

▼ C1

ANNEX VI

INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

GUIDANCE NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

STEP 1 — GATHER AND SHARE EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance. Wherever practicable, registrations should be submitted jointly, in accordance with Articles 11 or 19. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other substances, *in vivo* and *in vitro* testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests.

In addition, information on exposure, use and risk management measures in accordance with Article 10 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information.

STEP 2 — CONSIDER INFORMATION NEEDS

The registrant shall identify what information is required for the registration. First, the relevant Annex or Annexes to be followed shall be identified, according to tonnage. These Annexes set out the standard information requirements, but shall be considered in conjunction with Annex XI, which allows variation from the standard approach, where it can be justified. In particular, information on exposure, use and risk management measures shall be considered at this stage in order to determine the information needs for the substance.

STEP 3 — IDENTIFY INFORMATION GAPS

The registrant shall then compare the information needs for the substance with the information already available and identify where there are gaps. It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.

STEP 4 — GENERATE NEW DATA/PROPOSE TESTING STRATEGY

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes VII and VIII), or a testing strategy shall be proposed (Annexes IX and X), depending on the tonnage. New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.

In some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.

NOTES

Note 1: If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions.

▼ C1

Note 2: The registrant may wish to declare that certain information submitted in the registration dossier is commercially sensitive and its disclosure might harm him commercially. If this is the case, he shall list the items and provide a justification.

INFORMATION REFERRED TO IN ARTICLE 10(a) (i) TO (v)

1. GENERAL REGISTRANT INFORMATION

1.1. Registrant

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

1.2. Joint submission of data

Articles 11 or 19 foresee that parts of the registration may be submitted by a lead registrant on behalf of other registrants.

In this case, the lead registrant shall identify the other registrants specifying:

- their name, address, telephone number, fax number and e-mail address,
- parts of the present registration which apply to other registrants.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

Any other registrant shall identify the lead registrant submitting on his behalf specifying:

- his name, address, telephone number, fax number and e-mail address,
- parts of the registration which are submitted by the lead registrant.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

1.3. Third party appointed under Article 4

1.3.1. Name, address, telephone number, fax number and e-mail address

1.3.2. Contact person

2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCS number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including SMILES notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

▼ **C1**

- 2.3.3. Percentage of (significant) main impurities
- 2.3.4. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)
- 2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
- 2.3.6. High-pressure liquid chromatogram, gas chromatogram
- 2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)

- 3.1. Overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year in: the calendar year of the registration (estimated quantity)
- 3.2. In the case of a manufacturer or producer of articles: brief description of the technological process used in manufacture or production of articles.
Precise details of the process, particularly those of a commercially sensitive nature, are not required.
- 3.3. An indication of the tonnage used for his own use(s)
- 3.4. Form (substance, ► **M3** mixture ◀ or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in ► **M3** mixtures ◀ made available to downstream users and quantities of the substance in articles made available to downstream users.
- 3.5. Brief general description of the identified use(s)
- 3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses
- 3.7. Uses advised against (see Safety Data Sheet heading 16)
Where applicable, an indication of the uses which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.

4. CLASSIFICATION AND LABELLING

- 4.1. The hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC.
In addition, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification).
- 4.2. The resulting hazard label for the substance(s), resulting from the application of Articles 23, 24 and 25 of Directive 67/548/EEC.
- 4.3. Specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

5. GUIDANCE ON SAFE USE CONCERNING:

This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 31.

- 5.1. First-aid measures (Safety Data Sheet heading 4)
- 5.2. Fire-fighting measures (Safety Data Sheet heading 5)
- 5.3. Accidental release measures (Safety Data Sheet heading 6)
- 5.4. Handling and storage (Safety Data Sheet heading 7)
- 5.5. Transport information (Safety Data Sheet heading 14)

▼ C1

Where a Chemical Safety Report is not required, the following additional information is required:

- 5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)
- 5.7. Stability and reactivity (Safety Data Sheet heading 10)
- 5.8. Disposal considerations
 - 5.8.1. Disposal considerations (Safety Data Sheet heading 13)
 - 5.8.2. Information on recycling and methods of disposal for industry
 - 5.8.3. Information on recycling and methods of disposal for the public.

6. INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES PER YEAR PER MANUFACTURER OR IMPORTER
 - 6.1. Main use category:
 - 6.1.1. (a) industrial use; and/or
(b) professional use; and/or
(c) consumer use.
 - 6.1.2. Specification for industrial and professional use:
 - (a) used in closed system; and/or
 - (b) use resulting in inclusion into or onto matrix; and/or
 - (c) non-dispersive use; and/or
 - (d) dispersive use.
 - 6.2. Significant route(s) of exposure:
 - 6.2.1. Human exposure:
 - (a) oral; and/or
 - (b) dermal; and/or
 - (c) inhalatory.
 - 6.2.2. Environmental exposure:
 - (a) water; and/or
 - (b) air; and/or
 - (c) solid waste; and/or
 - (d) soil.
 - 6.3. Pattern of exposure:
 - (a) accidental/infrequent; and/or
 - (b) occasional; and/or
 - (c) continuous/frequent.

▼ C1

ANNEX VII

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF ONE TONNE OR MORE ⁽¹⁾

Column 1 of this Annex establishes the standard information required for:

- (a) non-phase-in substances manufactured or imported in quantities of 1 to 10 tonnes;
- (b) phase-in substances manufactured or imported in quantities of 1 to 10 tonnes and meeting the criteria in Annex III in accordance with Article 12(1)(a) and (b); and
- (c) substances manufactured or imported in quantities of 10 tonnes or more.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. For substances not meeting the criteria in Annex III only the physicochemical requirements as set out in section 7 of this Annex are required.

Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI with the exception of Section 3 on substance-tailored exposure waiving. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI ⁽²⁾.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q) SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.1. State of the substance at 20 °C and 101,3 kPa	
7.2. Melting/freezing point	7.2. The study does not need to be conducted below a lower limit of - 20 °C.
7.3. Boiling point	7.3. The study does not need to be conducted: <ul style="list-style-type: none"> — for gases, or — for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under

⁽¹⁾ This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.

⁽²⁾ Note: conditions for not requiring a specific test that are set out in the appropriate test methods in the Commission Regulation on test methods as specified in Article 13(3) that are not repeated in column 2, also apply.

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<p>reduced pressure may be estimated or measured, or</p> <ul style="list-style-type: none"> — for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
7.4. Relative density	<p>7.4. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient, or — the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.
7.5. Vapour pressure	<p>7.5. The study does not need to be conducted if the melting point is above 300 °C.</p> <p>If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.</p>
7.6. Surface tension	<p>7.6. The study need only be conducted if:</p> <ul style="list-style-type: none"> — based on structure, surface activity is expected or can be predicted, or — surface activity is a desired property of the material. <p>If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.</p>
7.7. Water solubility	<p>7.7. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours), or — the substance is readily oxidisable in water. <p>If the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall be performed.</p>
7.8. Partition coefficient n-octanol/water	<p>7.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.</p>
7.9. Flash-point	<p>7.9. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — the substance is inorganic, or — the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions, or — the estimated flash-point is above 200 °C, or — the flash-point can be accurately predicted by interpolation from existing characterised materials.
7.10. Flammability	<p>7.10. The study does not need to be conducted:</p> <ul style="list-style-type: none"> — if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability, or — for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit, or

▼C1

COLUMN 1 STANDARD INFORMATION REQUIRED			COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
			— for substances which spontaneously ignite when in contact with air.
7.11.	Explosive properties	prop-	<p>7.11. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are no chemical groups associated with explosive properties present in the molecule, or — the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200, or — the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 °C, or — for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: <ul style="list-style-type: none"> — less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard), — less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard). <p><i>Note:</i> Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.</p>
7.12.	Self-ignition temperature		<p>7.12. The study does not need to be conducted:</p> <ul style="list-style-type: none"> — if the substance is explosive or ignites spontaneously with air at room temperature, or — for liquids non flammable in air, e.g. no flash point up to 200 °C, or — for gases having no flammable range, or — for solids, if the substance has a melting point \leq 160 °C, or if preliminary results exclude self-heating of the substance up to 400 °C.
7.13.	Oxidising properties	prop-	<p>7.13. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — the substance is explosive, or — the substance is highly flammable, or — the substance is an organic peroxide, or — the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms). <p>The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties.</p> <p>Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.</p>
7.14.	Granulometry		<p>7.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.</p>

▼C1

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
<p>8.1. Skin irritation or skin corrosion</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>(1) an assessment of the available human and animal data,</p> <p>(2) an assessment of the acid or alkaline reserve,</p> <p>(3) <i>in vitro</i> study for skin corrosion,</p> <p>(4) <i>in vitro</i> study for skin irritation.</p>	<p>8.1. Steps 3 and 4 do not need to be conducted if:</p> <ul style="list-style-type: none"> — the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes, or — the substance is flammable in air at room temperature, or — the substance is classified as very toxic in contact with skin, or — an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).
<p>8.2. Eye irritation</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>(1) an assessment of the available human and animal data,</p> <p>(2) an assessment of the acid or alkaline reserve,</p> <p>(3) <i>in vitro</i> study for eye irritation.</p>	<p>8.2. Step 3 does not need to be conducted if:</p> <ul style="list-style-type: none"> — the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes, or — the substance is flammable in air at room temperature;
<p>8.3. Skin sensitisation</p> <p>The assessment of this endpoint shall comprise the following consecutive steps:</p> <p>(1) an assessment of the available human, animal and alternative data,</p> <p>(2) <i>In vivo</i> testing.</p>	<p>8.3. Step 2 does not need to be conducted if:</p> <ul style="list-style-type: none"> — the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or — the substance is flammable in air at room temperature. <p>The Murine Local Lymph Node Assay (LLNA) is the first-choice method for <i>in vivo</i> testing. Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.</p>
<p>8.4. Mutagenicity</p>	<p>8.4. Further mutagenicity studies shall be considered in case of a positive result.</p>

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.4.1. <i>In vitro</i> gene mutation study in bacteria	
8.5. Acute toxicity	8.5. The study/ies do(es) not generally need to be conducted if: <ul style="list-style-type: none"> — the substance is classified as corrosive to the skin.
8.5.1. By oral route	The study need not be conducted if a study on acute toxicity by the inhalation route (8.5.2) is available.

9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1. Aquatic toxicity	
9.1.1. Short-term toxicity testing on invertebrates (preferred species <i>Daphnia</i>) The registrant may consider long-term toxicity testing instead of short-term.	9.1.1. The study does not need to be conducted if: <ul style="list-style-type: none"> — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or — a long-term aquatic toxicity study on invertebrates is available, or — adequate information for environmental classification and labelling is available. <p>The long-term aquatic toxicity study on <i>Daphnia</i> (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble.</p>
9.1.2. Growth inhibition study aquatic plants (algae preferred)	9.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.
9.2. Degradation	
9.2.1. Biotic	
9.2.1.1. Ready biodegradability	9.2.1.1. The study does not need to be conducted if the substance is inorganic.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

▼ C1

ANNEX VIII

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE ⁽¹⁾

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 10 tonnes or more in accordance with Article 12(1)(c). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annex VII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI ⁽²⁾.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q) SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.1. Skin irritation 8.1.1. <i>In vivo</i> skin irritation	8.1.1. The study does not need to be conducted if: <ul style="list-style-type: none"> — the substance is classified as corrosive to the skin or as a skin irritant, or — the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or — the substance is flammable in air at room temperature, or — the substance is classified as very toxic in contact with skin, or — an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).
8.2. Eye irritation 8.2.1. <i>In vivo</i> eye irritation	8.2.1. The study does not need to be conducted if: <ul style="list-style-type: none"> — the substance is classified as irritating to eyes with risk of serious damage to eyes, or — the substance is classified as corrosive to the skin and provided that the registrant classified the substance as eye

⁽¹⁾ This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.

⁽²⁾ Note: conditions for not requiring a specific test that are set out in the appropriate test methods in the Commission Regulation on test methods as specified in Article 13(3) that are not repeated in column 2, also apply.

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	irritant, or — the substance is a strong acid ($\text{pH} \leq 2,0$) or base ($\text{pH} \geq 11,5$), or — the substance is flammable in air at room temperature.
8.4. Mutagenicity 8.4.2. <i>In vitro</i> cytogenicity study in mammalian cells or <i>in vitro</i> micronucleus study 8.4.3. <i>In vitro</i> gene mutation study in mammalian cells, if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2.	8.4.2. The study does not usually need to be conducted — if adequate data from an <i>in vivo</i> cytogenicity test are available, or — the substance is known to be carcinogenic category 1 or 2 or mutagenic category 1, 2 or 3. 8.4.3. The study does not usually need to be conducted if adequate data from a reliable <i>in vivo</i> mammalian gene mutation test are available. 8.4. Appropriate <i>in vivo</i> mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII.
8.5. Acute toxicity 8.5.2. By inhalation 8.5.3. By dermal route	8.5. The study/ies do(es) not generally need to be conducted if: — the substance is classified as corrosive to the skin. In addition to the oral route (8.5.1), for substances other than gases, the information mentioned under 8.5.2 to 8.5.3 shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided. 8.5.2. Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. 8.5.3. Testing by the dermal route is appropriate if: (1) inhalation of the substance is unlikely; and (2) skin contact in production and/or use is likely; and (3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.
8.6. Repeated dose toxicity 8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	8.6.1. The short-term toxicity study (28 days) does not need to be conducted if: — a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used, or — where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products, or — relevant human exposure can be excluded in accordance with Annex XI Section 3. The appropriate route shall be chosen on the following basis: Testing by the dermal route is appropriate if: (1) inhalation of the substance is unlikely; and (2) skin contact in production and/or use is likely; and

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<p>(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.</p> <p>Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.</p> <p>The sub-chronic toxicity study (90 days) (Annex IX, Section 8.6.2) shall be proposed by the registrant if: the frequency and duration of human exposure indicates that a longer term study is appropriate;</p> <p>and one of the following conditions is met:</p> <ul style="list-style-type: none"> — other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study, or — appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure. <p>Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Article 40 or 41 in case of:</p> <ul style="list-style-type: none"> — failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or — toxicity of particular concern (e.g. serious/severe effects), or — indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or — the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made, or — particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected), or — effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 or the 90 days study.
<p>8.7. Reproductive toxicity</p> <p>8.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from <i>in vitro</i></p>	<p>8.7.1. This study does not need to be conducted if:</p> <ul style="list-style-type: none"> — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or — relevant human exposure can be excluded in accordance with Annex XI section 3, or — a pre-natal developmental toxicity study (Annex IX, 8.7.2) or a two-generation reproductive toxicity study (Annex IX, Section 8.7.3) is available.

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
methods that the substance may be a developmental toxicant	<p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p> <p>In cases where there are serious concerns about the potential for adverse effects on fertility or development, either a pre-natal developmental toxicity study (Annex IX, Section 8.7.2) or a two-generation reproductive toxicity study (Annex IX, Section 8.7.3) may be proposed by the registrant instead of the screening study.</p>
8.8. Toxicokinetics 8.8.1. Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information	

9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1.3. Short-term toxicity testing on fish: the registrant may consider long-term toxicity testing instead of short-term.	<p>9.1.3. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or — a long-term aquatic toxicity study on fish is available. <p>Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.</p> <p>The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble.</p>
9.1.4. Activated sludge respiration inhibition testing	<p>9.1.4. The study does not need to be conducted if:</p> <ul style="list-style-type: none"> — there is no emission to a sewage treatment plant, or — there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water, or — the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant. <p>The study may be replaced by a nitrification inhibition test if</p>

▼ **C1**

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.
9.2. Degradation	9.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment.
9.2.2. Abiotic	
9.2.2.1. Hydrolysis as a function of pH.	9.2.2.1. The study does not need to be conducted if: <ul style="list-style-type: none"> — the substance is readily biodegradable, or — the substance is highly insoluble in water.
9.3. Fate and behaviour in the environment	
9.3.1. Adsorption/desorption screening	9.3.1. The study does not need to be conducted if: <ul style="list-style-type: none"> — based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or — the substance and its relevant degradation products decompose rapidly.

▼ C1

ANNEX IX

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE ⁽¹⁾

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 12(1)(d).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more in accordance with Article 12(1)(d). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII and VIII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI ⁽²⁾.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q) SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

7. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.	7.15. The study does not need to be conducted if the substance is inorganic.
7.16. Dissociation constant	7.16. The study does not need to be conducted if: — the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water, or — it is scientifically not possible to perform the test for instance if the analytical method is not sensitive enough.
7.17. Viscosity	

⁽¹⁾ This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.

⁽²⁾ Note: conditions for not requiring a specific test that are set out in the appropriate test methods in the Commission Regulation on test methods as specified in Article 13(3) that are not repeated in column 2, also apply.

▼ C1

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<p>8.4. If there is a positive result in any of the <i>in vitro</i> genotoxicity studies in Annex VII or VIII and there are no results available from an <i>in vivo</i> study already, an appropriate <i>in vivo</i> somatic cell genotoxicity study shall be proposed by the registrant.</p> <p>If there is a positive result from an <i>in vivo</i> somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.</p>
<p>8.6. Repeated dose toxicity</p> <p>8.6.1. Short-term repeated dose toxicity study (28 days), one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VIII requirements or if tests according to Section 8.6.2 of this Annex is proposed. In this case, Section 3 of Annex XI shall not apply.</p> <p>8.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.</p>	<p>8.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if:</p> <ul style="list-style-type: none"> — a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure, or — a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used, or — a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake), or — the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure. <p>The appropriate route shall be chosen on the following basis:</p> <p>Testing by the dermal route is appropriate if:</p> <ol style="list-style-type: none"> (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and (3) one of the following conditions is met:

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<ul style="list-style-type: none"> — toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or — systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or — <i>in vitro</i> tests indicate significant dermal absorption, or — significant dermal toxicity or dermal penetration is recognised for structurally-related substances. <p>Testing by the inhalation route is appropriate if:</p> <ul style="list-style-type: none"> — exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. <p>Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 in case of:</p> <ul style="list-style-type: none"> — failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects, or — toxicity of particular concern (e.g. serious/severe effects), or — indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity), or — particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected).
8.7. Reproductive toxicity	<p>8.7. The studies do not need to be conducted if:</p> <ul style="list-style-type: none"> — the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented, or — the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented, or — the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure. <p>If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.</p> <p>If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.</p>

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 414).	8.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.
8.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues.	8.7.3. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.

9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1. Aquatic toxicity	9.1. Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
9.1.5. Long-term toxicity testing on invertebrates (preferred species <i>Daphnia</i>), (unless already provided as part of Annex VII requirements)	
9.1.6. Long-term toxicity testing on fish, (unless already provided as part of Annex VIII requirements) The information shall be provided for one of the Sections 9.1.6.1, 9.1.6.2 or 9.1.6.3.	
9.1.6.2. Fish early-life stage (FELS) toxicity test	

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages 9.1.6.3. Fish, juvenile growth test	
9.2. Degradation 9.2.1. Biotic 9.2.1.2. Simulation testing on ultimate degradation in surface water 9.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil) 9.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment) 9.2.3. Identification of degradation products	9.2. Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil). 9.2.1.2. The study need not be conducted if: — the substances is highly insoluble in water, or — the substance is readily biodegradable. 9.2.1.3. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of soil is unlikely. 9.2.1.4. The study need not be conducted: — if the substance is readily biodegradable, or — if direct and indirect exposure of sediment is unlikely. 9.2.3. Unless the substance is readily biodegradable
9.3. Fate and behaviour in the environment 9.3.2. Bioaccumulation in aquatic species, preferably fish 9.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VIII	9.3.2. The study need not be conducted if: — the substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3) and/or a low potential to cross biological membranes, or — direct and indirect exposure of the aquatic compartment is unlikely. 9.3.3. The study need not be conducted if: — based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient), or — the substance and its degradation products decompose rapidly.
9.4. Effects on terrestrial organisms	9.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.4.1. Short-term toxicity to invertebrates	
9.4.2. Effects on soil micro-organisms	
9.4.3. Short-term toxicity to plants	

10. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

▼C1

ANNEX X

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 000 TONNES OR MORE ⁽¹⁾

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 12(1)(e).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 1 000 tonnes or more in accordance with Article 12(1)(e). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII, VIII and IX. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI ⁽²⁾.

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q) SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated.

8. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	<p>8.4. If there is a positive result in any of the <i>in vitro</i> genotoxicity studies in Annexes VII or VIII, a second <i>in vivo</i> somatic cell test may be necessary, depending on the quality and relevance of all the available data.</p> <p>If there is a positive result from an <i>in vivo</i> somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.</p>
	<p>8.6.3. A long-term repeated toxicity study (≥ 12 months) may be proposed by the registrant or required by the Agency in accordance with Articles 40 or 41 if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met:</p> <p>— serious or severe toxicity effects of particular concern</p>

⁽¹⁾ This Annex shall apply to producers of articles that are required to register in accordance with Article 7 and to other downstream users that are required to carry out tests under this Regulation adapted as necessary.

⁽²⁾ Note: conditions for not requiring a specific test that are set out in the appropriate test methods in the Commission Regulation on test methods as specified in Article 13(3) that are not repeated in column 2, also apply.

▼ C1

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
8.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex IX requirements	
8.9.1. Carcinogenicity study	<p>8.9.1. A carcinogenicity study may be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 if:</p> <ul style="list-style-type: none"> — the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure, and — the substance is classified as mutagen category 3 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions. <p>If the substances is classified as mutagen category 1 or 2, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.</p>

9. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
9.2. Degradation	9.2. Further biotic degradation testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
9.2.1. Biotic	
9.3. Fate and behaviour in the environment	
9.3.4. Further information on the environmental fate and behaviour of the substance and/or degradation products	9.3.4. Further testing shall be proposed by the registrant or may be required by the Agency in accordance with Articles 40 or 41 if the chemical safety assessment according to Annex I indicates the need to investigate further the fate and behaviour of the substance. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
9.4. Effects on terrestrial organisms	9.4. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.

▼ **C1**

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1	
9.4.4.	Long-term toxicity testing on invertebrates, unless already provided as part of Annex IX requirements.		
9.4.6.	Long-term toxicity testing on plants, unless already provided as part of Annex IX requirements.		
9.5.1.	Long-term toxicity to sediment organisms	9.5.1.	Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
9.6.1.	Long-term or reproductive toxicity to birds	9.6.1.	Any need for testing should be carefully considered taking into account the large mammalian dataset that is usually available at this tonnage level.

10. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.