

ANNEX II

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

- [^{F15}]. 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 considered as being of low-risk where it corresponds to any of the following:
- (a) it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as any of the following:
- carcinogenic category 1A, 1B or 2,
 - mutagenic category 1A, 1B or 2,
 - toxic to reproduction category 1A, 1B or 2,
 - skin sensitiser category 1,
 - serious damage to eye category 1,
 - respiratory sensitiser category 1,
 - acute toxicity category 1, 2 or 3,
 - specific Target Organ Toxicant, category 1 or 2,
 - toxic to aquatic life of acute and chronic category 1 on the basis of appropriate standard tests,
 - explosive,
 - skin corrosive, category 1A, 1B or 1C;
- (b) it has been identified as priority substance [^{F2}and is listed in Annex 10 to] Directive 2000/60/EC;
- (c) it is deemed to be an endocrine disruptor;
- (d) it has neurotoxic or immunotoxic effects.

Textual Amendments

F2 Words in [Annex 2 point 5.1.1\(b\)](#) substituted (31.12.2020) by [The Plant Protection Products \(Miscellaneous Amendments\) \(EU Exit\) Regulations 2019 \(S.I. 2019/556\)](#), regs. 1(1), **14(3)(r)** (with Sch. 1); 2020 c. 1, Sch. 5 para. 1(1)

- 5.1.2. An active substance, other than a micro-organism, shall not be considered as being of low-risk where it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

However, a naturally occurring active substance which does not correspond to any of points (a) to (d) of point 5.1.1 may be considered as being of low-risk, even if it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

- 5.1.3. An active substance, other than a micro-organism, emitted and used by plants, animals and other organisms for communication, shall be considered as being of low-risk where it does not correspond to any of points (a) to (d) of point 5.1.1.
- 5.2. Micro-organisms

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, Division 5. . (See end of Document for details)

- 5.2.1. An active substance which is a micro-organism may be considered as being of low-risk unless at strain level it has demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.
- 5.2.2. Baculoviruses shall be considered as being of low-risk unless at strain level they have demonstrated adverse effects on non-target insects.]

Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2017/1432 of 7 August 2017 amending Regulation \(EC\) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances \(Text with EEA relevance\).](#)

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, Division 5. .