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ANNEX

PART B

MICRO-ORGANISMS INCLUDING VIRUSES

8. EFFECTS ON NON-TARGET ORGANISMS

Introduction

- (i) The information on identity, biological properties and further information in Sections 1, 2, 3 and 7 is central to the assessment of impact on non-target species. Additional useful information may be found on fate and behaviour in the environment in Section 7 and on residue levels in plants in Section 6 which, together with information on the nature of the preparation and its manner of use, defines the nature and extent of potential exposure. The information submitted in accordance with Section 5 will provide essential information as to effects to mammals and the mechanisms involved.

Experimental data are normally required, unless it can be justified that an assessment of effects on non-target organisms can be performed with the information already available.

- (ii) The choice of the appropriate non-target organisms for testing of environmental effects shall be based on the identity of the micro-organism (including the host specificity, mode of action and ecology of the organism). From such knowledge it would be possible to choose the appropriate test-organisms, such as organisms closely related to the target organism.
- (iii) The information provided, taken together with that for one or more preparations containing the micro-organism, must be sufficient to permit an assessment of the impact on non-target species (flora and fauna), likely to be at risk from exposure to the micro-organism, where they are of environmental significance. Impact can result from single, prolonged or repeated exposure and can be reversible or irreversible.
- (iv) In particular, the information provided for the micro-organism, together with other relevant information, and that provided for one or more preparations containing it, shall be sufficient to:
- decide whether, or not, the micro-organism can be approved,
 - specify appropriate conditions or restrictions to be associated with any approval,
 - permit an evaluation of short- and long-term risks for non-target species — populations, communities, and processes — as appropriate,
 - classify the micro-organism as to biological hazard,
 - specify the precautions necessary for the protection of non-target species, and
 - specify the pictograms (once introduced), signal words, and relevant hazard and precautionary statements for the protection of the environment, to be mentioned on packaging (containers).
- (v) There is a need to report all potentially adverse effects found during routine investigations on environmental effects, to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and to assess the significance of these effects. All available biological data and information which are relevant to the assessment of the ecology profile of the micro-organism must be reported.

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- (vi) For all studies, average achieved dose in cfu/kg body weight as well as in other appropriate units must be reported.
- (vii) It may be necessary to conduct separate studies for relevant metabolites (especially toxins), where these products can constitute a relevant risk to non-target organisms and where their effects cannot be evaluated by the available results relating to the micro-organism. Before such studies are performed, the applicant shall seek agreement of the competent authorities on whether such studies need to be performed and, if so, the type of study to be conducted. The information from Sections 5, 6 and 7 has to be taken into account.
- (viii) In order to facilitate the assessment of the significance of test results obtained, the same strain (or recorded origin) of each relevant species shall, where possible, be used in the various tests specified.
- (ix) Tests must be performed unless it can be justified that the non-target organism will not be exposed to the micro-organism. If it is justified that the micro-organism does not cause toxic effects or is not pathogenic or infective to vertebrates or plants, only reaction to appropriate non-target organisms must be investigated.

8.1. **Effects on birds**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to birds must be reported.

8.2. **Effects on aquatic organisms**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to aquatic organisms must be reported.

8.2.1. *Effects on fish*

Aim of the test

Information on toxicity, infectiveness and pathogenicity to fish must be reported.

8.2.2. *Effects on freshwater invertebrates*

Aim of the test

Information on toxicity, infectiveness and pathogenicity to freshwater invertebrates must be reported.

8.2.3. *Effects on algae growth*

Aim of the test

Information on effects on algal growth, growth rate and capacity to recover must be reported.

8.2.4. *Effects on plants other than algae*

Aim of the test

Information on effects on plants other than algae must be reported.

8.3. **Effects on bees**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to bees must be reported.

8.4. **Effects on arthropods other than bees**

Aim of the test

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Information on toxicity, infectiveness and pathogenicity to arthropods other than bees must be reported. The selection of the test species should be related to the potential use of the plant protection products (e.g. foliar or soil application). Special attention should be given to organisms used for biological control and organisms playing an important role in integrated pest management.

8.5. **Effects on earthworms**

Aim of the test

Information on toxicity, infectiveness and pathogenicity to earthworms must be reported.

8.6. **Effects on non-target soil micro-organisms**

Impact on relevant non-target micro-organisms and on their predators (e.g. protozoa for bacterial inoculants) shall be reported. Expert judgement is required to decide whether additional studies are necessary. Such decision will take into consideration the available information in this Section and other Sections, in particular data on the specificity of the micro-organism, and the expected exposure. Useful information may also be available from the observations carried out in efficacy testing. Special attention shall be given to organisms used in integrated crop management (ICM).

8.7. **Additional studies**

The additional studies might include further acute studies on additional species or processes (such as sewage systems) or higher tier studies such as chronic, sub-lethal or reproductive studies on selected non-target organisms.

Before performing such studies, the applicant shall seek agreement of the competent authorities on the type of study to be performed.

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/556 reg. 21\(4\)](#)
- Annex Pt. A s. 8 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiv\)](#)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. B s. 9 words omitted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(vi\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 21\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 21\(2\)\(b\)](#)