Low-risk substances in the EU

By Bernd Brielbeck

The comprehensive package of new legislation published from 2009 onwards, including the EU agro-chemical registration Regulation (1107/2009) and the EU sustainable use of pesticides Directive (2009/128) have set a completely new framework for crop protection, introducing low-risk substan-ces in the EU regulatory framework.

Low-risk substances are often incorrectly considered the equivalent of biopesticides, for which no official definition exists under EU legislative frameworks. According to the European Commission's Health and Food Safety Directorate General's (DG SANTE's) criteria for low-risk pesticides (SANTE/11953/2015), low-risk substances are "in many cases botanical active substances, semio-chemicals, micro-organisms [biopesticides] or minerals. However, neither must the scope of low-risk active substances be limited to this non-exhaustive list of substance groups, nor can all substances belonging to these groups be considered as low-risk substances without further assessment". Thus, chemical active ingredients can also attain low-risk status, depending solely on the characteristics of the substance and not its origin.

Besides the regulatory framework, there are a lot of political and socio-economic developments and legislation supporting the introduction and use of non-conventional crop protection methods, based, for example, on the EU Common Agricultural Policy. Important steps are the "Motion for a European Parliament resolution on technological solutions for sustainable agriculture in the EU" (2015/2225(INI)) adopted in April 2016 and the European Parliament resolution of February 15th 2017 on low-risk pesticides of biological origin (2016/2903(RSP)). Considering economic, agricultural, ecological, food safety and political aspects, these resolutions not only demand "clear criteria for defining low-risk active substances for the development and use of low-risk pesticides" but also take the view that "non-chemical alternatives to plant protection products such as biological controls, should be given provisional approval for use and priority for evaluation". They not only state that the "faster approvals process would increase the availability of low-risk

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plant protection products on the market and reduce the risk of resistance to active substances and the effects on non-target species linked to commonly used plant protection products" but also "invite the member states to include the use of low-risk pesticides of biological origin in their national action plans on the protection of the environment and of human health".

This clearly shows that the low availability of low-risk crop protection products is not due to the lack of political will at an EU level. Rather, the adaption of the regulatory process at EU and member state level is the obstacle. Some of the main challenges to applicants do not differ between traditional chemical and low-risk crop protection products, such as the lack of harmonisation or the very signifi-cant delays in ai and product evaluations. As low-risk ais are often manufactured and registered by small and medium-sized enterprises, the resulting lack of planning reliability and delays in entry onto the market have an even more negative impact on low-risk ais than on traditional chemicals. Some member states, such as France, try to remedy these problems and promote low-risk products by additional national efforts or, as in case of the Netherlands, also support industry by providing re-spective guidance documents (CTGB (2017): Evaluation manual for the authorisation of biopesticides according to regulation (ec) no 1107/2009 - microorganisms, botanicals, semiochemicals version 1.0; July 2017).

Guidance related to low-risk and handling of low-risk criteria

SANTE-2016-10616–rev 7 of May 2017 provides an overview of the possible low-risk status of already existing ais after the renewal of these substances expiring between January 1st 2019 and December 31st 2021, indicating that a huge number may be classified as low risk in the future. Paradoxically, point 3 of Article 47 of Regulation 1107/2009 stipulates that "the member state shall decide within 120 days whether to approve an application for authorisation of a low-risk plant protection product". This, however, does not apply to the renewal of product authorisations regulated by Article 43 of Regulation 1107/2009, which states that "member states shall decide on the renewal of the authori-sation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance...".

One of the main challenges for low-risk substances, many of which belong to the very inhomogene-ous group of biopesticides comprising different types of micro-organisms and/or their metabolites, semiochemicals, botanicals and minerals is the lack, or sketchiness, of respective guidance and guide-lines. At present, this is especially true, for example, for the possible new definitions of the low-risk criteria for micro-organisms. Not showing multiple resistances to anti-microbials used in human or veterinary medicine is the only criterion given. Therefore, every micro-organism not showing such resistance in general qualifies for being low risk (draft SANTE/12376/2015 ANNEX 1). But, as the first evaluations and comments from national authorities imply, there may be a lot of exceptions and additional restrictions on a micro-organism-(strain)-specific basis. Thus, it is to be suspected that exceptions from the rule will become the rule. This, of course, will reduce the confidence of possible manufacturers and registrants in the EU low-risk/biopesticide regulatory system and restrict their willingness to take on the tedious and increasingly time consuming task of obtaining approvals and authorisations leaving the EU market as depleted of low-risk substances as it currently is.

Another major problem is that scientific argumentation and rationales are often not accepted to the full extent of their relevance or not at all and some authorities or the European Food Safety Authority use an exclusively regulatory approach similar to that for traditional chemical ais. But due to the huge variety of low-risk ais (botanicals, bacteria, fungi, viruses, semiochemicals etc) and their often very complex characteristics, a purely scientific approach is needed.

One promising step forward to facilitate the commercialisation of low-risk plant protection products is the upcoming guideline on "principles of efficacy evaluation for low-risk plant protection products (PP 1/296)," which was approved by the responsible working party in May 2017. It still needs to be adopted by the Council (scheduled for September 2017) and published (scheduled for early October 2017). Adaption of the efficacy requirements to the low-risk characteristics of the respective ais will reduce the costs for authorisation of low-risk products significantly, and thus (hopefully) will lead to an increase in product authorisations.

Experience and way ahead

Considering current and future economic, eco-logic and socio-economic requirements, the need for low-risk ais and products is without question and is also acknowledged by most stakeholders. As de-scribed above, there are several hurdles to overcome; some of them specific for low-risk ais, others related to general problems of the EU product registra-tion process such as the lack of harmonisation and significant, intolerable delays.

To achieve a significant increase in low-risk ai approvals and product authorisations, a cost-effective registration process that provides sufficient planning reliability to manufacturers and distributors is mandatory. This requires a "coherent, efficient, predictable, risk-based and scientifically robust as-sessment and approvals system" (2015/2225(INI)).

While it is imperative to have a cost-effective registration process for low-risk ais and products, it is also vital to maintain risk assessment at a high level mainly to keep "snake oil products" out of the market and to verify the importance and reliability of low-risk products for IPM and precision farming.

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