# 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

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

(**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.

**Changes to legislation:**
There are currently no known outstanding effects for the Regulation (EC) No 1107/2009 of the European Parliament and of the Council.