



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

SANCO/10087/2013 rev. 0

1 February 2013

**WORKING DOCUMENT
ON EMERGENCY SITUATIONS ACCORDING TO ARTICLE
53 OF REGULATION (EC) No 1107/2009**

**COMMISSION STAFF WORKING DOCUMENT – DOES NOT NECESSARILY
REPRESENT THE VIEW OF THE COMMISSION SERVICES**

This document has been conceived as a working document of the Commission Services, which was elaborated in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

1. Introduction

This guidance lays down the procedure for Member States when granting an authorisation under Article 53. This includes the use of a notification form that provides the necessary transparency and clarification.

The agronomic and environmental field situation in respect of plant protection continues to present emergency situations that pose a danger to plant production and ecosystems that cannot be contained by any available reasonable means as cited in the recital 32¹. These emergencies demand quick and effective responses that cannot await the outcome of the normal authorisation process. For this reason Regulation (EC) No 1107/2009 provides in Article 53 a possibility: *'in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products for limited and controlled use, where such a measure appears necessary because of a danger which cannot be controlled by any other reasonable means.'*

The purpose of the Regulation is to ensure a high level of protection for both human and animal health and the environment which prevails over the interest of crop production, and to improve the functioning of the internal market through the harmonisation of the rules for placing plant protection products on the market, while improving agricultural production. However, recital 32 recognises that certain exceptions are possible, and this materialises in Article 53. Use of this Article should be exceptional, and restricted to cases of obvious dangers to plant production or ecosystems that cannot be contained by any other reasonable means. It shall not jeopardize the before mentioned purposes of the regulation and shall be proportional in its sense. Member States should demonstrate, based on the application received, that the use authorised is justified in this sense and share detailed information about the situation and any measures taken to ensure consumer safety (see Annex) with the other Member States and the Commission, which may consult the European Food Safety Authority (EFSA). It may be helpful to develop further criteria to define emergency situations in the light of experience with this guidance in the medium term.

Finally, this guidance recognizes that emergency situations indicate the imminent need to make better use of alternatives already in place, e.g. those covered in Annex III of Directive 128/2009, and to develop solutions and alternatives. By thorough analysis and consideration, particularly in the case of repeated occurrence of a specific emergency situation, alternative approaches need to be achieved for the future and incentives considered to improve the use of existing alternatives. Consequently, this guidance highlights research as a general principle to be strengthened in order to limit the use of plant protection products under Article 53 to special circumstances in the long term, ensuring by this a high level of protection of human and animal health and the environment and recognising the precautionary principle laid down in Article 1 of Regulation No. 1107/2009.

It is important that member States uphold the integrity of the authorisation system. In particular, emergency authorisations should not be granted as a routine alternative to extensions of use or other forms of standard authorisation.

This working document applies to applications for emergency authorisations submitted after 11 February 2013.

¹ In exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production or ecosystems which cannot be contained by any other reasonable means. Such temporary authorisations should be reviewed at Community level

2. Use of Article 53

2.1. Use of a plant protection product containing approved active substance(s)

In many cases it is possible to solve an emergency situation by permitting the use of a plant protection product containing an approved active substance already authorised for other uses. The same applies to pending active substances. Such an authorisation is temporary in nature, in most cases only locally needed, and could be within the limits of the already existing Good Agricultural Practice (GAP) for other uses. In the majority of cases notifications of this type related in the past to speciality, or minor crops. While accepting that an emergency authorisation might be needed to address the immediate need, in the case that no other reasonable means of control are available, it should be clear that such emergency authorisations should generally be followed up by means of an Article 51 based, or other standard authorisation, and **not be repeated**. Misuse of the emergency case for minor uses has to be avoided. Therefore emergency authorisations relating to plant protection products containing approved active substances should not be repeated in a following cropping season, unless the emergency continues and clear reasoning has been provided. This reasoning may take into consideration the time necessary to prepare, evaluate and issue a standard authorisation, or extension of use.

In case the emergency measure relates to a plant protection product containing an EU approved active substance that has no authorised use in the Member State concerned the same reasoning applies.

2.2. Use of a plant protection product containing non-approved active substance(s)

In some cases it may only be possible to address an emergency with the temporary authorisation of a plant protection product containing a non-approved substance. A full and clear reasoning following the attached notification format should be provided. Member States should bear in mind the following points for authorisations in this category:

- Providing a complete and detailed report following the attached notification format
- Safeguarding the protection of human health and the environment.
- The use should generally be connected to a single pest species, or related group of pest species where the use is not for disinfection purposes.
- No other reasonable means of control is available (stand alone or in combination)
- The Member State should explain how use is limited and what conditions have been set. Use should preferentially be based on proven presence of the pest (group) on individual farms, if applicable.
- Use shall be monitored and exact data on the dose and frequency employed and the area treated should be delivered.
- Repeat authorisations should be avoided by all means. If still unavoidable, they shall follow the guidance set out above under 2.1 concerning the requirements of repetitions.

In very exceptional cases repeated authorisation of a plant protection product containing a non-approved active substance may remain necessary because the particular danger cannot be contained yet by any other means. In such cases use of a plant protection product containing a non-approved active substance may be continued under Article 53, provided in addition to the points listed above the following is fulfilled:

- Economic evidence should be provided by the applicant proving that the socio-agronomic system cannot be changed within a year, and that temporary continuation of the non-approved active substance is necessary to avoid unacceptable damage to local society.
- Use should be limited by setting a maximum frequency of treatment per production unit (field or farm) that stimulates the maximal combined use of existing other, partially effective measures.
- A research programme should be in place that searches for alternative acceptable solutions. Yearly reports should be made available to the Commission and Member States including details on the objectives of the program, a concrete time schedule and planned and taken efforts.

While accepting that such repeat cases may be necessary in extreme cases it is absolutely necessary to notify intentions of repeated authorisation at an early moment in order to allow for an early opinion of the Standing Committee on the Food Chain and Animal Health. Advice from the Commission, the EFSA and other Member States should be invited.

3. Procedure

3.1 Member States

Member States should evaluate applications for emergency use and immediately notify other Member States and the Commission of any emergency authorisations granted, using the format at Annex 1 to address the following points:

- a. In case emergency authorisations that are in fact extensions of already authorised uses for approved substances, or refer to pending substances, reference to an **ongoing** Article 51 (minor use) or Article 33 (other uses) or Article 40 (mutual recognition) procedure.
- b. In cases where the derogation is unlikely to be changed to a normal authorisation or extension of use, a summary of the steps taken to find a longer time solution should be provided.
- c. All possible existing alternative methods (also non-chemical) of control should be listed, including reasoning why the possible alternatives are (in combination) not reasonable and a non-control would cause an unacceptable damage to plant production or ecosystems.
- d. Indication of species, the nature and extent of the problem, including information on area infested, period the infestation has been present, and its possible expansion with time should be provided. Indication of its size in terms of economic and agronomic dimensions should be provided, particularly in case of repetition of emergency authorisation.
- e. The proposed GAP should be provided.
- f. Time period and further restrictions and limitations should be provided.
- g. Risk mitigating measures, if any, should be described.
- h. Compliance with existing MRL should be stated, and if not possible:
- i. A consumer risk assessment accompanied by a proposal for a temporary maximum residue level (t-MRL) setting must be provided. (PRIMO EFSA model to be attached), where applicable.
- j. Details of research undertaken to solve the danger in a sustainable way should be presented. This is **verifiable evidence of an application for a use**, or an existing **research programme (state or otherwise) focussing on non-**

chemical, chemical, combined, or other solutions. This requirement applies in case of dangers of a permanent nature, for which new acceptable solutions should be found, and where the derogation relates to a non-approved active substance.

In the exceptional case of extended or renewed notifications (which are emergency authorisations referring either to the same crop cycle, or to a next successive crop or next year) the MS should explain how the process of finding alternatives is progressing. All notifications will be placed via CIRCA on the agenda of the Standing Committee.

Unacceptable Applications

Derogations for emergency use are meant solely to be in the interest of agriculture, environment and governments. Applications solely based on industry interests should be refused.

3.2. Commission

The Commission may consult EFSA for advice. If so, that advice must be provided within one month of the request. Where the Commission concludes its intervention is justified, it may present a proposal to the Standing Committee providing for the Member State to extend or repeat the authorisation, or not, or requiring the Member State to withdraw it. It may be helpful to develop further on specific regulatory action to be taken within the Standing Committee in the light of experience with this guidance in the medium term.

On a regular basis the Commission will make the notifications of emergency authorisations received from Member States publically available.

Notification

AUTHORISATION IN THE SCOPE OF ARTICLE 53

Please note that, due to a danger to plant protection that cannot be contained by any other reasonable means, an authorisation in accordance with Article 53 of Regulation (EC) No 1107/2009, has been granted as follows:

| | | |
|----|--|---|
| 1 | Member State, and MS notification number | <i>(The number shall be a sequence number per year and by MS, E.g.: ES- 2011- 05.)</i> |
| 2 | In case of repeated derogation: no. of previous derogation(s) | |
| 3 | Names of active substances | |
| 4 | Trade name of Plant Protection Product | |
| 5 | Type of formulation and contents of active substance(s) <i>(e.g. 80% dry granule)</i> | |
| 6 | Applicant | |
| 7 | Danger | <i>(pest name EPPO, English and scientific) Group names only acceptable in case of approved substances)</i> |
| 8 | Crop, plants or situation | <i>(crop or plant name EPPO, English; no group names)</i> |
| 9 | Minor or major use | <i>Indicate if the use is considered to be minor</i> |
| 10 | Time period for authorisation | <i>(start date- end date)</i> |
| 11 | Further limitations | <i>(e. g. amount of product, restriction to certain regions or individual sites, conditions to be checked by regional plant protection service)</i> |
| 12 | MRL: Reference to product code number in Annex I of regulation (EC) No 396/2005 | |
| 13 | Compliance with MRL set in Regulation (EC) No 396/2005 | <i>(yes/no; if no, complete attached GAP table and provide proposal for tMRL and consumer risk assessment)</i> |
| 14 | Member State contact point | <i>(Name, e-mail and address of the contact person responsible for the technical contents of the notification.)</i> |

15. GAP

GAP rev. , date: year-month-day

PPP (product name/code) product name / Formulation: Type:
 code type
 active substance 1 active Conc. of as 1:
 substance 1 conc.
 active substance 2 active Conc. of as 2:
 substance 2 conc.
 active substance .. active Conc. of as ...:
 substance ... conc.
 safener safener Conc. of safener: conc.
 synergist synergist Conc. Of synergist: conc.

Applicant: company/institution

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|-------------|--|-------------------|--|------------------|--|---|--|--|--------------------------------|---------------|---|
| Use- No. | Crop and/ or situation (crop destination / purpose of crop) | F G or I | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | Application rate | | | PHI (days) | Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures |
| | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number (min. interval between applications) a) per use b) per crop/ season | kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season | g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | |
| 1 | | | | | | | | | | | |

16. Value of tMRL if needed, including information on the measures taken in order to confine the commodities resulting from the treated crop to the territory of the notifying MS pending the setting of a tMRL on the EU level. (PRIMO EFSA model to be attached)

17. Validated analytical method for monitoring of residues in plants and plant products.

18. Function of the product

(E.g. systemic long acting insecticide; foliar fungicide, used for regular control, elimination scenario etc)

19. Type of danger to plant production or ecosystem.

(Provide reasoning for what category the 120 day authorisation is given: quarantine pest; emergent pest, either invading non-native, or native; emerging resistance in a pest, etc. Whereas reference to the EU quarantine legislation may suffice for quarantine pests elaborate reasoning should be provided for the category 'any harmful pest')

20. Size and effect of danger

(Describe shortly the area affected, the development over time of the infestation, and the agronomic and economic effects it has)

21. Absence of any other reasonable means

(Describe the alternative control measures (chemical, non-chemical and cultural) and indicate why they do not (in combination) suffice. Describe which, if any, authorisations for the pest to be controlled exist in other Member States.

22. Rationale

(Reason the risk management decision based on the findings of 15 to 18, containing especially a description of measures taken to ensure consumer protection).

23. Mitigation measures

(Describe what mitigation measures are taken if needed for minimising risk to humans, animals, and the environment, attach summary risk assessment. Describe what measures are taken to limit and control use)

24. Applications in progress

(The use notified may have been applied for already, or a suitable alternative PPP may be in the process of authorisation. Describe such applications, including a possible date of authorisation)

25. Research activities

(Describe the research efforts undertaken and/or in progress, their aims, their funding, and their expected date of results. This is needed for all categories of dangers, except quarantine pests that can still be eliminated, or infrequent pests, for which no official application for a normal authorisation or extension of use of the plant protection product exists. In case of a repeated notification: indicate the state of works of the research projects.)

[To be uploaded on CIRCABC](#) in Pdf format²

² IG "Plant Protection Products and their residues, [section of the next SCFCAH-Meeting](#), subsection "Notifications under Art 53