

Regulation (EC) No 1107/2009 of the European Parliament and of the Council
of 21 October 2009 concerning the placing of plant protection products on
the market and repealing Council Directives 79/117/EEC and 91/414/EEC

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ANNEX I

Definition of zones for the authorisation of plant protection products...

Zone A — North

Zone B — Centre

Zone C — South

ANNEX II

Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II

1. Evaluation
 - 1.1. During the process of evaluation and decision-making provided for in...
 - 1.2. The evaluation by the assessing competent authority must be based...
 - 1.2A In this Annex, “ the assessing competent authority ” has...
 - 1.3. During the process of evaluation and decision-making provided for in...
2. General decision-making criteria
 - 2.1. Article 4 shall only be considered as complied with, where,...
 - 2.2. Submission of further information
 - 2.3. Restrictions on approval
3. Criteria for the approval of an active substance
 - 3.1. Dossier
 - 3.2. Efficacy
 - 3.3. Relevance of metabolites
 - 3.4. Composition of the active substance, safener or synergist
 - 3.4.1. The specification shall define the minimum degree of purity, the...
 - 3.4.2. The specification shall be in compliance with the relevant Food...
 - 3.5. Methods of analysis
 - 3.5.1. The methods of analysis of the active substance, safener or...
 - 3.5.2. The methods of residue analysis for the active substance and...
 - 3.5.3. The evaluation has been carried out in accordance with the...
 - 3.6. Impact on human health
 - 3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established...
 - 3.6.2. An active substance, safener or synergist shall only be approved...
 - 3.6.3. An active substance, safener or synergist shall only be approved,...
 - 3.6.4. An active substance, safener or synergist shall only be approved...
 - 3.6.5. An active substance, safener or synergist shall only be approved...
 - 3.7. Fate and behaviour in the environment
 - 3.7.1. An active substance, safener or synergist shall only be approved...
 - 3.7.1.1. Persistence
 - 3.7.1.2. Bioaccumulation
 - 3.7.1.3. Potential for long-range environmental transport:
 - 3.7.2. An active substance, safener or synergist shall only be approved...
 - 3.7.2.1. Persistence
 - 3.7.2.2. Bioaccumulation
 - 3.7.2.3. Toxicity
 - 3.7.3. An active substance, safener or synergist shall only be approved...
 - 3.7.3.1. Persistence
 - 3.7.3.2. Bioaccumulation
 - 3.8. Ecotoxicology
 - 3.8.1. An active substance, safener or synergist shall only be approved...
 - 3.8.2. An active substance, safener or synergist shall only be approved...
 - 3.8.3. An active substance, safener or synergist shall be approved only...
 - 3.9. Residue definition

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- 3.10. Fate and behaviour concerning groundwater
- 4. Candidate for substitution
- 5. Low-risk active substances
 - 5.1. Active substances other than micro-organisms
 - 5.1.1. An active substance, other than a micro-organism, shall not be...
 - 5.1.2. An active substance, other than a micro-organism, shall not be...
 - 5.1.3. An active substance, other than a micro-organism, emitted and used...
 - 5.2. Micro-organisms
 - 5.2.1. An active substance which is a micro-organism may be considered...
 - 5.2.2. Baculoviruses shall be considered as being of low-risk unless at...

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List of co-formulants which are not accepted for inclusion
in plant protection products as referred to in Article 27

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- 1. Conditions for comparative assessment
- 2. Significant difference in risk
- 3. Significant practical or economic disadvantages
The comparative assessment shall take authorised minor uses into account....

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Repealed Directives and their successive amendments as referred to in Article 83

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- (1) [OJ C 175, 27.7.2007, p. 44.](#)
- (2) [OJ C 146, 30.6.2007, p. 48.](#)
- (3) Opinion of the European Parliament of 23 October 2007 ([OJ C 263 E, 16.10.2008, p. 181](#)), Council Common Position of 15 September 2008 ([OJ C 266 E, 21.10.2008, p. 1](#)) and European Parliament Position of 13 January 2009 (not yet published in the Official Journal). Council Decision of 24 September 2009.
- (4) [OJ L 230, 19.8.1991, p. 1.](#)
- (5) [OJ C 187 E, 7.8.2003, p. 173.](#)
- (6) [OJ L 33, 8.2.1979, p. 36.](#)
- (7) [OJ L 31, 1.2.2002, p. 1.](#)
- (8) [OJ L 327, 22.12.2000, p. 1.](#)
- (9) See page 71 of this Official Journal.
- (10) [OJ L 270, 21.10.2003, p. 1.](#)
- (11) [OJ L 358, 18.12.1986, p. 1.](#)
- (12) [OJ L 200, 30.7.1999, p. 1.](#)
- (13) [OJ L 165, 30.4.2004, p. 1.](#)
- (14) [OJ L 70, 16.3.2005, p. 1.](#)
- (15) [OJ L 184, 17.7.1999, p. 23.](#)

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