Biopesticide registration in EU – implications of the General Food Law and EU's Green Deal

By Lars Huber, senior manager regulatory affairs, head of biorationals, fertilisers and IPM, Scientific Consulting Company (SCC), Germany.

Lars Huber

Recent months have brought some significant changes for plant protection products in general and biopesticides in particular in the EU. Via the Biodiversity and Farm to Fork Strategies, the EU's Green Deal highlighted the importance of and need for sustainable and environmentally friendly plant protection methods, changing the perception of biopesticides among the public, regulators and, especially for, farmers. The future requirements set out in EU's Green Deal clearly open up a variety of business opportunities for biopesticides in EU.

Similar, the REFIT (Regulatory Fitness and Performance Programme of EU legislation) of the General Food Law also highlighted the need to 'guarantee a high level of protection of human life and health and the protection of consumers' interests'. One of the major outcomes of the REFIT procedure is the effort to increase the transparency of the EU risk assessment in the food chain and to strengthen the reliability, objectivity and independence of the studies provided for the approval (or renewal of approval) of active substances used in plant protection products. The respective new Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain (The Regulation) was adopted on June 13th 2019 and applies from March 27th 2021 onwards.

Contrary to the EU Green Deal resolutions, the Transparency Regulation has several significant regulatory implications for the registration of biopesticides, from R&D to registration application. This is mainly due to the fact that various steps of the registration process were strongly modified. In general, the Transparency Regulation applies not only to biopesticides but all plant protection product active substances (and also to other regulated products such as food additives). However, because of the nature of biopesticides as well as the frequently applied R&D strategies involving academic research and public funding, the requirements of The Regulation have special significance for biopesticide registration.

The Regulation introduces several new regulatory procedures such as the mandatory Notification of Studies, the so-called Pre-Submission and Renewal Pre-Submission Advise, as well as the mandatory use of the electronic data submission platform IUCLID (International Uniform Chemical Information Database) for evaluations carried out on EU level, such as plant protection product active substances, MRL evaluation, or basic substance approval.
The overall scope of The Regulation is to increase the sustainability of the EFSA (European Food Safety Authority) risk assessment processes and its transparency and the related implementation of a series of measures to achieve these goals. In practise, the aims are an early publication of submitted data and evaluation results and easy access on the results for all stakeholders as well as the public through the EFSA webpage, the contribution of representatives from all member states as well as a more coherent and efficient risk communication.

Procedures for the so-called general pre-submission advice and renewal pre-submission advice are quite similar. The general pre-submission advice applies to all new active substances intended for approval in the EU. The procedure relates exclusively to relevant requirements set out in guidance documents or guidelines and is non-committal to any subsequent assessment. It is important to note that the general pre-submission advice procedure does not include discussions on the design of studies, hypotheses to be tested or risk management, but is solely focussed on administrative/guideline and guidance related issues. The general pre-submission advice is not mandatory and can be requested any time before submitting the application. But the EFSA strongly recommends to apply for pre-submission advice at least six months prior to application submission. If a request is accepted, the EFSA will transmit the request to the relevant national competent authorities (e.g. Rapporteur Member State) and prepare a joint advice in written form. The EFSA aims to provide the respective written general pre-submission advice within 1-2 months.

Contrary to the general pre-submission advice, the pre-submission advice for the renewal of active substances is a mandatory, proactive procedure.

Whereas the general pre-submission advice targets only general issues on administrative/guideline and guidance-related topics, the renewal pre-submission advice also allows for substance-specific topics, such as the design of a study and possible deviations from guidelines. Part of the renewal pre-submission advice is the list of intended studies for renewal. Here, the applicant has to declare all studies planned for the upcoming renewal of the substance. Upon receipt of the list of intended studies, the EFSA will launch a public consultation, gathering input on the planned studies not only from authorities, but also the general public. The EFSA will summarise the received comments and include them in the pre-submission advice. This step is independent from notification of studies (explained below). Both types of pre-submission advice are non-committal for authority as well as the applicant. Timelines for renewal-pre-submission advice are longer as the procedure also foresees due to the public commenting phase. In any case, the results, that is, the final pre-submission advice, will be published via the EFSA webpage.

The third major innovation is the mandatory notification of studies. This applies to all studies to be used on EU level, that is, for approval or renewal of an active substance, MRL applications, or basic substance approvals. All study notifications have to be submitted before the start of the study whereas starting date refers to the start of the experimental stage. For all study notifications submitted after the starting date, a justification for the delay is required. A study notification can be withdrawn any time before the planned completion date of the study but in this case a justification has to be provided. However, authorities can also request data from discontinued studies. Upon submission of the application, authorities will check whether all studies included in the application were notified and whether all notified studies are included in the application. In case there is a discrepancy and no justification is submitted explaining the discrepancy, the application is declared non-admissible. A re-submission of the application amending the discrepancies is possible with a six-month penalty.

Another major change is the proactive disclosure of underlying documents for evaluation, i.e. study reports. So far, only the summaries of the evaluation were made public in a sanitised form (e.g. dossier, DAR/RAR). Now, the underlying studies will also be disclosed. As before, applicants can request confidentiality for certain parts of the submitted information. Authorities will assess all confidentiality requests and decide whether information will be disseminated in a sanitised version. Confidentiality is the exception and can only be claimed under certain circumstances and certain information. For confidentiality claims, there has to be verifiable evidence that the disclosure of the information might undermine commercial interests or the protection of privacy and the integrity of the individual. According to the Transparency Regulation, confidentiality concerning plant protection can only be claimed for items according to Reg 1107/2009 Article 63 ("positive list"), such as method of manufacturing, specification and method of analysis of impurities (except relevant impurities), the results of 5-batch study, or the complete composition of a plant protection product. In addition, confidentiality can also be claimed for commercial information revealing business strategies, but this has to be justified in detail.

In view of the public and consumers, the need to notify all studies used for an active substance registration procedure, the mandatory public consultation phases, the publication of the pre-submission advice as well as restricted possibilities for confidentiality claims may improve the trust in the evaluation process carried out on EU level for active substances and thus, the use of plant protection products. Such an increased confidence and trust of consumers and the public is also of benefit for producers and distributors of plant protection products. However, on the one hand, these new provisions require a much closer consideration of regulatory requirements especially during R&D of an active substance and derived plant protection products. This is especially true for new biopesticides since R&D of biopesticides is often closely linked to research projects and academia and data thus developed to be used for active substance approval and product authorisation. Thus, acceptance of such data in the approval process already has to be considered during R&D of a biopesticide. In addition, as described in short above, the new transparency rules clearly fulfil the public need for a more transparent evaluation and registration procedure but also make information on innovations and developments easily accessible to competitors, if not carefully considered, at an early stage. Furthermore, especially on an international level, the new procedures may open up new possibilities for the reuse of the disclosed information. Thus, to safeguard business interests in regard to product development, competition and usability of data, these new regulatory requirements have to be incorporated in the R&D and registration process as early as possible and respective strategies to reduce any such risks have to be developed.

With regard to registration and use of plant protection products, the Transparency Regulation brings many practical changes, directly influencing the registration

procedures and with immediate effect. However, there are several other innovations in the agricultural sector with, at least at the moment, more indirect effects on registration procedures but maybe with deeper and more long-lasting impact. One of these innovations is the so-called Farm to Fork (F2F) Strategy and the closely related Biodiversity strategy, both being part of the EU's Green Deal. In general, the EU's Green Deal is a "roadmap for making the EU's economy sustainable by turning climate and environmental challenges into opportunities across all policy areas" (EU COM 11 December 2019). Targets of the F2F Strategy and the Biodiversity strategy are for example:

- Manage at least 10% of the agricultural area under high-diversity landscape features.
- Boost the development of EU organic farming area, with the aim to achieve 25% of total farmland under organic farming by 2030.
- Revise of the EU Thematic Strategy for Soil Protection by 2021.
- Reduce of the use and risk of chemical pesticides by 50% by 2030.
- Reduce of the use of more hazardous pesticides by 50% by 2030.
- Reduce the use of fertilisers by at least 20% by 2030.
- Revise the Sustainable Use Directive (for pesticides; SUD) to significantly reduce use and risk and dependency on pesticides and enhance Integrated Pest Management and to improve the link between the objectives of the SUD and other legislation linked to their implementation, such as the Common Agricultural Policy (CAP) and Water Framework Directive.

The EU's Green Deal and the respective F2F and Biodiversity Strategies were officially launched in December 2019 by the publication of the roadmap on the European Green Deal (COM/2019/640 final). Therefore, implementation of most of the actions and initiatives of the F2F strategy, including the revision of already available legislation or the adoption of new legislative acts, is scheduled for the upcoming years. However, preparatory work for many topics has already been started. For example, the basics for an action plan for the development of organic production was already published by Commission (COM(2021) 141 final) in March 2021. This, of course, also includes the new revised legislation on organic farming (Regulation 2020/1693 of November 2020 amending Regulation 2018/848 on organic production and labelling of organic products), which will enter into force on January 1st 2022.

Designed to boost the organic farming sector, the new regulation includes, for example, rules to strengthen the control system and precautionary measures along the entire supply chain, to facilitate organic farming certification for small farmers via a new system of group certification, as well as rules for a more uniform approach to reduce the risk of accidental contamination from pesticides. The new regulation also requires producers in third countries to comply with the same requirements as farmers producing in the EU. Furthermore, there are several public consultations of Commission ongoing at the moment, e.g. with regard to a new EU soil strategy or on the update of the EU rules for sustainable use of pesticides. The public consultation of Commission on soil health for example is in turn, accompanied by a new EU Parliament draft motion for a resolution on Soil protection (2021/0000(RSP)) published in February 2021.

In the draft motion, the EU Parliament not only highlights the importance of a better protection of soils in regard to environment and health. It also stresses the economic relevance, highlighting costs caused by 'inaction on soil degradation, with estimates in the Union exceeding €50 billion per year'. Thus, the Parliament calls on the Commission to design an EU-wide common legal framework for the protection and sustainable use of soil. To support efforts for sustainable use of pesticides, in March 2021, a six-month foresight study launched to assess and develop future vision scenarios to assure that by 2030 the pesticide use and risk reduction targets announced in the Farm to Fork and Biodiversity Strategies can be fulfilled. All of these field of work are flanked by respective R&D activities and funding, as for example, soil protection issues are an integral part of the Horizon Europe framework programme beginning in 2021.

Implementation of Green Deal, Sustainability and General Food Law strategies is not only ongoing at an EU-wide level as described above. As foreseen by several legislative acts, for example, the SUS (Sustainable Use Directive 128/2009) and the respective National Action Plans, implementation also takes place on national level in the individual Member States. In March/April 2021, for example, the Swedish authority, KEMI, published two national decisions. For one, the Swedish government decided

to completely ban the use of plant protection products in certain areas, such as public areas, parks or gardens. Exemptions from the ban are only foreseen for active substances in plant protection products that are deemed to pose a limited risk to human health and the environment, that is, mainly substances and products classified as low risk according to Regulation 1107/2009. In their decision, the Swedish authority explicitly refers to the ban of products containing the active substances glyphosate, pyrethrins, flupyradifuron and acetamiprid. The second decision targets the mandatory use of IPM by professional farmers as provided for in the SUS, particularly article 14, which states that 'Member States shall take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods, so that professional users of pesticides switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem'.

In this regard, in 2019, the Swedish authority rejected an application for re-authorisation of the plant protection product named Imprid Skog, based on the active substance acetamiprid, to be used against pine weevils on coniferous plants. The decision is based on the fact that there are ways to protect conifer plants from weevils with non-chemical, mechanical methods and that these methods are already widely used. A respective appeal at court by the registration holder of the plant protection product was finally also rejected in March 2021. Reasons for the judgement are mainly that the use of non-chemical control methods is more common than chemical control and thus the ban of the plant protection product 'Imprid Skog' does not cause any significant economic or practical disadvantages for the forest owners. This national decision is one of the first in the EU substituting chemical plant protection products.

These examples show that inter-relationships between the single legislative or political frameworks become more obvious and more important. It also shows that respective implementations of these legal and regulatory innovations become more frequent and faster. Thus, it is to be expected that besides direct, specific regulations, guidance and guidelines on scientific and regulatory issues for pesticide registration, the registration process will be accompanied and influenced more by various other legal frameworks.