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

CHAPTER III

PLANT PROTECTION PRODUCTS

SECTION 2

Use and information

Article 55

Use of plant protection products

Plant protection products shall be used properly.

Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management, as referred to in Article 14 of and Annex III to that Directive, which shall apply at the latest by 1 January 2014.

Article 56

Information on potentially harmful or unacceptable effects

1 The holder of an authorisation for a plant protection product shall immediately notify the Member States that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively.

In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.

To this end the authorisation holder shall record and report all suspected adverse reactions in humans, in animals and the environment related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by international organisations or by public bodies which authorise plant protection products or active substances in third countries.

2 The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener,

or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

3 Without prejudice to the right of Member States to adopt interim protective measures, the Member State which first granted an authorisation within each zone shall evaluate the information received and inform the other Member States, belonging to the same zone, where it decides to withdraw or amend the authorisation under Article 44.

That Member State shall inform the other Member States and the Commission where it considers that the conditions of the approval of the active substance, safener or synergist contained in the plant protection product are no longer fulfilled or whether in the case of a co-formulant it has been considered unacceptable and propose that the approval be withdrawn or the conditions amended.

4 The holder of an authorisation for a plant protection product shall report annually to the competent authorities of the Member States which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Article 57

Obligation to keep information available

1 Member States shall keep information electronically available to the public on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:

a the name or business name of the holder of the authorisation and the authorisation number;
b the trade name of the product;
c the type of preparation;
d the name and amount of each active substance, safener or synergist which it contains;
e the classification, risk and safety phrases in accordance to Directive 1999/45/EC and to the Regulation referred to in Article 65;
f the use or uses for which it is authorised;
g the reasons for withdrawal of an authorisation if they are related to safety concerns;
h the list of minor uses referred to in Article 51(8).

2 The information referred to in paragraph 1 shall be readily accessible and updated at least once every 3 months.

3 In accordance with the regulatory procedure referred to in Article 79(3), an authorisation information system may be set up to facilitate the application of paragraphs 1 and 2 of this Article.