June 2026

Responsible R&D in Crop Protection:

Advancing Innovation for Agriculture and Society

Executive Summary

Development of Crop Protection Products at Bayer

Global food systems are under increasing pressure. Geopolitical instability, climate change and water scarcity threaten agricultural productivity and food security for a rapidly expanding global population. Farmers work to meet the demand for food, feed and biofuels while fighting weeds, pests and diseases that are becoming resistant to existing crop protection products. At the same time, societal expectations for how food is produced are evolving rapidly, with heightened scrutiny of agricultural inputs and a growing need for solutions that safeguard human health and the environment while maintaining productivity.

Against this backdrop, Bayer is transforming how crop protection products are discovered, designed, developed, evaluated and stewarded. This report explains how Bayer's innovation process has evolved in recent years to deliver more precise and effective solutions with new modes of action and improved safety profiles for humans and the environment. It also illustrates how safety, sustainability and transparency are embedded throughout the full life cycle of Bayer's crop protection portfolio, from early discovery through commercialization and beyond.

Designing for Safety, Sustainability and Registrability

Bayer's approach to crop protection innovation is grounded in a clear objective: enabling farmers to grow more with fewer, better inputs. To achieve this, we offer a diversified toolbox that spans synthetic chemistry, biological solutions, biotechnology, formulation science and digital farming tools, enabling integrated solutions tailored to regional agronomic realities. Our innovation is focused on developing crop protection products that provide new modes of action to address resistance issues.

Central to this transformation is a fundamental shift in research and development. Today, Bayer applies advances in data science, artificial intelligence, computational chemistry and systems biology to design molecules with defined performance and safety attributes from the outset.

Through its next-generation CropKey discovery platform, Bayer is advancing target-based discovery focused on highly selective modes of action against agronomically important challenges. By identifying and precisely targeting proteins essential to insect pests, weeds or plant diseases, CropKey creates specific mechanisms for targeting these proteins while reducing impacts on humans and the environment.

A defining feature of Bayer's modern crop protection Research and Development process is profile-based design. New products are designed and optimized towards meeting defined criteria across efficacy, human and environmental safety, regulatory acceptance and sustainability parameters. These criteria are applied early and consistently throughout R&D.

Extending CropKey into product development formulation design plays a critical role in this transformation. Modern formulations are designed with a profile to reduce exposure risks, lower use rates and enable compatibility with emerging application technologies, such as precision sprayers and drones. Bayer is also increasingly shifting toward fully biodegradable formulation components.

Rigorous, Science-Based Safety Evaluation

Safety is the foundation of Bayer's crop protection product development. Before any product reaches the market, it must meet stringent regulatory requirements and Bayer's own voluntary internal safety standards, aligned with internationally recognized, science-based frameworks.

Bayer applies a risk-based approach to safety assessment, recognizing that risk is a function of both hazard and exposure. Extensive toxicological and environmental studies are conducted under Good Laboratory Practice conditions to characterize potential risks to operators, consumers and non-target organisms.

Stewardship, Sustainability Targets and Transparency

Responsible product stewardship is embedded across the entire life cycle of Bayer's crop protection products – from research and development through commercialization and eventual discontinuation. Guided by the Food and Agriculture Organization-World Health Organization (FAO-WHO) Code of Conduct on Pesticide Management, Bayer applies stewardship measures that support safe and effective use, including robust product labelling, quality management systems, safe use training, container management programs, resistance management and ongoing monitoring of product performance and incidents in real-world conditions.

Complementing product-level stewardship, Bayer has adopted a portfolio-wide, science-based approach to reducing environmental impact and set a sustainability target. Through our Crop Protection Environmental Impact Reduction (CP EIR) target, we aim to reduce the treated-area-weighted environmental impact per hectare of our global crop protection portfolio by 30% by 2030, compared with a 2014–2018 baseline. This target integrates product characteristics, application practices and emissions, and reflects Bayer's commitment to continuous improvement through innovation, portfolio evolution and responsible use.

Transparency and strong governance underpin these efforts. Bayer is expanding access to information on regulatory assessments and scientific research through publicly available study summaries, data-sharing initiatives, open laboratory programs and disclosures of scientific collaborations. Clear governance structures ensure that sustainability, safety and stewardship considerations are embedded in decision-making at all stages of product development and portfolio management, supported by internal oversight and external advisory input.

Conclusion

Crop protection remains essential to global food security, yet its continued role depends on trust, transparency and credible science. By adopting the latest advances in data science to transform how crop protection products are discovered, designed, evaluated and stewarded, Bayer is advancing solutions that are more precise, effective and aligned with evolving societal expectations. Through rigorous safety standards, life cycle stewardship, measurable environmental impact reduction and enhanced transparency, we are reshaping crop protection innovation to support sustainable agriculture in a changing world.

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1. Introduction

Plant diseases and pests destroy up to 40% of global crops each year, according to the FAO. These losses amount to an estimated $220 billion in annual economic damage from plant diseases, with invasive insects adding at least $70 billion more.[1] In addition, FAO estimates that weeds reduce agricultural output by 5–10% in developed economies and up to 20–30% in developing countries.[2]

It takes a diverse portfolio of agricultural tools to address these threats to our food supply, and Bayer has been a leader in supporting farmers with solutions spanning seeds and traits, crop protection and digital technologies, underpinned by a robust R&D function.3 Farmers have relied on our chemical and biological crop protection products (i.e., pesticides) for decades. Because pesticides are designed to control weeds, pests or plant diseases, it is essential to ensure that these products have no harmful effect on human health and no unacceptable effect on the environment. This report shows how we achieve that through stringent risk assessment, a transformed discovery process, rigorous governance, internal safety standards, regulatory compliance and stewardship throughout the entire product cycle. Recognizing increased stakeholder interest, consistent with our commitment to transparency and engagement, this report illustrates how Bayer's crop protection product development is guided by safety, economic and sustainability criteria.

2. Evolution of the R&D Process at Bayer

Bayer is reshaping crop protection innovation through one of the most advanced and best funded R&D platforms in agriculture. By integrating advances in crop protection technology, data analytics, artificial intelligence, and computational sciences, Bayer has transformed the discovery and development of new solutions. These capabilities allow researchers to process vast datasets at high speed to design crop protection molecules engineered to be highly target-specific, aiming for improved precision, safety and efficacy and minimal environmental footprint.

Target-Based Discovery Focusing on New and Selective Modes of Action

In the recent past, our crop protection R&D efforts focused, in large part, on incremental improvements to existing modes of action (MoAs) – essentially creating improved versions of current chemistry.
Today, our innovation strategy has shifted to target-based discovery. At the center of this strategy is

What is Mode of Action in Crop Protection Chemicals?

Mode of action (MoA) defines how a precisely designed active ingredient binds to a critical molecular target in the pest or weed, selectively switching off essential functions. This precise interaction initiates a cascade of effects that ultimately controls the harmful organism. Learn more here.

CropKey, Bayer's next-generation discovery platform. CropKey focuses on identifying and selectively targeting proteins that are essential to weeds, insects or plant diseases, creating highly specific interactions that disrupt these proteins while minimizing impacts on crops, humans and the environment.

In parallel, we have redefined our discovery engine toward a target-centric active ingredient search, enabling the rapid identification of molecules against well-defined protein targets. This is complemented by AI-augmented, multi-dimensional insight generation, integrating advanced automation in biological screening with digital phenotyping to uncover high-value starting points with greater speed and confidence.

The first outcomes of our CropKey approach are being brought from conception to reality, including a new herbicide molecule with the first new MoA in post-emergence weed control in 30 years, and a new fungicide molecule with a new MoA providing broad-spectrum control of leaf spot fungi.

CropKey extends to partnerships with key research organizations and academics to help us unlock the future of sustainable crop protection. In late 2022, we acquired German biotech startup Targenomix, whose innovative systems biology approaches will identify and select safe and sustainable active ingredients. We are also collaborating with research institution Rothamsted and industry partner Syngenta in the Pest Genomics Initiative, a project to sequence and assemble genomes of 20 of the world's most damaging crop pests. In 2025, Bayer entered into a partnership with the leading nonprofit artificial intelligence research consortium OpenFold to leverage its newly launched OpenFold3 open-source deep learning model that predicts three-dimensional structures of complex proteins and their interacting molecules with high accuracy. Bayer researchers are applying OpenFold3 to study proteins from plants, weeds and pests to accelerate the development of new crop protection molecules and traits.[4]

Profile-Based Design of New Molecules

After decades of discovery aimed at screening hundreds of thousands of candidates to find a promising existing molecule, we are now designing brand new molecules with extremely specific performance and safety profiles. Our priorities are new MoAs and new formulations and application systems, as well as ensuring that the candidates we design exceed today's early toxicology and environmental safety standards, address anticipated societal and regulatory standards, and include sustainability criteria from the beginning (e.g., persistence, mobility and bioaccumulation, as well as toxicity to non-target organisms in the environment).

Biologicals

Agricultural biologicals complement traditional crop protection tools as part of an integrated crop management system, using nature's own defenses to help safeguard plants against pests, improve yield and prevent disease. Agricultural biologicals encompass a wide range of product offerings that can be created from living organisms, derived from natural materials, contain them or use naturally occurring processes. In addition to crop protection products that use conventional synthetic molecules, biologicals (e.g., biopesticides, biostimulants) are important tools for crop protection or nutrition and encourage diversity in modern agricultural practices by providing a broad range of solutions to support farmers.

We are focused on the development of biologicals in two main categories: biocontrol (crop protection products) and biostimulants (crop nutrition products supporting plant processes, such as nitrogen fixation). In biocontrol, our immediate priority is to strengthen our portfolio for fruits and vegetables, followed by arable crops. With biostimulants, we are focusing on increasing our offering in nitrogen fixation seed treatment products, which will enable plants to get more nutrition from air or soil, leading to improved yield.

While the product development process for biologicals is different than that of synthetic crop protection products, the rigor with which the human and environmental safety of these products is evaluated is equally stringent. For biologicals, we have an open innovation approach, which attracts market-leading partners from different technology sectors. Through this approach, our external partners "plug in" their discoveries of promising biological candidates to our biological acceleration model, while Bayer provides resources for the development, registration and commercialization of these candidates. We are in a uniquely strong position because of our extensive global R&D and commercial infrastructure. Also, our expertise and experience across every aspect of agricultural inputs deliver effective integration of biologicals into fully tailored packages combining other technologies, practices and digital tools.

Formulations

Crop protection active ingredients – whether synthetic or biological – cannot be used on their own. They must be combined with other ingredients into finished formulations that allow very small amounts of active substance to be applied safely and evenly across fields or seeds. Formulation design uses different adjuvants (surfactants, emulsifying agents, solvents, stabilizers, defoamers, etc.) to ensure stability during storage, safe handling, efficient application and high product performance. It also ensures that products can be registered and produced at the lowest cost and best quality.

Formulation technology brings together multiple scientific disciplines to ensure products are delivered effectively to plants and target pests. Increasingly, companies are using data science and advanced analytics to move beyond trial-and-error development toward more efficient, model-based product design.

Several trends are accelerating innovation in formulations: advances in application technologies, rising grower expectations, the introduction of new active ingredients, including biologics, and increasingly stringent regulatory and sustainability requirements. Bayer is focusing on formulations that will work with both today's and future application systems, while aiming to lower the amount of active ingredient needed and reducing environmental impact. This aligns with Bayer's target for reducing the treated-area-weighted environmental impact per hectare of our global crop protection portfolio by 30% by 2030 against a 2014–2018 average baseline. Evolving application trends also are informing our innovation priorities. In parts of Asia, drones are rapidly replacing manual spraying, while larger farms elsewhere are driving demand for greater efficiency through lower spray volumes. As a result, we are testing existing crop protection products for precision and low-volume application systems – including Very-Low Volume (VLV)

applications by aerial systems, such as drones – and considering VLV features in the design of new formulations.

New formulations are now even more developed with a strong focus on safety and compliance with tightening regulatory requirements. One example of recent innovation is the shift away from long-lasting polymer-based microcapsules or polymeric seed coatings toward fully biodegradable alternatives, reducing environmental impact while maintaining performance. In response to European microplastics regulation, Bayer is implementing exclusive biodegradable encapsulation technologies and polymers for these important uses.

Open Innovation, Partnerships and Collaboration

To foster innovation and accelerate the development and delivery of sustainable crop protection products, we have adopted an “open innovation” approach to broaden our reach and gain new partnerships and collaborations that offer farmers more solutions in our portfolio. This approach helps broaden Bayer’s reach in innovation and allows us to expand beyond our core competencies and areas of expertise.

More specifically, we can leverage multiple partnership models adapted to Bayer’s needs and to the expectations of our partners. These are some examples that illustrate the diversity of these partnerships:

- Elemental Enzymes Ag and Turf, LLC: Use of soil microbes to improve plant health and crop efficiency, thereby increasing crop productivity
- Ginkgo Bioworks, Inc: Multi-year, strategic collaboration as the anchor partner of Ginkgo’s expanded agricultural biologicals platform, focusing on nitrogen fixation
- Grains Research and Development Corporation (GRDC): Partnership for the discovery and development of innovative weed management solutions (herbicides)
- Kimitec, Sociedad Limitada: Multi-year, strategic collaboration to deliver botanical products for agriculture
- American Autonomy, Inc.: Precision aerial pesticide applications via unmanned aerial vehicles (UAVs) with the added benefit of reducing soil compaction

3. Safety Evaluations

Safety Assessment of Crop Protection Products

Before any of our crop protection products reaches the market, they must meet stringent regulatory requirements of the respective countries. On top of that, we apply internal safety standards to ensure that the products are safe for humans – from operators to consumers – and cause no undue harm to the environment when used as directed. These standards are aligned with the most advanced science-based risk assessment frameworks developed by mature regulatory authorities around the world, including those in the U.S., EU, Canada, Brazil, Australia, New Zealand, Japan and China, as well as international organization guidelines from the FAO Code of Conduct on Pesticide Management, WHO and the Organization for Economic Cooperation and Development (OECD).

An essential part of our safety standard is having strong, reliable scientific data. Data requirements are developed and codified by national/regional authorities. The OECD with its member countries work to develop internationally harmonized test guidelines that can be used by OECD member countries (and others) to meet country-specific regulatory requirements. The data is reviewed by regulators to inform decisions on active ingredient approvals, product registrations, food residue limits and import tolerances. Using OECD standards ensures data quality and consistency across markets. We submit this data to regulators and commercialize only those crop protection products whose active ingredients are registered in at least one OECD country or a country with a mature risk-based regulatory framework.

The risk to people and the environment is not just a function of the products' hazard, but also of the level of exposure (e.g., pesticide application type, rate and timing, frequency, amount). To use an analogy, a shark in the water is a potential hazard. But, if you are standing safely ashore, there is no exposure to the hazard and, as a result, there is no risk. If you are in the water, you are directly exposed to the hazard – accordingly, there is a risk. Therefore, product toxicity does not equal risk.

Risk = Hazard x Exposure

While our safety standards follow a risk-based approach, we follow a hazard classification in our commitment to not market WHO Class 1 acute toxic formulations. All our products are classified according to WHO acute toxicity classes and are maintained in our internal electronic data processing (EDP) system, where established processes ensure that no product within the WHO Class 1 category can be marketed. We stopped selling these products in 2012 and have since also withdrawn the respective registrations across the globe, where possible.

We have processes in place to ensure adherence to the above commitments. All internal R&D and in-licensing projects are checked for these criteria and if they cannot be met, they are terminated.
For products on the market, our internal standards and commitment to product stewardship drive continued safety assessment to define label instructions for safe use to sustain registration.

Human Safety

Ensuring that our products can be used safely is our key priority. We conduct extensive tests to evaluate the safety of new active ingredients and pursue only those products that present no safety concerns for humans when used according to label instructions.

In addition to the regulatory requirements of countries where our products are registered, Bayer applies its own voluntary internal standard in geographies where pesticide regulations are still under development. If these risk assessments reveal an unacceptable risk, we implement mitigation measures to reduce exposure or voluntarily restrict product use to safe use scenarios.

For operator safety, we follow our published operator safety standard:
https://www.bayer.com/en/agriculture/information-about-operator-safety-standards

This standard includes application techniques that are uncommon in highly regulated countries such as Europe or the U.S. but are widespread in low- and middle-income countries (LMICs), such as different handheld application scenarios or small-scale treatment of seeds. For these scenarios, we have developed specific exposure models that consider actual use conditions and common practices, which are then applied for risk assessment of new products.

Bayer follows a risk-based approach by applying the following principles:

- Safety data collection: We conduct tests to understand the toxicity properties of our products to characterize their hazard and behavior in the body. In addition, we determine routes of exposure and how a substance can enter the human body (dermal/inhalation/oral absorption).
- Exposure and risk assessment principles: We conduct studies and gather information to understand local practices, equipment used, operator behavior and potential sources of exposure to our products during their application. The more data we can collect from actual field use, the more reliable our assessments of risk.
- Risk management activities: We drive enforceable risk mitigation measures for local use practices and implement risk management measures (e.g., personal protective equipment (PPE), use restrictions on labels, farmer trainings, formulation changes and product substitutions). By accounting for local practices and environments, we make sure our risk management is realistic and appropriate. We also frequently review scientific information to incorporate new study results and evaluate farmer practices based on field data, local scenarios and user feedback.[5]
- Data collection to determine the nature and magnitude of residues on food, as described below.

When a new use is proposed for a country where regulations are still emerging or do not cover consumer and operator risk assessments, Bayer's own voluntary internal standard is applied. This standard is aligned with guidance from international organizations, including Codex Alimentarius[a], the OECD, the FAO International Code of Conduct on Pesticide Management, as well as standards from reference regulatory authorities around the world. Bayer's safety standard is continuously updated by our scientists, based on the latest scientific consensus.

Thorough toxicological studies are conducted to characterize potential hazards of an active ingredient. These studies are conducted under Good Laboratory Practices (GLP) and according to standardized protocols described in international guidelines. To be sure that potential effects are well characterized, different in silico, in vitro and in vivo studies are performed. Different laboratory animal species need to be addressed in studies, covering different routes of administration, different dose levels – mostly beyond those to which humans would be exposed – and different durations of exposure (from single application to lifelong repetitive exposure). The evaluations examine the main organs and systems (e.g., hormonal, respiratory, immune, reproductive). Studies cover acute and repeated dose toxicity, genotoxicity, carcinogenicity, developmental and reproductive toxicity, effects on the endocrine system and neurotoxicity. Study designs are carefully considered for statistical relevance and reproducibility but also include the scope for ethical treatment via 3R: reduction, refinement and replacement of animal tests. The data generated are analyzed with appropriate statistical methods to compare the response of treated animals with respective controls, to define the dose-response curve and to determine the No-Observed-Adverse-Effect Level (NOAEL), which is the highest dose level at which there are no biologically significant adverse effects.

The NOAEL is then used to derive health-based guidance values determining the exposure threshold below which consumer and operator exposures are considered safe and drive the determination of an Acceptable Daily Intake (ADI) value, an Acute Reference Dose (ARfD) value (if the active ingredient is acutely toxic) and an Acceptable Operator Exposure Level (AOEL), including in each case at least a 100-fold safety factor. By this, we ensure that human exposure is well below any levels of concern.

[a] The Codex Alimentarius Commission (CODEX) is a regulatory body for FAO and the WHO that sets standards for food, food additives, labelling and food hygiene. It establishes Maximum Residue Levels (MRLs), which are utilized around the world, unless a country establishes its own MRLs.

In the mid- to long-term future, traditional animal methods for safety testing will be increasingly replaced by New Approach Methods (NAMs) that aim to reduce animal usage and increase predictivity of testing for humans. Bayer is actively developing NAMs for Next Generation Risk Assessment to shape the regulatory environment towards reasonable scientific approaches.

In the case of consumer exposure via residues on food, several regulatory authorities have looked at the cumulative risk assessment of residues from multiple active ingredients, but to date have concluded that no concern for consumer health is seen.[6,7] From a Bayer point of view, we carefully monitor the literature on cumulative risk assessment to ensure that no risks are identified for our active ingredients and products, and we provide cumulative risk assessments when requested by regulatory authorities.

After setting the health-based guidance values for the active ingredient for a consumer risk assessment, we generate data to determine the nature of residues in food items by investigating the active ingredient and any breakdown products in metabolism studies, as well as the magnitude of residues in field trials. To estimate consumer exposure, the risk assessment combines the level of residues in food with the food intake by each specific population (e.g., infants, toddlers, adults) and compares it with the ADI (chronic risk assessment) or ARfD (acute risk assessment). We also determine the risk cup for each population and country, where we calculate the aggregated risk from multiple food sources potentially treated with the same pesticide. Aggregated risk should never exceed the ADI or ARfD, and if we see potential for exceedance, we can reduce risk by not applying for additional crop uses or reducing the maximum application rates on the labels.

Bayer complies with Maximum Residue Levels (MRLs) in the countries where our products are used or where treated goods are imported to. An MRL is a legal value that represents the maximum concentration of a residue that is permitted to be present in or on a food, agricultural commodity or animal feedstuff. MRLs are set by country regulatory authorities for each active ingredient and crop. MRLs are important to enable trade of agricultural commodities and ensure food safety.

To assess operator safety, we evaluate how products are used in the field, including local farming practices, equipment used, product formulation and operator behavior to apply our internal safety standards. We collect as much real-world data as possible and consider various use scenarios during the handling and application of a product to ensure that our assessments are reliable.

The estimated operator exposure is compared with the AOEL to determine if a product can be handled safely when used according to label prescriptions. Risk management/mitigation activities include adding guidance on protective equipment to our product labels (https://www.bayer.com/en/agriculture/information-about-operator-safety-standards).

Environmental Safety

Environmental safety is a critical success factor for our new active ingredients. As part of our CropKey strategy, we integrate environmental safety parameters into the design process of these molecules during research and development. By utilizing a toolbox of predictive assays and models, we gather extensive information about these compounds before making development decisions. This information is also essential for generating a comprehensive regulatory data package required for the registration of active ingredients.

Our regulatory environmental safety assessments for crop protection products are conducted by expert teams trained in ecotoxicology and environmental chemistry. Over the past 50 years, these fields have evolved rapidly, merging knowledge and techniques from ecology and exposure sciences to understand the environmental fate and behavior of these active ingredients after they are applied.

Testing the potential impact of crop protection products on non-target organisms is crucial, as one of our primary goals is that our products do not cause any unacceptable effects to the environment. We conduct an extensive series of studies to characterize the fate and exposure of the active ingredient and its relevant environmental metabolites in both aquatic and terrestrial environments. These studies help us understand how quickly the active ingredient degrades and the formation and fate of its metabolites in different ecosystems.

By combining results from effect and exposure level testing on both the active ingredients and its metabolites, we can assess the potential risks to non-target organisms associated with the intended uses of our products. All safety studies needed for this assessment are conducted according to internationally harmonized test guidelines and in compliance with stringent GLP quality assurance regulations.

To evaluate the potential environmental risks of a crop protection product, we begin by characterizing the intrinsic hazards of the active ingredient and its relevant metabolites across a wide range of non-target organisms. The groups of non-target organisms tested are defined by regulatory authorities and selected based on the ecological functions they provide. Since it is impractical to test every species, we test surrogate non-target organisms, many of which represent key ecological services, such as pollination and biological pest control.

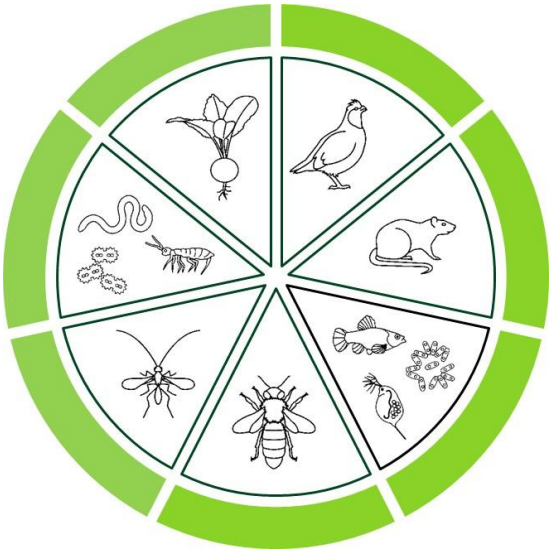
In the terrestrial environment, we test representative non-target organisms, including bird species, wild mammals, bees, beneficial insects, soil macro- and microorganisms and non-target plants. In the aquatic environment, we assess a variety of non-target organisms that comprise the aquatic food web, such as primary producers (e.g., algae and aquatic plants), primary consumers (e.g., invertebrates) and secondary consumers (e.g., fish).

To characterize the magnitude and duration of environmental exposure for a pesticide to non-target organisms, we conduct laboratory and field experiments. These studies elucidate the physico-chemical properties and the fate and distribution of substances across different environmental compartments (e.g., soil, air, surface water), as well as their degradation and the metabolites they form. Based on our understanding of the environmental fate (e.g., degradation, metabolism, mobility) of the active ingredient and its usage patterns, we can predict the concentrations in various environmental compartments after application by farmers. These predicted environmental concentrations are calculated using established and validated scientific models approved by regulatory authorities for specific countries or regions.

When developing a commercial product that contains multiple active ingredients, we evaluate acute toxicity to ensure an acceptable margin of exposure. Established procedures exist for predicting the combined additive toxicity of two or more active ingredients to non-target organisms (e.g., fish and bees). In many cases, formulations containing multiple active ingredients are directly tested with an appropriate battery of non-target organisms. The results from these formulation studies are then evaluated within an ecological risk assessment to support safe registration and use.

Scope of Terrestrial and Aquatic Testing that Support Ecological Risk Assessments Globally

- To protect avian populations, the potential for acute and reproductive effects are evaluated.
- To protect pollinators, the potential for acute and chronic effects are investigated with larval and adult bees.
- To protect potential effects to wild mammals, data is drawn from the extensive battery of toxicology studies that have been designed to assess effects on survival, growth and development, and reproduction.
- To protect the biological functions and biodiversity of non-target arthropods (insects), beneficial insects –such as green lacewings, beetles and parasitic wasps that are important for biological control – are tested for potential effects on survival and reproduction.
- To protect non-target plant communities and the organisms that depend on them, studies are conducted on a diverse group of plant species to assess potential effects on seedling emergence and growth of emerged plants.



- To protect non-target soil macro-organism populations and the services they provide (e.g., detritivory, nutrient cycling), acute and reproduction studies are conducted on representative soil organisms (e.g., earthworms) and for potential functional effects on carbon and nitrogen cycling.
- To protect the aquatic communities, acute and chronic effects on all levels of aquatic food web are tested (e.g., algae, plants, invertebrates, fish). In addition, a study is performed to understand the potential for a substance to bioaccumulate in organisms and through the food web.

Environmental model calculations consider a range of environmental conditions that are representative for agricultural areas, combined with information on application rate, application timing, application method (e.g., ground vs. aerial), number of applications, and the crop to which a product will be applied. This allows us to predict environmental concentrations of the active substance and its metabolites in soil after the compound is applied on the field, in water and sediment after exposure via spray drift, drainage or run-off. The parameters that are used for environmental exposure modeling provide predictions of realistic worst-case concentrations, which will generally not be exceeded under real-world conditions and are, therefore, protective of non-target organisms.

If the predicted concentrations indicate a potential risk, mitigation measures are required to reduce exposure and achieve acceptable risk. There is a wide range of such risk mitigation measures for all routes of environmental exposure and for all environmental risk assessments. For example, a simple but efficient mitigation measure to eliminate the exposure of bees is a restriction that the compound must not be sprayed while the crop is flowering. We also confirm the efficiency of such measures with experimental studies and modelling, which allow the authorities to evaluate their appropriateness during the registration process. The best-known examples of standard mitigation options are those that reduce or eliminate exposure of areas around the treated field, such as:

- Drift-reducing spray application nozzles to reduce off-site movement.
- No-spray (untreated) buffer zones at the edge of fields to reduce drift to neighboring areas, including water bodies where non-target organisms are found.
- Vegetated buffer strips to reduce run-off from reaching neighboring areas, including water bodies where non-target organisms are found.

4. Regulation of Crop Protection Products

Crop protection products are among the most stringently regulated products in the global economy. Regulations are designed to ensure that crop protection products are effective for their intended purpose and do not pose risks to humans, animals or the environment when used according to label instructions. Generally, regulatory authorities evaluate the dossier of an active ingredient and crop protection product to:

- // Determine safe uses for the environment, the operator, bystanders, residents and consumers.
- // Authorize the use of plant protection products in the respective territory.
- // Regulate the trade of food and feed with a specified MRL.

Before plant protection products can enter the market, they undergo strict evaluation by country regulatory authorities to ensure that they may be used safely by humans under local conditions and have no unacceptable effect on the environment. For this purpose, Bayer conducts hundreds of metabolism, residue, toxicological, eco-toxicological, environmental, physio-chemical and efficacy studies. All this scientific information containing active ingredient and formulated product composition, individual study reports, summaries, risk assessments and proposals for risk mitigation is compiled into a comprehensive registration dossier tailored to local regulatory requirements. Regulatory authorities evaluate these dossiers and decide whether a product can be approved, under what conditions and whether additional safeguards are required.

The Global Landscape of Regulatory Frameworks

The global regulatory landscape is diverse and constantly evolving, with different countries and regional organizations frequently updating their regulations based on scientific advancement and local political, environmental and agronomical priorities. Bayer applies a high level of rigor to testing the safety of crop protection products, including synthetic and biological products. Our regulatory experts track evolving regulations and update product dossiers to maintain strict regulatory compliance.

While regulatory systems differ across regions, Bayer's objective is consistent: protecting people and the environment while supporting reliable food production.

In North America, risk-based regulation is the standard. The U.S. Environmental Protection Agency (EPA) regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a comprehensive statute that governs the manufacture, distribution and use of pesticides to ensure that pesticides cannot cause "unreasonable adverse effects on human health or the environment." The Federal Food, Drug and Cosmetic Act (FFDCA) requires the establishment of 'tolerances' (legal limits) for pesticide residues in or on agricultural commodities. The Food Quality Protection Act of 1996 amended both FIFRA and FFDCA to include that pesticides can be used with "a reasonable certainty of no harm" and introduced major requirements that must be applied to all food commodities through stricter safety standards, endocrine disruption testing, aggregate exposure and cumulative effects. Aggregate exposure, represented by a 'risk cup' that includes all dietary sources of potential exposure, ensures that consumers are not exposed to unsafe levels of pesticides used on multiple crops.

The Endangered Species Act (ESA) requires federal agencies, including EPA, to ensure that actions they authorize, such as pesticide registrations, are not likely to jeopardize listed species or adversely modify designated critical habitat. EPA evaluates whether a pesticide could impact listed species or their habitat, and if a potential impact is identified, EPA must consult with the U.S. Fish and Wildlife Service or the National Oceanic and Atmospheric Administration (NOAA) Fisheries.

In addition, pesticide regulation follows a federal-state framework under FIFRA: EPA establishes the federal requirements a pesticide must meet to be registered for use in the U.S., and pesticides must also

be registered at the state level before they can be sold or distributed within a state. States may impose additional requirements or restrictions beyond federal registration.

In the EU, crop protection products must pass hazard-based criteria followed by a highly sophisticated risk assessment. In the EU, the key law governing the approval of plant protection products is Regulation (EC) No 1107/2009. After an initial evaluation by a Rapporteur Member State, the European Food Safety Authority (EFSA) independent risk assessor oversees the peer review of active substances used in plant protection products through its Pesticides Unit, which is supported by a network of experts from Member States. In parallel, the European Chemicals Agency (ECHA) conducts a hazard assessment of the active ingredient, potentially leading to a hazard classification under the Classification, Labeling and Packaging (CLP) Regulation (EC) No 1272/2008, which is used by EFSA in its evaluation process. EFSA is responsible for proposing and monitoring MRLs and assessing the actual risk of pesticide residues to consumers, which is addressed via Regulation (EC) No 396/2005. Public sector scientific experts from the Member States carry out peer reviews for EFSA through written comments or by participating in expert consultations. Based on EFSA's scientific risk assessments of active substances, the Risk Managers, who include the European Commission and representatives of the Member States, decide whether to approve an active substance before further assessing formulated plant production products that include the active substance and respective uses at zonal and national levels. Outside of the EU, the regulatory systems for the rest of the Europe, Middle East and Africa (EMEA) region are diverse, with some countries using the evaluations of more developed regulatory systems such as the U.S. and EU to guide their own local decision-making.

Latin America (LATAM) is characterized by diverse regulatory standards across countries. In some LATAM countries, only formulated products get evaluated, while in others, such as Brazil, registrations of the active ingredient, as well as the formulated product are required. In addition, Brazil is moving towards a risk-based regulatory framework. Other LATAM countries are strengthening regulatory standards, often in response to export requirements. In addition, we are having science-based discussions with regulators regarding plant protection product evaluations, label approvals for the use of drones (UAV) and new regulations for biological products.

The regulatory standards across Asia also vary. Many countries in this region are increasing regulatory scrutiny of crop protection chemistries because of food safety and environmental concerns, leading to restrictions and even bans. These actions, influenced by observation of the globally evolving regulatory landscape, are sometimes not aligned with international standards, such as FAO guidelines. For example, effective January 2021, China adopted a unique procedure where it no longer accepts international OECD GLP studies and, as a consequence, such internationally conducted and accepted study packages cannot be used to register new active ingredients in China. In India, the regulatory framework primarily relies on hazard assessment, although there are no defined hazard cut-off criteria. Instead, regulators rely on hazard signals and related scientific explanations for decision-making. Presently, risk assessment is followed to assess dietary exposure, and regulatory efforts are ongoing towards enhancing the regulatory framework for risk-based assessment and decision-making. Decisions from other agencies (such as the EU and EPA) are also considered when creating regulatory frameworks and reaching regulatory decisions.

Modern agriculture depends on access to global markets. One of the main barriers to trade can be differences in MRLs on traded commodities between countries. While some countries and regions accept FAO's Codex MRL rules, many have adopted their own, including the U.S., Canada, the EU, the UK, Japan, Taiwan, Korea, the Russian Federation and Australia. On top of that, a number of large European retailers have their own MRL requirements. Discrepancies between MRLs can make it hard for farmers to plan which products to use to enable access to all desired markets.

To address this, Bayer integrates trade considerations in the development and launch of each new product. Trade enablement strategies aim to establish MRLs for key crops as early as possible in relevant export markets, or to develop use instructions that result in no measurable residues. This increases the farmers' confidence in the marketability and profitability of their crops.

Dossier Compilation and Submissions

To secure product registrations in various countries, Bayer must compile and submit a data package, or dossier, to regulatory authorities. The data package includes the results of toxicological and environmental testing of the active ingredient and the product, as well as studies on product chemistry, environmental fate, residue chemistry, toxicology and ecotoxicology, and risk assessment studies and proposed risk mitigation measures, if applicable. After reviewing the dossiers, regulatory authorities issue their decision on whether to approve a product. Safety assessments by authorities follow their specific regional or national laws, schemes and guidance. Therefore, non-approval in one geography does not mean non-approval in another. This also explains why approval decision and risk mitigation measures on the label may differ between countries. Bayer promotes safe use in countries where products are approved through stewardship programs, training, specific application restrictions on the label and advancing the science underlying product safety. Beyond the compliance with regulatory requirements, Bayer promotes safe handling of plant protection products through stewardship programs and trainings.

Bayer's product development process and the extensive toxicological and environmental safety studies it includes are designed to comply with the requirements of mature regulatory systems and OECD standards. Despite similarities in requirements at country level and OECD's attempts to coordinate which studies are required globally, significant differences between regions still exist. For instance, some countries require studies on specific species, soil types and crops unique to that country. While some countries require full study details from design to results, others request only summaries. The dossier format also varies; most regulatory authorities accept digital dossiers, while others still require paper, which, for a typical dossier, could be tens of thousands of pages.

Studies Used to Assess Human and Environmental Safety of a Plant Protection Product

How hazard, exposure and potential risk to humans and the environment are evaluated

Area of Investigation	Type and Duration of Study	Description
Chemistry Assess the physical and chemical properties of the active ingredient and the formulated product. Typically, more than 40 tests per active ingredient or product in a representative dossier.	// Evaluations of parameters, such as flammability, explosivity, reactivity, chemical and formulation stability // Study duration: one day to two years (depending on the scientific question)	These studies confirm that the active ingredient and the final product can be manufactured, stored, transported and used safely. They examine key physical and chemical properties under different conditions. Stability testing also shows whether the product remains reliable over its shelf life, including in its packaging and under heat or humidity stress. Together, these studies provide scientific evidence to support regulatory submissions, safeguard long-term product quality and marketability and reduce product and supply-chain risks.

Area of Investigation	Type and Duration of Study	Description

Biology
Assess how a new compound works in practice by examining its efficacy, crop tolerance and resistance behavior.
 	
Throughout the development, typically around 1,000 greenhouse and field trials around the globe are conducted to build and develop the specific use recommendations of a product in its target crops and markets.
	// Greenhouse trials (duration of one trial: a few weeks)
	// Regulated open-field trials in relevant geographies and crops-authorized trial locations; conducted under permits/protocols and monitored; trial duration: typically, one crop season, occasionally longer
	// From compound discovery to registration submission, it takes >10 years
		Biology studies explore the potential of an active ingredient for its agricultural use. Based on its potential, product concepts are proposed, tested and optimized, while incorporating information from the other functions involved.
		These studies assess how well the product controls pests, diseases or weeds, including resistance origins, and whether crops can tolerate it sufficiently. They also assess how the product is acting under different environmental conditions, how it must be prepared and what mixtures are most beneficial. To implement a new product, the entire cropping cycle, as well as adjacent and subsequent crops, must be evaluated to ensure safe use. To prove its value, a new product must perform effectively within various and dynamic global production systems. These studies, which are part of the regulatory submissions, determine how the product fits into specific regional farming systems and how it can be used and placed on a global scale.

Toxicology
Assess potential hazards and risks of an active ingredient or formulation to humans and determine safe use based on human exposure.
 	
Typically, more than 60 tests per active ingredient or product in a representative dossier.
	// In silico, in vitro, in vivo studies
	// Acute (take days), sub-chronic, mid-term (take weeks to months) and chronic studies (last months to more than two years), multi-generational studies
	// They address acute toxicity, skin and eye irritation, skin sensitization, phototoxicity, genotoxicity/mutagenicity, neurotoxicity, developmental toxicity, reproduction toxicity, endocrine disruption, carcinogenicity
		The human safety assessment ensures that active substances do not have harmful effects on human health and that products can be used safely. It evaluates intrinsic hazards and human exposure to define risk, starting with hazard identification (what effects occur) and hazard characterization (at what dose).
		Human exposure is determined through dedicated studies and modelling of non-dietary (e.g., worker exposure) and dietary exposure (including residue studies in treated crops as described in the residue studies section below). The final assessment relates hazards with exposure and concludes on safety of the use. In this calculation, additional safety factors have to be included to account for animal-to-human extrapolation and variability within the human population.

Ecotoxicology
Assess potential hazards and risks of an active ingredient or formulation to wildlife.
 	
Determine safe use based on exposure.
 	
Typically, more than 100 tests per active ingredient or product in a representative dossier.
	// From lower-tier short- and long-term laboratory studies to higher-tier semi-field or field studies
	// Acute (typically a few days), sub-chronic (mid-term, typically take weeks) and chronic studies (can last months to more than one year)
	// Investigated are representative organisms from the environmental compartments the product may reach, such as water, sediment, soil and other terrestrial habitats
		Ecotoxicology studies are designed to determine whether a plant protection product can be used safely under realistic field conditions. Testing follows a tiered approach, beginning with highly conservative laboratory studies on representative organisms from the environmental compartments the product may reach. These organisms are tested in natural or organism-relevant matrices, including soil, sediment, water and plant surfaces, and in some cases under deliberately conservative worst-case exposure conditions. Depending on the results, the assessment may progress to higher-tier semi-field (e.g., tunnel tests for bees) or field studies involving populations or communities of organisms under more environmentally and agronomically realistic conditions. As part of the tiered assessment, observed effects are evaluated alongside exposure modelling. Lower tiers apply conservative exposure assumptions; higher tiers apply more realistic exposure conditions.

Area of Investigation	Type and Duration of Study	Description

Metabolism
Assess how the active ingredient breaks down.
 	
Typically, more than 40 tests per active ingredient in a representative dossier.
	// Advanced in vitro studies and toxicological, ecotoxicological and dietary risk assessments
	// Studies on the fate and distribution of substances and metabolites in plants and animals
	// Duration of studies: weeks to two years
		Metabolism studies assess how the active ingredient is absorbed, distributed and excreted from plant and animal matrices. These matrices include primary crops and animal feed, rotational crops, processed products (hydrolysis), ruminant animals, poultry, fish as well as drinking water. Early studies also include advanced in vitro models and other assessments to support early de-risking. The metabolites identified and structurally elucidated in these studies are then assessed for human and environmental safety through toxicological, ecotoxicological and dietary risk assessments.
		The main goals of metabolism studies are to identify and characterize metabolite chemical structure, determine how these metabolites are distributed within different parts of the crop and animal, establish the metabolic pathway and derive residue definitions for risk assessments.

Environmental fate
Assess potential environmental exposure of an active ingredient and its metabolites.
 	
Typically, more than 50 tests per active ingredient in a representative dossier.
	// In silico, in vitro, in vivo studies
	// Studies and modelling on the distribution, degradation and movement of substances and metabolites in soil, air and water
	// Duration of studies: weeks to more than 12 months
		Environmental fate studies examine the degradation, sorption and translocation of an active substance and its metabolites, including their identification and structural elucidation in environmental matrices, such as soil, water, sediment and air. These studies are generally conducted under controlled aerobic and anaerobic laboratory conditions, using radio-labelled substances to allow precise determination of mass balance, half-life, sorption parameter, metabolic pathways and respective transformation products in the above-mentioned environmental matrices.
		Field studies conducted with non-radio-labelled substances provide a more refined understanding of environmental behavior under typical, and, therefore, more variable environmental conditions over time.
		Once these properties are understood, they are subjected to kinetic evaluation and used as input parameters for regulatory accepted in-silico models to predict environmental concentrations of the active substance and its metabolites in surface and ground water, soil, sediment and air under realistic and worst-case agronomic use conditions. These exposure values are then used in ecotoxicology to assess potential risks to different groups of organisms.

Residue studies Each agronomic use of a product is addressed by a suite of residue studies to assess the magnitude of residues in food and feed items	// Realistic field residue trials, processing studies and feeding studies // Worst-case conditions (e.g., highest application rate, shortest pre-harvest interval)	Residue studies are performed to measure residues of the product according to the residue definition under realistic worst-case conditions, taking into account climatic conditions of the country of use according to country-specific requirements. For example, in the EU, two different climatic zones have to be addressed and a total 16 trials need to be conducted for a specific use.

Bayer's dossier compilation is managed by several dedicated teams:

// **Quality and compliance specialists** audit Bayer and external contract laboratories for compliance with GLP criteria, preserve study records and raw data, and manage audit requests by governmental authorities.
// **Human and environmental safety scientists** conduct laboratory and field studies in many countries around the globe. They analyze the data, perform risk assessments and write the dossiers. Several hundreds of studies can be conducted for each active ingredient and related formulated products, depending on the number of crops and countries for which we are seeking regulatory approval. Many dossiers can contain up to 80,000 pages, including hundreds of pages for each study report and more pages of documented raw data, all of which are stored for at least 30 years.
// **Global, regional and country regulatory managers** are Bayer's primary contacts with regulatory authorities and are responsible for preparing the dossiers according to the requirements of each regulatory authority. Regulatory managers shepherd submitted dossiers through review, which can take several years before a decision is issued.
// **Submission management specialists** support Bayer colleagues in preparing, coordinating, compiling and submitting dossiers. These specialists employ dedicated digital tools for dossier submissions and maintain global internal access to all data and other pertinent information.

Regulation of Biologicals

As with conventional crop protection products, regulators assess a wide variety of potential human health and environmental effects associated with the use of biological products. "Biological products" is an umbrella category that includes distinct product types such as biopesticides and biostimulants. Since biopesticides tend to originate in nature, regulatory agencies typically require different data to register a biopesticide compared to a conventional pesticide. Depending upon the nature of the biological, however, regulatory authorities may require additional studies. In many cases, regulatory agencies require registrants to submit studies that address the composition, efficacy, toxicity and other characteristics of biologicals. In recent years, some countries have developed specific regulations and data requirements for biologicals which reflect the diversity of biological products (e.g., biopesticides versus biostimulants). Similar to conventional crop protection products, Bayer conducts thorough assessments of biologicals in compliance with regulatory requirements to ensure their safety for humans and non-target species.

Labelling

One of the most important tools for safe and effective use of crop protection products is the information on the product label. Labels are legal documents and are required to contain Directions For Use, including how to properly mix, apply, store and dispose of a pesticide product. These directions are designed to help ensure the safe and effective use of crop protection products. Failure to comply with label directions can potentially harm humans and the environment, as well as lead to possible legal liability. Product labels are highly regulated and undergo intense review and approval by regulatory agencies at country level. Crop protection products by Bayer are labelled in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Codes and the FAO Guideline on Good Labelling Practice for Pesticides[8]. Whenever possible, we use this reference to advocate for label improvements when local regulations deviate from that.

Label instructions ensure that the product is used in the right amount, at the right time, in the right areas and on the right parts of a crop. The product label also reflects safe use conditions, including the use of personal protective equipment (PPE), and mitigation measures, such as buffer zones near water bodies, use of drift-reducing nozzles, or incorporating the product into soil after application. Label instructions are legally binding for farmers when using crop protection products.

Additionally, the label directs the proper disposal of the product and its container, which can significantly reduce the potential impact on humans, the environment and non-target organisms when followed. Regulatory authorities may randomly audit farmers' compliance with label instructions, requiring farmers to document their use of crop protection products.

Our product labels are created in accordance with our internal Group Regulation on Product Stewardship Commitment, Principles and Key Requirements.[9] We comply with local regulatory requirements through a

decentralized model, which means that Bayer country entities are responsible for artwork, branding and content, and are tightly integrated with the production process to secure internal label approvals.

Bayer and the industry support continuous improvement in label communication techniques. As an example, Bayer is incorporating pollinator protection pictograms into its pesticide labels. This includes the pictogram developed by CropLife International and endorsed by FAO in 2022 or its equivalents.

In-Licensed Active Ingredients and Formulated Products

Bayer adds value by in-licensing products developed by other companies to serve an unmet need in the marketplace. This may include competitors' registered active ingredients and formulated products that we determine may be beneficial additions to our portfolio, either to expand into new crops, new regions, or new countries or to complement proprietary products, providing a more convenient solution for the grower. We apply our robust internal safety standards, aligned with the standards and guidelines of the FAO, WHO and the OECD, to in-license products and active ingredients in the same way as for Bayer-developed active ingredients and formulated products. This rigorous risk assessment also applies to molecules, products and technologies we develop with our innovation collaborators, as well as the continuing review of our crop protection portfolio.

5. Product Stewardship

At Bayer, we commit to the pesticide industry principles laid out in the FAO-WHO Code of Conduct on Pesticide Management and have adopted the FAO-WHO Code's life cycle approach to product stewardship, which addresses all aspects of responsible product management along the product's life cycle, from Research and Development to product discontinuation.

Stewardship During Product Development

From the earliest stages of research and development, we apply stewardship practices that support high-quality products, responsible use and compliance with regulatory and agricultural best practices.

We are committed to substituting higher risk profile formulants with alternatives that have lower risk profiles and minimizing the potential for unintended release and exposure to non-target areas. We also seek to develop products, services and technologies that reduce the need for personal protective equipment (PPE), to support programs that enhance the availability and affordability of PPE, and to align PPE with user education and abilities in the countries where our products are sold. In parallel, we invest in improved application technologies and best practices to reduce occupational and environmental exposure.[10]

Where required, we obtain country-specific import approvals and permits for conducting testing with non-registered products or materials. Strict safeguards are in place when performing trials to prevent non-registered products from entering the food or feed chain or being released into the environment without regulatory authorization.

Research and development of our biological and chemistry technologies, including the use and application of experimental products and services or materials in trials, is only performed by trained personnel. All experimental products are clearly labelled, include safe-handling instructions and are managed through processes to prevent unintended co-mingling or cross contamination. Crops and harvests from trials with non-registered products and uses are destroyed unless regulation and/or laws permit other means of disposal.

Before commercialization, Bayer secures regulatory approvals in countries where products will be sold, as well as import tolerances or authorizations in key export markets. Our data packages are developed to comply with national and international regulatory requirements and are supported by studies conducted under internationally recognized testing standards. At a minimum, studies follow the International FAO Code of Conduct or the regulatory standards of OECD countries, unless local regulations require otherwise.

We conduct residue trials in accordance with national/regional regulatory requirements before marketing products. These tests must, at a minimum, comply with the Codex Alimentarius Commission[11] and FAO guidelines on good analytical practice and crop residue data to provide a basis for establishing appropriate maximum residue limits.

More information on stewardship of our products may be found in our 2025 Bayer Impact Report.[12]

Compliance and Quality During Production

Bayer has instituted mandatory quality management systems that include standards and ongoing assessments to ensure that our products meet the highest quality standards. Each production batch is tested using defined processes and industry-standard analytical methods before release, sale or transport. When products are introduced into new markets, Regulatory Affairs works closely with Product Supply to ensure that manufactured products comply with regulatory requirements. Bayer uses the RegPrime information system as the single source of truth for product registrations, specifications and market authorizations worldwide, enabling transparency, traceability and consistent execution across regions.

All Bayer global manufacturing sites and laboratories are ISO (International Organization for Standardization) certified. ISO standards are independent, internationally recognized criteria that focus on process improvement to ensure quality, safety and efficiency. The standards guide continuous evaluation of our quality system management, which includes identifying and implementing improvements. ISO certification is voluntary and an independent third-party certification body verifies that all applicable ISO standards are met.

Continuous product improvement is embedded through structured risk assessments, Corrective and Preventive Actions (CAPA), and Plan-Do-Check-Act (PDCA) cycles. Mandatory Quality Management Reviews are conducted twice annually and reported to senior management. These reviews summarize our efforts and corrective actions to reduce or mitigate potential quality risks. We also regularly assess our IT platforms to ensure an integrated, end-to-end approach for continuous improvement of tracking, production batch quality, key performance indicators and follow-up on action items.

Regulatory authorities govern the production of crop protection products, including the preparation of regulatory certificates of composition (CoC). These certificates contain all necessary information for planning, development and production (i.e., a formulated product's composition), including the chemical name, the product name, and the function and content of each component in the formulated product. As these product "recipes" vary according to regulatory requirements across global markets, we maintain a robust platform that provides our production sites with detailed information on registered product specifications and composition. Bayer also must gain advance regulatory approval for any changes in the production of a product, such as a new active ingredient source, a change in the concentration of ingredients or components of a formulation, or changes in production sites.

Monitoring and Portfolio Screening

Our internal risk assessments incorporate on-the-ground insights from our local experts, especially in low-and middle-income countries (LMICs), where agronomic conditions, application practices and access to PPE can differ significantly from developed markets. Our operator risk assessments align the minimum requirements for PPE with FAO and WHO recommendations. For situations where advanced PPE may not be accessible or realistically expected to be used, Bayer does not consider advanced PPE as a mitigation measure.

After identifying multiple exposure scenarios in LMICs and in Europe that were not adequately addressed in local guidelines and risk assessment approaches, Bayer developed exposure models common for those areas. Examples include hand-held product application in densely grown crops or exposure to treated crops during the cultivation of sugar beets, whereby some varieties produce seed stalks instead of beets. Bayer conducted a study to determine the exposure of workers responsible for removing the seed stalks, known as 'bolts.' The results were published in a peer-reviewed journal, and the raw data were submitted to regulators for evaluation.[13] The exposure scenario was taken up by binding European regulations.[14]

In-field surveys or other product use monitoring are the responsibility of government authorities, according to the FAO and WHO Code of Conduct. Bayer conducts in-field surveys with farmers when mandated by government authorities or to gather additional insights beyond mandates. These in-field surveys can be utilized to develop or enhance safe product use training.

To reduce exposure to humans and the environment, Bayer invests in technological advances. In addition to risk reduction, these technologies enhance productivity. Examples include partnering with major drone manufacturing companies and local professional drone spray service providers to promote product application by drones, which not only replaces handheld applications but also improves efficacy. Complementary efforts include the development of guidance documents in collaboration with regional CropLife organizations, the delivery of continuing training courses for our employees and research partners, continuous evaluation of potential new exposure sources (e.g., frequent refills or battery exchanges), and the promotion of professionalized application services, particularly in emerging markets.

Guided by our high internal safety standards and sustainability strategy, we are continually screening our current portfolio against evolving social, environmental and economic parameters to identify areas that

need attention and develop action plans to encourage the development of new solutions that can contribute to sustainable farming. We take action where needed through research projects, reformulations or product substitutions. We work with regulators and other stakeholders to encourage effective and predictive science- and risk-based regulatory systems that enable this innovation, substantiating these discussions with our high safety standards.

Incidents Management

Bayer seeks to avoid product-related incidents wherever possible, and effective prevention depends on reliable data about how, when and where incidents occur. Information on any incidents is also collected in various ways, such as through direct contacts (e.g., via Bayer sales staff, hotline numbers printed on Bayer's product packaging, local authorities); national safety call centers or poison control information centers in the U.S., Brazil, Canada, China, Colombia, Germany, Mexico, and South America; medical staff; or verified media reports.

We collaborate with many organizations to overcome the challenges posed by the lack of coordinated worldwide monitoring systems. In addition to working with universities and environmental and regulatory authorities to gain reliable monitoring data on product residues in water and on agricultural produce, we are expanding our partnerships with poison control centers and rural doctors, equipping them with tools to facilitate reporting of poisonings related to crop protection products.

Our internal incident management system, whose backbone is the software solution CAIRnew, was instituted in 2014. It includes data we receive from poison control centers as well as incidents we record through our network of Bayer colleagues and external partners. CAIRnew improves our risk mitigation, enabling efficient and consistent reporting, managing, documentation, and analysis of external adverse incidents, complaints, and, if necessary, product recalls in keeping with our Product Stewardship Commitment, Principles, and Key Requirements.[15]

To increase awareness and strengthen reporting channels, our Stewardship incident managers play an important role in providing CAIRnew training for key users, who then train local users in the respective functions and countries.

Incidents can be reported directly to Bayer through sales staff or hotline numbers provided on product labels. We also use verified media reports and gather information from medical professionals and poison control centers. Our incident management system and the continuous review of product use allow us to monitor the safety of our products and identify any necessary improvements or additional targeted stewardship measures. These measures may be in response not only to human health incidents but also to those involving domestic animals, pollinators or the environment. Risk mitigation steps may include enhanced training efforts, formulation changes, revised application recommendations, use limitations, or even product withdrawal, in line with the FAO-WHO Code.

Bayer also supports actions by local authorities to implement official systems for data collection. More comprehensive data will enable us to better identify how we can further improve our portfolio and service management to continue making the use of our products safer. We also believe that collective effort at all levels can have a positive impact on the safe management of crop protection products around the world.

Stewardship During Commercialization

Once products are in the market, stewardship focuses on maximizing product potential while minimizing risk. This includes region-specific measures that support integrated weed, pest and disease management and ensure safe use throughout the product life cycle, from spraying to safe disposal of empty packages, containers or obsolete product inventory or waste in accordance with local regulations.

Training

Prior to product launch, Bayer conducts a "reality check" with local agronomic partners to assess whether proposed use patterns are compatible with local cropping systems, application practices, and exposure conditions. This includes evaluating whether certain combinations of crop structure and application methods are appropriate. For example, in dense rice cultivation systems, backpack sprayer application can lead to unacceptably high operator exposure; in such cases, Bayer does not proceed with these use

scenarios. This pre-launch assessment is a critical safeguard to prevent foreseeable misuse and to ensure that ethical considerations are embedded in commercialization decisions from the outset.

Once local scenarios have been confirmed, Bayer conducts targeted training courses in which we show farmers, seed treatment professionals, product distributors and applicators the safe handling of products during use, transport, storage and disposal. Training also demonstrates the correct use of protective clothing and equipment, as well as first-aid measures in the event of an emergency.

As of 2025, we continue to reinforce a hybrid training model that combines virtual accessibility with in-person delivery where feasible, ensuring flexibility and effectiveness. Training is tailored by location, crop and local requirements, and delivered in local languages through formats such as on-site presentations, manuals, brochures, videos and live chats. To extend our outreach, we also conduct training sessions during product launches, field days or other events. We assess the impact of our training programs through farmer surveys and follow-up over time. In 2025, the flexible approach and use of digital tools enabled us to reach almost 4.1 million external contacts worldwide (e.g., farmers, field workers, distributors, retailers and other stakeholders in the agriculture industry), including around 3.4 million smallholder farmers. We continue to focus many of our training activities in countries where legal requirements for farmer certification in the safe handling of crop protection products remain limited or are not yet enforced. Most of the people we trained were in Asia, followed by Africa and Latin America. Our partnerships increase the reach of these activities and enable joint events with universities, information centers, or local, regional and international associations.

Bayer has also provided training and engagement in LMICs through the Bayer Safe Use Ambassador initiative,[16] launched in 2017. The program partners with more than 60 agricultural universities across Asia and Africa to train students on the safe use of crop protection products, prioritizing safety for both users and the environment. These students serve as Safe Use Ambassadors and transfer their knowledge to farmers during internships. In the medical sector of the Safe Use Ambassador initiative, we provide physicians and poison control centers with guidance about the hazards, toxicity and treatment of crop protection product poisoning as well as the treatment of snake bites. Since 2023, the program has been connecting with the medical sector in Africa, fostering exchange and building knowledge among healthcare professionals. So far, more than 2,000 medical professionals, agriculture students and Bayer employees participated in the safety training sessions and the latest medical webinar series, “One Health: Pesticide Toxicology & Management of Poisoning,” where they learned about prevention, treatment and safety in the field.

Bayer maintains a continuous feedback loop to understand how products are used in practice. Stewardship teams rely on ongoing input from local teams and external partners to gather information about farmer behavior and application techniques. While off-label use is not captured in a structured manner, this feedback enables Bayer to identify patterns that may signal misuse or emerging risks and that support targeted stewardship interventions, such as additional training, revised guidance, or engagement with authorities.

6. Product Authenticity

Anti-Counterfeit

Delivering effective crop protection solutions that meet the needs of global agriculture requires more than product innovation. How products are safeguarded in the marketplace is just as important.

Authentic crop protection products and seed varieties undergo intensive testing and strict regulatory evaluation before being placed on the market. When something of value enters the market, fakes follow, and the agriculture industry is no exception. Counterfeit products in agriculture are encountered in markets around the globe. Counterfeit or otherwise illegal crop protection products are unsafe as their content is unknown, untested and do not meet the regulatory standards. Such illegal products aren't just of questionable origin and efficacy; they also pose a real risk to the farmer, the consumer and the environment, as they may contain harmful substances not accounted for on the label. Counterfeit products compromise sustainable agriculture, reliable food production and efforts to improve farmers' livelihoods, especially those of smallholders.

With the global pesticide market valued at over $60 billion, global revenues associated with the trade of illegal pesticides are estimated by the OECD at USD $6-$10 billion, making it one of the leading organized crime activities in the world. Bayer takes a zero-tolerance position towards illegal activities and has implemented a global strategy to effectively combat production, transport, trade and use of counterfeit and illegal crop protection products and seeds.[17]

The Bayer Safety Seal enables farmers and distributors to distinguish original Bayer crop protection products and seeds from counterfeits. The seal employs optical security features and a QR code that can be scanned with the Bayer Seal Scan App, which provides reliable information about the product's authenticity in local languages. The Bayer Safety Seal is found on all Bayer core crop protection products filled in bottles in EMEA and LATAM regions. The Bayer Safety Seal technology was expanded to include selected solid crop protection products in some high-risk markets in 2021, and row crop seeds in Europe began in 2022. In 2024, these features were rolled out in Brazil and Mexico.

In addition, we are working with the industry towards eliminating counterfeit products that could compromise the safety of people and the environment. These measures include safety features that we developed that allow a reliable differentiation between counterfeits and original Bayer products.

Safety Seal as an Enabler for Digital Transformation in Agriculture

More information on Anti-Counterfeit initiatives at Bayer and proactive measures may be found at Counterfeits in Agriculture | Bayer Global.

At farm level, we are expanding our innovative Bayer Safety Seal technology to provide farmers with additional digital information, including location and/or product-specific information, such as weather and soil conditions, product name, batch number and production date, quality data, use instructions, stewardship recommendations, and crop system information.

Linking the physical product directly to trusted digital information will increase customer confidence and improve the overall user experience. Consolidating this data behind a single QR code also eliminates the need to scan multiple codes, offering farmers convenient access to guidance on proper and sustainable product use. In this way, the Safety Seal serves not only as an anti-counterfeit measure, but also as an enabler of digital transformation in agriculture.

7. Measurable Sustainability Targets

Bayer is committed to enabling more sustainable growing practices around the globe. As we develop and refine our crop protection portfolio, we are consciously considering how Bayer products can help reduce the environmental impact of farming.

Crop Protection Environmental Impact Reduction (CP EIR)

Agriculture must strike a balance between the need for tools, like crop protection, and potential trade-offs posed by the increased use of such tools. With new products and technologies, we aim to ensure that our solutions serve farmers' needs and well-being, while also reducing the environmental impact and contributing to food security. As the world's leading provider of crop protection products, we adopted a methodology for CP EIR and set a target for reducing the treated-area-weighted environmental impact[b] per hectare of our global crop protection portfolio by 30% by 2030 against a 2014-2018 average baseline. We are proud to be the first company within our industry to set such a measurable target across the entire global crop protection portfolio with publicly available models.[18]

Our scientific, data-driven approach for CP EIR is based on two independently developed external models (PestLCI and USEtox®), which have been peer-reviewed and adopted by leading public authorities. USEtox is being developed under the auspices of the United Nations Environment Programme (UNEP) and the Society of Environmental Toxicology and Chemistry (SETAC).

Oftentimes, environmental impact is correlated with the volume of product used. While volume certainly plays a role, there are more important factors in determining a product's efficacy and environmental impact. Bayer strives to look beyond volumes per hectare. Broadly speaking, the environmental impact of crop protection is determined by three main variables: the environmental profile of the crop protection product, the volume applied per hectare and the emissions of crop protection into the environment.

Through CP EIR, we aim to reduce the environmental impact of our global crop protection portfolio while maintaining or even increasing the benefits of crop protection products in securing yields. We have identified a number of technologies that can accelerate progress towards our target, which aims to:

// Improve the chemistry of crop protection products
// Reduce the amount of crop protection products needed per hectare
// Reduce crop protection emissions into the surrounding environment, and
// Ensure safe, responsible use of crop protection products.

The reduction in crop protection environmental impact is the result of our product development standards, stewardship, and Bayer's ability to combine crop protection products with tailored solutions from seeds and traits development or digital technologies.

Based on data from 2020–2024, Bayer has reduced the treated-area-weighted environmental impact per hectare of its global crop protection portfolio by 14% against the 2014–2018 baseline. The reduction was mainly the result of changes in our crop protection product portfolio in recent years. For more information on our CP EIR target, please see the methodological report.[19]

[b] Environmental impact is defined as the potential effect on non-target organisms. The assessment is limited to the current scientific consensus of USEtox®, which covers aquatic non-target organisms and substances, which can be characterized in USEtox.

8. Trust and Transparency

Bayer has made a commitment to enhancing our corporate transparency efforts with our stakeholders. Some of these efforts include supplying detailed disclosures on materials, project expenses, research activities, regulatory study reports and collaborations; establishing advisory bodies; and engaging in dialogue with customers and stakeholders. We rely on these regular, constructive and transparent engagements to recognize important trends and developments in society and our markets at an early stage and take this information into account in how we conduct business.

Science and innovation have transformed health and nutrition around the world. In our work, science has allowed us to develop products that can support farmers as they seek to provide enough food to feed a growing population. While the science behind modern agriculture is held to rigorous standards, information about how companies test and develop new products has not typically been accessible to the public.

As such, Bayer has made a commitment to continually enhance our corporate transparency efforts throughout many facets of our business, including:[20]

- We aim to remove barriers to obtaining detailed information on the safety of our products by enabling access to product safety information and regulatory submission documents in parallel with background materials and information on our rigorous crop protection safety standards. Summaries of human and environmental safety studies for many of our crop protection active substances are available on our website. Moreover, upon request and for non-commercial use, we are also sharing full study reports of crop protection safety studies that have been submitted to and evaluated by regulatory authorities for our commercially available products.[21]
- We are opening our doors via our Crop Science OpenLabs program, allowing viewers to connect with our scientists, observe them carrying out a crop protection safety study in our labs and in the field under GLP conditions, and learn about how our scientists conduct safety assessments for genetically modified crops. We conduct live public-facing webinars periodically, allowing anyone interested to connect with our scientists, observe them carrying out a crop protection safety study in our labs and in the field under GLP conditions, and learn about how our scientists conduct safety assessments for genetically modified crops.
- Since 2021, we have shared our crop protection operator safety standards on our website.[22] Our voluntary standards reflect the guidelines and standards of international organizations, such as FAO, WHO and OECD, as well as those of reference regulatory authorities around the world.
- We increase transparency and visibility of Bayer's innovative research activities within the external scientific community through our Science in Spotlight platform, listing peer-reviewed scientific publications authored by Bayer employees.[23]
- To generate more transparency around our scientific collaborations, we launched the Bayer Science Collaboration Explorer in 2021. In this publicly accessible database, we disclose information on new contract-based scientific collaborations with universities, public institutions and individuals. Data on collaborations in Germany, the U.S., Switzerland, and Brazil is currently available. Further countries will follow.
- We make detailed disclosures on material and project expenses and headcount of the essential political liaison offices in the transparency registers of the European institutions and the U.S. Congress. We also report data for countries in which there is no legal disclosure obligation.

External Advisory Bodies

In the spirit of improved two-way communication, Bayer seeks guidance and perspective on our R&D and sustainability efforts from these independent advisory bodies:

- The Bioethics Council ensures a broad independent perspective and guidance on complex ethical questions related to emerging life science technologies. The Bioethics Council consists of a diverse

external group of thought leaders in the field of bioethics who engage in regular dialogue with Bayer executives and Bayer product development teams.[24]

- The independent external Sustainability Council[25] advises the Board of Management and other functions in sustainability matters, provides guidance on the contribution that Bayer can make with its research and development, and independently examines the progress made by Bayer in the implementation of its sustainability targets.[26]
- An external panel of experts has independently performed an assessment of how Bayer measures performance against its CP EIR target, along with additional methodological considerations. To ensure that the external panel could perform a full assessment, the panel members have received access to the full dataset, which (for legal reasons) cannot be disclosed publicly. This enables the panel to verify the impact assessment methodology and understand target achievement and performance against the baseline. More information is available on this webpage.[27]

Engagement with Stakeholders

Stakeholder engagement is an important aspect of every product's life cycle, from the early R&D stage to use in the field. Bayer's Strategy and Sustainability Engagement (SSE) group leads efforts to engage stakeholders in meaningful ways as we develop and deploy new products as part of our commitment to transparency and our desire to strengthen trust in agricultural innovation and technology.

Bayer engages with a broad range of stakeholders, including farmers and farmer organizations, local communities, international organizations, NGOs, governments, sustainability platforms, industry associations, academia, food value chain companies, and ESG data providers and investors. Our process follows a structured, continuous improvement cycle: defining purpose; identifying and prioritizing stakeholders; developing tailored engagement plans; implementing dialogue and collaboration; and monitoring outcomes to refine future engagement. This process is guided by Bayer's mission "Health for all, Hunger for none" and our Code of Conduct.

We focus on partnerships that align with our sustainability priorities and strategic objectives – addressing climate change, food security, biodiversity, and environmental impact reduction – while also engaging in dialogue with organizations that share these focus areas but may not be fully aligned with our approach. Through open exchange, we work to understand perspectives, identify common ground and explore opportunities for mutual alignment where possible.

Three guiding principles underpin all engagement activities: inclusive stakeholder participation, equitable representation of underserved groups, and farmer- and society-centered value creation. These principles ensure that engagement outcomes remain transparent, grounded in real-world needs and aligned with our sustainability strategy. You can learn more about our engagement with stakeholders here.[28]

9. Governance

Sustainability and Stewardship Governance Internal Committees

From product development to commercialization, several management and governance bodies – such as internal committees that include and/or ladder up to senior leadership – ensure alignment with our sustainability strategy.

The **Chairman of the Board of Management** holds the function of Chief Sustainability Officer (CSO). Together with the full Board of Management, this role forms the first level of responsibility for managing the impacts, risks and opportunities associated with sustainability. Moreover, each Board member takes ownership of sustainability-related topics within their integrated responsibilities. In exercising these responsibilities, the Board of Management is supported by the Public Affairs, Sustainability & Safety Enabling Function and the global company organization.

The **Supervisory Board** is directly involved in decisions on matters of fundamental importance to the company, regularly conferring with the Board of Management on the company's strategic alignment and the implementation status of the business strategy. The **ESG Committee** of the Supervisory Board oversees and advises the Board of Management on matters relating to sustainability. This mainly pertains to the way sustainability is incorporated into the business strategy; the establishment of sustainability targets; non-mandatory ESG reporting and the auditing thereof, if applicable; opportunities and risks; and organizational structures and processes in ESG areas, provided the Audit Committee is not already responsible for these matters.

The **Head of Strategy and Sustainability** in Crop Science holds overall governance for sustainability focus areas and is a member of and reports into the Crop Science Leadership Team (CS LT) as the highest divisional oversight body with a focus on current performance and strategy, ensuring the necessary connection to other functions, particularly the heads of R&D and commercial teams. The Head of Strategy and Sustainability also chairs our **Executive Leadership Team License to Operate (ELT LtO) Sub-Committee**, which is dedicated to driving critical decision-making on Crop Science and/or product LtO matters. Members of this committee represent R&D, Product Supply, Legal, Communications, Finance, and Commercial Operations. Reporting to the LtO Committee is our **Regulatory LtO & Product Safety Committee,** which addresses topics that may result in business and/or reputational impacts. This committee also steers regulatory procedures and issues, oversees product stewardship plans and incidents, provides oversight to guide addressing a product's potential impact on Bayer's product safety and sustainability strategy, and defines structures of topic-related sub-committees and processes. The Head of Strategy and Sustainability is also a member of the Global Public Affairs, Sustainability & Safety leadership team.

The following sub-committees report into the Regulatory LtO and Product Safety Committee (RLSC):

- The **Regulatory Policy and Issues Committee** ensures that important topics or problems involving or impacting regulatory authorities or scientific processes that may impact Bayer's LtO are addressed and elevated to the RLSC when needed.
- The **Product Safety and Stewardship Committee** has a scope that includes new technologies in seeds and traits, crop protection and biological products. The committee services, reviews and approves proper principles, processes, procedures and strategies to assure proper product life cycle stewardship; assesses stewardship plans; collects, evaluates and responds to product stewardship issues; and resolves identified concerns or divergent positions.

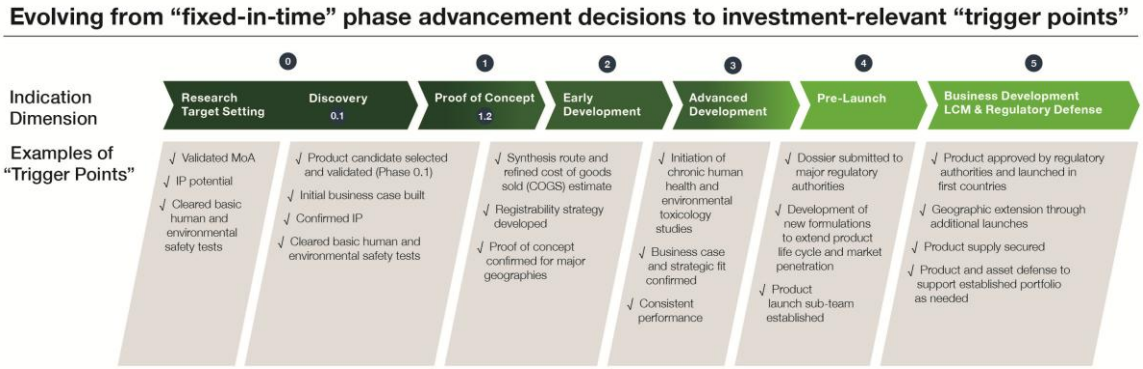
Indication Product Teams exist for each indication within the Asset Management function. They are accountable for optimizing the business value of R&D projects. They endorse and supervise the implementation of asset/segment strategies, ensuring alignment to respective strategies within/across crops, and prioritize and position assets within segments, including out/in-licensing tactical decisions.

Many everyday and larger stewardship matters are discussed here, together with commercial, stewardship, regulatory, product supply and others.

Within the Crop Science division, the **Sustainability & Strategic Engagement (SSE)** function is dedicated to driving and integrating sustainability strategies across the organization's operations. Through innovative solutions, strategic partnerships, and broad stakeholder engagement, the team works to realize Bayer's mission of creating value and resilience for farmer customers. The SSE team steers the sustainability downstream targets at Crop Science on key topics such as CP EIR, on-field GHG emissions reduction, increased water productivity and support of smallholder farmers. With additional responsibility for biodiversity and Anti-Counterfeit, the function reports to the management of the division on its strategy and performance in these focus areas.

Crop Protection R&D Governance: Processes, Phase Gate Criteria and Committees

Our R&D innovation pipeline for Crop Protection has six phases, beginning with Phase 0, the discovery of hits or targets, and ending with Phase 5, which represents full business development, including life cycle management and regulatory defense. As a result of the implementation of the new operating model Dynamic Shared Ownership within the R&D organization the decisions for phase advancements have been pushed forward and sit now in empowered project teams, who make decisions based on trigger points which are relevant to the needs of R&D investments and connected to the critical path. Project teams are empowered to decide within a frame and are accountable to escalate such decisions at those trigger points, including phase advancement recommendations, to ensure radical transparency, stakeholder consultation, documentation and communication. The Research Indication Product Teams are the governance body for the Phase 0 to 1.2 stage gate promotions. The Crop Protection Franchise (or Crop Protection Enterprise) Team is the ultimate body to decide on the global crop protection strategy, portfolio classification and overall framework setting; confirm development pipeline advancements or discontinuation decisions, cancelations and trade off decisions across indications, high level resource allocation and trade off decisions across pipeline phases, indications and regions.



// **Phase 0:** Research target setting and discovery
// **Phase 1:** Identifying and profiling the best candidates that meet "proof of concept"
// **Phase 2:** Early product development to demonstrate consistent, competitive performance with no prohibitive safety, technical or regulatory findings
// **Phase 3:** Advanced development, conducting all necessary studies to create global regulatory data dossiers for registration
// **Phase 4:** Pre-launch evaluation of dossiers by regulatory authorities in key markets and preparation for product launch
// **Phase 5:** Business development, including expansion into other markets, product and asset defense as needed, and development of new formulations to extend the product life cycle and market penetration

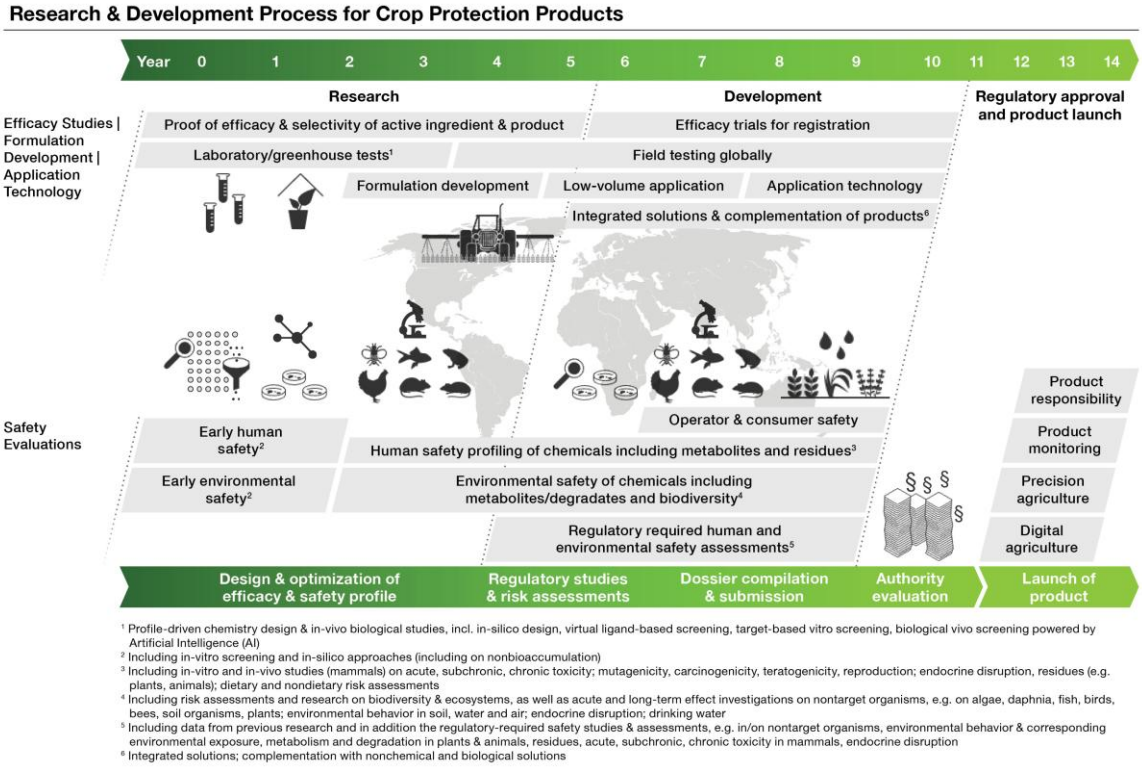
Fully empowered project teams with the ultimate endorsement of the Crop Protection Franchise Team applies specific criteria to promote product concepts through the stages of development. To enter **Phase 1**, concepts must demonstrate potential to address research targets. Small molecules must have confirmed interesting levels of biological activity in greenhouse trials, show potential to create proprietary IP, demonstrate no prohibitive findings in basic human and environmental safety tests, and exhibit stability and physicochemical properties that support potential to transfer greenhouse activity to the field. Biologics must show potential to create proprietary IP, pass basic toxicology and technical efficacy tests in greenhouse studies, and make a strong economic case.

To enter **Phase 2**, concepts must demonstrate a probability of technical and regulatory success and business potential, and the first assessment of potential for development of tailored solutions is conducted. Small molecules must further confirm high biological activity in comparison to market standards with stable formulations, show crop safety and dose response, reveal no prohibitive findings in basic human and environmental safety tests, have established proprietary IP allowing for patent application, and have an identified preliminary use pattern and product concept for key markets. Biologics must demonstrate efficacy in preliminary field testing at high doses (20%), have identified patent and regulatory strategies, pass human and environmental safety tests, and develop first-generation formulation concepts.

Phase 3 entry requires an evaluation of development projects based on an attractive business case evidenced by full-fledged economic and risk profiles, and a full assessment of the potential for development of tailored solutions. In addition, small molecules must show consistent performance over years and across target crops and geographies, and competitive market performance under relevant agronomic conditions with no unacceptable crop penalties. Small molecules must also demonstrate no prohibitive safety, technical or regulatory findings. It is at this stage that the core “package” is defined: optimized product/formulation concepts, and core crops and countries specified. Crop residues must also be sampled. Biologics must have a successful scale-up of the fermentation process with economical cost of goods sold; an identified production site; a second-generation strain identified, if needed; a selected formulation concept; and initiation of pre-submission regulatory meetings and pivotal toxicity studies.

In **Phase 4**, both small molecules and biologics require submission of the global dossier to regulatory authorities in the first key market(s). At this stage, the core formulation concept has been established and classified internally as “free for registration,” meaning it is considered suitable to proceed with regulatory registration. In addition, a technical profile for the new active ingredient has been defined, a launch sub-team is established as part of a global project team, and a product supply strategy is in place.

To enter **Phase 5**, projects must have progressed into the Business Development phase based on the following criteria: product has launched in the first countries, global registration is secured, launch plans are ready, and the product supply plan is in place, as well as a regulatory defense team. Both small molecules and biologics must also have launch plans for the remaining core countries and country extensions, and regulatory defense plans. Launch teams are identified and in place, as needed. Human and environmental safety studies continue to demonstrate no findings that would be prohibitive and jeopardize regulatory approval.



Within Crop Science R&D, different teams, including fully empowered Project Teams and, ultimately, the Crop Protection Franchise Team, ensure the implementation of our sustainability strategy and safety commitments for our portfolio and the R&D pipeline, and guide products through each phase of the product development cycle. The Crop Protection Franchise Team includes representatives of the three key indications from the Strategy and Sustainability team (StS) plus Portfolio Analysis, three representatives of R&D, one representative from Finance, one representative from Product Supply, and one representative of each of the four commercial regions (Crop Protection product teams at L2), along with the participation of the Heads of Regulatory Science (RS), Field Solutions (FS), Small Molecules (SMOL), Insights, Partnerships & Biologics (IBP), and R&D Operations.

In the early phases, **Product Unit leads in Small Molecules** steer our research portfolio through the research phases of development (Phases 0 and 1) towards the systematic exploration of cross-technological mid-to long-term target delivery, and they also determine the right balance of investments. They also coach the Project Teams in selecting candidates who will enter the next phase of development and in allocating resources.

Project Teams, with the ultimate endorsement of the Crop Protection Franchise Team, decide and recommend candidates for promotion to Phases 2 and 3 and for resource commitment, based on their technical and regulatory assessment. They also ensure consistency across our development functions when broader cross-functional alignment is necessary.

The **Crop Protection Franchise Team** steers cross-crop strategies, our research target pipeline and associated resources in continuing development and business phases. Members of the CP Franchise Team implement overarching business strategy across functional teams, serve as arbiter when trade-offs are required across indications, and endorse the decisions coming from Project Teams, especially those related to phase advancements.

Good Laboratory Practice

Good Laboratory Practice (GLP) is a quality system of management controls to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of the data generated during product testing through non-clinical safety tests, from physio-chemical properties through acute to chronic toxicity tests.

GLP principles are mandatory for many studies within Bayer and must be followed by test facilities carrying out studies to be submitted to regulatory authorities to assess the health and environmental safety of chemicals and products. Overarching international safety frameworks, supported by scientific principles, define testing standards used in safety studies and are set by organizations such as the FAO and OECD. To gain product authorization, country-specific safety and data requirements must also be met. These are established by national regulatory agencies, such as the EPA, EFSA and Health Canada. GLP violations can lead to criminal sanctions.

GLP principles direct our test facility organization and study personnel, quality assurance (QA) programs, facilities, apparatus, materials and reagents, test systems, standard operating procedures, reporting of study results, and storage and retention of records and materials. The core principles of GLP are:

- **Responsibility and Liability**
  The test facility management, study personnel, study director and QA specialists are responsible for the structure and completion of the study within the GLP standards. All personnel must be qualified with the appropriate education, training and/or experience.
- **Organization and Study Management**
  Studies must be clearly planned, conducted, reported and monitored from start to finish, with reviews and QA audits throughout the study. Test facilities are regularly inspected by regulatory authorities to ensure their adherence to GLP standards.
- **Documentation and Archives**
  Studies must be clearly and thoroughly documented to ensure each step is retraceable, reliable and transparent, including the recording and resolution of unexpected deviations or planned changes during their conduct. Upon study completion, all raw data for every study is archived for the life of the product for records retention, retrievability and study re-constructability purposes.

Internal Policies and Regulations

As part of our Integrated Management System, Bayer has established a clearly defined structure of binding internal regulations for our company (including legal and regulatory regulations) that describe fundamental principles and framework conditions, standards of conduct, proceedings and methods, as well as the related roles and responsibilities. At the global level, each division and enabling function is responsible for its own management system in accordance with business requirements and the applicable legal and regulatory requirements. In addition, compliance management systems and risk management systems are established accordingly. For example, Bayer has specific internal regulations for managing potential product-related stewardship and compliance incidents, including minimum requirements for the identification, management, and resolution of incidents, ensuring proper handling and minimizing potential adverse consequences and/or impacts to the Bayer Group and relevant stakeholders.

Governance of Highly Hazardous Pesticides

It is important to first clarify the definition of Highly Hazardous Pesticides (HHPs). The FAO/WHO International Code of Conduct on Pesticide Management - endorsed by FAO and WHO Members - provides the broad definition of HHP, which is complemented by the FAO/WHO guidelines on HHP providing the criteria to identify them. As for every crop protection product, this guidance requires a sound real-life risk assessment of the intended uses, which inform mitigation measures. Specific conditions of use are detailed on the product label so that farmers, operators and workers can safely use the product.

As per the FAO website[1]: "**The Guidelines on Highly Hazardous Pesticides** set up *a step-wise process on how to manage HHPs. The process is organized around three key steps:*

1. ***Identification***
   Countries[2] analyze their pesticide registries against eight criteria to identify which products are highly

hazardous. The FAO Pesticide Registration Toolkit provides a spreadsheet tool that can be used to document the HHP identification process.

2. ***Needs and risks assessment***
   Countries assess the actual needs and benefits for these products and their risks to human health and the environment, taking into consideration available alternatives.

3. ***Mitigation options***
   Countries identify risk mitigation measures. The most appropriate mitigation measures may be different for each highly hazardous pesticide and for each condition of use. A key enabling factor in mitigation is the availability of alternatives."

The FAO Pesticide Registration Toolkit provides tools for the evaluation of appropriate risk mitigation measures in the Risk Mitigation module of the toolkit.[29]

While the FAO and WHO have defined criteria for identifying HHPs, they have never published a global list. Instead, national authorities are expected to identify HHPs using these criteria.

The HHPs in Bayer's portfolio are managed based on a clear, globally consistent applied approach, grounded in the FAO and WHO 'Guidelines on Highly Hazardous Pesticides.'

In many countries, our products are considered an important part of the farmers' toolbox, especially in cases where they have no/very few other options to produce sufficient food, feed or fiber under their specific climatic, technical, agronomical or biological realities. We understand this need and consider that it should be addressed without compromising safety. Our sound risk assessments and mitigation measures enable farmers to use all our products safely as per their label prescription, whether they are defined as HHPs or not. We do this by looking at real-world situations, considering regional differences in pest or disease pressure, as well as local cropping systems, personal protective equipment (PPE) requirements and application technologies.

Our stewardship efforts support the safe use of our products and can include safe use training, specific local stewardship programs such as drone application or container management, and collaborations with industry partners such as CropLife International to build local knowledge and capacity for sustainable pesticide management. The "Sustainable Pesticide Management Framework" (SPMF) is currently CropLife International's most comprehensive program. It helps countries to reduce their reliance on HHPs (based on proper risk assessments), to increase innovations in these markets and to make them available to farmers, and to propel responsible use with effective in-country stewardship.

With this approach we contribute to the international agreement on HHP management adopted in 2023 (Target A7 of the new Global Framework on Chemicals of UN) that states that "by 2035, stakeholders have taken effective measures to phase out highly hazardous pesticides in agriculture where the risks have not been managed and where safer and affordable alternatives are available, and to promote transition to and make available those alternatives."[30] [31]

Furthermore, Bayer stopped selling WHO Class 1 crop protection products (FAO HHP criterion #1) in 2012, and we comply with the relevant applicable requirements issued in the Rotterdam Convention and Stockholm Convention as well as in the Montreal Protocol. Today, HHP-related sales account for a low single-digit percentage of the sales of the Bayer Group.

[1] Addressing Highly Hazardous Pesticides (HHPs) | Pest and Pesticide Management | Food and Agriculture Organization of the United Nations | IPM and Pesticide Risk Reduction | Food and Agriculture Organization of the United Nations

[2] National Competent Authorities
https://www.fao.org/pesticide-registration-toolkit/special-topics/highly-hazardous-pesticides-hhp/identification-of-hhps/en/

10. Conclusion

Crop protection remains essential to global food security and to helping farmers manage growing agronomic pressures in a changing world. At the same time, its continued role depends on trust, transparency, credible science and responsible use. By adopting the latest advances in data science to transform how crop protection products are discovered, designed, evaluated and stewarded, Bayer aims to advance solutions designed to be more precise, effective and better aligned with evolving stakeholder expectations. Rigorous safety standards, stewardship to support safe use, strong governance, environmental impact reduction and transparency are central to our approach to crop protection innovation and more sustainable agriculture. Throughout this report, we have addressed questions that often arise related to the development of these products. Bayer strives to meet expectations for transparency from investors and other stakeholders and appreciates the opportunity to engage in productive dialogue. We hope this report can deepen the quality of our engagement and improve mutual understanding.

For additional information, we invite you to read our reports:

Bayer 2025 Annual Report

Bayer 2025 Impact Report

Sustainability Council Report

Other In-Depth Reports

Endnotes

[1] https://www.nifa.usda.gov/about-nifa/blogs/researchers-helping-protect-crops-pests
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[31] https://www.unep.org/global-framework-chemicals