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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 22(3) in conjunction with Article 78(1)(a) thereof,

Whereas:

(1) Regulation (EC) No 1107/2009 aims at facilitating the placing on the market of plant protection products containing low-risk active substances by setting criteria for identification of low-risk active substances and accelerating the authorisation procedure for low-risk products.

(2) Directive 2009/128/EC of the European Parliament and of the Council ([2]) promotes integrated pest management with priority for the use of plant protection products and other non-chemical techniques having the least side effects on human health, non-target organisms and the environment. In particular, its Article 12 provides for use of low-risk plant protection products to be considered in the first place in case of use of plant protection products in certain specific areas such as those used by the general public.

(3) In accordance with Article 22 of Regulation (EC) No 1107/2009, point 5 of Annex II to that Regulation applies to the identification of low-risk active substances complying with the criteria of Article 4 of that Regulation.

(4) Point 5 of Annex II refers to a number of hazard categories laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]). For the sake of clarity and to reflect the contemporaneous application of that Regulation, it is appropriate to provide more details as regards those hazard categories.

(5) In accordance with Article 16 of Directive 2000/60/EC of the European Parliament and of the Council ([4]), substances presenting a significant risk to or via the aquatic environment are defined as priority substances at Union level and listed in Annex X to that Directive. Therefore such listed priority substances should not be considered as low-risk active substances.

(6) The criteria pertaining to persistence and bioconcentration, in light of current scientific and technical knowledge, could prevent approval as low-risk substances, of certain naturally occurring substances presenting considerably less of a risk than other active substances, such as certain botanicals or minerals. It is therefore appropriate to allow for the approval of such substances as being of low-risk, in cases where they comply with Article 22 of Regulation (EC) No 1107/2009.

(7) Semio-chemicals, which are substances emitted by plants, animals and other organisms which are used for intra- and inter-species communication, have a target-specific and non-toxic mode of action and are naturally occurring. They are generally effective at very low rates, often comparable to levels that occur naturally ([5]). In light of current scientific and technical knowledge it is also appropriate to provide that semio-chemicals should be considered as low-risk substances.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).
([5]) OECD Report of the 5th Biopesticides Steering Group Seminar on application techniques for microbial pest control products and semiochemicals: use scenarios and associated risks ENV/JM/MONO(2015)38.

(8) Active substances in the meaning of Article 2 of Regulation (EC) No 1107/2009 include micro-organisms whose properties differ from those of chemical substances. It is appropriate that the low-risk criteria applicable to micro-organisms are provided for based on the current scientific and technical knowledge.

(9) Micro-organisms which are to be included in plant protection products are assessed at strain level in conformity with specific data requirements laid down in part B of the Annex to Commission Regulation (EU) No 283/2013 ([1]). Consequently, micro-organisms should be identified and characterised at strain level also when assessed for compliance with the criteria concerning low-risk substances as toxicological properties of different strains belonging to the same species of micro-organism can vary greatly. A micro-organism may be considered to be of low-risk unless at strain level it has demonstrated multiple resistance to antimicrobials used in human or veterinary medicine.

(10) It should be clearly indicated that baculoviruses which are a host-specific family of viruses infecting exclusively arthropods and occurring predominantly in the insect order of *Lepidoptera*, are to be considered as low-risk substances as there is no scientific evidence that baculoviruses have any negative effect on animals and humans ([2]). A baculovirus should be considered of low-risk unless at strain level it has demonstrated adverse effects on non-target insects.

(11) Point 5 of the Annex II to Regulation (EC) No 1107/2009 should therefore be amended accordingly.

(12) The amended criteria reflect the current state of scientific and technical knowledge and clarify the existing criteria in point 5. The new criteria should therefore apply as soon as possible, except where the relevant Committee has voted on the draft Regulation presented to it without that Regulation having been adopted by the Commission by 28 August 2017.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1107/2009 is amended in accordance with the Annex to this Regulation.

Article 2

Point 5 of Annex II to Regulation (EC) No 1107/2009, as amended by the present Regulation, shall apply as of 28 August 2017, except for procedures where the Committee has voted on the draft Regulation presented to it without that draft Regulation having been adopted by 28 August 2017.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

([2]) EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2013. Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update). *EFSA Journal* 2013;11(11):3449,107 pp. doi:10.2903/j.efsa.2013.3449.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 August 2017.

For the Commission
The President
Jean-Claude JUNCKER

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.'