

## ANNEX

Point 5 of Annex II to Regulation (EC) No 1107/2009 is replaced by the following:

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 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 under Directive 2000/60/EC;
      - (c) it is deemed to be an endocrine disruptor;
      - (d) it has neurotoxic or immunotoxic effects.
    - 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
  - 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.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) 2017/1432, ANNEX.