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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	[...] (2020) XXX draft - D068379/02
Subject:	COMMISSION DIRECTIVE (EU) .../... of XXX amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the prohibition of allergenic fragrances in toys

Delegations will find attached document [\[...\]](#)(2020) XXX draft - D068379/02.

Encl.: [\[...\]](#)(2020) XXX draft - D068379/02



EUROPEAN
COMMISSION

Brussels, **XXX**
[...](2020) **XXX** draft

COMMISSION DIRECTIVE (EU) .../...

of **XXX**

**amending Annex II to Directive 2009/48/EC of the European Parliament and of the
Council as regards the prohibition of allergenic fragrances in toys**

(Text with EEA relevance)

D068379/01

COMMISSION DIRECTIVE (EU) .../... of **XXX amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the prohibition of allergenic fragrances in toys**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys¹, and in particular point (b) of the first subparagraph of Article 46(1) thereof,

Whereas:

- (1) Directive 2009/48/EC lays down a general prohibition of 55 allergenic fragrances in toys, as listed in the table in the first paragraph of point 11 of Part III of Annex II to that Directive, in order to protect children from allergies that those fragrances can cause when used in toys.
- (2) The Scientific Committee on Consumer Safety (SCCS), which assists the Commission as an independent risk assessment body in the area of cosmetic products, notes in its opinion of 26 and 27 June 2012² that contact allergy to fragrances is a common, significant and relevant problem in Europe, and that exposure to fragrances occurs from the use of other consumer products, such as toys. The SCCS also notes that, in recent years, it has become a trend to add fragrance chemicals to many types of consumer products, such as children's toys, which may contribute significantly to the fragrance exposure of the consumer by the dermal route. The SCCS adds that the consumer is exposed to fragrance substances from a wide variety of cosmetic products, other consumer products, pharmaceuticals and occupational exposures, and that all those exposures are of importance in the context of contact allergy as it is not the source of exposure that is critical, but the cumulative dose per unit area.
- (3) A survey of allergenic substances in products for children carried out by the Environmental Protection Agency in Denmark³ shows the presence of allergenic fragrances in toys, namely modelling clays, slimes, a doll, a teddy bear, and rubber bands.
- (4) The Expert Group on Toys Safety advises the Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety. The mission of its subgroup on Chemicals in Toys (subgroup Chemicals) is to provide advice with regard to chemical substances which may be used in toys.

¹ OJ L 170, 30.6.2009, p. 1.

² SCCS opinion on fragrance allergens in cosmetic products, 26 – 27 June 2012 (SCCS/1459/11).
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

³ Ministry of Environment and Food of Denmark - Environmental Protection Agency. Survey of allergenic substances in products targeted children – toys and cosmetic products. Survey of Chemical Substances in Consumer Products No. 148, 2016.
<https://www2.mst.dk/Udgiv/publications/2016/08/978-87-93529-00-7.pdf>

- (5) The Expert Group on Toys Safety recalled, at its meeting on 13 September 2019⁴, that an allergenic substance, whether present in cosmetic products or in toys, is always allergenic. That so-called intrinsic property of the substance is independent from the use of the substance and is therefore present irrespective of whether the allergenic substance is used in cosmetics or in toys. Consequently, the Expert Group considered that an allergenic substance presenting a risk in cosmetic products could equally present a risk in toys. It therefore underlined the importance to take thorough account of the opinions of the SCCS and of its predecessor committees on allergenic fragrances in cosmetic products when regulating allergenic fragrances in toys.
- (6) Directive 2009/48/EC allows the Commission to prohibit or to require labelling of allergenic fragrances in toys. Contrary to Regulation (EC) No 1223/2009 of the European Parliament and of the Council⁵, which regulates cosmetic products, it does not allow the Commission to set maximum limits for allergenic fragrances.
- (7) In its opinion of 26 and 27 June 2012 the SCCS concluded that cosmetic products containing atranol or chloroatranol are not safe. The SCCS thus confirmed the opinion of the Scientific Committee on Consumer Products (SCCP) of 7 December 2004⁶ that atranol and chloroatranol should not be present in consumer products. The subgroup Chemicals therefore recommended, at its meeting on 3 May 2018⁷, to prohibit the use of atranol and chloroatranol in toys, by adding them to the table in the first paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC.
- (8) In its opinion of December 1999⁸, the Scientific Committee on Cosmetic Products and non-food Products intended for Consumers (SCCNFP), which was a predecessor of the SCCS, included methyl heptine carbonate among the fragrance chemicals less frequently reported as contact allergens. On the basis of that opinion, methyl heptine carbonate was included among the allergenic fragrances that have to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, in accordance with the third paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC. In its opinion of 25 September 2001⁹, the SCCNFP recommended that the level of methyl heptine carbonate in finished cosmetic products should not exceed 0,01 %.
- (9) Considering the above, and in particular the SCCS opinion concluding that cosmetic products containing atranol or chloroatranol are not safe, the SCCP opinion that

⁴ Minutes of the meeting of the Expert Group on Toys Safety of 13 September 2019
<https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=17996>

⁵ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

⁶ SCCP opinion on atranol and chloroatranol present in natural extracts (e.g. oak moss and tree moss extract), 7 December 2004 (SCCP/00847/04).
https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_006.pdf

⁷ Minutes of the Meeting of the Subgroup “Chemicals” of the Expert Group on Toy Safety of 3 May 2018.
<https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=19025>

⁸ Opinion concerning Fragrance Allergy in Consumers – A review of the problem. Analysis of the need for appropriate consumer information and identification of consumer allergens, 8 December 1999 (SCCNFP/0017/98 Final), Table 6b, p. 23.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf

⁹ Opinion concerning An initial List of Perfumery Materials which must not form Part of Cosmetic Products except subject to the Restrictions and Conditions laid down, 25 September 2001 (SCCNFP/0392/00 final), p. 8.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out150_en.pdf

atranol and chloroatranol should not be present in consumer products and the SCCNFP opinion that methyl heptine carbonate should not exceed 0,01 % in cosmetic products, the Expert Group on Toys Safety recommended, at its meeting on 13 September 2019, to prohibit the use of atranol, chloroatranol and methyl heptine carbonate in toys.

- (10) In light of the opinions of the SCCS, the SCCP and the SCCNFP, and of the recommendation of the Expert Group on Toys Safety the use of atranol, chloroatranol and methyl heptine carbonate in toys should be prohibited.
- (11) Directive 2009/48/EC should therefore be amended accordingly.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Committee established under Article 47(1) of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2009/48/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by ... *[18 months after publication in the OJ]* at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from ... *[18 months + 1 day after publication in the OJ]*.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen



Brussels, XXX
[...] (2020) XXX draft

ANNEX

ANNEX

to the

Commission Directive

amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the prohibition of allergenic fragrances in toys

ANNEX

In Part III of Annex II, point 11 is amended as follows:

(1) in the first paragraph, in the table, the following entries are added:

No	Name of the allergenic fragrance	CAS number
‘(56)	Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde)	526-37-4
(57)	Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde)	57074-21-2
(58)	Methyl heptine carbonate	111-12-6’;

(2) in the third paragraph, in the table, entry 10 is deleted.