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GUIDANCE ON EMERGENCY AUTHORISATIONS ACCORDING TO ARTICLE 53 OF REGULATION (EC) No 1107/2009

UNDER REVIEW

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

This guidance has been developed 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.

Version history

Version	Applicable from	What
0	February 2013	Original version ("Working Document on emergency situations according to Article 53 of Regulation (EC) No 1107/2009")
1	1 March 2021	Updated to: • Update the title of the document • Reflect the use of the Plant Protection Products Application Management System (PPPAMS) to manage the workflow of emergency applications and authorisations and its link to the EU Pesticides database • Clarify details on the procedure and provide guidance on the fields that are to be completed in PPPAMS by applicants and Member States. • Provide more detail on the information required in applications (in particular to justify an application) and considerations required by Member States when considering if an authorisation can be granted • Provide further clarification on the granting of emergency authorisation for the treatment of seeds and the sale and use of treated seeds • To ensure consistent data collection and practices between Member States • Take into account experience gained in the area of emergency authorisations since 2013.

Contents

1. Background and summary

Article 53 of Regulation (EC) No 1107/2009 ("the Regulation") allows Member States to authorise the placing on the market of plant protection products, in special circumstances and derogating from the regular authorisation process, for a period not exceeding 120 days and for limited and controlled use, where such a measure is necessary because of a danger which cannot be contained by any other reasonable means.

Member States are required to inform the Commission and other Member States when granting such authorisations (so called 'emergency authorisations') in accordance with Article 53 of the Regulation, providing detailed information about the situation and any measures taken to ensure consumer safety.

This guidance explains the process that should be followed by applicants and Member States for application for emergency use as well as specifying the information that should be provided in such applications and their resulting authorisations. The use of the Plant Protection Products Application Management System (PPPAMS) as the EU tool for the submission of applications and the notification of their resulting authorisations for emergency use ensures that detailed information about the situation and about the need for emergency use is shared swiftly with the other Member States and the Commission and that information on emergency authorisations is made publicly available.

Based on the information submitted by Member States, the Commission may consult the European Food Safety Authority (EFSA) in accordance with Article 53(2) of the Regulation to provide scientific or technical advice.

Application for emergency authorisations should be processed and finalised in real time in PPPAMS, and if granted, notifications of authorisations granted should be published in PPPAMS without delay (preferably before the authorisation enters into force or as soon as possible thereafter, depending on the specific decision-making procedure in the Member State). Authorisation information completed in PPPAMS does not constitute the legal authorisation granted by the Member State. Applicants should provide the necessary information to the Member State authorities in order to enable the Member State to carry out an evaluation and reach a decision on whether an emergency authorisation can be granted or not as quickly as possible.

2. Necessary conditions to grant authorisations under Article 53 of Regulation (EC) No 1107/2009

The agronomic and environmental situation with respect to plant protection may present situations that pose a danger to plant production and ecosystems that cannot be contained by any available reasonable means as referred to in recital 32[1] of the Regulation.

The availability of solutions, both chemical and non-chemical (e.g. biological control), including solutions that are outside of the scope of the Regulation such as cultural and

[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.

agronomic techniques, and invertebrate biocontrol agents, continues to change and growers or public authorities may face challenges to combat particular pests (e.g. but not restricted to invasive or quarantine pest species) or other dangers to ecosystems. These emergencies demand quick and effective responses that often cannot await the outcome of the regular authorisation process in accordance with the requirements laid down in Article 29 of the Regulation, which takes up to 18 months for a new plant protection product application or a period of up to 120 days for mutual recognition of a product authorised in another Member State. In addition, emergency authorisation may be exceptionally required for use of products containing active substances that are not approved in the EU (this includes active substance that have never been approved in the EU since an application for approval has never been submitted, are no longer approved in the EU or for which an evaluation for approval is ongoing) or in the case of authorised products, for additional crops/uses that may not be covered by a current authorisation and for which an authorised product may not be used according to the requirements of the Regulation. For this reason the Regulation provides in Article 53 that *'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*.'

It is important that Member States uphold the integrity of the regular authorisation system. The use of Article 53 should be restricted to cases of obvious dangers to plant production or ecosystems that cannot be contained by any other reasonable means, including non-chemical methods.
Emergency authorisations shall not jeopardise the purpose of the Regulation and shall be proportionate (in particular when considering the granting of repeated emergency authorisations). Member States should demonstrate clearly, based on the application received and the information contained therein, that the requirements in Article 53 of the Regulation are fulfilled and hence that the granting of an emergency authorisation is justified.

Emergency authorisations may be granted for plant protection products that contain active substances that are either approved or not approved in the European Union:

- Use of a plant protection product containing an approved active substance(s):

  In some cases, an emergency situation may be solved by granting an emergency authorisation for the use of a plant protection product containing an approved active substance which is not currently authorised in the Member State where the danger exists. However, such a product may already be authorised in another Member State (even for the particular crop/pest combination for which an emergency authorisation is sought).

  In cases where a plant protection product is already authorised in another Member State for the use required to solve the particular danger, an application according to Article 40 should be considered in the first instance, rather than an application for emergency authorisation, where time permits.

  It may be possible to solve an emergency situation by granting an emergency authorisation for a plant protection product already authorised in the pertinent Member State (where the particular danger exists) but not for the particular crop/pest combination in question. Such an authorisation may be within the limits of the already existing good agricultural practice (GAP) for other uses or may be for a completely

different GAP. Usually notifications of this type relate to uses in minor crops but it is also possible that new and emerging phytosanitary risks and other phytosanitary issues in major crops need immediate action. Such emergency authorisations are expected to be eventually replaced by an authorisation under Article 51 or a regular authorisation. In accordance with Article 51, Member States should facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

It may also be possible to solve an emergency situation by granting an emergency authorisation for a plant protection product containing an approved active substance(s) that is not yet authorised in any Member State.

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

  In some cases, it may only be possible to address an emergency situation with the emergency authorisation of a plant protection product containing a substance that is not approved in the European Union (never approved since an application for approval was never submitted, no longer approved or for which an evaluation for approval is ongoing). In such cases particular attention should be given to ensure that a robust justification for the authorisation is provided, first by the applicant as part of the application, and, subsequently, if an authorisation is granted, by the Member State authority issuing the authorisation. Particular attention should be paid to the reasons underpinning the non-approval of the active substance when assessing applications, taking into account the most recent EFSA Conclusion on the substance, where available. The lack of critical endpoints (such as health-based reference values) for carrying out risk assessments is of particular importance and should be carefully considered, in particular when ensuring consumer safety. Such emergency authorisations may be followed up by an application for approval of the active substance followed by a subsequent request for regular authorisation of plant protection products containing it.

  Emergency authorisation of plant protection products containing active substances that are not approved should be a last resort, only when there are no other possibilities, inducing authorisation of plant protection products containing approved active substances.

Applicants and Member States should consider the following **general points** when applying for and assessing applications for emergency authorisations and Member States should also take these points into consideration when granting emergency authorisations in order to comply with Article 53 of the Regulation:

- An authorisation can only be granted if no other reasonable means of control - including non-chemical ones - are available (stand alone or in combination).
- When considering if other reasonable means are sufficient to contain the danger, the agronomic and economic acceptable level of control should be considered. It should be considered why possible alternatives are (in combination) not reasonable and why non-control would cause unacceptable damage to plant production or ecosystems.
- The authorisation must not exceed a 120-day period. The period for use should be limited to one growing season per authorisation. If a repeated authorisation is needed

the following season/year, a second application for emergency authorisation in the same year should be submitted and the Member State should confirm that the justification in terms of continuing danger and lack of reasonable alternatives remains valid[2]. Applicants should provide information to demonstrate how the emergency use will be limited.

- An authorisation should generally be connected to a specific danger e.g. a single pest species or group of pest species (e.g. different species of aphids), that may apply to one or multiple crops.
- Appropriate risk mitigation measures should be imposed. In particular, use should be limited and the maximum area that is permitted to be treated (in hectares) should be indicated – this can either be a specific area, if the Member State restricts to a certain region/local area/number of hectares of crop, **or** in cases where the authorisation is for the entire territory or crop area, the total area for the crop concerned can be indicated.

  For products for which use cannot be expressed in hectares (e.g. volume treated), the appropriate value and unit should be provided.

  If applicable, details of how the product(s) will be supplied and/or used should be provided. Special conditions for placing on the market and use may also be imposed if considered necessary.
- The protection of human and animal health and the environment should be safeguarded, complying - as far as possible - with the requirements laid down in the Regulation and with the Uniform Principles[3] for evaluation and authorisation of plant protection products (although the available information to demonstrate safety may not be in line with the normal requirements).
- Consumer safety must be ensured – measures taken to do so must be detailed. A Member State may authorise the placing on the market only within its territory of treated food or feed not complying with MRLs established by Regulation (EC) No 396/2005 in exceptional circumstances[4]. If a temporary MRL is required, treated produce should be restricted to the territory of the Member State granting the authorisation until such level is set at EU level[5]. The same applies for treated plant material that could be transferred to other Member States in order to produce crops there, for example treated plant material used for vegetative propagation of crops, or treated seeds (where Article 49(1)-(3) do not apply). An emergency authorisation could however also be granted in such cases to allow transfer to Member States that have granted an identical or similar emergency authorisation taking into account the consumer exposure, without a temporary MRL being set.

  Details on the national emergency authorisation allowing for the placing on the market of non-complying food/feed must be immediately notified to the other Member States, the Commission and EFSA together with an appropriate risk assessment. For edible crops, the calculations from the Pesticide Residue Intake Model (PRIMo)[6] should be

[2] For perennial crops good Integrated Pest Management could provide control after the season of use.

[3] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127.

[4] In accordance with Article 18(4) of Regulation (EC) No 396/2005.

[5] Where no specific MRL has been established in the Annexes to Regulation (EC) No 395/2005 for an active substance, then the default value applies, according to Article 18(1)(b) of that Regulation, unless the active substance is listed in Annex IV to that Regulation in which case MRLs are not required.

[6] PRIMo – Pesticide Residue Intake Model. See https://www.efsa.europa.eu/en/applications/pesticides/tools

attached to the consumer risk assessment. The Commission can then either propose the setting of a temporary EU wide MRL for a specified period of time or take any other necessary measure.

In addition, Member States should pay careful attention to substances for which health-based reference values are not established at EU level in the context of carrying out a consumer risk assessment and the need to set a temporary MRL.

- Member States may consider if monitoring of the conditions and restrictions of the use(s) authorised is appropriate and set the necessary measures to collect the data on the use of the product. Such information may be useful to inform decisions on future applications for emergency authorisation of the same or similar products.
- Article 53 of the Regulation is interpreted as allowing Member States to grant emergency authorisations for treatment of seeds and, consequently, for the sale and use of the treated seeds – see Section 3.4 for further information.
- Member States should keep documented evidence of the decision making process, including the assessments carried out to support the final decision.
- A complete and detailed reasoning must be provided following the format of the 'Justification and consumer safety' tab under the authorisation section in PPPAMS. It should be clearly explained how use is limited in time and area, as well as what conditions or restrictions have been set. Justification should preferentially be based on proven (or clearly to be expected) presence of the pests (group/s) in specific crops and area(s), if applicable.

Repeated emergency authorisations should be avoided, in particular for products containing substances that are not approved in the EU – longer term solutions should be sought for persistent or recurring pest problems. In case emergency authorisations are repeated, a clear reasoning should be provided why no other solution has been found. This reasoning may take into consideration the time necessary to acquire an applicant who is ready to prepare and submit an application as well as the time needed by the authorities to evaluate and issue a regular authorisation, or extension of use. Applicants should use the regular authorisation process to seek a longer-term solution to a recurring danger.
Member States may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses, in accordance with Article 51 of the Regulation. Applicants may also make use of the list of plant protection needs (crop/pest combinations) identified by Member States, available in the European Minor Uses Database EUMUDA (www.eumuda.eu). This will allow applicants to identify needs to include in their regular applications and may help to prevent repeated requests for emergency authorisations.

The repeated granting of a specific emergency authorisation indicates the need to intensify efforts to find other permanent solutions such as the granting of a regular authorisation. Furthermore, in accordance with Directive 2009/128/EC on the sustainable use of pesticides[7], Member States should promote low pesticide-input pest management, in particular integrated pest management, and establish the necessary conditions and measures for its implementation.

[7] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. OJ L 309, 24.11.2009, p. 71

Member States are also encouraged to strengthen research to look for such alternatives in order to limit the use of plant protection products under Article 53 to special circumstances and to closely cooperate with each other, especially at zonal level.

In cases where repeated emergency authorisation of a plant protection product containing a non-approved active substance remains necessary, the following aspects should be considered:

- The applicant should demonstrate that no other viable options exist and provide economic evidence proving that the socio-agronomic system could not be changed within the period of time since the first emergency authorisation was granted, and that temporary continuation of the use of the non-approved active substance is necessary to avoid unacceptable damage to plant production or ecosystems.
- Use should be limited as much as possible by setting a maximum frequency of treatment per production unit (field or farm) that stimulates the maximal combined use of other existing alternative (possibly partially) effective measures.
- Applicants should provide details of on-going and future activities aimed at finding a long-term/permanent solution to eliminate the need for repeat applications for an emergency authorisation in the future.
- The need for a programme of research that searches for alternative acceptable solutions (including holistic based approaches) should be considered. Available reports should be communicated to the Commission and Member States including details on the objectives of the programme, a concrete time schedule and planned and taken efforts.

3. Applications and authorisation for emergency use

The submission of applications and their resulting authorisations for emergency use in the EU should be carried out via the Plant Protection Products Application Management System (PPPAMS). This tool ensures that detailed information about the situation and about the need for emergency use is shared with the other Member States and the Commission in a timely manner and that a summary notification of an emergency authorisation granted is made publicly available. However, it should be noted that dossiers and other supporting information is not uploaded in PPPAMS and should be submitted according to the procedure applicable in the Member State where authorisation is requested.

Applicants may contact the relevant competent authorities in the concerned Member State in order to obtain advice and to ensure that sufficient time is available to complete the decision-making process. Applicants may also need to discuss with the relevant authorisation holders or manufacturers of the concerned plant protection products about the supply of the plant protection products concerned.

The following workflow shows the procedure to be followed in PPPAMS:

Step 1. Select an existing PPP in PPPAMS or create a PPP (Applicant*)

⬇

Step 2. Create and submit an application for the authorisation of the PPP in accordance with Article 53(1) (Applicant*)

⬇

Step 3. Management of the application (Member State authority)

⬇

Step 4: Creation of an emergency authorisation[8] and publication of a summary notification of the authorisation (Member State authority)

PPPAMS contains an online help-function, which includes a step-by-step guide to processing applications and creating authorisations. Furthermore, the PPPAMS webpages provide other useful tools including quick reference guides and procedure tables: https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams_en

Support for the use of PPPAMS can be sought via the PPPAMS Functional Mailbox if required: SANTE-PPPAMS@ec.europa.eu.

3.1 Create and submit applications

In the context of Article 53 of the Regulation, applicants are typically growers' associations, agricultural cooperatives or other representatives of growers or regional administrations. However, applications may also come from companies that are holders of authorisations for plant protection products who may act on behalf of growers in submitting an application. However, emergency authorisations should solely be in the interest of agriculture or protection of the environment (e.g. invasive species). Applications solely based on the interests of industry are not acceptable and must be refused.
Applicants should provide as much information as possible to enable the Member State authorities to progress the evaluation efficiently and reach a decision as quickly as possible, without the need to request further information.

** National Competent Authorities in Member States may create a product and application on behalf of an applicant.*

[8] The information provided does not constitute a complete legal authorisation – Member States are fully responsible for granting emergency authorisations. The information provided is the sole responsibility of Member State and therefore any questions related to specific authorisations should be addressed directly to the relevant Member State competent authority.

a) Submission of an application

Applications for emergency use should be submitted via PPPAMS to the relevant Member State by the applicant. In case the applicant has no access to PPPAMS and is unlikely to submit further applications in the future, applications may also be created by the Member State authority on behalf of the applicant. Applications should be submitted taking into account the applicable administrative requirements of the relevant Member State.

Applications should be completed *fully and accurately*. Applicants should clearly justify the need for emergency authorisation of the plant protection product for the intended use and provide the necessary information to enable an appropriate evaluation and risk assessment. Further details of the fields that need to be completed and the type of information to be included in PPPAMS can be found in Annex I.

b) Submission of supporting documents and information to justify an application

Supporting documentation (reports, tests, studies, etc.) are not submitted via PPPAMS, rather these should be submitted to the Member State following the specific guidance of the Member State, as appropriate. The applicant should ensure that the classification and labelling (C&L), GAP and justification tabs in the application section in PPPAMS are fully and accurately completed; this – together with a timely submission of supporting documents - will enable the Member State to process the application quickly. Applicants may wish to discuss the application and the information required with the authorisation holder of the plant protection product or data owner for relevant data needed to support the application.

When considering the type of information required to demonstrate that there are no other reasonable means to control the specific danger, applicants may also consider the protocols[9] developed by EFSA for the purposes of evaluating whether the conditions under Article 4.7 of Regulation 1107/2009 are met.

3.2 Processing of applications by Member States and granting of authorisations

Member States shall evaluate applications for emergency use submitted in PPPAMS, process the application, and notify other Member States and the Commission of any emergency authorisations granted by completing and publishing a summary of the authorisation in PPPAMS once it has been issued. Member States should in particular:

- ensure that the justification tab is fully and correctly completed, taking care to not include any personal data or confidential information – Annex 2 provides details of

[9] Protocol concerning the application of herbicide active substances to control a serious danger to plant health: https://www.efsa.europa.eu/en/supporting/pub/en-1060
Protocol for the evaluation of data concerning the necessity of the application of fungicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2017.EN-1345
Protocol for the evaluation of data concerning the necessity of the application of insecticide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2017.EN-1201

the information that should be included by Member States as part of the authorisation information in PPPAMS.

- evaluate applications and complete information about the granting of authorisations in real time so that PPPAMS contains accurate and up to date information. Backlogs must be avoided.
- ensure that information on authorisations is included and published in PPPAMS **as soon as possible once they are issued in the Member State.**

In PPPAMS, Member States have the possibility to:

- refuse at an early stage applications that are clearly not in line with the provisions of Article 53 without having to assess them by changing the status to 'application rejected'.

Or

- accept applications but based on the assessment give a negative/unfavourable opinion; for these application the status 'application complete – authorisation cannot be granted' should be selected.
- grant authorisations by changing the status to ''application complete – authorisation to be granted'.

In the exceptional case of repeated emergency authorisations referring either to the same crop cycle, or to a next successive crop or next year, the applicant (in their application) and the Member State (in the authorisation) should explain how the process of finding alternatives is progressing.

When an authorisation is granted by the Member States and the user in the Member State authority selects the 'publish' button to complete the process in PPPAMS, the system generates a summary notification which is sent to the applicant, to all other Member States and to the Commission. The information contained in the summary notification is also made publicly available in the EU pesticides database[10].

3.3 Evaluation of applications

In addition to the points listed in Section 2, the following points and principles should be taken into account by Member States when evaluating whether to grant an authorisation for emergency use, in order to ensure a robust, transparent and harmonised approach:

a. The GAP proposed in the emergency authorisation should be checked for accuracy, including the selection of the correct EPPO codes to describe the crop and pest (including the correct scientific names) and the rates and timings of the use of the authorised plant protection product.

b. The description of the danger should include the indication of pest species, the nature and extent of the problem, including information on the area and or period of infestation (or predicted infestation), and its possible expansion with time should be provided. Indication of potential ecological and agronomic impacts

[10] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp

should be provided, particularly in case of repetition of an application for emergency authorisation.

c. Authorisations should be granted for a specific need/danger:

The danger may be relevant for several related crops and therefore multiple crops can be included in a single authorisation; An authorisation may cover several products that are identical or equivalent (e.g. other trade names and products sold under parallel trade permits). Multiple trade names can be included in PPPAMS.

d. All applicable risk mitigation measures necessary according to the assessment performed must be described.

Member States should include details about the area for which use is permitted under the authorisation in view of the need to ensure use is limited as far as possible. The maximum area permitted to be treated (number of hectares) should be given. For products for which use cannot be expressed in hectares (e.g. volume treated), the appropriate value and unit should be provided.
This should be added to the 'Area permitted to be treated' field in the general details of the authorisation page.

If the actual area treated is significantly different to the maximum provided for in the initial authorisation, Member States may correct the value post-authorisation.

e. In cases where the emergency authorisation is unlikely to be eventually replaced by a regular authorisation or extension of use of an existing authorisation, a summary of the steps taken to find a longer-term solution should be provided, where relevant (in particular for repeated authorisations).

f. All possible existing alternative methods (including non-chemical methods and techniques) of control should be explored and listed where appropriate, including reasoning how and/or why the possible alternatives are (by themselves or in combination) not reasonable and how/why non-control would cause an unacceptable damage to plant production or ecosystems.

g. For products containing approved active substances, the conditions of approval for the substance, in particular any restrictions, should be considered and taken into account, as far as possible.

h. The protocols developed by EFSA to determine whether substances are needed to control a serious danger to plant health (for derogation under Article 4.7) may be used to determine whether sufficient alternatives exist.

i. The time period of validity of the emergency authorisation and further restrictions and limitations should be indicated and fully described.

j. Details of how the supply of the product(s) and the use will be limited should be provided, where applicable.

k. Details of measures taken to ensure consumer safety should be included in the relevant field in the authorisation section in PPPAMS. Compliance with existing MRLs should be confirmed[11], and if not possible a consumer risk assessment accompanied by a proposal for a temporary maximum residue level (tMRL) must

[11] In PPPAMS, the compliance with the relevant MRL (unless the substance is listed in Annex IV to Regulation (EC) No 396/2005 in which case an MRL is not required) should be confirmed in the 'Consumer safety' section.

be provided. PRIMo calculations should be attached, where applicable. This information should be submitted to DG SANTE: sante-consult-E4@ec.europa.eu and copied to EFSA: ***pesticides.mrl@efsa.europa.eu***.

l. In case of applications for emergency authorisations that are in fact extensions of already authorised uses of products containing approved substances, reference to an *ongoing* Article 51 (minor use) or Article 33 (other uses) or Article 40 (mutual recognition) procedure should be given, where applicable.

m. Details of research undertaken to solve the danger in a more permanent and sustainable way should be presented. This should be verifiable evidence of an application for a use, or an existing research programme 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 emergency authorisation relates to a non-approved active substance or a restricted use of an approved active substance.

n. All fields should be completed with a sufficient level of detail, in English.

3.4 Treatment of seeds and the sale and use of treated seeds

Article 53 of the Regulation is interpreted as allowing Member States to grant emergency authorisations for treatment of seeds and, consequently, for the sale and use of the treated seeds. Otherwise, authorisations granted for the use of plant protection products for the treatment of seeds in accordance with Article 53 would be without purpose. Therefore, the emergency authorisation granted in accordance with Article 53 should provide for an explicit reference to both the treatment of the seed and its sale and use.

Seeds treated with products for which an authorisation has been granted under Article 53 do not benefit from free movement, as Article 49(1) requires that seeds are treated with a PPP authorised for that use in at least one Member State. As this is not the case, Article 49(1)-(3) do not apply. The term 'authorisation' is interpreted as an authorisation granted according to Article 28 of Regulation (EC) No 1107/2009 but not an emergency authorisation granted under Article 53 of Regulation (EC) No 1107/2009.
Seeds treated under Article 53 are only intended for limited and controlled sowing in the territory of the authorising Member State – specific conditions may be imposed. Article 49(4) applies. The emergency authorisation granted on the basis of Article 53 should specify the period of use of the treated seeds.

However, in exceptional situations, a Member State that has a specific danger but does not have the highly specialised seed treatment facilities and the treatment of seed in that Member State is not technically feasible, this Member State may, in the spirit of the Union, ask for emergency authorisation for the treatment of seeds in another Member State. In such cases, the Member State in which the treated seeds will be sown should also issue an emergency authorisation according to Article 53 that justifies that it has a danger that cannot be controlled by other available means and has itself granted an emergency authorisation for the sowing of the treated seeds in its territory.
In such cases, when authorising a plant protection product in accordance with Article 53 for use as a seed treatment, information shall be provided as regards where (in which Member State) the seeds are going to be treated and what area (e.g. region of the same Member State or another one) is going to be sowed. The Member States concerned should closely cooperate

in such cases. Both Member States should issue an emergency authorisation in such cases, clearly explaining if it is for the treatment of seed or the sale and sowing of treated seeds.

An emergency authorisation for the sale and sowing of seeds that are treated in third countries, hence outside the EU, could also be granted, provided that the treatment of the seeds fulfils the criteria/quality standards set by the Member State granting the emergency authorisation.

However, it is not possible to ask for or grant an emergency authorisation for treatment of seeds if the treated seeds are to be exported and sown outside the European Union (treatment of seeds for export) because there is no specific danger in an EU Member State in such a case.

3.5 Post-authorisation follow up

Member States may request information from applicants and/or authorisation holders about the actual situation and the use of the authorised plant protection product(s) post-authorisation. Such information allows for retrospective assessment of the emergency authorisations that have been granted and can be useful to inform the assessment of future applications, including repeated applications.

4. Role of the Commission and EFSA

The Standing Committee on Plants, Animal, Food and Feed, Section - Phytopharmaceuticals Legislation, will be informed about authorisations granted by Member States. The Commission and Member States may discuss and scrutinise notifications, including the justifications underpinning the emergency authorisation, where appropriate. Member States are also invited to analyse and comment on the notifications provided by other Member States. Where the justification provided by the Member State is not considered complete or acceptable, the Member State may be asked by the Commission to provide further information.

In cases where a Member State proposes to set a temporary MRL, such proposals will be referred for discussion to the Standing Committee on Plants, Animal, Food and Feed – Section Phytopharmaceuticals - Pesticides Residues.

Furthermore, following the notification of emergency authorisations in accordance with Article 53(1) of the Regulation, in accordance with Article 53(2), the Commission may consult EFSA for an opinion or for scientific or technical assistance – in particular, this may be done in case of repeated emergency authorisations. If so, EFSA shall provide its opinion or results of its work within one month of the request. Where, based on EFSA's advice, the Commission concludes that an emergency authorisation is not justified, it may present a proposal to the Standing Committee in accordance with Article 53(3) providing that the Member State may not extend the duration of the authorisation or may not repeat it, or requiring the Member State to withdraw or amend it.

Annex 1

APPLICATION FOR AUTHORISATION OF A PLANT PROTECTION PRODUCT IN ACCORDANCE WITH ARTICLE 53

Information to be provided by the applicant when submitting applications in PPPAMS

This Annex provides guidance on the type of information requested when applying for an Emergency Authorisation via the PPPAMS. The fields that should be completed by the applicant when submitting an application are displayed alongside a brief description of the information required. The dossier and assessment supporting the application is not submitted via PPPAMS and should be provided to the Member States according to the applicable procedures in each Member State.

Personal data or confidential information (in accordance with Article 63 of the Regulation) should not be included in PPPAMS.

Product details

Field/item	**Information to be provided**
Product company code	*Enter the internal company code for the product*
Formulation type	*Select the formulation type from the drop-down list.* *The list is from the Catalogue of pesticide formulation types and international Coding Systems GCPF (GIFAP)*
Function	*Select the function or action of the product from the drop-down list.*
Substances	*Choose the substances (Active Substance, Safener or Synergist) from the drop-down list and add their content in the product, selecting the appropriate units and where relevant indicate the CIPAC variant.*

General application details

Field/item	**Information to be provided**
Application type	*Select the application type - 'application for emergency authorisation'*
Product trade name(s)	*Enter the trade name of the product. Multiple trade names can be listed.*
Concerned Member State	*Select the Member State for which the use(s) are requested – can only be a single Member State.*

Note that some additional administrative fields are completed by the Member State when they process the application but are not listed here.

Classification and Labelling

Field/item	Information to be provided
Classification	*Select from the drop down list the classification(s) that apply to the product in accordance with Regulation (EC) No 1272/2008*
GHS pictograms	*Select the relevant pictorial required based on the classification to communicate information on the hazard(s) concerned taking into account Articles 19 and 26 of Regulation (EC) No 1272/2008 and ECHA "Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008*[12]*".*
Signal	*Select the relevant signal word indicating the relative level of severity for hazards of the product in accordance with Article 20 of Regulation (EC) No 1272/2008 and ECHA "Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008"*
Hazard statement	*Select from the drop-down list the relevant hazard statements to describe the nature and severity of hazards for the product., taking into account Regulation (EC) 1272/2008, in particular Articles 21 and 27 and ECHA "Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008"*
Precautionary statement	*Select from the drop-down list the relevant precautionary statements which provide advice on measures to prevent or minimise adverse effects to human or the environment arising from that hazards of the product, taking into account Regulation (EC) 1272/2008, in particular Articles 22 and 28 and ECHA "Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008"*

GAP Table

Field/item	Information to be provided
Type of use	*Indicate whether the use is major or minor.*
Type of user	*Select the type of the user of the product (for emergency authorisations users must be professionals).*
Crops	*Search for and select the crop or situation for which the product is used. The codes for crops are taken from the EPPO Database. Multiple codes can be selected in case qualifiers are required to describe a use. See the user guide within PPPAMS for further guidance.*
Growing Crops	*Identify whether the crop is grown in open field or in greenhouses or whether the product is used indoors (e.g.*

[12] *https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65*.

	in storage facilities)
Pests / Harmful organisms	*Search for and select the pests (or purpose) for which the product is used. The codes for pests are taken from the EPPO database.*
Method / Kind	*Select the application method detailing how the plant protection product is applied (spraying, soil sterilisation, etc)*
Timing / Growth stage of crop and season	*Select the BBCH growth stage ranges in which application is intended.*
Maximum number per use	*Add the maximum number of applications per growing season/cycle used for the named crop/pest combination intended under practical conditions of use* *It should be indicated in the remarks column whether the displayed number of applications is per season, per crop cycle or per pest generation.*
Maximum number per crop / season	*Add the proposed maximum number of uses in the crop including applications on all pests/targets on the same crop.*
Minimum interval between applications	*Enter the minimum interval (in days) between applications of the same product*
Maximum application rate per product	*Enter the maximum rate of application of the product per application/treatment*
Maximum total rate per product per crop/season	*Enter the maximum rate of application of the product per growing season or per crop cycle*
Maximum application rate per active substance	*This field provides the maximum amount of active substance applied per treatment* *This field is normally auto-calculated from the concentration of active substance in the product and the maximum rate per application. In some cases the user needs to manually input the value.*
Maximum total rate per active substance per crop/season	*This field provides the maximum amount of active substance applied per crop/season* *This field is normally auto-calculated from the concentration of active substance in the product and the maximum total rate per crop/season. In some cases the user needs to manually input the value.*
Minimum water volume	*Enter the value - numeric value in l/ha*
Maximum water volume	*Enter the value - numeric value in l/ha*
Whether or not the water volume is dependent upon the development stage of crop	*Tick if the water volume range depends on the development stage of the crop (i.e. low volume – early crops stage, high volume – late crop stage)*
PHI (days)	*Enter the minimum pre-harvest interval.* *For some crop situations a specific PHI may not be relevant. If so an explanation (e.g. the PHI is covered by the time remaining between application and harvest.)*

	should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).
Seed treatment	*For seed treatments the seed density in kg/ha should also be listed.*
Remarks	*Enter any key information to further explain the use of the product e.g. details of growing cycles, restrictions, mandatory tank mixes.*

Consumer safety and justification

Field/item	**Information to be provided**
Consumer safety	
Compliance with the MRL: reference to products	*Compliance with the maximum residue level (MRL) in place for each crop defined in the GAP table taking into account the active substances in the PPP should be confirmed. PPPAMS will automatically try to find the relevant MRL for the crop selected, however, in some cases a manual search must be performed. Compliance should be indicated by ticking the box.*
Value of tMRL if needed,	*Indicate the necessary tMRL that is required, if relevant. Include information on the measures taken in order to confine the commodities resulting from the treated crop to the territory of the Member State in which the application is submitted pending the possible setting of a tMRL at EU level. (PRIMo EFSA calculations to be included).*
Validated analytical method	*Provide details of the availability of the method for monitoring of residues in plants and plant products, in case a tMRL is established.*
Measures taken to ensure consumer safety	*Include a description of measures taken to ensure consumer protection.* *It should be indicated if the active substance(s) contained in the plant protection product being authorised is listed in Annex IV to Regulation (EC) No 396/2005 (i.e. no MRLs are required), or would be expected to be listed in that Annex.*
Justification	
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 plant health regime may suffice for quarantine pests, more elaborate reasoning should be provided for the category 'any harmful pest'.*
Size and effect of danger	*Describe the area affected (or predicted to be affected), the development over time of the infestation, and the agronomic and economic effects it has or is predicted to have. Indicate the magnitude and the type of danger that*

	the pest poses to the particular crop/use, and the likely duration for the danger. *Indication of potential impacts should be provided e.g. impacts on the ecosystem, potential loss in yield and quality, financial consequences, socio-economic consequences, particularly in case of repetition of an application for emergency authorisation.* *It may be indicated if the plant protection need (crop/pest combinations) has been declared by Member States and is listed in the European Minor Uses database EUMUDA (www.eumuda.eu).*
Absence of any other reasonable means	*Describe the alternative control measures (chemical, non-chemical, including biological control and cultural methods) that have been considered and indicate why they do not (by themselves or in combination) suffice or why non-control would cause an unacceptable damage to plant production or ecosystems. Describe which, if any, alternative methods and/or authorisations of plant protection products for the pest to be controlled exist in other Member States.* *The protocols developed by EFSA for the purposes of evaluating whether the conditions under Article 4.7 of Regulation 1107/2009 are met may be taken into account to enable a consideration of suitable alternatives to the substance being considered for emergency authorisation.* Fungicides: https://www.efsa.europa.eu/en/supporting/pub/en-1345 Herbicides: https://www.efsa.europa.eu/de/supporting/pub/en-1060 Insecticide: http://www.efsa.europa.eu/de/supporting/pub/en-1201
Rationale	*Provide the rationale based on the available information to justify the emergency authorisation.* *A description of the consequence if authorisation is not given (e.g. crop losses, costs, environmental risks) should be considered.* *Describe what measures are taken to limit and control use.*
Mitigation measures	*Describe the mitigation measures necessary for minimising risk to humans, animals, and the environment.* *Details of how the supply of the product(s) and the use will be limited should be provided, where applicable.*

Applications in progress	*The use notified may have been applied for already, or a suitable alternative PPP may be in the process of authorisation under a regular procedure. Describe such applications, including the date the application was submitted, or if known the anticipated date of a decision.* *In case of applications for emergency authorisations that are in fact extensions of already authorised uses of products containing approved substances, reference to an ongoing Article 51 (minor use) or Article 33 (other uses) or Article 40 (mutual recognition) procedure should be given, where applicable.*
Research activities	*Describe the research efforts undertaken and/or in progress to find alternative solutions, 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 application for a regular authorisation or extension of use of the plant protection product exists.* *In case of a repeated application: the status of the research projects should always be indicated.*

Annex 2

AUTHORISATIONS GRANTED IN ACCORDANCE WITH ARTICLE 53

Information to be provided by Member States in PPPAMS when granting authorisations

Member States must check all the information provided by the applicant (see Annex 1) and if deemed necessary return the application to the applicant for further update or correct or complete data themselves in the case where the Member State created the application on behalf of the applicant. In this case, they shall provide all the missing necessary information (as outlined in Annex 1).

Only Member States have the competency to issue Emergency Authorisations and to complete information on emergency authorisations in PPPAMS.

When a Member States completes all of the authorisation fields in PPPAMS and clicks the 'publish' button, the system generates a summary notification, which is sent to all Member State users and the Commission, plus the applicant (assuming users have activated notifications in PPPAMS). This notification summarises all the information provided by the applicant and validated by the Member State. At the same time, the information is made publicly available in the EU pesticides database.

The following fields are completed and checked by Member States as part of the authorisation process in PPPAMS:

Authorisation number	*Provide the national number that is given when the PPP is authorised.*
Authorisation date	*Indicate the date of the authorisation i.e. the date when the decision to authorise was taken.*
Previous derogation	*In this field the previous emergency authorisation number can be added in case the authorisation that the Member State is creating has already been granted for this application for a period of 120 days and now needs to be repeated.*
Authorisation holder	*Details of the organisation to whom the authorisation is granted should be selected or added.*
Entry into force date	*Enter the date from which the authorisation applies.*
Expiry date	*Enter the expiry date of the authorisation.*
Member State contact point	*The contact point for the authorisation within the Member State Competent Authority should be selected.*
Further limitations	*Any specific mitigation, conditions or restrictions that have been imposed on the uses based on the assessment should be added (restrictions to certain regions or individual sites, conditions to be checked by regional plant protection service, etc.).* *Details of how the supply of the product(s) and the use will be limited should be provided, where applicable.*
Area permitted to be treated	*Add the maximum permitted area to be treated (number of*

	hectares) under the conditions of the emergency authorisation. *For products for which use cannot be expressed in hectares (e.g. volume treated), the appropriate value and unit should be provided.* *This value may be amended post-authorisation by the designated Member State Corrections Officer in PPPAMS.*
Classification and Labelling	*Check and if needed correct or complete the information provided by the applicant.*
GAP	*See Annex I for full details of each field.* *Indicate for each use whether authorisation is granted or not.*
Consumer safety and justification	*See Annex I for full details of each field.* *The Member State must verify the information provided in each field by the applicant and confirm if the MRL is complied with. Information on measures taken to ensure consumer safety should be described. If needed the Member State should correct or complete the information provided by the applicant, adding further justification to support the authorisation being granted. Additional information and justification for granting the emergency authorisation can be added. The justification in the authorisation notification is the responsibility of the Member State.* *When completing and checking the information the Member State should not include personal data or confidential information (in accordance with Article 63 of the Regulation).*