ANNEX

INTRODUCTION**Information to be submitted, its generation and its presentation**

1. The information submitted shall meet the following requirements.

1.1. The information shall be sufficient to evaluate efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans, including vulnerable groups, animals and the environment and contain at least the information and results of the studies referred to in this Annex.

1.2. Any information on potentially harmful effects of the plant protection product on human and animal health or on groundwater shall be included as well as known and expected cumulative and synergistic effects.

1.3. Any information on potentially unacceptable effects of the plant protection product on the environment, on plants and plant products shall be included as well as known and expected cumulative and synergistic effects.

1.4. The information shall include all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species. A summary of this data shall be provided.

1.5. The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such information shall not be required, where one of the following conditions is fulfilled:

(a) it is not necessary owing to the nature of the product or its proposed uses, or it is not scientifically necessary;

(b) it is technically not possible to supply.

In such a case a justification shall be provided.

1.6. Where relevant, the information shall be generated using test methods, which are included in the list referred to in point 6. In the absence of suitable internationally or nationally validated test guidelines, test guidelines accepted by the European competent authority shall be used. Any deviations shall be described and justified.

1.7. The information shall include a full description of the test methods used.

1.8. Where relevant, the information shall be generated in accordance with Directive 2010/63/EU of the European Parliament and of the Council[(1)].

1.9. The information shall include a list of endpoints for the plant protection product.

1.10. The information shall include the proposed classification and labelling of the plant protection product in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(2)], where relevant.

1.11. Information as provided for in Commission Regulation (EU) No 283/2013[(3)] may be required by the competent authorities on co-formulants. Before requiring additional studies to be performed, the competent authorities shall assess all available information provided in accordance with other Union legislation.

1.12. The information provided for the plant protection product and that provided for the active substance, shall be sufficient to:

(a) decide whether, or not, the plant protection product is to be authorised;

(b) specify conditions or restrictions to be associated with any authorisation;

(c) permit an evaluation of short and long-term risks for non-target species, populations, communities and processes;

(d) identify relevant first aid measures as well as appropriate diagnostic and therapeutic measures to be followed in the event of poisoning in humans;

(e) permit a risk assessment of acute and chronic consumer exposure, including, where relevant, a cumulative risk assessment deriving from exposure to more than one active substance;

(f) permit an estimation of acute and chronic exposure to operators, workers, residents and bystanders including, where relevant, the cumulative exposure to more than one active substance;

(g) permit an evaluation to be made as to the nature and extent of the risks for humans, animals (species normally fed and kept by humans or food producing animals) and of the risks for other non-target vertebrate species;

(h) predict the distribution, fate, and behaviour in the environment, as well as the time courses involved;

(i) identify non-target species and populations for which hazards arise because of potential exposure;

(j) permit an assessment of the impact of the plant protection product on non target species;

(k) identify measures necessary to minimise contamination of the environment and impact on non-target species;

(l) classify the plant protection product as to hazard in accordance with Regulation (EC) No 1272/2008.

1.13. Where relevant, tests shall be designed and data analysed using appropriate statistical methods.

1.14. Exposure calculations shall refer to scientific methods accepted by the European Food Safety Authority (the Authority), when available. Additional methods, when used, shall be justified.

2. The requirements set out in this Regulation shall represent the minimum data to be submitted. Additional requirements at national level may be necessary in specific circumstances, that is to say specific scenarios, patterns of use other than those taken into account for approval. Careful attention shall be given to environmental, climatic and agronomic conditions when tests are set up and approved by the competent authorities.

3. **Good laboratory practice (GLP)**

3.1. Tests and analyses shall be conducted in accordance with the principles laid down in Directive 2004/10/EC of the European Parliament and of the Council[(4)] where testing

is done to obtain data on the properties or safety with respect to human or animal health or the environment.

3.2. By way of derogation from point 3.1, tests and analyses, required under the provisions of Sections 6 of Parts A and B, may be conducted by official or officially recognised testing facilities or organisations which satisfy at least the following requirements:

(a) they have at their disposal sufficient scientific and technical staff having the necessary education, training, technical knowledge and experience for their assigned functions;

(b) they have at their disposal suitable equipment required for correct performance of the tests and measurements which they claim to be competent to carry out; that equipment is properly maintained and calibrated, where appropriate, before being put into service and thereafter according to an established programme;

(c) they have at their disposal appropriate experimental fields and, where necessary glasshouses, growth cabinets or storage rooms; the environment in which the tests are undertaken shall not invalidate their results or adversely effect the required accuracy of measurement;

(d) they make available to all relevant personnel operating procedures and protocols used for the trials;

(e) they make available, where requested by the competent authority, prior to the commencement of a test, information on its location and on the tested plant protection products;

(f) they ensure that the quality of the work performed is appropriate to its type, range, volume and intended purpose;

(g) they maintain records of all observations, calculations and derived data and calibrations records and final test report as long as the product concerned is authorised in a Member State.

3.3. Officially recognised testing facilities and organisations, and, where requested by the competent authorities, official facilities and organisations shall:

— report to the relevant national authority all information necessary to demonstrate that they can satisfy the requirements provided for in point 3.2,

— permit at any time the inspections, which each Member State shall regularly organise on its territory in order to verify the compliance with point 3.2.

3.4. By way of derogation from point 3.1:

3.4.1. For active substances consisting of micro-organisms or viruses, tests and analyses performed to obtain data on their properties and safety with respect to other aspects than human health, may be conducted by official or officially recognised testing facilities or organisations which satisfy at least the requirements specified at points 3.2 and 3.3.

3.4.2. Studies conducted before the application of this Regulation, although not fully compliant with GLP requirements or with current test methods, may be integrated into the assessment, when accepted by the competent authorities as scientifically valid, thereby removing the need for repeating animal tests, especially for carcinogenicity and reprotoxicity studies. This derogation applies to studies on all vertebrate species.

4. **Test material**

4.1. Due to the influence that impurities and other components can have on toxicological and ecotoxicological behaviour, a detailed description (specification) of the material used shall be provided for each study submitted. Studies shall be conducted using the plant protection product to be authorised or bridging principles may be applied, for example use of a study on a product with a comparable/equivalent composition. A detailed description of the composition used shall be provided.

4.2. Where radio-labelled test material is used, radio-labels shall be positioned at sites (one or more as necessary), to facilitate elucidation of metabolic and transformation pathways and to facilitate investigation of the distribution of the active substance and of its metabolites, breakdown and reaction products.

5. **Tests on vertebrate animals**

5.1. Tests on vertebrate animals shall be undertaken only where no other validated methods are available.

Alternative methods to be considered shall include *in vitro* methods and *in silico* methods. Reduction and refinement methods for *in vivo* testing shall also be encouraged to keep the number of animals used in testing to a minimum.

5.2. The principles of replacement, reduction and refinement of the use of vertebrate animals shall be fully taken into account in the design of the test methods, in particular when appropriate validated methods become available to replace, reduce or refine animal testing.

5.3. Tests involving the deliberate administration of the active substance or the plant protection product to humans and non-human primates shall not be performed for the purpose of this Regulation.

5.4 For ethical reasons, study designs shall be carefully considered, taking into account the scope for reduction, refinement and replacement of animal tests. For example, by including one or more additional dose groups or time points for blood sampling in one study, it may be possible to avoid the need for another study.

6. For purposes of information and of harmonisation the list of test methods and guidance documents relevant to the implementation of this Regulation shall be published in the *Official Journal of the European Union*. This list shall be regularly updated.

(**1**) OL L 276, 20.10.2010, p. 33.

(**2**) OJ L 353, 31.12.2008, p. 1.

(**3**) See page 1 of this Official Journal.

(**4**) OJ L 50, 20.2.2004, p. 44.

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)