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QUESTION AND ANSWERS

Regulation (EC) No 1107/2009 concerning the placing of plant protection product on the market¹

TABLE OF CONTENTS

1. INTRODUCTION	4
2. ARTICLE 2 (SCOPE)	4
Definition of plant protection products and products in bulk.....	4
<i>In situ</i> generated active substances and plant protection products	5
Scope of adjuvants, synergists and safeners	5
3. ARTICLES 6 (CONDITIONS AND RESTRICTIONS) AND 13 (APPROVAL REGULATION).....	6
Assessment of confirmatory information	6
4. ARTICLE 23 (APPROVAL CRITERIA FOR BASIC SUBSTANCES)	7
Mixture of basic and active substances and Article 23(1)(c)	7
5. ARTICLE 28 (AUTHORISATION FOR PLACING ON THE MARKET AND USE OF PLANT PROTECTION PRODUCTS).....	8
Plant protection products intended for use in another Member States	8
Mere storage of plant protection products	9
6. ARTICLE 31 (CONTENT OF THE AUTHORISATION – CLASSIFICATION OF THE PPP)	9

¹ OJ L 309, 24.11.2009, p. 1.

Who is deciding on the classification of a PPP in the situation when the active substance is not subject to a harmonised classification?.....	9
Who is deciding on the classification of a PPP in the situation when there is a harmonised classification and the substance is listed in Annex VI to Regulation (EC) No 1272/2008?	10
7. ARTICLE 36 (EXAMINATION FOR AUTHORISATION)	10
Zonal authorisations of plant protection products	10
8. ARTICLE 46 (GRACE PERIOD).....	11
Minor changes of authorisation and grace period.....	11
Scope and time limits	12
9. ARTICLE 49 (PLACING ON THE MARKET OF TREATED SEEDS).....	13
Definition of "seed"	13
Standard labelling phrases for treated seed	14
Seeds treated with plant protection products.....	14
Seeds treated with a plant protection product containing non-authorized active substances.....	15
Storage of treated seeds and export of treated seeds in third countries	16
10. ARTICLE 50 (COMPARATIVE ASSESSMENT OF PPP CONTAINING CANDIDATES FOR SUBSTITUTION).....	17
How will the evaluation of plant protection products containing substances listed as candidates for substitution take place?	17
How Member States should assess an application for mutual recognition of products containing candidates for substitution?	17
11. ARTICLE 58 (ADJUVANTS)	18
12. ARTICLES 60 (LIST OF TEST AND STUDY REPORTS).....	18
Confidentiality in the list of the test and study reports.....	18
13. ARTICLE 62 (SHARING OF TESTS AND STUDIES INVOLVING VERTEBRATE ANIMALS).....	19
Tests and studies involving vertebrate animals	19
14. ARTICLE 63 (CONFIDENTIALITY)	20
Links between a producer or importer and the applicant or the authorisation holder.....	20
15. ARTICLE 66 (ADVERTISING).....	20
Meaning of the terms "warning phrases and symbols" stated in Article 66(6)	20
16. ARTICLE 67 (RECORD-KEEPING)	21

Addressees of the record-keeping duties 21
Addressees of the record-keeping duties – Meaning of the term "suppliers" 22

UNDER REVISION

1. INTRODUCTION

This document gathers questions and agreed answers regarding the interpretation of 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.

This document is aimed at providing guidance to both Member States and economic operators and it will be complemented by other questions and answers, if and when the implementation of this Regulation will raise further interpretative problems.

These answers represent the position of the Commission services but may not necessarily represent the opinion of the Commission. This guidance document does not constitute any formal commitment on behalf of the Commission. Only the European Court of Justice can give an authoritative interpretation of EU law.

This document will be regularly updated and published on the website of the European Commission at the following address:

http://ec.europa.eu/food/plant/pesticides/legislation/docs/qanda_regulation_1107-2009_en.pdf

2. ARTICLE 2 (SCOPE)

Definition of plant protection products and products in bulk

The definition of plant protection products in Article 2 of Regulation (EC) No 1107/2009 reads: "*This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses ...: .../...*"

The question arose whether the terms 'the form in which they are supplied to the user' refer to the content of the plant protection product, or whether this wording should be interpreted as referring to the form in which the plant protection products is placed on the market such as the way they are packaged and labelled for the end users.

It is considered that the terms '*in the form in which they are supplied to the user*' refer to the content of the plant protection products because the second part of Article 2 refers to the substances contained in the plant protection products with the intended uses and appears to place the emphasis on the content of the product and its uses and not on its form such as package and label. ("*...consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:*").

Moreover, the fact that according to Article 28(1) a "plant protection product shall not be placed on the market or used unless it has been authorised" (emphasis added) in accordance with Regulation (EC) No 1107/2009 confirms that the definition of PPP is focused on the composition of the product and not on the fact that it is packaged and labelled. In fact, for the use of PPPs the fact that they are packaged and labelled for the end users is irrelevant.

As a consequence, plant protection products whose composition allows them to be used by end-users without further manufacturing steps are regulated under Regulation (EC) No 1107/2009.

This interpretation is in line with a number of provisions. For instance, the provisions on record keeping (Article 67) cover all actors involved in the whole distribution chain (producers, suppliers, distributors, importers and exporters) and these actors deal with PPPs whether or not they are in a packaging for the end users or in bulk.

In the same way, provisions on controls (Article 68) foresee that controls should cover all steps in the process including manufacture, distribution and use of plant protection products. Also this Article concerns companies that trade plant protection products both packaged for the end users or in bulk. This interpretation will allow control of bulk plant protection products traded in the EU and imported from third countries.

***In situ* generated active substances and plant protection products**

Are *in situ* generated active substance and plant protection products covered by the scope of Regulation (EC) No 1107/2009? Do the machineries that produce plant protection products or active substances *in situ* fall under the rules of this Regulation?

Article 2(1) of Regulation (EC) No 1107/2009 defines "plant protection products" as the "products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the [...] uses" listed in points (a) to (e) of the provision. The terms "in the form in which they are supplied to the user" in Article 2(1) underline the necessity to identify a specific composition to be used as plant protection product and not the need of a physical transfer of a plant protection product from a company to the user.

This interpretation is confirmed by the wording of Article 28(1) of Regulation (EC) No 1107/2009, according to which "[a] plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation". This Article does not limit the authorisation requirement to market transactions for which there is a physical transfer from one company to the user, but covers all uses of plant protection products.

As a consequence, *in situ* generated active substances and plant protection products are covered by the scope of Regulation (EC) No 1107/2009. Hence, the use of plant protection products requires an authorisation in accordance with Article 28(1) of the Regulation even if the plant protection product, or its active substance(s), is generated *in situ*.

On the contrary, the manufacturing process of the active substance does not fall within the rules for the authorisation of plant protection products. Thus, the machineries that produce plant protection products or active substances *in situ* are not covered by the authorisation requirement.

Scope of adjuvants, synergists and safeners

Some questions arise to clarify the definitions of safeners, synergists and adjuvants laid down in Article 2(3) of Regulation (EC) No 1107/2009.

According to Article 2(3)(d), "adjuvants" are "substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties".

What does the wording "other pesticidal properties" in Article 2(3)(d) relates to? If an adjuvant comes to have pesticidal properties, should this compound be considered as an active substance? Is an adjuvant only for tank mixing and not to be used in a formulated product?

Article 2(3)(d) of Regulation (EC) No 1107/2009 should be read as referring to the fact that adjuvants should enhance the effectiveness of plant protection products or should enhance "other pesticidal properties" of plant protection products. Therefore, this provision does not indicate that adjuvants should have pesticidal properties themselves.

An adjuvant as defined in Regulation (EC) No 1107/2009 should be placed on the market separately from the plant protection product and not contained in the formulation of the plant protection products. In fact, according to Article 2(3)(d) of the Regulation, adjuvants, which are supposed to be sold separately, are mentioned as "in the form in which they are supplied for the user".

Article 2(3)(a) of Regulation (EC) No 1107/2009 defines "safeners" as "substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants". According to Article 2(3)(b) of the Regulation, "synergists" are "substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product".

According to these definitions, should synergists and safeners be considered only as part of a formulated product?

Safeners and synergists are always part of a formulated product including an active substance. In fact, Article 2(3)(a) states that a safener is added to a plant protection product (and a plant protection product contains per definition an active substance) and Article 2(3)(b) affirms that a synergist can give enhanced activity to the active substance.

Moreover, the reference "in the form in which they are supplied for the user" mentioned in Article 2(3)(d) as far as adjuvants are concerned is missing in Articles 2(3)(a), (b) and (c) for safeners, synergists and co-formulants.

3. ARTICLES 6 (CONDITIONS AND RESTRICTIONS) AND 13 (APPROVAL REGULATION)

Assessment of confirmatory information

What is the procedure for the assessment of confirmatory information required for active substances already included in Annex I to Directive 91/414/EEC² and substances falling

² Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

under the transitional rules laid down in Article 80(1) of Regulation (EC) No 1107/2009? What are the criteria to be followed to perform this assessment?

Article 6(f) of Regulation (EC) No 1107/2009 points out that the submission of further confirmatory information is a condition for the approval of an active substance. This reflects the general principle according to which the submission and assessment of confirmatory information is linked with the approval procedure itself. As a consequence, Article 13(3) of Regulation (EC) No 1107/2009 indicates the procedure and criteria to be followed for the assessment of further confirmatory information.

According to this rationale, the criteria for the assessment of the confirmatory information are the criteria applicable to the approval itself. Therefore, for substances already included in Annex I to Directive 91/414/EEC as well as for substances falling under the transitional measures of Article 80(1), the criteria are those indicated in Directive 91/414/EEC and not in Article 4 of Regulation (EC) No 1107/2009.

More detailed information on the procedures for submission and assessment of confirmatory information is provided in the "Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009 (SANCO/5634/2009)".

4. ARTICLE 23 (APPROVAL CRITERIA FOR BASIC SUBSTANCES)

Mixture of basic and active substances and Article 23(1)(c)

According to Article 23 of Regulation (EC) No 1107/2009, basic substances must be approved as active substances for an unlimited period of time. A basic substance is defined, among other things, as an active substance that "is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent" [Article 23(1)(c)].

Can a mixture of a basic substance and another active substance be registered? Will, in such a mixture, only the active substance be evaluated?

Article 23 of Regulation (EC) No 1107/2009 affirms that basic substances should be approved. A basic substance which is approved must be included in an Annex to Regulation (EC) No 540/2011 implementing Regulation (EC) No 1107/2009 as regards the list of approved active substances.³

If a basic substance is mixed with an active substance and it is intended to be used for one of the purposes listed in Article 2(1) paragraphs a) to e) of Regulation (EC) No 1107/2009, the mixture will be considered as a plant protection product. This plant protection product may not be placed on the market or used unless it has been authorised in the Member State concerned.

The active substance contained in the plant protection product needs to be approved as described in Articles 4 to 13 of Regulation (EC) No 1107/2009. The basic substance

³ OJ L 153, 11.6.2011, p. 1.

which is contained in the plant protection product does not need to be approved as an active substance following the procedure described in Articles 7 to 12, nor according to the procedure described in Article 23. In fact, in case of a product containing at least one active substance, it is irrelevant if the other components are basic substances or not. Pursuant to Article 28(2)(a) no authorisation is needed for the "use of products containing exclusively one or more basic substances". In this case the product does not contain exclusively basic substances.

When a Member State receives an application for the authorisation of a plant protection product consisting of a mixture of a basic substance with an active substance, it will evaluate the plant protection product containing the basic substance in the same way as in the case of a plant protection product containing a co-formulant.

5. ARTICLE 28 (AUTHORISATION FOR PLACING ON THE MARKET AND USE OF PLANT PROTECTION PRODUCTS)

Plant protection products intended for use in another Member States

Article 28(1) of Regulation (EC) No 1107/2009 reads: *"A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation."*

Article 28(2) reads: *"By way of derogation from paragraph 1, no authorisation shall be required in the following cases: .../...*

(c) production, storage or movement of a plant protection product intended for use in another Member State, provided that the product is authorised in that Member State and that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is not used in its territory; .."

To benefit from the derogation laid down in Article 28(2)(c), any product which is produced, stored or moved in a Member State but intended for a other Member State must be covered by an authorisation in the Member State of destination in the EU. This includes products entering the EU from third countries and destined to a different Member State than the country of entry.

This means that companies (producers, storage companies, distributors, traders) which want to benefit from the above mentioned derogation must provide evidence that the product destined to another Member State which they intend to produce, store or move is covered by an authorisation in the Member State of destination.

If the product is not destined to the country of production, storage or movement, Member State authorities need to control if the product is covered by an authorisation in the country of destination in the EU. Without this authorisation, the product does not benefit from the derogation in Article 28(2)(c).

MS authorities may verify with the authorities of the country of destination in the EU whether the product is covered by a valid authorisation in that country. Through the **PPP Application Management System**, Member States authorities can find information on PPP authorisations in different countries.

In addition according to Article 28(2)(c) the derogation is only applicable if the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is not used in its territory.

Mere storage of plant protection products

Does the mere storage of a plant protection product require an authorisation? Which legal consequences are provided for in case of storage of non-authorised plant protection products?

Article 28(1) of Regulation (EC) No 1107/2009 states that only plant protection products which are authorised can be placed on the market and used.

The mere storage does not require an authorisation as neither the term "use" nor the wording "placing on the market" refer explicitly to the phase of storage. In fact, Regulation (EC) No 1107/2009 defines the "placing on the market" as "the holding for the purpose of sale within the [Union], including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller". As a consequence, the "placing on the market" includes the phase of acquiring or buying plant protection products, as these transactions constitute forms of transfer.

If someone is storing plant protection products which are not authorised there can be a presumption that these products have been bought, which implies that these products were illegally placed on the market. The operator may prove that the plant protection products were not acquired by him or herself. Alternatively, he or she may invoke the derogations stated in Article 28(2) of Regulation (EC) No 1107/2009 in order to demonstrate that the products are intended to be used in another Member State or in a third country.

Moreover, the national rules regulating the storing of the products on the basis of the EU provisions on the grace period will apply in the case of products for which the authorisation is withdrawn after a non-inclusion or a non-approval of the active substance.

6. ARTICLE 31 (CONTENT OF THE AUTHORISATION – CLASSIFICATION OF THE PPP)

Who is deciding on the classification of a PPP in the situation when the active substance is not subject to a harmonised classification?

Under Article 4 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, it is the responsibility of the manufacturer or importer to classify a mixture before placing the mixture on the market.

This is also the case when a producer of a plant protection product is submitting an application for an authorisation under Regulation (EC) No 1107/2009 on plant protection products. The producer of the plant protection product will have to apply the provisions of Regulation (EC) No 1272/2008 and propose a classification of the product in line with the criteria set under this Regulation.

Article 31 of Regulation (EC) No 1107/2009 provides that the authorisation granted by the authority shall include a classification. Therefore Member States, preferably in the frame of the zonal procedure, will decide on the classification when granting the authorisation.

In the case of disagreement between the classification proposed by the manufacturer and the authority in charge of granting an authorisation for PPP, the product should be labelled according to the PPP authorisation.

As from 1 June 2015, Directive 99/45/EC is repealed and replaced by Regulation (EC) No 1272/2008. As a consequence references to Directive 99/45/EC in Regulation (EC) No 1107/2009 should be interpreted as referring to Regulation (EC) No 1272/2008.

Who is deciding on the classification of a PPP in the situation when there is a harmonised classification and the substance is listed in Annex VI to Regulation (EC) No 1272/2008?

When there is a harmonised classification and the substance is listed in Annex VI of Regulation (EC) No 1272/2008, manufacturers and Member States are bound by the harmonised classification. This is especially the case if the entry in Annex VI is the result of an assessment by the Risk assessment committee (RAC) of ECHA for all hazards. This is the main principle of the harmonised classification.

One needs to be careful in the situation where the harmonised classification and entry in Annex VI is not the result of a RAC assessment for all hazards. In this exceptional case, a departure from the harmonised classification by MS could be possible. In this case a dialogue should start and the company could show that the Member State is erroneously applying the classification, labelling and packaging (CLP) legislation.

7. ARTICLE 36 (EXAMINATION FOR AUTHORISATION)

Zonal authorisations of plant protection products

The Member State examining the application (zonal Rapporteur) for placing the plant protection products on the market can:

- (a) provide for a positive assessment for the zone and authorize the use of a plant protection product in its territory;
- (b) provide for a negative assessment for the zone and refuse the use authorisation of a plant protection product in its territory;
- (c) refuse the use authorisation of a plant protection product in its own territory but providing for a positive assessment for the zone which indicates that the use of such product is acceptable for the zone.

Two questions arise concerning zonal authorisations.

In case of the refusal of an authorisation by the zonal Rapporteur, does Regulation (EC) No 1107/2009 preclude the applicant from requesting the examination of its application by another Member State on the basis of Article 33?

Under the system of zonal authorisations, an applicant who wishes to place a plant protection product on the market still has to apply for an authorisation to each Member State where the plant protection product is intended to be placed on the market. Each Member State thus keeps the power to carry out authorisation procedures. Nevertheless pursuant to Article 35, 3rd paragraph, when the assessment is pending with the zonal Rapporteur, the other Member States in the same zone shall refrain from proceedings with the file pending such assessment.

If an authorisation is refused by the zonal Rapporteur for the zone, however, no assessment is pending any more. An applicant may thus newly apply for authorisation - and even propose another Member State as zonal Rapporteur. However, the practical advantages of such a step would seem to be normally rather limited. In fact, in order to reach the objective of the system of zonal authorisation, the Member State indicated by the applicant for the second procedure can not disregard the conclusions of the first zonal Rapporteur that led to the refusal of an authorisation.

Can the "concerned Member States" grant authorisations, on the basis of Article 36(2) Regulation (EU) No 1107/2009 after a non-authorisation of the zonal rapporteur, if the latter stated that the use would be acceptable in the zone in principle, but not under the special conditions of its own territory?

Article 36(2) states that "[t]he Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application".

Therefore, if the zonal Rapporteur has come to the unambiguous conclusion that the use of a given plant protection product is acceptable in the zone in principle, but not in its own territory for conditions specific to that territory, this conclusion should be considered a positive assessment by the "zonal Rapporteur".

On the basis of this positive assessment the Member States in the zone to which an application was sent shall grant authorisations unless the provisions of Article 36(3) are applicable.

However, in this circumstance it is necessary to underline an important difference between the zonal evaluation and the mutual recognition. According to Article 40 Regulation (EC) No 1107/2009, mutual recognition can only be based on an existing authorisation. Therefore, the statement of the zonal rapporteur according to which the use would be acceptable in the zone in principle, but not under the special conditions of its own territory, can not be used for an application under Article 40 of the Regulation.

8. ARTICLE 46 (GRACE PERIOD)

Minor changes of authorisation and grace period

Article 46 of Regulation (EC) No 1107/2009 states that "[w]here the [...] amendment [...] of the authorisation [...] [is] not related to the protection of human and animal health or the environment, the grace period shall be limited".

Does this provision apply also to minor changes to the authorisation, such as changes of pure administrative nature or label amendments, which do not have impact on the safe use of the product?

Article 46 of Regulation (EC) No 1107/2009 should only be applicable when the amendment introduces a restriction to the authorisation. In fact, this Article must be read in combination with Articles 44 and 45 of the Regulation, which both state that "Article 46 shall apply where appropriate".

The term "amendment of an authorisation" in Articles 44 and 45 covers situations providing for a change to the authorisation conditions, such as the cases listed in Article 44(3) or when the amendment provides for a restriction to the authorisation or limits the authorisation to a particular use or crop. In these circumstances, the Member States may consider appropriate to grant a grace period for the disposal, storage, placing on the market and use of existing stocks as stated in Article 46 of Regulation (EC) No 1107/2009. This behaviour will make sure that at a certain date all products placed on the market and used are compliant with the amended authorisation.

Minor changes concerning the authorisation which were requested by the authorisation holder or Member State should not be considered as amendments to an authorisation in the sense of Articles 44 and 45 of the Regulation since they do not have any impact on the safe use of the product. Therefore, the provisions of Article 46 concerning the grace period do not apply to them.

Scope and time limits

Article 46 of Regulation (EC) No 1107/2009 affirms that Member States may grant a grace period for the disposal, storage, placing on the market and use of existing stocks. The second paragraph of the provision states that "the grace period [...] shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned".

Does Article 46 allow the Member States to set grace periods which are shorter than the time limits indicated in the provision? Does this provision refer to any existing stocks or can the Article be interpreted as referring only to the products that have already been placed in the market?

Article 46 gives a large discretionary power to Member States in relation with the implementation of the grace period, in particular for the setting of its duration and its scope, as long as the Member States do not exceed the limits provided for in the same Article.

Therefore, a Member State may grant a grace period which is shorter than the limit set in the second paragraph of Article 46.

Similarly, the Member States may also narrow the scope of the grace period authorising only the placing on the market of plant protection products which have already been placed on the market.

9. ARTICLE 49 (PLACING ON THE MARKET OF TREATED SEEDS)

Definition of "seed"

a) What is the definition of the term "seeds" in Article 49 of Regulation (EC) No 1007/2009? Does this notion comprehend also potato tubers to be sown?

Regulation (EC) No 1107/2009 does not give a definition of "seed". According with the general principle of effectiveness, the notion of "seed" laid down in Article 49 of the Regulation must be interpreted extensively in order to give full effect to EU law.

Moreover, recital 33 of Regulation (EC) No 1107/2009 states that Article 49 was included in the Regulation since the "Community seeds legislation [...] does not contain a specific provision concerning seeds treated with plant protection products". Therefore the notion of seed must be interpreted in the framework of the EU seeds legislation. In the seeds legislation, Article 2(d) of Directive 2008/62/EC⁴ defines for instance "seed" as "seed and seed potatoes, unless seed potatoes are expressly excluded".

Therefore the term "seeds" in Article 49 of Regulation (EC) No 1107/2009 should be interpreted as also including potato tubers.

b) Does the term "seeds" in Article 49 of Regulation (EC) No 1007/2009 include seeds improper for any cultivation purpose or dead seeds which are treated with a plant protection product (also called "dummy pills")?

It appears that seeds improper for cultivation or dead seeds are used as a support for a plant protection product. The seed improper for cultivation or dead seed coated with a plant protection product is "planted" next to a living seed. This provides the leaving seed and the seedling roots with a certain amount of PPP. These "dummy pills" are therefore used in a similar way as PPP in the form of granular. In addition the notion of "seed" under Regulation 1107/2009 should be interpreted with reference to EU seed legislation. This legislation is not covering seeds which are improper for cultivation.

As a consequence "dummy pills" cannot be considered as "seeds" under Regulation 1107/2009 but they should be considered as plant protection products. Dummy pills don't benefit from the provisions of Article 49(1) on the free circulation of seeds but should be authorised under Article 28 as PPP.

c) Does the term "seeds" in Article 49 of Regulation (EC) No 1007/2009 include flower bulbs?

The notion of "seed" under Regulation 1107/2009 should be interpreted with reference to the EU seed legislation. Only Directive 98/56/EC on the marketing of propagating material of ornamental plants covers bulbs for ornamentals. Therefore the term "seeds" in Article 49 of Regulation (EC) No 1107/2009 should be interpreted as excluding bulbs. In addition the treatment of bulbs is performed with a very different process compared to the

⁴ Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties (OJ L 162, 21.6.2008, p. 13).

treatment of seeds. As a consequence bulbs should not be considered as “seeds” under Regulation 1107/2009.

Standard labelling phrases for treated seed

Which information shall be reported on the label and documents accompanying the treated seeds? Is there a particular provision for small packaging?

Article 49(4) of Regulation (EC) No 1107/2009 affirms that the label and documents accompanying treated seeds shall include:

- the name of the plant protection product;
- the name of the active substance of the product;
- standard phrases for safety precautions as provided for in Directive No 99/45/EC concerning the classification, packaging and labelling of dangerous preparations;⁵
- risk mitigation measures set in the authorisation of the plant protection product.

Since the Directive 95/45/EC is repealed as from 1 June 2015, the terms "Standard phrases for safety precautions as provided for in Directive 99/45/EC" should be read as referring to precautionary statements referred to in Article 22 of Regulation (EC) No 1272/2008.

The wording of the precautionary statements applicable to the plant protection product applied on the seed can be found in Annex IV to Regulation (EC) No 1272/2008.

Article 49(4) of Regulation (EC) No 1107/2009 does not impose to place on the label the danger symbol provided for in Directive 67/548/EEC nor to report the hazard pictograms listed in Regulation (EC) No 1272/2008 on the classification, labelling packaging of substances and mixtures⁶.

Finally, Regulation (EC) No 1107/2009 does not contain any particular provision providing for reduced labelling obligations for small packaging.

Seeds treated with plant protection products

Does the treatment of seeds constitute a use of plant protection product? Is it possible to treat in a Member State seeds using a plant protection products not authorised in that Member State?

Article 2(1) of Regulation (EC) No 1107/2009 states that the Regulation applies to the products intended for one of the uses listed in the provision and especially to protect "plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of

⁵ OJ L 200, 30.7.1999, p. 1.

⁶ OJ L 353, 31.12.2008, p. 1.

hygiene rather than for the protection of plants or plant products" [Article 2(1)(a)]. Article 3(5) defines "plants" as "live plants and live parts of plants, including fresh fruit, vegetables and seeds".

Therefore, the treatment of seeds is considered as one of the possible uses of plant protection products and the notion of "use" covers the treatment of seeds and not the sowing of treated seeds.

The Regulations approving the active substances, which include certain conditions for the use of a plant protection product, might include conditions concerning the use of a plant protection product for the treatment of seeds. In certain cases, the treatment of seeds is the only possible authorised use.

Moreover, Article 28(1) of Regulation (EC) No 1107/2009 states that a plant protection product cannot be used unless it has been authorised in the Member State concerned. The Member State concerned is the State where the product is used, i.e. the Member State where the seeds are treated. As a consequence, the treatment of seeds with plant protection products in a Member State must be authorised in that State irrespective of the final destination of the treated seeds.

In fact, Article 49 of Regulation (EC) No 1107/2009 does not imply that an undertaking producing, for instance, treated seeds in Member State A can treat them with a product authorised in Member State B. The treatment of seeds must be done in the Country in which the product used for the treatment has been authorised.

Seeds treated with a plant protection product containing non-authorized active substances

If an active substance is not authorised in the European Union, can seeds treated with a plant protection product containing that active substance be placed on the market?

Article 49 of Regulation (EC) No 1107/2009 affirms that "Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State".

Article 49, paragraph 1, does not specifically address the placing on the market and use of seeds treated with plant protection products not authorised in any Member State. However, this behaviour is considered contrary to the objectives of Regulation (EC) No 1107/2009.

In fact, the second paragraph of Article 49 provides for the possibility to adopt restrictive measures "[w]here there are substantial concerns that treated seeds as referred to in paragraph 1 are likely to constitute a serious risk to human or animal health or to the environment". The fact that Article 49, paragraph 2, is referring only to the treated seeds mentioned in the first paragraph of the provision means that only seeds "treated with plant protection products authorised for that use in at least one Member State" can be placed on the market and used in the Union.

As a consequence, seeds treated with a plant protection product not authorised in any Member State should not be placed on the market.

Storage of treated seeds and export of treated seeds in third countries

Can seeds treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid be stored at seed treatment facilities, at retail level or farm level after 1st December 2013? Is it allowed to treat seeds with plant protection products containing clothianidin, thiamethoxam or imidacloprid inside the EU and afterwards export them in third countries?

Article 2 of Commission Implementing Regulation (EU) No 485/2013⁷ prohibits the placing on the market of seeds treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid, with the exception of seeds used in greenhouses.

Article 3(9) of Regulation (EC) No 1007/2009 define the "placing on the market" as "the holding for the purpose of sale within the Community, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. Release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation".

As a consequence, under Regulation (EU) No 485/2013 it is allowed to sell stocks of treated seeds for the purpose of exporting them outside of the EU. In fact, the definition of "placing on the market" laid down in Article 3 of Regulation (EC) No 1107/2009 can be interpreted as excluding the offering for sale for the purpose of exporting. Obviously, operators need to keep evidence that the seeds are destined to third countries and Member States authorities should be in a position to control this. On the contrary, the storage of the treated seeds linked with the offering for sale in the EU is prohibited under Article 2 of Implementing Regulation (EU) No 485/2013.

Outside the situation of "holding for the purpose of sale within the Community", storage of seeds is not regulated under Regulation (EC) No 1107/2009. Therefore the storage of seeds at farm level is not regulated under Regulation (EC) No 1107/2009 and thus not prohibited under Regulation (EU) No 485/2013. It is also not prohibited to return after 1st December 2013 stocks of treated seeds to the previous seller since the return of a product to the previous seller is not covered under the definition of "placing on the market". Finally, also the storage of treated seeds in view of their placing on the market for permitted uses such as use in greenhouse is allowed.

Is Article 4 of Implementing Regulation (EU) No 485/2013 (and therefore Article 46 of Regulation (EC) No 1107/2009) valid for treated seeds?

According to Article 4 of Implementing Regulation (EU) No 485/2013, "[a]ny period of grace granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire 30 November 2013 at the latest".

⁷ Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ L 139, 25.5.2013).

Article 46 is not applicable to treated seeds. In any case under Regulation (EU) No 485/2013 the placing on the market and use of the treated seeds should stop at the same time as the placing on the market and use of the plant protection products containing the 3 substances (1st December 2013).

Finally, it is important to highlight that from 1st December 2013 seeds cannot be treated anymore in the EU for whatever purposes in accordance with Article 3 and 4 of Implementing Regulation (EU) No 485/2013.

10. ARTICLE 50 (COMPARATIVE ASSESSMENT OF PPP CONTAINING CANDIDATES FOR SUBSTITUTION)

How will the evaluation of plant protection products containing substances listed as candidates for substitution take place?

Article 50(1) of Regulation (EC) No 1107/2009 requires a comparative assessment of a product containing a candidate for substitution. This assessment will be performed at national level after the zonal evaluation. The assessment is based on the national circumstances. If the result of the comparative assessment indicates that the conditions of Article 50(1) (a) to (d) are fulfilled, then Member States will not authorise the product.

For products falling under Article 50(2), Member States have the possibility to perform, under certain conditions, a comparative assessment for an application for authorisation of a product containing a substance which is not a candidate for substitution. If the result of the comparative assessment shows that the conditions of Article 50(1) (a) to (d) are fulfilled, then Member States will not authorise the product. In fact, the provisions of Article 50(2) are derogating (explicitly) from Article 36(2).

How Member States should assess an application for mutual recognition of products containing candidates for substitution?

Article 41(2) (b) of Regulation (EC) No 1107/2009 provides that when a Member State is examining a request for mutual recognition under Article 40 for a product containing a candidate for substitution, that Member State may grant an authorisation. This means that in the case of those products, there is no obligation to mutually recognise. There is no reference to the fact that in the frame of the mutual recognition the Member State must perform a comparative assessment. Article 40 does not make reference to the procedure of Article 50(1).

Therefore, Member States have the choice either to perform the comparative assessment or to accept or refuse the mutual recognition if products include a candidate for substitution.

Under Article 40 and 41 there is no derogation provided for the cases which are described in Article 50(2). As a consequence, for products not containing a candidate for substitution, there is no possibility to refuse the mutual recognition, unless Article 36(3) or the other exceptions of Article 41(2) would apply.

11. ARTICLE 58 (ADJUVANTS)

The question was raised whether a product containing a substance, which is approved or not-approved as an active substance, could still be an adjuvant in applications for which the substance is proven to have no efficacy.

Pursuant to Article 58, adjuvants should be authorised by MS. As there are no harmonised data requirements and assessment procedure for those products yet, MS can set their own data requirement and assessment procedure.

The definition of adjuvants in Article 2(3)(d) is making reference to co-formulants. Only a substance or a mixture of substances consisting of co-formulants can be authorised as adjuvants.

For co-formulants, some criteria are set in Article 27. Also a list of substances which cannot be used as co-formulants is to be adopted.

Active substances are defined in Article 2(2) as substances having general or specific action against harmful organisms or on plants, parts of plants or plant products.

Concerning adjuvants containing a non-approved substance:

There is nothing in the legislation which would bar the authorisation by a MS of an adjuvant containing a non-approved active substance. Nevertheless the MS should assess this product in accordance with Article 58 and the substances should comply with the criteria of Article 27 on co-formulants. Information submitted in a procedure that has led to a non-approval of an active substance should be taken into account.

Concerning adjuvants containing an approved active substance:

A product containing an active substance listed in Annex to Regulation 540/2011 is generally considered as a PPP and should be authorised according to Article 29 of R 1107/2009. Therefore it is the responsibility of the applicant to demonstrate that in this particular case the substance used as part of an adjuvant is not falling in the definition of an active substance (e.g. because of the (low) dose applied). The substance should not “have a general or specific action against harmful organisms or on plants, parts of plants or plant products”. This will be assessed by the MS. The MS should assess this product in accordance with Article 58 and the substance should comply with the criteria of Article 27 on co-formulants. Information submitted in a procedure that has led to the approval of an active substance should be taken into account.

12. ARTICLES 60 (LIST OF TEST AND STUDY REPORTS)

Confidentiality in the list of the test and study reports

Must secondary applicants for an authorisation of plant protection product be informed of the studies produced by the primary applicant? In case of a positive answer, which procedure should be used by the Member States to provide this information for the existing dossiers?

In order to comply with Articles 61 and 62 of Regulation (EC) No 1107/2009, it is necessary that secondary applicants for the authorisation of plant protection products are aware of the studies produced by the primary applicant in order to support the approval of the active substance contained therein. For this reason, Article 60 of this Regulation obliges the Member States to keep and make available to any interested party upon request the information listed in this Article. Similar provisions are also contained in Article 5(4) of Regulation (EU) No 1141/2010 on renewal of inclusion of a second group of active substances in Annex I to Directive 91/414/EEC.⁸

For dossiers submitted in view of an authorisation before the entry into force of Regulation (EC) No 1107/2009, Member States should follow a procedure which is in line with the provisions of Article 60(2) of this Regulation, whenever possible.

In no case, an entire list of test and study reports submitted in order to support the first authorisation and its amendment or renewal can be considered as confidential information.

13. ARTICLE 62 (SHARING OF TESTS AND STUDIES INVOLVING VERTEBRATE ANIMALS)

Tests and studies involving vertebrate animals

Article 62 of Regulation (EC) No 1107/2009 provides for specific rules concerning in particular the duplication and sharing of "tests and studies involving vertebrate animals".

Which experiments are considered as "tests and studies involving vertebrate animals" in the meaning of Regulation (EC) No 1107/2009?

The terms "tests and studies involving vertebrate animals" should be interpreted as experiments within the scope of Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes⁹ and, after 1 January 2013, within the scope of Directive 2010/63/EU on the protection of animals used for scientific purposes.¹⁰

Directive 86/609/EEC covers animals used in "experiments" defined as "any use of an animal for experimental or other scientific purposes which may cause it pain, suffering, distress or lasting harm".

According to Articles 1(5)(f) and 3(1) of Directive 2010/63/EU, if the study involves a procedure which will cause the animal pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by an introduction of a needle, this study is covered by Directive 2010/63/EU.

⁸ OJ L 322, 8.12.2010, p. 10.

⁹ OJ L 358, 18.12.1986, p. 1.

¹⁰ OJ L 276, 20.10.2010, p. 33.

Therefore, as far as monitoring studies are concerned, only the studies involving procedure(s) causing a certain level of distress, suffering or lasting harm will be covered. Coherently with this approach, also non-invasive interventions such as restraints and/or restrictions to housing/care are considered as "tests and studies involving vertebrate animals" if the minimum threshold of pain, suffering distress or lasting harm is reached.

Finally, with regard to studies approved and performed after 1 January 2013, it should be clear which studies are included in Article 62 of Regulation (EC) No 1107/2009 since the performance of the studies falling within the scope of Directive No 2010/63/EU will require a case by case project evaluation and authorisation prior to the work being allowed to start.

14. ARTICLE 63 (CONFIDENTIALITY)

Links between a producer or importer and the applicant or the authorisation holder

Article 63(2)(e) of Regulation (EC) No 1107/2009 states that the disclosure of the "links between a producer or importer and the applicant or the authorisation holder" "shall normally be deemed to undermine the protection of the commercial interests [...] of the individuals concerned".

Does this provision apply to parallel trade or is it limited to cases in which plant protection products are imported from third countries?

Article 63(2)(e) of Regulation (EC) No 1107/2009 does not apply to parallel trade since the Article makes reference to situations in which the products are imported from third countries. In fact, the term "importer" refers to the natural or legal person that imports the product within the EU and not to parallel traders. Moreover, parallel trade is often characterized by the absence of commercial links between the producer and the parallel trader.

If a parallel trader believes that the disclosure of relevant information might undermine his/her commercial interests, he/she can request that his/her information is treated as confidential as provided in Article 63(1) of Regulation (EC) No 1107/2009 and provide verifiable evidence.

15. ARTICLE 66 (ADVERTISING)

Meaning of the terms "warning phrases and symbols" stated in Article 66(6)

Article 66(6) of Regulation (EC) No 1107/2009 affirms that "[a]dvertising or promotional material shall draw attention to the appropriate warning phrases and symbols as laid down in the labelling".

Must the advertising of a plant protection product be accompanied by a specific expression established in advance or are these words flexible implying the possibility to summarize or paraphrase the content of the warning? Are there particular indications stating how to communicate warning sentences during TV or radio advertisement?

The term "warning phrases and symbols" in Article 66(6) of Regulation (EC) No 1107/2009 refers to phrases and pictogrammes required under Regulation (EC) No 1272/2008¹¹ concerning the classification, packaging and labelling of substances and mixtures as well as phrases required by Regulation (EU) No 547/2011 fixing labelling requirements for plant protection products.¹² The latter Regulation provides for standard words aimed at supplementing, in the field of plant protection products, the general rules of the Directive. In fact, Regulation (EU) No 547/2011 fixes standard phrases for special risks to human or animal health or to the environment (Annex II) and standard expressions for safety precautions aimed at protecting human or animal health or the environment (Annex III).

Article 66(6) does not impose to copy these phrases and pictograms as such on the advertisement. However, this provision should be read together with paragraph 1 of the same Article, which requires that every advertisement for a plant protection product must be accompanied by the following sentences: "Use plant protection products safely. Always read the label and product information before use". In order to comply with Article 66(6), the company should add a specific mention drawing the attention to warning phrases and pictograms. For instance, the sentence could warn the consumer to "[p]ay attention to the specific risk indications and follow the specific safety precautions on the label". Nevertheless, the warning phrases included in the EU legislation should not be summarised or paraphrased on the advertisement since this behaviour could be misleading.

As far as TV advertisement is concerned, these expressions could be placed in a note on the lower part of the screen, whereas during radio advertisement they will have to be said aloud in the course of the broadcast.

16. ARTICLE 67 (RECORD-KEEPING)

Addressees of the record-keeping duties

Article 67 of Regulation (EU) No 1107/2009 affirms that "[p]rofessional users of plant protection products shall, for at least 3 years, keep records of the plant protection products which they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used".

Who are the professional users of plant protection products? Who should keep records if plant protection products have been used not by owner of the farm, but by other subjects such as his employees? Who should keep records about plant protection products that have been used by companies providing service in plant protection or by their employees?

¹¹ Article 65 of Regulation (EC) No 1107/2009 refers to Directive 99/45/EC. However, as from 1 June 2015, Directive 99/45/EC is repealed and replaced by Regulation (EC) No 1272/2008, references to Directive 99/45/EC in Regulation (EC) No 1107/2009 should be interpreted as referring to Regulation (EC) No 1272/2008.

¹² OJ L 155, 11.6.2011, p. 176.

Article 3(1) of Directive 2009/128/EC on the sustainable use of pesticides¹³ affirms that "«[p]rofessional user» means any person who uses pesticides in the course of their professional activities, including operators, technicians, employers and self-employed people, both in the farming and other sectors".

As far as farmers are concerned, they should keep records of the plant protection products as provided for in Article 67(1) when the products are used by themselves, their employees or any third person on their behalf. Farmers have the responsibility to provide the relevant information from these records to the authorities on the basis of the second paragraph of Article 67(1).

According to Article 67(1), other professionals, such as municipalities and golf clubs, who use plant protection products in the course of their professional activities have to keep records of the plant protection products when the products are used by themselves, their employees or any third person on their behalf. On the basis of the same provision, these professionals should also provide information to authorities.

Furthermore, service companies applying plant protection products on an area as a service to farmers or other landowners have also the responsibility to keep such records and provide information to authorities according to Article 67(1). Therefore, it cannot be excluded that the same information is recorded two times, once by the farmer or the landowner and a second time by the service company.

Finally, Article 67(1) does not require that all landowners keep records of plant protection products which have been used on the areas which they own.

Addressees of the record-keeping duties – Meaning of the term "suppliers"

Article 67 of Regulation (EC) No 1107/2009 states that "[p]roducers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years".

The provision refers to "producers, suppliers, distributors, importers and exporters". Regulation (EC) No 1107/2009 defines only "producers" [Article 3(11)], Directive 2009/128/EC gives a wide definition of "distributor" [Article 3(2)], but the EU legislation on plant protection products does not clarify the meaning of the term "supplier".

In the absence of a definition of "supplier", it is thus necessary to analyse both the context in which this notion is mentioned and the objectives of Article 67 of the Regulation. This assessment shows that with the term "supplier" the legislator was referring to all the companies involved in production and distribution chain, including undertakings packaging, repackaging and/or labelling plant protection products.

First of all, this interpretation of the term "supplier" in Article 67 is coherent with the objective of the record-keeping duty which consists in "ensuring the traceability of potential exposure [and] increase[ing] the efficiency of monitoring and control" in order

¹³ OJ L 44, 14.2.2009, p. 1.

to improve "protection of human and animal health and the environment" (recital 44). If companies packaging, repackaging and/or labelling plant protection products were excluded from this obligation, these objectives would be much more difficult to achieve. The importance of having information about these companies is also confirmed by the fact that Annex I to Regulation No 547/2011 points out that the name and address of the person responsible for the final packaging and labelling shall be included clearly and indelibly on the packaging of plant protection products.

Moreover, it is reasonable to affirm that the legislator intended to address the Chapter VIII entitled "Control" of Regulation (EC) No 1107/2009 to the same companies, creating a link between Article 67 and 68 of the Regulation. Article 68 empowers the Commission to adopt a Regulation "set[ting] out provision for the controls, in particular for the packaging, labelling, storage, marketing, formulation, parallel trade and use of plant protection products". The fact that this Article explicitly mentions the "packaging" and "labelling" indicates that all companies in the distribution chain fall within the scope of Chapter VIII.

Finally, the intention of the EU legislator to address the rules on the record-keeping to companies at all stages of the production and distribution chains of pesticides is strengthened also by recital 46 of Regulation (EC) No 1107/2009 according to which "Regulation (EC) No 882/2004¹⁴ [...] provides for control measures for the use of plant protection products at all stages of the production of food, including record-keeping on the use of plant protection products. Similar rules on monitoring and controls relating to the storage and use of plant protection products not covered by Regulation (EC) No 882/2004 should be adopted by the Commission".

In the light of these considerations, the term "supplier" in Article 67 of Regulation (EC) No 1107/2009 must be interpreted as including also other companies in the distribution chains, such as companies packaging, repackaging and/or labelling plant protection products.

¹⁴ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).