ANNEX

PART A

CHEMICAL PLANT PROTECTION PRODUCTS

SECTION 6

Efficacy data

Introduction

1. The data supplied shall be sufficient to permit an evaluation of the plant protection product to be made. It shall be possible to evaluate the nature and extent of benefits that accrue following use of the plant protection product, in comparison to an untreated control and where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

2. The number of trials to be conducted and reported shall reflect factors such as the extent to which the properties of the active substances it contains are known and on the range of conditions that arise, including variability in plant health conditions, climatic differences, the range of agricultural practices, the uniformity of the crops, the mode of application the type of harmful organism and the type of plant protection product.

3. Sufficient data shall be submitted to confirm that patterns of use of the plant protection product are representative of the regions and the range of conditions, likely to be encountered in the regions concerned, for which its use is intended. Where the applicant claims that tests in one or more of the proposed regions of use are unnecessary because conditions are comparable with those in other regions where tests have been carried out, the applicant shall substantiate the claim for comparability with documentary evidence.

4. In order to assess seasonal differences, if any, sufficient data shall be generated and submitted to confirm the performance of the plant protection product in each agronomically and climatically different region for each particular crop (or commodity)/harmful organism combination. Trials on effectiveness and phytotoxicity, where relevant, usually in at least two growing seasons shall be reported.

5. If the trials from the first season adequately confirm the validity of claims made on the basis of extrapolation of results from other crops, commodities or situations or from tests with closely similar plant protection products, the applicant shall provide a justification for not carrying out a second season's work. Where, because of climatic or plant health conditions or other reasons the data obtained in any particular season are of limited value for the assessment of performance, trials in one or more further seasons shall be conducted and reported.

6.1. Preliminary tests

Reports in summary form of preliminary tests, including glasshouse and field studies, used to assess the biological activity or dose range finding of the plant protection product and of the active substances it contains, shall be submitted as relevant when requested by the competent authority. These reports shall provide additional information for the competent authority in order to justify the recommended dose of the plant protection product and, where the plant protection product contains more than one active substance, the ratio of the active substances.

6.2. Testing effectiveness

The tests shall provide sufficient data to permit an evaluation of the level, duration and consistency of control or protection or other intended effects of the plant protection product in comparison to suitable reference products, where they exist.
Test conditions

A trial shall, where possible, consist of the following three components: test product, reference product and untreated control.

The performance of the plant protection product shall be investigated in relation to suitable reference products, where they exist. A plant protection product shall be considered a suitable reference product if it fulfils the following requirements: it is authorised and has proved a sufficient performance in practice under the conditions of the area of intended use (plant health, agricultural, horticultural, forestry, climatic, environmental, as appropriate). The working spectrum, time and method of application, mode of action shall be close to those of the tested plant protection product. If this is not possible, reference product and test product shall be applied according to their specified use.

Plant protection products shall be tested in circumstances where the target harmful organism has been shown to have been present at a level causing or known to cause adverse effects (yield, quality, operational benefit) on an unprotected crop or area or on plants or plant products which have not been treated or where the harmful organism is present at such a level that an evaluation of the plant protection product can be made.

On plant protection products for control of harmful organisms trials shall be performed which show the level of control of the species of harmful organisms concerned or of species representative of groups for which claims are made. Trials shall include the different stages of growth of life cycle of the harmful species, where this is relevant and the different strains or races, where these are likely to show different degrees of susceptibility. Where relevant, these considerations may be addressed in laboratory studies.

Trials to provide data on plant protection products which are plant growth regulators, shall show the level of effects on the species to be treated, and include investigation of differences in the response of a representative sample of the range of cultivars on which its use is proposed.

In order to clarify the dose response, dose rates lower than the recommended one shall be included in some trials in order to enable assessment of whether the recommended rate is the minimum necessary to achieve the desired effect.

The duration of the effects of treatment shall be investigated in relation to the control of the target organism or effect on the treated plants or plant products, as appropriate. When more than one application is recommended for the proposed use pattern of the product, trials shall be reported, which establish the duration of the effects of an application, the number of applications necessary and the desired intervals between them.

Evidence shall be submitted to show that the dose, timing and method of application recommended give adequate control, protection or have the intended effect in the range of circumstances likely to be encountered in practical use.

If there is clear evidence that the performance of the plant protection product is likely to be affected by environmental factors, such as temperature or rain, an investigation of the effects of such factors on performance shall be carried out and reported, particularly where it is known that the performance of chemically related products is so affected.

Where proposed label claims include recommendations for the use of the plant protection product with other plant protection products or adjuvants information on the performance of the mixture shall be provided.

Trials shall be designed to investigate specified issues, to minimise the effects of random variation between different parts of each site and to enable statistical analysis to be applied to results amenable to such analysis. The design, analysis, conduct and reporting of trials shall be in accordance with the specific standards of the European and Mediterranean Plant Protection Organisation (EPPO), where available. Deviations from available EPPO guidelines, may be acceptable provided the trials design meets the minimum requirements of the relevant EPPO standard, and is fully described and justified. The report shall include a detailed and critical assessment of the data.

A statistical analysis of results amenable to such analysis shall be carried out; where necessary the test guideline used shall be adapted to enable such analysis.

Where relevant, evidence of yield and quality may be required as a demonstration of effectiveness.

6.3. **Information on the occurrence or possible occurrence of the development of resistance**

Laboratory data and where it exists, field information relating to the occurrence and development of resistance or cross-resistance in populations of harmful organisms to the active substances, or to related active substances, shall be provided. Where such information is not directly relevant to the uses for which authorisation is sought or to be renewed (different species of harmful organism or different crops), it shall, if available, nevertheless be provided in summary form, as it may provide an indication of the likelihood of resistance developing in the target population.

Where there is evidence or information to suggest that, in commercial use, the development of resistance is likely, evidence shall be generated and submitted as to the sensitivity of the population of the harmful organism concerned to the plant protection product. In such cases a management strategy designed to minimise the likelihood of resistance developing in target species shall be provided. This management strategy shall have regard for and refer to any relevant existing strategies and restrictions already in place.

6.4. **Adverse effects on treated crops**

6.4.1. *Phytotoxicity to target plants (including different cultivars), or to target plant products*

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of the possible occurrence of phytotoxicity after treatment with the plant protection product.
Test conditions

For herbicides testing with a dose which is twice the recommended dose shall be required. For other plant protection products for which adverse effects, however transitory, are seen during the trials, performed in accordance with point 6.2, the margins of selectivity on target crops shall be established, using higher doses than the recommended rates of application. Where serious phytotoxic effects are seen, an intermediate application rate shall also be investigated.

Where adverse effects occur, but are claimed to be unimportant in comparison with the benefits of use or transient, evidence to support this claim is required. If necessary, yield measurement shall be submitted.

The safety of a plant protection product to the main cultivars of the main crops for which it is recommended shall be demonstrated, including effects of crop growth stage, vigour, and other factors which may influence susceptibility to damage or injury.

The extent of information necessary on other crops shall reflect their degree of similarity to the main crops already tested, the quantity and quality of data available on those main crops and how far the manner of use of the plant protection product, if relevant, is similar. It is sufficient to perform the test with the main plant protection product type to be authorised.

Where proposed label claims include recommendations for the use of the plant protection product with another plant protection product, this point shall apply to the mixture.

Observations concerning phytotoxicity shall be performed in the tests set out in point 6.2.

Where phytotoxic effects are seen, they shall be accurately assessed and recorded.

A statistical analysis of results amenable to such analysis should be carried out, where necessary the test guideline used shall be adapted to enable such analysis.

6.4.2. *Effects on the yield of treated plants or plant products*

The test shall provide sufficient data to permit an evaluation of the performance of the plant protection product and of possible occurrence of yield reduction or loss in storage of treated plants or plant products.
Circumstances in which required

The effects of plant protection products on the yield or yield components of treated plant products shall be determined where relevant. When treated plants or plant products are likely to be stored the effect on the yield after storage, including data on storage life, shall be determined where relevant.

6.4.3. *Effects on the quality of plants or plant product*

Appropriate observations of quality parameters may be required for individual crops (for example cereal grain quality, sugar content). Such information can be gathered from appropriate assessments in trials described under 6.2 and 6.4.1.

Where relevant, taint testing shall be conducted.

6.4.4. *Effects on transformation processes*

Where relevant, tests for effects on transformation processes shall be conducted.

6.4.5. *Impact on treated plants or plant products to be used for propagation*

Where relevant, sufficient data and observations shall be provided to permit an evaluation of possible adverse effects of a treatment with the plant protection product on plants or plant products to be used for propagation.
Circumstances in which required

Those data and observations shall be submitted, except where the proposed uses preclude use on crops intended for production of seeds, cuttings, runners, tubers or bulbs for planting, as appropriate.

6.5. **Observations on other undesirable or unintended side-effects**

6.5.1. *Impact on succeeding crops*

Sufficient data shall be provided to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops.
Circumstances in which required

Where data, generated in accordance with point 9.1, shows that significant residues of the active substance, its metabolites or breakdown products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials, such as straw or organic material up to sowing or planting time of possible succeeding crops, observations shall be submitted on effects on the normal range of succeeding crops.

6.5.2. *Impact on other plants, including adjacent crops*

Sufficient data shall be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on other plants, including adjacent crops.
Circumstances in which required

Observations shall be submitted on adverse effects on other plants, including the normal range of adjacent crops, when there are indications that the plant protection product could affect these plants via drift. Sufficient data shall be submitted to demonstrate that residues of the plant protection product do not remain in the application equipment after cleaning, and that there is no risk to subsequently treated crops.

6.5.3. *Effects on beneficial and other non-target organisms*

Any effects, positive or negative, on the incidence of other harmful organisms, observed in the tests performed in accordance with the requirements of this Section, shall be reported. Any observed environmental effects shall also be reported, such as effects on wildlife and non-target organisms, and especially effects on beneficial organisms in case of Integrated Pest Management (IPM).

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 284/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

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)