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ANNEX

PART B

PREPARATIONS OF MICRO-ORGANISMS INCLUDING VIRUSES

2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

The extent to which plant protection products for which authorisation is sought comply with relevant FAO specifications, as agreed by the Group of Experts on Pesticide Specification of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards, must be stated. Divergences from FAO specifications must be described in detail, and justified.

2.1. **Appearance (colour and odour)**

A description of both the colour and odour, if any, and the physical state of the preparation, must be provided.

2.2. **Storage stability and shelf-life**

2.2.1. *Effects of light, temperature and humidity on technical characteristics of the plant protection product*

- (i) The physical and biological stability of the preparation at the recommended storage temperature including information on the growth of contaminating micro-organisms must be determined and reported. The conditions under which the test has been performed must be justified.
- (ii) Additionally in the case of liquid preparations, the effect of low temperatures on physical stability, must be determined and reported in accordance with CIPAC Methods MT 39, MT 48, MT 51 or MT 54 as appropriate.
- (iii) The shelf life of the preparation at the recommended storage temperature must be reported. Where shelf life is less than two years, the shelf life in months, with appropriate temperature specifications, must be reported. Useful information is given in GIFAP Monograph No 17.

2.2.2. *Other factors affecting stability*

Effect of exposure to air, packaging, etc., on the product stability must be explored.

2.3. **Explosivity and oxidising properties**

Explosivity and oxidising properties will be determined as defined in point 2.2 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.4. **Flash point and other indications of flammability or spontaneous ignition**

Flash point and flammability must be determined, as defined in point 2.3 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.5. **Acidity, alkalinity and if necessary pH value**

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Acidity, alkalinity and pH will be determined as defined in point 2.4 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.6. Viscosity and surface tension

Viscosity and surface tension will be determined as defined in point 2.5 of Part A of this Annex, unless it can be justified that it is technically or scientifically not necessary to perform such studies.

2.7. Technical characteristics of the plant protection product

The technical characteristics of the preparation must be determined to permit a decision to be made as to its acceptability. If tests have to be performed, they must be done at temperatures compatible with survival of the micro-organism.

2.7.1. Wettability

The wettability of solid preparations which are diluted for use (e.g. wettable powders and water dispersible granules), must be determined and reported in accordance with CIPAC Method MT 53.3.

2.7.2. Persistent foaming

The persistence of foaming of preparations to be diluted with water, must be determined and reported in accordance with CIPAC Method MT 47.

2.7.3. Suspensibility and suspension stability

— The suspensibility of water dispersible products (e.g. wettable powders, water dispersible granules, suspension concentrates) must be determined and reported in accordance with CIPAC Method MT 15, MT 161 or MT 168 as appropriate.

— The spontaneity of dispersion of water dispersible products (e.g. suspension concentrates and water dispersible granules) must be determined and reported in accordance with CIPAC Methods MT 160 or MT 174 as appropriate.

2.7.4. Dry sieve test and wet sieve test

In order to ensure that dustable powders have a suitable particle size distribution for ease of application, a dry sieve test must be conducted and reported in accordance with CIPAC Method MT 59.1.

In the case of water dispersible products, a wet sieve test must be conducted and reported in accordance with CIPAC Method MT 59.3 or MT 167 as appropriate.

2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

(i) The size distribution of particles in the case of powders, must be determined and reported in accordance with OECD Method 110.

The nominal size range of granules for direct application must be determined and reported in accordance with CIPAC MT 58.3, for water dispersible granules in accordance with CIPAC MT 170.

(ii) The dust content of granular preparations, must be determined and reported in accordance with CIPAC Method MT 171. If relevant for operator exposure the particle size of dust must be determined and reported in accordance with OECD Method 110.

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- (iii) The friability and attrition characteristics of granules, must be determined and reported once internationally agreed methods are available. Where already data are available they must be reported together with the method used.

2.7.6. *Emulsifiability, re-emulsifiability, emulsion stability*

- (i) The emulsifiability, emulsion stability and re-emulsifiability of preparations which form emulsions, must be determined and reported in accordance with CIPAC Method MT 36 or MT 173 as appropriate.
- (ii) The stability of dilute emulsions and of preparations which are emulsions, must be determined and reported in accordance with CIPAC Method MT 20 or MT 173.

2.7.7. *Flowability, pourability (rinsability) and dustability*

- (i) The flowability of granular preparations must be determined and reported in accordance with CIPAC Method MT 172.
- (ii) The pourability (including rinsed residue) of suspensions (e.g. suspension concentrates, suspo-emulsions), must be determined and reported in accordance with CIPAC Method MT 148.
- (iii) The dustability of dustable powders must be determined and reported in accordance with CIPAC Method MT 34 or another suitable method.

2.8. **Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorised**

2.8.1. *Physical compatibility*

The physical compatibility of recommended tank mixes must be determined and reported.

2.8.2. *Chemical compatibility*

The chemical compatibility of recommended tank mixes must be determined and reported except where examination of the individual properties of the preparations would establish beyond reasonable doubt that there is no possibility of reaction taking place. In such cases it is sufficient to provide that information as justification for not practically determining the chemical compatibility.

2.8.3. *Biological compatibility*

The biological compatibility of tank mixes must be determined and reported. Effects (e.g. antagonism, fungicidal effects) on the activity of the micro-organism after mixing with other micro-organisms or chemicals must be described. The possible interaction of the plant protection product with other chemical products to be applied on the crops under the expected condition of use of the preparation shall be investigated, based on the efficacy data. Intervals between application of the biological pesticide and chemical pesticides shall be specified, if appropriate, in order to avoid loss of efficacy.

2.9. **Adherence and distribution to seeds**

In the case of preparations for seed treatment, both distribution and adhesion must be investigated and reported; in the case of distribution in accordance with CIPAC Method MT 175.

2.10. **Summary and evaluation of data presented under points 2.1 to 2.9**

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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. 22\(4\)](#)
- Annex Pt. B s. 11 words omitted by [S.I. 2019/556 reg. 22\(5\)\(c\)\(v\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 22\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 22\(2\)\(b\)](#)