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European Union

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#### COVER NOTE

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 29 July 2020

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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No. Cion doc.: [...] (2020) XXX draft - D0688374

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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 labelling of allergenic fragrances in toys

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Delegations will find attached document [...] (2020) XXX draft - D0688374.

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Encl.: [...] (2020) XXX draft - D0688374



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 labelling of allergenic fragrances in toys**

(Text with EEA relevance)

D068374/01

**COMMISSION DIRECTIVE (EU) .../... of XXX amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the labelling 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 toys<sup>1</sup>, and in particular point (b) of the first subparagraph of Article 46(1) thereof,

Whereas:

- (1) Directive 2009/48/EC lays down a general obligation to list on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, the names of 11 allergenic fragrances if the concentrations of those fragrances exceed 100 mg/kg in the toy or components thereof. Those allergenic fragrances are listed in the table in the third paragraph of point 11 of Part III of Annex II to that Directive.
- (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 2012<sup>2</sup> 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. In the opinion, a number of established contact allergens in humans are listed in Table 13-1.
- (3) A survey of allergenic substances in products for children carried out by the Environmental Protection Agency in Denmark<sup>3</sup> 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.

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<sup>1</sup> OJ L 170, 30.6.2009, p. 1.

<sup>2</sup> 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](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf)

<sup>3</sup> 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 2019<sup>4</sup>, 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) At the meeting of the subgroup Chemicals of 3 May 2018<sup>5</sup>, the majority of its members concluded that the established contact allergens in humans listed in Table 13-1 of the SCCS opinion of 26 and 27 June 2012 should be added to the list of allergenic fragrances that have to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, laid down in the table in the third paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC.
- (7) On 13 September 2019, the Expert Group on Toys Safety confirmed the conclusions of the subgroup Chemicals.
- (8) At its meeting on 13 September 2019, the Expert Group on Toys Safety noted that entry 4 in the table in the third paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC on citronellol, CAS number 106-22-9, covers only the mixture of the two enantiomeric forms of citronellol. The labelling requirements should however, according to the Expert Group, also cover the two individual enantiomeric forms listed as CAS numbers 1117-61-9 and 7540-51-4 in Table 13-1 of the SCCS opinion of 26 and 27 June 2012.
- (9) In light of the SCCS opinion of 26 and 27 June 2012 and the recommendation of the Expert Group on Toys Safety of 13 September 2019, the allergenic fragrances listed in Table 13-1 of the SCCS opinion of 26 and 27 June 2012 should be subject to labelling requirements when present in toys. The fragrances that are not yet subject to a prohibition or labelling requirements laid down in Directive 2009/48/EC, should therefore be included in the table in the third paragraph of point 11 of Part III of Annex II to that Directive.
- (10) Directive 2009/48/EC should therefore be amended accordingly.
- (11) 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.

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<sup>4</sup> 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>

<sup>5</sup> 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>.

## *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 labelling of allergenic fragrances in toys**

## ANNEX

In the third paragraph of point 11 of Part III of Annex II, the table is amended as follows:

(1) entry 4 is replaced by the following:

No	Name of the allergenic fragrance	CAS number
'(4)	Citronellol	106-22-9; 1117-61-9; 7540-51-4';

(1) the following entries are added:

No	Name of the allergenic fragrance	CAS number
'(12)	Acetylcedrene	32388-55-9
(13)	Amyl salicylate	2050-08-0
(14)	trans-Anethole	4180-23-8
(15)	Benzaldehyde	100-52-7
(16)	Camphor	76-22-2; 464-49-3
(17)	Carvone	99-49-0; 6485-40-1; 2244-16-8
(18)	beta-Caryophyllene (ox.)	87-44-5
(19)	Rose ketone-4 (Damascenone )	23696-85-7
(20)	alpha-Damascone (TMCHB)	43052-87-5; 23726-94-5
(21)	cis-beta-Damascone	23726-92-3
(22)	delta-Damascone	57378-68-4
(23)	Dimethylbenzyl carbiny acetate (DMBCA)	151-05-3
(24)	Hexadecanolactone	109-29-5
(25)	Hexamethylindanopyran	1222-05-5
(26)	(DL)-Limonene	138-86-3
(27)	Linayl acetate	115-95-7
(28)	Menthol	1490-04-6; 89-78-1; 2216-51-5
(29)	Methyl salicylate	119-36-8
(30)	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-ol	67801-20-1
(31)	alpha-Pinene	80-56-8
(32)	beta-Pinene	127-91-3

(33)	Propylidene phthalide	17369-59-4
(34)	Salicylaldehyde	90-02-8
(35)	alpha-Santalol	115-71-9
(36)	beta-Santalol	77-42-9
(37)	Sclareol	515-03-7
(38)	alpha-Terpineol	10482-56-1; 98-55-5
(39)	Terpineol (mixture of isomers)	8000-41-7
(40)	Terpinolene	586-62-9
(41)	Tetramethyl acetyloctahydro naphthalenes	54464-57-2; 54464-59-4; 68155-66-8; 68155-67-9
(42)	Trimethyl benzenepropanol (Majantol)	103694-68-4
(43)	Vanillin	121-33-5
(44)	Cananga odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
(45)	Cedrus atlantica bark oil	92201-55-3; 8000-27-9
(46)	Cinnamomum cassia leaf oil	8007-80-5
(47)	Cinnamomum zeylanicum bark oil	84649-98-9
(48)	Citrus aurantium amara flower oil	8016-38-4
(49)	Citrus aurantium amara peel oil	72968-50-4
(50)	Citrus bergamia peel oil expressed	89957-91-5
(51)	Citrus limonum peel oil expressed	84929-31-7
(52)	Citrus sinensis (syn.: Aurantium dulcis) peel oil expressed	97766-30-8; 8028-48-6
(53)	Cymbopogon citratus / schoenanthus oils	89998-14-1; 8007-02-01; 89998-16-3
(54)	Eucalyptus spp. leaf oil	92502-70-0; 8000-48-4
(55)	Eugenia caryophyllus leaf / flower oil	8000-34-8
(56)	Jasminum grandiflorum / officinale	84776-64-7; 90045-94-6; 8022-96-6
(57)	Juniperus virginiana	8000-27-9; 85085-41-2
(58)	Laurus nobilis fruit oil	8007-48-5
(59)	Laurus nobilis leaf oil	8002-41-3
(60)	Laurus nobilis seed oil	84603-73-6
(61)	Lavandula hybrida	91722-69-9



(62)	Lavandula officinalis	84776-65-8
(63)	Mentha piperita	8006-90-4; 84082-70-2
(64)	Mentha spicata	84696-51-5
(65)	Narcissus spp.	Diverse, including 90064-25-8
(66)	Pelargonium graveolens	90082-51-2; 8000-46-2
(67)	Pinus mugo	90082-72-7
(68)	Pinus pumila	97676-05-6
(69)	Pogostemon cablin	8014-09-3; 84238-39-1
(70)	Rose flower oil (Rosa spp.)	Diverse, including 8007-01-0, 93334-48-6, 84696-47-9, 84604-12-6, 90106-38-0, 84604-13-7, 92347-25-6
(71)	Santalum album	84787-70-2; 8006-87-9
(72)	Turpentine (oil)	8006-64-2; 9005-90-7; 8052-14-0'.