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Technical guidance for applicants regarding the notification of potentially harmful or unacceptable effects under Article 56 of Regulation (EC) No 1107/2009.

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1. PURPOSE

This guidance document describes the process for the identification, assessment, communication and archiving of notifications under Article 56 of Regulation (EC) No. 1107/2009. Its purpose is to propose terminology and an approach that can be used by Industry to fulfil its obligations under the article. It is recommended that authorisation holders develop their mandatory reporting policies on this basis.

The full text of the article is included in the annex for convenience. Quotations from the article are shown in italics in the text below.

This document does not substitute for the thorough reading of all articles mentioned and in particular Article 56.

2. INTRODUCTION

Article 56 of Regulation 1107/2009 requires the notification to Member States of information on *potentially harmful* effects which suggests that criteria for the approval of an active substance or authorisation of a plant protection product (PPP) are no longer met.

The article refers to the plant protection product itself, its active substance(s) and metabolites, and any safener, synergist or co-formulant contained in the product. It requires that the authorisation holder records and reports *suspected adverse reactions* related to the use of the plant protection product, including effects on or situations of:

- human or animal health,
- ground water,
- plants or plant products,
- the environment,
- unexpected poor control, resistance, damage to the treated crop
- regulatory decisions by non-EU agencies and organizations if relevant for EU regulatory decisions

The objective of this Article is, through the reporting of potentially adverse effects, to identify areas where the approval/authorisation criteria and conditions may no longer be complied with. This Article therefore applies to situations where the product is/has been used as authorised. The consequences of other situations such as illegal use or accidents are not explicitly covered and will not be addressed in this document. It is up to each authorisation holder to decide whether or not to report them the authorities.

3. CRITERIA FOR NOTIFICATION UNDER ARTICLE 56

The requirement to notify applies to information that meets any of the following criteria:

- ➔ potentially harmful or unacceptable effects on human or animal health or on groundwater or
- ➔ potentially unacceptable effects on plants or plant products or the environment or
- ➔ decisions or assessments by international organisations or by public bodies which authorise plant protection products or active substances in third countries.

and that information suggests that the product no longer complies with the criteria for the approval of active substances (Article 4) or the authorisation of plant protection products (Article 29).

It is ECPA's opinion that the authorisation holder has to comply with these requirements only in situations where its products have been used under authorised conditions.

In addition, authorisation holders must report to Member States annually indications of *lack of efficacy, […] development of resistance and any unexpected effects on plants, plant products or the environment.* "Lack of efficacy" is not defined by the regulation but can be interpreted as poor control that cannot be explained by normal agronomic, application or climatic parameters which are referenced on the product label.

The authorisation holder should document and evaluate the information and circumstances of each case and assess whether the PPP should no longer be considered as fulfilling the criteria and conditions of its authorisation. If it is the Company's conclusion that the information meets one or more of the above criteria, it must notify the finding to the Member State(s) which have granted authorisations and provide an assessment. Whether or not the effect is notified, records of the decision making process should be held in the Company's records.

4. SCOPE OF THE INFORMATION REQUIRED

Any of the following should lead an authorisation holder to consider reporting:

1. **Human incidents** – all adverse human incidents suspected of being associated with the use of PPPs authorised in one or more Member States and which are brought to the attention of the authorisation holder. The likelihood that effects are related to a specific PPP should be assessed on the basis of available data.
2. **Animal incidents** should be reported, whether widespread or not.

3. **Groundwater contamination**, i.e. detections (active substances or relevant metabolites) in EU Member states above the established EU trigger (0.1 µg/L for active substances), from company or official water monitoring programs whose results are not publicly available.
4. **Environmental impact** – potentially harmful or unacceptable effects on soil, water or air quality, aquatic ecosystems, non-target organisms (e.g. beneficial arthropods, terrestrial vertebrates) or other environmental compartments/systems, and which may result from the authorised use of the PPP and suggest that it may no longer comply with the conditions of authorisation.
5. **Lack of efficacy** – situations showing poor control when the PPP is used according to authorised conditions of use and label directions.
6. **Unacceptable effects on plants** – situations showing unexpected and significant damage to the treated crop when the PPP is used according to authorised conditions of use and label directions.
7. **Development of resistance** – situations suggesting or demonstrating the development of resistance by the target organism, reported through annual publications of international resistance management organisations [IRAC (www.irac-online.org), FRAC (www.frac.info) and HRAC (www.hracglobal.com)], company resistance monitoring programs or any other source that brought the information to the Company's attention.
8. **New data**: unsubmitted data on the active substance or formulated product from regulatory and technical studies and reports, which demonstrate that the product no longer complies with the criteria for the approval for the active substance (Article 4) or the authorisation of the PPP (Article 29).
9. **Official Decisions or assessments by international or public bodies** which may be relevant to the regulatory approval/decision in the EU or individual Member States and which are brought to the attention of the authorisation holder. The origin of such decisions may be non-EU regulatory agencies but also international organizations involved in the evaluation of pesticides such as FAO and WHO. Examples may include the setting of an ADI by the JMPR at a level significantly lower than in the EU based on new data not yet evaluated in the EU.

Article 56.2 requires that the notification includes an assessment of whether and how the approval/authorisation criteria specified in Articles 4, 27 or 29 may no longer be complied with. It is ECPA's recommendation that, where the assessment concludes that these criteria continue to be met despite the new data, the authorisation holder anyhow retains the assessment in its company files for possible future justification.

5. PROCEDURE

5.1. Forms and sources of potentially reportable information

Potentially reportable information may come to the attention of the Company under and from any of the following forms and sources (non-exhaustive):

- Regulatory and technical studies and reports, before or after approval/authorisation, which change the end points or conclusions drawn from submitted data.
- Post-authorisation data suggesting adverse effects on humans or the environment, reported by company 'field staff', customers, users, distributors, company regulatory or stewardship personnel, *etc.*
- Regulatory or scientific decisions or data from international organisations, regulatory authorities, public bodies or NGOs, within or outside the EU (further information and clarification should be sought from the reporting person/body to the extent possible).
- Peer reviewed scientific literature (data must be scientifically robust to justify reporting).

Authorisation holders may wish stay alert on possible adverse effects from other sources on an *ad hoc* basis.

5.2. Interpretation of information and data to decide whether they are reportable

A positive answer to any question below should lead the authorisation holder to consider reporting:

1. Is the information new (never reported and never used for regulatory purposes before) and does its nature change the current basis upon which the substance is approved or the product authorised?
2. Was it previously not reported because it was not subject to notification requirements?
3. Is the information sufficiently robust and complete to identify adverse or unacceptable effects without further investigation or data?
4. Is it related to an authorised use? Were label directions followed?
5. Does it result in potentially adverse/harmful effects on humans, animals, other non-target organisms or ground water?
6. Does it result in potentially unacceptable effects on plants or plant products or the environment?
7. Most importantly, does it affect the regulatory decision and the conditions of approval/authorisation?

5.3. Timing of notification of adverse effects

Authorities must be notified *immediately*

- If the information suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4. This includes data from peer reviewed scientific literature, if scientifically robust and relevant to the approval/authorisation.
- Of Regulatory decisions from non-EU agencies or organizations, which were taken on the basis of new data that had not yet been evaluated in the EU.

"*Immediately*" is usually interpreted as meaning as soon as practicable or without undue delay. This should usually be within 14 days of the registration holder becoming aware of the information but should allow the opportunity to adequately review the relevance of such data.

Authorities must be provided *annually* with information suggesting poor control (lack of efficacy), development of resistance and any *unexpected effects on plants, plant products or the environment*. It is suggested to report at the end of the calendar year.

5.4. To whom should the information be sent?

The information needs to be sent to Regulatory Authorities of all Member States in which the product(s) was authorised.

5.5. Evaluation of the information and subsequent action

The submitted information will be evaluated by the zonal Rapporteur Member State(s) who will i) evaluate if the criteria or conditions of approval/authorisation are still fulfilled ii) inform the other Member States and the Commission and iii) decide whether to amend or cancel authorisations for its own territory. The other Member States may adopt interim protective measures until they have to reflect the decision of the zonal rapporteur (PPP) or of the Commission (active substance).

6. Disclaimer

ECPA, its representatives and members cannot be held responsible, on the basis of this document, for failure to comply with the provisions of Regulation 1107/2009.

Annex

Article 56

Information on potentially harmful or unacceptable effects

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

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

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

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

2. The notification shall include an assessment of whether and how the new information would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

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

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

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