EU policy and legislation on pesticides

Plant protection products and biocides

IN-DEPTH ANALYSIS

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This publication presents an overview of European Union policy on pesticides. It describes the context in which the policy was formed, presents both the negative and positive impacts of the products in question and reports on the debate surrounding this issue. It outlines European Union legislation on plant protection products and biocidal products, with particular focus on the approval process for active substances and product authorisation. The publication also gives an insight into the opportunities and challenges associated with the legal framework. The views of stakeholders and the European Parliament are also discussed. Lastly, it describes the measures that the European Commission is expected to take in the field in the years to come.
EXECUTIVE SUMMARY

Substances used to suppress, eradicate and prevent organisms that are considered harmful are grouped under the term ‘pesticide’. The term includes both plant protection products (used on plants in agriculture, horticulture, parks and gardens) and biocidal products (used in other applications, for example, as a disinfectant or to protect materials).

The use of pesticides offers numerous advantages; above all, biocidal products help to fight vector-borne or food-borne diseases, and plant protection products have contributed to the leap in agricultural yield since the Second World War. However, the use of pesticides also brings a number of disadvantages, in particular, its impact on the environment (presence in the air, water or soil), risks to human health (for example, as a result of exposure to residues) and repercussions for crop protection. The use of synthetic plant protection products is fiercely debated in society, dividing supporters and critics. In recent years the debate has crystallised around certain aspects, not least, identification criteria for endocrine disruptors, restrictions on some neonicotinoids and renewed approval of the active substance glyphosate.

European Union (EU) legislation on pesticides is designed to ensure a high level of protection for human health and the environment and to improve the functioning of the internal market. Plant production products and biocides are subject to a dual approval process: active substances are approved at EU level and products are subsequently authorised predominantly at Member State level. The 2009 regulation on plant protection products and the 2012 regulation on biocidal products establish the approval criteria, the procedures (along with the timescales) and the derogations that may be applied. Two European agencies are involved in the process: the European Food Safety Authority (EFSA) for plant protection products and the European Chemicals Agency (ECHA) for biocidal products. In addition, a regulation from 2005 sets the standardised maximum levels for residues of plant protection products in food, and a directive from 2009 establishes a framework for action for sustainable pesticide use.

Many aspects of EU policy on pesticides can be considered opportunities or challenges, for example, issues surrounding costs for the agrochemical sector (regulatory costs and costs for research and development of new substances), approval procedures (evaluation and substitution of active substances, possible conflicts of interest, emergency authorisations and the cumulative effects of residues), sustainability (integrated pest management, recourse to biopesticides) and other related aspects (counterfeit pesticides and minor use of plant protection products).

The European Commission is assessing the legislation on plant protection products and their residues. The conclusions of that study are expected by the end of 2018.
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### Definitions

**Acceptable daily intake:** an estimated quantity of a substance, expressed in relation to body weight, that can be ingested through food every day over a lifetime without appreciable risk to the consumer (threshold for chronic toxicity).

**Active substance:** in plant protection products and biocidal products, the active component which counters harmful organisms. Active substances are approved at EU level.

**Acute reference dose:** an estimated quantity of a substance, expressed in relation to body weight, that can be ingested through food in one day without significant risk to the consumer (threshold for acute toxicity).

**Adjuvant:** a substance or preparation composed of co-formulants that is mixed with a plant protection product to enhance its efficacy.

**Biocidal product:** a product designed to combat organisms harmful to human or animal health and organisms that are detrimental to human activities. Such products include disinfectants, material protection products, rodenticides, insecticides and repellents. They are authorised at Member State or European Union level.

**Biocidal product family:** a group of biocidal products with similar applications, the same active substances, a similar composition and similar risk and efficacy levels.

**Biological control agent:** see biopesticide.

**Biopesticide** (also known as a ‘biological control product’): a product comprised of substances that are derived from living organisms and certain minerals.

**CLP Regulation:** Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

**Co-formulant:** a substance or preparation used in a plant protection product or biocidal product which is neither an active substance, a safener, nor a synergist.

**Comparative assessment:** an evaluation of risks and benefits managed by a Member State as part of the assessment process for a plant protection product or biocide in the context of planned substitutions of active substances.

**ECHA:** European Chemicals Agency. ECHA is principally involved in approving the active substances in biocidal products and in some authorisation procedures for biocidal products.

**Ecological focus area:** in the context of greening in the EU’s Common Agricultural Policy, an area which supports biodiversity either directly or indirectly and represents at least 5% of arable land in holdings larger than 15 hectares.

**EFSA:** European Food Safety Authority. EFSA is principally involved in approving the active substances in plant protection products.

**Good phytosanitary practices** (also known as ‘good agricultural practices’): making use of plant protection products in accordance with authorised conditions of use in a way that ensures optimal efficacy with the minimum quantity necessary; taking into consideration local conditions and the scope for using agricultural and biological controls.

**Harmful organism:** an undesirable organism that is detrimental to human activities. Harmful organisms include pathogens (bacteria, viruses, moulds and nematodes), invertebrates (mainly insects, acari and molluscs), a small number of vertebrates, and weeds.

**Hazard:** the capacity of a substance, as a result of its inherent properties, to cause adverse effects for humans and the environment.

**Integrated pest management** – also known as ‘integrated plant protection’: the integrated introduction of biological, biotechnological, chemical, physical or agricultural measures.
relating to a range of plants, strictly restricting the use of synthetic plant protection products to the absolute minimum necessary.

**Maximum residue level (MRL):** the maximum concentration of pesticide residue authorised in food, set, in order to protect vulnerable consumers, on the basis of good food practices and the lowest possible exposure.

**Minor use** (in the context of the regulation of plant protection products): the use of a plant protection product either against harmful organisms or on crops that are limited in number in a Member State. Plant protection product authorisation granted for use on some selected crops may be extended to minor use for another crop under certain conditions.

**Mutual recognition:** for specific cases, the scope for a Member State to recognise the authorisation granted in another Member State for a plant protection product or biocide.

**NGO:** non-governmental organisation.

**Parallel trade:** the option of using a simplified procedure to place on the market plant protection or biocidal products whose composition is identical to a product that is already authorised in another Member State.

**Pesticide:** a substance that suppresses or eradicates a harmful organism, or prevents its activity. The term includes both plant protection products and biocidal products (although in current usage it is often used synonymously with plant protection products).

**Plant protection product:** a product composed of active substances that protects vegetation from harmful organisms or prevents their activity. Such products are mainly used in agriculture, but also in horticulture, silviculture and in green spaces and gardens. They are authorised at Member State level.

**Preparation:** a solution or mixture comprised of two or more substances.

**Rapporteur Member State:** The Member State overseeing the assessment of an active substance, a safener or a synergist.

**Risk:** the likelihood of adverse effects occurring when humans or the environment are exposed to a hazard. In other words, risk = hazard x exposure.

**Safener:** a substance or preparation added to a plant protection product to suppress or reduce its effects on some plants.

**Simplified cultivation techniques** (no-till farming): in agriculture, practices that limit ploughing and therefore turning over the soil.

**Substance:** a chemical element either naturally occurring or industrially manufactured.

**Substance of concern:** a substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment.

**Synergist:** a substance or preparation that enhances the activity of the active substance or substances in a plant protection product.

**Treated article** (in the context of regulation of biocidal products): an article, a substance or a mixture that has been treated with biocidal products or contains biocidal products.
1. Background

Substances used to suppress, eradicate and prevent organisms that are considered harmful are grouped under the term ‘pesticide’. That term includes both plant protection products and biocidal products (see below). Pesticides can be grouped not only by type of use but also in different categories according to other important criteria, such as their target, the origin of their active substances or their hazard category. Within the principal synthetic pesticide categories that target specific harmful organisms (insecticides, fungicides and herbicides), the modes of action against harmful organisms are set out, as are the different generations of substances.\(^1\)

**Figure 1 – Classification of pesticides according to a number of criteria**

<table>
<thead>
<tr>
<th>Use</th>
<th>Target</th>
<th>Origin</th>
<th>Hazard category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PLANT PROTECTION PRODUCTS</strong></td>
<td><strong>INSECTICIDES</strong></td>
<td><strong>SYNTHETIC PESTICIDES</strong></td>
<td><strong>EXTREMELY HAZARDOUS</strong></td>
</tr>
<tr>
<td>protection of plants before, during and after cultivation, mainly in agriculture but also in horticulture, silviculture and green spaces and gardens</td>
<td>target insects</td>
<td>products that stem from a chemical synthesis process</td>
<td>class Ia</td>
</tr>
<tr>
<td><strong>FUNGICIDES</strong></td>
<td>target fungi and mould</td>
<td><strong>HIGHLY HAZARDOUS</strong></td>
<td>class Ib</td>
</tr>
<tr>
<td><strong>HERBICIDES</strong></td>
<td>target weeds</td>
<td><strong>MODERATELY HAZARDOUS</strong></td>
<td>class II</td>
</tr>
<tr>
<td><strong>PLANT GROWTH REGULATIONS</strong></td>
<td>stimulate or restrict growth of specific plant parts</td>
<td><strong>SLIGHTLY HAZARDOUS</strong></td>
<td>class III</td>
</tr>
<tr>
<td><strong>OTHERS</strong></td>
<td>acaricides (targeting acari), nematicides (targeting nematodes), etc.</td>
<td><strong>UNLIKELY TO PRESENT ACUTE HAZARD</strong></td>
<td>class U</td>
</tr>
</tbody>
</table>

(As per World Health Organization classification)

An estimated 67,000 pest species are harmful to plants (of which 50,000 are pathogens, 9,000 insects and acari, and 8,000 weeds).\(^2\) The plants’ vulnerability to those organisms tends to increase if humans have intervened to increase their yield and if they are grown in monocultures.\(^3\) The increase in yields achieved in recent decades, particularly through the use of fertilisers, has added further impetus to the phenomenon by making cultivated

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varieties even more attractive to pathogens and insects and by impairing their ability to compete with weeds.\textsuperscript{4}

The use of plant protection products is an integral part of the \textbf{twin challenges} facing agriculture: satisfying the nutritional needs of a rapidly expanding human population, and not increasing – or even decreasing – pressures on the environment.

\section*{1.1. Pesticide market}

\subsection*{1.1.1. Plant protection products}

In 2014, plant protection product output in the European Union was worth almost €10 billion, and in 2010, it provided employment for some 26 000 people.\textsuperscript{5} The global market for plant protection products, which stands out for its relatively small number of large companies, is even more concentrated.\textsuperscript{6}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure2.png}
\caption{Sales of plant protection products by utilised agricultural area (2014)}
\end{figure}


Since 2011 sales of plant protection products in the European Union have fluctuated between 350 000 and 400 000 tonnes per year. Five countries (Spain, France, Italy, Germany and Poland) account for almost three quarters of that volume.\textsuperscript{7} Sales of plant protection products per hectare of utilised agricultural area in the EU amount to 2.3 kilogrammes (kg) per hectare. Variation between Member States is considerable, with two countries reaching sales per hectare of almost 10 kg, and 18 countries with less than 2 kg (see figure 2).\textsuperscript{8} There are contrasting trends in the different Member States

\textsuperscript{4} E.-C. Oerke et al., Crop production and crop protection: estimated losses in major food and cash crops, Elsevier, Amsterdam, 1994, pp. 757-758.


\textsuperscript{6} At the beginning of 2017, the European Commission reviewed three merger proposals between large groups in the sector: Dow and DuPont, ChemChina and Syngenta, and Bayer and Monsanto.

\textsuperscript{7} Eurostat, \textit{Pesticide sales (aei_fm_salpest09)}, 2017.

\textsuperscript{8} The volume expressed in kilograms does not necessarily reflect the cost for farmers, the environmental impact or the result on agricultural yield.
between 2011 and 2014.\textsuperscript{9}

Fungicides and herbicides are the \textbf{main types of plant protection product} sold in the European Union (see figure 3). The figures for those types also varies between Member States. The level of insecticides used in countries with a Mediterranean climate is higher than the European average.

\textbf{Figure 3} – Plant protection products by target in 2014\textsuperscript{10}

Data source: Eurostat, \textit{Pesticide sales} (aei_fm_salpest09) and European Crop Protection Association, \textit{Annual Review 2015}, 2016, p.15. The figures show the breakdown of the market, including the 28 Member States, Iceland, Lichtenstein, Norway and Switzerland.

\subsection{1.1.2. Biocidal products}

No detailed, consolidated information is available on the market for biocidal products in the European Union. In 2014, the value of the global market was estimated at US$8 billion; in 2000, Europe accounted for 27\% of the global market.\textsuperscript{11} In 2000, the European market was dominated by three companies who controlled 25\% of the market, although small and medium-sized enterprises were also active on the market, particularly with regard to the production of highly-specialised biocidal products.\textsuperscript{12}

Biocidal products are used in industry sectors (such as agri-food, automotive, paper, cleaning products and paints) where they may be incorporated in some products (such as paints and detergents), used during the production process (for example, disinfectants used on surfaces or materials to ensure food safety in the agri-food sector), or used in some services (for example, professional cleaning services). The biocidal market is made up of a multitude of unconnected end-users with different profiles. Demand for biocidal products is expected to increase in the coming years, driven mainly by their use in

\begin{itemize}
  \item Sales have declined in 13 countries but increased in 11 others. In certain cases, the variations are significant; for example, Denmark (-63\%), Ireland (-26\%), Malta (-16\%), Greece (-15\%); Latvia (+32\%), Estonia (+30\%), France (+23\%).
  \item Differences between the volume in kilograms and market shares can be explained mainly by the fact that certain more established products (such as sulphur and copper) can have a greater volume and be less expensive than some of the newer synthetic products.
\end{itemize}
industrial applications, in the beverage and take-away sector, and in cosmetic products.\textsuperscript{13}

\subsection*{1.2. Impact of pesticides}

Using pesticides has a number of \textbf{benefits}. Biocidal products help to fight vector-borne diseases (transmitted by a living organism from one host to another) such as malaria, food-borne diseases such as salmonellosis, and nosocomial infections (contracted in a healthcare facility). The main advantage of plant protection products is their contribution to increased agricultural yields. The modernisation of agriculture since the Second World War and its practices have more than doubled the agricultural yield of cereal crops in the 28 Member States since the beginning of the 1960s (see Figure 4); synthetic plant protection products have contributed significantly to that increase, which can also be partly attributed to the use of mineral fertilisers, variety selection, irrigation and mechanisation.

\textbf{Figure 4 – Production and yield of cereal crops in the EU-28 (1961-2014)}

![Figure 4](image)


In spite of physical, biological and chemical cultivation methods \textbf{agricultural losses due to harmful organisms} are estimated at 42 \% of the achievable production worldwide and at 28 \% of achievable production in Europe. Those losses can be attributed in equal measures to harmful animals, pathogens and weeds. Without physical, biological or chemical intervention, it is estimated that, worldwide, potential losses could be 70 \% of achievable production.\textsuperscript{14} In economic terms, crop production in the European Union is worth some €200 billion.\textsuperscript{15}

\begin{itemize}
\item \textsuperscript{14} Estimates for eight crops (rice, wheat, barley, corn, potato, soya, cotton and coffee) based on academic literature and land surveys by the agrochemical industry. ‘Achievable production’ is taken to mean the maximum production for a given site, using all protective measures currently available, without considering the economic cost of those measures for a farmer. Thus, achievable production is greater than the financially optimal level of production for a farmer. Nor does it take into account any potential impact on human health or the environment. E.-C. Oerke et al., op. cit., pp.75-80 et pp.748-752.
\item \textsuperscript{15} European Commission, \textit{Statistical Factsheet European Union}, 2016, p. 9.
\end{itemize}
Plant protection product residues in food

In its report on the control programmes carried out in 2015 on pesticide residues in food, the European Food Safety Authority (EFSA) stated that, ‘considering the frequency of pesticide residues detected in food commonly consumed, a wide range of European consumers is expected to be exposed to these substances via food’. However, with regard to acute exposure, it concluded that ‘the probability of European citizens being exposed to pesticide residue levels that could lead to negative health outcomes was low, but for a limited number of samples an acute dietary risk could not be completely ruled out’.

The report set out that of the 84,341 samples analysed, 53.3% had no measurable residue, 43.9% had a residue below the statutory limit and 2.8% had a residue that exceeded the statutory limit. Amongst samples imported from third countries, the presence of residues above the statutory limit is more pronounced, at 5.6%. Twenty-eight per cent of the samples tested contained more than one pesticide residue. The results were very similar to those from previous years.

However, pesticide use also has drawbacks. They include:

- **Environmental effects**, in particular where pesticides can be found in the air, water or soil. Their presence in the environment, particularly in the case of persistent substances, can have adverse effects on non-target species, thus affecting habitats, contributing to the loss of biodiversity and reducing the quality of services provided by ecosystems (such as pollination by insects, soil formation and composition, and drinking water supplies).

- **Human health hazards** associated with, for example, farmers altering plant protection products and also suspected risks to health mainly due to long-term exposure to residues found on food or in drinking water.

- **Their impact on crop protection**, (in particular the resurgence of specific harmful organisms with the disappearance of their natural predators, the emergence of secondary harmful organisms and the development of resistance to the products used) which requires continuous development of new products.

Some approaches can be adopted to mitigate the drawbacks mentioned above. They include:

- **Integrated pest management**: this consists of prioritising preventative measures and, in the event that they prove to be insufficient, of favouring non-chemical management methods and of only using synthetic plant protection products as a last resort.

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17 With regard to long-term (chronic) toxicity, EFSA noted in its report on the monitoring programmes carried out in 2014 that ‘according to current scientific knowledge, it is unlikely that residues from the pesticides [studied as part of the EU coordinated monitoring programme] pose a long-term health risk to consumers’.


19 For example, see Science for Environment Policy, *Banned pesticides continue to affect toxicity in streams*, 2017.

• **Biological control products**: made from substances derived from living organisms, these products (also known as ‘biopesticides’) can offer a range of benefits. In particular, they are often less hazardous to the environment and to mammals, pests are less likely to develop resistance against them, and their residues cause fewer problems. However, they are not without their drawbacks; they cost more, are not as effective and are less universally adopted.

• **Precision agriculture**: this practice entails only applying synthetic plant protection products (and other inputs such as fertiliser or water) where they are required, according to multiple variables, measured in precise relation to the relevant space and time and making use of new technologies.  

1.3. **Opposing views**

The use of synthetic plant protection products is vigorously debated in society, with two competing views being aired. The main arguments supporting the two viewpoints are outlined as follows:

• Against the current backdrop of significant population growth, some of those in favour of synthetic plant protection products emphasise the moral obligation to bolster agricultural practices with a view to combating worldwide famine and safeguarding food security in the European Union. They point out that the move to bolster practices, which increases crop yields but also their appeal to harmful organisms, must be accompanied by the use of synthetic plant protection products in order to preserve yields, and they also highlight the socio-economic consequences of a decline in agricultural yield. Lastly, the use of synthetic plant protection products provides the option of using ‘simplified cultivation techniques’, which can improve soil quality and reduce greenhouse gas emissions from agricultural holdings.

• Those against synthetic plant protection products emphasise the moral obligation to protect the environment for future generations and to allow a plurality of agricultural practices and choice of food. They point out that agriculture must be seen as a multi-functional activity that produces not only food, but also assets for people (such as biodiversity or drinking water). They claim that yield can be maintained while simultaneously reducing the use of some plant protection products, and that instead of maximising agricultural production, the source of increased agricultural output should be protected. Lastly, they highlight the impact on valuable species and water and soil resources, along with the suspected adverse effects on human health.

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21 For further details, see R. Schrijver et al., *Precision agriculture and the future of farming in Europe: Scientific Foresight Study*, EPRS, European Parliament, 2016.

22 See, for example, European Crop Protection Association, *With or Without Pesticides*.

23 See, for example, E.-C. Oerke et al., op. cit., pp. 759 and 765.

24 See, for example, European Crop Protection Association, *Low Yield Legislation*, 2016.


26 See, for example, A. Bailey et al., *Biopesticides: Pest Management and Regulation*, CABI, Wallingford, 2010.

27 See, for example, M. Lechenet et al., *Reducing pesticide use while preserving crop productivity and profitability on arable farms*, Nature Plants, 2017; or Science for Environment Policy, *Herbicide reduction can preserve crop yields as well as biodiversity benefits of weeds*, 2016.

2. European policy

The general objective of EU environmental policy as set out in Article 191 of the Treaty on the Functioning of the European Union,\(^\text{29}\) is to put in place ‘a high level of protection’. Furthermore, the Treaty establishes four principles that underpin EU environmental policy and are pertinent to policy on pesticides (the precautionary principle, the principle that preventive action should be taken, the principle that environmental damage should as a priority be rectified at source and the principle that the polluter should pay).

In the Sixth Environment Action Programme of the European Community adopted in 2002,\(^\text{30}\) the European Union set itself the target of ‘reducing the impacts of pesticides on human health and the environment and more generally to achieve a more sustainable use of pesticides as well as a significant overall reduction in risks and of the use of pesticides consistent with the necessary crop protection’. In the Seventh Environment Action Programme of the European Community, adopted in 2013,\(^\text{31}\) the European Union intends to ‘ensure that ... the use of plant protection products does not have any harmful effects on human health or unacceptable influence on the environment, and such products are used sustainably’, in particular, by monitoring the implementation of EU legislation and reviewing it, ‘as necessary, to keep it up to date with the latest scientific knowledge’.

3. European legislation

3.1. The placing of products on the market

The placing of pesticides on the European market is governed by the Regulation on Plant Protection Products,\(^\text{32}\) adopted in 2009, and the Regulation on Biocidal Products,\(^\text{33}\) adopted in 2012. Those regulations have two objectives: ‘to ensure a high level of protection of both human and animal health and the environment’ and ‘to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products’ and biocidal products. Moreover, the objectives are based on the precautionary principle\(^\text{34}\) and are designed to prevent testing on vertebrate animals.

Plant production products and biocides are subject to a dual approval process: active substances are approved at EU level and products are subsequently authorised.


\(^{34}\) For more details on the precautionary principle, see D. Bourguignon, \textit{The precautionary principle: Definitions, applications and governance}, EPRS, European Parliament, 2015.
predominantly at Member State level. Applicants pay a fee to the authorities to assess applications.\(^\text{35}\) The application processes are accompanied by obligations to make selected information available to the public.\(^\text{36}\) Furthermore, in the event of a serious risk to human or animal health or the environment, safeguarding measures may be taken.

The **Regulation on Plant Protection Products** covers all plant protection products, whether they are intended for agricultural use or for another purpose (for example, horticultural use, or in green spaces and gardens), whether they are synthetic products or are bio-based (biostarsicides)\(^\text{37}\) and regardless of their mode of action. Aside from plant protection products that are ready for use, the Regulation also covers active substances, safeners, synergists, co-formulants and adjuvants that are incorporated into the end products.\(^\text{38}\)

The **Regulation on Biocidal Products** covers biocidal products and articles treated with biocides, with the exception of products or articles that are governed by other legislation.\(^\text{39}\) It lists 22 types of biocidal products divided into four groups (disinfectants, preservatives, pest control products and other biocidal products) according to their applications.\(^\text{40}\)

**3.1.1. Approval of active substances**  
Active substances are approved at EU level. To be granted approval, an active substance, safener, co-formulant\(^\text{41}\) or synergist has to satisfy a number of **exemption criteria**, mainly based on the hazard posed by a substance (and not on the risk linked to exposure to the substance). The main exemption criteria are listed below.

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\(^\text{35}\) Member States’ fees for biocidal products are set in line with the provisions of Article 80 of Regulation (EU) No 528/2012. Implementing Regulation (EU) No 564/2013 sets the fees payable to ECHA. The majority of Member States charge a fee for plant protection products.

\(^\text{36}\) Plant protection products: as part of the substance approval process, EFSA is obliged to make the summary report and the draft assessment report available to the public, after it has removed any confidential information from them. Those documents can be accessed via the EFSA website: *summary report* (then click on ‘Pesticides dossier’) and *draft assessment reports* (to view the draft assessment reports published in recent years, see the *search results for ‘public consultation on the active substance’*). The Member States are obliged to publish a list of approved or withdrawn products (see the list of *national databases*).

Biocidal products: a whole range of information relating to approved substances and authorised products must be made accessible to the public by electronic means. That information is available on the ECHA website: *biocidal active substances* and *biocidal products*.

\(^\text{37}\) However, beneficial micro-organisms (a type of biopesticide) are not covered by the scope of the regulation.

\(^\text{38}\) For definitions of the different terms, see definitions pp.3-4.

\(^\text{39}\) The other legislative acts mainly concern medication (for human and animal use), food hygiene, plant protection products and toy safety.

\(^\text{40}\) The list of product types is set out in Annex V to the Regulation. See also ECHA; *Product-types*.

\(^\text{41}\) Those co-formulants used in plant protection products which do not meet the established criteria are itemised in a list in Annex III to the Regulation on Plant Protection Products. At the present time, no substances are on the list.
Two European agencies involved in granting substance approval

Founded in 2002, the **European Food Safety Authority (EFSA)** provides scientific guidance in any domain that has a direct or indirect impact on food or food safety. It is based in Parma (Italy) and has an annual budget of some €79 million. Its Management Board comprises 15 members, 14 of whom are appointed by the Council after consultation with Parliament, from candidates proposed by the Commission (four of the members have a background in organisations representing consumers and other interest groups in the food chain) and the other is a representative of the Commission. Ten panels focusing on different scientific areas, including a ‘Panel on plant health, plant protection products and their residues’, are tasked with risk assessment.

The **European Chemicals Agency (ECHA)**, brought into being by the REACH Regulation, was founded in 2007 and performs a number of functions in accordance with several legislative acts of the European Union. It is based in Helsinki (Finland) and has an annual budget of some €108 million. At the head of ECHA is a Management Board comprising a representative of each of the 28 Member States appointed by the Board, three representatives of the Commission, two independent representatives appointed by Parliament, and three observers from other interested parties. ECHA’s ‘Biocidal Products Committee’ is responsible for preparing opinions on issues related to biocidal product regulations.

<table>
<thead>
<tr>
<th>Table 1 – Principal exemption criteria for substance approval</th>
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<tbody>
<tr>
<td><strong>Plant protection substances</strong></td>
</tr>
<tr>
<td>Effects on human health</td>
</tr>
<tr>
<td>Effects on the Environment</td>
</tr>
</tbody>
</table>

Source: European Parliamentary Research Service (EPRS).


\(^44\) For further information, see ECHA, [Biocidal Products Committee](https://echa.europa.eu/about/our-board/our-committees/biocidal-products-committee).

\(^45\) Substances cannot be classified as carcinogenic, mutagenic or toxic to reproduction (either category 1A or 1B) as per the [CLP regulation](https://ec.europa.eu/environment/chemicals/graphql).

\(^46\) According to certain criteria (for now unspecified) that the European Commission is required to define. In the expectation that the criteria will be adopted, substances classified as carcinogenic and/or in category 2 for reproductive toxicity in accordance with the [CLP Regulation](https://ec.europa.eu/environment/chemicals/graphql) are considered endocrine disruptors. Furthermore, substances classified under category 2 for reproductive toxicity and which have toxic effects on endocrine organs may also be considered to have endocrine disrupting properties.

\(^47\) Following the criteria defined in Annex II to the Regulation on plant protection products and Annex XIII to the [REACH Regulation](https://eur-lex.europa.eu/eli/reg/2006/1831/oj) for biocidal products. For more information on these types of substances, see D. Bourguignon, *EU policy and legislation on chemicals: Overview, with a focus on REACH*, EPRS, European Parliament, 2016.
The approval process, which generally takes between two and a half and three years from the time when the application is declared admissible, can be broken down as follows:

- An application is submitted to a Member State (for plant protection substances) or to the European Chemicals Agency (for biocidal substances). It is accompanied by documentation including toxicological and ecotoxicological studies, along with information on residues, and on the fate and behaviour in the environment of the pesticide. Applications describe the intended uses, particularly the treated crops (for plant protection products) and the type of product (for biocidal products).
- A national authority (called the ‘Rapporteur Member State’ for plant protection substances and the ‘evaluating Competent Authority’ for biocidal substances) confirms the admissibility of the application within a defined time frame and carries out its assessment within one year, which can be extended if additional information is required.
- The national authority submits its assessment report to the relevant European agency (EFSA for plant protection substances and ECHA for biocidal substances), which submit their conclusions to the Commission within a set time frame.
- The European Commission adopts a regulation after the ‘Standing Committee on the Food Chain and Animal Health’ (plant protection substances) or the ‘Standing Committee on Biocidal Products’ has adopted it. Approval is granted for one or more specific uses. It may be subject to conditions and granted for a maximum period of 10 years.

A number of derogations are permitted in special cases.

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48 For plant protection products, the information that has to be included is listed in Commission Implementing Regulation (EU) No 283/2013. For biocidal products, the information is given in Annex II to the Regulation on biocidal products.

49 The assessment report is called ‘draft assessment report’ in the procedure for plant protection substances and ‘assessment report’ and the ‘conclusions of the evaluating Competent Authority’ in the procedure for biocidal substances.

50 For plant protection substances, EFSA opens the draft assessment report to public consultation for a period of 60 days and issues its conclusions in 120 days, or longer if experts have to be consulted or if additional information is required. For biocidal substances, ECHA issues its conclusions within 270 days.

51 Plant protection substances: The list of approved active substances is published in Commission Implementing Regulation (EU) No 540/2011. The list is also accessible via the register of approved active substances on the European Commission website.

Biocidal substances: The list of approved active substances is available on the ECHA website.

52 Those regulations are adopted in accordance with the regulatory procedure for plant protection substances and the examination procedure for biocidal substances. For more detail on the procedures in question, see A. Hardacre and M. Kaeding, Delegated and Implementing Acts: EIPA Essential guide, 2013, p. 9 and p. 16.
Table 2 – Main derogations applicable to substance approval

<table>
<thead>
<tr>
<th>Max. duration</th>
<th>Plant protection substances</th>
<th>Biocidal substances</th>
</tr>
</thead>
</table>
| 5 years       | substance does not meet approval criteria but is ‘necessary to control a serious danger to plant health which cannot be contained by other available means’ | substance does not meet approval criteria unless:  
• the risk is negligible; or  
• the substance is required to prevent or overcome a serious hazard; or  
• non-approval would have disproportionate negative consequences for society |
| 7 years       | substitution of substance planned owing to high risk to human health or the environment⁵³ |                     |
| 15 years      | low-risk substance⁵⁴        |                     |
| unlimited     | basic substance⁵⁵           | Substance with no grounds for concern⁵⁶ |

Source: European Parliamentary Research Service (EPRS).

Approval can be renewed for a maximum duration of 15 years upon application by the manufacturer, subject to a similar procedure to that for initial approval. The Commission may review the approval of a substance at any time.

At the beginning of 2017, in the European Union, 488 active substances for plant protection products were approved, whilst 205 approvals were granted for an active substance for use in a particular biocidal product type (see Figure 5). With regard to plant protection products, included in the figures for approved active substances were 75 substances which are candidates for substitution, 17 basic substances, and seven low-risk substances; the high number of non-approved active substances for plant protection products (696) is the result of a review that took place between 1993 and 2009, upon completion of which some 70% of the active substances that were on the market before 1993 were withdrawn. With regard to biocidal products, 29 active substances approved for a particular product type meet the substitution criteria;⁵⁷ a review of existing active substances is underway (scheduled for completion in 2024).⁵⁸

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⁵³ Following the criteria listed in Annex II, point 4 to the Regulation on Plant Protection Products, and Article 10 of the Regulation on Biocidal Products.

⁵⁴ A low risk substance is understood in this context as a substance that: is not carcinogenic, mutagenic, toxic to reproduction, sensitising, toxic, explosive or corrosive (in accordance with the CLP Regulation), is not persistent, neurotoxic or immunotoxic, an endocrine disruptor, and does not have bioconcentration potential.

⁵⁵ The term ‘basic substance’ means a substance which is not a substance of concern and which is not intended primarily for use as a plant protection product (and is not marketed as such) but which may be useful in protecting plant health.

⁵⁶ By this is meant a substance which meets the conditions listed in Article 28 of the Regulation on Biocidal Products and which causes no grounds for concern. A list of these substances can be found in Annex I to the Regulation.

⁵⁷ CIRCABC, Information on approved active substances with regard to certain exclusion substitution criteria.

⁵⁸ The review methods are defined in Commission Delegated Regulation (EU) No 1062/2014. See also ECHA, Existing active substance.
3.1.2. Product authorisation

In general, products are authorised at Member State level. To receive authorisation, a plant protection product or biocide must meet a number of criteria, including that its active substances are approved; in realistic conditions of use, it is sufficiently effective, it does not have any harmful effects, either directly or indirectly, on humans or animals and it does not have any unacceptable impact on the environment.

Three administrative zones have been set out in the European Union to handle plant protection product approvals (see figure 7), and applications are assessed by one
Rapporteur Member State per zone. The zones do not apply to the authorisation of biocidal products. Biocidal products are authorised on a product-by-product basis, or by product family.

**Figure 7 – Administrative zones for plant protection product authorisation**

Several **procedures** for placing products on the market have been set up. Which procedure is followed depends on the circumstances.

**Table 3 – Procedures for placing plant protection products and biocides on the market**

<table>
<thead>
<tr>
<th>Plant protection products</th>
<th>Biocidal products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation by the Rapporteur Member State</td>
<td>National authorisation</td>
</tr>
<tr>
<td>The applicant submits an application for authorisation to a Member State, which then assesses it.</td>
<td>Within one year, the Member State issues an assessment (positive or negative) and then grants or declines the authorisation.</td>
</tr>
<tr>
<td>Within one year, the Member State issues an assessment and then grants or declines the authorisation.</td>
<td>Within one year, the Member State issues an assessment and then grants or declines the authorisation.</td>
</tr>
</tbody>
</table>

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60 Unless the application relates to greenhouse use, post-harvest treatment, treatment of empty storage premises or seed treatment, in which case, one Member State assesses the application on behalf of all three zones.

61 The application contains all the information listed in Implementing Regulation (EU) No 284/2013 (plant protection products) and Annex III to the Regulation on Biocidal Products. It provides the intended uses, among other information.
### EU policy and legislation on pesticides

**Plant protection products**

<table>
<thead>
<tr>
<th>Authorisation by Member States concerned</th>
<th>Mutual recognition in parallel</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the outcome of the assessment is positive, the other Member States in receipt of an application grant authorisation. The Member States concerned grant authorisation within 120 days, and may apply conditions or measures to mitigate any risks. If, in spite of any measures, ‘the product in question still poses an unacceptable risk to human or animal health or the environment’, a Member State may refuse to grant authorisation.</td>
<td>The Member States concerned have 90 days to agree on the product characteristics, then grant authorisation within 30 days. For specific reasons already laid down, a Member State may, with the consent of the applicant or the approval of the Commission, impose conditions on the authorisation or refuse to grant it.</td>
</tr>
</tbody>
</table>

**Mutual recognition**

| If a plant protection product has been authorised in one Member State, it can be used, or placed on the market in another Member State provided that the second Member State can demonstrate that the product composition is identical to a product already authorised in its territory. A parallel trade permit may be issued in 45 working days by following a simplified procedure. | A parallel trade permit may be issued in 60 days by following a simplified procedure. |

### Biocidal products

<table>
<thead>
<tr>
<th>Simplified procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A simplified procedure may be used to authorise a low-risk product.</td>
</tr>
</tbody>
</table>

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62 Those reasons include environmental protection, public policy, human, animal or plant health, the protection of cultural heritage, the target organisms not being present in harmful quantities, or a product containing an active substance that is a candidate for substitution or which has been approved by way of derogation.

63 1) The Member States belong to the same zone; 2) the Member States belong to two different zones (in this case the authorisation granted by recognition cannot be used to gain recognition in a third Member State); or 3) the authorisation relates to greenhouse use, post-harvest treatment, treatment of empty storage premises or seed treatment.

64 If an unacceptable risk to human or animal health or the environment is posed, if the two Member States belong to different zones, if the product contains a substance that is a candidate for substitution, if the product has been authorised provisionally (see table 4), or if the product contains a substance approved by way of derogation to ‘control a serious danger to plant health which cannot be contained by other available means’.

65 The product must meet the criteria laid down in Article 47 of the Regulation on Plant Protection Products (in particular, the product’s active substances must have been approved as low-risk substances, the product may not contain any substances of concern), or the criteria laid down in Article 25 of the Regulation on Biocidal Products (in particular, the product’s active substances must appear in Annex I to the Regulation, the product may not contain any substances of concern or nanomaterials, and its handling and intended use must not require personal protective equipment).
Plant protection products | Biocidal products
---|---
If those conditions are met, a Member State may issue authorisation for its own territory within 120 days. | A Member State assesses the application and issues an authorisation within 90 days, if the required conditions are met. That authorisation enables the product to be placed on the market in the other Member States upon simple notification.

Minor uses
Upon application by the authorisation holder or other stakeholders, authorisation for a product in a Member State may be extended to less widely grown crops (known as ‘minor uses’). | Union authorisation
The applicant submits an application to ECHA. The application is then assessed by a Member State, which submits its draft assessment report to ECHA within one year. Then, within 180 days, ECHA issues an opinion to the Commission, which announces authorisation at EU level. This procedure is subject to additional conditions. It will be gradually introduced by 2020.66

Other provisions are added to these procedures. Member States work together in different ways.68 When a product contains a substance that is a candidate for substitution, the authorities carry out a ‘comparative assessment’ to identify whether there are alternatives (including non-chemical alternatives) for the same uses and if they warrant substitution. Authorisation can be renewed by following a procedure that is similar to that for initial approval, as long as the application is lodged within the specified time frame. In addition, authorisation of a plant protection product or biocide can be re-evaluated at any time. In the event of withdrawal or non-renewal of or amendment to an authorisation, a ‘grace period’ of a maximum of 18 months may be granted to dispose of or use up existing stock.

Derogations are permitted in special cases.

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66 Biocidal products have similar conditions of use across the European Union; they do not contain active substances that have been approved by derogation; they do not belong to product types 14, 15, 17, 20 and 21.

67 At the start of 2017, no Union authorisation had yet been issued. For more details, see ECHA, Union authorisation.

68 For plant protection products, the uniform principles that guide application assessment are laid down in Implementing Regulation (EU) No 546/2011. Practical mechanisms are put in place to make cooperation between Member States feasible within a zone (for example, submission of the assessment report by the Rapporteur Member State to the other Member States in the zone, or coordination within the Steering Committee of the zone). Moreover, the Regulation on Plant Protection Products stipulates that if an authorisation application has been introduced in more than one zone, the rapporteur Member States agree on the evaluation of data not linked to environmental and agricultural conditions. For biocidal products, in the event of dispute in the mutual recognition procedure, the issue is brought before a ‘cooperation group’ (comprised of representatives from the Member States and the Commission), which has 60 days to reach an agreement. If no agreement is reached, the matter is deferred to the Commission, which may decide on the basis of an ECHA opinion.
Table 4 – Derogations for placing plant protection products and biocides on the market

<table>
<thead>
<tr>
<th>Plant protection products</th>
<th>Biocidal products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emergency authorisation</strong></td>
<td>A competent authority may issue an authorisation for a maximum period of 180 days. The Commission may extend an authorisation by a maximum period of 550 days by means of an Implementing Act (adopted in accordance with the examination procedure).  (^{70})</td>
</tr>
<tr>
<td>An exception may be granted for a product that does not meet the authorisation criteria in the event of a ‘danger which cannot be contained by any other reasonable means’. A Member State may issue an authorisation of that kind for a maximum period of 120 days. The Commission may decide by adopting an Implementing Act in accordance with regulatory procedure(^{69}) whether and under what conditions the Member State may extend, repeat, amend or withdraw the exception.</td>
<td></td>
</tr>
<tr>
<td><strong>Provisional authorisation</strong></td>
<td>Condition: the evaluating authority recommended approval of the substance.</td>
</tr>
<tr>
<td>Under certain conditions, a product containing a new substance that is not yet approved may be authorised for a maximum period of three years. Conditions: the application was submitted before June 2016, the approval dossier for the active substance is admissible, maximum residue levels have been defined.</td>
<td>Condition: the application was submitted before June 2016, the approval dossier for the active substance is admissible, maximum residue levels have been defined.</td>
</tr>
<tr>
<td><strong>Research and development</strong></td>
<td>Condition: the evaluating authority recommended approval of the substance.</td>
</tr>
<tr>
<td>A non-authorised product may be used for research and development purposes. Condition: the Member State concerned has assessed the available data and issued a permit for trial purposes.</td>
<td>Condition: the Member State concerned has assessed the available data and issued a permit for trial purposes.</td>
</tr>
<tr>
<td><strong>Treated seeds</strong></td>
<td><strong>Protection of cultural heritage</strong></td>
</tr>
<tr>
<td>Seed treated with a product authorised in a Member State for that purpose may be placed on the market (and sown) throughout the European Union.</td>
<td>If there is no alternative solution, the Commission may adopt an Implementing Act, in accordance with the advisory procedure, to enable a Member State to authorise a product which contains a non-approved active substance for the purposes of protecting cultural heritage.</td>
</tr>
</tbody>
</table>

Source: European Parliamentary Research Service (EPRS).

\(^{69}\) For more information on regulatory procedure, see A. Hardacre and M. Kaeding, op. cit., p. 9.

\(^{70}\) For more information on the examination procedure, see A. Hardacre and M. Kaeding, op. cit., p. 16.
Authorised products are subject to special provisions with regard to packaging, labelling and advertising.\textsuperscript{71} Member States are obliged by law to make monitoring and control arrangements, and some involved parties must maintain a register.\textsuperscript{72}

**Figure 8 – Number of products authorised in the Member States**

![Graph showing the number of authorised products in different Member States for both plant protection and biocidal products.](image)


\textsuperscript{71} Implementing Regulation (EU) No 547/2011 outlines the labelling requirements for plant protection products.

\textsuperscript{72} For plant protection products, professionals in the sector must retain records on the quantities produced, distributed, imported and exported for a period of five years, whilst professional users must retain records of the products used for three years. For biocidal products, the authorisation holder must retain data on the products placed on the market for ten years.
Contentious issues

A number of issues related to the authorisation of plant protection products and biocides have been the subject of media discussion in recent years. They include the identification criteria for endocrine disruptors, which the Commission was required to propose before the end of 2013, and which had not yet been adopted by early 2017. The Commission began to submit proposals through the comitology procedure from mid-2016 on, but has not succeeded in obtaining a qualified majority of the representatives of the Member States. Another contested issue is the suspected impact of neonicotinoids on bees and the resulting consequences for crop pollination. In 2013, the Commission introduced restrictions on the use of three active substances in the neonicotinoid family of plant protection products (on coated seeds in particular). Many companies in the sector have challenged the restrictions before the Court of Justice of the European Union. EFSA is reassessing the risk posed to bees by the three neonicotinoids. The findings are expected at the end of 2017.

In 2016, controversy surrounded the renewed approval of glyphosate following diverging scientific assessments by the International Agency for Research on Cancer and EFSA. In March 2017, on the basis of published studies and unpublished industry studies, the ECHA Committee for Risk Assessment concluded that glyphosate should not be classified as a carcinogen in the light of a re-evaluation of the harmonised classification of the substance in accordance with the CLP Regulation.

3.2. Plant protection product residues

A Regulation from 2005 on maximum residue levels establishes standardised rules across the EU on the admissible level of residues of plant protection products in food. It is applicable to all active substances (those that are currently approved, that are no longer approved and that have never been approved in the European Union), and also

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73 For more details see in particular N. Scholz, Commission proposals on identifying endocrine disruptors, EPRS, European Parliament, 2016.

74 The criteria are adopted in accordance with regulatory procedure with scrutiny (plant protection products) and by delegated act (biocidal products). In both cases, the Commission submits a proposal to the representatives of the Member States (Standing Committee on the Food Chain and Animal Health for plant protection substances, and to the ‘Standing Committee on Biocidal Products’), adopts the act and then refers it to the Council and Parliament, which may oppose it. For more detail on the procedures in question, see A. Hardacre and M. Kaeding, op. cit., p. 10 and p. 12.

75 For a contextual understanding, see, for example, J. Weissenberger, Les abeilles: un bilan de santé inquiétant, EPRS, European Parliament, 2014. For an understanding of the links between ecosystem services, agriculture and neonicotinoids, see, for example, European Academies Science Advisory Council (EASAC), Ecosystem services, agriculture and neonicotinoids, 2015.

76 On the economic and environmental costs associated with the ban on neonicotinoids, see in particular, HFFA Research GmbH, Banning neonicotinoids in the European Union: An ex-post assessment of economic and environmental costs, 2017 (study carried out by the agrochemical industry).

77 Mainly by BASF, Bayer and Syngenta. Matters were being examined at the start of 2017.

78 For more details, see, for example, D. Bourguignon, Renewing authorisation for glyphosate, EPRS, European Parliament, 2016.

79 ECHA, Hot topics: glyphosate; ECHA, Glyphosate not classified as a carcinogen by ECHA, press release, 15 March 2017. For more information on the process of harmonised classification, see D. Bourguignon, EU policy and legislation on chemicals: Overview, with a focus on REACH, EPRS, European Parliament, 2016, p.21.

identifies certain active substances for which no maximum residue levels are required. All food products for humans and animals are covered.

All interested parties\(^{81}\) may submit an application to a Member State to set or revise a maximum residue level for an active substance. The application must be accompanied by information and documentation on pertinent good agricultural practices, concerns raised in scientific literature and toxicological characteristics (including the ‘acute reference dose’ and the ‘acceptable daily intake’). The Member State draws up an assessment report ‘without undue delay’. On the basis of that report, EFSA gives its reasoned opinion on the application within three months, paying particular attention to any risks to human health. Using the EFSA opinion as its point of departure and within three months, the Commission draws up a regulation on the setting of, amendment(s) to or scrapping of the maximum residue level\(^{82}\) or gives a decision rejecting the application. Maximum residue levels must take into account the risk to vulnerable consumers (such as infants or children) and levels used outside the European Union.\(^{83}\)

Maximum residue levels can be set by food product or by active substance.\(^{84}\) If no level has been set, a default value of 0.01 mg/kg is applied. In special or exceptional circumstances, Member States retain the option of deviating from those rules.

Member States are required to carry out controls on samples representative of the market, establish national control programmes and make provision for sanctions to enforce compliance with the regulation. The activities of the Member States are coordinated under a Community control programme, whereas the methods of analysis are coordinated by the European Union research laboratories. Each year, EFSA publishes a report on pesticide residues.

### 3.3. Sustainable use of pesticides

A 2009 directive lays out a framework for action to achieve sustainable pesticide use.\(^{85}\) It applies to plant protection products\(^{86}\) and is designed to reduce the ‘risks and impacts of pesticide use on human health and the environment’ and to encourage ‘the development and introduction of integrated pest management and of alternative approaches or techniques’.

The Directive establishes a series of obligations for Member States, for example, they must: create National Action Plans that include indicators, timetables and objectives with

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\(^{81}\) Including stakeholders of the plant protection and agri-food industry, farmers, non-governmental organisations that are active in the health sector, the Member States, and third countries that import food products into the EU.

\(^{82}\) The regulation is then adopted in accordance with regulatory procedure with scrutiny, which enables Parliament to oppose the proposal. For more information on this procedure, see A. Hardacre and M. Kaeding, op. cit., p. 10.

\(^{83}\) In this context, a specific level for imported products (‘import tolerance’) may be set to meet the needs of international trade, provided that it has been requested.

\(^{84}\) The maximum residue levels by food product and active substance can be consulted in the European Commission database.


\(^{86}\) The text of the Directive states that it is anticipated that the scope of the Directive will be extended to include biocidal products.
a view to working towards achieving the aims of the Directive,\(^\text{87}\) promoting the adoption of integrated pest management in line with a series of general principles\(^\text{88}\) by January 2014; ensure access to appropriate training for professional users, distributors and advisors; inform the general public and raise awareness; establish regular inspections of pesticide application equipment; prohibit aerial spraying, except in exceptional circumstances; take measures to protect the aquatic environment and drinking water supply; and reduce the use of plant protection products in specific areas (such as parks, playgrounds, schools, hospitals and protected areas). Furthermore, as part of the Common Agricultural Policy’s greening rules, the Commission plans to ban the use of plant protection products under certain circumstances in ‘ecological focus areas’.\(^\text{89}\)

### 3.4. Other legislation

Some European Union legislation which is not specific to the pesticide domain is also relevant. The Regulation on Persistent Organic Pollutants\(^\text{90}\) gives effect to two international treaties (the Aarhus Protocol and the Stockholm Convention) establishing control measures.\(^\text{91}\) The Regulation on the Export and Import of Hazardous Chemicals\(^\text{92}\) gives effect to the Rotterdam Convention.\(^\text{93}\) The Water Framework Directive\(^\text{94}\) lays down rules on upstream control measures to reduce emissions, discharges and the loss of pesticides identified as priority substances. The Drinking Water Directive\(^\text{95}\) sets limits on pesticides in drinking water.\(^\text{96}\)

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\(^{87}\) National Action Plans were required to be communicated to the Commission by the end of November 2012 and must be reviewed at least every five years.

\(^{88}\) Of note amongst those principles (listed in Annex III to the Directive) are: prevention, monitoring of harmful organisms, preferential use of non-chemical methods, limiting use of pesticides to the absolute minimum necessary, application of anti-resistance strategies. Member States were obliged to submit reports by the end of June 2013.

\(^{89}\) European Commission, Draft delegated regulation, 2016. The European Parliament has to approve or reject the draft between now and June 2017 (procedure 2017/2571(DEA)).


\(^{91}\) Half of the substances covered by the Stockholm Convention are pesticides. For more details on the Aarhus Protocol, the Stockholm Convention and Regulation (EC) No 850/2004, see D. Bourguignon, EU policy and legislation on chemicals: Overview, with a focus on REACH, EPRS, European Parliament, 2016, pp.24-25.


\(^{93}\) Of the 47 substances covered by the Rotterdam Convention, 33 are pesticides. For more details on the Rotterdam Convention and Regulation (EC) No 649/2012, see D. Bourguignon, EU policy and legislation on chemicals: Overview, with a focus on REACH, EPRS, European Parliament, 2016, pp.23-24.


\(^{96}\) Maximum concentration is set at 0.1 μg/l for a specific pesticide and its relevant metabolites; and at 0.5 μg/l for all pesticides.
Other European Union legislation deals with aspects particularly relevant to pesticides, for example the Regulation Concerning Statistics on Pesticides and the Directive with regard to Machinery for Pesticide Application.97

Lastly, the purpose of the International Plant Protection Convention, which has been signed by all Member States of the European Union, is to prevent and control harmful organisms from being introduced to plants and plant products and from being spread.98

<table>
<thead>
<tr>
<th>Case-law</th>
</tr>
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<tbody>
<tr>
<td>Several judgments of the Court of Justice of the European Union have interpreted legislation on pesticides. On access to documents, the General Court annulled a Commission decision refusing access to certain documents on the definition of endocrine disruptors and stated that the Commission was required to provide detailed reasons for refusing access to the documents.99 The Court also ruled that the use of a plant protection product or biocidal product equated to ‘emissions into the environment’, a subject about which the general public has the right to obtain information (including data on the composition and quantity of pesticides used, the date and place of use, and information on the environmental impact of these emissions).100 With regard to the definition of endocrine disruptors, the General Court judged that the Commission had failed to fulfil its obligation to act by failing to adopt criteria for the definition of these substances.101</td>
</tr>
</tbody>
</table>

4. Opportunities and Challenges

A number of aspects of European Union policy on pesticides present both opportunities and/or challenges. They include:

Costs

- **Regulatory costs for the pesticide industry**: for the agrochemical sector, costs related to regulations on pesticides and the CLP regulation are estimated at 4.6% of value added (or 1% of turnover), i.e. approximately €142 million per year. On a more general level, the total cost of legislation on chemical products for the agrochemical sector is estimated at 12.8% of value added (or 2.6% of turnover), i.e. €388 million per year.102

- **Research and development costs for new pesticides**: a study carried out by the agrochemical industry shows that developing a new active substance and placing a new product on the market takes 11 years on average, while the average expenditure required for the research and development of a new plant protection product

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98 The International Plant Protection Convention entered into force in 1952.


100 Judgments of 23 November 2016 relating to cases C-442/14 (Bijenstichting / Bayer, points 95-96) and C-673/13 P (Commission v Greenpeace Netherlands and PAN Europe, points 79-81).

101 Judgment of 16 December 2015 relating to case T-521/14 (Sweden v Commission, point 78).

102 Maroulis, N. et al., Cumulative Cost Assessment for the EU Chemical Industry, European Commission, 2016, p. 104 and p. 130. That estimate is an average for the period from 2004 to 2014. Compared with REACH, legislation on pesticides creates greater financial obligations per active substance or per product placed on the market, particularly given the costs for registration and the requirement for products to be separately authorised in the Member States.
amounts to US$ 286 million.\footnote{Phillips McDougall, \textit{The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019}, 2016, pp.3-4.} For a biocide, the average cost is estimated to be between €3.3 million and €11.7 million.\footnote{European Commission, \textit{SWD(2016)211 Annex 14}, op.cit., pp.330.} Research and development takes place against a backdrop of a reduction in the number of effective plant protection products that are available and quickening emergence of resistance to existing products.\footnote{See, for example, A. Bailey et al., op. cit., pp.20-39.}

### Approval procedures

- **Assessment of active substances**: In a decision in 2016, the European Ombudsman considered that, in its assessment of active substances for plant protection products and in particular with the procedure for further confirmatory information,\footnote{Laid down in Article 6(f) of the Regulation on Plant Protection Products.} the European Commission may have been too lenient in its practices and may not have been taking the precautionary principle sufficiently into account. Following its assessment, the Ombudsman considered that the Commission had largely accepted its proposals for a solution.\footnote{European Ombudsman, \textit{Decision}, case 12/2013/MDC, 18.02.2016.}

- **Potential conflicts of interest**: the regulatory process has been criticised in the past for its potential conflicts of interest. In December 2011, the European Ombudsman recommended that EFSA stepped up its rules and procedures on ‘revolving door’ situations.\footnote{European Ombudsman, \textit{Draft recommendations}, case 775/2010/ANA, 07.1.2011. See also European Ombudsman, \textit{Decision}, case 775/2010/ANA, 23.5.2013.} In May 2012, Parliament postponed signing off the EFSA budget, citing, among other things, concerns over conflicts of interest, in particular concerning the Chair of the Management Board.\footnote{European Parliament decision of 10 May 2012 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2010, \textit{2011/2226(DEC)}. The Chair of the EFSA Management Board resigned from her post on 9 May 2012 (see EFSA, \textit{press release}, 9.5.2012).} In a report from October 2012 on the management of conflict of interest in selected EU agencies, the European Court of Auditors indicated that the management of conflict of interest by EFSA and ECHA was not appropriate, on account of shortcomings in internal policies and procedures, and/or their implementation.\footnote{European Court of Auditors, Management of conflict of interest in selected EU Agencies, Special Report No 15/2012, 11.10.2012. The four agencies audited were the European Aviation Safety Agency, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority. The report identified ECHA as having ‘significant shortcomings’ and EFSA as having ‘shortcomings’.}

- **Emergency authorisation**: A 2017 report by environmental NGOs states that from 2013 to 2016, Member States issued 1 100 emergency plant protection product authorisations that did not meet the criteria (authorised for a period of 120 days to contend with a ‘danger which cannot be contained by any other reasonable means’). The report states that a large number of these authorisations do not provide information on the nature or impact of the ‘danger’, or the ‘other reasonable means’ that could be used.\footnote{PAN Europe, ClientEarth and Bee Life, \textit{Bee Emergency Call}, 2017.}

- **Substitution of active substances**: In January 2015, experts from the Member States validated a list of 75 active substances for plant protection products which are
expected to be replaced by another less hazardous substance.\footnote{European Commission, \textit{Draft list of candidates for substitution (January 2015)}.} Since 1 August 2015, as part of the authorisation process for plant protection products containing active substances, Member States have been obliged to carry out a comparative assessment to ascertain if alternatives (whether chemical or non-chemical) exist. A list of candidates for substitution has also been drawn up for biocidal products. The Commission highlights that exclusion and the comparative assessment are ‘very powerful mechanisms’ which have not yet reached their full potential.\footnote{European Commission, Report on the sustainable use of biocides, \textit{COM(2016) 151}.}

- **Assessment of cumulative risks posed by residues of plant protection products:** studies suggest that the combined effect of residues of plant protection products may be significantly higher than the sum of the effects of each residue taken separately.\footnote{See, for example, Graillot, V. et al., \textit{Genotoxicity of pesticide mixtures present in the diet of the French population}, Environmental and Molecular Mutagenesis, 2012, number 53, pp.173–184.} Those cumulative effects are not currently considered in EFSA’s annual reports on pesticide residues. An assessment methodology is still being developed. Against that backdrop, in 2013, EFSA adopted an approach grouping the active substances according to similarity of toxicological properties for a specific organ or system (such as the thyroid or central nervous system).\footnote{EFSA, \textit{EFSA presents cumulative assessment group methodology for pesticides}, press release, 12.07.2013. In 2016, specific software was developed to manage cumulative risk assessment (EFSA, \textit{Pesticides: breakthrough on cumulative risk assessment}, press release, 27.01.2016).} In the longer term, EFSA hopes to begin to gradually incorporate cumulative risk assessments into its annual analysis of the chronic and acute risks that plant protection products present for consumers.

**Sustainability**

- **Integrated pest management:** it is not clear whether a regulatory obligation (as set out in the Directive on the Sustainable Use of Pesticides) is sufficient to persuade farmers to adopt integrated pest management practices. A 2014 study identifies four key factors for the adoption of those practices: cost effectiveness ratio, market forces, farmers’ attitudes, and public policy instruments.\footnote{Lefebvre, M., et al., \textit{Incentives and policies for integrated pest management in Europe: A review}, Agronomy for Sustainable Development, 2014, number 35(1), pp.27–45.} The European Union’s action on this issue primarily consists of financing a project coordinating research activities on integrated pest management.\footnote{Coordinated Integrated Pest Management in Europe (\textit{C-IPM}).}

- **Use of biopesticides (plant protection products of biological origin):** some experts state that European legislation, designed primarily for chemical pesticides, could be an obstacle to approving active substances of biological origin and the marketing of biocidal pest control products. They also point out that many of the benefits of biopesticides (such as high specificity, ease of isolation, or potential for self-sustaining control) may deter the agrochemical industry, which is based on a model with opposing properties.\footnote{See, for example, A. Bailey et al., op. cit., pp.3-6.} According to a study conducted for the agrochemical sector, 7.3 % of expenditure on research and development was allocated to biocontrol products in 2014.\footnote{Phillips McDougall, op. cit., p.23. The study projects that this proportion will increase to 9.2 % in 2019.}

**Other legislation**

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\footnote{European Commission, \textit{Draft list of candidates for substitution (January 2015)}.}
\footnote{See, for example, Graillot, V. et al., \textit{Genotoxicity of pesticide mixtures present in the diet of the French population}, Environmental and Molecular Mutagenesis, 2012, number 53, pp.173–184.}
\footnote{Lefebvre, M., et al., \textit{Incentives and policies for integrated pest management in Europe: A review}, Agronomy for Sustainable Development, 2014, number 35(1), pp.27–45.}
\footnote{Coordinated Integrated Pest Management in Europe (\textit{C-IPM}).}
\footnote{See, for example, A. Bailey et al., op. cit., pp.3-6.}
\footnote{Phillips McDougall, op. cit., p.23. The study projects that this proportion will increase to 9.2 % in 2019.}
• **Counterfeit plant protection products**: according to recent estimations, counterfeits cost the legitimate industry about €1.3 billion annual revenue (i.e. almost 14% of sales).\(^{120}\) The phenomenon, which appeared in the early 2000s, gained momentum from 2006 to 2008. Imported counterfeits come mainly from China, enter the European Union via the major ports in north-western Europe and then transit to their final destination, contravening the parallel trading system in the process. The lower cost and the wish to continue using products that are no longer authorised may explain why users buy counterfeit products with full knowledge of the facts.\(^{121}\)

• **Minor uses of plant protection products**: minor uses concern crops that are not widely grown in a given Member State. The Commission estimates that ‘minor’ crops are worth about €70 billion per year.\(^{122}\) Even though the authorisation process for plant protection products for those crops is not economically viable for the agrochemical industry, the use of plant protection products is important for farmers. National funds help to finance efficacy and residue trials for minor uses with a view to obtaining extensions to authorisations. In addition, most Member States allocate structural money and manpower to address this issue.\(^{123}\) In 2015, the Commission created a coordinating facility\(^ {124}\) to ‘promote synergies’ and ‘to ensure that national funds are efficiently invested’.

### 5. European Parliament position

The European Parliament stresses that the implementation of the **regulatory framework for plant protection products** urgently needs to be reviewed and a coherent assessment system that is efficient, predictable and based on risks and scientific argument urgently needs to be developed. It also highlights the need for farmers to have more instruments to protect their crops and deplores the slow implementation of the Directive on the sustainable use of pesticides by the Member States and the Commission.\(^{125}\)

Parliament stresses the need to improve the availability of **low-risk pesticides**, without further delay, as the current authorisation procedure is not ideal for low-risk pesticides of biological origin. It calls on the Commission to present a legislative proposal before the end of 2018 that amends the Regulation on plant protection products, prioritising the development of low-risk pesticides of biological origin and placing them on the European Union market.\(^{126}\) Furthermore, it calls on the Commission to make every possible effort to pave the way for the **full and complete disclosure of the scientific data**


\(^{121}\) Food Chain Evaluation Consortium (FCEC), *Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU*, 2015, pp. ii-iii.

\(^{122}\) European Commission, Report on the establishment of a European fund for minor uses in the field of plant protection products, *COM(2014) 82*, p.8. Minor uses mainly concern the fruit and vegetable sector (64%) and the ornamental plant sector (35%). The vast majority (72%) of the fruit and vegetable sector is located in Member States belonging to zone C (south).

\(^{123}\) Ibid, p. 9.

\(^{124}\) EU Minor Uses Coordination Facility (MUCF).

\(^{125}\) European Parliament resolution of 7 June 2016 on technological solutions for sustainable agriculture in the EU *2015/2225 (INI)*.

used in the assessment process for plant protection substances at European level.\textsuperscript{127} Finally, it urges the Commission to maintain its ban on the use of neonicotinoids by referring to the body of scientific evidence that demonstrates the negative effect that those products can have on pollination or natural pest control mechanisms.\textsuperscript{128}

6. Stakeholders' views

The European Crop Protection Association – ECPA (European association for the agrochemical sector) takes the view that the current regulatory framework is flawed. It complains of a politicised process that ignores science and innovation, does not recognise the merits of risk management and does not consider the need for farmers to have appropriate tools. It points out the risk that the substitution process may cause a 10\% to 14\% reduction in yield for main crops and up to 85\% for specialised crops, with consequences for employment, trade and greenhouse gas emissions.\textsuperscript{129}

The International Biocontrol Manufacturers Association (IBMA) advocates a new approach to the approval and authorisation of low-risk plant protection substances and products by speeding up and prioritising assessment of low-risk substances and products and not restricting the validity period of the approvals and authorisations granted for these active substances and low-risk products.\textsuperscript{130}

The European Farmers' Association and their Copa & Cogeca cooperatives are opposed to the ban on using plant protection products on protein crops in ecological focus areas, as proposed by the Commission.\textsuperscript{131}

The environmental NGO Pesticide Action Network Europe (PAN Europe) criticises the conflict of interest and approach taken by EFSA with regard to cumulative risk assessment.\textsuperscript{132} It also highlights shortcomings in the approval process for active substances for plant protection products, above all, the fact that some independent scientific studies are not considered during the Member States' risk assessments on the basis of guidelines issued by EFSA.\textsuperscript{133}

7. Outlook

Action expected to be taken by the Commission includes:

\textsuperscript{127}European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate, 2016/2624(RSP).

\textsuperscript{128}European Parliament resolution of 2 February 2016 on the mid-term review of the EU’s Biodiversity Strategy, 2015/2137(INI).

\textsuperscript{129}European Crop Protection Association, Low Yield Legislation, 2016.

\textsuperscript{130}International Biocontrol Manufacturers Association, IBMA proposed approach to revise procedures via amendment or adoption of Regulation (EC) 1107/2009 for the EU approval of Low-risk Active Substances and authorisation and placing Low-risk Products on the market in EU Member States, 2015.

\textsuperscript{131}Copa-Cogeca, Copa and Cogeca outline key elements of future Common Agricultural Policy (CAP) to EU Farm Ministers, press release, 2016.

\textsuperscript{132}Pesticide Action Network Europe, A poisonous injection: how industry tries to water down the risk assessment of pesticides mixtures in everyday food, 2014.

\textsuperscript{133}Pesticide Action Network Europe, Missed & dismissed: Pesticide regulators ignore the legal obligation to use independent science for deriving safe exposure levels, 2014; Pesticide Action Network Europe, Twisting and binding the rules: In 'resubmission' all efforts are aimed to get pesticides approved, 2012.
• An evaluation of the legislation on plant protection products and their residues: initiated in November 2015 and scheduled for completion in November 2018, the purpose of the exercise is to evaluate the implementation of EU legislation. At the same time, the Commission intends to prepare the reports that it is required to publish on the implementation of the regulations on plant protection products and on residues.

• The publication of other reports on Member States' experiences in implementing national targets for the sustainable use of pesticides, and on the Union authorisation procedure for biocidal products.

• The adoption of criteria for the definition of endocrine disruptors and guidelines for assessing the risk posed by those substances.

• An examination of the legislation on pesticides by the scientific advice mechanism of the European Commission.

In 2016 the Commission stated that it did not intend to extend the scope of the sustainable pesticides Directive to include biocides.

The following should, however, be noted: the approval process remains resource-intensive, particularly for those national and European authorities tasked with authorisation, which can result in the process being prolonged. With this in mind, for the system to function properly, it is essential that trust exists between authorities in the different Member States. Furthermore, discrepancies between the deadlines laid down in the Regulation on Plant Protection Products and the Regulation on Residues may lead to difficulties for all concerned.

Looking forward, it can be expected that the European Union's policy on pesticides will continue to be influenced by a number of factors, in particular, constantly evolving scientific knowledge, public perception of pesticides (illustrated by the recent European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides'), and the search for new crop protection methods, including allowing candidate products to be substituted.

134 European Commission, REFIT Evaluation of the EU legislation on plant protection products and pesticides residues, 2016.


136 The deadlines set in the legislation for the publication of the reports are 26 November 2018 (Directive 2009/128/EC, Article 4) and 31 December 2017 (Regulation (EU) No 258/2012, Article 42).

137 Council of the European Union, Outcome of the 3497th meeting of the Agriculture and Fisheries Council, ST 14271/16, p.15.

138 European Commission, Scientific Advice Mechanism: Topics.

139 European Commission, op. cit., COM(2016) 151, p.13. Good agricultural practices are established by the Member States, industry associations, and the new European standard EN16636.

140 European Commission, European Citizens’ Initiative: official register.
Lastly, unknown factors could change the overall situation, for example, the impact of climate change on crop yields that could see reduced output in Mediterranean areas, or an increase in boreal areas.\textsuperscript{141}

8. Main references


\textsuperscript{141} In particular, see European Environment Agency, \textit{Climate change, impacts and vulnerability in Europe 2016}, 2017, p.25.
Substances used to suppress, eradicate and prevent organisms that are considered harmful are grouped under the term ‘pesticide’. The term includes both plant protection products (used on plants in agriculture, horticulture, parks and gardens) and biocidal products (used in other applications, for example, as a disinfectant or to protect materials).

Pesticides can be useful in a number of circumstances, for example, in overcoming diseases and increasing agricultural yields. However, they are not without their disadvantages – above all, their environmental impact, the risks that they pose to human health and their effects on crop protection.

European Union pesticide legislation is designed to ensure a high level of protection for human health and the environment and to improve the functioning of the internal market. Plant production products and biocides are subject to a dual approval process: active substances are approved at EU level and products are subsequently authorised predominantly at Member State level. Furthermore, standardised maximum levels are set for the residues of plant protection products in food, and a framework for action is focused on sustainable pesticide use.

A number of aspects of European Union policy on pesticides can be considered as either opportunities or challenges, in particular, issues surrounding costs for the industry, the approval process, and sustainability.

The Commission is currently assessing the legislation on plant protection products and their residues. The conclusions of that study are expected by the end of 2018.