CAS number 13301-61-6) is self-classified by a total of 26 notifiers as skin sensitiser category 1; while 4 other notifiers did not self-classified Disperse Orange 37.

Ahuja and co-workers (2010) assessed the sensitising potential of various disperse dyes using a biphasic protocol of the local lymph node assay in mice finding that an administration of 50 µl of a 10 and 30% solutions of Disperse Orange 37 on a surface of 2 cm^2 was able to increase the cell counting in auricular lymph nodes of mice by 16 and 53%, respectively. It allowed to the authors to postulate Disperse Orange 37 as a very weak.

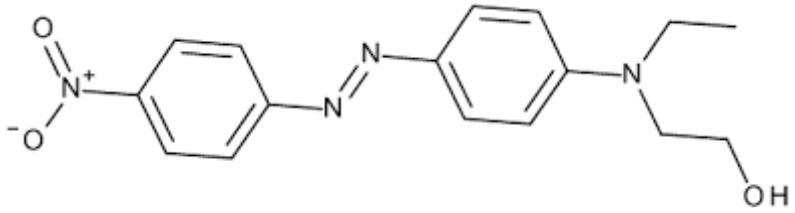
Sonnenburg and co-workers (2012) used the LCSA for combined testing of the sensitising and irritative properties of these substances. It was found that Disperse Orange 37/76 (CAS number 13301-61-6) was considered an extreme sensitiser with an EC_{50} of 1 µM.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to

disperse dyes during the period 1990–2012 noting lack of studies with positive results against Disperse Orange 37.

Finally, Disperse Orange 37/59/76 was identified in the ANSES study (2018) as responsible for cases of skin sensitisation reported by patients to physicians after wearing clothing articles or footwear.

CI Disperse Red 1
The chemical name of this substance is 2-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]ethanol. The chemical structure is shown below and its CAS number is 2872-52-8.



Chemical structure of CI Disperse Red 1 (CAS number 2872-52-8)

Disperse Red 1 is self-classified by a total of 57 notifiers as skin sensitiser category 1; while 2 other notifiers did not self-classified Disperse Red 1.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 9 (7 non-occupational and 2 occupational) (5.8%) positive reaction against Disperse Red 1.

Malinauskiene and co-workers (2013) reviewed studies, reports on contact allergy to disperse dyes during the period 1990–2012 finding 17 aimed, and 13 screening studies with positive results against Disperse Red 1. The prevalence was 7.5% (17/2266) and 0.8% (236/30120) in the aimed and screening studies; respectively.

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and 6 of them showed positive answer to Disperse Red 1. In another study 4/60 patched patients showed positive reaction against Disperse Red 1 (Ryberg et al., 2009).
Contact allergy to Disperse Red 1 was tested in 2 different studies at the Department of Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 2/159 patients (1.3%) were positive, while in the second study 1.6% (3/500) was positive (Morgardt-Ryberg 2009).

Seidinari and co-workers (2005) patch tested with Disperse Red 1 a total of 1094 children (509 boys and 585 girls) from 1995 to 2001 finding a positive response in 2.3% of them.
On the opposite to the above stated results, Lazarov (2003) studied in Israel 644 (441 female

and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding no positive reactions against Disperse Red 1.

Ahuja and co-workers (2010) assessed the sensitising potential of various disperse dyes using a biphasic protocol of the local lymph node assay in mice finding that an administration of 50 µl of a 3, 10 and 30% solution of Disperse Red 1 on a surface of 2 cm^2 was able to increase the cell counting in auricular lymph nodes of mice by 26, 50 and 61%; respectively. It allowed to the authors to postulate Disperse Red 1 as a moderate sensitiser.

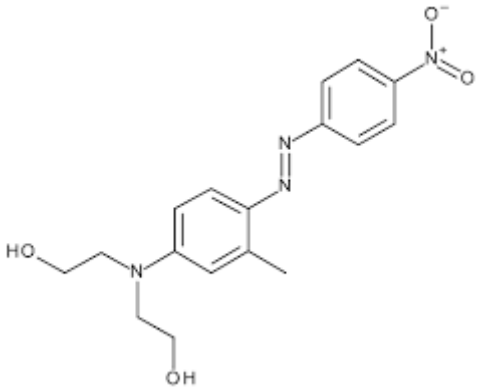
Sonnenburg and co-workers (2012) used the LCSA for combined testing of the sensitising and irritative properties of these substances. It was found that Disperse Red 1 was considered an extreme sensitiser with an EC_{50} of 3 µM.

CI Disperse Red 17

The chemical name of this substance is 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol. The chemical structure is shown below, and its CAS number is 3179-89-3. Disperse Red 17 is self-classified by a total of 3 notifiers as skin sensitiser category 1; while 84 other notifiers did not self-classified Disperse Red 17.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 6 non-occupational (3.9%) positive reactions against Disperse Red 17.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding 16 aimed and 5 screening studies with positive results against Disperse Red 17. The prevalence was 3.4% (64/1883) and 0.3% (17/6511) in the aimed and screening studies; respectively.



Chemical structure of CI Disperse Red 17 (CAS number 3179-89-3).

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and five of them showed positive answer to Disperse Red 17. In another study 3/60 patched patients showed positive reaction against Disperse Red 17 (Ryberg et al., 2009).

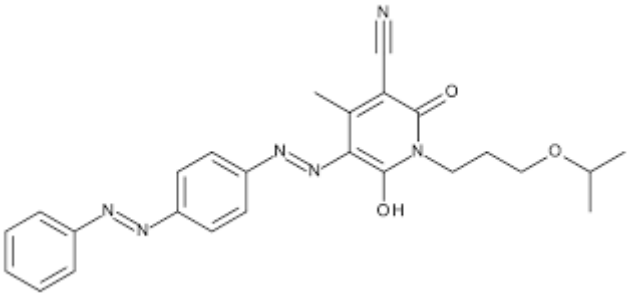
Contact allergy to Disperse Red 17 was tested in 2 different studies at the Department of Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 6/159 patients (3.8%) were positive, while in the second study 1.2% (6/500) was positive (Morgardt-Ryberg 2009).

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding 4 positive reactions (0.6%) against Disperse Red 17.

The case of a 35-year-old man with a 2-year history of severe facial dermatitis was presented by Hansson and co-workers (1997). The patient had operated at the work an automatic colour film-developing machine for the past 5 years. After 3 years of this work, he developed strongly pruritic erythematous dermatitis on his forehead. The patient was patch tested with several allergens and gave positive against Disperse Red 17.

CI Disperse Orange 149

The chemical name of this substance is 6-hydroxy-1-(3-isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo)phenylazo]-1,2-dihydro-3-pyridinecarbonitrile. The chemical structure is shown below, and its CAS number is 85136-74-9.



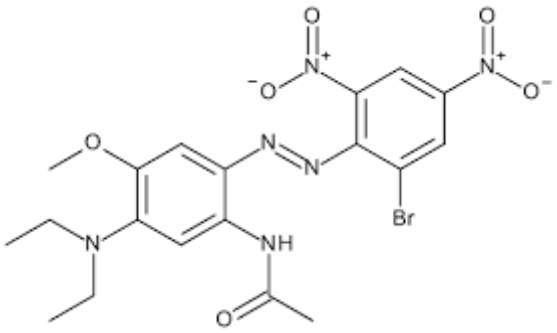
Chemical structure of CI Disperse Orange 149 (CAS number 85136-74-9).

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding lack of data on patch testing with Disperse Orange 149. Moreover, the REACH registration dossier of this substance does not contain information about skin sensitisation. No experimental evidences could be found by RAC to support a potential dermal sensitising capability of Disperse Orange 149.

CI Disperse Blue 291

According to DS CAS and EC numbers are not specified for CI Disperse Blue 291 because there are numerous CAS and EC numbers associated with this chemical. According to DS 1 CAS and EC numbers are not specified for CI Disperse Blue 291 because there are numerous CAS and EC numbers associated with this chemical. However, RAC found that this disperse dye corresponds to the substance with name chemical name N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)-4-methoxyphenyl]acetamide which chemical structure is shown below. Two different CAS numbers (56548-64-2 and 83929-84-4) were found associated to CI Disperse Blue 291.

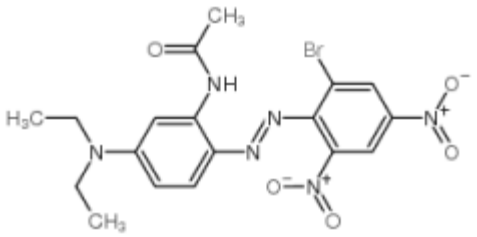
Disperse Blue 291 (CAS number 56548-64-2) is self-classified by a total of 21 notifiers as skin sensitiser category 1; while 19 other notifiers did not self-classified Disperse Blue 291.



Chemical structure of CI Disperse Blue 291 (CAS number 56548-64-2).

CI Disperse Violet 93

The chemical name of this substance is C.I. Disperse Violet 93:1. The chemical structure is shown below, and its CAS number is 122463-28-9.

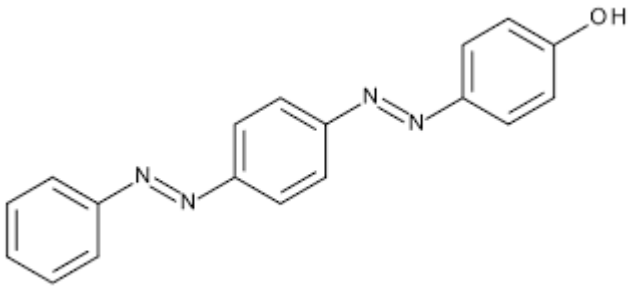


Chemical structure of CI Disperse Violet 93 (CAS number 122463-28-9).

No experimental evidences could be found by RAC to support a potential dermal sensitising capability of Disperse Violet 93.

CI Disperse Yellow 23

The chemical name of this substance is p-[[p-(phenylazo)phenyl]azo]phenol. The chemical structure is shown below, and its CAS number is 6250-23-3.



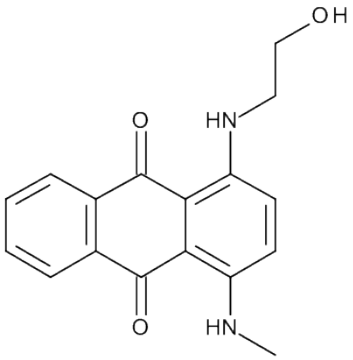
Chemical structure of CI Disperse Yellow 23 (CAS number 6250-23-3).

No experimental evidences could be found by RAC to support a potential dermal sensitising capability of Disperse Yellow 23. However, Disperse Yellow 23 was identified in the ANSES study (2018) as responsible for cases of skin sensitisation reported by patients to physicians after wearing clothing articles or footwear. The Dossier Submitter therefore included the substance in the scope of the restriction proposal.

1.2 Anthraquinone dyes

CI Disperse Blue 3

The chemical name of this substance is 9,10-anthracenedione, 1,4-diamino-, N,N'-mixed 2-hydroxyethyl and methyl derivatives. The chemical structure is shown below, and its CAS number is 2475-46-9.



Chemical structure of CI Disperse Blue 3 (CAS number 2475-46-9)

CI Disperse Blue 3 is self-classified by 31 notifiers as skin sensitiser category 1; while other 4 notifiers do not classify the substance for skin sensitisation.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding 6 (5 non-occupational and 1 occupational) (3.9%) positive reactions against Disperse Blue 3.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding 13 aimed and 3 screening studies with positive results against Disperse Blue 3. The prevalence was 1% (14/1441) and 0.2% (3/2682) in the aimed and screening studies; respectively.

Morrone and co-workers (2014) patched tested 480 consecutive patients in northern Ethiopia exhibiting symptoms of contact dermatitis finding 2.3% of the individuals responding positively to Disperse Blue. However, RAC noted that in this case the allergen were generally identified as Disperse Blue and therefore it is not possible to determine whether these positive reactions were specifically attributable to Disperse Blue 3 or to other substances belonging to the family of the so-called Disperse Blue.

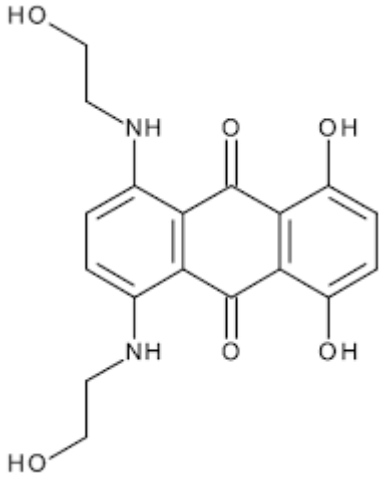
By the other hand, Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact

dermatitis patients suspected of having textile allergic contact dermatitis finding no positive reactions against Disperse Blue 3.

CI Disperse Blue 7

The chemical name of this substance is 1,4-dihydroxy-5,8-bis[(2-hydroxyethyl)amino]anthraquinone. The chemical structure is shown below, and its CAS number is 3179-90-6.

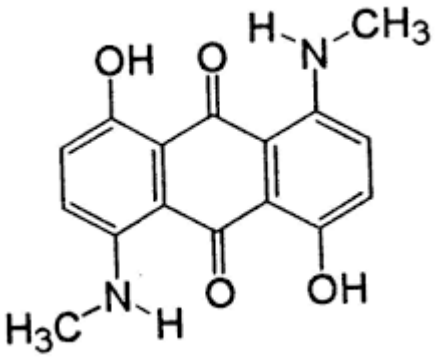
Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding 3 aimed studies with positive results against Disperse Blue 7 and a prevalence of 16.7% (2/12).



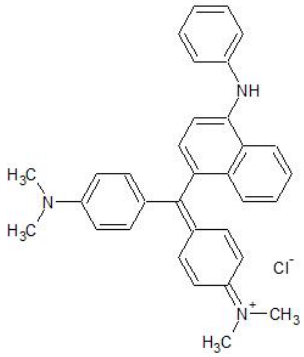
Chemical structure of CI Disperse Blue 7 (CAS number 3179-90-6)

CI Disperse Blue 26

CI disperse Blue 26 is a substance with four different synonyms with chemical names C.I. Disperse Blue 26:1 (CAS number 100357-99-1), 9,10-Anthracenedione, 1,5-bis(dimethylamino)-(CAS number 13324-23-7, chemical structure shown below), 4,8-dihydroxy-1,5-dihydroxy-4,8-bis(methylamino)anthraquinone (CAS number 3860-63-7), and [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1 idene]dimethylammonium chloride (CAS number 2580-56-5, chemical structure shown below).



Chemical structure of CI Disperse Blue 26 (CAS number 13324-23-7)



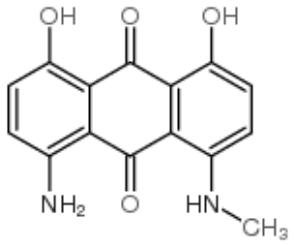
Chemical structure of CI Disperse Blue 26 (CAS number 2580-56-5)

The substance with CAS number 2580-56-5 has been registered under REACH regulation. In the registration dossier, the substance was considered sensitiser based on a valid and reliable QSAR prediction. This substance is self-classified by two notifiers as skin sensitiser category 1; while other 183 notifiers do not classify the substance for skin sensitisation.

The substance with CAS number 3860-63-7 is listed within Annex III of REACH (substances for which it is predicted that they are likely to meet the classification criteria for any health or environmental hazard classes under Regulation (EC) No 1272/2008) as suspected of respiratory sensitiser.

CI Disperse Blue 35

CI disperse Blue 35 is a substance with two different synonyms with chemical names C.I. Disperse Blue 35 (CAS number 12222-75-2) and 1-amino-4,5-dihydroxy-8-(methylamino)anthraquinone (CAS number 56524-77-7, chemical structure shown below).



Chemical structure of CI Disperse Blue 35 (CAS number 56524-77-7)

This substance with CAS number 12222-75-2 is self-classified by 23 notifiers as skin sensitiser category 1.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding 13 aimed and 3 screening studies with positive results against Disperse Blue 35. The prevalence was 1.7% (30/1779) and 0.3% (11/4135) in the aimed and screening studies; respectively.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding one non-occupational (0.6%) positive reaction against Disperse Blue 35.

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding five positive reactions (0.8%) against Disperse Blue 35.

Ryberg and co-workers (2006) assessed the prevalence of allergic patch test reactions to different textile dyes in Southern Sweden. Fifty patients (28 men and 22 women) were patch tested and three of them showed positive answer to Disperse Blue 35. In another study only 1/60 patched patients showed positive reaction against Disperse Blue 26 (Ryberg et al., 2009).

Contact allergy to Disperse Blue 35 was tested in two different studies at the Department of Dermatology of the Katholieke Universiteit in Leuven (Belgium). In the first study 6/159 patients (3.8%) were positive, while in the second study 0.4% (2/500) was positive (Morgardt-Ryberg 2009).

Ahuja and co-workers (2010) assessed the sensitising potential of various disperse dyes using a biphasic protocol of the local lymph node assay in mice finding that an administration of 50 µl of a 10 and 30% solution of Disperse Blue 35 on a surface of 2 cm^2 was able to increase the cell counting in auricular lymph nodes of mice by 24 and 32%; respectively. It allowed to the authors to postulate Disperse Blue 35 as a weak sensitiser.

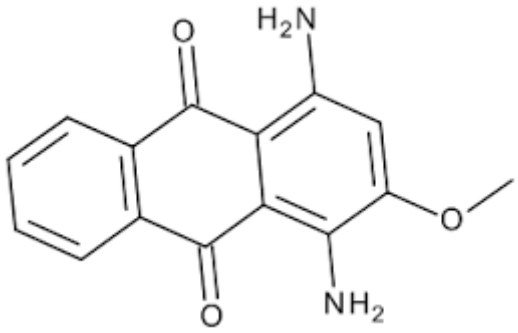
Sonnenburg and co-workers (2012) used the LCSA for combined testing of the sensitising and irritative properties of these substances. It was found that Disperse Blue 26 was considered an extreme sensitiser with an EC_{50} of 6 µM.

In Europe, Disperse Blue 35 is included in the textile dye mix used in patch testing includes among others, supporting the scientific evidences presented above.

Finally, the substance with CAS number 56524-77-7 is listed within Annex III of REACH (substances for which it is predicted that they are likely to meet the classification criteria for any health or environmental hazard classes under Regulation (EC) No 1272/2008) as suspected of respiratory sensitiser.

CI Disperse Red 11

The chemical name of this substance is 1,4-diamino-2-methoxyanthraquinone. The chemical structure is shown below, and its CAS number is 2872-48-2.



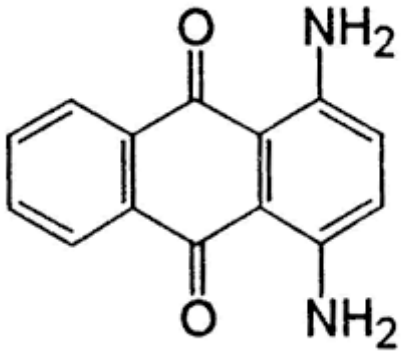
Chemical structure of CI Disperse Red 11
(CAS number 2872-48-2)

Disperse Red 11 is self-classified by a total of 5 notifiers as skin sensitiser category 1; while 37 other notifiers did not self-classified Disperse Red 11.

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding two aimed studies reporting a prevalence of 0% (0/24).

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding 11 positive reactions (1.7%) against Disperse Red 11.

CI Disperse Violet 1
The chemical name of this substance is 1,4-diaminoanthraquinone. The chemical structure is shown below, and its CAS number is 128-95-0.



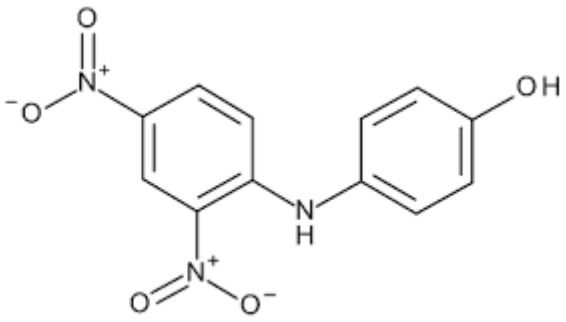
Chemical structure of CI Disperse Violet 1 (CAS number 128-95-0).

Disperse Red 17 is self-classified by a total of 73 notifiers as skin sensitiser category 1; while 32 other notifiers did not self-classified Disperse Violet 1. No experimental evidences could be found by RAC to support a potential dermal sensitising capability of Disperse Violet 1.

1.3 Nitro dyes

CI Disperse Yellow 1

The chemical name of this substance is 4-(2,4-dinitroanilino)phenol. The chemical structure is shown below, and its CAS number is 119-15-3.

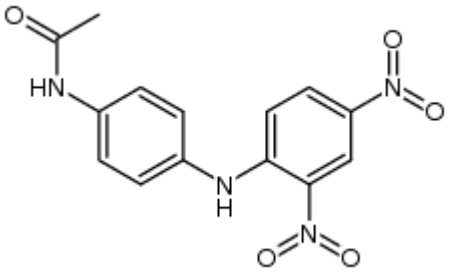


Chemical structure of CI Disperse Yellow 1 (CAS number 119-15-3).

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding one aimed study with positive results against Disperse Yellow 1 with a prevalence of 5% (2/40).

CI Disperse Yellow 9

The chemical name of this substance is N-(2,4-dinitrophenyl)benzene-1,4-diamine. The chemical structure is shown below, and its CAS number is 6373-73-5.



Chemical structure of CI Disperse Yellow 9 (CAS number 6373-73-5).

Disperse Yellow 9 is self-classified by 2 notifiers as skin sensitiser category 1.

Lisi and co-workers (2014) investigated clinical and epidemiological features of textile contact dermatitis in an Italian multicentre study. They studied the positive patch test reactions to textile allergens in 154 (132 non-occupational and 22 occupational) patients affected by allergic textile contact dermatitis finding two non-occupational (1.3%) positive reactions against Disperse Yellow 9.

Lazarov (2003) studied in Israel 644 (441 female and 203 male) contact dermatitis patients suspected of having textile allergic contact dermatitis finding one positive reaction (0.2%) against Disperse Yellow 9.

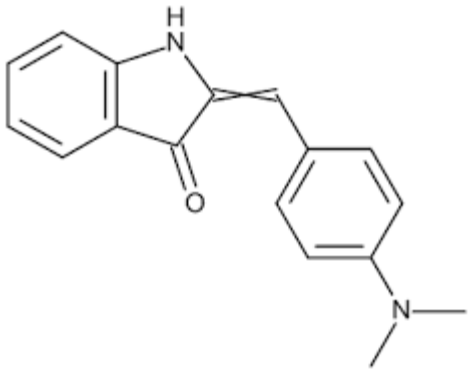
Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to

disperse dyes during the period 1990–2012 finding 13 aimed and 2 screening studies with positive results against Disperse Yellow 9. The prevalence was 1.6% (26/1607) and 0.06% (2/2355) in the aimed and screening studies; respectively.

1.4 Methine dyes

CI Disperse Yellow 39

The chemical name of this substance is (2Z)-2-{[4-(dimethylamino)phenyl]methylidene}-2,3-dihydro-1H-indol-3-one. The chemical structure is shown below, and its CAS number is 12236-29-2.

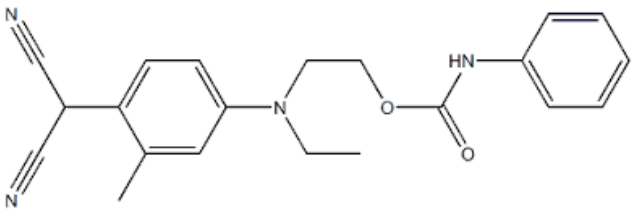


Chemical structure of CI Disperse Yellow 39 (CAS number 12236-29-2).

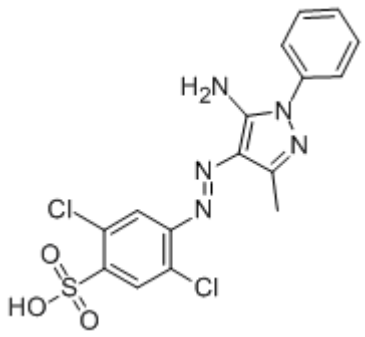
Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding one aimed study with a prevalence of 0% (0/6) for Disperse Yellow 39.

CI Disperse Yellow 49

CI Disperse Yellow 49 is a substance with two different synonyms with chemical names 4-[(5-amino-3-methyl-1-phenyl-1H-pyrazol-4-yl)azo]-2,5-dichlorobenzenesulphonic acid (CAS number 12239-15-5, chemical structure shown below) and Disperse Gelb 49 which is a methine dye corresponding to the CAS number 54824-37-2 (chemical structure shown below).



Chemical structure of CI Disperse Yellow 49 (CAS number 54824-37-2).



Chemical structure of CI Disperse Yellow 49 (CAS

number 12239-15-5).

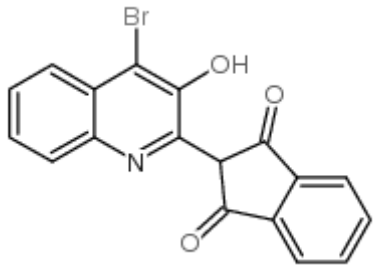
The methine dye with the CAS number 54824-37-2 has no REACH registration dossier or C&L Inventory. No experimental evidences could be found by RAC to support a potential dermal sensitising capability of Disperse Yellow 49.

The substance with the CAS number 12239-15-5 presents the structure of an azo dye and might be related to the class of acid dyes. The REACH registration dossier of the substance with CAS number 12239-15-5 contains a QSAR report performed with OECD QSAR toolbox v3.3 and with log kow as the primary descriptor. According to this report, Disperse Yellow 49 was predicted to be not sensitising to the skin.

1.5 Quinoline dyes

CI Disperse Yellow 64

The chemical name of this substance is p-[[p-(phenylazo)phenyl]azo]phenol. The chemical structure is shown below, and its CAS number is 10319-14-9.



Chemical structure of CI Disperse Yellow 64 (CAS number 10319-14-9).

Malinauskiene and co-workers (2013) reviewed studies and reports on contact allergy to disperse dyes during the period 1990–2012 finding one aimed study with a prevalence of 20% (1/5) for Disperse Yellow 64.

ANNEX III. SPECIFIC SUBSTANCES OR GROUP OF SUBSTANCES TARGETED FOR INFORMATION ON HAZARD AND EXPOSURE

Allergenic disperse dyes

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

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

Chromium (VI) compounds

In leather, hexavalent chromium may be unintentionally formed during the manufacturing process. Chromium salts are also used as a catalyst in the manufacturing process for textiles and as a dye for wool.

Chromium compounds on the IN-list comprise:

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

Diisocyanates

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

- *4,4'-methylenediphenyl diisocyanate* (MDI) (CAS 101-68-8, EC 202-966-0)
- *m-tolylidene diisocyanate* (TDI) (CAS 26471-62-5, EC 247-722-4)
- *3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate (*IPDI) (CAS 4098-71-9, EC 223-861-6)
- *4-methyl-m-phenylene diisocyanate* (CAS 584-84-9, EC 229-54-5)
- *o-(p-isocyanatobenzyl)phenyl isocyanate* (CAS 5873-54-1, EC 227-534-9)
- *Hexamethylene diisocyanate* (HDI) (CAS 822-06-0, EC 212-485-8)
- *2-methyl-m-phenylene diisocyanate* (CAS 91-08-7, EC 202-039-0)

Meth(acrylates)

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

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

Formaldehyde

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

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

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

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

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

Direct dyes

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

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

Acid dyes

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

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

Rosin

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

- *Tall-oil rosin* (CAS 8052-10-16, EC 232-484-6)
- *Rosin* (CAS 8050-09-7, EC 232-475-7)

Dicyclohexyl phthalate (DCHP, CAS 84-61-7, EC 201-545-9)

Dicyclohexyl phthalate is used as a plasticiser in the coating of textiles and other articles such as luggage and sport equipment. DCHP can also be present in pigment printed textiles (KemI, 2019).

1,4-paraphenylene diamine (CAS 106-50-3, EC 203-404-7)

Para-phenylenediamine is used in dark dyes in leather or textile or in azo dye manufacturing.

Glutaraldehyde (Pentanedial, CAS 111-30-8, EC 203-856-5)

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

ANNEX IV. CALCULATIONS, DOSSIER SUBMITTER PROPOSALS AND FORUM ADVICE TAKEN INTO CONSIDERATION TO DERIVE THE RAC SUPPORTED VALUES FOR TEXTILE AND OTHER MATERIALS AND LEATHER, HIDES AND FURS.

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

Allergenic disperse dyes

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

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

$$\text{Limit in textile and other materials} = \frac{0.0003}{0.05 * 1 * 3} = 0.002 \text{ µg/cm}^2 \text{ article}$$

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

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

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

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

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

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

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

The Dossier Submitter proposed a ban since the derived concentration limits are below the current quantification limit for disperse dyes (30-50 mg/kg) based on test method ISO 16373-1:2015 for dyestuffs in textiles. The ban has to be interpreted as a concentration limit not exceeding the limit of detection. According to the opinion of the Forum on the proposed restriction, a ban without an associated concentration limit value could lead to enforceability

issues. If no concentration limit value is set in Annex XVII, non-compliance depends on the limit of detection of the available method.

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

Chromium (VI) compounds

RAC agreed to use an elicitation threshold of 0.02 µg/cm² and a migration factor of 30 % to derive a concentration limit for chromium (VI) compounds in textile and leather articles.

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

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

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

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

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

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

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

The entry 47 of REACH Annex XVII already restricts chromium (VI) with a concentration limit of 3 mg/kg in leather articles due to its allergenic properties. In this restriction, the concentration limit of 3 mg/kg is based on the limit of quantification of the analytical method used to determine the content of hexavalent chromium in leather (ISO 17075:2007). An illustrative risk assessment was available in the Background Document. However, the risk characterisation was mainly based on prevalence of chromium (VI) allergy in the general

population. In particular, RAC highlighted in their opinion that the estimation of 45% of newly chromium allergy cases caused by leather or leather articles was possibly an under-estimation. Patch testing results from Leuven in Belgium concluded that 86% of patients with a contact allergy to potassium dichromate were considered to have been due to exposure via footwear (ECHA, 2012b).

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

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

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

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

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

During the consultation, in-house methods with quantification limits lower than 3 mg/kg were described, some of them with an LOQ of 0.5 mg/kg Cr (VI). The Dossier Submitter concluded that technological advances in test methods make it possible to detect 1 mg/kg of chromium VI and proposed a practical concentration limit of 1 mg/kg for Cr VI in leather in order to prevent skin sensitisation. However, the Forum was not aware that anything was done, after

that restriction on chromium (VI) in leather came into force, to improve the reliability around the limit value of the restriction. Therefore, according to the Forum, a measurement of 1 mg/kg of chromium (VI) extracted from leather cannot currently be guaranteed with current methods.

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

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

Formaldehyde

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

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

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

$$\text{Concentration limit in textile and other materials} = \frac{67 * 10\,000}{1000 * 0.2} = 3\,350\ mg/kg$$

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

$$\text{Limit in leather} = \frac{20.1}{0.1 * 1 * 2} = 101\ \mu g/cm^2 \text{ article}$$

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

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

concentration limit of 30 mg/kg for formaldehyde in textile and other materials as well as in leather, fur and hides.

Nickel compounds

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

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

$$\text{Limit in textile} = \frac{0.74}{0.1 * 1 * 3} = 2.5 \text{ µg/cm}^2 \text{ article}$$

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

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

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

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

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

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

RAC is of the opinion that limit values of 125 and 25 mg/kg should be retained for nickel in textile and other materials or leather, fur and hides, respectively. (expressed as Ni metal that can be extracted from the textile and leather material respectively)

Cobalt compounds

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

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

$$\text{Limit in textile} = \frac{0.44}{0.1 * 1 * 3} = 1.47\ \mu g/cm^2 \text{ article}$$

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

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

$$\text{Limit in leather} = \frac{0.44}{0.1 * 1 * 2} = 2.2\ \mu g/cm^2 \text{ article}$$

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

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

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

i.e. Cobalt and its compound

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

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

<u>1.4-paraphenylene diamine</u>

RAC agreed to use an elicitation threshold of 1.5 µg/cm² and a default migration factor

of 10 % to derive a concentration limit for 1.4-paraphenylene diamine in textile and leather articles.

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

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

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

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

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

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

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

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

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

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

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

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

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

Limit in leather $= \frac{0.8}{0.1 * 1 * 2} = 4.0$ µg/cm² article

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

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