Briefing
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Authorisation of pesticides in the EU
With a focus on glyphosate

SUMMARY

In the European Union, plant protection products, often referred to as 'pesticides', are subject to a dual approval process: active substances are approved at European Union (EU) level, provided they meet a number of criteria. Commercial plant protection products containing one or more active substances are subsequently authorised at Member State level if they satisfy certain conditions.

A controversy has emerged since 2015 over the renewal of the approval of glyphosate. One of the active substances most commonly found in broad-spectrum herbicides in the world, glyphosate is mainly used in agriculture. The controversy started as a result of diverging assessments of its carcinogenicity: the International Agency for Research on Cancer, a branch of the World Health Organization, classified glyphosate as probably carcinogenic to humans, while the European Food Safety Authority found it unlikely to pose a carcinogenic hazard to humans. The European Chemicals Agency later concluded that glyphosate did not classify as a carcinogen. Several national authorities outside the EU also came to the same conclusion. The European Commission eventually renewed the approval of glyphosate for five years in December 2017.

The views of stakeholders and Member States on the topic have been strongly divided.

The European Parliament has called for phasing out all uses of glyphosate by the end of 2022. Parliament is expected to vote, in February 2018, on the creation of a special committee on the Union's authorisation procedure for pesticides.

In this briefing:

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Glossary

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

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

Plant protection product: a commercial product containing one or more active substances protecting vegetation from harmful organisms, as well as other substances. They are authorised at Member State level.

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

Risk assessment: a scientific process generally carried out by technical experts (in Member State authorities and/or EU bodies such as the European Food Safety Authority).

Risk management: a more political process carried out by policy-makers, such as Member State representatives in the 'Standing Committee on Plants, Animals, Food and Feed' and the European Commission.

Background

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). However, 'pesticide' is often used as a synonym of 'plant protection product'.

The use of pesticides offers numerous advantages: above all, plant protection products have contributed to a leap in agricultural yield and to reduced labour requirements in agriculture 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 (such as the development of resistance to the products used). The use of synthetic plant protection products is fiercely debated in society, dividing supporters and critics.

Principles underpinning EU legislation on pesticides

In the European Union, risk assessment and management of plant protection products may be described as being underpinned by a number of principles: a **hazard-based approach**, assessing active substances on the basis of their intrinsic properties rather than on the basis of the risks they may pose; the **precautionary principle**, whereby measures may be taken when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high; the **principle of substitution**, which led to the publication, in 2015, of a list of 75 active substances which are expected to be replaced by other less hazardous substances, products or processes; **sustainability**, in particular through the concept of 'integrated pest management' whereby non-chemical methods are to be preferred if they provide satisfactory pest control; and **mutual recognition**, whereby national authorities can authorise a product on the basis of a risk assessment carried out by another national authority.

Authorisation procedure for pesticides

The 2009 Regulation on plant protection products sets rules for the authorisation of pesticides used in agriculture, horticulture, parks and gardens. It aims '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, while improving agricultural production'.

Pesticides are subject to a **dual approval process**: active substances are approved at EU level and commercial products (incorporating one or more active substances) are subsequently authorised at Member State level.

Approval of active substances

To be granted approval, an active substance has to meet a number of **cut-off criteria**, without which it cannot be approved.[1] These are mainly based on the hazard posed by a substance (and not on the risks linked to exposure to the substance). Active substances are approved at EU level.

The approval **process**, which generally takes between two and a half and three years from the time when an application is declared admissible, can be summarised as follows. A manufacturer submits an application to a Member State (called the 'Rapporteur Member State'[2]) along with documentation including toxicological and ecotoxicological studies, as well as information on residues, and on the fate and behaviour of the substance in the environment. The competent national authority[3] confirms the admissibility of the application and carries out an initial risk assessment within one year, a period which can be extended if additional information is required. The national authority submits a 'draft assessment report' to the European Food Safety Authority (EFSA), which conducts a 'peer-review process' and consults stakeholders. On the basis of EFSA's conclusions, the European Commission carries out a risk-management exercise[4] and adopts a regulation after endorsement by the Standing Committee on Plants, Animals, Food and Feed of Member State representatives (PAFF Committee).[5] Approval is granted for one or more specific uses. It may be subject to conditions and is typically granted for 10 years. A number of derogations are applicable in specific cases.

Authorisation of plant protection products

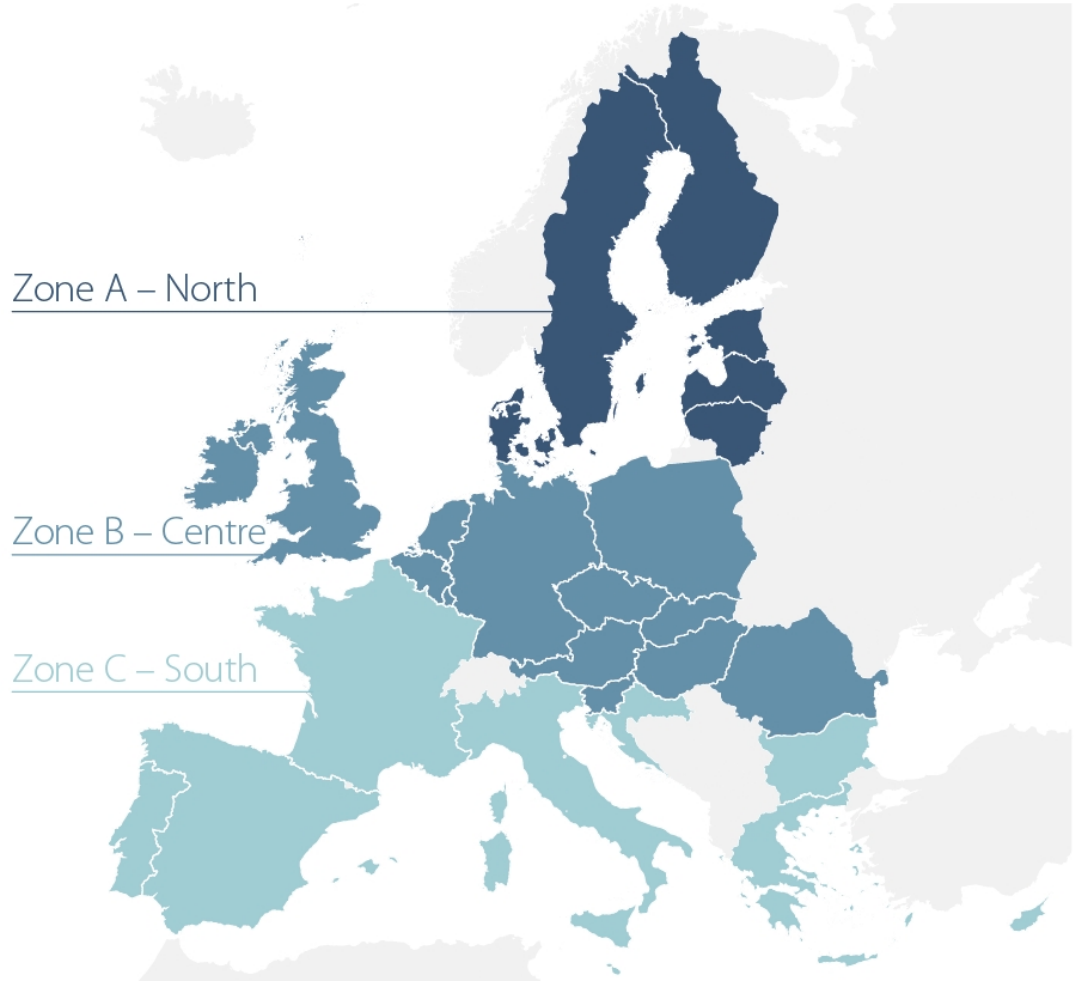
To receive an authorisation, a plant protection product must satisfy a number of criteria, including that its active substances are approved; it is sufficiently effective in realistic conditions of use; it does not have any (direct or indirect) harmful effects on humans or animals; and it does not have any unacceptable impact on the environment. Plant protection products are authorised at Member State level.

To facilitate the authorisation process, three administrative zones have been set out to handle plant protection product authorisations (see Figure 1). Applications are assessed by one Rapporteur Member State per zone and can subsequently be authorised by other Member States in the same zone, without additional assessment. There are several procedures for placing plant protection products on the market, and a number of derogations in specific cases.[6]

In recent reports, the European Commission highlighted a number of **challenges** associated with the authorisation of plant protection products. A 2017 overview report on a series of audits carried out in EU Member States on the authorisation systems in place in Member States found that a majority of Member States fail to use the zonal system, mainly as a result of specific national requirements and a lack of harmonised methodology for conducting evaluations; it also noted significant delays in processing requests, contributing to a higher number of emergency authorisations without a full evaluation being performed.[7] A 2017 report on the sustainable use of pesticides found

that Member States have not yet set clear criteria for implementing the principles of integrated pest management, and that they are not systematically checking compliance with these principles on the ground.

Figure 1 – Zones for plant protection product authorisation



Source: European Parliamentary Research Service (EPRS).

Focus on glyphosate

Glyphosate is an active substance used in broad-spectrum herbicides. On the market since 1974, it has been one of the world's most commonly used active substances in plant protection products. Since patent rights expired in 2000, many companies in the agrochemical sector have marketed glyphosate-based products.[8] Glyphosate is used as an active substance in several hundred commercial plant protection products. Research indicates that, in 2014, 826 million kg of glyphosate were used globally, of which 90 % in agriculture. Other uses are mainly for weed control in gardens and non-cultivated areas.

Glyphosate was first put on the market in the EU according to national rules in place at the time. In 2002, glyphosate was approved for the first time at EU level, for a duration of 10 years, under a 1991 directive setting a harmonised framework for placing pesticides on the market. Glyphosate-based plant protection products are currently authorised in all EU Member States.

In the past few years, **controversy** has emerged **over the renewal of the approval of glyphosate**, particularly in light of diverging assessments of its carcinogenicity. Key elements may be summarised as follows:

- In 2010, the Glyphosate Task Force, a consortium of manufacturers, submitted a request for renewing the approval of glyphosate to German authorities, which acted as Rapporteur Member State.
- In November 2010, the Commission extended the approval of glyphosate until 31 December 2015, in view of the Glyphosate Task Force's renewal request and the time needed to complete the assessment.
- In December 2013, the German Federal Institute for Risk Assessment (BfR), responsible for carrying out the initial risk assessment, delivered its 'draft assessment report', which found, among other things, that glyphosate was not carcinogenic.
- In January 2014, EFSA started the 'peer-review process' involving other national institutions and experts. It subsequently carried out a stakeholder consultation and requested additional information from the Glyphosate Task Force on some aspects.
- In March 2015, the International Agency for Research on Cancer (IARC), a body of the World Health Organization, published a report which concluded that glyphosate is 'probably carcinogenic to humans'.
- In May 2015, the Commission mandated the risk assessors (BfR and EFSA) to consider IARC's findings in their risk assessment.
- In October 2015, the Commission extended the approval of glyphosate until 30 June 2016, to allow for the risk assessment process to be finalised.
- In November 2015, EFSA published its conclusions on the risk assessment of glyphosate. It found that glyphosate is 'unlikely to pose a carcinogenic hazard to humans', although it highlighted concerns about certain substances used in some plant protection products alongside glyphosate, in particular POE-tallowamine.
- In February 2016, the Commission proposed, on the basis of EFSA's conclusions, to renew the approval of glyphosate for 15 years. However, the proposal failed to gain the support of a qualified majority of Member States in the Standing Committee on Plants, Animals, Food and Feed, as a number of large Member States abstained.
- At the end of June 2016, the Commission extended the approval of glyphosate until the end of December 2017, in order to allow the European Chemicals Agency (ECHA) to conduct an assessment of the potential carcinogenicity of glyphosate in the context of a review of its harmonised classification and labelling.
- In August 2016, the Commission banned the use of POE-tallowamine alongside glyphosate in plant protection products.
- In March 2017, the European Chemicals Agency concluded that glyphosate did not class as a carcinogen.
- In May 2017, the Commission proposed on the basis of these conclusions to renew the approval of glyphosate for 10 years. However, the proposal failed to gain the support of a qualified majority of Member States in the Standing Committee on Plants, Animals, Food and Feed. Several rounds of discussion and votes were held in the second half of 2017, as the Commission revised its proposal a number of times.
- On 6 October 2017, the 'Stop glyphosate' European Citizens' Initiative was submitted to the Commission, having collected over a million signatures.
- On 24 October 2017, the European Parliament called among other things for phasing out glyphosate by December 2022 (see below for more details).

- On 27 November 2017, Member State representatives in an Appeal Committee approved a revised proposal from the Commission to renew the approval for five years.
- On 12 December 2017, the Commission renewed the approval of glyphosate until 15 December 2022. In its reply to the European Citizens' Initiative published on the same day, the Commission pledged to put forward, by May 2018, a legislative proposal updating transparency requirements in scientific assessments carried out by EFSA.

Several **authorities outside the EU** came to the same conclusions as EFSA and ECHA. The Joint Meeting on Pesticide Residues (JMPR) of the Food and Agriculture Organization and the World Health Organization concluded that 'glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet'. Among national regulatory authorities, the Australian Pesticides and Veterinary Medicines Authority (APVMA), the New Zealand Environmental Protection Agency (NZ EPA), the Canadian Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (US EPA) concluded that glyphosate is unlikely to pose a human cancer risk.

Some **elements can explain the divergence in the assessments** produced by IARC, on one hand, and EFSA, ECHA and other bodies, on the other, as highlighted by some authors:[9]

- First, the selection of participants in the process differs: whereas IARC relies only on highly qualified experts without involvement from politics and wider society, EFSA and ECHA are mandated to associate stakeholders in scientific appraisals.
- Second, the rules for selecting evidence differ: whereas IARC experts only consider reports that have been published in scientific journals (mainly academic papers but also published data from regulators), EFSA and ECHA consider a much broader range of evidence, including unpublished papers from industry, in line with the idea that the manufacturer has to prove that its active substance meets the cut-off criteria.[10]
- Third, the object of the studies may differ as well: whereas tests carried out by the agrochemical industry according to international guidelines relate to the active substance (pure glyphosate), published studies tend to focus on the commercial products used by farmers in the field (i.e. containing the active substance glyphosate as well as other substances).

The controversy also extended beyond diverging assessments. The release of internal industry documents (known as the 'Monsanto Papers') in the context of lawsuits filed in the United States have triggered allegations that industry sought to influence the scientific evidence. The European Parliament organised a public hearing on the topic on 11 October 2017.

A report published in November 2017 by the French National Institute for Agricultural Research (INRA) on possible alternatives to glyphosate in French agriculture noted that although technical alternatives exist (and are being used by some farmers), a glyphosate ban would create difficulties for some farmers. The report highlights that a glyphosate ban could generate extra costs (which are difficult to quantify) and would require wide-ranging changes in agricultural practices.

Stakeholders' views

The Glyphosate Task Force, representing manufacturers, expressed its disappointment over the decision to renew the approval for five years only and criticised the politicisation of the EU renewal process. The consortium also called on Member States to follow

scientific evidence when assessing requests for the authorisation of glyphosate-based plant protection products.

COPA-COGECA, representing European farmers and agri-cooperatives, regretted the decision to renew the approval of glyphosate for 5 years and not 15 years. It highlighted that without glyphosate, food supplies would be put at risk.

Pesticide Action Network Europe, a non-governmental organisation, had called for banning uses of glyphosate as of 2017 in a number of cases (such as uses in public areas, by non-professionals and in agriculture where alternative methods exist) and for phasing out all uses by the end of 2020. It also called for increased transparency in the approval process.

The 'Stop Glyphosate' European Citizens' Initiative regretted that the Commission had not addressed its requests for a ban of glyphosate, a reform of the EU pesticide approval process and mandatory EU targets to reduce pesticide use.

Six Member States (Belgium, France, Greece, Luxembourg, Malta and Slovenia) called on the European Commission to accompany the renewal decision with measures to limit risks associated with the substance and to prepare a phase-out of glyphosate, including with support measures for farmers.

European Parliament

In its resolution of 13 April 2016, Parliament called on the Commission to renew the approval of glyphosate for seven years only, and not to allow uses by non-professionals as well as in and around public areas. It also called on the Commission and EFSA to disclose all the scientific evidence used in the risk assessment.

In its resolution of 24 October 2017, Parliament called on the Commission and Member States not to allow household uses of the substance, uses in and around public areas, as well as agricultural uses where non-chemical alternatives exist, after 15 December 2017, with all agricultural uses to be phased out by 15 December 2022. It also called for risk assessments to be based only on published, peer-reviewed and independent studies.

The European Parliament is expected to vote, in February 2018, on the creation of a special committee on the European Union's authorisation procedure for pesticides. The special committee, composed of 30 members working over nine months, would assess the authorisation procedure for pesticides in the EU; potential failures in how substances are scientifically evaluated; the role of the European Commission in renewing the approval of glyphosate; possible conflicts of interest in the approval procedure; and the role of EU agencies, including whether they are adequately staffed and funded to fulfil their obligations.

Main references

Bourguignon D., The precautionary principle: Definitions, applications and governance, EPRS, European Parliament, 2015.

Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017.

Bozzini E., Pesticide Policy and Politics in the European Union, Palgrave Macmillan, 2017.

Endnotes

[1] To be approved, an active substance may not be classified as carcinogenic, mutagenic or toxic to reproduction (CMR), and may not be considered an endocrine disruptor; a persistent, bio-accumulative and toxic (PBT) substance; a very persistent, very bio-accumulative substance (vPvB); or a persistent organic pollutant (POP).

[2] In its reply to the 'Stop Glyphosate' European Citizens' Initiative, the European Commission indicated that when submitting a request for renewing an approval, the Rapporteur Member State 'is assigned by the Commission and cannot be chosen freely.

[3] These are usually independent regulatory agencies, like the Health and Safety Executive (HSE) in the United Kingdom, the Bundesinstitut für Risikobewertung (BfR) in Germany and the Kemikalieinspektionen (Kemi) in Sweden.

[4] Some academics note however that the distinction between risk assessment and risk management is difficult to maintain in practice. See for instance E. Bozzini, Pesticide Policy and Politics in the European Union, Palgrave Macmillan, 2017, p. 46.

[5] Those regulations are now adopted in accordance with the examination procedure. For more details, see A. Hardacre and M. Kaeding, Delegated and Implementing Acts: EIPA Essential guide, 2013, p. 16.

[6] For more details, see D. Bourguignon, EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, pp. 17-21.

[7] Emergency authorisations can be granted for a period of 120 days to contend with a 'danger which cannot be contained by any other reasonable means'. A 2017 report by environmental non-governmental organisations found that from 2013 to 2016, Member States issued 1 100 emergency authorisations for plant protection products that did not meet the criteria laid out in legislation.

[8] The Glyphosate Task Force, a consortium of companies who pooled resources to submit a joint request for renewing the approval of glyphosate in the EU, has 22 confirmed members.

[9] See for instance E. Bozzini, Pesticide Policy and Politics in the European Union, Palgrave Macmillan, 2017, pp. 87-91.

[10] To illustrate these differences in practice: the IARC report assessed five cohort studies and 14 case-control studies, while BfR and EFSA have indicated that their reports assessed hundreds of papers, including all of those considered by IARC.

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