European Crop Protection

POSITION PAPER
Updated 6/08/2019 – REF/18/PD/30182

ECPA position paper on emergency authorisations under Article 53, Regulation 1107/2009

KEY MESSAGES

- ECPA supports the concept of emergency authorisations as provided for under Regulation 1107/2009.
- We understand the view that there is an increasing reliance on emergency authorisations. However, this is a symptom of the poor implementation of certain aspects of the regulation, which is failing to provide sufficient crop protection solutions to EU farmers.
- Ultimately growers require predictability to enable them to plan; reliance on emergency authorisations from one season to the next unfortunately does not provide this.

Executive summary

Unanticipated plant disease and pest pressure will always necessitate the flexibility for Member States to temporarily approve some form of emergency uses in the absence of viable solutions for growers. This need was foreseen at the time of the adoption of Reg 1107/2009 and is still relevant today.

ECPA understands the concerns being raised regarding what is perceived as an increasing reliance on the emergency authorisation provisions in Article 53 of Reg 1107/2009. However, we believe this is a symptom of the ineffective implementation of certain aspects of the regulation.

While we support the concept of emergency authorisations as envisaged in Reg 1107/2009, a number of improvements to the functioning of the regulation should be implemented, which would increase the availability of crop protection solutions to EU farmers and also reduce the reliance on emergency uses.

Introduction

Under Article 53 of Reg 1107/2009, in exceptional circumstances Member States may grant emergency authorisations for uses of plant protection products to deal with a specific pest or phytosanitary need. In these cases Member States may authorise the product for a period not exceeding **120 days,** for *"…limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means…".* Commission guidance document SANCO/10087/2013 (see Attachment 1) lays down the procedure Member States should follow when granting an authorisation under Article 53. Notably, the guidance highlights that the use of Article 53 should be exceptional and it requires Member States to ensure that a high level of protection for human health and the environment is maintained.

Concerns have been raised regarding the use of emergency authorisations and what is considered an increasing reliance on this mechanism. The European Parliament's PEST committee[1], has criticised the procedure, viewing it as a means of circumventing the normal requirements of Reg 1107/2009. Following reviews undertaken by EFSA, the Commission also has written to some Member States requesting them not to grant repeat emergency authorisations for certain uses.

This paper describes ECPA's position on the provisions of Article 53 and how these are currently being applied.

Current use of Article 53 emergency authorisations

The numbers of emergency authorisations approved between 2008-2018 are provided in Attachment 2; this includes the number of approvals according to year and Member State. Key points to highlight are:

- the vast majority of emergency authorisations are for uses on minor or speciality crops of products containing active substances approved at EU level.
- a small number are used in organic farming (substances listed as approved for organic farming under Reg 889/2008).

[1] http://www.europarl.europa.eu/committees/en/pest/home.html

- only a small number are for products containing active substances which are no longer authorised for use in the EU[2].
- the greatest number of authorisations have been granted by Spain, France and Portugal.
- although variable from year to year, and from Member State to Member State, overall there has been a gradual increase in the number of emergency approvals between 2008 and 2018.

The increase in the number of these authorisations is linked to the reduced availability of EU approved active substances due to the renewal programme under Reg 1107/2009. A significant number of products and/or uses have either not been supported or non-approved largely due to the new approval criteria introduced in Reg 1107/2009. Approximately 75% of active substances approved in 1991 are no longer available today.

In addition, procedures for the approval of new active substances are slow. The time to first product authorisation in Member States are amongst the longest in all regions globally. New crop protection solutions are not being authorised in a timely manner, and the existing authorised alternatives are dwindling due to the renewal programme, making the use of the Article 53 provisions essential to "fill the gaps".

One of the main reasons for granting emergency authorisations is the lack of registered products available for minor and speciality crops (mainly fruits and vegetables) which are important in certain Member States, in particular southern Member States: France , Portugal, Spain, Greece and Italy. These 5 countries alone make up 47% of emergency authorisations granted across the EU, but importantly are responsible for the majority of the production of fruit and vegetables grown in Europe. Southern countries are also often the most exposed to phytosanitary threats due to their climatic conditions, yet they grow crops unique in the EU which require specific crop protection solutions (e.g. rice in Italy and Spain, cotton in Greece and Spain).

Despite the existence in some Member States of fast track procedures for the approval of uses for minor and speciality crops (as provided for in Article 51 of Reg 1107/2009), this solution is not optimal as it only works when there is a product already registered for a major crop that serves as reference for the minor use. Currently the use of emergency authorisations is often the only legally viable procedure available to retain crop protection solutions which are essential to the production of certain crops. While decreasing the reliance on emergency authorisations is a valid objective, it should not be pursued until improvements to the regulatory process have been implemented which guarantee the availability of a sufficient range of crop protection solutions for EU growers.

It is also worth highlighting that Invasive Alien Species (IAS) are a major threat to native plants and animals in Europe, causing damage worth billions of euros to the European economy every year[3]. Reg 1143/2014 provides a set of measures to be taken in relation to IAS, these include prevention, early detection and rapid eradication and management. Access to an effective range of tools, including plant protection products, is essential for Member States to combat IAS.

Possible procedural improvements

While ECPA supports the need for an emergency authorisation mechanism, a number of improvements to the functioning of Reg 1107/2009 should be implemented, which would reduce the overall number of emergency uses required. These improvements include:

- removing barriers to the granting of authorisations of plant protection products by mutual recognition across Member States as foreseen in Article 40 of Reg 1107/2009.
- accelerating the approval of new active substances and products containing these substances.

---

[2] Ecorys study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005), page 47: "*The number of emergency authorisations at the EU level shows a steady increase since 2011, reaching 714 authorisations at the EU level in 2017. Of these authorisations, 561 involved approved active substances, 43 active substances pending approval, 79 active substances with restricted approval (neonicotinoids) and 31 active substances not approved in the EU.*" https://publications.europa.eu/en/publication-detail/-/publication/7244480c-d34d-11e8-9424-01aa75ed71a1

[3] http://ec.europa.eu/environment/nature/invasivealien/index_en.htm

- developing and implementing a simple and pragmatic (fast-track) process to extend approvals of products to minor uses and speciality crops, including supporting scientific read-across of data from major to minor crops based on Commission guidance document SANCO 7525/VI/95[4].
- effectively implementing the zonal authorisation process under Articles 33-42 of Reg 1107/2009 including minimising national requirements; and;
- developing a risk/benefit evaluation and approval process that permits retaining plant protection products where no viable alternative exists and until an alternative is identified and approved for use. Such a process exists in other chemical sectors (e.g. REACH and biocides) to retain indispensable products under controlled conditions.

ECPA would also support more timely publication of information on approved emergency authorisations to increase transparency of the Article 53 procedure and the benefit each use provides to growers. Information from Member States should be harmonised and made available at European level via the Commission's product authorisation management system (PPPAMS).

ECPA position

As a principle ECPA does not support the concept of regulation by derogation; this does not provide the necessary predictability for companies to invest and develop new innovative products, nor does it provide growers with the visibility and reassurance of what products may be available from one season to the next. Agricultural production is a multi-year investment and farmers need certainty that they will have the tools they require to protect their crops.

ECPA's clear preference is to have a predictable, transparent and proportionate regulatory framework that allows companies to innovate and to develop new crop protection solutions. This framework should rightly ensure a high level of protection for human health and the environment while also providing growers with access to a range of effective plant protection options.

While the current regulatory framework under Reg 1107/2009 does provide a high level of protection, it is clearly not delivering on the objective of safeguarding the competitiveness of EU agriculture and ensuring the availability of the plant protection products in the Member States. The increasing use of Article 53 emergency authorisations is a symptom of the ineffective implementation of certain aspects of the regulation (see the needed procedural improvements listed above). Until these issues are addressed, ECPA will continue to support the concept of emergency authorisations as described in Article 53 of Reg 1107/2009.

Unanticipated plant disease and pest pressure will always necessitate the flexibility for Member States to temporarily approve some form of emergency uses in the absence of viable solutions for growers. This need was clearly foreseen at the time of the adoption of Reg 1107/2009 and is still relevant today. However, we believe that steps should be taken to improve the current functioning of the regulation which could also reduce the reliance on Article 53. If a number of fundamental improvements are made to the implementation of Reg 1107/2009 which ensure a greater availability of plant protection solutions to EU growers, a wider review of the emergency authorisation provisions could be initiated including involving regular audits by EFSA. While decreasing the reliance on emergency authorisations is a valid objective, this should not be pursued at the risk of removing crop protection solutions for growers.

Ultimately, the regulation of pesticides should be aligned with the legislation for biocides and general chemicals (Reg 528/2012 and Reg 1907/2006 respectively); whereby a key provision allows regulators to maintain products if a socio-economic analysis demonstrates that the risks of withdrawing the products outweighs the risks of retaining them. Unfortunately, such a mechanism is not included in Reg 1107/2009 for pesticides and is one of the main reasons why the use of emergency authorisations has become such an essential procedure for EU growers and for certain crops.

[4] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf

Attachment 1. Legislative background

Regulation 1107/2009
The purpose of Reg 11707/2009 includes:

- ensuring a high level of protection of human and animal health and the environment while safeguarding the competitiveness of Community agriculture **(recital 8)** as well as,
- increasing the free movement of plant protection products and the availability of these products in the Member States **(recital 9)**.

Recital 32 provides that in exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions of Reg 1107/2009, where it is necessary to do so because of a danger or threat to plant production which cannot be contained by any other reasonable means.

Article 53 (emergency authorisations) states that:

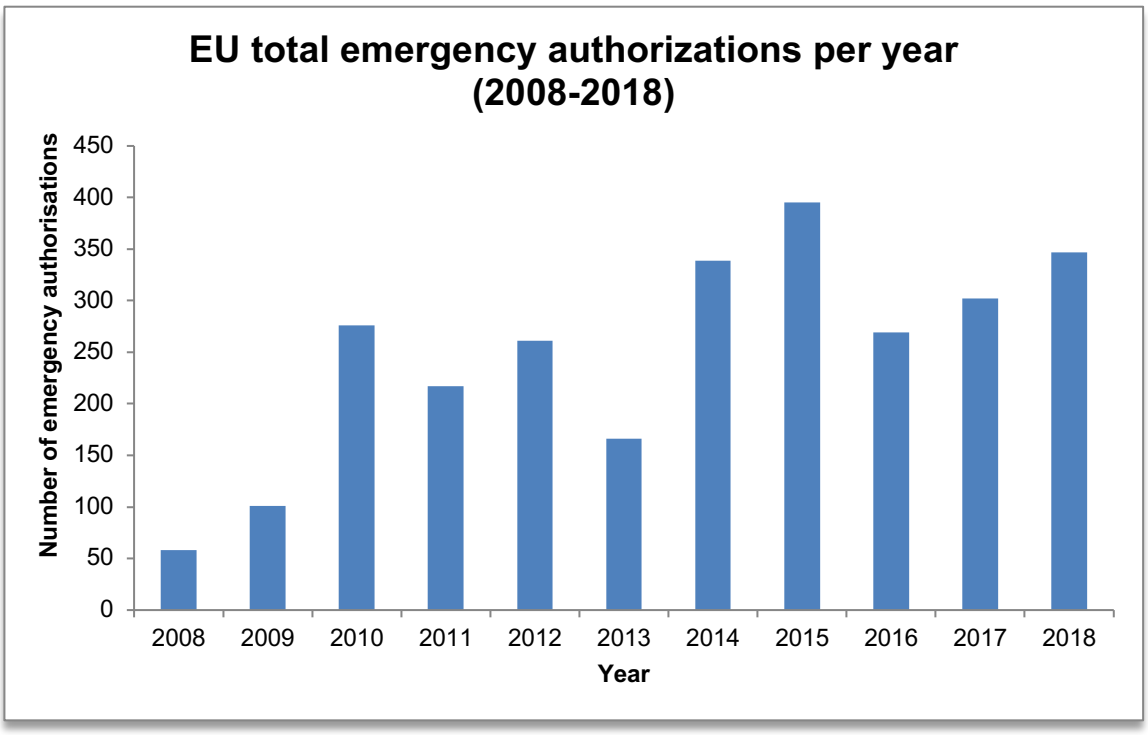
- *"in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means".*
- *"Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety"*.

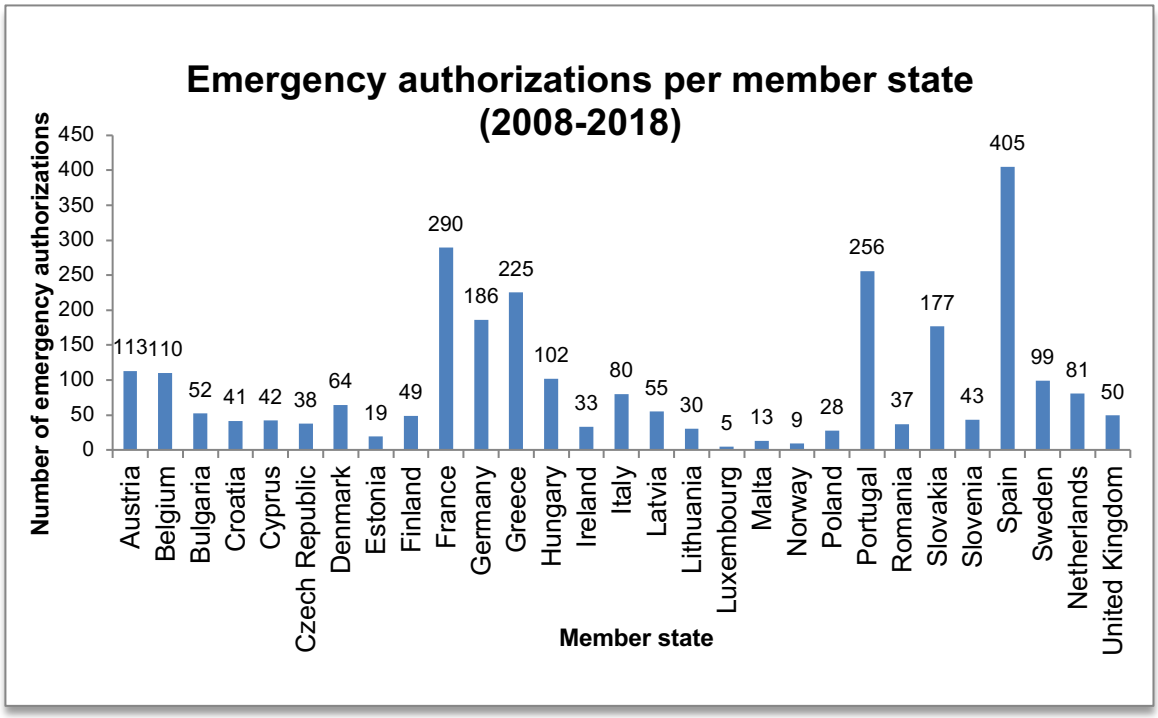
Commission guidance document SANCO/10087/2013
Guidance document SANCO/10087/2013 lays down the procedure for Member States when granting an authorisation under Article 53. The guidance document outlines that:

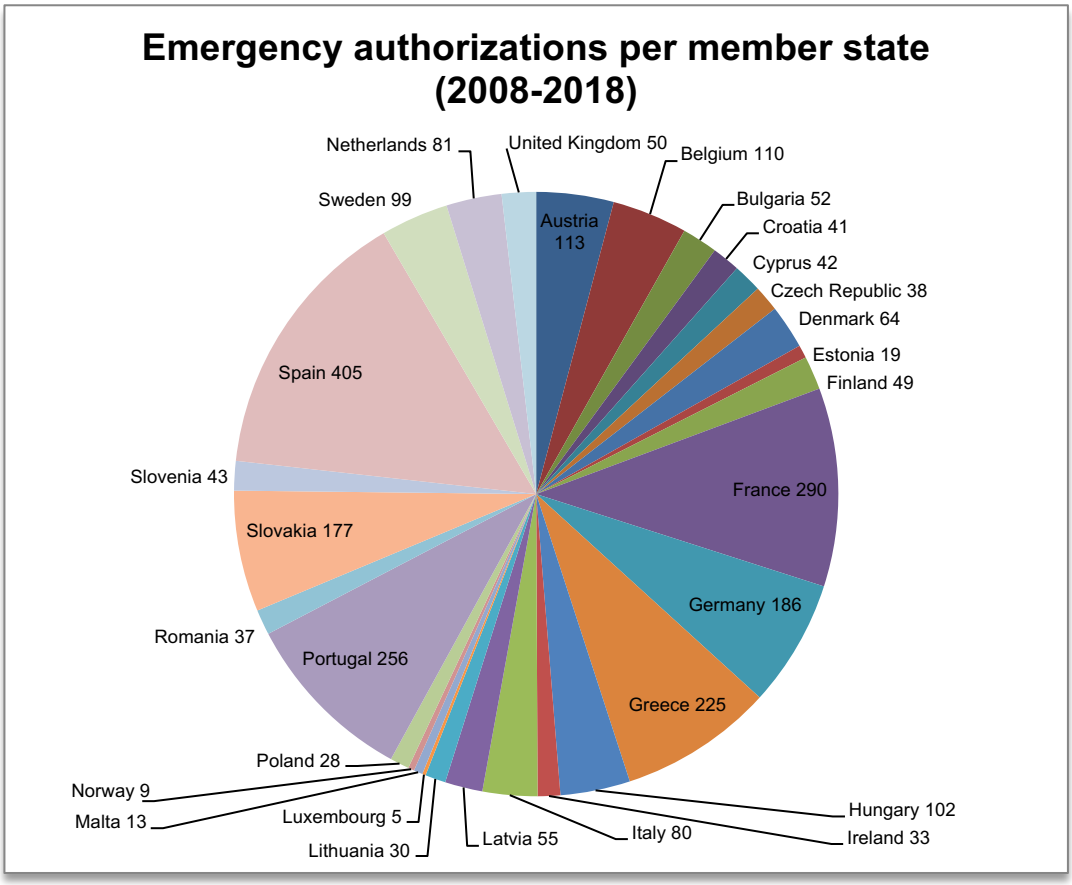
- Use of Article 53 should be exceptional, and restricted to cases of obvious dangers to plant production that cannot be contained by any other reasonable means. It shall not jeopardise the objective of Reg 1107/2009 to ensure a high level of protection for human health and the environment and shall be proportional in its sense.
- Member States should demonstrate, based on the application received, that the use authorised is justified and share detailed information about the situation and any measures taken to ensure consumer safety with the other Member States and the Commission, which may consult EFSA.
- 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[5], and to develop solutions and alternatives.
- Alternative approaches need to be achieved for the future and incentives considered to improve the use of existing alternatives particularly in the case of repeated occurrence of a specific emergency situation.
- Research should be strengthened to limit the use of plant protection products under Article 53 to special circumstances in the long term.
- Member States should uphold the integrity of the authorisation system. Emergency authorisations should not be granted as a routine alternative to extensions of use or other forms of standard authorisation.
- For emergency authorisations for **approved** active substances:
  - Where no other reasonable means of control are available, emergency authorisations should not be repeated and should be followed up by means of an Article 51 application or other standard authorisation.
  - Misuse of the emergency case for minor uses should be avoided. Therefore emergency authorisations relating to PPPs containing approved active substances should not be repeated in a following cropping season, unless the emergency continues and clear reasoning has been provided.
- For emergency authorisations for **non-approved** actives substances:
  - Member States should bear in mind safeguarding the protection of human health and the environment.
  - Member States 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 reported.
- Member States should evaluate applications for emergency use and immediately notify other Member States and the Commission of any emergency authorisations granted.

[5] General principles of integrated pest management, Annex III, of Directive 128/2009, framework for the sustainable use of pesticides

Attachment 2. Article 53 emergency authorisations, 2008-2018







- In total 2,731 emergency authorisations were approved across the EU from 2008-2018.
- The highest number 405, was approved in Spain
- 5 Southern member states (ES, FR, PT, EL and IT) make up 46% of all the approved emergency authorisations
- Most emergency authorisations are for products containing approved active substances for uses on minor and speciality crops (fruits and vegetables), making these crops most at risk.