



EUROPEAN
COMMISSION

Brussels, **XXX**
[...] (2025) **XXX** draft

ANNEX

ANNEX

to the

Commission Regulation

**amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council
as regards carcinogens, germ cell mutagens or reproductive toxicants subject to
restrictions**

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ANNEX

Annex XVII is amended as follows:

(1) in the Table, entries 28, 29 and 30, column 2 ('Conditions of restriction'), point (1), the first paragraph is replaced by the following:

'Shall not be placed on the market, or used,

- as substances,
- as constituents of other substances or,
- in mixtures,

for supply to the general public:

- when the individual concentration in the substance or mixture is equal to or greater than the relevant specific or generic concentration limit specified in Part 3 of Annex VI, or Annex I, to Regulation (EC) No 1272/2008 respectively, or
- for substances subject to additivity rules set out in the notes to section 1.1.3 of Annex VI to Regulation (EC) No 1272/2008 for classification purposes, when the sum of the individual concentrations in the substance or mixture is equal to or greater than the relevant specific or generic concentration limit specified in Part 3 of Annex VI or Annex I to that Regulation respectively.';

(2) in Appendix 1 ('Entry 28 – Carcinogens: Category 1A'), the Table is amended as follows:

(a) in the entry for 'Hydrocarbons, C4; Petroleum gas' with index number '649-113-00-2', the fourth column ('CAS No'), the CAS number is replaced by the following:
'87741-01-3';

(b) the following entry is inserted after the entry for 'Vinyl chloride; chloroethylene' with index number '602-023-00-7'¹:

'fluoroethylene	602-111-00-5	200-832-6	75-02-5';	
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(3) in Appendix 2 ('Entry 28 – Carcinogens: Category 1B'), the Table is amended as follows:

(a) in the entry for 'Extract residues (coal), tar oil alkaline, naphthalene distillation residues; Naphthalene oil extract residue' with index number '648-137-00-0', fourth column ('CAS No'), the CAS Number is replaced by the following:
'73665-18-6';

(b) in the entry for 'Extracts (petroleum), light paraffinic distillate solvent' with index number '649-003-00-4', fourth column ('CAS No'), the CAS Number is replaced by the following:
'64742-05-8';

(c) the following entry is inserted after the entry for 'O-hexyl-N-ethoxycarbonylthiocarbamate' with index number '006-102-001'²:

¹

The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

‘multi-walled carbon tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 μm and a length ≥ 5 μm and aspect ratio $> 3:1$, including multi-walled carbon nanotubes, MWC(N)T	006-104-00-2	-	-’;	
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(d) the following entry is inserted after the entry for ‘Benzophenone’ with index number ‘606-153-00-5’³:

‘acetone oxime	606-156-00-1	204-820-1	127-06-0’;	
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(e) the following entry is inserted after the entry for ‘Sodium *N*-(hydroxymethyl)glycinate; [formaldehyde released from sodium *N*-(hydroxymethyl)glycinate]’ with index number ‘607-746-00-1’⁴:

‘benthiavalicarb-isopropyl (ISO); isopropyl [(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate	607-771-00-8	-	177406-68-7’;	
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(f) the following entry is inserted after the entry for ‘2-Nitrotoluene’ with index number ‘609-065-00-5’⁵:

‘1,4-dichloro-2-nitrobenzene	609-074-00-4	201-923-3	89-61-2’;	
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(g) the following entry is inserted after the entry for ‘Indium phosphide’ with index number ‘015-200-00-3’⁶:

‘trimethyl phosphate	015-209-00-2	208-144-8	512-56-1’;	
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(h) the following entry is inserted after the entry for ‘Cadmium nitrate; cadmium dinitrate’ with index number ‘048-014-00-6’⁷:

‘barium chromate	056-006-00-9	233-660-5	10294-40-3’;	
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(i) the following entry is inserted after the entry for ‘Bromoethylene’ with index number ‘602-024-00-2’⁸:

‘1,1-dichloroethylene; vinylidene chloride	602-025-00-8	200-864-0	75-35-4’;	
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(4) in Appendix 4 (‘Entry 29 – Germ cell mutagens: Category 1B’), the Table is amended as follows:

(a) the following entry is inserted after the entry for ‘*N*-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]’ with index number ‘616-230-00-5’⁹:

² The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

³ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

⁴ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

⁵ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

⁶ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

⁷ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

⁸ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

‘N,N'-methylenediacrylamide	616-243-00-6	203-750-9	110-26-9 ⁹ ;	
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(b) the following entry is inserted after the entry for ‘dimethyl propylphosphonate’ with index number ‘015-208-00-7’¹⁰:

‘trimethyl phosphate	015-209-00-2	208-144-8	512-56-1 ¹¹ ;	
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(5) in Appendix 6 (‘Entry 30 – Reproductive toxicants: Category 1B), the Table is amended as follows:

(a) the following entry is inserted before the entry for ‘Dibutyltin hydrogen borate’ with index number ‘005-006-00-7’¹¹:

‘trimethyl borate	005-005-00-1	204-468-9	121-43-7 ¹² ;	
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(b) the following entry is inserted after the entry for ‘Disodium octaborate anhydrous; [1] Disodium octaborate tetrahydrate [2]’ with index number ‘005-020-00-3’¹²:

‘perboric acid, sodium salt [1] perboric acid, sodium salt, monohydrate [2] perboric acid (HBO(O ₂)), sodium salt, monohydrate [3] sodium peroxoborate [4] sodium perborate [5]	005-022-00-4	234-390-0 [1] 234-390-0 [2] - [3] - [4] 239-172-9 [5]	11138-47-9 [1] 12040-72-1 [2] 10332-33-9 [3] - [4] 15120-21-5 [5]	
perboric acid (H ₃ BO ₂ (O ₂)), monosodium salt trihydrate [1] perboric acid, sodium salt, tetrahydrate [2] perboric acid (HBO(O ₂)), sodium salt, tetrahydrate [3] sodium peroxoborate, hexahydrate [4]	005-023-00-X	239-172-9 [1] 234-390-0 [2] - [3] - [4]	13517-20-9 [1] 37244-98-7 [2] 10486-00-7 [3] - [4]	
sodium peroxometaborate	005-024-00-5	231-556-4	7632-04-4 ¹³ ;	

(c) the following entry is inserted after the entry for “reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane’ with index number ‘603-244-00-1’¹³:

‘reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol	603-247-00-8	-	-’;	
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⁹ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹⁰ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹¹ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹² The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹³ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

(d) the following entry is inserted after the entry for ‘Cyclic 3-(1,2-ethanediylacetale)-estra-5(10),9(11)-diene-3,17-dione’ with index number ‘606-131-00-5’¹⁴:

‘2-(dimethylamino)-2-[(4-methylphenyl) methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	606-158-00-2	438-340-0	119344-86-4’;	
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(e) the following entry is inserted after the entry for ‘6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid’ with index number ‘607-765-00-5’¹⁵:

‘Sodium 3-(allyloxy)-2-hydroxypropanesulphonate	607-775-00-X	258-004-5	52556-42-0’;	
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(f) the following entry is inserted after the entry for ‘Bis(α,α-dimethylbenzyl) peroxide’ with index number ‘617-006-00-X’¹⁶:

‘tert-butyl 2-ethylperoxyhexanoate	617-024-00-8	221-110-7	3006-82-4’;	
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(g) the entries for Index Numbers ‘005-017-00-7’, ‘005-017-01-4’, ‘005-018-00-2’, ‘005-018-01-X’, ‘005-019-00-8’ and ‘005-019-01-5’ are deleted;

(h) the following entry is inserted after the entry for ‘Mancozeb (ISO); manganese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt’ with index number ‘006-076-00-1’¹⁷:

‘dinitrogen oxide	007-031-00-9	233-032-0	10024-97-2’;	
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(i) the following entry is inserted after the entry for ‘dimethyl propylphosphonate’ with index number ‘015-208-00-7’¹⁸:

‘trimethyl phosphate	015-209-00-2	208-144-8	512-56-1’;	
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(j) the following entry is inserted after the entry for ‘Diphenylether; octabromo derivate’ with index number ‘602-094-00-4’¹⁹:

‘2-bromo-3,3,3-trifluoroprop-1-ene	602-112-00-0	-	1514-82-5’;	
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(k) the following entry is inserted after the entry for ‘reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol’ with index number ‘603-247-00-8’²⁰:

‘2,3-epoxypropyl isopropyl ether	603-248-00-3	223-672-9	4016-14-2’;	
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(l) the following entry is inserted after the entry for ‘4,4’-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF’ with index number ‘604-099-00-7’²¹:

¹⁴ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹⁵ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹⁶ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹⁷ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹⁸ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

¹⁹ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

²⁰ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

‘ α,α' -propylenedinitrilodi-o-cresol	604-103-00-7	202-374-2	94-91-7’;	
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(m) the following entry is inserted after the entry for ‘Sodium 3-(allyloxy)-2-hydroxypropanesulphonate’ with index number ‘607-775-00-X’²²:

‘2-ethylhexanoic acid, monoester with propane-1,2-diol	607-776-00-5	285-503-5	85114-00-7	
tetrahydrofurfuryl methacrylate	607-778-00-6	219-529-5	2455-24-5	
9-octadecenoic acid (Z)-, sulfonated, potassium salts [1] Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2] 9(or 10)-sulphooctadecanoic acid, potassium salt [3]	607-779-00-1	271-843-1 [1] - [2] 267-966-5 [3]	68609-93-8 [1] - [2] 67968-63-2 [3]’;	

(6) in Appendix 11 (‘Entries 28 to 30 — Derogations for specific substances’), the Table is amended as follows:

(a) entry 1 is deleted;

(b) the following entry is added²³:

‘3. dinitrogen oxide CAS No 10024-97-2 EC No 233-032-0	<p>1. As a substance on its own, as a constituent of other substances, or in mixtures in either of the following:</p> <p>(a) cartridges containing the substance, with a maximum volume of 24 ml, for use as a food additive, provided that:</p> <ul style="list-style-type: none"> - the sale of such cartridges is limited to such a number that a maximum total volume of 120 ml per individual per day; and - the sale of such cartridges is restricted to individuals who are 18 years of age or older; - the age of the buyer is checked by an effective age verification system; <p>(b) aerosol dispensers for food products, where the substance is used as a propellant, and the dispenser is designed for use of the substance as food additive;</p> <p>(c) food within the meaning of Article 2 of Regulation (EC) No 178/2002 that has been prepared with dinitrogen oxide used as a food additive.</p> <p>2. Paragraph 1 is without prejudice to national legislation setting stricter measures to prevent the abuse of dinitrogen oxide as a drug.’.</p>
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²¹ The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

²² The column sequence is as follows: Substances, Index No, EC No, CAS No, Notes.

²³ The column sequence is as follows: Substances, Derogations.