



Our views on *Emergency Authorizations of Plant Protection Products in the European Union*

Background

In the European Union (EU), rules for the approval of active substances and the placing on the market of plant protection products are laid out in Regulation (EC) No 1107/2009.¹

The preamble to this regulation recognizes that individual Member States may face exceptional situations where a plant protection product which is not (or not yet) authorized is the only tool available to successfully handle an imminent threat to crop production.

For these cases, Article 53 of the Regulation lays out specific conditions under which Member States can grant a temporary authorization for a plant protection product. This allows the product to be sold and used in a “limited and controlled” way over a period of up to 120 days. Member States must justify the emergency authorization with reference to Article 53, and the justifications are many and varied. For example, the authorization may concern:

- // The use of an approved product on a crop which does not feature among the currently approved uses on the label;
- // A new active substance which has already been approved at EU level, but does not yet have the national-level authorization for products containing this substance in place;
- // A product or active substance that is not approved in the EU, but where no (or insufficient) approved alternatives exist.

The European Commission stores information on all such authorizations in the Emergency Authorizations database,² a publicly available resource hosted on the Commission’s website. As of August 2020, Member States had granted over 2500 emergency authorizations since 2016.

At a Glance

- // The EU’s plant protection regulation allows Member States to grant temporary authorizations of plant protection products that have not, or not yet, been approved. This is only permitted in exceptional, emergency situations and according to specific conditions.
- // The public can consult all granted emergency authorizations – totalling over 2500 as of August 2020 – via the European Commission’s online database.
- // Bayer recognizes the necessity of emergency authorizations to protect against otherwise unavoidable crop losses and supports such authorizations as long as the conditions laid out in the regulation are met.
- // Bayer believes that it is not the role of industry to proactively apply for emergency authorizations, yet is prepared to support requests made by third parties – as long as such requests are compliant with the conditions of Article 53 – and will do so on a case-by-case basis.

All applications for emergency authorizations must be made to the relevant Member State’s competent authority, which then alerts the European Commission via the Plant Protection Products Application Management System (PPPAMS). PPPAMS was developed by the European Commission to enable industry users to create applications for plant protection products and submit these to EU countries for evaluation. Consequently, Member States and companies that develop plant protection products are familiar with this tool. Other parties, such as farmer groups or trade associations, do not develop pesticide products themselves, and so they are less familiar with this tool.

1. Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. Full text accessible at <http://data.europa.eu/eli/reg/2009/1107/oj>
2. <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home>



Bayer's Views

Bayer supports the principle of Member States granting emergency authorizations, provided that the conditions laid out under Article 53 are met. Article 53 provides stringent guardrails to ensure that emergency authorizations are granted only when strictly necessary. This is a vital component of the Regulation which provides farmers with effective agricultural solutions for emergency situations.

Bayer recognizes the necessity of Article 53 to enable Member States to respond quickly and proportionately to immediate threats to agricultural production in their territory. By helping farmers to swiftly protect their crops against otherwise unavoidable losses, the impact of Article 53 is manifold:

- // It supports agricultural productivity and therefore contributes to food security, both at European level and globally. With a growing world population, it is more important than ever that farmers have access to solutions that support them in providing enough food for us all.
- // By providing solutions to secure the harvest, it protects the farmer's livelihood and safeguards the profitability of their operations. In turn, this helps to support employment across the EU, particularly in rural areas, and contributes to overall economic performance.
- // On a larger scale, it fosters the competitiveness of European agriculture and supports exports by working to mitigate threats to the quality and quantity of agricultural outputs.

The fact that EU Member States have already made use of emergency authorizations more than 2500 times is testimony to its importance for food security and agricultural productivity in the EU.

Bayer believes that it is not the role of industry to proactively apply for emergency authorizations. Bayer does not, and will not, apply for emergency uses for its own commercial gain. Emergency authorization requests are usually initiated by third parties within a Member State, such as growers' groups and national agricultural associations, in response to an imminent threat to their crops or harvest. These groups possess a detailed understanding of the local agronomic conditions and the solutions available to them at any one time and are therefore best placed to apply for emergency authorizations when necessary. Bayer believes that such applications should be made by the parties concerned who have identified the agronomic need. Bayer is prepared to support requests made by these third parties – as long as such requests are compliant with the conditions of Article 53 – and will do so on a case-by-case basis. In exceptional cases, Bayer will enter the application, but only at the express request of the Member State or the third party that has identified the agronomic need for the emergency use.

