

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)

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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...

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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

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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

- Product-Type 1 Human hygiene
- Product-Type 2 Disinfectants and algacides not intended for direct application to humans...
- Product-Type 3 Primary hygiene
- Product-Type 4 Food and feed area
- Product-Type 5 Drinking water

MAIN GROUP 2

- Product-Type 6 Preservatives for products during storage
- Product-Type 7 Preservatives
- Product-Type 8 Preservatives
- Product-Type 9 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 Slime
- Product-Type 13 Working or cutting fluid preservatives

MAIN GROUP 3

- Product-Type 14 Acaricides
- Product-Type 15 Acaricides
- Product-Type 16 Molluscicides, vermicides and products to control other invertebrates
- Product-Type 17 Pesticides
- 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

- 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

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INTRODUCTION

1. This Annex sets out the common principles for the evaluation...
2. The principles set out in this Annex can be applied...
3. In order to ensure a high and harmonised level of...
4. A risk assessment on the active substance(s) present in the...
5. Additional risk assessments shall be carried out, in the same...
6. In order to carry out a risk assessment, data are...
7. The results of the risk assessments carried out on the...
8. When making evaluations of a biocidal product the evaluating body...
9. The application of these common principles shall, when taken together...
10. In the case of biocidal products containing active substances covered...
11. During the process of evaluation, applicants and the evaluating bodies...
12. The judgments made by the evaluating body during the evaluation...

ASSESSMENT

General principles

13. The data submitted in support of an application for authorisation...
14. A risk assessment on the active substance present in the...
15. In carrying out the assessment, the possibility of cumulative or...
16. For each active substance and each substance of concern present...
17. The results arrived at from a comparison of the exposure...
18. The risk assessment shall determine:
19. In certain cases it may be concluded that further data...
20. The information provided on the biocidal product family shall permit...
21. Where relevant the technical equivalence for every active substance contained...

Effects on human and animal health

Effects on human health

22. The risk assessment shall take account of the following potential...
23. The effects previously mentioned result from the properties of the...
24. The populations previously mentioned are:
25. The hazard identification shall address the properties and potential adverse...
26. The evaluating body shall apply points 27 to 30 when...
27. For repeated dose toxicity and reproductive toxicity the dose-response relationship...
28. For acute toxicity, corrosivity and irritation, it is not usually...
29. For mutagenicity and carcinogenicity, a non-threshold assessment should be carried...
30. With respect to skin sensitisation and respiratory sensitisation, in so...
31. When carrying out the risk assessment special consideration shall be...
32. An exposure assessment shall be carried out for each of...
33. The exposure assessment shall be based on the information in...
34. When conducting the exposure assessment, special consideration shall be given...
35. Where, for any of the effects set out in point...

Effects on animal health

36. Using the same relevant principles as described in the section...

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Effects on the environment

37. The risk assessment shall take account of any adverse effects...
38. The hazard identification shall address the properties and potential adverse...
39. A dose (concentration) — response (effect) assessment shall be carried...
40. The PNEC shall be determined from the data on effects...
41. An assessment factor is an expression of the degree of...
42. For each environmental compartment, an exposure assessment shall be carried...
43. A PEC, or where necessary a qualitative estimate of exposure,...
44. The PEC, or the qualitative estimation of exposure, shall be...
45. When conducting the exposure assessment, special consideration shall be given...
46. For any given environmental compartment, the risk characterisation shall, as...
47. If it has not been possible to derive a PEC/PNEC...
48. The evaluating body shall conclude that the biocidal product does...

Effects on target organisms

49. An assessment shall be made to demonstrate that the biocidal...
50. The evaluating body shall, where relevant, evaluate the possibility of...

Efficacy

51. Data submitted by the applicant shall be sufficient to substantiate...
52. Testing should be carried out according to Union guidelines where...

Summary

53. In each of the areas where risk assessments have been...
54. For biocidal product containing more than one active substance, any...

CONCLUSIONS

General principles

55. The purpose of the evaluation is to establish whether or...
56. In establishing compliance with the criteria set out in point...
57. The evaluating body shall, when seeking to establish whether a...
58. If the conclusion arrived at by the evaluating body is...

Effects on human and animal health

Effects on human health

59. The evaluating body shall consider possible effects on all human...
60. The evaluating body shall examine the relationship between exposure and...
61. Typically, the margin of exposure (MOE_{ref}) — the ratio between...
62. The evaluating body shall, where appropriate, conclude that criterion (iii)...
63. If, for non-professional users, the wearing of personal protective equipment...

Effects on animal health

64. Using the same relevant criteria as described in the section...

Effects on the environment

65. The basic tool used in the decision-making is the PEC/PNEC...
66. For any given environmental compartment, if the PEC/PNEC ratio is...
Water

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67. The evaluating body shall conclude that the biocidal product does...

68. The evaluating body shall conclude that the biocidal product does...

69. The evaluating body shall conclude that the biocidal product does...

70. The proposed instructions for use of the biocidal product, including...

Soil

71. The evaluating body shall conclude that the biocidal product does...

Air

72. The evaluating body shall conclude that the biocidal product does...

Non-target organisms

73. The evaluating body shall conclude that the biocidal product does...

74. The evaluating body shall conclude that the biocidal product does...

Effects on target organisms

75. Where the development of resistance or cross-resistance to the active...

76. A biocidal product intended to control vertebrates shall not normally...

Efficacy

77. The level, consistency and duration of protection, control or other...

Summary

78. In relation to the criteria set out in points (iii)...

OVERALL INTEGRATION OF CONCLUSIONS

ANNEX VII

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- (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.](#)

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