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GUIDANCE DOCUMENT: OUTLINE ON PRE-SUBMISSION CONSULTATIONS FOR MICROBIAL PEST CONTROL PRODUCTS

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FOREWORD

This document dealing with microbial pesticides is intended to provide guidance to both industry and regulatory authorities, in the context of pre-submission consultations prior to submission of applications for the registration of microbial biological control agents. This document has been developed in the framework of the OECD BioPesticides Steering Group (BPSG), a sub-group of the OECD Working Group on Pesticides (WGP) that helps member countries to harmonise the methods and approaches used to assess biological pesticides and to improve the efficiency of control procedures.

The EU served as the lead in the preparation of this guidance document. It was developed with the aim to provide guidance on the information/data requirements and to facilitate the submission of a more complete data package/dossier which will in turn facilitate the review and decision-making process.

This OECD guidance document was prepared in consultation with OECD member countries and the regulated industry participating in the OECD BPSG.

The present guidance document received final approval of the OECD BPSG on 19 May 2015 and of the OECD WGP by written procedure on 31 July 2015.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be declassified and made available to the public.

1. Introduction

1. In various member countries, pre-submission consultations between prospective applicants and regulatory authorities prior to submission of the registration dossier for review have been highly beneficial. These consultations ensure that the eventually submitted registration application is of a high standard in terms of completeness, based on the assumption that the pre-submission consultation guidance was followed as pertains to data requirements. To organise pre-submission consultations as a routine practice is also one of the recommendations from the REBECA-project[1].

2. It is considered that such consultations should be consistently offered by member countries to prospective applicants especially if it concerns applications for microbial pest control products. In this respect microbials are defined as *"any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material".*

3. This Outline describes the procedure and the information which should be submitted at a pre-submission consultation. This can be in the light of an application to an individual member country, but is also applicable to (Global) Joint Reviews. Since the data required in support of registration depend on the identity and biological properties of the MPCA, the nature of the product and the intended use pattern, applicants are encouraged to contact the implicated regulatory authority for pre-submission consultation(s) early on during the development phase of the data package to be submitted in support of registration of the product.

4. The main objective of pre-submission consultations is to provide guidance on the information/data requirements. Although the standard data requirements may be readily available from regulatory authorities (e.g., test guidelines, dossier guidance documents), applicants may need additional guidance on how to interpret these data requirements and determine whether published literature and/or waiver rationales, in lieu of studies (i.e., actual test data), can be considered.

5. In order to simplify the pre-submission consultation process, applicants are asked to submit summaries on both the nature of the product proposed for registration as well as the available supporting data or data that are under development. This information is required for the purposes of discussing, with the implicated regulatory authority, the relevant data requirements needed to support a registration application.

6. A pre-submission consultation should allow for an open exchange between the applicant and implicated regulatory authority on the critical areas that are likely to be of most significance in the evaluation and risk assessment phase.

7. It is anticipated that a pre-submission consultation will facilitate the submission of a more complete data package/dossier which will in turn facilitate the review and decision-making process.

2. Pre-submission Consultation Process - Procedure

8. Applicants should contact the member country for information on appropriate regulatory contacts for a pre-submission consultation.

[1] REBECA was an EU policy support action to review possible risks of biocontrol agents, compare regulations in the EU and the USA and to propose alternative, less bureaucratic and more efficient regulation procedures maintaining the same level of safety for human health and the environment but accelerating market access and lowering registration costs.

9. If it is determined in consultation with the implicated regulatory authority that a pre-submission consultation meeting is advised, to facilitate the process, a pre-submission consultation information package should be submitted electronically and at least 30 days[2] prior to the proposed meeting date. In addition to a cover letter requesting a pre-submission meeting and a proposed agenda of the issues to be discussed, the information package should contain, at a minimum, information on the label, product, proposed use pattern, international regulatory status, characterization of the MPCA. Depending on the stage of development of the proposed product, short summaries of available information regarding efficacy, manufacturing processes, product specifications, safety to the environment and human health as well as scientific rationales to support proposed data waivers may be included. Proposed study protocols, if available, should also be submitted. Finally, if the applicant intends to make a presentation to regulatory authorities during the meeting, an electronic version of the presentation should be submitted preferably several days in advance of the meeting date.

10. Document O[3] (forms for the checking of the completeness) that lists all data that may be required for the registration of a microbial product –or similar structured- forms, which follow the order of the data requirements, should be used to indicate the information submitted in the pre-submission package. In consultations regarding proposed products in the latter stages of development, these forms may also indicate which data are available or where waivers will be requested.

11. Current practices for Global Joint Reviews of conventional pesticides and NAFTA Joint Reviews of biopesticides require that the applicant be responsible for taking meeting notes and sharing these draft notes with the regulatory authorities for correction/clarification prior to being finalized. Another option is that during the pre-submission meeting, notes may be written directly into the form. The form could be projected during the meeting, and meeting notes and changes made to the electronic file as the meeting proceeds. At the end of the meeting, copies could be distributed to all attendees, and would be maintained in the authority's records as the official meeting minutes. This has the advantage that virtually no time lapses between the meeting and meeting notes. Reference to pre-submission consultations which have previously taken place should be mentioned in the cover letter when submitting the application for registration.

12. Australia's APVMA[4] encourages applicants to consult with the APVMA prior to submitting their application. Pre-application assistance helps potential applicants to understand how to prepare or make an application to the APVMA. This includes information how to meet the application requirements or address the statutory criteria for a particular application. Pre-application assistance can be requestion in relation to any application and will be provided on a fee-for-service basis.

13. For off-site meeting participants, a webinar or teleconference can be arranged by regulatory authorities.

14. As a result of a pre-submission meeting it is also suggested to develop an initial project plan proposing a date for the dossier submission and dates for the interim milestones of the completeness checking and evaluation. The plan can then be refined as contact is maintained between the applicant and authority.

[2] Although 30 days seems an appropriate time limit member countries may set another time limit.

[3] OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials), August 2006.

[4] Further details are available from their website (http://www.apvma.gov.au/).

3. Pre-submission Consultation Process - Information Requirements

15. Applicants will initiate a pre-submission consultation by submitting to the regulatory authority(ies) an information package that includes the following elements, where available:

- Identification and taxonomic position of the MPCA
- Natural distribution of the species in particular on food and feed and in agriculture
- Background/history (e.g. approval status in other countries, other fields of use outside of the scope of PPP regulations, etc.)
- Environmental fate data
- Non-target data
- Modes of action and host range
- Toxicity data
- Metabolites produced by the MPCA
- Intended use of the product (target organisms)
- Efficacy data
- Formulation of the product
- Site and method of application
- Health and medical reports
- Absence from the list provided in Dir. 2000/54 EC[5] concerning worker's protection from micro-organisms (EU-requirement)
- Maximum growth temperature
- List of available effective antibiotics

16. The information package will be used by regulatory authorities to tailor the data requirements to be commensurate with the level of risk anticipated from the proposed use(s) of the product. The information may also be used to provide additional guidance on areas of specific concern to the MPCA (e.g., production of toxic secondary metabolites, broad host range, growth at high temperatures, etc.).

17. In general for a microorganism with totally unknown properties the full battery of tests for registration of MPCAs [and their toxins] is designed to give basic hazard and exposure information. In actual practice, an MPCA is usually well identified, which may facilitate prediction of its properties and

[5] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC).

behaviour. This is particularly true for the areas of human health and plant pathogenicity. Clinical medicine and agricultural science have identified most micro-organisms associated with diseases. If an MPCA is taxonomically similar to a clinically or agriculturally significant microorganism, this particular area of concern should be examined closely. Conversely, if the MPCA belongs to a group of micro-organisms that have never been found in association with any disease, a case may be made for reducing, or waiving, the testing requirements for this area of concern.

4. Pre-submission Consultation Process - Legal Status

18. It must be emphasized that the pre-submission consultation procedure may differ among member countries based on country-specific legislative or policy requirements. In some countries, regulatory authorities (e.g., U.S. EPA, Health Canada's PMRA, and Australia's APVMA) can provide guidance directly to the applicant regarding data requirements. In the EU, an individual member state can only give advice on the information requirements to an applicant because the other member states (currently the EU consists of 28 member states) and the EFSA must be given the opportunity to express their opinion.

19. Statements about how legally binding advice is at the pre-submission stage varies among member countries. It should be noted that in the EU such meetings do not have any legal standing, whereas they do in the US, for example. Also the pre-application assistance provided by APVMA cannot be taken as an agreed position and should be considered as guidance only.

5. List of Abbreviations

APVMA: Australian Pesticides and Veterinary Medicines Authority

EFSA: European Food Safety Authority

EPA: Environmental Protection Agency (USA)

EU: European Union

MPCA: Microbial Pest Control Agent

OECD: Organisation for Economic Co-operation and Development

PMRA: Pest Management Regulatory Agency (Canada)

REBECA: Regulation of Biological Control Agents

6. References

Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides (http://www.oecd.org/chemicalsafety/pesticides-biocides/46754279.pdf)

Guidelines for the Registration of Microbial Pest Control Agents and Products; PMRA, Regulatory Directive DIR2001-02, March 30, 2001

Guidelines for the Registration of Non-Conventional Pest Control Products; Health Canada, Regulatory Directive DIR2012-01, 27 February 2012

NAFTA Technical Working Group on Pesticides: Updated Procedures for the Joint Review of Biopesticides (i.e., Microbials and Biochemicals), November 2010

(http://www.epa.gov/oppfead1/international/naftatwg/guidance/jointreview-biope.pdf)

REBECA - Regulation of Biological Control Agents; Deliverable 10: Proposals for improved regulatory procedures for microbial BCAs, September 2007

TECHNICAL REPORT OF EFSA, Evaluation of the European Union Pesticide Safety Review Process (Question No EFSA-Q-2008-399), 27 August 2008