

IBMA Position Paper on Commission Regulation (EU) No 2017/1432 and low-risk status of semiochemical active substances and plant protection products

Executive Summary:

The European Union actively promotes safer agriculture, with a low-impact on humans, animals and the environment. In line with this goal, the intention of the Sustainable Use Directive (Directive 2009/128/EC) and the Regulation (EC) No 1107/2009, is to reduce risk by favouring safer methods, and in particular, low-risk plant protection products.

Low-risk active substances and corresponding plant protection products can benefit from shorter authorization timelines. Low-risk criteria for active substances were amended in August 2017 by Reg. (EU) 2017/1432.

The very broad approach for deciding on low-risk status may not always guarantee that semiochemical PPPs will benefit from the same favourable authorisation conditions as low-risk PPPs, even if the semiochemicals released by these products expose humans, animals and the environment by the same route and at the same level as the natural exposure. In fact, Semiochemicals are naturally occurring substances used for intra- and inter-species communication by plants, animals and other organisms. They are currently used in agriculture as plant protection products with a target-specific and non-toxic mode of action. They are a useful tool in Integrated Pest Management strategies.

Currently, the use of semiochemicals in plant protection falls within the same regulatory framework as conventional pesticides, resulting in long timelines for the authorization of products based on these substances, despite the relatively small data packaged required.

IBMA asks the Commission to address this issue during the PAFF Standing Committee and actively support the low-risk status of defined representative uses of semiochemical active substances. This will facilitate the introduction of biological alternatives onto the market, will ensure consistency with the reduced data requirements as indicated by SANTE/12815/2014, and will allow compliance with the objectives set out by Directive 2009/128/EC for a more sustainable use of pesticides.

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The International Biocontrol Manufacturers Association (IBMA) Professional Group on Semiochemicals prepared this position paper to address the low-risk status of plant protection products containing semiochemical active substances following the entry into force of Regulation (EU) 2017/1432.

It is stated in the EU that there is a need to reduce the risk to human and animal health and the environment (Sustainable Use Directive (Directive 2009/128/EC)). This is achieved through the adoption, at Member State level, of National Action Plans.

Regulation (EC) No 1107/2009 lays down rules for the authorisation, the placing on the market, the use and the control within the Community of plant protection products (PPPs). Its purpose is *“to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture”*.

Regulation (EC) No 1107/2009 also sets out identification criteria in Annex II (5) and specific derogations for low-risk active substances in article 22 and for the placing on the market of low-risk plant protection products as defined by Article 47. Due to the status as low-risk to human and animal health and the environment, these active substances and products are favoured by incentives such as, the extended duration of data protection (up to 13 years), the extended duration of first approval (up to 15 years), the publication of specific principles for efficacy evaluation (EPPO PP 1/296 (1)) and, most importantly, the shorter authorisation processes (120 days).

The intention behind both the above-mentioned legislative texts, i.e. Directive and Regulation, is to reduce risk by favouring safer methods, in particular low-risk plant protection products.

The Commission Regulation (EU) No 2017/1432 amends Annex II (5) of Regulation (EC) No 1107/2009 by setting modified criteria for low-risk substances.

IBMA considers this amendment a useful clarification. However, there remains some situations in which some potentially low-risk plant protection products can still be excluded.

Specifically, plant protection products based on certain semiochemical active substances are not recognized as low-risk, even if the specific use and application method of such products provides an actual low-risk situation in line with the intentions of the current legislative framework.

As clearly stated in Regulation (EU) 2017/1432, *“semiochemicals 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. In light of current scientific and technical knowledge it is also appropriate to provide that semiochemicals should be considered as low-risk substances”*.

However, the same criteria for active substances other than microorganisms set out by this Regulation, are, in some cases, not all fulfilled by semiochemical active substances, as some semiochemical active substances showed skin sensitisation potential and/or generated mixed results under current aquatic toxicity test methodologies.

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The European Commission Health & Food Safety Directorate-General has issued a Guidance Document, SANTE/12815/2014, on *semiochemical active substances and plant protection products*, which is applicable to all applications submitted from 1 January 2017 onwards. This guidance aims to provide practical solutions on how procedures and data requirements can be applied to facilitate the approval of semiochemicals at EU level and the authorisation of plant protection products containing these active substances at Member State level. The guidance states that:

"When the exposure route is by the vapour phase only (retrievable dispensers, non-retrievable dispensers and dosable matrix) and where the exposure (by the same route) caused by the use of the plant protection product is similar (within one order of magnitude) to or lower than natural exposure levels of the semiochemical", the risk characterization is limited to the physical-chemical properties, the analytical methods and the efficacy of the product.

This reduced data package for semiochemical PPPs emitting only into the air compartment and having an exposure similar (within one order of magnitude) to the natural exposure level is perfectly compatible with a 120 days authorisation process laid out for low-risk PPPs.

Therefore, IBMA considers that, where the above conditions are met, semiochemical PPPs must benefit from the same conditions as those given for other low-risk PPPs according to Article 47 of Regulation (EC) No 1107/2009 and IBMA asks the Commission to address this issue during the PAFF Standing Committee supporting the low-risk status of defined representative uses of semiochemical active substances.

Conclusions

Low-risk criteria for active substances have been amended by Reg. (EU) 2017/1432. However, the very general approach for deciding on low-risk may not always guarantee that semiochemical PPPs will benefit from the same favourable authorisation conditions as low-risk PPPs, even if the semiochemicals released from these products expose humans, animals and the environment by the same route and at same level as the natural exposure.

IBMA asks the Commission to address this issue during the PAFF Standing Committee and actively support the low-risk status of defined representative uses of semiochemical active substances. This will facilitate the introduction of biological alternatives onto the market, will ensure consistency with the reduced data requirements as indicated by SANTE/12815/2014, and will allow compliance with the objectives set out by Directive 2009/128/EC for a more sustainable use of pesticides.

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