

N. 6

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



IRITANTE

2. Il candidato illustri le buone pratiche di comportamento in laboratorio chimico volte a ridurre il rischio di incendi ed esposizione a sostanze pericolose.

3. Il candidato illustri brevemente il funzionamento di una cappa chimica.

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2. As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.

3. This Article shall apply to producers of articles adapted as necessary.

Article 13

General requirements for generation of information on intrinsic properties of substances

1. Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.

2. These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Commission, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133(4), and the Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. Amendments to that Commission Regulation shall be adopted in accordance with the procedure specified in paragraph 3 and amendments to the Annexes of this Regulation shall be adopted in accordance with the procedure referred to in Article 131.

3. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. The Commission shall adopt that Regulation, designed to amend the non-essential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4).

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

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N. 3

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



2. Il candidato illustri quali sono i dispositivi di sicurezza a norma di legge necessari in un laboratorio chimico

3. Il candidato illustri le modalità di stoccaggio di sostanze chimiche pericolose.

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5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- (b) the Agency has grounds for suspecting that:
 - (i) the substance is released from the articles, and
 - (ii) the release of the substance from the articles presents a risk to human health or the environment;
- (c) the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7. From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).

8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 8

Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance on its own, in ►**M3** mixtures ◀ or in articles, formulates a ►**M3** mixture ◀ or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

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N. 4

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



TOSSICO

2. Il candidato illustri quali sono i dispositivi di sicurezza a norma di legge necessari in un laboratorio chimico

3. Il candidato illustri le modalità di utilizzo di cappe chimiche con sostanze chimiche pericolose.

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(b) the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.

4. A submission for registration shall be accompanied by the fee required in accordance with Title IX.

*Article 7***Registration and notification of substances in articles**

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- (b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. The information to be notified shall include the following:

- (a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
- (b) the registration number(s) referred to in Article 20(1), if available;
- (c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
- (d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
- (e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
- (f) the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

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N. 5

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



IRRITANTE

2. Il candidato illustri le modalità per utilizzare le bombole di gas in sicurezza
3. Il candidato illustri le etichettature delle bombole di gas compressi.

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7. Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

CHAPTER 2

*Substances regarded as being registered**Article 15***Substances in plant protection and biocidal products**

1. Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC ⁽¹⁾ or in Commission Regulation (EEC) No 3600/92 ⁽²⁾, Commission Regulation (EC) No 703/2001 ⁽³⁾, Commission Regulation (EC) No 1490/2002 ⁽⁴⁾, or Commission Decision 2003/565/EC ⁽⁵⁾ and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

2. Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽⁶⁾ or in Commission Regulation (EC) No 2032/2003 ⁽⁷⁾ on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded

⁽¹⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1). Directive as last amended by Commission Directive 2006/136/EC (OJ L 349, 12.12.2006, p. 42).

⁽²⁾ Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10). Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).

⁽³⁾ Commission Regulation (EC) No 703/2001 of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs for those substances (OJ L 98, 7.4.2001, p. 6).

⁽⁴⁾ Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 224, 21.8.2002, p. 23). Regulation as last amended by Regulation (EC) No 1744/2004 (OJ L 311, 8.10.2004, p. 23).

⁽⁵⁾ Commission Decision 2003/565/EC of 25 July 2003 extending the time period provided for in Article 8(2) of Council Directive 91/414/EEC (OJ L 192, 31.7.2003, p. 40).

⁽⁶⁾ OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/140/EC (OJ L 414, 30.12.2006, p. 78).

⁽⁷⁾ OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63).

Omissis

N. 1

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



2. Il candidato illustri gli obblighi del lavoratore che opera nell'ambito di un laboratorio chimico

3. Il candidato illustri le modalità di utilizzo in sicurezza delle cappe chimiche.

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7. The following shall be exempted from Titles II, V and VI:
- (a) substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
 - (b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;
 - (c) substances on their own or in ►M3 mixtures ◄, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain who shows that:
 - (i) the substance being re-imported is the same as the exported substance;
 - (ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;
 - (d) substances, on their own, in ►M3 mixtures ◄ or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:
 - (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
 - (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.
8. On-site isolated intermediates and transported isolated intermediates shall be exempted from:
- (a) Chapter 1 of Title II, with the exception of Articles 8 and 9; and
 - (b) Title VII.
9. The provisions of Titles II and VI shall not apply to polymers.

CHAPTER 2

Definitions and general provision

Article 3

Definitions

For the purposes of this Regulation:

1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
2. ►M3 mixture ◄: means a mixture or solution composed of two or more substances;

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N. 2

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



COMBURENTE

2. Il candidato illustri quali sono i dispositivi di sicurezza a norma di legge necessari in un laboratorio chimico

3. Il candidato illustri le modalità di stoccaggio di sostanze chimiche infiammabili.

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▼ **CI***Article 9***Exemption from the general obligation to register for product and process orientated research and development (PPORD)**

1. Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:

- (a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI;
- (b) the identity of the substance, as specified in section 2 of Annex VI;
- (c) the classification of the substance as specified in section 4 of Annex VI, if any;
- (d) the estimated quantity as specified in section 3.1 of Annex VI;
- (e) the list of customers referred to in paragraph 1, including their names and addresses.

The notification shall be accompanied by the fee required in accordance with Title IX.

The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3. The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the competent authority of the Member State(s) concerned.

4. The Agency may decide to impose conditions with the aim of ensuring that the substance or the ►**M3** mixture ◀ or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a ►**M3** mixture ◀ or article and that remaining quantities will be re-collected for disposal after the exemption period.

In such cases, the Agency may ask the notifier to provide additional necessary information.

5. In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.

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N. 7

1. Il candidato illustri il significato e le precauzioni del seguente pittogramma di pericolo chimico:



**PERICOLOSO
PER L'AMBIENTE**

2. Il candidato illustri le buone pratiche per lo stoccaggio di sostanze pericolose.

3. Il candidato illustri le norme di sicurezza per l'utilizzo di liquidi criogenici.

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4. Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.

5. If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex VI.

*Article 14***Chemical safety report and duty to apply and recommend risk reduction measures**

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a ►**M3** mixture ◀ or in an article or a group of substances.

▼M3

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:

- (a) the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;
- (b) 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.

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3. A chemical safety assessment of a substance shall include the following steps:

- (a) human health hazard assessment;
- (b) physicochemical hazard assessment;
- (c) environmental hazard assessment;
- (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

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