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# Implementation of EU regulations regarding the placing of plant protection products on the market

## Regulation (EC) No 1107/2009[1], repealing Council Directive 91/414[2], entered into force on June 14, 2011. This Regulation concerns the authorization of plant protection products in commercial form and their placing on the market, use and control within the EU. It also includes provisions that apply to the components of such products.

Council Directive 91/414 made a distinction between active substances and plant protection products. Only plant protection products, the active substance of which were included in Annex I of said Directive, were authorized.

Regulation (EC) No 1107/2009 makes a distinction between active substances, basic substances, safeners, synergists and adjuvants, all of which being subject to an approval procedure, as well as co-formulants that are authorized unless they are included in a list of co-formulants which should not be included in plant protection products.

Manufacturers that place on the market products, the substances of which have already been approved under Council Directive 91/414, do not have to follow the approval procedure again: substances already approved pursuant to Council Directive 91/414 (i.e. substances included in Annex I of such Directive) are deemed to have been approved under Regulation (EC) No 1107/2009[3]. Safeners and synergists placed on the market before June 14, 2011 shall be gradually reviewed under a work program to be established by the EU Commission.

Regulation (EC) No 1107/2009 can be considered as a "framework" Regulation insofar as it sets out a number of principles but fails to provide the related implementation measures. This is the reason why this Regulation specified that further regulations – to be adopted before June 14, 2011 – would set out the provisions necessary for its implementation.

It is within this context that a series of regulations have been adopted:

## Regulation 544/2011 on data requirements for active substances[4]

Regulation (EC) No 1107/2009 establishes an approval procedure for all active substances (it being specified that such procedure also apply to applications for amendments to the conditions of an approval that has already been granted). In summary, an application for the approval of an active substance or for an amendment to the conditions of an approval must be submitted by the producer of the active substance to a Member State, referred to as the "rapporteur Member State", together with a summary and a complete dossier on the basis of which the rapporteur Member State will make a decision on the acceptability or non-acceptability of the relevant substance[5]. Such dossiers must contain a number of information and data[6] that must meet certain requirements. Regulation 544/2011 sets forth the data requirements applicable to the information contained in the summary dossier[7], including, but not limited to, the requirements relating to the information concerning the identity of the active substance, its physical and chemical properties, its effects, the analytical methods required for post-registration control and monitoring purposes, the necessary toxicological studies, the information necessary to make an evaluation of the risk for man, the behavior of the active substance in the environment, its impact on flora and fauna, etc.

Specific provisions shall apply to active substances consisting of micro-organisms (including viruses). On the whole, Regulation 544/2011 does not substantially modify previously applicable rules.

## Regulation 545/2011 on data requirements for plant protection products[8]

Dossiers submitted by producers of active substances in the framework of an application for approval must contain – in addition to the information on the active substance itself – a number of data on plant protection products that contain the relevant substances[9]. Regulation 545/2011 sets out the requirements applicable to such data. It defines notably the requirements applicable to the identity, properties, application and efficiency of the plant protection products, toxicology studies, residues in or on treated products, food and feed, etc. Again, specific provisions shall apply to active substances consisting of preparations of micro-organisms.

On the whole, Regulation 545/2011does not radically change previously applicable rules.

## Regulation 546/2011 on uniform principles for evaluation and

## authorization of plant protection products[10]

Pursuant to Regulation (EC) No 1107/2009, the placing of a plant protection product on the market is subject to (i) the approval of its active substances, safeners and synergists and (ii) the delivery of a market authorization[11].

Regulation (EC) No 1107/2009 specifies that the principles governing the evaluation and authorization of plant protection products are to be defined by a specific regulation.

This is precisely the purpose of Regulation 546/2011. This Regulation makes a distinction between the evaluation and authorization principles applicable to chemical plant protection products and those applicable to plant protection products consisting of micro-organisms.

On the whole, Regulation 546/2011 does not substantially modify previously applicable rules.

## Regulation 547/2011 on labeling requirements for plant protection products[12]

Because plant protection products may be dangerous for human or animal health and for the environment, their labeling must inform users of the risks incurred and of the safety precautions to be taken. Regulation 547/2011 sets forth the labeling requirements applicable to plant protection products (information to be included in the product label or that may be indicated on a separate leaflet, information that must not appear on the label, derogatory provisions applicable to plant protection products used for experiments or tests for research and development purposes and language requirement), the standard phrases for risks to appear on the label in order to mention the special risks and the safety precautions. Products labeled in accordance with Directive 91/414 may continue to be placed on the market until June 14, 2015[13]. The labeling of plant protection products, as chemical products, must also meet the requirements of the so-called CLP Regulation (Classification, Labeling and Packaging) that entered into force on January 20, 2009 and that gradually supersedes the Directives that it repeals[14].

All of these Implementing Regulations entered into force on June 14, 2011.

As such, producers of plant protection products must, as of now, make sure that they comply with the rules set forth in such Implementing Regulations but also, more generally, with the terms of Regulation (EC) No 1107/2009.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of October 21, 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[2] Council Directive 91/414/EEC of July 15, 1991 concerning the placing of plant protection products on the market

[3] Commission Implementing Regulation (EU) No 540/2011 of May 25, 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances incorporates the list of active substances that have been approved for incorporation into plant protection products since Annex I of Directive 91/414 has been repealed following the entry into force of Regulation (EC) No 1107/2009

[4] Commission Regulation (EU) No 544/2011 of June 10, 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances

[5] Article 7 of Regulation (EC) No 1107/2009

[6] Article 8 of Regulation (EC) No 1107/2009

[7] Article 8 §1 b) of Regulation (EC) No 1107/2009

[8] Commission Regulation (EU) No 545/2011 of June 10, 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products

[9] Article 8 §1 c) of Regulation (EC) No 1107/2009

[10] Commission Regulation (EU) No 546/2011 of June 10, 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorization of plant protection products

[11] Articles 28 and 29 of Regulation (EC) No 1107/2009

[12] Commission Regulation (EU) No 547/2011 of June 8, 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labeling requirements for plant protection products

[13] Article 80 §6 of Regulation (EC) No 1107/2009

[14] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 16, 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC.

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