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***Neonicotinoids: Bayer's
Systematic Risk Mitigation &
Portfolio Evolution Towards
Minimized Risk for the
Environment***

Content



Executive Summary

1. Introduction

2. Measures Taken to Address Areas of Concern

A. Mitigating Risks Associated with Seed Treatment – SeedGrowth Stewardship

A. 1. Measures to Address Risk From Dust

A. 2. Certification Schemes

A. 3. Training

A. 4. Implementation in Different Regions

B. Mitigating Risks Associated with Spray Application

B. 1. Labelling

B. 2. Training

C. Pollinator Research

D. Portfolio Innovation

3. Adverse Incidents

4. Transparent Engagement

A. Trust and Transparency

B. Product Safety

C. Engagement with Critical Stakeholders

D. Engagement with Customers

E. Emergency Uses

5. Beyond Neonicotinoids

6. Conclusion

7. Appendix

2022 Report Updates

This is the second edition of Bayer's report 'Neonicotinoids: Bayer's Systematic Risk Mitigation & Portfolio Evolutions Towards Minimized Risk for the Environment.' The report has been updated to reflect new developments since the publishing of last year's edition in April 2021. In addition to statistics and links to background documents, which were updated as appropriate, here is a summary of key developments included in the 2022 report:

Labeling Developments

// Bayer has continued to make updates to product labels to improve pollinator safety. All clothianidin- and/or imidacloprid-containing product labels (foliar and seed treatment) have improved language regarding pollinator safety. Soon, these labels will include a pollinator safety icon developed by CropLife International, which is awaiting approval by the Food and Agriculture Organization of the United Nations (FAO).

2021 Trainings

// Bayer reached more than 2.7 million external contacts (i.e., farmers, field workers, distributors, retailers and other stakeholders in the agriculture industry) around the world, focusing on training activities in countries where there are no statutory certification requirements for farmers concerning the safe handling of crop protection products.

// Bayer organized four workshops related to the safe handling of crop protection products for more than 1,200 students, faculty members of universities and other relevant stakeholders in 14 countries, especially in Asia and Africa.

Adverse Incident Updates

// A clarification was made regarding Bayer's incident reporting system, CAIRnew, to indicate that Bayer uses the information entered into CAIRnew to qualitatively calibrate its risk management based on early awareness of cases/hotspots and takes follow-up actions. In addition to CAIRnew, Bayer would appreciate a more systematic official management process of data collection, regarding human and environmental safety, so we can better interpret risk management processes.

Regulatory Developments

// Health Canada's Pest Management Regulatory Agency (PMRA) issued:

// A decision to uphold continued registration of most products containing imidacloprid, including a number of uses originally proposed for cancellation (May 19, 2021).

// A decision concerning acceptable environmental risk to squash bees following exposure to imidacloprid, clothianidin and thiamethoxam used on cucurbits, determining that the risks to squash bees are acceptable under the current conditions of use (February 24, 2022).

Emergency Authorizations

// The European Commission mandated the European Food Safety Authority (EFSA) to assess the justification of 17 emergency approvals granted by 11 Member States since January 2020. All the granted emergency approvals allowed uses that protect sugar beet from viruses. In their reports (one per Member State) published on November 18, 2021, EFSA concluded that, in all cases, the emergency approvals were justified and granted in accordance with the conditions of the regulation.

Executive Summary



The introduction of the neonicotinoid class of insecticides in the 1990s brought new features to improve sustainability and to reduce the environmental impact of insecticides in agriculture. Neonicotinoids marketed by Bayer include: imidacloprid, clothianidin (seed treatment only) and thiacloprid. These neonicotinoids fall into two sub-classes: nitro-substituted (imidacloprid & clothianidin) and cyano-substituted (thiacloprid). Thiacloprid has very low toxicity to bees and does not require many of the mitigation measures.

Neonicotinoids replaced older, frequently much more toxic insecticides, reinforced the concept of seed treatment minimizing environmental exposure to agrochemicals, and brought a broad spectrum of efficacy and new mode of action to assist integrated resistance and pest management on many crops. As the pioneer of neonicotinoid research, Bayer gained significant market share of up to 85% in 1996 with the launch of imidacloprid. Bayer's market share has now declined to around 20% as other companies launched their neonicotinoids and then generic manufacturers entered the market. The purchase of Monsanto in 2018 included a seed business, where the seeds are often protected by treatment with neonicotinoids.

Some years after their introduction, there were few reports of incidents where the use of neonicotinoid products was associated with negative effects on non-target insects, like bees. The most severe example was when dust from treated seeds was accidentally released during planting in Germany in 2008, which resulted in significant intoxication of bees nearby.

The incidents triggered a period of internal review/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 (e.g., taking toxicity to pollinators systematically into account already in the early compound candidate selection process in Research).

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 maize), small quantities of insecticidal dust from the coating may be abraded. Those may be emitted to the environment during drilling. Mitigating measures include:

// Bayer's adoption of the Heubach test, a method for measuring dust abrasion of the treated seeds, optimized by Bayer and other seed companies.

// Innovation in seed coatings to improve adhesion: seed coatings protect operators and the environment from dust with emissions reduced by up to 95%.

// Fluency agent: The use of a lubricant improves planting performance while further reducing the amount of dust potentially released during planting.

// Bayer's invention of S.T.E.P. technology enhances the quality of the treated seeds by avoiding abrasion.

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



Seed Treatment Site Certification Schemes

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

Mitigating the Risk for Bees Through Exposure to Neonicotinoids After Spray Application

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

// Ongoing label revisions and use reductions – systematic and explicit exclusion of flowering application of imidacloprid products onto bee-attractive crops or close to beehives. Since mid-2021, Bayer has run a process to update all clothianidin- and/or imidacloprid-containing product labels (foliar and seed treatment) by improving label language, especially regarding pollinator safety, and adding a mode of action icon. A pollinator icon has been developed by CropLife and is currently in the approval process by the FAO.

// Bayer follows the FAO *Guidelines on Good Labelling Practice for Pesticides* and the globally harmonized system (GHS) for the classification and labelling 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.

Fostering Bee Health Through Pollinator Research

Beyond ensuring the environmental safety of our products, Bayer has constantly been conducting and supporting bee health and pollinator safety through research partnerships with leading scientists worldwide.

// Over a period of 10 years, Bayer engaged in more than 50 research collaborations on all continents, including large-scale bee health programs in North and Latin America and a long-term project in Europe to protect wild bees in the agricultural landscape.

// Healthy Hives and Salud Apícola are multiyear research initiatives in the U.S. and in Latin America, working to find measurable and tangible solutions for improving honeybee colony health and apicultural practice. This research is funded by Bayer in the amount of \$4 million.

Mitigating the Risk to Bees Through Portfolio Innovation

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

Adverse Incident Reporting

Bayer has used its own internal adverse incident reporting system, CAIRnew, for many years. The information entered in the system is used to qualitatively calibrate Bayer's risk management based on early awareness of cases and hotspots and to prompt follow-up actions.

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.

// In compliance with FAO's *International Code of Conduct on Pesticide Management* and our own commitments to sustainability, Bayer trained more than 2.7 million external contacts (i.e., farmers, field workers, distributors, retailers and other stakeholders in the agriculture industry) around the world, focusing on training activities in countries where there are no statutory certification requirements for farmers concerning the safe handling of crop protection products.

// Given the controversial nature of the continued uses of neonicotinoids via the emergency use provisions included in the EU pesticide legislation (Regulation (EC) No 1107/2009), the European Commission mandated the EFSA to assess the justification of 17 emergency approvals granted by 11 Member States since January 2020. All the granted emergency approvals allowed uses that protect sugar beet from beet yellows viruses transmitted by aphids. In their [reports](#)¹ (one per Member State) published on November 18, 2021, EFSA concluded that, in all cases, the emergency approvals were justified and granted in accordance with the conditions of the regulation. This demonstrates that, in specific cases, continued access to these neonicotinoids is beneficial to EU farmers and endorsed by their governments. Bayer only supplies products in cases where local growers identify the agronomic need, the justification is consistent with the terms of the regulation and seed treatment occurs at ESTA-certified sites.

In 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 needs 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 safer chemicals to the market. We promote and champion stewardship measures. We partner with other stakeholders to support these activities. Our transparency site enables anyone who wishes to examine the studies that support our registrations.

We issue an extensive [report](#)² 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 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 to reduce the environmental impact of insecticides in agriculture. They replaced older, frequently much more toxic insecticides, reinforced the concept of seed treatment minimizing environmental exposure to agrochemicals, and brought a broad spectrum of efficacy and new mode of action to assist integrated resistance and pest management on many crops, including corn, soybean, cotton, sugar cane, canola (oil seed rape), and many fruits and vegetables. As the pioneer of neonicotinoid research, Bayer gained significant value capture and an initial market share of up to 85%. The first neonicotinoid to be commercialized was imidacloprid, which began entering markets around the world from the early 1990s, with thiamethoxam and clothianidin following a few years later. Cumulative global market sales of neonicotinoids reached 1 billion euros (€) around 15 years after first launch (2006) and continued to rise to around 3 billion € in 2016. The Bayer share declined gradually during this period, as other companies launched their neonicotinoids, and then generic manufacturers entered the market to a level close to 20% market share in 2019. In addition, since much of the neonicotinoid use is to treat seeds, the purchase of Monsanto and its seed business has resulted in significant additional Bayer business that is protected by neonicotinoid treatment. In 2021, ~2.5% of our global Crop Science sales were recorded with the neonicotinoid products imidacloprid, clothianidin (seed treatment only) and thiacloprid.

During the years following introduction of the first neonicotinoids, some incidents were reported where honeybee colonies were affected. The most severe example was when release of dust from treated corn seeds during planting intoxicated more than 10,000 nearby bee colonies in the Upper Rhine Valley, Germany, in 2008.

The incidents triggered a period of internal review and stimulated new research activities into suitable risk mitigation measures for existing products and the search for potential replacements with reduced toxicity to bees. It also changed the risk assessment and profiling of existing and new products in Research and Development (e.g., taking toxicity to pollinators systematically into account already in the early compound candidate selection process in Research) and directing research programs at the discovery of substances that were not intrinsically toxic 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.

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 and elucidate its causes
- 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 in EU national regulations
- Bayer initiates international bee research collaborations

2012

- Scientific reports in *Science* magazine claim neonicotinoid use is linked with adverse effects on bee health and generate public attention
- Bayer starts to develop a bee testing program to address IBAMA's (Brazil) request

2013

- EU restricts use of three neonicotinoids—imidacloprid, thiamethoxam and clothianidin—to non-flowering and non-bee-attractive crops
- 2013-2015 Bayer and Syngenta establish 5-Point Action Plan (5PAP) and roll it out to Regions (2015-2018)

2014

- Development and launch of ESTA certification scheme: seed treatment in the EU only at certified sites since 2015

2015

- Dust deflectors are introduced across the EU and then to other Regions (2016-2018)
- Flupyradifurone is registered as a reduced risk insecticide by US EPA and approved in the EU
- Healthy Hives USA initiative begins

2016

- 2016-2022 19 EU Member States, including France and Germany, approve emergency uses of the three neonicotinoids: imidacloprid, thiamethoxam and clothianidin

2017

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

2018

- EU restricts use of imidacloprid, thiamethoxam and clothianidin to indoors in permanent greenhouses only
- 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 releases its reports after assessing the justification of emergency neonicotinoid uses granted by EU Member States since 2020. The reports conclude that in all cases the emergency approvals were justified
- Health Canada's PMRA announces the final decision on the re-evaluation of imidacloprid, upholding continued registration of most products containing imidacloprid

2022

- Health Canada publishes a Special Review decision on potential environmental risk to squash bees following exposure to neonicotinoids (imidacloprid, clothianidin and thiamethoxam) used on cucurbits, determining that the risks to squash bees are acceptable under the current conditions of use

2. Measures Taken to Address Areas of Concern

Regulatory reviews of neonicotinoids occur on a regular basis around the world. These reviews examine the latest data from registrants and the scientific literature and determine if the risks to man and the environment of specific uses of these insecticides are acceptable or if restrictions or bans are appropriate. At present (April 2022), decisions are expected in the U.S., Brazil, Argentina and India before the end of the year with reviews ongoing in China, New Zealand, Australia, Chile and Japan. These jurisdictions adopt high standards of environmental safety by determining whether identified risks can be satisfactorily mitigated or managed. Many neonicotinoid uses, particularly seed treatments, have been assessed by these authorities (and EFSA in the EU) as not presenting significant risks to man or the environment when used as directed.

In August 2018, the PMRA had proposed cancellation of all agricultural uses for clothianidin and thiamethoxam due to concerns over the potential risk to aquatic invertebrates. New information received in response to that proposal (including a large amount on water monitoring data generated by registrants and other stakeholders) has allowed for a reversal of that cancellation proposal for certain uses.

The final Special Review decision for clothianidin related to the risks to aquatic invertebrates is posted to the PMRA website, and the Special Review decision documents for this active ingredient, which provides details of the science assessment and rationales for the decision, are available [here](#).³

On April 11, 2019, Health Canada's PMRA determined that, with required amendments, continued registration of products containing thiamethoxam is acceptable. Certain uses of thiamethoxam were cancelled to address potential risks of concern to pollinators. View the decision [here](#).⁴

On May 19, 2021, Health Canada's PMRA announced its [decision](#)⁵ upholding continued registration of most products containing imidacloprid, including a number of uses originally proposed for cancellation. Only certain uses were cancelled to address potential risks of concern to the environment.

The most [recent regulatory decision by Health Canada's PMRA](#)⁶ was published on February 24, 2022. The Special Review decision concluded that the environmental risk to squash bees following exposure to imidacloprid, clothianidin and thiamethoxam used on cucurbits is acceptable under the current conditions of use, and no further mitigations are proposed for the protection of squash bees.

Neonicotinoids have become a controversial and emotive group of insecticides. Numerous publications and reports exist, which raise questions about a variety of sublethal and other adverse effects upon bees, other pollinators, etc. In many cases, these studies are conducted under laboratory conditions and highlight a potential risk, although the potential effects are rarely demonstrated under realistic field conditions when products are used according to the label directions. The regulatory authorities assess many of these studies on their scientific merits in addition to studies provided by Bayer (and other registrants). This holistic approach, conducted on a regular basis by authorities, independent of each other, is the best way to determine the levels of risk associated with different use patterns and to require appropriate risk mitigation or to restrict uses that are considered to pose an unacceptable risk.

Bayer respects the importance of the precautionary principle to protect the public and the environment and adheres to measures introduced by authorities around the world,

as they apply the precautionary principle to local pesticides legislation. The interpretation and implementation of the precautionary principle varies from jurisdiction to jurisdiction.

The 2008 incident in Germany directed attention towards the risks that could arise from seeds treated with certain coating techniques (e.g., film coating in maize), where small quantities of insecticidal dust from the coating might be abraded. Those may be emitted to the environment during drilling, in particular when vacuum-pneumatic drilling machines are used. Appendix I is the risk management approach that Bayer presented to an International Congress and was published in 2009. Appendix II provides some details of the measures that have been developed and are being adopted.

These are summarized in the following section:

A. Mitigating Risks Associated with Seed Treatment – SeedGrowth Stewardship

A.1. Measures to Address Risk From Dust

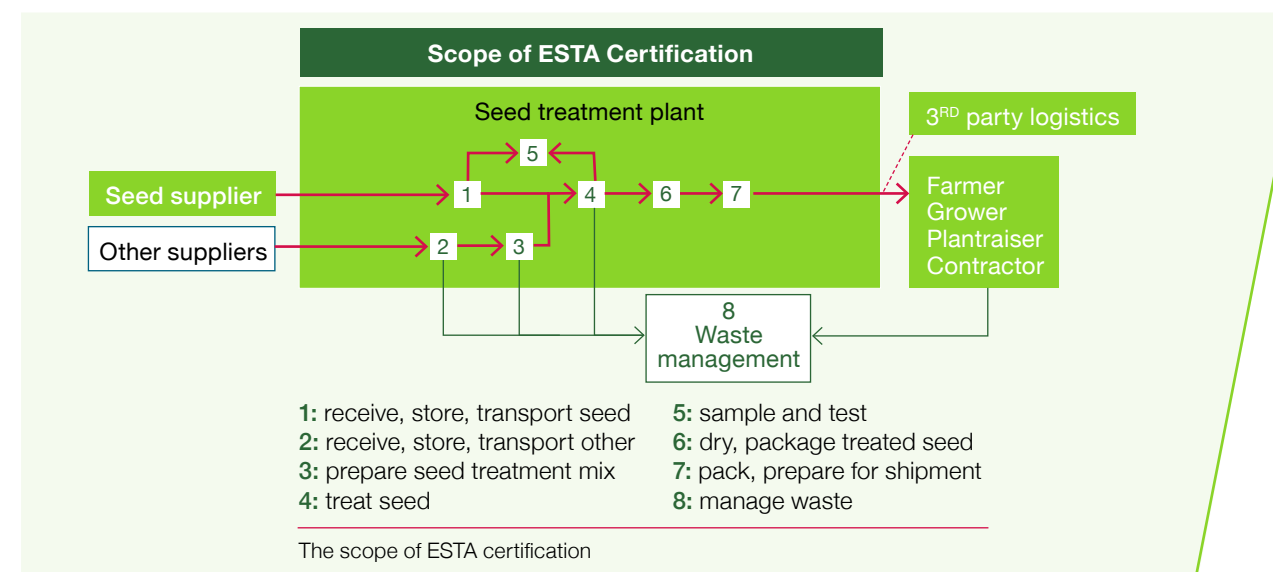
Initially, the critical areas of concern were identified, and measures continue to be implemented around the world to ensure safe seed treatment applications of neonicotinoids. The main measures are:

- // Film coatings – Improving the quality of the seed coating and minimizing abrasion via the use of film coatings and addition of a [fluency agent](#).⁷
- // Quality assurance – measuring and analyzing dust using the [Heubach abrasion test](#).⁸
- // Deflector technologies – deflectors attached to pneumatic sowing equipment ensure that at least 90% of the dust particles released from the seeder are directed onto the soil and not into the air. Further reducing dust emissions in this way minimizes the potential risk of exposure for watercourses and pollinators, like honeybees.

A.2. Certification Schemes

Initially, efforts were made to encourage 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 in the market and follows a strict [governance process](#).⁹



This certification scheme was then used as a reference to promote similar practices elsewhere. As one result, CropLife Canada, of which Bayer is a member, introduced the “[accredited seed treatment operation standards](#).”¹⁰ And very recently, Julius Kuehn-Institut, 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.

A.3. Training

Over the years, a series of Best Management Practices (BMP) were developed and implemented, 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 seed treatment and handling, including labelling of treated seed “BagTag.” As a result of the COVID-19 pandemic, the trainings are in the process of being adapted to hybrid (mix of in-person and virtual) formats.

A.4. Implementation 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 country groups: West and Central Europe (France, Germany, UK, Poland, Belgium and Italy), East Europe and Africa (Russia, Ukraine, South Africa, Turkey, Hungary and Romania), North America (U.S., Canada), Latin America (Brazil, Argentina and Mexico) and Asia-Pacific (Peoples Republic of China, India, Australia and New Zealand). Stewardship measures are described, and their uptake by growers and those who treat the seed are addressed, as well as the establishment of partnerships. In some cases, Bayer has championed the mandatory requirement for the use of seed coatings to help avoid drift of contaminated dust, while in others, the use of mechanical means, such as deflector shields, have been introduced to further mitigate the risk of dust drifting off-target.

Bayer is not acting alone and has established partnerships with other seed companies, notably a [5-point action plan \(5PAP\)](#) with Syngenta,¹¹ as well as implementation of SeedGrowth stewardship measures with generic suppliers (e.g., Makhteshim Agan India, Nufarm).

In **West and Central Europe**, mandatory certification schemes were announced in 2015, and training modules developed in 2016, aimed at sugar beet and oil seed 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, 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**, although a specific BMP training was developed for potato seed treatment. The ESTA certification scheme was introduced outside the EU, in Ukraine and Turkey from 2015-2017, in parallel with the rollout of the 5PAP with Syngenta. 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 the other countries.

In **North America, the U.S. and Canada** are major markets for neonicotinoid-treated seed and were an early target of mitigation and stewardship activities. During 2016, a program of dust collection and analysis was completed for corn, soy, cotton, oil seed rape (canola) and cereals to determine the scale of the dust problem. A guidance for BPM was developed for small seed treatment operations to clean wastewater from the

treatment facilities. The U.S. states with commercial seed treatment facilities all require certification while the Canadian authorities have partnered with CropLife Canada to introduce a similar scheme. A fluency agent has been introduced to reduce abrasion and dust generation.


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 upon the ESTA model, and launched it towards the end of 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, use of film coatings was ensured and mandated. Despite the COVID-19 pandemic, the Bayer Brazilian SeedGrowth Center was able to provide frequent, best-in-class trainings to seed treating customers.

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 the larger growers provided by the Bayer local SeedGrowth Center. More work is needed in India where the seed treatment market is highly fragmented and to a large extent, small holder driven. In this context, a training video focusing on stewardship measures with the ultimate objective to protect operators and the environment is currently being rolled out to bring these messages across broadly and thereby reaching out to as many farmers as possible.


B. Mitigating Risks Associated with Spray Application

B.1. Labelling

As a general best practice principle, applications of 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.



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 and use reductions – systematic and explicit exclusion of flowering application of imidacloprid products onto bee-attractive crops or close to beehives. Appendix III provides an example of such a label for the product Admire PRO, the Imidacloprid SC550 formulation in the USA.

// Bayer follows the [FAO Guidelines on Good Labelling Practice for Pesticides](#)¹² and the GHS for the classification and labelling 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.

In compliance with [FAO's Code of Conduct on Pesticide Management](#)¹³ and fulfilling our stated sustainability commitments, Bayer reached more than 2.7 million external contacts (i.e., farmers, field workers, distributors, retailers and other stakeholders in the agriculture industry) around the world in 2021, focusing on training activities in countries where there are no statutory certification requirements for farmers concerning the safe handling of crop protection products. Bayer also organizes safety training for our own employees and contract workers from outside companies, in particular, for sales force [employees](#).¹⁴

The industry association CropLife International developed an icon for pollinator safety, which will be presumably approved by the FAO. Once that new icon is released, Bayer will include it on related product labels.



(Draft submitted to the FAO)

B.2. Training

As part of Bayer's Safe Use Ambassador Program launched in 2017, we entered into partnerships with Asian universities and offer students annual training in the safe use of crop protection products with a focus on safety for users and the environment. The goal is for the students to share their knowledge with farmers during internships on farms. In 2021, Bayer organized four workshops related to the safe handling of crop protection products for more than 1,200 students, faculty members of universities and other relevant stakeholders in 14 countries, especially in Asia and Africa.

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.

C. Pollinator Research

Beyond ensuring the pollinator safety of our products by cutting-edge research, Bayer has since been partnering for many years with leading research institutes and universities in a broad variety of scientific projects and initiatives to foster bee health and pollinator safety in [agriculture](#).¹⁵ Over a period of 10 years, Bayer engaged in more than 50 research collaborations on all continents, including large-scale bee health programs in [North America](#)¹⁶ and [Latin America](#),¹⁷ and a long-term project in Europe to protect wild bees in the agricultural landscape. Appendix IV illustrates our international collaborations for pollinator research, and Appendix V is the 2020 report from the Salud Apícola collaborations.

D. 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.

A stepwise, sequential testing procedure is followed during the development of a new insecticide in order to characterize pollinator safety. When a product is of low intrinsic toxicity to bees, lower-tier tests (tier 1) may be sufficient to conclude that a product is safe (even under worst-case exposure conditions) and that higher-tier testing may not be required. In all other cases, tier 1 tests provide only an indication of a product's hazard potential, as they inherently do not consider agronomic, environmental and biological factors that minimize risk and exposure relative to the worst-case possibility. Taken in isolation, decisions based on such lower-tier tests could unnecessarily eliminate useful crop protection products from the market without bringing any real benefit in terms of improved safety to bees. Higher-tiered studies refine baseline assumptions of tier 1 studies by incorporating additional factors that potentially reduce bee risk, elucidating mechanisms underlying observations in tier 1 studies in order to better inform relevance in the environment or characterizing potential effects at levels of biological organization that are more closely aligned with protection goals. These higher-tier studies are more complex and are not always necessary in cases where low hazard is identified in tier 1 studies. The totality of tier 1 and higher-tier data 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 bees and other non-target organisms.

Novel compound development processes at Bayer now include various tier 1 and higher-tier test designs to characterize the toxicity to bees at a much earlier stage of the early development process in order 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 risk to bees. Broader efforts include collaborative research between 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.

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, U.S. 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 U.S. that can be attributed to exposure following a legal application of imidacloprid, despite its widespread use in agriculture. Annual monitoring reports confirm that the number of harmful incidents remains rather low in European countries, such as the UK and Germany (Jones, 2016, Appendix VI; Thompson & Thorbahn, 2009, Appendix VII).

Bayer has developed its own internal adverse incident reporting system, CAIRnew, and has been using it 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. Bayer uses the information entered into CAIRnew to qualitatively calibrate its risk management based on early awareness of cases/hotspots and takes follow-up actions. In addition to CAIRnew, Bayer would appreciate a more systematic official management process of data collection, regarding human and environmental safety, so we can better interpret risk management processes.

// Address reported incidents in a comprehensive and timely manner.

// Implement measures to reduce the likelihood of recurrence.

// Report them to corporate leadership as required by internal Bayer standards. Further details are available in the [Bayer Product Stewardship](#) brochure.¹⁸

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 or suboptimal application of mitigation measures, to be unfounded or due to some reason other than the effects of neonicotinoid use, there is no further action from the authorities that involves Bayer.

4. Transparent Engagement

A. Trust and Transparency

In recent years, we have intensified the dialogue with critical stakeholders, and it is our shared objective to make crop protection safer for farmworkers and consumers and to minimize any risk of adverse effects on the environment. By enabling access to our safety studies in the context of our Transparency program, we embarked on a path to increase societal and public understanding of the science of evaluating risk. With transparency and willingness to engage in continually evolving safety standards, we want to help build trust in the regulatory system for the approval of pesticides.

As a leading life-science company, we recognize our responsibility to communicate how we assess our products' safety. With our Transparency initiative launched in 2017, Bayer has taken a pioneering role in breaking down barriers to science. The initiative provides access to safety-relevant information about [Bayer's crop protection products](#).¹⁹

We fully support efforts to improve transparency around crop protection safety studies – and we have signed the [transparency commitment made by the global crop protection industry](#).²⁰

By sharing what was once mostly available to authorities, we want to show the scientific rigor that's involved in evaluating the safety of our products and hope to connect the public with our scientific community and foster a fair, science-based dialogue. Through a specially designed [website](#),²¹ visitors can consult summarized test results and evaluations; these give information on the human and environmental safety of active substances. We have also enabled access to the full study reports (limited to non-commercial users) on which the summaries are based. Moreover, the website offers videos, infographics and other communication materials to help put regulatory science into context. For substances submitted by a task force or containing other data not fully owned by Bayer, we have to analyze potential contractual restrictions imposed on us, requiring us to respect third-party rights.

The EFSA assessment reports of our active substances are publicly available on the EFSA website. Similarly, the EU Commission makes its Pesticides Database available to the public and information about specific substances, the latest assessments, approval status, etc., may be accessed [here](#).²²



B. Product Safety

Bayer's commitment to product safety goes beyond just meeting local regulatory requirements. In 2012, we stopped selling any World Health Organization (WHO) acute class 1 pesticides, regardless of regulatory approval status. Additionally, since 2016, we have committed to only sell products with active ingredients that have a registration for use in at least one Organization for Economic Co-operation and Development (OECD) country or for new active ingredients with a complete OECD safety data package.

We work to continuously incorporate new scientific knowledge in our risk assessments. All new products are evaluated against our latest Bayer safety standards, leading to improvement of our product portfolio. For our assessment, we apply criteria that reflect the standards of reference authorities who represent different agronomic realities and whose programs for regulating pesticides are, in general, well-developed. These include the regulatory authorities in the U.S., Canada, Brazil, EU, Australia, New Zealand, Japan and China. We will continue to enhance this approach. We will, at the same time, constantly review our current portfolio and make timely decisions wherever needed.

C. 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 and can adversely affect our reputation. 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.

We seek common ground with critical stakeholders, listen carefully to diverse points of view and engage in thoughtful dialogue. This requires that all engagements and communications be truthful and transparent. We also respect the independence of journalists and media representatives. This means that we engage openly and transparently with journalists and media representatives and provide accurate information. This also includes engagements in open discussions or panel discussions, as we try to maintain a dialogue on science with critical stakeholders.

D. Engagement with Customers

We maintain regular dialogue with our customers to advise of forthcoming developments, whether these be new products, label changes, training opportunities or measures to prepare for the consequences of regulatory restrictions.

A recent example followed the decision to withdraw imidacloprid from the EU renewal process for plant protection products. Customers (farmers and growers) outside the EU were alerted and advised of the timeline and implications since Bayer anticipated that the withdrawal would then be followed by action to amend existing maximum residue levels (MRLs) and potentially reduce them to the limit of quantification. In countries where imidacloprid could still be used, it was important to ensure that any food or feed that would be exported to the EU, in the future, would respect the anticipated maximum permitted residue levels. A series of trials were arranged to confirm use patterns of imidacloprid products that would result in zero, or undetectable, residue levels, while maintaining efficacy. In cases where these criteria could not be met, alternative products (potentially from competitors) were recommended.

E. Emergency Uses

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 use of a 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.

Bayer believes that the EU Member States need access to the emergency option provided the conditions laid out in Article 53 are met. Bayer 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 fuller description of the emergency procedure, are available [here](#).²³

Since early 2020, the European Commission's [Emergency Authorizations database](#)²⁴ has been publicly available and includes all the emergency approvals notified to the Commission by Member States.

Currently, 21 EU Member States have approved at least one emergency use of a neonicotinoid. This demonstrates that continued access to these neonicotinoids is beneficial to EU farmers and endorsed by their governments.

France changed its national law in 2016 to prohibit any use of neonicotinoids, even via the emergency route. However, following seasons with substantial damage to sugar beet yields due to beet yellows virus, transmitted by aphids, after public consultations and exchanges between 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 have been granted again for the 2022 season.

Given the controversial nature of continued uses of these neonicotinoids via the emergency use provisions included in the EU pesticide legislation (Regulation (EC) No 1107/2009), the European Commission mandated EFSA to assess the justification of 17 emergency approvals granted by 11 Member States since January 2020. All the granted emergency approvals allowed uses that protect sugar beet from beet yellows viruses transmitted by aphids. In their [reports](#)²⁵ (one per Member State) published on November 18, 2021, EFSA concluded that, in all cases, the emergency approvals were justified and granted in accordance with the conditions of the regulation. This demonstrates that, in specific cases, continued access to these neonicotinoids is beneficial to EU farmers and endorsed by their governments. Bayer only supplies products in cases where local growers identify the agronomic need, the justification is consistent with the terms of the Regulation and seed treatment occurs at ESTA-certified sites.



5. 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 2021 [Bayer Sustainability Report](#)²⁶ contains the most up-to-date information on a wide range of safe use initiatives.

Bayer has committed to collaborate with farmers to reduce the environmental footprint of agriculture. Bayer aims to reduce the field greenhouse gas emissions – per kilogram of crops produced in major agricultural markets – and the environmental impact of crop protection by 30% by 2030 in each case. To this end, Bayer will help farmers apply more sustainable practices, such as reducing tillage to help sequester carbon in the soil, and ensuring the more precise use of crop protection and fertilizer through product innovation and digital tools.

New technologies not only enable crop production to be increased, but also promote the safe and responsible use of crop protection products. This includes the targeted application of crop protection products using data from satellites and drones. In 2019, Crop Science continued its strategic partnership with Chinese drone producer XAG for the use of this technology in farming, including for the targeted treatment of field crops. Furthermore, sensors on the latest tractors and harvesters can supply important information on soil conditions and plant health. This data is incorporated into the digital applications developed by the digital farming business of Crop Science – The Climate Corporation – to help farmers achieve more efficient and sustainable agricultural operations.

Our digital farming platform FieldView™ enables seamless linking and unlimited storage of machine-generated agronomic data on farmers' accounts. The application of this data not only helps farmers but also creates substantial advantages for the environment. Precision agricultural machinery and digital tools enable farmers to use inputs, such as seeds, water, fertilizer and crop protection products, only when and where they are necessary. FieldView is currently available in North America, Latin America and EMEA.

To meet increasing demands for environmental protection and occupational safety more effectively, Bayer engaged in the development of closed transfer systems. In a move consistent with the CropLife Europe commitment to making closed transfer systems universally available to European farmers and operators by 2030, Bayer has joined the cross-industry group developing the “easyconnect” closed transfer system. The system aims to provide a compelling solution that is fast, safe and convenient for farmers and operators across Europe. At the same time, Bayer will continue to support implementation of closed transfer systems via commercially available solutions, such as the jointly developed “easyFlow” system from agrotop GmbH. This closed, contamination-preventing discharge system for liquid crop protection products enables full or partial discharge and is fully self-cleaning. The system is already being used in practice for small-scale spraying of fruit and vegetables. A new variant for use in field crops was introduced to the market with Bayer's support.

For water protection against contamination through plant protection products in agricultural areas, Crop Science recommends the use of biological remediation systems, such as Phytobac™. This system is designed to prevent water contamination with residues of crop protection chemicals generated during the filling and cleaning of spraying devices or the disposal of residual liquids. The system is used in many EU countries and is offered commercially by various suppliers. More than 5,000 remediation systems are currently in operation in Europe. Promotion has been implemented in Australia, Canada, China, Thailand, Argentina, Brazil and Colombia. Together with external partners, we are developing a digital geoinformation system for agriculture in order to protect neighboring water bodies from contamination with crop protection products. Site-related risks are visualized by means of high-resolution maps supplemented with risk mitigation proposals.

6. 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 needs 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 who wishes to examine the studies that support our registrations.

We issue an extensive report 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 Europe, is responsible, beneficial and entirely consistent with the UN Global Compact environmental principles.



7. Appendices

- 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
- IV: Poster demonstrating the global nature of collaborative bee research
- V: Annual Report (2021) Healthy Hives LATAM / Salud Apícola
- VI: Monitoring bee poisoning incidents in the UK (2016)
- VII: Monitoring bee poisoning incidents in the EU (2009)

Endnotes

1. <https://www.efsa.europa.eu/en/news/neonicotinoids-efsa-assesses-emergency-uses-sugar-beet-202021>
2. <https://www.bayer.com/sites/default/files/2022-03/Bayer-Sustainability-Report-2021.pdf>
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