Neonicotinoid Insecticides @ Bayer

Systematic Risk Mitigation & Portfolio Evolution Towards Minimized Risk for the Environment
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. 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. As the pioneer of neonicotinoid research, Bayer gained significant market share of up to 85% in 1996 with the launch of imidacloprid. Bayer 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 neonicotinoid solutions.

Some years after the introduction, there were some 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 introduction of the Heubach test, which enables the measurement dust abrasion of the treated seeds.
- Innovation in seed coatings to improve adhesion; seed coatings protect operators and beneficial insects 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 BayStep 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

- 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 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.
// Ongoing label revisions and use reductions – systematic and explicit exclusion of flowering application of imidacloprid products onto bee-attractive crops or close to beehives.
// 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.
// In the last 10 years, Bayer has been 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 Apicola are multi-year 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 identify and remove unfavorable chemistry from the research phase.

Adverse Incident Reporting
Bayer has used an adverse incident reporting system for many years. It records the reported incidents and the follow-up actions. The latest version, CAInew, includes just seven imidacloprid-related incidents, globally, concerning bees or other non-targets, since 2008. Many countries also have such systems and, where these are publicly accessible, Bayer monitors any bee-related incidents.

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 Code of Conduct on Pesticide Management, and our own commitments to sustainability, Bayer trained more than 1.7 million farmers around the world in 2020, focusing on training activities in countries where there are no statutory protection requirements or certification for users regarding the safe handling of crop protection products.
// In 18 EU Member States, emergency approvals of neonicotinoid seed treatments have been granted, since 2016, which 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, each year, on sustainability at Bayer. Our commitments to sustainability are in the public domain so we can be held to account. 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 mid-90s with thiametoxam and clothianidin following a few years later. Cumulative Global Market sales of neonicotinoids reached 1 billion euros around 10 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 2020, ~3% of our global Crop Science sales were recorded with the neonicotinoid products imidacloprid, clothianidin 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 hundreds of 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-targets 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.
2. Measures Taken to Address Areas of Concern

Regulatory reviews of neonicotinoids occur on a regular basis around the world. These 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. These regulations are all underpinned by the precautionary principle. At present (March 2021), decisions are expected in the U.S., Canada, Brazil, Argentina and India before the end of the year, with reviews ongoing in China, New Zealand, Australia, and Chile, and scheduled in 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, indeed, the European Food Safety Authority, EFSA, in the EU) as not presenting significant risks to man or the environment when used as directed.

The most recent regulatory decision was published on March 31, 2021, by the Pest Management Regulatory Agency (PMRA) in Canada. In August 2018, the PMRA had proposed cancellation of all agricultural uses for clothianidin and thiametoxam 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, is available here.

Neonicotinoids have become a controversial and emotive group of insecticides. Numerous publications and reports exist, which raise questions about a variety of “adverse or sub-lethal effects” upon bees, other pollinators, etc. In some 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 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:

- Improving the quality of the seed coating and minimizing abrasion via the use of film coatings and addition of a fluency agent: https://www.cropscience.bayer.us/seedgrowth/fluency-agent-advanced.
- 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. Key technologies developed include AirWasher and SweepAir: https://www.seedgrowth.bayer.com/explore/stewardship/sweepair.

A.2. Certification schemes

Initially, efforts were to encourage adoption of the European Seed Treatment Association (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. https://www.euroseeds.eu/esta-the-european-seed-treatment-assurance-industry-scheme/

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.” https://awsa.ca/accredited-seed-treatment-operation-standards/
A.3. Training
A series of Best Management Practices (BMP) have been developed and implemented, including a range of training courses, arranged in collaboration with local authorities, implementation of “zero-dust” in-field solutions and development and communication of guidelines for seed treatment and handling, including labeling of treated seed “BagTag” (https://e-bagtag.com/home). Wherever possible, we aim to supply our products to trained professionals, only. https://www.seedgrowth.bayer.com/explore/stewardship

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, Mexico) and Asia-Pacific (Peoples Republic of China, India, Australia, 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 (SPAP) (https://www.seedgrowth.bayer.com/explore/stewardship/five-point%20action%20plan%20for%20bees%20health) with Syngenta, and as well as implementation of SeedGrowth stewardship measures with generic suppliers (e.g., Makhteshim Agam India, Nutar). In West and Central Europe, mandatory certification schemes were announced in 2015, 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 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 SPAP with Syngenta. The second wave of dust deflector distribution moved to Hungary in 2015-2016. Stewardship activities, partnering with international and local partners, including a survey of sowing machinery. Dust monitoring measurements in China, there have been some advances, including training programs for the larger growers. However, more work is needed in China and India.

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.

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. Bayer follows the FAO Guidelines on Good Labelling Practice for Pesticides (http://www.fao.org/fileadmin/templates/ghome/documents/Pests_Pesticides/CodeOfGoodLabellingPrac.pdf) 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.
In compliance with FAO’s Code of Conduct on Pesticide Management, and fulfilling our stated sustainability commitments, Bayer trained more than 1.7 million farmers around the world in 2020, focusing on training activities in countries where there are no statutory protection requirements or certification for users regarding the safe handling of crop protection products. Bayer also organizes safety training for its own employees and contract workers from outside companies, in particular for sales force employees. (https://www.cropscience.bayer.com/who-we-are/sustainable-agriculture/taking-product-responsibility)

B.2. Trainings

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 2019, Bayer trained students at 29 universities in seven Asian countries. In Africa, we support the CropLife Africa Middle East concept of Spray Service Providers (SSPs) who are trained and certified for applying crop protection products safely. The SSP concept was successfully introduced in 14 African countries so far with more than 12,000 SSPs.

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. (https://www.cropscience.bayer.com/people-planet/biodiversity/bee-health), In the last 10 years, Bayer has been engaged in more than 50 research collaborations on all continents, including large-scale bee health programs in North America (https://www.cropscience.bayer.com/people-planet/biodiversity/a/healthy-hives-2020-research) and Latin America (https://www.cropscience.bayer.com/people-planet/biodiversity/bee-health-hives-latin-america), 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 is not required. In all other cases, tier 1 tests provide only an indication of a product’s hazard potential. When potential risk exposure relative to the worst-case possibility, is determined, 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-tier 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 animals.

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 screening process in order to identify and remove unfavorable chemistry from early research phases. Bayer’s efforts to provide growers with critical tools that are compatible with relevant pollinators for the crop continues 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 in order to better inform Bayer compound development prioritization and risk evaluations of uses.
3. Adverse Incidents

Crop protection neonicotinoid products have been used by farmers around the world for over 20 years. During that time, routine incident monitoring reports have documented relatively few instances of harmful pesticide-pollinator interactions. In their 2018 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 low, with further decreasing trends, in European countries, such as the UK and Germany. Jones, 2016, Appendix VI; Thompson & Thorton, 2009, Appendix VI, as well.

Bayer has a system for recording and responding to adverse incidents, “CAIRnew.” Should an incident occur, the country/country cluster organization is required to: assess all reported accidental or intentional exposures in which Bayer products and services may be implicated and if they are found to have been involved, and as appropriate, complete an incident report in accordance with internal Bayer standards.

// 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.

In the latest annual report (March 2020 report on incidents in 2019), under the category “Safety-Toxicity,” external incidents are included under the following topics:

- Bees / Non-Target Arthropods (e.g., other pollinators); Domestic Animals (livestock and pets);
- Environmental/Water/Soil/Air; Environment/Wildlife; Human; Premises; Unauthorized Residues; and Other.

In 2019, 66 countries reported 5,158 cases in total of which 815 were external incidents (no emergencies, suspected to cause the death of bees).

Further details are available in the Bayer Product Stewardship Brochure.

Since the 2006 incident in Germany, our records include just seven imidacloprid-related adverse incidents, globally, concerning bees or other non-targets, or wildlife since 2006 for a range of products that are used in the 60+ countries that enter records into CAIRnew. Five cases in CAIRnew are from the U.S., and one each from France and Uruguay:

- 2006 Uruguay: Pironil and Imidacloprid suspected to cause the death of bees.
- 2006 U.S.: Livestock honey bee exposed to Imidacloprid/Gaucho, residual concentrations in honey and wax.
- 2010 U.S.: A few hours after Trimax (imidacloprid) application to cotton fields, neighbour reported bee deaths (4-6 hives).
- 2010 France: Reports of dead birds (partridges, pigeons) with treated seeds in gizzard.
- 2010 France: Reports of dead birds (partridges, pigeons) with treated seeds in gizzard.
- 2013 U.S.: Report of decline in bee health (>100 hives) near a citrus production area. Exposure allegedly through misapplication of imidacloprid product.
- 2013 U.S.: Applicator was spraying leverage 360 (beta-cyfluthrin + imidacloprid) on soybean field for farmer customer. Adjacent neighbour has 11 honey bee hives affected. Colonies remained active.
- 2014 U.S.: Allegation of bee deaths by beekeeper following applications of Admire Pro (imidacloprid) in immediate vicinity and surrounding groves.

These products are under particular scrutiny due to widely publicised claims about the harm they can do to pollinators. We are aware that many more 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 misuse, or to be unfounded, or due to some reason other than the effects of imidacloprid 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 farm workers, 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 in 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 (https://www.cropscience.bayer.com/transparency-crop-science).

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 (https://croplifeeurope.eu/commitments/industry-data-transparency/).

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, visitors can consult summarized test results and evaluations; these give information on the human and environmental safety of active substances used in products currently sold in the European Union. 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: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances?event=as.details&sas_id=1186.

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 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 a constant 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 take timely decisions wherever needed.

C. Engagement with critical stakeholders

We seek common ground with critical stakeholders and 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.

Sometimes a scientific article makes claims, or provides new information that merits a response, or further enquiries, or may be the origin of a media report where journalists approach Bayer for comment. They have often raised their concerns about different active ingredients or other neonicotinoids and their potential of harming pollinators or other organisms. Neonicotinoids are intensively studied with hundreds of scientific papers and media articles published every year. Many of them repeat broad claims without additional substantiation. Although we cannot provide comprehensive responses to all of these, we try to engage in a scientific and constructive dialogue whenever we can. Our scientists assess new studies and reports and their methodologies, thoroughly, on their scientific merit, and we aim to provide science-based answers to the questions they raise.

D. Engagement with customers

We maintain a 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 was 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 on the Bayer transparency site: https://www.cropsience.bayer.com/who-we-are/transparency/emergency-authorizations

Since early in 2020, the European Commission’s Emergency Authorizations database has been publicly available and includes all the emergency approvals notified to the Commission by Member States: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home

Currently, 18 EU Member States, have approved at least one emergency use of a restricted 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 the neonicotinoids, even via the emergency route. However, following seasons with substantial damage to sugar beet yields due to beet yellow virus, transmitted by aphids, after public consultations, 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 Feb. 5, 2021.
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.

Appendix VIII describes Bayer’s stewardship objectives, commitments, activities and partnerships.


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, South America and Europe.

To meet increasing demands for environmental protection and occupational health and safety more effectively, Crop Science has developed the easyflow system together with agrotech 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 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 filing and cleaning of spraying devices or the disposal of residual liquids. The system is used in many EU countries and offered commercially by various suppliers. More than 4,600 remediation systems are currently in operation in Europe. Projects to introduce the system have also been implemented in Australia, Canada, China, Thailand and Latin America (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.