From authorisation to dialogue: managing concerns about plant protection

Plant protection products prevent damage to crops from pests and diseases. They help ensure a reliable food supply and a profitable agricultural sector, but can also have adverse effects on humans, animals and the environment. Therefore, a robust system of laws and regulations is in place to protect against the undesired effects of these products. An important part of this system is the authorisation procedure. This procedure is based on the precautionary principle: products may only be authorised for market entry once it has been demonstrated that they pose no unacceptable risks. The Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) independently assesses these products and – based on scientific knowledge – determines whether they meet European and national regulatory standards. The assessment is rigorous and provides a high level of protection against risks.

Despite this high level of protection, the authorisation system cannot provide absolute certainty. For example, certain health effects cannot yet be taken entirely into account in the assessment. These include neurodegenerative diseases (such as Parkinson's disease) and the effects of cumulative exposure, (often called the "cocktail effect"). There is currently no assessment framework to evaluate these effects. This has raised concerns among local residents and prompted calls to ban products. However, based on current insights, there are no grounds to withdraw the authorisation of individual products.

While current insights provide no grounds to withdraw authorisations, concerns among local residents persist. In the Netherlands, agricultural businesses are often located near residential areas. Such proximity can lead to nuisance and societal unrest, which are increasingly resulting in legal proceedings. Take the recent ruling of the 's-Hertogenbosch Court of Appeal on a lily cultivation operation, for example. In response to legal proceedings initiated by local residents, the court ruled that a lily grower cannot use plant protection products for the time being.

Environmental organisations also regularly raise concerns about the use of plant protection products near Natura 2000 sites. The Habitats Directive requires EU countries to prevent the deterioration of natural habitats. However, assessing such deterioration falls outside the scope of the authorisation system. Again, this problem results from the proximity of various land-use functions – in this case agricultural activities and protected nature.

Discussions arising from concerns about plant protection products often focus on the authorisation system, seen by some as inadequate and by others as proof of safety. But authorisation is only one part of a much wider system that ensures a healthy living environment. The national government and local authorities have the competence to take measures regulating the use of plant protection products, taking into account local circumstances not considered in the authorisation procedure.

European and national frameworks beyond the authorisation system offer tools to reduce the use of authorised products, enhancing their sustainability and making spatial planning choices. For example, based on Directive 2009/128/EC (Sustainable Use of Pesticides), the use of plant protection products in non-agricultural areas was banned. Local authorities can also opt for policies such as no-spray zones around residential areas, schools, healthcare institutions or other vulnerable spatial functions. It is precisely at local level that authorities can make choices about balancing the interests of farmers and those of local residents. Such choices are beyond the scope of the authorisation system.

This means that an authorisation decision by the Ctgb is not the end of the discussion. Responsiobility for the broader system – covering authorisation, product use, nature conservation and spatial planning – rests with multiple levels of government. This calls for an open dialogue among all relevant authorities, including the national government, provinces, municipalities, enforcement agencies and authorisation authorities. The background information below is intended to support such dialogue.

Background

Introduction

Plant protection products are designed to control harmful insects, fungi and weeds, thereby preventing or curing diseases and pests in agricultural crops. In doing so, they help farmers and growers achieve a good harvest. These products contain active substances that are designed to counteract these organisms. Such substances are often toxic. This makes them effective, but they can also have adverse effects on human health or the environment. Therefore, the marketing and use of these products are strictly regulated.

In the Netherlands, the national government has the authority to establish national policy on plant protection products and, together with provinces and municipalities, is responsible for regulating their use. The Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is the competent authority for assessment and authorisation. The Ctgb assesses whether a product, when used in accordance with the instructions, complies with European and national legal requirements. This assessment is rigorous and science-based but does not provide absolute certainty – and that leads to questions, including those about the health of local residents.

Beyond the authorisation system, national and local governments can regulate the use of authorised products, taking local conditions and spatial planning into account. Together, these regulatory frameworks form a coherent system that protects humans, animals and the environment.

This background article addresses local residents' health concerns and the scope to address them, both within and beyond the authorisation system. It was written in response to recent court rulings, such as that of the 's-Hertogenbosch Court of Appeal on the use of plant protection products in lily cultivation.[1] The focus is therefore on potential health effects for local residents, although similar issues arise with environmental risks. Considerations specific to environmental concerns are not addressed in this article.

How does the authorisation process for plant protection products operate?

The precautionary principle as the basis for authorisation

The precautionary principle is the starting point for the European regulation on the authorisation of plant protection products.[2] According to Regulation (EC) No 1107/2009, a plant protection product cannot be placed on the market unless it has been demonstrated that substances or products do not have any harmful effect on human or animal health or any unacceptable effects on the environment.[3] This means that the precautionary principle not only guides the authorisation system but is also its

[1] Gerechtshof 's-Hertogenbosch 22 July 2025, ECLI:NL:GHSHE:2025:2043

[2] According to the precautionary principle, if there are reasonable grounds to suspect a potentially serious risk to health or the environment, and scientific uncertainty persists despite assessment of available data, then temporary and proportionate measures may be taken. These measures should be non-discriminatory and are subject to revision as new information becomes available. See also Communication from the Commission on the precautionary principle of 2 February 2000, COM (2000)1 final, Precautionary principle - EUR-Lex and Article 7 of Regulation (EC) 178/2002.

[3] Article 1(4) of Regulation (EC) No 1107/2009.

legal foundation. Moreover, authorisation authorities can take measures after a product has been authorised if new insights indicate a real and potentially serious risk.[4]

In a general sense, the precautionary principle allows for measures to be taken situations of scientific uncertainty, provided there is a well-founded concern about a potentially unacceptable risk. In practice, the Ctgb may only withdraw authorisations when there are concrete indications of a serious risk associated with a specific substance or product. [5] The precautionary principle does entail automatic prohibition in the face of uncertainty; rather, it requires a careful, evidence-based assessment of the available information.

How are plant protection products assessed?

The assessment of plant protection products is based on the *assessment framework*: the set of legal requirements, guidelines, quantitative models and testing protocols that specify how to demonstrate that a product has no adverse health effects or unacceptable effects on the environment. The health assessment focuses on two key questions: *how toxic is a substance?* And *what is the human exposure to this substance?*

Toxicity of the substance

During the authorisation procedure, toxicologists evaluate the potential adverse effects of substances on human health, primarily based on extensive laboratory animal studies conducted according to European guidelines. If epidemiological studies or legally established limits are available, these are also used. From these studies, the highest dose at which no adverse effects can be observed in the most sensitive laboratory animal is derived: the *No Observed Adverse Effect Level* (NOAEL). This dose is used as the basis for health-based limit values, such as the *Acceptable Daily Intake* (ADI).

Margins are applied to reduce uncertainties: limit values for humans are by default at least 100 times lower than the NOAEL. First, the value is lowered by a factor of 10 to accommodate the differences between humans and animals. This is followed by a reduction by another factor of 10 to account for vulnerable groups, such as pregnant women, babies and children. In the case of severe effects or limited data, an additional margin may be applied on top of that.

Degree of exposure

Besides toxicity, the level of exposure – through inhalation, ingestion or skin contact – also determines the risk. The Ctgb therefore calculates exposure using *worst-case* scenarios, considering multiple exposure routes – through food, air, skin and contact with surfaces. For example, the following worst-case scenario is assumed when calculating the exposure of local residents: a person stands close by during daily spraying with a product and is exposed to the spray mist on their entire skin surface. Furthermore, the person inhales the fumes 24 hours a day, has 2 hours of contact with contaminated surfaces and 15 minutes of contact with the sprayed crop. Actual exposure is likely much lower. This strict approach is deliberately chosen to avoid underestimating the risks.

Risk characterisation

The calculated exposure is then compared with the health-based limit values. If the exposure remains below these values, the specific use is not considered harmful to health, and the product can be authorised. If the exposure exceeds the guidance values, the Ctgb will not authorise the product.

[4] Article 44 of Regulation (EC) No 1107/2009

[5] See also Parliament letter Legal rulings on plant protection products and clarification of precautionary principle | Lower House of the States General

Advances in scientific insight: what requires attention?

Science is constantly evolving. New insights may prompt changes to the assessment framework. This is an ongoing process in which up-to-date knowledge is translated into guidelines, quantitative models and testing methods used in risk assessment. Translating new scientific insights into a robust assessment methodology is a complex and time-consuming process. As a result, there is an unavoidable delay between the emergence of new insights and their actual use in assessments. Two topics are currently in the spotlight in this regard.

Neurodegenerative disorders

There is growing attention to a possible link between exposure to chemicals, including certain plant protection products, and neurodegenerative diseases such as Parkinson's disease.[6] In 2020 and 2021, the Health Council and RIVM concluded that a link is plausible, but that it is not yet possible to determine which substances play a role and whether this is relevant to the situation in the Netherlands.[7] There are strong indications for five substances (or groups of substances): paraquat, rotenone, chlorpyrifos, organochlorine compounds and mancozeb/maneb. All these have been banned in Europe.

The neurodegenerative effect of these substances cannot simply be extrapolated to all other substances in plant protection products. Active substances vary widely in their chemical structure and mode of action. Not all substances reach the brain and not all substances have similar properties to these substances. To assess whether measures were needed, in 2022 RIVM investigated whether substances with a similar chemical structure to those mentioned above occur in products authorised in the Netherlands. They concluded that this is not the case.[8] Current knowledge therefore provides no scientific basis to ban currently authorised products.

The lack of a standardised method to assess neurodegenerative effects is, however, a serious concern. Because of the plausible link, the Ctgb believes it is important that these test methods become available to make it possible to determine exactly which substances have neurodegenerative effects and which do not. The Ctgb regularly draws attention to this issue at national and European level. In a letter to EFSA in 2021, the Ctgb explicitly requested further analysis and research on possible risks for Parkinson's disease when using active substances currently approved in Europe.[9] Several studies are currently ongoing, both in the Netherlands at RIVM[10] and in Europe at EFSA[11]. The Ctgb is closely monitoring these developments.

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[6] See, for example, Dorsey, E. Ray, et al. "Environmental toxicants and Parkinson's disease: recent evidence, risks, and prevention opportunities." *The Lancet Neurology* 24.11 (2025): 976-986.

[7] See, for example, Gezondheidsraad | No. 2020/10 and Heusinkveld, H., et al. "Gewasbeschermingsmiddelen en neurodegeneratieve ziekten: mogelijkheden om de toelatingsvereisten te verbeteren." (2021) (Plant protection products and neurodegenerative diseases: options for improving authorisation requirements.

[8] RIVM reported that one comparable substance was approved in Europe: metiram. It has been prohibited since 2023. See also: Geen maatregelen nodig na onderzoek naar schadelijke stoffen in gewasbeschermingsmiddelen | RIVM (No measures needed after investigation into harmful substances in plant protection products | RIVM)

[9] See also the letter the Ctgb wrote about this in 2021: EFSA mogelijke relatie gewasbeschemingsmiddelen en ziekte van Parkinson | Brief | College voor de toelating van gewasbeschermingsmiddelen en biociden (EFSA possible relationship crop protection products and Parkinson's disease | Letter | Board for the Authorisation of Plant Protection Products and Biocides)

[10] Onderzoek 'SPARK' naar bestrijdingsmiddelen en Parkinson | RIVM en Onderzoek Bestrijdingsmiddelen en Omwonenden | RIVM ('SPARK' study on pesticides and Parkinson's disease | RIVM and Study on Pesticides and Residents | RIVM)

[11] EFSA Pilot Project on New Approach Methodologies (NAMs) for Tebufenpyrad Risk Assessment. Part 1. Development of Physiologically-Based Kinetic (PBK) Model Coupled With Pulmonary and Dermal Exposure

Cumulative exposure

The current risk assessment looks at whether exposure to the product (or products) in each product falls below the health-based limit value. However, people are exposed to multiple substances from various products. Hence, the question is whether the sum of these exposures – the cumulative exposure – remains below the health-based limit value. For dietary exposure to active substances in plant protection products, RIVM and EFSA have developed a methodology to determine the combined risk of groups of substances with similar effects. Initial analyses show that even with combinations of residues in food, risks remain below the health-based guidance values. RIVM studies confirm that the current assessment methodology for residues from individual products provides sufficient protection.[12] This analysis focuses exclusively on dietary exposure to various substances. The RIVM study on ambient exposure (OBO, 2019) suggests that residues in food account for most of the total exposure of local residents.[13] Based on current knowledge, there is therefore no ground to ban products or change authorisations because of cumulative exposure.

The Ctgb believes it is important that the cumulative exposure method becomes a standard part of the assessment process as soon as possible and is actively working to accelerate its inclusion. To this end, the Ctgb collaborates with RIVM and EFSA.

From authorisation to broader considerations

Regulation (EC) No 1107/2009 determines whether a plant protection product may be placed on the market. The authorisation system therefore leads to a "yes-no" decision: an application is either authorised or rejected. The authorisation system is not intended to regulate use or spatial planning decisions or to weigh the interests of various parties. Especially in the Netherlands, where agricultural businesses are located near residential areas, this may require additional measures. Concerns raised by local residents cannot be addressed simply by referring to an authorisation. Addressing these concerns involves choices about local context, societal desirability and balancing the interests of growers and local residents. Ctgb may support the discussion on these choices by sharing knowledge and expertise on substances and products and how they are assessed in the authorisation system. Responsibility for these choices, however, lies with policymakers at national, provincial and municipal level, not with an implementing authority like the Ctgb.

Additional frameworks and tools

Beyond the authorisation system, there are legal and policy frameworks that do allow for regulating use and taking spatial planning into account, such as the Sustainable Use of Pesticides Directive (2009/128/EC) and the Environment Act. These provide policy tools to take measures to protect the living environment.

Within these frameworks, governmental bodies – national and local – can deploy tools such as the following:

- Stimulate the reduction of plant protection product use.

[12] Blootstelling aan combinaties van gewasbeschermingsmiddelen via voedsel | RIVM (Exposure to combinations of plant protection products via food | RIVM)

[13] See Bestrijdingsmiddelen en omwonenden (Pesticides and local residents): Samenvattend rapport over blootstelling en mogelijke gezondheidseffecten | RIVM and Bestrijdingsmiddelen en omwonenden (Summary report on exposure and potential health effects | RIVM and Pesticides and residents): Samenvattend rapport over blootstelling en mogelijke gezondheidseffecten | RIVMAdvies Onderzoek bestrijdingsmiddelen en omwonenden en het bodemonderzoek Westerveld aan I&W en LNV | Brief | College voor de toelating van gewasbeschermingsmiddelen en biociden (Summary report on exposure and possible health effects | RIVM Advice Research pesticides and residents and Westerveld soil survey to I&W and LNV | Letter | Board for the Authorisation of Plant Protection Products and Biocides)

- Stimulate use of low-risk alternatives, such as non-chemical products, measures or methods to protect crops.
- Establish minimum distance requirements or no-spray zones around vulnerable spatial functions such as residential areas, schools or healthcare institutions.

The Ministry of Agriculture, Fisheries, Food Security and Nature (LVVN) is currently commissioning research on no-spray zones to support municipalities in fulfilling their responsibilities under the Environment Act.[14] The question of which distance requirements actually address the concerns is not a purely scientific issue. How to determine an appropriate distance when potential risks, such as neurodegenerative effects, are not yet fully understood? This illustrates that the challenge is not only technical, but also societal, administrative and spatial in nature.

Invitation to dialogue

The authorisation of plant protection products is only one part of a broader task: creating a healthy living environment with space for agriculture, housing and nature. This requires close cooperation between the authorities – municipalities, provinces, the national government, enforcement agencies and the Ctgb – and an open dialogue about statutory tasks, legal competences and choices.

[14] Antwoord op vragen van het lid Kostic over 'de rechterlijke uitspraak dat Nederland burgers onvoldoende beschermt tegen landbouwgif' | Tweede Kamer der Staten-Generaal (Reply to questions by member Kostic on 'court ruling that the Netherlands does not adequately protect citizens from agricultural poisons' | Lower House of the States General)