Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 546/2011

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implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular Article 29(6) and Article 84 thereof,

After consulting the Standing Committee on the Food Chain and Animal Health,

Whereas:

(1) In accordance with Regulation (EC) No 1107/2009 the uniform principles for evaluation and authorisation of plant protection products are to contain the requirements set out in Annex VI to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(2)].

(2) It is therefore necessary for the implementation of Regulation (EC) No 1107/2009 to adopt a regulation containing the requirements, as set out in Annex VI to Directive 91/414/EEC. Such a regulation is not to include any substantial modification,

HAS ADOPTED THIS REGULATION:

Article 1

The uniform principles for evaluation and authorisation of plant protection products provided for in Article 29(6) of Regulation (EC) No 1107/2009 shall be as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 14 June 2011.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 546/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 546/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF PLANT PROTECTION PRODUCTS, AS PROVIDED FOR IN ARTICLE 29(6) OF REGULATION (EC) No 1107/2009

PART I

Uniform principles for evaluation and authorisation of chemical plant protection products

A. INTRODUCTION

1. The principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorisation of plant protection products, provided they are chemical preparations, results in the implementation of the requirements of Article 29(1)(e) in conjunction with Article 4(3) and Article 29(1)(f), (g) and (h) of Regulation (EC) No 1107/2009 by all the Member States at a high level of protection of human and animal health and the environment.

2. In evaluating applications and granting authorisations Member States shall:

(a)
- ensure that the dossier supplied is in accordance with the requirements of the Annex to Commission Regulation (EU) No 545/2011[(3)], at the latest at the time of finalisation of the evaluation for the purpose of decision-making, without prejudice, where relevant, to the provisions of Articles 33, 34 and 59 of Regulation (EC) No 1107/2009,
- ensure that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,
- evaluate, where relevant, justifications submitted by the applicant for not supplying certain data;

(b) take into account the data concerning the active substance in the plant protection product of the Annex to Commission Regulation (EU) No 544/2011[(4)], submitted for the purpose of approval of the active substance under Regulation (EC) No 1107/2009, and the results of the evaluation of those data, without prejudice, where relevant, to the provisions of Article 33(3) and Articles 34 and 59 of Regulation (EC) No 1107/2009;

(c) take into consideration other relevant technical or scientific information they can reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects of the plant protection product, its components or its residues.

3. Where in the specific principles on evaluation reference is made to data of the Annex to Regulation (EU) No 544/2011, this shall be understood as being the data referred to in point 2 (b).

4. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications must be evaluated and a decision made for the proposed use.

Taking account of justifications provided and with the benefit of any subsequent clarifications, Member States shall reject applications for which the data gaps are such that it is not possible to finalise the evaluation and to make a reliable decision for at least one of the proposed uses.

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5. During the process of evaluation and decision-making, Member States shall cooperate with the applicants in order to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Annex or of Regulation (EC) No 1107/2009.

Member States shall come to a reasoned decision within 12 months of receiving a technically complete dossier. A technically complete dossier is one that satisfies all the requirements of the Annex to Regulation (EU) No 545/2011.

6. The judgements made by the competent authorities of the Member States during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level (for example, by the EPPO), and be made with the benefit of expert advice.

B. EVALUATION

1. **General principles**

1.1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information referred to in point 2 of Part A and in particular:

(a) assess the performance in terms of efficacy and phytotoxicity of the plant protection product for each use for which authorisation is sought; and

(b) identify the hazard arising, assess their significance and make a judgment as to the likely risks to humans, animals or the environment.

1.2. In accordance with the terms of Article 29 of Regulation (EC) No 1107/2009, which, inter alia, specifies that Member States shall have regard to all normal conditions under which the plant protection product may be used, and to the consequences of its use, Member States shall ensure that evaluations carried out have regard to the proposed practical conditions of use and in particular to the purpose of use, the dose, the manner, frequency and timing of applications, and the nature and composition of the preparation. Whenever possible Member States shall also take into account the principles of integrated control.

1.3. In the evaluation of applications submitted, Member States shall have regard to the agricultural, plant health or environmental (including climatic) conditions in the areas of use.

1.4. In interpreting the results of evaluations, Member States shall take into consideration possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.

The first evaluation made shall be based on the best available data or estimates reflecting the realistic conditions of use of the plant protection product.

This should be followed by a repeat evaluation, taking account of potential uncertainties in the critical data and of a range of use conditions that are likely to occur and resulting in a realistic worst-case approach, to determine whether it is possible that the initial evaluation could have been significantly different.

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1.5. Where specific principles of Section 2 provide for the use of calculation models in the evaluation of a plant protection product, those models shall:

— make a best possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,

— be submitted to an analysis as referred to in B, point 1.4,

— be reliably validated with measurements carried out under circumstances relevant for the use of the model,

— be relevant to the conditions in the area of use.

1.6. Where metabolites, degradation or reaction products are referred to in the specific principles, only those that are relevant for the proposed criterion shall be taken into consideration.

2. Specific principles

Member States shall, for the evaluation of the data and information submitted in support of applications, and without prejudice to the general principles of Section 1, implement the following principles.

2.1. *Efficacy*

2.1.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate the possibility that this organism could be harmful under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use.

2.1.2. Where the proposed use concerns an effect other than the control of or protection against an organism, Member States shall evaluate whether significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use if the plant protection product were not used.

2.1.3. Member States shall evaluate the efficacy data on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011 having regard to the degree of control or the extent of the effect desired and having regard to the relevant experimental conditions such as:

— the choice of the crop or cultivar,

— the agricultural and environmental (including climatic) conditions,

— the presence and density of the harmful organism,

— the development stage of crop and organism,

— the amount of the plant protection product used,

— if required on the label, the amount of adjuvant added,

— the frequency and timing of the applications,

— the type of application equipment.

2.1.4. Member States shall evaluate the performance of the plant protection product in a range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use and in particular:

(i) the level, consistency and duration of the effect sought in relation to the dose in comparison with a suitable reference product or products and an untreated control;