European Crop Protection Association
member of CropLife International

Registering **plant protection products** in the EU

About plant protection products

What are plant protection products?

Plant protection products (PPPs) are the treatments used in both conventional and organic agriculture, to keep crops healthy by protecting them against pests and diseases. Also known as pesticides, PPPs are to plants the equivalent of medicines for humans. PPP companies manufacture synthetic products as well as products based on natural chemicals and minerals.

Ever since the first cultivation of plants for food, these plants have needed to be protected against pests and diseases. The level of sophistication of this protection has increased with time. The Romans used ashes, crushed cypress leaves and diluted urines to protect their crops. This century, a wide range of synthetic products have been developed to give much safer, more targeted and effective control of pests and diseases. The development of modern PPPs began in the 1940s, when Europe faced food shortages and rationing in the wake of World War II and the protection of crop yields had heightened importance. Since the 1970s, this dynamic has shifted with more pressure to balance the need to increase food production with the need to ensure the safety of people, food and the environment.

Benefits

The use of PPPs brings a wide range of benefits, among which:

Healthy diet

- By protecting crops, PPPs contribute to the production of a plentiful supply of high-quality and affordable food.
- They help the production of a choice of fruit & vegetables that are essential in a healthy diet.
- They reduce the exposure of consumers to naturally-produced toxins which plants develop if pests and diseases remain uncontrolled.

Economical

- PPP use increases yields and improves farm revenues. Without PPPs up to 50% of yields would be lost due to the presence of detrimental fungi, insects or weeds.
- They contribute towards EU self-sufficiency in cereals and other crops.

Environmental

- PPP use allows more food to be produced on a given area of land, which reduces pressure to cultivate un-cropped land and therefore ensures the maintenance of important natural habitats and protected natural areas.
- They help to reduce greenhouse gas emissions by replacing mechanical crop protection.
- They promote low-tillage agricultural systems, which reduce the loss of soil nutrients and prevent soil erosion.

Active substance vs plant protection product

The active substance within a plant protection product is the material responsible for its action against the target pest, weed or fungal disease.

The term 'plant protection products' designates the form in which farmers and other users apply the products. They contain one or several active substances along with other materials (such as water, solvents, carriers, inert material, wetting agents or adjuvants) to give optimum product efficacy.

Improvement of plant protection products

Safety to human health and the environment are top priorities for the members of the European Crop Protection Association (ECPA). They are also the shared prime goal of farmers, food companies and consumers. Today, PPPs are responsibly integrated as an element of traditional farming methods, and are a cornerstone of a flourishing and sustainable EU agriculture.

Investment in new crop protection products continues in order to provide solutions to farmers that meet the increasingly stringent regulatory standards in Europe and worldwide. On average it costs €189 million and takes 10 years for a new active substance to be brought to market. For every active substance that is registered for use, there are over 140,000 that do not make it past the development stage. Companies are also continuously developing plant protection formulations, with the aim of improving product effectiveness in controlling pests as well as increasing the level of safety for consumers and the environment.

To provide PPPs that address farmers' demand while complying with the evolving regulatory standards, developers employ around 30,000 people in the EU. Industry constantly increases its investment in capital and manpower to comply with the ever-stricter regulations in Europe.

Improving the use of plant protection products

In addition to investments in improved products, the crop protection industry also invests heavily in a wide array of measures to promote the optimal safe use of its products. For example, industry sponsors numerous stewardship programmes aimed at ensuring that everyone handles and uses PPPs correctly in order to protect workers, consumers and the environment. Such initiatives include, among others, projects on safer container disposal, proper application techniques and equipment, and water protection.

How are plant protection products regulated?

Overview of EU legislation

The core legislation regulating the approval of PPPs on the EU market is Regulation (EC) No 1107/2009, directly applicable in Member States. Based on the predominance of health and environment protection over agricultural production, it sets EU-wide requirements for their registration. Other legislations related to PPPs include:

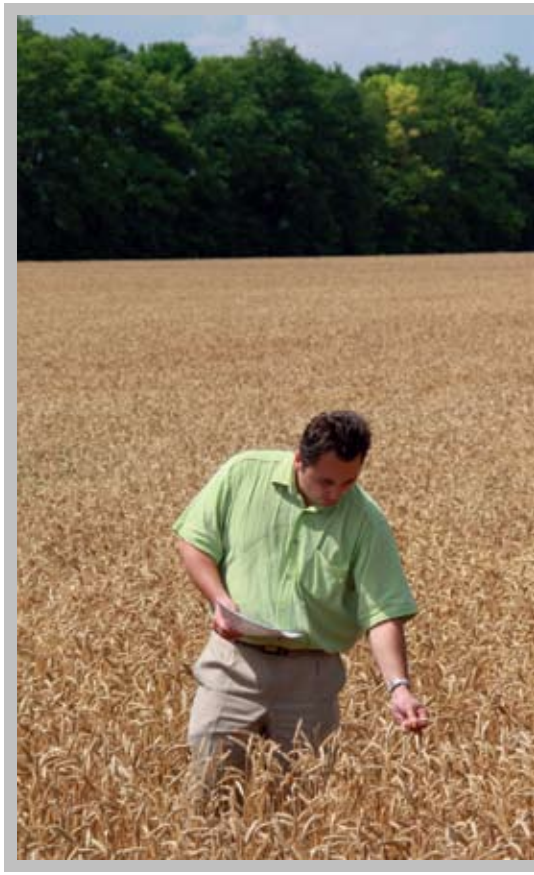
- **Directive 2009/128/EC** establishing a framework for sustainable use of pesticides;
- **Regulation (EC) No 1185/2009** concerning statistics on plant protection products;
- **Regulation (EC) No 396/2005** on maximum residue levels of pesticides in or on food and feed;
- **Regulation (EC) No 1272/2008** on product classification, labelling and packaging;
- **Directive 2000/60/EC** establishing a framework for water policy;
- **Directive 98/83/EC** on quality of water intended for human consumption;
- **Directive 2006/118/EC** on the protection of groundwater;
- **Directive 2004/35/CE** on environmental liability.

EU legislation requires the comprehensive testing of active substances, which is increasingly extensive and continuously updated in line with scientific advances. Therefore the products used today are the safest ever made.

Residues

The majority of foodstuffs do not contain any measurable pesticide residues. Where residues remain following application, they are strictly regulated and assessed according to Regulation (EC) No 396/2005. Maximum Residue Levels (MRLs) are set by EU scientific authorities for each pesticide used on each crop. These always include wide safety margins and are well below levels that could have any adverse effect on the health of consumers. MRLs act as an indicator of the correct use of pesticides as specified on the label, and as trading standards for imported and exported food. They are based on two key safety benchmark values, the Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD):

- An ARfD is the amount of PPP in food that can be ingested in one day without harmful effects; and
- An ADI value is an estimate of the human daily intake of the product over a lifetime, which would have no harmful effects.



Regulating the use of plant protection products

Today's awareness of health and environmental issues within the crop protection industry and amongst farmers is very high. The use of PPPs is not only regulated at national level, but also covered in particular by the European Directive 2009/128/EC on the sustainable use of pesticides. Farmers take care to use PPPs in a responsible way, and they precisely assess when and how to apply these products, and in which quantities they are needed. The plant protection products authorised for use in the EU are thoroughly tested to ensure they can be used safely.

Tests and studies required for PPPs

Today, before a PPP is approved in the EU, more than 100 specific tests are made on:

Physical and chemical properties

These data include among others the colour, odour and solubility of a PPP. This is a guarantee of consistent composition and quality of the product.

Analytical methods

These are validated methods to determine purity and potential residues detection.

Toxicity and metabolism studies

The acute (short-term) and chronic (long-term) toxicity is assessed for humans and animals. Metabolism studies assess what happens to the product once it has entered an organism, its movement and absorption, and how it is degraded and excreted.

Residues in food

These tests assess the presence of residues on crops as a result of recommended uses. This ensures that food is safe to eat as the MRLs permitted under European legislation are well below any level of concern and include wide safety margins.

Environmental and ecotoxicological studies

These tests assess the fate of a product in soil, water and air, but also any potential effects on birds, bees, aquatic species and other non-target organisms.

Efficacy

These data show whether the PPP performs its expected role in controlling target weeds, pests or diseases.

How does the approval process work?

There are two parts to the EU PPP approval process: the active substance(s) must be approved at EU level, and the formulated product must be authorised at Member State level. Before being placed on the market, all active substances are evaluated by experts in one of the EU's national regulatory authorities, their preliminary results are then peer reviewed by the European Food Safety Authority (EFSA), before the active ingredient is considered for approval by the European Commission's Standing Committee on the Food Chain and Animal Health. Once an active substance has been approved at EU level, the formulated product containing it must then be registered in each Member State.

Scientific review of data

The EU approval process of an active substance starts with the submission of results of the necessary tests and studies by the entity applying for an approval. This is provided to the authority of a designated "rapporteur" Member State, who prepares a "Draft Assessment Report" of the submitted data. This document is then independently peer reviewed by the EFSA, within experts' meetings considering all test results in all domains (e.g. environment, human health etc.). Based on the outcome of the experts' meetings, the EFSA sends its conclusions to the Commission, which bases its proposed decision on these conclusions.

Reviews and controls

A registration may be reviewed at any time in the light of new scientific evidence. Long-term health studies are undertaken to monitor possible links between health problems and exposure to PPPs. Older products must be routinely reviewed both by manufacturers and by the authorities to ensure that they meet the same safety standards as new products. Residues in food are also monitored at EU level. More than 70,000 samples of nearly 200 different types of food were analysed for pesticide residues in 2010 (figures 2008).

Active substance approval decision

All draft Commission decisions regarding active substances' approval must be accepted by the European Commission's Standing Committee on the Food Chain and Animal Health (SCFCAH). The SCFCAH is a Committee that helps the Commission in its role of implementing EU legislation. Its members are experts nominated by Member States. Based on the Draft Assessment Report and the EFSA conclusions, the SCFCAH votes on full or conditional approval of the active substance, or may refuse its approval. In most cases, the first approval lasts for a maximum of 10 years, but substances may be reviewed at any time in the light of new available information.

Plant protection product authorisation

Following EU approval of the active substance, data to defend formulated products containing the approved active substance must be fully examined. Each country where they are intended to be used takes approval decisions, taking into account specific local variations in climate, cropping patterns and diet. A Member State can grant either a full authorisation, an authorisation restricted to some crops, or reject authorisation. Both the data requirements for PPP approval by the Member States, and the criteria by which the EU and the Member States evaluate PPPs (Uniform Principles) are harmonised at EU level.

The EU framework legislation has always encouraged mutual recognition and the authorisation Regulation (EC) No 1107/2009 requires greater cooperation among Member States within three geographical zones in the EU: Northern, Central and Southern. The product authorisation process established by the Regulation foresees that one designated Member State in any one zone evaluates and authorises a product, and the other Member States within that zone decide on an authorisation, based on the assessment of the designated assessing Member State.

EU registration process under Regulation (EC) No 1107/2009

Company generates required data for active substance and product.	3-4 years
Application by submission of the data to a Rapporteur Member State, who checks the completeness of the data package.	45 days
Member State reviews data & prepares Draft Assessment Report (DAR).	12 months
DAR is published for public comments.	90 days
EFSA prepares its conclusions based on DAR and comments.	120 days (150 days if experts consulted)
Commission prepares proposal for decision based on DAR and EFSA conclusion.	6 months
Standing Committee on the Food Chain and Animal Health votes on approval.	
Once the substance is approved, company applies in each Member State for product approval.	
A Rapporteur for the zone evaluates the submitted PPP data.	12 months
Other Member States in the zone decide on PPP authorisation based on zonal Rapporteur evaluation.	120 days
From development to marketing	6.5 years
From application to approval	3.5 years

About ECPA

The European Crop Protection Association (ECPA) represents the crop protection industry interests at European level. Its members include all major companies and national associations across Europe. ECPA promotes modern agricultural technology in the context of sustainable development, one which protects the health of humans and the environment, and at the same time contributes towards an affordable healthy diet, competitive agriculture and high quality of life.

ECPA members support fair, science-based regulation as a guarantee to the consumer and the user of high standards and safe products.

The crop protection industry plays a positive and trustworthy role in sustainable European food production in using expert knowledge to support good legislation in collaboration with other stakeholders.

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