Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

CHAPTER IX

CANCELLATION, REVIEW AND AMENDMENT OF AUTHORISATIONS

CHAPTER X

PARALLEL TRADE

CHAPTER XI

TECHNICAL EQUIVALENCE

CHAPTER XII

DEROGATIONS

CHAPTER XIII

TREATED ARTICLES

CHAPTER XIV

DATA PROTECTION AND DATA-SHARING

CHAPTER XV

INFORMATION AND COMMUNICATION

SECTION 1

Monitoring and reporting

SECTION 2

Information about biocidal products

CHAPTER XVI

THE AGENCY

CHAPTER XVII

FINAL PROVISIONS

ANNEX I

ANNEX II

INFORMATION REQUIREMENTS FOR ACTIVE SUBSTANCES

1. This Annex sets out the information requirements for the preparation...

2. The data elements set down in this Annex comprise a...

3. A detailed and full description of the studies conducted or...

4. The formats made available by the Agency must be used...

5. Tests submitted for the purpose of the approval of an...

6. Tests performed should comply with the relevant requirements of protection...

7. Where testing is done, a detailed description (specification) of the...

8. Where test data exist that have been generated before 1...

9. New tests involving vertebrates shall be conducted as the last...

TITLE 1

CHEMICAL SUBSTANCES

Core data set and additional data set for active substances...

TITLE 2

MICRO-ORGANISMS

Core data set and additional data set for active substances...

ANNEX III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

1. This Annex sets out the information requirements that shall be...

2. The data elements set down in this Annex comprise a...

3. A detailed and full description of studies conducted and of...

4. The formats made available by the Agency shall be used...

5. Tests submitted for the purpose of authorisation shall be conducted...

6. Tests performed should comply with the relevant requirements of protection...

7. Where testing is done, a detailed quantitative and qualitative description...

8. Where test data exist that have been generated before 17...

9. New tests involving vertebrates shall be conducted as the last...

TITLE 1

CHEMICAL PRODUCTS

Core data set and additional data set for chemical products...

TITLE 2

MICRO-ORGANISMS

Core data set and additional data set

ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

This Annex sets out rules to be followed when the...
The reasons for such adaptations to the data requirements must...

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY
   - 1.1. Use of existing data
     - 1.1.1. Data on physical-chemical properties from experiments not carried out according...
     - 1.1.2. Data on human health and environmental properties from experiments not...
     - 1.1.3. Historical human data
   - 1.2. Weight of evidence
   - 1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)
   - 1.4. In vitro methods
   - 1.5. Grouping of substances and read-across approach

2. TESTING IS TECHNICALLY NOT POSSIBLE

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING
   3.1. Testing in accordance with some endpoints in Sections 8 and...
   3.2. In all cases, adequate justification and documentation shall be provided....

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

MAIN GROUP 1 — Disinfectants
- Product-type 1 — Human hygiene
- Product-type 2 — Disinfectants and algaecides not intended for direct application to humans...
- Product-type 3 — Veterinary hygiene
- Product-type 4 — Food and feed area
- Product-type 5 — Drinking water

MAIN GROUP 2 — Preservatives
- Product-type 6 — Preservatives for products during storage
- Product-type 7 — Film preservatives
- Product-type 8 — Wood preservatives
- Product-type 9 — Fibre, leather, rubber and polymerised materials preservatives
- Product-type 10 — Construction material preservatives
- Product-type 11 — Preservatives for liquid-cooling and processing systems
- Product-type 12 — Slimicides
- Product-type 13 — Working or cutting fluid preservatives

MAIN GROUP 3 — Pest control
- Product-type 14 — Rodenticides
- Product-type 15 — Avicides
- Product-type 16 — Molluscicides, vermicides and products to control other invertebrates
- Product-type 17 — Piscicides
- Product-type 18 — Insecticides, acaricides and products to control other arthropods
- Product-type 19 — Repellents and attractants
- Product-type 20 — Control of other vertebrates

MAIN GROUP 4 — Other biocidal products
- Product-type 21 — Antifouling products
- Product-type 22 — Embalming and taxidermist fluids

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

TERMS AND DEFINITIONS

Technical definitions

(a) Hazard identification
(b) Dose (concentration) — response (effect) assessment
(c) Exposure assessment
(d) Risk characterisation
(e) Environment

ANNEX VII

(**1**) OJ C 347, 18.12.2010, p. 62.

(**2**) Position of the European Parliament of 22 September 2010 (OJ C 50 E, 21.2.2012, p. 73) and position of the Council at first reading of 21 June 2011 (OJ C 320 E, 1.11.2011, p. 1). Position of the European Parliament of 19 January 2012 (not yet published in the Official Journal) and decision of the Council of 10 May 2012.

(**3**) OJ L 123, 24.4.1998, p. 1.

(**4**) OJ L 396, 30.12.2006, p. 1.

(**5**) OJ L 189, 20.7.1990, p. 17.

(**6**) OJ L 169, 12.7.1993, p. 1.

(**7**) OJ L 331, 7.12.1998, p. 1.

(**8**) OJ L 342, 22.12.2009, p. 59.

(**9**) OJ L 31, 1.2.2002, p. 1.

(**10**) OJ L 268, 18.10.2003, p. 29.

(**11**) OJ L 354, 31.12.2008, p. 16.

(**12**) OJ L 312, 22.11.2008, p. 3.

(**13**) OJ L 55, 28.2.2011, p. 13.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) No 528/2012 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.