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Technical guidance on the interpretation of points 3.6.3. to 3.6.5, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use

DRAFT - May 2015

This document has been conceived as a guidance document. It does not represent the official position of the European Commission nor does it intend to be legally binding. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

Contents

1. Introduction

Annex II of Regulation (EC) No 1107/2009 provides in its points 3.6.3 / 3.6.4 / 3.6.5 (human exposure) and point 3.8.2 (environment), that active substances, safener or synergists, classified on the basis of Regulation (EC) No 1272/2008 as carcinogen category 1A or 1B or toxic for reproduction category 1A or 1B, or having endocrine disrupting properties which may cause adverse effects on humans, cannot be approved "*unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible*". The purpose of this document is to provide guidance regarding the interpretation of this wording, i.e. "negligible exposure".

In particular, this guidance document describes the rationale recommended to be followed during the approval/non approval decisions of active substances, safeners, and synergists under Regulation (EC) No 1107/2009 concerning points 3.6.3 to 3.6.5 and 3.8.2 of Annex II. Substances approved considering these provisions will be listed in accordance with Article 24 of this Regulation as candidates for substitution. Therefore, they would be approved for a period not exceeding 7 years (Article 24), evaluations for authorisations for plant protection products containing such active substances would be subject to comparative risk assessment (Article 50)[1] and Member States may derogate from mutual recognition (Article 41(2.b))[2].

When performing risk assessments in the context of Regulation (EC) No 1107/2009, applicants, Member States authorities evaluating the corresponding applications, as well as the European Food Safety Authority (EFSA) may refer to this guidance document in order to address in a targeted way the information needs of risk managers.

This guidance document was adopted in accordance with Article 77 of Regulation (EC) No 1107/2009. Based on discussions between experts appointed by the EU Member States a document was drafted, which was further consulted with relevant stakeholders and at the Standing Committee on Plants, Animals, Food and Feed.

[1] See also Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009SANCO/11507/2013 rev. 12, 10 October 2014, available at http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/comparative_assessment_substitution_rev_1107-2009.pdf

[2] See also Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009, SANCO/13169/2010 rev. 5, 11 March 2011.

2. Context and background

Points 3.6.3 / 3.6.4 / 3.6.5 (human exposure) of Annex II to Regulation (EC) No 1107/2009 state that "[a]*n active substance, safener or synergist shall only be approved, if … it is not or has not been classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen* category 1A or 1B, [toxic for reproduction category 1A or 1B, or it is not considered to have endocrine disrupting effects that may cause adverse effects in humans], *unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005*" (emphasis added). In addition, point 3.8.2. of the same Annex states that "[a]*n active substance, safener or synergist shall be approved only if … it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible*" (emphasis added).

The fact that Regulation (EC) No 1107/2009 is providing for the approval of active substances *if exposure is negligible*, implies that a zero release policy is not intended by the legislator and that a certain – negligible - exposure to humans or non-target organisms could be tolerated. For instance, if a zero release policy would be the intention of the legislation, points 3.6.3 to 3.6.5 would not be so clearly different from point 3.6.2 of the same Annex, where no reference to negligible exposure is made indicating a zero release policy. This is in particular evident by the fact that residues, although at the default level set in accordance with Article 18 of Regulation (EC) No. 396/2005, are allowed under points 3.6.3 to 3.6.5, but not under point 3.6.2.

In addition, the legislation is not defining some of the qualifying terms given in relation to the exposure to the active substance (i.e. 'negligible', 'closed systems' and 'excluding contact with humans'). A technical interpretation of these definitions is needed, in particular under consideration that some of these qualifiers are technically difficult to achieve (see Section 2.2). Also other technical interpretations concerning points 3.6.3 to 3.6.5 of Annex II are given in Section 2.2.

As a consequence of this situation, a working definition of "negligible exposure" is proposed in this guidance, which will allow implementing the provisions of Regulation (EC) No 1107/2009 in a consistent way when taking decisions of approval of active substances, or when authorising plant protection products.

2.1. Approval criteria for decision making under Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 introduced, in Article 4(1) read in combination with points 3.6.2 to 3.6.5 and point 3.7 of Annex II, hazard-based criteria (often called "cut-off" criteria) for the approval of active substances, safeners and synergists into the authorisation procedure of plant protection products in the European Union. Although these criteria are based mainly on hazard properties, some of these provisions allow for the approval of active substances, safeners or synergists in case of negligible exposure to these substances in a plant protection product under realistic conditions of use is proven.

The approval criteria refer to different properties of the active substance (i.e. genotoxicity, carcinogenicity, reproductive toxicity, endocrine disrupting properties that may cause adverse effects on humans and/or non-target organisms, persistence in the environment, bioaccumulation) and cross-reference themselves, leading to a complex decision-making scheme. Different situations linked to the different chemical properties of the active substances can be distinguished, which are inter-linked in a tiered way (see also Figure 1 below):

1. Substances which are classified (or are to be classified) in accordance with Regulation (EC) No 1272/2008 as **mutagen** category 1A or 1B (point 3.6.2 of Annex II) shall **not be approved**. The same applies to substances which are considered to be **persistent organic pollutant (POP)** (point 3.7.1 of Annex II), **persistent, bioaccumulative and toxic (PBT)** (point 3.7.2 of Annex II), and/or **very persistent and very bioaccumulative (vPvB)** (point 3.7.3 of Annex II). Annex II to Regulation (EC) No 1107/2009 does not provide for the possibility to approve these active substances if negligible exposure is demonstrated.

2. Substances which are classified (or are to be classified) in accordance with Regulation (EC) No 1272/2008 as **carcinogen** category 1A or 1B (point 3.6.3 of Annex II), or **toxic for reproduction category** 1A or 1B (point 3.6.4 of Annex II) can be **approved as candidates for substitution[3] provided "*negligible exposure to the active substance in a plant protection***

[3] Article 24(1) of Regulation (EC) No 1107/2009 reads: "*An active substance complying with the criteria provided for in Article 4 shall be approved, for a period not exceeding seven years, as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. By way of derogation from Article 14(2), the approval may be renewed once or more for periods not exceeding seven years.*" Point 4 of Annex II point out that "[a]*n active substance shall be approved as a candidate for substitution pursuant to Article 24 where any of the following conditions are met:*

…

- it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3,

- it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4,

— if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that

product under realistic conditions of use is demonstrated*, that is the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005*" (emphasis added). Also substances which are considered to have **endocrine disrupting properties that may cause adverse effects in humans and/or on non-target organisms** (points 3.6.5 and 3.8.2 of Annex II) can be approved as candidates for substitution provided that negligible exposure under realistic conditions of use is demonstrated. For the dietary route of exposure a clear reference to a default value is made in the legislation (Regulation (EC) No 396/2005) as reference to exposure.

3. Some substances assessed under the previous point may be approved on the basis of Article 4(7) of Regulation (EC) No 1107/2009 "*to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods*". Such derogation can be granted "*on the basis of documented evidence included in the application*" and the active substance can be approved "*for a limited period necessary to control that serious danger* [to plant health] *but not exceeding five years*", provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. Derogations under Article 4.7 are not applicable to substances classified (or to be classified) as carcinogens categories 1A or as 1 B without a threshold, or as toxic for reproduction category 1A.

Derogations on the basis of Article 4(7) are mentioned here for information only as they are outside the scope of this guidance document.

may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5."

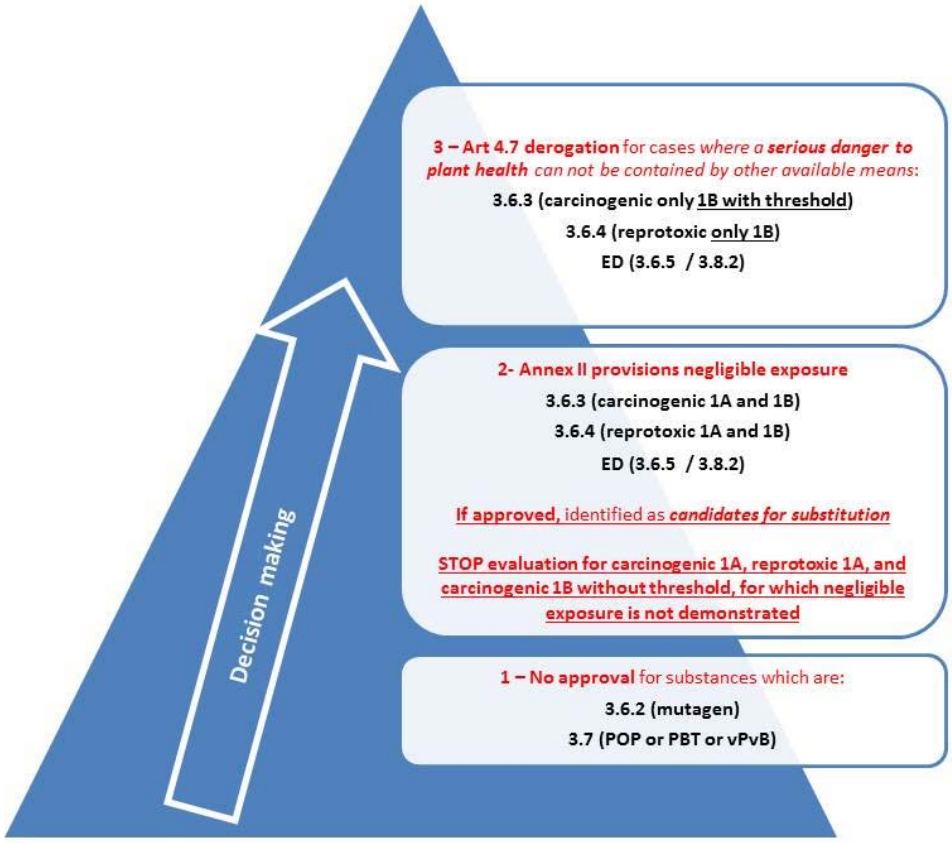

Figure 1: Decision making scheme for substances with mutagenic or carcinogenic properties, substances which are toxic for reproduction, substances with endocrine disrupting properties, as well as persistent and/or bioaccumulative substances, as mentioned in Regulation (EC) No 1107/2009 in Article 4.1, Annex II points 3.6.2 to 3.6.5 and point 3.7, and Article 4.7 (which refers in addition to point 3.8.2.). Please note that Article 4.7 derogations are not covered by this guidance document.

2.2. Interpretation of terminology mentioned in Annex II, points 3.6.2 to 3.6.5 and 3.8.2

The terms "*active substance …* [which] *is … classified*" designate a substance for which a harmonised classification is adopted under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures and which are listed in Annex VI to that Regulation.

The terms "*active substance … [which] has … to be classified'* designate TO BE COMPLETED (Discussion on-going).

The terms "*active substances [which] … is … considered to have endocrine disrupting properties that may cause adverse effect in humans*" and/or "*on non-target organisms*" (respectively point 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009), designate substances which are identified according to the interim criteria specified in point 3.6.5 of Annex II of this Regulation, pending the adoption of the criteria provided for in the same Regulation.

Moreover, Regulation does not give a definition of some of the qualifying terms (i.e. 'closed systems', 'negligible', and 'excluding contact with humans') given in relation to negligible exposure. A consideration and practical interpretation of some of these qualifying terms is presented below.

- "*Closed systems*": Points 3.6.3 to 3.6.5 of Annex II to Regulation (EC) No 1107/2009 points out that "*the exposure … is negligible*" when "*the* [plant protection] *product is used in closed systems*". Considering human exposure, it is not possible to demonstrate 'closed systems' throughout the entire life-cycle of a plant protection product. In fact, often cited examples of 'closed systems' relate to a certain phase in the life of a product. For instance, a bulk transfer system may be perceived as 'closed' during mixing and loading but not during application; a bait-box may be perceived as 'closed' during most of the use phase but release into the environment can occur via secondary poisoning of predators or on disposal of the container; high-tech greenhouses, usually perceived to be 'closed systems', may still result in exposure of operators during mixing and loading or workers on re-entry and leakages into the environment are also possible (see EFSA, 2014[4]). Even 'closed systems' supported by measurements at the Limit of Detection (LOD) or Limit of Quantitation (LOQ) are not synonymous with no exposure as the active substance, safener or synergist could still be present at levels which can't be detected using current analytical methods. For these reasons the following definition is considered appropriate: '*Equipment and procedures designed to reduce as far as technically possible the escape of an active substance, safener or synergist into the environment either during or after the use of the plant protection product*.'

- 'Negligible': 'Negligible' is not equal to zero (see also Section 2) and is defined in the Oxford English Dictionary as "so small or unimportant as to be not worth considering; insignificant". For risk assessment purposes 'negligible' can be considered to be a level so small that it does not appreciably add to the risk and can safely be ignored.

- "*Excluding contact with humans*": The legislator clearly set provisions regarding dietary exposure when stating *"… where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article*

[4] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

18(1)(b) of Regulation (EC) No 396/2005" (emphasis added). However, in the context of non-dietary exposure Regulation (EC) No 1107/2009 does not give a clear indication concerning the scope of the non-dietary risk assessment and clarifications are needed for consistency, in particular because it is impossible to demonstrate the existence of "closed systems" (see previous paragraph). Therefore, it is necessary to assess if exposure is negligible in the context of non-dietary exposure. For the purposes of the human exposure non-dietary risk assessment related to different human populations need to be considered (i.e. operators, bystanders/residents and workers coming into contact with the concentrate or diluted product and/or surface residues). In addition, exposure to be assessed is considered to relate to direct human contact via all relevant routes of exposure (dermal, inhalation and oral). Human contact may arise, albeit at very low levels, from the subsequent transport and degradation of the active substance, safener or synergist in the environment (e.g. contamination of groundwater, long range transport in air or via the food chain) but is considered outside the scope of the non-dietary risk assessment.

2.3. Classifications under Regulation (EC) No 1272/2008: relevant routes of exposure and classification of mixtures in the context of the approval criteria

The provisions of Annex II, points 3.6.3 to 3.6.5, to Regulation (EC) No 1107/2009 are based on the classifications that the substances subject to the assessment under Regulation (EC) No 1107/2009 could receive in a separate assessment process conducted pursuant to Regulation (EC) No 1272/2008 (carcinogenic 1A, 1B, 2; toxic for reproduction 1A, 1B, 2).

Annex I of Regulation (EC) No 1272/2008 gives technical details regarding the classification of 1) hazardous substances and 2) mixtures which contain classified hazardous substance, in particular:

- Some substances are only classified (i.e. hazardous) for certain routes of exposure provided enough evidence is available during the classification process (see Table 3.6.3 and 3.7.3 of Annex I of Regulation (EC) No 1272/2008). The relevance of these non-relevant routes of exposure for the assessment of approval criteria under Regulation (EC) No 1107/2009 might be considered on a case by case basis.

- Under Regulation (EC) No 1272/2008, mixtures containing classified substances are not classified as hazardous under certain conditions specified in Annex I (e.g. when the concentration of a substance classified as "carcinogenic category 1B with a threshold" is lower than 0.1 %, see also Tables 3.6.2 and 3.7.2 of Annex I).

Negligible exposure to an active substance in a plant protection product under realistic conditions of use would need to be proven in any case for substances falling under Regulation (EC) No 1107/2009 in Annex II points 3.6.3 to 3.6.5.

3. Negligible exposure to humans

On the basis of the fact that negligible exposure does not equal zero (see also Section 2), procedures need to be set in order to ensure consistency during the decision making regarding approval / non approval of active substances under Regulation (EC) No 1107/2009, which differ between the dietary and non-dietary routes of exposure.

3.1. Dietary exposure

The legislator set clear provisions regarding dietary exposure when stating in points 3.6.3, 3.6.4, 3.6.5 of Annex II to Regulation (EC) No 1107/2009 that exposure is negligible *"where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005*". The default value is initially set at 0.01 mg/kg and shall not be exceeded, but it might be changed to the LOQ according to Article 18(1)(b) of Regulation (EC) No 396/2005. It is recommended to ensure the validated analytical methods are available for at least the four main plant matrix groups: dry (high protein/ high starch content), high water, high oil, and high acidic content (SANCO/825/00 rev 8.1; 16/11/2010).

The condition set in points 3.6.3, 3.6.4, 3.6.5 of Annex II to Regulation (EC) of 1107/2009 does not prejudge the application of Regulation (EC) No 396/2005, in particular the verification of the safety of these default maximum residue limit (MRLs) following the normal agreed procedures.

3.2. Non-dietary exposure

All non-dietary exposure groups (operators, workers, bystanders and residents) included in the EFSA Guidance Document on assessment of exposure (EFSA, 2014[5]) need to be considered. This Guidance Document is providing a harmonised risk assessment and a calculation tool covering these groups. The application methods and exposure scenarios not included in the EFSA guidance document would need to be considered on a case by case basis and supported by a robust scientific case and/or data, including if applicable exposure studies.

In order to address non-dietary routes of exposure, two aspects are to be considered:

[5] EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

1) Available risk mitigation measures should be applied for the proposed uses of the plant protection product, with the aim to minimise exposure of humans to the active substance as much as technically possible;

2) A decision making framework, which includes risk calculations and consideration of exposure studies if applicable, is needed in order to verify if the scenarios of use proposed are leading to negligible exposure.

These two aspects are explained in further details in the subsections below.

3.2.1. Measures to achieve negligible exposure

The measures taken to minimise exposure of humans to the active substance as much as technically possible shall consider all relevant routes of exposure for the different exposed groups, i.e. operators, workers, bystanders and residents.

In general terms, in order to minimise exposure, it is recommended only to authorise professional uses of plant protection products containing active substances with properties falling under the criteria laid down in points 3.6.3, 3.6.4 and/or 3.6.5. A non-exhaustive list of risk mitigation measures which contribute to achieve reduced exposure of humans to PPP during the different use-phases (such as mixing/loading, cleaning, application) is provided for in the Annex to this guidance document.

Applicants are expected to provide details of the relevant risk mitigation measure(s) available to reduce exposure as far as possible below the stated threshold (see below).

3.2.2. How to verify that exposure is negligible?

Non-dietary negligible exposure can be assumed where levels to which humans are exposed are equal to or lower than natural background levels in the environment, i.e. excluding background levels which have been increased during time by anthropogenic activities and/or which are considered to be a concern.

As stated above in Section 3.2 of this guidance document, for decision-making under consideration of negligible exposure under realistic proposed conditions of use, in a 1st tier, the EFSA guidance on exposure assessment (EFSA, 2014) including, where applicable, the calculator developed by EFSA, should be used in order to allow a harmonised risk assessment . An additional and protective

"threshold" to the relevant toxicological reference value (e.g. AOEL) is set. The level of this additional safety has been decided by risk managers to be XXX.[6]

As a 2nd tier, the Margin of Exposure to the study critical for the relevant classification for under Regulation (EC) No 1272/2008 could be applied. As Margin of Exposure the ratio of the no-observed-adverse effect level (NOAEL) for the critical effect (e.g. carcinogenicity or reproduction toxicity), corrected for oral absorption to ensure systemic exposure, to the estimated or actual exposure should be considered. For the purpose of demonstrating negligible exposure, a sufficient safety margin (at least 1000) is necessary. Further guidance on this 2nd tier approach may need to be developed in future.

The rationale behind this 2nd tier approach is that there is often a higher margin of safety than the standard factor of 100 when comparing the NOAEL from the study critical for classification for carcinogenicity or reproduction toxicity (fertility or development) under Regulation (EC) No 1272/2008 and the toxicological reference values set under Regulation (EC) No 1107/2009 (e.g. acute reference dose (ARfD), acceptable operator exposure level (AOEL), or Acceptable daily intake (ADI)), resulting in higher margins of safety which may differ between active substances.

4. Negligible exposure to non-target organisms in the environment

According to Regulation (EC) No 1107/2009 negligible exposure to non-target organisms in the environment needs to be defined only for substances considered to have endocrine disruptors (cf. point 3.8.2 of Annex II to this Regulation).

In general terms, for environmental risk assessments the protection goals of the legislator are recommended to be set at population level in accordance with EFSA (EFSA, 2010[7]). This approach would imply that an exposure assessment would need to consider a temporal and geographical scale which is according to a population level protection goal (EFSA, 2010).

This section is expected to be further detailed at later versions of the guidance document.

[6] Applying this concept implies accepting the concept of threshold and of lead toxicity. In cases new development in science are available, the method used or the threshold set may be revised.

[7] EFSA 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10):1821. [55 pp.] doi:10.2903/j.efsa.2010.1821. Available online: www.efsa.europa.eu/efsajournal.htm

5. Decision making process including conditions of approval

Regarding dietary exposure, Annex II to Regulation (EC) No 1107/2009 (points 3.6.2 to 3.6.5) specifies the conditions under which negligible exposure is assumed (see Section 3.1 above for more details). Since these conditions are a precondition for approval of substances in accordance with Article 4 of the Regulation read in combination with these points, it is recommended to assess them in the first instance before proceeding with the assessment of non-dietary exposure routes. If these conditions are not met, derogation can be granted on the basis of Article 4(7) of Regulation (EC) No 1107/2009 provided that the requisites laid down in this Article are met.

In the case the assessment of the application for approval of the substance fulfilling the properties mentioned before (carcinogenic category 1A or 1B, toxic for reproduction category 1A or 1B, endocrine disrupting properties) concludes that there is negligible exposure (points 3.6.3 / 3.6.4 / 3.6.5 of Annex II of Regulation (EC) No 1107/2009), the substance will be approved as a candidate for substitution in accordance with Article 24 of Regulation (EC) No 1107/2009 read in combination with point 4 of Annex II of Regulation (EC) No 1107/2009. In addition, among the conditions and restrictions of Article 6 of Regulation (EC) No 1107/2009, the Regulation approving (or renewing the approval of) the active the substance have to specify that negligible exposure have to be demonstrate for any new use of a plant protection product containing this substance. Furthermore, restrictions on the use scenarios of a product where exposure has been demonstrated negligible might be considered (Article 6 of Regulation (EC) No 1107/2009). For instance, in general only professional uses of PPPs containing active substances with properties falling under points 3.6.3, 3.6.4, and/or 3.6.5 should be authorised. These measures will contribute to ensure that human exposure is as at the lowest level that can be achieved based on the available technologies.

6. Annex: non exhaustive list of professional use risk mitigation measures which contribute to reduce exposure of humans to PPPs

This Annex provides a non-exhaustive list of risk mitigation measures relevant for professional use of PPPs, which may contribute to reduce exposure of humans to plant protection products during the different use-phases.

The listed examples provide for a variable reduction in exposure during the different phases of the use of a plant protection product. The different measures may be combined for developing representative use scenarios, which may facilitate negligible exposure under realistic conditions of use. In any case, risk calculations supported by data and consideration of exposure studies if applicable, are needed in order to demonstrate that exposure is reduced and to verify if the scenarios of use proposed are leading to negligible exposure.

Personal protection equipment (PPE) may be considered when proposing representative use scenarios. However, it should be noted that the availability of appropriate PPE, the level of training of operators in their correct use, maintenance and replacement is likely to vary between European Member States. As a consequence Member States may implement different approaches regarding this risk mitigation option when considering the authorization of plant protection products at a national level.

Further, it needs to be noted that the availability of data which supports the different scenarios varies as summarized below, referring to EU-wide accepted data.

- A: No data available
- B: Exposure assumed to be low. Quantitative data will need to be provided.
- C: Some quantitative data available
- D: Quantitative data available
- E: No exposure expected if completely automated but no data on e.g. cleaning & maintanance available

Operators

- Mix/loading:
  - baits (ready to use)[B]
  - water-soluble packages[B]
  - closed transfer systems (liquids) - equipment designed and manufactured to be used to move agricultural chemicals from their original container into a sprayer tank, and to accurately measure the volume of chemical being transferred with compatible packaging[B]
  - closed transfer systems (solids and liquids)– container designed to be attached directly to the application device where measuring of dose is integral to the application device[B]
  - packaging modifications (e.g. removal of secondary foil seal, integral measuring systems such as 'squeeze to fill')[A]
  - maximize filler opening and stability of application equipment when placed on the ground (e.g. some backpacks for use with spot guns or CDA lances)[A]
  - induction, stirring or recirculating systems which avoid foaming[A]
  - use of stationary LEV (local exhaust ventilation) systems in indoor situations[A]

- Application
  - baits (ready to use and pre-prepared disposable bait stations)[B]
  - automatic application systems (e.g. gantry sprayers or misting equipment in glasshouses, automated dipping or drenching equipment)[E]
  - minimized run-off from treated material (e.g. electrostatic spraying booth for forestry transplants or foam treatment equipment for onion sets)[A]
  - closed cabins, self-flushing filters, hydraulically operated boom, built in tank washing systems[C]
  - drift reduction technology including 'low drift' nozzles[D]
  - direct injection systems (e.g. tree injection)[A]
  - in-furrow application[A]
  - use of LEV (local exhaust ventilation) systems in indoor situations[A]

- Cleaning
  - self-cleaning systems[A]
  - baits (ready to use, pre-prepared disposable bait stations)[A]

Workers

- baits (well concealed and protected)[B]
- pre-emergence application[B]
- direct injection systems (e.g. tree injection)[B]
- restricted re-entry intervals / waiting periods[C]
- mechanically harvested crops and automated sorting/grading devices[B]
- automated bagging and loading[B]

Bystanders and residents

- enclosed treatments (e.g. glasshouses and grain stores where minimal venting and leakage can be attained)[C (env. data available, to be adjusted for bystanders/residents)]
- baits (well concealed and protected)[B]
- direct injection systems (e.g. tree injection)[B]
- drift reducing nozzles (e.g. twin-fluid nozzles, air-induction nozzles, pre-orifice nozzles)[D]
- drift reducing pesticide application equipment (e.g.rotary atomizers, air assistance for field crop sprayers, shrouded boom sprayers for sports turf and other amenity areas, recirculating tunnel sprayers for spraying fruit bushes and trees[, A]
- lowest possible boom height, forward speed and spray pressure[A]
- deflectors on vacuum pneumatic seed drills and other devices designed to reduce dust drift.[B]