Biopesticides and the EU regulatory process

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Do biopesticides exist in EU legislation?
The regulatory approach in Europe, according to EU plant protection Regulation 1107/2009, does not recognise "biopesticides" as a regulatory category of plant protection active ingredients. In the lack of an unequivocal regulatory definition of biopesticides, many countries around the world use this term. In many cases, they have to decide on a case-to-case basis if an ai falls under this category, for instance, if an ai is not a natural biochemical but only biochemical-like. To avoid any confusion or discrimination of ais with similar favourable characteristics ascribed to "biopesticides", a risk based approach was chosen in the EU under which, irrespective of the origin of an ai, categories of basic substances and low risk substances were introduced. Nevertheless the term "biospeticide" is widely used also in the EU by all participants in the regulatory system.

What about special characteristics of the different biopesticide categories such as microorganisms or plant extracts?
The characteristics of specific substances such as plant extracts or microorganisms and differences between them regarding data requirements and points to be addressed in a registration dossier are considered by respective guidance documents.

How different is the approval process of a biopesticide compared with a chemical ai?
In general the approval process is identical for biopesticides and chemicals, at least regarding the ai approval, with the exemption of basic substances for which the approval process and the requirements differ hugely compared with low risk or conventional ais. Differences exist between conventional and low risk plant protection products after the low risk status of an ai is confirmed by an approval. Authorisation of low risk plant protection products for example only takes 120 days compared with the 12 months process for conventional ais. Furtehrmore, very often the authorisation fees are less for low risk ais and respective products.

What is so special about basic substances?
Basic substances are substances with a low toxicity profile such as foodstuffs, that are not already placed on the market as plant protection product or are not predominantly

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used for plant protection purposes but, nevertheless, could be useful in plant protection. Application for approval is made by a member state or by any interested party. The evaluation is mainly based on already existing evaluations for a substance carried out in accordance with other EU legislation regarding possible effects on human or animal health or the environment. Should studies be necessary, no data protection is granted.

And what about low risk substances?
Low risk substances have to fulfil certain criteria such as being not carcinogenic, mutagenic or toxic to reproduction. The criteria are listed in Annex II of Regulation 1107/2009, but are currently under review and will be adapted to the technical and scientific progress, for example, regarding sensitisation potential of micro-organisms.

As already mentioned, the general approval process is similar to conventional chemical ais, but a more scientific approach can be used including the use of literature data to demonstrate the natural occurrence or the natural background levels for the use in risk assessments and scientific justifications in place of formal studies.

Is it simpler? How are the requirements for making an application for a biopesticide different from that of a chemical ai?
Due to the huge variety of substances falling under the category biopesticides such as plant extracts, micro-organisms, pheromones etc, this question is not easy to answer. This is a problem each country in which the "biostimulant approach" is used encounters. In the US for example there is a special committee which decides on a case-to-case basis, if a substance is eligible as a "biostimulant". This is why the EU approach is

easier to handle, because it deals with the actual risk of a substance not with artificial categories. Being a biological substance is not automatically the same as being harmless. The same applies vice versa for chemicals.

Special "biological features" are accounted for by the respective guidance documents as far as they are already available. For example, plant extracts very often consist of a variety of components which cannot be characterised in a way a synthetically produced chemical ai can be. In such cases, the main constituents can be identified and used for scientific argumentation in a registration dossier.

I already referred to the huge variety of substances and the differences between them if they are of natural origin. There are still guidance and guidelines missing but a sound scientific approach is to be recommended and the way forward to a successful registration.

Is the time frame for the approval of a new biopesticide ai shorter compared with a chemical ai?
Regrettably not, and this is one of the reasons, why many companies still refrain from a registration. One of the main improvements, and a huge incentive for industry, would be a shorter time frame or prioritisation schemes for the approval of low risk ais. This, as well as lower registration fees which are already reduced in many member states, but not yet everywhere.

How many biopesticides are currently approved in the EU?
Difficult to tell as there is no "biopesticide stream" as in other countries. The low risk and basic substance concept was only introduced with Regulation 1107/2009 some years ago, but we expect the number of low risk ais will increase in future, not only due to new substances to be approved, but also due to substances evaluated as low risk in context of the currently on-going or outstanding renewal process for many substances. Potential candidates are many substances included in the fourth list for first Annex I inclusion according to Directive 91/414/EEC.

Currently, eleven basic substances and five low risk substances are approved. The fourth list for first Annex I inclusion according to Directive 91/414/EEC contains about 90 ais and a lot of them possibly qualify as low risk ais. Therefore, an increase in the number of low risk ais could be expected in the next years. It remains to be seen if the number of new approvals will increase in future. That will mainly depend on whether the regulatory and scientific requirements are adapted in a way to attract industry to apply for approval of new low risk ais, that is, "biopesticides".

What are SCC's recommendations for the EU registration process for biopesticides?
SCC's recommendation is very clear. In any case, use a sound scientific approach incorporating studies, if necessary, as well as scientific peer reviewed literature and start

communication with the possible rapporteur member state as early as possible. At best, discussions should already start during R&D of an ai. In addition, consideration of regulatory requirements for ais as well as products is often made too late. In our experience, many companies invest a lot of time and money in studies, especially regarding the efficacy of their ais and the respective products, without having sufficient regard for guidelines and regulatory needs. This is unfortunate, since very often small changes and amendments in a study design and the study programme would be sufficient to cover the scientific and regulatory requirements and make a study eligible and valid for the use in a registration dossier. That can save a lot of time and money.

Do you recommend a separate regulation for biopesticide registration or amendments to certain aspects of EU Regulation 1107/2009?

In our opinion, a separate regulation for biopesticides is neither required nor would it be productive. To the contrary, we would have favoured, if plant biostimulants would also have been included in the plant protection regulation – by applying adequate registration requirements of course – and not in the fertiliser regulatory framework. With the inclusion of biostimulants in the fertiliser regulation many substances and products most likely will not be deployable to their full beneficial potential.

The problem we currently encounter with biopesticides is not the joint regulation, but mostly the harmonisation of the implementation of Regulation 1107/2009. Certain amendments, of course, would be beneficial, as well as absolutely necessary, if the sustainable use of plant protection products is to be fostered further and European agriculture is to be advanced.

Some improvements are already under way, such as the modification and adaption of low risk criteria by separate guidance for example, others are not.

As already mentioned, the time frame for approval of a low risk ai is currently similar to that of the approval of a conventional ai. That should be remedied. Also, a two-step approval process would be helpful to give companies a solid basis that the active they want to register is really a low risk substance. In step one, which should be as short as possible, the low risk criteria could be assessed. In a second step, the full evaluation should be conducted as needed to fulfil the complete regulatory requirements in order to safeguard the special safety requirements characterising such low risk substances. By using a scientific approach, as described above, this can be already done today, but there is no certainty that such a concept will be approved by all member states in the end - an insufficient basis for business decisions especially for small companies.

In other areas, more clarification is required, for example, regarding the differentiation of basic substances and active substances. This also applies for certain data requirements stipulated in various guidelines which are not binding and can be interpreted differently by the parties involved in the approval/authorisation process.