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Neonicotinoids: Bayer's Systematic Risk Management & Portfolio Evolution

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2025 Report Updates

This is the fifth edition of Bayer's report *'Neonicotinoids: Bayer's Systematic Risk Mitigation & Portfolio Evolution.'* The report has been updated to reflect new developments, remove information that has become outdated or no longer relevant, and provide additional context about the value farmers find in using neonicotinoid products.



Executive Summary



The introduction of the neonicotinoid class of insecticides in the 1990s brought new features to improve sustainability and reduce the environmental impact of insecticides in agriculture. Neonicotinoids replaced older insecticides, which frequently met less strict safety standards, reinforced the concept of seed treatment minimizing environmental exposure to agrochemicals, and brought a broad spectrum of efficacy and a new mode of action to assist integrated resistance and pest management on many crops.

Neonicotinoids marketed by Bayer include imidacloprid, clothianidin (seed treatment only), thiacloprid and acetamiprid. These neonicotinoids fall into two sub-classes: nitro-substituted (imidacloprid and clothianidin) and cyano-substituted (thiacloprid and acetamiprid). Thiacloprid and acetamiprid have very low toxicity to bees and do not require many of the mitigation measures that can be required for nitro-substituted neonicotinoids.

Some years after the introduction of neonicotinoids, concerns about their safety to honeybees and other non-target organisms were raised. Concerns centered on the potential impact of neonicotinoid residues found in the flowers of seed-treated crops on the honeybees feeding on these plants. To this end, comprehensive studies conducted under realistic field conditions have shown that residues of neonicotinoids in the flowers of seed-treated crops are clearly below the levels that could cause adverse effects on honeybee colonies. Neonicotinoids, like all pesticides, are highly regulated, and all Bayer products undergo extensive testing to ensure they don't have unacceptable adverse effects on non-target insects and the environment.

Other concerns were caused by several isolated incidents that took place in Germany in 2008 when dust from treated seeds was accidentally released during planting, resulting in significant intoxication of bees nearby. Bayer developed a series of mitigation measures and advanced their implementation, as described in this report, to prevent such incidents from happening again.

At Bayer, the discussion about neonicotinoid effects triggered a period of internal review and research into suitable risk mitigation measures or product replacements. It also changed the risk assessment and profiling of existing and new products in Research and Development (R&D) (e.g., systematically considering intrinsic toxicity to pollinators in the early compound candidate selection process).

Several initiatives and processes were introduced to minimize any further risk through the exposure of bees to neonicotinoid insecticides.

Mitigating the Risk for Bees Through Exposure to Neonicotinoids After Seed Treatment

From seeds treated with certain coating techniques (e.g., film coating in corn), small quantities of insecticidal dust from the coating may be abraded and emitted to the environment during planting. Mitigation measures included adopting a method of measuring dust abrasion of treated seeds to facilitate the enforcement of a consistent quality standard for seed treatment, the use of planter box applied fluency agents (specially designed lubricants) and polymer coatings applied in the treatment process to reduce the amount of dust potentially released during planting, the introduction of new seed treatment technologies, and the use of deflectors during sowing to direct dust particles into the soil.

Seed Treatment Site Certification Schemes

Seed treatment site certification schemes, such as the European Seed Treatment Association (ESTA) scheme, foster compliance with certain safety and quality standards. Certification of treatment sites optimizes seed treatment practices to support sustainable agriculture. (For details, please see page 13.)

Mitigating the Risk to Bees Through Exposure to Neonicotinoids Associated With Foliar Application

As a general best practice principle, applications of nitro-substituted neonicotinoids, such as imidacloprid, should be strictly avoided in bee-attractive crops during flowering to avoid exposure to bees. Adjacent beehives should be covered or removed. Applications should be strictly avoided when flowering weeds are present in the treated crop. Bayer follows the Food and Agriculture (FAO) Guidelines on Good Labelling Practice for Pesticides and the globally harmonized system (GHS) for the classification and labeling of chemicals to compile global label references for our products. Since mid-2021, Bayer has updated all imidacloprid-containing product labels to reinforce pollinator safety.

Fostering Bee Health Through Pollinator Research

Recognizing the importance of bees in agriculture, Bayer has devoted significant resources to research activities focused on pollinator health over the years. Today, pollinator-focused research focuses on the safety testing of products in Bayer's portfolio that goes beyond what regulatory standards require. For example, we seek to develop new methods for toxicogenomic assessments to help us understand the molecular mechanisms behind the pesticide sensitivity of bees. These methods might help advance the future development of new insecticides with low toxicity to pollinators.



Beyond ensuring the environmental safety of our products, Bayer has conducted and supported bee health and pollinator safety through research partnerships with leading scientists worldwide. Over a period of more than 10 years, Bayer engaged in more than 50 research collaborations on all continents, including the large-scale bee health programs Healthy Hives and Salud Apícola in North and Latin America and a long-term project in Europe to protect wild bees in the agricultural landscape. These programs, funded by Bayer in the amount of more than \$4.5 million, focused on finding measurable and tangible solutions for improving honeybee health, apicultural practices, and protecting wild pollinators. Bayer continues to believe in the value of scientific research in advancing pollinator safety. In 2023, Bayer entered into a partnership with the Free University of Berlin, Germany, to elucidate the mechanisms behind the sublethal effects of insecticides, namely neonicotinoids, on honeybees and their relevance at the colony level, using novel digital technologies.

Mitigating the Risk to Bees Through Portfolio Innovation

Bayer now includes various tests in R&D to characterize the toxicity of novel development compounds to bees at a much earlier stage of the screening process. This will further optimize the establishment of pollinator-safe use patterns as an integral part of product development.

Adverse Incident Reporting

Bayer has binding internal regulations in place that provide clear guidance on handling incidents. CAIRnew is Bayer's own internal incident reporting system, which has been in use for many years. CAIRnew is an important tool that helps us to continuously optimize the safety of our products by collecting information on product-related issues that may arise under practical conditions. While CAIRnew is an important information collection tool, it cannot be as comprehensive in nature as an official country-level system would be, as it is limited to Bayer products and can only cover incidents that are actively reported to us.

Transparent Engagement

Bayer was the first company in the agricultural sector to enable public access to the regulatory safety data of its crop protection products, beginning in 2017 with the pollinator safety studies of the neonicotinoid imidacloprid. Our [transparency site](#) enables access to anyone wishing to examine the studies that support our registrations.¹

Bayer issues an extensive sustainability [report](#)² each year. Our commitments to sustainability are in the public domain, so we can be held accountable. We believe that continuing to manufacture and market neonicotinoids under the conditions authorized by regulatory authorities around the world, including the emergency provisions in Europe, is responsible, beneficial and entirely consistent with the UN Global Compact environmental principles.



1. Introduction

The introduction of the neonicotinoid class of insecticides in the 1990s brought new features to improve sustainability and reduce the environmental impact of insecticides in agriculture. They replaced older, frequently more toxic insecticides, reinforced the concept of seed treatment minimizing environmental exposure to agrochemicals, and brought a broad spectrum of efficacy and a new mode of action to assist integrated resistance and pest management on many crops, including corn, soybean, cotton, sugar cane, canola (oilseed rape), and many fruits and vegetables.

During the years following the introduction of the first neonicotinoids, several isolated incidents were reported where honeybee colonies were affected. These incidents, where dust from treated corn seeds was released during planting (including the most severe one where more than 10,000 nearby bee colonies in the Upper Rhine Valley, Germany, were affected in 2008), triggered a period of internal review at Bayer. The company undertook new research activities into suitable risk mitigation measures for existing products and effective technical solutions to minimize dust emission during planting. It also changed the internal risk profiling of existing and new products in R&D (e.g., taking toxicity to pollinators systematically into account in the early compound candidate selection process) and directing research programs toward the discovery of substances that are of low intrinsic toxicity to bees.

A number of initiatives and processes were introduced to minimize any further risk through the exposure of bees and other non-target organisms to neonicotinoid insecticides via a range of stewardship measures. These are detailed in the present report, and the timeline makes reference to some of the key events, including regulatory measures and risk mitigation initiatives.

This report also provides context to explain why farmers continue to rely on neonicotinoids to address their needs.

Timeline

2008

- Dust from clothianidin-treated corn seeds is released during planting in Upper Rhine Valley, Germany, resulting in damage to nearby bee colonies
- Bayer starts an extensive research program to investigate the incident
- Bayer introduces quality charter for seed treatment, including film coatings

2009

- Bayer publishes risk management approach following 2008 incident (Appendix I)
- 2009-2010: Bayer recommends use of dust deflectors

2010

- Bayer proposes inclusion of Heubach values for dust abrasion of seed treatment products in EU national regulations

2012

- 2012-2019: Bayer Bee Care Program conducts scientific activities to foster bee health and safety in a holistic way
- Scientific reports in Science magazine and other journals claim neonicotinoids to be linked to adverse effects on bee health, generating public attention
- Bayer starts to develop a program of studies with imidacloprid to address IBAMA's (Brazil) request for bee risk assessment

2013

- EU restricts use of three neonicotinoids – imidacloprid, thiamethoxam and clothianidin – to non-flowering and non-bee-attractive crops

2014

- ESTA launches certification scheme: seed treatment in the EU only at certified sites starting in 2015

2015

- Healthy Hives USA initiative begins

* EFSA: European Food Safety Authority
IBAMA: The Brazilian Institute for the Environment
and Renewable Natural Resources

MRLs: Maximum Residue Levels
PMRA: Health Canada Pest Management
Regulatory Agency

2016

- 2016-2018: Dust deflectors are introduced across the EU and then to other regions
- 2016-2022: 19 EU Member States approve emergency uses of imidacloprid, thiamethoxam and clothianidin

2017

- Two initiatives begin: Healthy Hives in Latin America (“Salud Apícola”) and Bayer Safe Use Ambassador Program
- Bayer launches a transparency site, enabling public access to regulatory safety data, beginning with the pollinator safety studies of imidacloprid

2018

- EU restricts imidacloprid, thiamethoxam and clothianidin to indoor uses in permanent greenhouses
- Bayer withdraws clothianidin from the EU renewal process

2020

- France changes its 2016 national law prohibiting any use of neonicotinoids in order to allow emergency uses

2021

- EFSA concludes that emergency neonicotinoid approvals granted by EU Member States since 2020 were justified
- Health Canada’s PMRA upholds continued registration of most products containing imidacloprid

2022

- Health Canada determines that the risks to squash bees following exposure to imidacloprid, clothianidin and thiamethoxam used on cucurbits are acceptable under the current conditions of use
- India continues to allow the use of clothianidin, thiamethoxam, imidacloprid, dinotefuran, acetamiprid and thiacloprid with the caution statement “Do not spray on flowering stage of crop” on product labels
- Brazil publishes the Environmental Re-evaluation of Imidacloprid for Pollinators, concluding that its use will be maintained with some restrictions and mitigation measures

2023

- The EU Commission publishes Regulation 2023/334 reducing MRLs for clothianidin and thiamethoxam in or on certain products based on environmental factors that would impede the import of crops treated with these products to the EU
- Food export companies file an application in the European Court requesting the annulment of Regulation 2023/334, claiming that it violates MRL regulations
- French authorities declare they will not grant an exemption for 2023 for neonicotinoid use in France, based on a ruling by the European Court of Justice, and will uphold the decree to ban neonicotinoids in the country, which had previously been put on hold

2. Stewardship Measures and Risk Mitigation



In addition to complying with regulatory requirements around the world (covered in detail on page 22), Bayer has implemented robust stewardship and risk mitigation measures to address concerns related to neonicotinoids.

Bayer has developed a risk management approach with regard to risks that could arise from seeds treated with certain coating techniques where small quantities of insecticidal dust from the coating might be abraded and emitted to the environment during planting, in particular when vacuum-pneumatic drilling machines are used. Appendix I illustrates this risk management approach that Bayer first presented at an international congress and subsequently published in 2009. Appendix II provides some details of the measures that have been developed and are being adopted, which are summarized in the following sections:

2.1 Mitigating Potential Risks Associated With Seed Treatment – SeedGrowth Stewardship

2.1.1 Measures To Address Risk From Dust

Initially, the critical areas of concern were identified, and measures continue to be implemented around the world to ensure safe seed treatment applications of neonicotinoids. The main measures are:

- // Broad adoption of the [Heubach test](#), a method for measuring dust abrasion of the treated seeds as a quality measurement of seed treatment, optimized by Bayer and other seed companies.³ The Heubach test has been widely adopted by seed treatment companies and accepted by regulators.
- // Use of the latest innovations in the seed coating space to improve adhesion; state-of-the-art seed coatings protect operators and the environment from dust emissions by up to 95%.
- // Use of planter box applied fluency agents and polymer coatings applied in the seed treatment process can improve planting performance while further reducing the amount of contaminated dust potentially released during planting.⁴
- // Bayer's invention of S.T.E.P. (Seed Treatment End Point) technology enhances the quality of the treated seeds by avoiding abrasion.

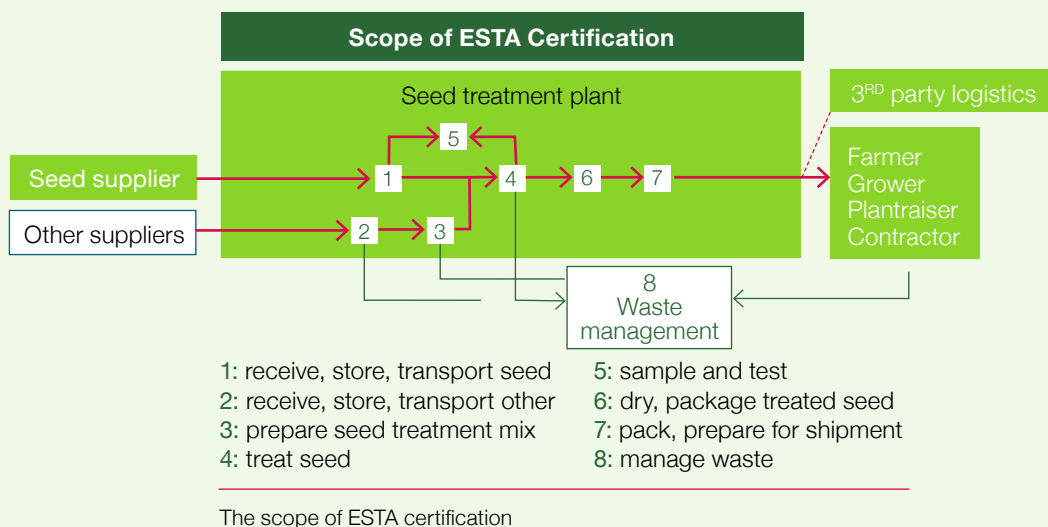
S.T.E.P technology is an innovative technology specifically developed to automate the process of accurately determining the optimal seed treatment cycle time in batch treaters. On average, it enhances the quality of treated seeds by avoiding overmixing in batch treaters.

- // Deflectors are attached to pneumatic sowing equipment to ensure that at least 90% of the dust particles released from the seeder are directed onto the soil and not into the air.

2.1.2 Certification Schemes

Initially, efforts were made to encourage the adoption of the ESTA scheme in Europe to promote correct seed treatment at certified sites.

ESTA certifies that only seed meeting the agreed quality standards is being put on the market and follows a strict [governance process](#).⁵



This certification scheme is used as a reference to promote similar practices in other regions. For example, CropLife Canada, of which Bayer is a member, introduced the “accredited seed treatment operation [standards](#).”⁶ The Julius Kuehn Institute, the German Federal Research Centre for Cultivated Plants, certified Bayer’s Global SeedGrowth Center as a lab-scale seed treatment facility supporting trial work for further developing seed treatments.

2.1.3 Training

Over the years, Bayer has developed and implemented a series of Best Management Practices (BMP), including a range of training courses, arranged in collaboration with local authorities; implementation of dust-reducing, in-field solutions; and development and communication of guidelines for treated seed handling that are included on each bag of treated seed.

2.1.4 Implementation of Certification Schemes in Different Regions

Bayer has taken a prominent, leading role in advocating and lobbying for certification schemes and stewardship measures that are summarized across five regions: Europe (France, Germany, UK, Poland, Belgium, Italy, Hungary, Romania, Russia, and Ukraine); Middle East and Africa (South Africa, Turkey); North America (US, Canada); Latin America (Brazil, Argentina and Mexico); and Asia-Pacific (China, India, Australia, and New Zealand).

Bayer is not acting alone and has established partnerships with other seed companies, notably a [5-point action plan](#) (5PAP)⁷ with Syngenta, as well as implementation of seed treatment stewardship measures with generic suppliers (e.g., Makhteshim Agan India, Nufarm).

In **Western and Central Europe**, regulatory authorities announced mandatory certification schemes in 2015, and training modules were developed in 2016, aimed at sugar beet and oilseed rape in the first instance. The certification came into effect for the 2017 season. Considerable advances were made to mitigate any risk from dust emitted during planting. For example, in France, Germany, the UK and Belgium, dust threshold monitoring (Heubach) and deflectors were made mandatory in corn, and film coatings were used.

The focus was directed at corn and cereals in **Eastern Europe and Africa**, and additional BMP training was developed specifically for potato seed treatment. The ESTA certification scheme was introduced outside the EU, in Ukraine and Turkey, from 2015 to 2017. The second wave of dust deflector distribution moved to Hungary in 2015-2016. Stewardship activities and partnering with international and local partners (e.g., Enabling the Business of Agriculture [EBA] and the International Finance Corporation [IFC]) have been implemented and frequently performed in Ukraine with room for improvement in other countries.

The **US and Canada** are major markets for neonicotinoid-treated seed and were an early target of mitigation and stewardship activities. In 2016, a program of dust collection and analysis was completed for corn, soy, cotton, canola (oilseed rape) and cereals. Since that work, various tools and approaches, such as planter box applied fluency agents and polymer coatings applied in the treatment process, are available to treaters and growers to reduce the potential dust-off of pesticide from treated seed at planting. In addition, planter equipment manufacturers have implemented design modifications to reduce dust emissions during planting operations. The tools and approaches most compatible with the individual crop seed and treatment are adopted as best management practices. Bayer plays a leading role in US industry associations, such as CropLife America, Growing Matters, and the American Seed Trade Association, to develop and deliver stewardship information to product users and applicators via outreach tools like [BeSure](#)⁸ and [The Guide to Seed Treatment Stewardship](#).⁹ In Canada, Bayer has championed requirements and implementation for certification of all commercial seed treatment facilities by partnering with CropLife Canada, Seeds Canada and the Agricultural Warehousing Standards Association.

Considerable effort was invested in gaining a better understanding of treatment and sowing practice in **Latin America**, including a survey of sowing machinery. Dust monitoring programs were conducted in **Brazil** before and after the introduction of stewardship and mitigation methods. Similarly, the feasibility of introducing deflectors was investigated (2016-2018). Bayer developed a certification scheme for Brazil based on the ESTA model and launched it in 2016. It has become the industry reference. Additionally, a training program was conducted in Brazil, under which customer seed treatment personnel were trained in correct seed treatment practices. This was performed by Bayer experts at or from the Bayer SeedGrowth Center in Paulínia. Additionally, through Bayer-owned seed treatment application equipment located at customer sites, the use of optimized film coatings was ensured and mandated.

Dust reduction measures have been widely adopted and applied in **Australia and New Zealand**, along with training programs. Following initial work to support Heubach dust measurements in **China**, there have been some advances, including training programs for professional seed treaters provided by the local Bayer SeedGrowth Center.

2.2 Mitigating Potential Risks Associated With Foliar Application

B.1. Labelling

As a general best practice principle, applications of imidacloprid and other nitro-substituted neonicotinoids should be strictly avoided in bee-attractive crops during flowering to avoid exposure to bees. Adjacent beehives should be covered or removed. Applications should be strictly avoided when flowering weeds are present in the treated crop.



APPLICATION RESTRICTIONS EXIST FOR THIS PRODUCT BECAUSE OF RISK TO BEES AND OTHER INSECT POLLINATORS. FOLLOW APPLICATION RESTRICTIONS FOUND IN THE DIRECTIONS FOR USE TO PROTECT POLLINATORS.



Look for the bee hazard icon in the Directions for Use for each application site for specific use restrictions and instructions to protect bees and other insect pollinators.

This product can kill bees and other insect pollinators.

Bees and other insect pollinators will forage on plants when they flower, shed pollen, or produce nectar.

Bees and other insect pollinators can be exposed to this pesticide from:

- Direct contact during foliar applications, or contact with residues on plant surfaces after foliar applications
- Ingestion of residues in nectar and pollen when the pesticide is applied as a seed treatment, soil, tree injection, as well as foliar applications.

When Using This Product Take Steps To:

- Minimize exposure of this product to bees and other insect pollinators when they are foraging on pollinator attractive plants around the application site.
- Minimize drift of this product on to beehives or to off-site pollinator attractive habitat. Drift of this product onto beehives or off-site to pollinator attractive habitat can result in bee kills.

(continued)



There are ongoing label revisions, which include:

1. The addition of a pollinator safety logo developed by CropLife and in review by the FAO
2. Adding the following safety phrases related to pollinators and birds in the Environmental Safety statements:



Foliar: This product is toxic to bees. To protect bees, do not apply to bee-attractive crops during bloom starting from the time when flower buds are visible. Avoid spray drift to bee-attractive crops or other bee-attractive plants. Do not apply when bee-attractive weeds are flowering in the crop or remove flowering weeds before application. Prior to application, remove, cover or otherwise protect beehives immediately adjacent to the target application site.

Drench: This product is toxic to bees. For basal (soil) drench application to established trees or shrubs, dig a small trench around the base of the tree/shrub sufficient in diameter and depth to prevent the application volume from running off. Apply the calculated volume of product evenly in the trench. Once the product has absorbed into the soil, push the dirt back into the trench firmly. Take care to remove any vegetation, seeds, or fruits from the area of application.

Seed treatment: This product is toxic to bees. Dust from treated seeds may harm bees if carried by air or when it is deposited onto flowering crops or flowering weeds. Consequently, when seeds are being planted, ensure that dust emission is minimized. Approaches to minimize dust emission include but are not limited to, the use of well-treated seeds, applying the product in combination with a high-quality seed coating, a seed lubricant, and deflectors or filters on the planting equipment holding dust either back or redirecting it to the ground and hereby close to the seeds. Handle bags or containers with treated seeds with care to avoid dust formation via the strain of unnecessary movements, like vibrations, shaking, dropping, dumping, and overturning. Avoid very dry and windy conditions during planting.

3. Adding the Mode of Action (Group 4A insecticide) to the label to assist with resistance management. Appendix III provides an example of such a label for the product Admire PRO, the Imidacloprid SC550 formulation in the US.

// Bayer follows the [FAO Guidelines on Good Labelling Practice for Pesticides](#),¹⁰ which now include the CropLife pollinator icon above and the GHS for the classification and labeling of chemicals to compile global label references for our products. In countries in transition, our local regulatory colleagues use these references to advocate for the GHS system and achieve label improvements. Moreover, we evaluate local use scenarios to ensure that products are only placed on the market when the required personal protective equipment has proven suitable for the country.



Many regulatory authorities have their own labeling scheme and do not implement FAO icons, like the US (see rectangular label above on the left), Japan (middle above with red circle) or Chile (last one above with yellow outline).



2.2.2 Training

Safe use trainings are important levers to share knowledge with growers – especially, but not limited to, smallholder farmers. Additionally, our safe use trainings include field workers, seed treatment professionals, distributors, retailers, and further stakeholders who are in direct contact with our products. In compliance with [FAO's Code of Conduct on Pesticide Management](#)¹¹ and fulfilling our stated sustainability commitments, Bayer reached almost 5.4 million external contacts worldwide (i.e., farmers, field workers, distributors, retailers and other stakeholders in agriculture), including around 4.1 million smallholder farmers in 2024, focusing on training activities in countries where there are no legal requirements for farmers to be certified in the safe handling of crop protection products. In addition to special training measures for farmers and those who use crop protection products, we combine training activities with events, such as product launches or field days, to reach a large number of farmers and distributors. Bayer also trains internal staff on the responsible use of pesticides used at our sites that support product research and development, plant breeding and seed production.¹²

We are fostering best practice exchange and capacity building on the safe use and disposal of crop protection products, with a focus on low- and middle-income countries (LMICs). This includes holistic platforms, like Better Life Farming (our flagship program for 360° smallholder support) and the BayGAP training program, as well as stewardship-specific tools, like Bayer DressCode (a web-based tool that gives farmers label-conform instructions about the personal protective equipment to use in their individual situation).

To maximize impact and reach in LMICs, we collaborate with local universities to train agriculture students, aiming to create a network of Bayer Safe Use Ambassadors who, in return, transfer their knowledge by training thousands of smallholder farmers in their communities. Since 2017, we have partnered with more than 50 universities across Asia-Pacific, the Middle East and Africa.¹³ During 2024, more than 1,400 students were trained on the sustainable use of crop protection products.¹⁴

We evaluate local use scenarios to ensure that products are only placed on the market when the required personal protective equipment has proven suitable for the country. At the same time, we work with industry, governments and distributors to make personal protective equipment increasingly available to farmers.

2.3 Pollinator Research

Numerous publications and reports have raised questions about adverse effects on bees and other pollinators. In many cases, these studies were conducted under laboratory conditions and highlighted a potential hazard, although the potential effects are rarely demonstrated under realistic field conditions when products are used according to the label directions. In 2023, Bayer started a research partnership with the Free University of Berlin, Germany, to elucidate the mechanisms behind the sublethal effects of insecticides, namely neonicotinoids, on honeybees, and their relevance at colony level, using novel digital technologies.

Beyond ensuring the pollinator safety of our products by cutting-edge research, Bayer has partnered for many years with leading research institutes and universities on a broad variety of scientific projects and initiatives to foster bee health and pollinator safety, including large-scale bee health programs in [North America](#)¹⁵ and [Latin America](#)¹⁶ and a long-term project in Europe to protect wild bees in the agricultural landscape.¹⁷ Today, pollinator research activities include safety testing of products in Bayer's portfolio that goes beyond what regulatory standards require. For example, we seek to develop new methods for toxicogenomic assessments to help us understand how bees can effectively detoxify certain pesticides in their bodies. These methods could be applied to develop new insecticides with low toxicity to honeybees and other pollinators in a more targeted way. These efforts include collaborative research with Exeter University, Rothamsted Research and Bayer to enhance the understanding of bee metabolism and underlying mechanisms of sensitivity to better inform Bayer compound development prioritization and risk evaluations of uses. The studies identified the enzymes in bees that are responsible for the rapid breakdown of certain neonicotinoids and other insecticides, contributing to their low toxicity to bees.

2.4 Safety Testing and Portfolio Innovation

Balancing the need for crop protection with the need to protect pollinators is a key criterion of Bayer's research pipeline and product life cycle development. As with all pesticides, neonicotinoid products in Bayer's portfolio have undergone a stepwise, sequential testing procedure during regulatory risk assessments in order to characterize their pollinator safety. When a product is of low intrinsic toxicity to bees, lower-tier assessments (tier 1) may be sufficient to conclude that a product is safe (even under highly conservative (worst-case) exposure conditions) and that higher-tier assessment may not be required. In all other cases, tier 1 evaluations provide only an indication of a product's hazard potential, as they inherently do not consider agronomic, environmental and biological factors that could influence risk and exposure relative to the very conservative worst-case scenario. Taken in isolation, decisions based on such lower-tier assessments would unnecessarily eliminate useful crop protection products from the market without bringing any benefit in terms of improved safety to the environment.

Higher-tiered studies/assessments refine baseline assumptions of tier 1 evaluations by incorporating additional real-life factors that potentially reduce bee risk, elucidating mechanisms underlying observations in tier 1 assessments in order to better inform relevance in the environment and characterizing potential effects at levels of ecological and biological factors that are more closely aligned with protection goals. These higher-tier assessments are more complex and are not always necessary in cases where low hazard is identified in tier 1 assessments. Overall, tier 1 and higher-tier assessments enable regulators and manufacturers to take reasonable precautionary steps to ensure

critically needed crop protection products are used in a way that is compatible with the safety of bees and other non-target organisms based on a comprehensive understanding of ecological risks. They help protect biodiversity and maintain ecosystem health while allowing for the responsible use of chemical products.

Novel compound development processes at Bayer now include a range of preliminary test designs to characterize the toxicity to bees at a much earlier stage of the development process to identify and remove unfavorable chemistry from development. Bayer's efforts to provide growers with critical tools that are compatible with relevant pollinators for the crop continue from early research through the life cycle of the asset. Specific to neonicotinoids, this is demonstrated by Bayer's effort to provide higher-tier studies to better characterize risks associated with specific use conditions, as well as refine uses and mitigations to minimize the risk to bees.

Another important way of mitigating potential risks associated with foliar spray applications is through the use of appropriate spray application technology, such as nozzles or tips that reduce drift, ensuring that the crop protection product stays within the designated buffer zones. Precise application techniques maximize the effectiveness of products and minimize accidental dispersion, protecting the environment and human health. DriftRadar, Bayer's integrated drift management concept, simplifies pesticide application by using product label information and real time wind data to create an application map. If necessary, it activates drift-reducing nozzles and maintains buffer zones and distance control automatically.¹⁸ Experiments conducted by Bayer Brazil in 2024 in collaboration with academic experts evaluated the performance of different types of spray tips used on a terrestrial sprayer by comparing the resulting drift. This helped identify the optimal spray tips that ensured that the application reached the target with greater safety, reducing particle movement and underscoring that drift can be reduced by using the correct application technology.



3. Adverse Incidents



Neonicotinoid crop protection products have been used by farmers around the world for over 30 years. During that time, routine incident monitoring reports have documented a limited number of instances of harmful pesticide-pollinator interactions. In their 2016 preliminary pollinator risk assessment of imidacloprid, US regulators noted very few bee incidents over many years of use. In fact, there has not been a single documented honeybee colony loss in the US that can be attributed to exposure following a legal application of imidacloprid, despite its widespread use in agriculture. Bayer continues to monitor public sources and the scientific literature for external reports on incidents.

Bayer has binding internal regulations in place that provide clear guidance on handling incidents and has developed its own internal adverse incident reporting system, CAIRnew, which has been in use for many years. It is a worldwide software solution for reporting, managing, documenting, and analyzing incidents, complaints, and product recalls with the goal of enhancing risk mitigation capabilities. This system aims to optimize response, traceability, compliance and collaboration. Bee-related incidents can be entered into the system, along with other types of incidents. While CAIRnew is an important information collection tool, it is not as comprehensive in nature as an official, country-level system would be, as it is limited to Bayer products and can only cover incidents that are actively reported to us.

We are aware that complaints/incidents are reported to national authorities via their own incident reporting procedures and platforms. To the best of our knowledge, in the majority of cases where the incident is investigated and shown to be due to off-label use, there is no further action from the authorities that involves Bayer. The same is true in cases when the incident is due to suboptimal application of mitigation measures, the claim is unfounded, or the incident is due to some reason other than the effects of neonicotinoid use.

We encourage incident reporting through sales staff and hotlines and source additional information from media reports and medical professionals trained through our Safe Use Ambassador Program. Our incident management system and product use review form the basis of our safety monitoring and improvements. We analyze data to identify potential issues and hotspots and derive learnings to develop targeted stewardship measures. These measures may include enhanced training, formulation changes, revised application recommendations, use limitations or even product withdrawal following the FAO-WHO (World Health Organization) International Code of Conduct on Pesticide Management guidelines.¹⁹

4. The Use of Neonicotinoids in Agriculture

4.1 The Value of Neonicotinoids to Growers

The first neonicotinoid to be commercialized was imidacloprid, which began entering markets around the world in the early 1990s, with thiamethoxam and clothianidin following a few years later. The systemic and long-lasting efficacy of neonicotinoids replaced several foliar spray applications of other products and boosted the seed treatment market. The agronomic need for neonicotinoids remains high, and with €550 million in sales, Bayer holds approximately 4% market share globally. Neonicotinoids have significant relevance for Bayer's €4 billion seed franchise as seed treatment on corn, canola, cotton and soybean.

Designed to be less toxic to humans, neonicotinoids have a better safety profile for users, consumers and the environment than some alternative products. Today, neonicotinoids are a key technology in a farmer's toolbox to address pest pressure in a targeted, timely and resource-efficient way. Farmers rely on neonicotinoids to protect a wide range of crops, including canola, corn, cereals, potatoes, sugar beet and soybean, as well as horticulture, like tomato and citrus, and specialty crops, such as tea. Neonicotinoids also provide an alternative mode of action to prevent pest resistance and improve the effectiveness of integrated pest management (IPM).

IPM is “a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks.”²⁰

Without neonicotinoid seed treatment, farmers would have great difficulty controlling certain soil-borne and early-season seedling pests and would have to use more expensive and less environmentally friendly methods. In many cases, farmers don't have a practical alternative to seed treatments to protect crops from pests. The value of neonicotinoids for farmers has been documented in several studies.

One such example is a comprehensive study of the socio-economic benefits of neonicotinoid insecticides in North America published in 2015 and conducted by a group of independent economists and scientists. The study provides compelling evidence that these products are vital to agriculture. The report confirms that neonicotinoids significantly increase crop yield and bring billions of dollars to the economy, benefiting farmers and entire communities. Neonicotinoid seed treatments are the most highly valued insecticide management practice in corn, soybean and canola by farmers, valued at more than \$1.4 billion.²¹ An analysis of 1,550 field studies conducted over 20 years (1993–2014) showed that neonicotinoids provided average yield increases between 3.6% and 71.3% in corn, soybean, wheat, cotton, sorghum, canola, potato and tomato.²²

\$1.4 billion equals €1.36 billion (01/15/2025 exchange rate)



In Europe, after imidacloprid, clothianidin and thiamethoxam were removed from the farmers' toolbox, some farmers abandoned the cultivation of certain crops due to their inability to protect these crops from certain pests. For example, in the UK, the area of cultivated oilseed rape fell both in the 2014-2015 and 2015-2016 seasons, with farmers citing their inability to control the cabbage stem flea beetle as one of the top three reasons for discontinuing cultivation. Crop losses were 3% and 5% in the respective seasons, with clear differences in the crop area treated (1.14 vs 0.77 million ha) and the number of insecticide applications per crop (2.0 vs 1.4) to combat the cabbage stem flea beetle in 2014-15 and 2015-16, respectively.²³ Growers suffered significant economic impact due to yield and quality losses, alongside the increased costs of alternative crop protection methods. In 2020, French sugar beet growers found alternative products to be ineffective against the beet yellow virus, which reduced yields by up to 50% and caused economic loss of approximately €100 million for growers.²⁴



4.2 Overview of the Regulatory Landscape for Neonicotinoids

Regulatory reviews of neonicotinoids, as with all other kinds of pesticides, are conducted on a regular basis around the world. Neonicotinoids are registered in more than 80 countries for use in crop protection, including the US, Canada, Brazil, Australia, New Zealand, Japan, and China. At present, a decision is expected in Argentina in 2025, a review has been initiated in Costa Rica, with reviews ongoing in China, New Zealand, Australia, Chile, Japan, Korea, Israel and the US. In the US, the EPA is expected to release its Proposed Interim Registration Review Decision in 2025. These jurisdictions adopt high standards of environmental safety by determining whether identified risks can be satisfactorily mitigated or managed. Many neonicotinoid uses, including seed treatments, have been assessed by these authorities (and EFSA in the EU) as not presenting unacceptable risks to people or the environment when applied as directed.

Brazil and India released regulatory decisions that allowed the continued use of neonicotinoids:

// Brazil's Agriculture Ministry (MAPA) published the [Environmental Re-evaluation of Imidacloprid for Pollinators](#) in 2022, concluding that its use will be maintained with some restrictions and mitigation measures.²⁵

// After a nine-year review (2013-2022), India also continued to allow the use of six neonicotinoids (clothianidin, thiamethoxam, imidacloprid, dinotefuran, acetamiprid and thiacloprid) with the caution statement, "Do not spray on flowering stage of crop" on product labels.²⁶

These decisions in Brazil and India followed a series of positive decisions by Canada's authorities, culminating by the 2021 withdrawal of a proposed cancellation of all agricultural outdoor uses for clothianidin and thiamethoxam and confirmation of continued use of products containing imidacloprid.

In 2023, Uzbekistan proposed a ban on all imidacloprid uses. However, recognizing that farmers had no viable alternatives, authorities decided to accept applications to re-register imidacloprid products again.²⁷

On May 5, 2023, the US Environmental Protection Agency released an assessment²⁸ of endangered or threatened species at greatest risk from registered uses of the neonicotinoid insecticides clothianidin, imidacloprid and thiamethoxam. These analyses were built upon the Biological Evaluations (BEs)²⁹ that the EPA finalized in June 2022. The process is not completed until after the legally required consultation with the wildlife agencies that have primary responsibility for endangered species.³⁰



4.2.1 Emergency Uses

In the EU, emergency authorizations are temporary approvals, which are only permitted in exceptional situations and according to specific conditions, according to Article 53 of EU Regulation 1107/2009. They allow an otherwise unapproved product to be used on a specific crop in a limited and controlled way for a maximum period of 120 days in one year. These approvals are granted by the Member State, which then informs the Commission.

Since the EU outdoor use restrictions for most neonicotinoid pesticides in 2018 and subsequent non-renewal, some EU Member States granted emergency authorizations for specific uses (e.g., in sugar beet) on mainly grower associations' requests because of a danger, which cannot be contained by any other reasonable means. Emergency authorizations are not applied for by Bayer, and related sales are not business critical. In a judgment rendered in January 2023, the European Court of Justice expressed the opinion towards a Belgium court, which requested this guidance, that emergency authorizations cannot be granted for the placing on the market of plant protection products for seed treatment and the placing on the market and use of seeds treated with those products, where the placing on the market and use of seeds treated with those products have been explicitly prohibited by an implementing regulation. This, however, is the case for the neonicotinoids restricted in 2018, as they were specifically restricted in the EU. While the judgment only directly concerns seeds treated with certain neonicotinoids, the judgment triggered a debate on its relevance for other cases of emergency authorizations.

Bayer believes that the EU Member States need access to the emergency use option provided the conditions laid out in Article 53 are met. Bayer has not and will not apply for such approvals itself or for economic gain. In some cases, we will assist grower groups or local associations who have identified an agronomic need but are not familiar with the approval procedures for plant protection products. Our position and a more detailed description of the emergency procedure are available [here](#).³¹ The [Emergency Authorizations database](#)³² is publicly available and includes all the emergency approvals notified to the Commission by EU Member States.

France changed its national law in 2016 to prohibit any use of neonicotinoids, even via the emergency use route. However, following seasons with substantial damage to sugar beet yields due to the beet yellows virus, transmitted by aphids, and after public consultations and exchanges between the General Assembly and the Senate, the law was changed in December 2020, and the decree to allow emergency use on sugar beet was published on February 5, 2021. Derogations to apply neonicotinoids to sugar beet seeds were granted for the 2022 season. However, in January 2023, as a result of the European Court of Justice (ECJ) ruling, French authorities declared that they would not grant an exemption for 2023.³³



5. Transparent Engagement

5.1 Trust and Transparency

Transparency is very important to Bayer, especially with respect to the safety of our products. Through transparency, we aim to strengthen our customers' and stakeholders' confidence in our products. Bayer was the first company in the agriculture industry to enable access to safety-relevant data on crop protection products and genetically modified crops to the public. Summaries of scientific studies assessed by EFSA in connection with the registration procedures for 30 of our crop protection products are available on our [online transparency platform](#),³⁴ including toxicological and ecotoxicological studies and investigations into degradability in the environment. Comprehensive reports on the registration studies for the approval of our crop protection products and genetically modified crops are available upon specific request. The platform is continuously updated to provide the most recent status of safety-relevant information on crop protection products and genetically modified crops, as well as information on plant breeding. In addition, we facilitate access to information – including official documents and data – on the procedure for granting emergency authorizations for crop protection products, including why this process is so important for European agriculture.³⁵

In 2023, Bayer set a new milestone in transparency by publishing our first report on sustainable pesticide management. The report details how we live the FAO-WHO International Code of Conduct on Pesticide Management as a company, including tangible examples of our stewardship activities along the full life cycle of our crop protection products.³⁶

The EFSA assessment reports of our active substances are publicly available on the [EFSA website](#).³⁷ Similarly, the European Commission makes its EU Pesticides Database available to the public and information about specific substances, the latest assessments, approval status and so on may be accessed [here](#).³⁸

5.2 Commitment to Product Safety

Bayer's commitment to product safety goes beyond just meeting local regulatory requirements. In 2012, we stopped selling any WHO acute class 1 pesticide products, regardless of regulatory approval status. Additionally, we market only those crop protection products whose active ingredients are registered in at least one Organisation for Economic Co-operation and Development (OECD) country or a country with a mature risk-based regulatory framework.

We work to continuously incorporate new scientific knowledge into our risk assessments. All new products are evaluated against our latest Bayer safety standards, leading to the improvement of our product portfolio. For our assessment, we apply criteria that reflect the standards of reference authorities that represent different agronomic realities and whose programs for regulating pesticides are, in general, well-developed. These include the regulatory authorities in the US, Canada, Brazil, the EU, Australia, New Zealand, Japan and China.

Bayer is one of the founding members of [Growing Matters](#),³⁹ an initiative that is committed to open and scientific discourse on stewardship, benefits and alternatives to neonicotinoid insecticides in North America. Together with its partners, Growing Matters launched the BeSure! campaign, designed to strengthen awareness and adoption of stewardship practices to protect bees and other pollinators during the handling, planting and disposal of neonicotinoid-treated seeds and other neonicotinoid applications used during the growing season.

5.3 Engagement With Critical Stakeholders

Modern agricultural methods, such as the application of certain classes of crop protection products, are often the subject of intense public debate. The risk of an increasingly negative public debate that is not primarily based on science may, for example, lead to legislative and regulatory decisions that are unfavorable to our company, significantly limiting the use of our products or even resulting in voluntary or mandated product withdrawals. We are engaged in constant dialogue with interest groups and regulators to promote scientifically founded, rational and responsible discussions and decision-making processes. You can learn more about Bayer's ongoing dialogue with stakeholders in our [2024 Impact Report](#).⁴⁰



6. Beyond Neonicotinoids

Our objective is to continuously increase the outreach of our training activities and to bring to the market innovative technologies that promote greater environmental responsibility through safer and more targeted pesticide use.

The [2024 Impact Report](#)⁴¹ contains the most up-to-date information on a wide range of safe use initiatives.

6.1 Crop Protection Environmental Impact Reduction (CP EIR)

Bayer has adopted a methodology for CP EIR and made a commitment to reducing the environmental impact of our crop protection products. Seed-applied crop protection tools are one lever to achieve this commitment because they can significantly reduce the treated area and, therefore, the potential exposure to wildlife and the environment. For updates on our progress, please see page 48 of our [2024 Impact Report](#).

6.2 Integrated Pest Management

We work with farmers to help them strike a balance between combatting and deterring pests that can destroy crops while at the same time supporting beneficial insects, like pollinators or natural antagonists of pests. This is done through IPM, a strategy that focuses on long-term prevention of pests and their damage through a combination of techniques, such as crop scouting and crop rotation, biological control, chemical control, targeted habitat management, and the use of genetically modified organisms (GMOs) and resistant crop varieties. Seed treatments are a good fit in IPM because they effectively and efficiently combat the growth of pest and disease populations and thus reduce the need for farmers to resort to additional foliar spray applications.⁴³ You can learn more about IPM on our [website](#).⁴⁴

6.3 Digital and Precision Agriculture

For Bayer, digital technologies are key enablers for creating a better balance between agricultural productivity and environmental conservation. Our digital farming platform, Climate FieldView™, enables farmers to use data to optimize their agricultural inputs (costs) used on the field and to improve their output (yields). Thanks to precision agricultural machinery and digital tools, inputs such as seeds, water, and crop protection products are only used when and where they are necessary. FieldView is currently available in North America, South America, Europe, Turkey, South Africa and Australia.⁴⁵

Partnering with Netafim™, we developed a new mode of targeted crop protection application. DripByDrip Automated Irrigation delivers water and crop protection directly to the roots, leading to less runoff, less drift and less product needed.⁴⁶



6.4 Research and Development

Our portfolio features insect-protected crops that reduce the need for foliar insecticides, as well as biological solutions that offer farmers important complementary products as part of integrated solutions to safeguard their harvests. To accelerate the development and availability of these biological products on the market, Bayer uses the open innovation model to enter into strategic partnerships with companies around the world. You can learn more in our 2024 R&D Pipeline [here](#).⁴⁷

Bayer's R&D process constantly evolves, as it incorporates breakthroughs in crop protection technology, data generation and analytics, artificial intelligence, and computational sciences that make it possible to process vast amounts of information at unprecedented speeds. Thanks to these scientific advances that were not available even a decade ago, Bayer is transforming its approach to R&D to design entirely new solutions to include early human and environmental safety assays as a guiding dimension for our design of new molecules. As a result, we understand the safety aspects of molecules early on and guide projects to create highly innovative products with an outstanding safety profile for humans and the environment.

For more information, please read our report [*Toward Innovative, Sustainable Solutions That Meet Agriculture's Challenged and Societal Expectations: Bayer's Approach for the Development and Use of Crop Protection Products*](#).⁴⁸

6.5 Bayer ForwardFarming Initiative

Farmers' livelihoods are increasingly challenged by the changing climate, limited natural resources and growing societal demands. Together with farmers, we continually seek to move agriculture forward with our eyes on a more sustainable future. This comes to life through [Bayer ForwardFarming](#),⁴⁹ a knowledge platform that fosters dialogue and showcases on-farm sustainable practices with farmers. On ForwardFarms around the world, farmers, value chain partners, academia, scientists, and civil society engage in dialogue and experience modern sustainable agriculture firsthand. Across the ForwardFarming network, Bayer partners with independent farmers to show how tailored solutions, modern tools and practices, proactive stewardship measures, and partnerships are enabling farmers to run successful businesses while providing enough food for a growing world population in a way that preserves the environment.



7. Conclusion

Bayer continues to demonstrate a responsible, precautionary and innovative approach to balancing the needs of our customers to protect their crops, thereby safeguarding our food supply, with the need to protect pesticide users, bystanders, consumers and the environment from any risks associated with the use of our products. We continue to support training programs that enable millions of pesticide users to protect themselves and the environment by using our products correctly. We bring new technologies and safe chemicals to the market. We promote and champion stewardship measures. We partner with other stakeholders to support these activities. Our transparency site enables anyone to examine the studies that support our registrations.

We issue an extensive [report](#)⁵⁰ each year on sustainability at Bayer. Our commitments to sustainability are in the public domain, so we can be held accountable. We believe that continuing to manufacture and market neonicotinoids under the conditions authorized by regulatory authorities around the world, including the emergency provisions in the European Union, is responsible, beneficial and entirely consistent with the UN Global Compact environmental principles.

8. Appendices

The appendices are available for download on the report landing page.

- I: Bayer neonicotinoid risk management proposal (2009)
- II: Descriptions of risk mitigation measures for seed treatment
- III: Admire PRO label highlighting specific precautions to protect bees



Endnotes

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