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Biopesticides in the framework of the European Pesticide Regulation (EC) No. 1107/2009

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Abstract

BACKGROUND: The European Pesticide Regulation (EC) No. 1107/2009 encourages the use of less harmful active substances. Two main concerns involve the application of cut-off criteria for pesticides without losing tools for future agriculture (especially for minor uses) and the implementation of zonal evaluations. Biopesticides are considered to have lower risks than synthetic pesticides; consequently, there is strong interest for their use in integrated pest management practices.

RESULTS: This paper provides an analysis of the current European situation, starting with the first attempts to regulate the use of plant protection products and focusing on the implications of the new legislative criteria for biopesticides.

CONCLUSION: It is important to be aware that biopesticides are still pesticides and fall under the same regulations as their synthetic counterparts. Although manufacturers are still reluctant to commit to such alternatives due to difficulties with approval and registration, biopesticides could be alternatives for traditional plant protection products, either as a base for the synthesis of new products or integrated with traditional plant protection products. In addition, biopesticides have to be used only as indicated on the label, which provides critical information about how to safely handle and use plant protection products.

Keywords: biopesticides; cut-off criteria; European Regulation (EC) No. 1107/2009; integrated pest management

1 INTRODUCTION

The last major revision of the law regulating plant protection products in the European Union (EU) was mainly enacted through the introduction of the current Regulation (EC) No. 1107/2009, which entered into force on 14 June 2011.[1] No formal definition of biopesticides exists at the European level. The United States Environmental Protection Agency (US EPA) defines biopesticides as crop-protection agents derived from natural materials such as animals, plants, bacteria and certain minerals.[2] Regulation (EC) No. 1107/2009 will be applied to substances, including micro-organisms, with general or specific action against harmful organisms or on plants, parts of plants or plant products. Substances are defined as those chemical elements and their compounds that occur naturally or by manufacture. Therefore, biopesticides are covered by this regulation.

2 BIOPESTICIDES: CLASSIFICATION, ADVANTAGES AND DRAWBACKS

A general classification of biopesticides is based on living organisms and natural products. According to several authors, the term biopesticide should be reserved only for living organisms.[3] However, this definition would not include products derived from the metabolism of biological organisms such as pheromones, allelochemical molecules or plant extracts. Therefore, in the context of current crop protection, a broader definition of biopesticides, encompassing all molecules of biological origin, seems to be more appropriate.

In general, there are significant differences in the mode of action between the two groups of biopesticides: living organisms and natural products. In fact, it is possible to identify/classify biopesticides using these characteristics. Living organisms act by exploitation, competition, antibiosis, lysis and/or induced resistance,[4] while natural products act by contact, ingestion, systemic action, suffocation and/or attraction/repulsion.[5]

Currently, biopesticides must overcome important barriers such as a need for the improvement of formulations, slower pest control and higher manufacturing costs compared with conventional agrochemicals, as well as problems related to the registration for their commercialization. In addition, biopesticide shelf life is often low, and it is therefore difficult to achieve a viable product after one or two years under ambient conditions.[6] Many biopesticides have a highly specific activity (e.g. the fungus *Verticillium lecanii*),[7] which has also been generally perceived as a disadvantage, because accessible biopesticide markets are smaller than those for products with broad spectrum activity.[3] This narrow specificity often forces

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biopesticide use in conjunction with conventional agrochemicals. However, this practice should be developed carefully because it can lead to incompatibility problems such as inhibition or death of the living organism biopesticide by exposure to the traditional pesticide. Furthermore, many biopesticides are only effective against specific stages in the development cycles of pests or disease organisms (e.g. the fungus *Verticillium chlamydosporium*).[8]

However, some biopesticides have important advantages that favour their use within the modern legislation, such as new modes of action that make them beneficial tools for controlling the evolution of resistance to the conventional pesticides currently available, as well as limiting their impact on non-target organisms.[4] It should also be noted that some biopesticides have a relatively broad spectrum of activity (e.g. *Bacillus thuringiensis* and active substances from natural products such as azadirachtin A and B, among others), which encourages their widespread use and market penetration.[5,9]

3 PROGRESS OF EUROPEAN LEGISLATION ON PESTICIDES

The first attempts to harmonize national pesticide laws in the EU occurred in the 1970s.[10] The Maastricht Treaty, approved at the beginning of the 1990s,[11] illustrated the immediate need for the harmonization of national legislation on marketing. Council Directive 91/414/EEC of 15 July 1991 was developed to harmonize the registration of plant protection products.[12] This directive could not fully establish a unique European registration for plant protection products to finally be commercialized. However, it provided a mixed solution by setting a unique positive list of approved active substances in all Member States (Annex I of the Directive) and established a common registration procedure, applicable in all Member States, for the authorization of plant protection products containing these active substances in their respective territories. The unique market was cemented by the requirement of mutual recognition, establishing that any authorization granted by a Member State must be recognized by others to the extent that agricultural, plant health and environmental conditions relevant to the use of the product are comparable in the regions concerned.[13] This directive urged Member States to determine that plant protection products are both effective and have no harmful effects. A programme to review active substances existing in the EU market before 1993 was developed to determine their inclusion in or exclusion from Annex I.[12] This review programme was divided into four stages.[14–16] The first three stages were focused on conventional chemicals, whereas the fourth stage pooled various groups of substances that were considered to be of low risk, including biopesticides. Austria, followed by Greece, Spain and Poland, in that order, played an important role as Rapporteur Member States of this last stage, as they evaluated the largest number of substances (45.5%; Fig. 1B). The active substances were approved by inclusion directives into Annex I, which established a programme to review the authorizations by the Member States of plant products containing such substances. This process is called re-registration.[17] Thanks to the experience gained, the European legislation was improved. Therefore, in June 2011, Regulation (EC) No. 1107/2009 replaced Directive 91/414/EEC, solving several of its deficiencies.[1] This Regulation includes three climatically similar zones within the EU (northern, central and southern zones, Fig. 1A) to share the workload, together with the improvement of mutual recognition of authorizations and tight deadlines. These mechanisms are accelerating the arrival of new solutions for plant protection onto the market.[1] As in the previous directive, harmonization of the *risk assessment* (which addresses the risk of a situation, based on scientific data) among Member States is an important goal of this regulation.[1,18] This goal was defined by the uniform principles for formulated products, implemented by Regulation 546/2011.[19] Furthermore, risk mitigation measures need additional harmonization, each Member State in a given territory is resposible for participating in risk management surrounding the use of pesticides. Harmonization will prevent a situation in which the risk-reduction efforts of one Member State are contrary to a divergent approach taken by a neighbouring Member State.

4 FUTURE OF BIOPESTICIDES UNDER ACTUAL REGULATION NO. 1107/2009

European Pesticide Regulation (EC) No. 1107/2009 has been developed with the aim of not approving compounds with unacceptable risks to human/animal health and the environment. Consequently, several active substances will not be reapproved because of the new registration requirements, purely as a result of their classification (cut-off criteria). No registration may be granted when a substance falls into one of these environmental criteria: persistent organic pollutant (POP); persistent, bioaccumulative and toxic (PBT); and/or very persistent, very bioaccumulative (vPvB). Substances classified as carcinogens (C1A and C1B), mutagens (M1A and M1B) or toxic for reproduction (R1A and R1B) will also be discarded based on these toxicological criteria. Finally, ecotoxicological cut-off criteria in the regulation involve adverse endocrine effects to non-target organisms and honeybees.[1] In Fig. 1C, it can be observed that most of the currently used active substances will have to be re-assessed for renewal of their approval between 2016 and 2019. It is expected that most biopesticides, included in the fourth stage substances, will not be classified within any of the above-mentioned categories. Consequently, the market presence of biopesticides will most likely increase.

On the other hand, within the Regulation, substances may be approved in various categories, which include 'standard', 'low-risk' and 'basic' substances, and 'candidates for substitution'; substances in these categories can be approved for 10 years, 15 years, without a specific time limit and 7 years, respectively. The classification of substances as candidates for substitution could delay their disappearance, by creation of a list at the UE level by 2014 and based on the criteria mentioned in Annex II, point 4 of the Regulation. However, Member States will perform a comparative risk assessment of the plant protection products containing these substances as soon as possible. This comparison will take into consideration the availability of means of the plant protection as well as sufficient active substances in the market with other modes of action to prevent the appearance of resistance. In this situation, applicants should look for alternatives to conventional plant protection products, and biopesticides seem to be one of the most realistic alternatives. Furthermore, approvals may be renewed for up to 15 years in the case of standard and low-risk substances, or up to 7 years in the case of candidates for substitution. However, basic substances do not need be renewed; it is understood that a basic substance is a substance placed on the market for other purposes than plant protection, but that can be used for it. All of the above circumstances favour the

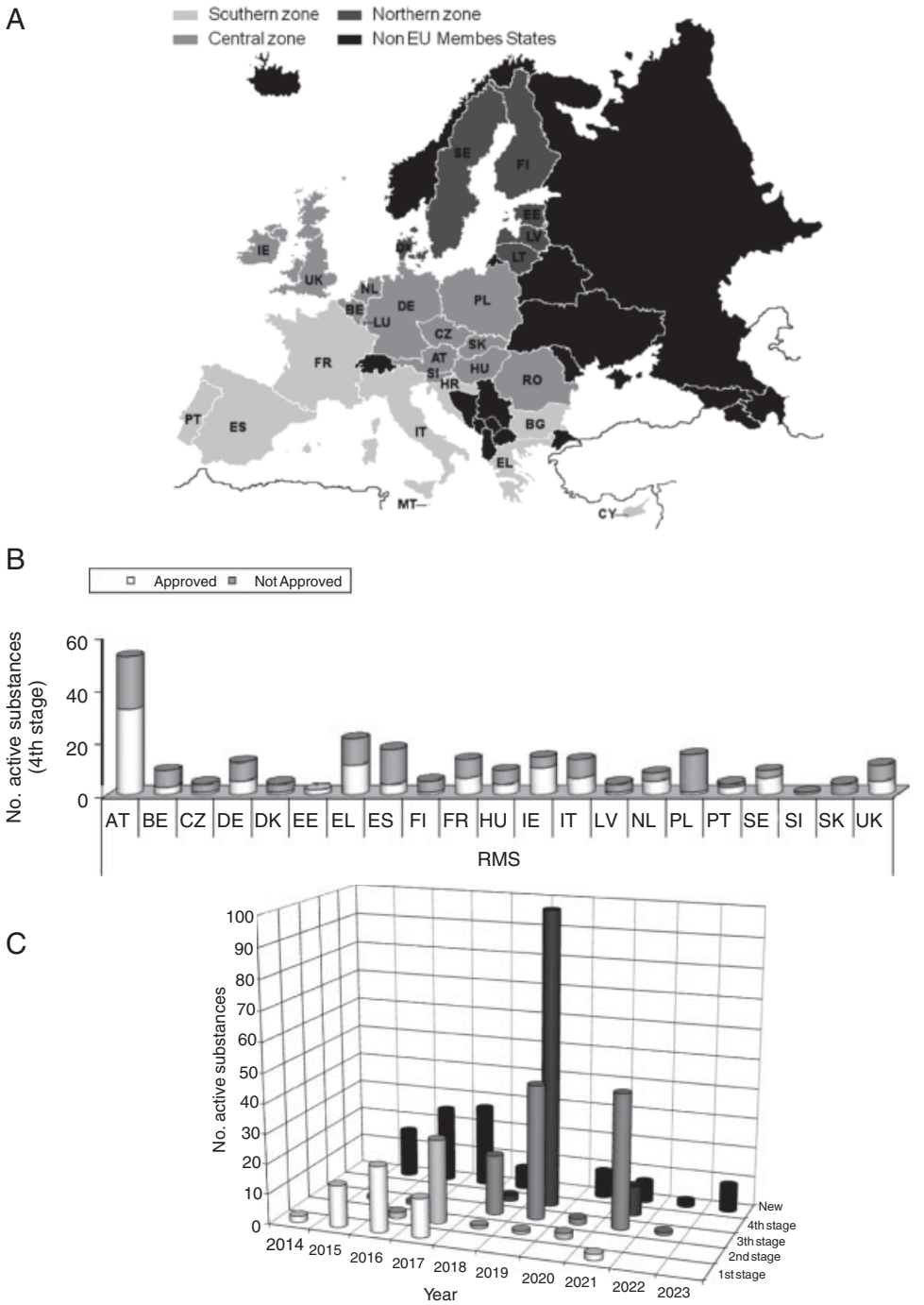

Figure 1. (A) Northern, central and southern zones established in EU Regulation (EC) 1107/2009. (B) Number of active substances evaluated in the fourth stage, per country as Rapporteur Member State (RMS). White indicates the number of substances that were included in Annex I (Approved), and grey indicates those substances that were recalled following the review programme (Not Approved). (C) Programme for the renewal of active substances according to the year and stage in which they were included.

development and use of low-risk substances and basic substances such as biopesticides.

Information, tests and analysis that the applicant must submit (data requirements) were implemented by regulations 283/2013 and 284/2013;[20,21] the first regulation is for the active substance, and the latter is for the plant protection product. In the case of low-risk substances, a reduced dossier for registration including a demonstration of sufficient efficacy is accepted,[1] which again favours biopesticide development.

5 CONSEQUENCES OF DIRECTIVE 2009/128/EC IN THE SUSTAINABLE USE OF BIOPESTICIDES

The EU has promoted the registration of low-risk substances for pest control by their sustainable use through Directive 2009/128/EC.[22] Member States shall describe in their National Action Plans how they will ensure a rational use of plant protection products integrated with other practices and control measures,

including general principles of integrated pest management (IPM) practices, by all professional users by 2014. This directive is an essential element of the actual European thematic strategy on the sustainable use of pesticides[23] and will be implemented in stages from 2011 to 2020.[22]

The general objectives of the thematic strategy and of the Directive 2009/128/EC include: (1) the promotion of IPM plans within the National Action Plans, to reduce the impacts of pesticide use on human health and the environment; (2) the improvement of awareness and training of end users (professional users and general public) to avoid the inappropriate use of these compounds; (3) the improvement of spraying equipment, as well as the banning of aerial spraying (except in special cases) to limit the contamination risks for population and environment and maximize the efficacy of treatments; (4) the measurement of risk reduction through appropriate indicators; and (5) the establishment of a system of information exchange at the EU Community level.[22,23]

Based on the foregoing comments, it seems that biopesticides may play an important role in the implementation of the IPM, as they generally have multiple modes of action and usually have low restricted entry and pre-harvest intervals. Therefore, biopesticides might be an alternative for traditional plant protection products, either as a base for the synthesis of new products or to be integrated with traditional plant protection products. However, the evaluation and adoption of some biopesticides will not be easy. For example, natural products and living organisms differ considerably in their identity among themselves and conventional plant protection products, making it difficult to establish risk assessment criteria. This scenario might generate regulatory barriers to biopesticide commercialization. In addition, new legislative requirements for low-risk substances remain to be determined (e.g. half-life in the soil should be < 60 days)[6] and may cause problems for some agents (e.g. living organisms). Member States are currently working on procedures and data requirements to be applied for the approval of these substances. Guidance documents are being developed on botanical active substances used in plant protection products,[24] the assessment of new substances falling into the group of straight chain lepidopteran pheromones (SCLPs),[25] the assessment of new isolates of baculovirus species[26] and for the evaluation and authorization of plant protection products containing micro-organisms.[27]

6 CONCLUSIONS

Currently, biopesticides are evaluated in Europe through European Pesticide Regulation (EC) No. 1107/2009, which encourages the development of less-harmful substances. Biopesticides are evaluated according to uniform principles, guaranteeing a high degree of protection for both human and animal health and the environment at the EU level. Many biopesticides have gained favour in recent years due in part to the perception that, because they originated in nature, they are more safe and/or natural than the synthetic pesticides. However, it is important to be aware that biopesticides are still pesticides and fall under the same regulations as their synthetic counterparts. Biopesticides must be used only as indicated on the label, which provides critical information about how to safely handle and use plant protection products. Only by strictly following these instructions will the use of the biopesticide be safe.

Although biopesticides are substances with a general lower risk, lower cost of registration and favourable perception by society as compared with traditional pesticides, it is necessary to use them correctly to achieve safer and more efficacious agricultural practices in Europe.

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