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Toward Innovative, Sustainable Solutions That Meet Agriculture's Challenges and Societal Expectations: Bayer's Approach for the Development and Use of Crop Protection Products

Science for a better life

BAYER

Report Updates

The report, originally published in December 2023, was updated in March 2024 to include updated progress metrics on Bayer's Crop Protection Impact Reduction Targets (CP EIR) and training programs. Furthermore, this report has undergone additional updates in February 2025 to reflect recent business developments on pages 4, 6, 14, 22, and 38.

Executive *Summary*

Report Goal

Global agriculture and food systems are facing major challenges, including climate change, water scarcity, population growth and increasing demands for feedstocks to produce animal-based proteins, as well as biobased fuels, such as ethanol and diesel. Geopolitical instability is another risk factor that undermines food security around the world. In this context, growers continue to fight weeds, pests and diseases that are increasingly resistant to established crop protection products. Yet, the pressure is not only to preserve yields, but to do so while meeting changing societal expectations about sustainable agriculture. At Bayer, we believe we can achieve that by enabling farmers to grow more with fewer, better inputs through innovation in seeds and traits, crop protection, digital farming technology, and new business models.

Bayer offers growers a diverse toolbox that spans chemical, biological and biotechnology products, coupled with data-driven digital solutions. To meet our commitment to innovation, our robust R&D function is focused on the discovery of new solutions. Similar to other industries, our innovation process has evolved to incorporate advances in data science, artificial intelligence and predictive analytics. This report explores how our development of crop protection products (also known as pesticides) has been changing to support our goal of creating the most efficacious active ingredients that do not pose a risk to human health or an unacceptable risk to the environment when used according to label instructions. We illustrate how Bayer's R&D organization is reimagining the discovery and design of crop protection solutions, taking into consideration not only safety and efficacy criteria, but also our crop protection environmental impact reduction (CP EIR) commitment, product development costs and registrability. The report also covers the various internal and external processes and regulations that ensure that our products meet the highest standards for human and environmental safety.

The Executive Summary and the full report will cover:

- // Risk assessment of crop protection products
- // The evolution of the discovery process at Bayer
  - New and selective Modes of Action
  - Profile-based design of new molecules
  - Biologicals
  - Formulations
  - Open innovation, partnerships and collaborations
- // Safety evaluations
  - Human safety
  - Environmental safety
  - Internal safety standards
  - Crop Protection Environmental Impact Reduction
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  - Global landscape of regulatory frameworks
  - Regulation of biologicals
  - Dossier compilation and submissions
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  - In-licensed active ingredients and formulated products
- // Product Stewardship
  - Stewardship during product development
  - Compliance and quality during production
  - Monitoring and portfolio screening
  - Incidents management
  - Stewardship during commercialization
- // Anti-Counterfeit
  - Safety Seal

// Governance
  - Sustainability and stewardship governance internal committees
  - Crop protection R&D governance process and phases
  - Good Laboratory Practice (GLP)
  - Internal policies and regulations
  - Governance of Highly Hazardous Pesticides (HHPs)

// Bayer's transparency commitments
  - Corporate transparency efforts
  - External advisory bodies
  - Engagement with stakeholders

Risk Assessment of Crop Protection Products

Safety guides everything we do at Bayer. Our safety standards for chemical and biological crop protection products ensure that these products are safe for humans – from operators to consumers – and cause no undue harm to the environment when used according to label instructions. Our products meet regulatory requirements in all countries where they are registered and we apply additional safety measures aligned with the standards and guidelines of the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD). The OECD provides very thorough, harmonized guidelines for assessing the potential effects of chemicals on human health and the environment, meaning that studies and test results generated by companies in compliance with the OECD Test Guidelines and OECD Principles of Good Laboratory Practice are accepted in all OECD countries.[1] We market 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. We also follow closely scientific approaches and risk assessment concepts from reference regulatory systems around the world, including the U.S., Canada, Brazil, EU, Australia, New Zealand, Japan and China. In low and middle-income countries (LMIC) that do not have sufficient capacity to fully evaluate product safety, we raise the safety bar by following our internal guidelines on top of local regulations, while considering the unique needs of growers in those markets. For products already in the market, Bayer conducts regular portfolio screenings to determine if the product can continue to be used safely under local conditions. If needed, we derive and implement additional stewardship measures to mitigate risk and to safeguard the effective and safe use of our products. When it comes to crop protection products, it is important to understand that their intended purpose is to be toxic to pests, weeds and plant diseases. Their inherent toxicity to target organisms represents their hazard. 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, etc.).

The Evolution of the Discovery Process at Bayer

Bayer's R&D process is constantly evolving as it incorporates breakthroughs in crop protection technology, data generation and analytics, artificial intelligence, and computational sciences that make it possible to process vast amounts of information at unprecedented speeds. Thanks to these scientific advances that were not available even a decade ago, Bayer is transforming its approach to R&D to design entirely new solutions that meet the current and future expectations of society and farmers.[2] We call this approach CropKey – our initiative to transform crop protection chemistry by reaching new levels in precision, safety, sustainability and, of course, effectiveness. CropKey discovery is based on two major strategic pillars: target-based discovery and profile-driven design of new molecules.

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

All living organisms are made up of proteins – including the pests that damage crops (weeds, insect pests, and diseases, such as fungi). If we can change the activity of a certain protein or inhibit it in the organism of a pest, we can stop the pest from attacking the crop. In our CropKey approach, we think of these proteins as locks. Our challenge is to identify the perfect lock: one that is essential to the target organism – i.e., a completely unique protein that the pest cannot survive without that it will react to when the right key is inserted into it. The CropKey approach uses computational target discovery based on systems biology and omics, proprietary algorithms, machine learning, high-end modelling tools and artificial intelligence, and early assessment of safety. Taking advantage of massive amounts of data and machine learning, we can accelerate and improve through increased accuracy the identification of these target proteins (or locks). This approach is similar to the development of highly targeted pharmacological therapeutics in human health.

An important element of our CropKey approach includes early human and environmental safety assays as a guiding dimension for our design of new molecules. Research projects do not continue until a thorough early target safety assessment has been passed successfully. As projects progress, safety studies continue, generating safety data using both computer-based models and laboratory tools, in parallel with the collection of efficacy data. As a result, we understand the safety aspects of molecules early on and guide projects to create highly innovative products with an outstanding safety profile for humans and the environment.

Profile-Based Design of New Molecules

For many years, discovering crop protection products required screening hundreds of thousands of molecules to identify promising ones. Today, our CropKey approach to innovation is quite different: rather than screening **existing** molecules and selecting promising leads, we are focused on designing the next generation of **new** crop protection molecules with extremely specific properties and safety profiles that will meet both agronomic needs (including integrated pest management (IPM)) and societal expectations for human safety and environmental protection. We consider many factors, such as indication, mode of action, crop segment, efficacy, feasibility of synthesis and production, and, most importantly – safety for humans and the environment. The new molecules are designed to minimize the potential for off-target effects to non-target organisms in the environment, thus protecting biodiversity. The CropKey approach also leverages models early in the development phase to determine the environmental impact of molecules to ensure the solution has sustainable properties, e.g., it degrades rapidly. Finally, CropKey uses computational tools and artificial intelligence to create synthesis routes for the chemistry to anticipate production costs. CropKey allows us to fill our pipeline with solutions that act with high specificity for their targets(s) and meet safety, regulatory and societal requirements.

Biologicals

In addition to crop protection products that use conventional synthetic molecules, Bayer's portfolio includes biologicals (e.g., biopesticides, biostimulants, etc.). Agricultural biologicals are crop production and protection tools that are largely created from living organisms, derived from natural materials, contain them, or use naturally occurring processes. Biologicals complement synthetic crop protection tools as part of integrated crop management. They are an important part of our commitment to encourage diversity in modern agricultural practices by providing a broad range of solutions to support farmers.

Formulations

Active substances (synthetic or biological) for controlling weeds, diseases, insect pests or any other biologically active substances cannot be applied in pure form and always need to be combined with various ingredients (the formulation) into a final product, which guarantees that small amounts of active substances can be evenly distributed over large areas of fields or on lots of seeds. Formulation technology is a multidisciplinary field of science, including bio-delivery aspects in soil, plants and pest species; chemistry; colloid science; process technology; etc. Data science plays an increasingly relevant role in improving data analytics, moving from mostly empirical approaches in designing formulation to a more data-driven, model-based approach. Today, the design of new formulations takes into consideration product safety and tightening regulatory standards. A recent innovation example is the replacement of durable polymer-based microcapsules or polymeric seed coatings with biodegradable solutions.

Open Innovation, Partnerships and Collaborations

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 to offer farmers more solutions in our portfolio. Read more on page 15.

Safety Evaluations

Human Safety

Safety is our priority when it comes to crop protection. During the development process, we pursue only project ideas considered safe to humans when used according to label instructions. We conduct two main types of risk assessments to account for the most significant routes of human exposure: dietary and operator exposure.

The foundation for human risk assessments is the evaluation of the hazard by numerous studies, including:

// Toxicological studies with active ingredient substances to determine adverse effects on all major organs (liver, brain, thyroid, reproductive organs, nervous system, etc.)

// Carcinogenicity, mutagenicity, reproductive toxicity and endocrine disruption
// Absorption, distribution, metabolism and excretion (ADME) pathways
// The maximum dose at which No Adverse Effects (NOAEL) were observed in mammalian species

For dietary risk assessments, every product is tested by applying the pesticide to crops following label instructions and analyzing for residues in food, animal feed and animal products. In addition, we look at potential residues in surface and groundwater that could be used for drinking water. The total exposure is estimated by using consumption data, which best represents the country or region being assessed and their multiple potential consumers. We then compare the estimated total exposure to the safe level determined from toxicity studies, which are vetted by regulatory authorities, and then we add additional safety factors to ensure that consumer consumption stays significantly below the maximum amount of pesticide residue they could be exposed to in their diet.

For operator safety evaluation (e.g., safety of farmers applying a plant protection product), Bayer follows the FAO code of conduct[3] and its rationale to determine a risk for operators applying a plant protection product. Based on this guidance, we assess both hazard and exposure using conservative and realistic information to reliably determine potential operator risk. We then use risk management tools to ensure operator safety. The exposure of an operator applying a product is evaluated mostly by using exposure models that reflect agronomic practices in the respective country or region in scope. We then compare the operator exposure to the Acceptable Operator Exposure Level (AOEL), which is set at a minimum 100 times lower than the dose that produces no effects in animals (NOAEL) in the relevant safety study.[4]

Environmental Safety

Environmental safety assessments for our crop protection products are conducted by groups of experts trained in the fields of ecotoxicology and environmental chemistry. Critical compound-specific parameters, like persistence, mobility and bioaccumulation of a molecule, are decisive for the decision to develop and register a new product. After the development decision, testing the potential impact of a crop protection product on non-target organisms is especially important, as one of our key goals is to protect these organisms and the habitats they rely on. An extensive battery of studies is performed to characterize exposure to the active ingredient and its relevant environmental metabolites in aquatic and terrestrial environments. The active ingredient and the identified metabolites are subsequently tested in standardized ecotoxicological tests with several different species. For aquatic, these include different non-target organisms that comprise an aquatic food web, such as primary producers (e.g., algae and plants), primary consumers (invertebrates) and secondary consumers (e.g., fish). For terrestrial, there are acute and chronic studies for avian species, wild mammals, bees, beneficial insects, soil macro- and micro-organisms (e.g., earthworms, soil mites), and non-target plants. The results from these studies are used to characterize the range of realistic environmental exposures in aquatic and terrestrial environments. By combining the results from effect and exposure studies, we can assess the potential for risk to non-target organisms. If the predicted environmental concentrations show a potential risk, mitigation measures are required to reduce exposure and achieve acceptable risk. For example, a simple but effective mitigation measure to reduce the exposure of aquatic organisms is to require a no-spray buffer zone between the edge of the field and an aquatic waterbody.

For both human and environmental safety, we confirm the efficacy of mitigation measures with experimental studies and modelling, which authorities evaluate during the product registration process. In regions with well-developed programs to regulate crop protection products, our safety assessments are based on the specific regional or national safety standards. In LMICs, we make sure that our products meet the safety standards of the majority of leading regulatory regions and countries, plus the local regulations, and assess if the products can be safely used under local conditions.

Internal Safety Standards

Since 2021, we have shared our crop protection operator safety standards on our website. These voluntary standards reflect the guidelines and standards of international organizations, such as the FAO, the WHO and the OECD, as well as those of reference regulatory authorities around the world. For more, see page 20.

Crop Protection Environmental Impact Reduction

The advances in our R&D approach over the past decades are one of the enabling factors that helps Bayer meet its commitment to reduce the environmental impact of our global crop protection portfolio per hectare by 30% by 2030.[5] We are proud to be the only company within our industry to make such a measurable commitment across the entire crop protection portfolio with publicly available models. We have adopted a scientific, data-driven approach: Crop Protection Environmental Impact Reduction (CP EIR), which is based on two independently developed external models. Through CP EIR, we are aiming to reduce the environmental impact of crop protection while maintaining or even increasing the benefits of crop protection products in securing yields. We have identified a number of different technologies that can be deployed to help progress towards our commitment. These technologies fall into four main categories: improving the chemistry of crop protection products, reducing the amount of crop protection products needed per hectare, reducing crop protection emissions into the surrounding environment, and ensuring safe, responsible use of crop protection products. By designing the most efficacious chemical molecules with the least impact on the environment, we can meet our CP EIR targets. More information on CP EIR may be found on page 22 of this report.

Regulation of Crop Protection Products

The Global Landscape of Regulatory Frameworks

Crop protection products are thoroughly regulated to ensure they are safe when used according to label instructions. Before plant protection products can enter the market and be used by farmers, they undergo country-dependent strict evaluations and approval by local authorities to ensure that they may be used safely by humans under local conditions and pose no unacceptable harm to the environment. For this purpose, we conduct hundreds of metabolism, residue, toxicological, eco-toxicological, environmental, physio-chemical and efficacy studies.

Dossier Compilation and Submissions

All the scientific data and results from the studies are compiled in a specific registration dossier meeting the requirements of each country, containing the active ingredient and/or the formulated product composition, individual study reports, summaries, and risk assessments, including proposals for risk mitigation. These dossiers, compliant with the applicable regulations, are submitted to regulatory authorities around the world who review the submitted data and risk assessments, and grant or deny approval of active substances and products based on their specific regulations and conclusions. This entire process, including identification, data generation, submission, review until approval and trade enablement, can take as much as 10-15 years.

Regulation of Biologicals

Bayer applies a high level of rigor to testing the safety of crop protection products being biologicals or synthetical products since ‘natural’ does not always equal ‘safe.’ Bayer assesses biologicals for risks to humans and the environment and submits required data to regulatory agencies, including studies that address the composition, efficacy, toxicity, degradation and other characteristics of these products.[6]

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 on 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. Bayer’s crop protection products are labelled in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Codes and the and the FAO Guideline on Good Labelling Practice for pesticides; whenever possible, we use this reference to advocate for label improvements when local regulations deviate from that.

In-Licensing Active Ingredients and Formulated Products

For the in-licensing of crop protection products, Bayer complies with regulatory standards in targeted countries. In LMICs with less comprehensive regulatory systems, Bayer applies its own standards that are aligned with the standards and guidelines of the FAO, the WHO and the OECD. These standards are applied to the in-licensing of more than 100 competitor active ingredients that have already received regulatory approval.

Product Stewardship

At Bayer, we commit to the pesticide industry principles laid out in the FAO-WHO Code of Conduct on Pesticide Management. We 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 (see more here: Group Regulation on Product Stewardship Commitment, Principles and Key Requirements and our Report on Sustainable Pesticide Management in line with the FAO-WHO Code). Besides diligent product testing in R&D, as outlined earlier, we apply comprehensive stewardship processes and programs during development, production and commercialization.

Stewardship During Development

We follow strict stewardship guidelines for product use during development trials, which cover product testing according to sound and recognized scientific methods, the public sharing of test results according to the Bayer Transparency Initiative, and the safe handling of new molecules and formulations. In addition, where required, we obtain country-specific import approvals and authorizations for non-registered products or materials and ensure that these products or materials don't enter the food or feed chain. All product testing is performed by trained personnel and the crops and harvests from trials of non-registered products are destroyed, unless other disposition is allowed by regulations and/or laws. It is also during the development phase of an active ingredient or formulated product that commercial stewardship plans are defined, so that they are in place at the time of product launch. Stewardship measures are predicated depending upon the product's risk profile, i.e., the specific risks that need to be mitigated, as well as consideration of local agronomic conditions.[7]

Compliance and Quality During Production

Bayer safeguards that products are produced and commercialized in compliance with the registered quality via stringent internal processes. A specifically tailored SAP-based platform forwards detailed information on registered product specifications and compositions to the production sites. At the production sites, only those product recipes are cleared, which are fully aligned with the respective registration in the country of destination. Correct product manufacturing and shipping is continuously monitored via the "RegPrime dashboard," which combines information from internal regulatory and business IT systems.

Monitoring and Portfolio Screening

For products on the market, we conduct regular reviews of our portfolio, prioritized by critical parameters that consider actual, local working and agronomic conditions. Our existing portfolio contains more than 300,000 uses, for which we are also committed to continual screening when safety standards evolve. Systematic checks follow a stepwise approach, starting with substances that have lower toxicological thresholds and high exposure. Over time, we have continuously reduced the overall risk of our portfolio by phasing out old compounds and introducing innovations with a superior risk-benefit ratio.

Find out more on our Stewardship commitment and our activities along the value chain here:

Sustainable Pesticide Management at Bayer

Bayer Crop Science Sustainability Progress Report, September 2023

External Adverse Incident Management

We keep track of product-related incidents globally via our internal management system and the "CAIRnew" software, a solution for reporting, managing, documenting, and analyzing incidents, complaints and product recalls. Systems and processes, including complaint management, are implemented and monitored regularly to review marketing and business operations to assure the highest quality of Bayer products and services, as well as to safeguard people and the environment. 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. Our internal regulation on External Adverse Incident Management for Crop Protection Products provides clear guidance on handling incidents in an orderly fashion. Steps to mitigate risks can vary from increased training efforts, change of formulation, revised application recommendations, use limitations to product withdrawal.

Stewardship During Commercialization

For products in the market, stewardship maximizes product potential and minimizes risk. It includes sustainable Integrated Weed Management (IWM), Integrated Pest Management (IPM) and Integrated Disease Management (IDM) programs and extensive trainings in compliance with the FAO to ensure safe product use throughout their life cycle, from spraying to safe disposal of empty containers or waste in accordance with local regulations. In 2023, for example, we reached more than 5.3 million people with safe use training, including around 4 million smallholder farmers.[8]

Beyond training, we also build local capacity in line with and beyond industry responsibilities laid out in the FAO-WHO certificates of composition (CoC). As many topics relate to the industry, but not Bayer alone, we partner via our industry association CropLife International, and collaborate with national authorities and other stakeholders. This includes a broad range of topics, from science-based risk assessments and mitigation to broader knowledge sharing with farmers and applicators, as well as effective incident management, amongst other practices. We also support the certification of professional spray service providers, best agricultural management practices for resistance, integrated pest and weed management, and effective structures for empty containers, as well as obsolete stocks management.

Anti-Counterfeit

Authentic crop protection products and seed varieties undergo intensive testing and strict regulatory evaluation before being placed on the market. All with the objective of offering safe and high-quality products that contribute towards sustainable agriculture. 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 does not meet the regulatory standards. Such illegal products aren't just of questionable provenance and efficacy, they 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 the efforts to improve the livelihood of farmers, especially that of smallholders.

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. The implementation of the Bayer Crop Science Anti-Counterfeit strategy and the execution of it mainly involves preventive activities that are realized through a global network comprising all countries where we do business. Close cooperation with governmental agencies, law enforcement and non-governmental organizations, as well as close engagement with all relevant intermediaries, other industries and associations, are key elements of Bayer´s Anti-Counterfeit approach.

Safety Seal

At farm level, we do not stop at raising awareness. With our innovative Bayer Safety Seal, we are the first producer of crop protection products and seeds to enable farmers to reliably authenticate our original products. Read more at Counterfeits in Agriculture | Bayer Global.

Governance

Bayer has strict, distinct institutionalized governance processes that supervise the development of new products and are critical to fulfilling our corporate sustainability commitments. A number of committees provide oversight of our products throughout our products' life cycle, and accountability is assumed at the highest levels of company management.

Sustainability and Stewardship Governance Internal Committees

At senior leadership level, the Executive Leadership Team (ELT) License to Operate (LtO) sub-Committee, consisting of leaders in Strategy & Sustainability, R&D, Product Supply, Legal, Communications, Finance, and Commercial Operations, holds ultimate responsibility for global product safety. The Regulatory LtO & Product Safety Committee reports into the ELT LtO sub-Committee and steers regulatory procedures and regulatory or policy issues that impact Crop Science products throughout the life cycle, oversees product stewardship plans and incidents, provides oversight to guide addressing a product's potential impact to Bayer's product safety and sustainability commitments, and defines the structure of topic-related committees and processes with the final step of the process, reporting to the Crop Science representative of Bayer's Board of Management.

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, which is discovery of research targets and ending with Phase 5 for business development. The complete list of phases can be found on page 31. Within the R&D organization, several committees govern the process of discovery and product development. The Research Portfolio Committee, the Development Project Committee and the Strategic Portfolio Committee determine priorities and research allocation; validate compliance with regulatory standards; weigh in on crop strategies; decide on project phase advancement or discontinuation; coordinate R&D pipeline reporting, both internally and externally; and escalate topics, as appropriate, to the Regulatory LtO & Product Safety Committee and the ELT LtO sub-Committee.

Good Laboratory Practices

At Bayer, we drive innovation using Good Laboratory Practices (GLP). GLP principles are enshrined in laws and regulations that outline how safety studies are planned, performed, monitored, recorded, reported and archived to maintain quality and integrity of study data that support regulated products. GLP principles are firmly anchored in our binding group-wide "Bayer Societal Engagement (BASE) Principles," especially addressing transparency (i.e., publication and collaboration). For each new crop protection product, more than 150 different safety studies conducted according to GLP are required to evaluate and demonstrate safety. GLP violations can lead to criminal sanctions in some jurisdictions, such as the United States. Some regulatory authorities, such as the United States Environmental Protection Agency (EPA), conduct independent inspections on companies' processes, test facilities and studies to confirm compliance with GLP standards. In the EU, member countries are required to designate the authorities responsible for GLP inspections in their territory, who carry out independent audits.

Internal Policies and Regulations

Bayer has established a clearly defined structure of binding internal regulations that describe fundamental principles and framework conditions, standards of conduct, proceedings and methods, as well as the related roles and responsibilities. The crop protection product development process is also governed by these bounding policies.

Governance of Highly Hazardous Pesticides

The FAO and the WHO have defined criteria to identify products and substances calling them Highly Hazardous Pesticides (HHP). The only few HHPs – as defined by WHO/FAO – we have today in our portfolio are managed based on a clear, globally consistently applied approach that is grounded in the FAO-WHO 'Guidelines on Highly Hazardous Pesticides.'

Bayer's Transparency Commitments

We have come to recognize that there is an information gap about food production and the technologies used to produce food, including crop protection products (i.e., pesticides). As a result, Bayer has expanded its transparency commitments to engage in more conversations about science and food production with internal and external stakeholders.

Trust and Transparency

We have formalized our continued dialogue by establishing a transparency-focused platform, which enables interested consumers and the scientific community to access summarized test results and evaluations on the human and environmental safety of active substances used in our crop protection products.

External Advisory Bodies

We seek guidance and perspective on our sustainability efforts from two external advisory bodies. The first is the Sustainability Council, which advises the Bayer Board of Management and examines Bayer's progress on its sustainability targets. The second is the Bioethics Council, which is a diverse group of external independent thought leaders in the field of bioethics. Additionally, we solicit reviews by external panels of experts on specific initiatives. Read more on page 36.

Engagement with Stakeholders

We follow the Bayer Societal Engagement principles that are publicly available as a Board of Management regulation and establishes how we interact globally with stakeholders, such as members of the media, customers, consumers, scientists, critics, stockholders and more. We strive to have open and transparent communication, even during difficult or critical conversations.

Conclusion

We recognize that crop protection products are a topic of interest and concern for our stakeholders and have created this report in the spirit of shedding additional light on how we continue to improve the development of these products.

[1] https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_72d77764-en
[2] https://bayer.com/en/agriculture/sustainability-stakeholder-outreach
[3] https://www.who.int/publications/i/item/9789251085493
[4] https://www.bayer.com/sites/default/files/210323_Bayer-Operator_Safety_Standard-FINAL_2.pdf

[5] https://www.bayer.com/sites/default/files/2024-03/bayer-sustainability-report-2023.pdf
[6] https://www.epa.gov/ingredients-used-pesticide-products/what-are-biopesticides#:~:text=Biopesticides%20are%20certain%20types%20of,applications%20and%20are%20considered%20biopesticides
[7] https://www.bayer.com/sites/default/files/2022-11/RZ_Stewardship_221108.pdf
[8] https://www.bayer.com/sites/default/files/2024-03/bayer-sustainability-report-2023.pdf

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1. Introduction

According to the Food and Agriculture Organization of the United Nations (FAO), every year, 20-40% of global food production is lost to pests. Plant diseases cost the global economy around $220 billion annually, and invasive insects cost around $70 billion.[9] FAO estimates that losses caused by weeds may be between 5-10% in the agriculture of developed countries and up to 20-30% in developing countries.[10]

It takes a diverse portfolio of agricultural tools to address these threats to our food supply and Bayer has been a leading supplier of solutions – from seeds and traits to chemical, biological and digital – thanks to our robust R&D function. Chemical and biological crop protection products (i.e., pesticides) have been a tool farmers have used for decades. By definition, pesticides are designed to attack weeds, pests or plant diseases, which makes it particularly important to ensure that these products have no effect on human health and only minimum side effects on the environment. This report intends to show how we achieve that through stringent risk assessment, a revamped discovery process, rigorous governance, internal safety standards, regulatory compliance, and stewardship throughout the entire product cycle. Recognizing increased stakeholder interest and fulfilling our commitment to transparency and engagement, this report provides an overview of Bayer's safety, economic and sustainability criteria, which guide the crop protection product development cycle.

Risk Assessment of Crop Protection Products

Before any of our crop protection products are brought to market, they must be approved as per the applicable regulation requirements of the respective countries. To assess the safety of our products, secure these approvals and to align with the most advanced risk-based approaches to product safety, we apply our internal safety standards that follow risk assessment concepts and scientific approaches developed by mature regulatory authorities around the world, such as the U.S., Canada, Brazil, EU, Australia, New Zealand, Japan and China, as well as international organization guidelines and standards put forward by the FAO Code of Conduct on Pesticide Management, the World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD).

Our safety standards are the evaluation criteria we apply to ensure that our crop protection products can be used without risks to human health and cause no undue harm to the environment when following label instructions.

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, etc.). 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 we always follow local regulatory requirements when bringing a product to the market, in geographies that do not have sufficient capacity to fully evaluate product safety, we raise the bar by applying our internal safety standards to evaluate risk, which are consistently higher than local regulations. This tends to be the case particularly in low and middle-income countries (LMICs). Therefore, we follow a risk-based approach (with risk being a function of hazard times exposure) and also consider local agronomic use conditions. For example, this includes application techniques that are uncommon in Europe or the U.S., but are widespread in LMICs, such as handheld application of plant protection products in a dense crop scenario or treatment of seeds using a concrete mixer. For these scenarios, we have developed specific exposure models that consider actual use conditions, which are then considered in the risk assessment of new products. If the outcome of these risk assessments reveals an unacceptable risk for operators, we implement mitigation measures to further limit the exposure, voluntarily restrict product use to safe use scenarios or decide to stop the project. As part of our commitment to ensure globally consistent safety standards for our crop protection products, we published the Bayer Safety Standard for Operator Safety, which we apply in the risk assessment of our crop protection products. Our operator safety standards are publicly available and continuously evolve based on the latest scientific knowledge. We also invite internationally respected

researchers from academia and other expert groups to review our standard. In 2021, for example, we held a review panel with eight external scientists.[11]

An essential part of our safety standard is the availability of sufficient scientific data. To ensure consistent data quality, the OECD provides data requirements for pesticide approval processes, including the preparation of complete dossiers for crop protection products and their active ingredients in support of regulatory decisions in OECD countries. This includes the results of all test and study reports and other relevant information submitted by the company and other interested parties. The data need to be made available to facilitate review by regulatory authorities as a basis for making a decision on approval of individual active ingredients, the registration of crop protection products, the establishment of a maximum residue limit, or the determination of an import tolerance, as appropriate. By acknowledging this OECD reference, we have a proxy for high and consistent data quality. As the regulatory systems vary from one OECD country to another, we follow country regulations and apply our internal risk evaluation on top of the OECD data requirements and ensure access to relevant data before we place a new product in the market. We market 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.

While the commitments described above relate to risk-based approaches, our commitment to not market WHO Class 1 acute toxic formulations relates to a hazard classification. 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. Also, we check our actual crop protection sales portfolio once per quarter to assure adherence to these commitments.

For products on the market, our internal standards and commitment to product stewardship drive continuing risk assessment to define label instructions for safe use to sustain registration. We also screen our product portfolio to check safe use under actual, local working and agronomic conditions. We maximize products' potential while minimizing risk, implementing specific measures to ensure full regulatory compliance.

2. Evolution of the R&D Process at Bayer

As the company with a strong commitment to innovation and the largest R&D budget in the agriculture industry to support it, Bayer is transforming its crop protection innovation approach by leveraging advances in crop protection technology, data generation and analytics, artificial intelligence, and computational sciences. The ability to process vast amounts of information at unprecedented speeds has enabled a discovery approach capable of yielding new molecules that reach unprecedented levels in precision, safety, effectiveness and sustainability.

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

In the recent past, our crop protection R&D efforts relied, in large part, on advancing incremental innovations to existing modes of action (MoAs) – essentially creating new, improved versions of current chemistry.

What is Mode of Action (MoA) in Crop Protection Chemicals?

In general, MoA describes a series of key events that take place at the cellular or molecular level after a living organism is exposed to a substance. These events can lead to functional or anatomical change in the cells. Learn more here.

Today, our innovation strategy is very different. Rather than *screening and selecting* molecular leads in the hunt for the next promising MoA, we are focused instead on *designing* the next crop protection molecules with very specific performance and safety profiles that will meet both the agronomic needs of farmers and societal expectations for human and environmental safety. This is our CropKey approach – a radically new approach to discovering “locks” that change or inhibit the action of a protein necessary to a weed, insect or disease pest – and one that we believe will lead to groundbreaking innovations in crop protection.

CropKey employs recent breakthroughs in life sciences and digital technologies (e.g., artificial intelligence and machine learning) to unlock new areas for research and to open doors for unprecedented chemistry-based solutions. Digital tools, data science and analytics are helping us find, design and evaluate molecules more quickly for efficacy and safety. At the same time, we have transformed our candidate screening tools to support better and faster evaluation and decision-making. Advanced automation supports biological screening work, and we’re employing digital phenotyping tools – such as optical, hyperspectral imaging, triangulation – to help us find new research starting points.

So far, our CropKey approach has delivered more than 30 new molecular targets under investigation. More than 10 newly validated targets have been moved to the early research stage, and more than five novel MoAs and screening technologies are in advanced research evaluation. The first representatives 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 to 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 compounds. We announced a new collaboration with Oerth Bio in 2023; its unique technology seeks to unlock natural processes in plants to protect crops from disease and pests while leaving all other species and the biome unaffected. 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.

Profile-Based Design of New Molecules

For decades, our discovery strategy was based on high-throughput screening, with a goal of selecting promising molecules out of hundreds of thousands of candidates. We are now moving beyond traditional discovery pathways and are applying new technologies powered by artificial intelligence and computational modeling to design new molecules with desirable performance and safety profiles. Rather than screening **existing** molecules to identify those most promising, we are now able to design **new** molecules with extremely specific performance and safety profiles that will meet both agronomic needs and societal expectations for human safety and environmental protection. In this approach, our chemists are working alongside our data scientists using digital models, massive data sets and revolutionary new digital technologies. Our goal is to deliver groundbreaking, highly effective and competitive crop protection compounds with favorable profiles, further improving safety and sustainability, reducing potential environmental risk and meeting the future needs of farmers. To achieve this, we are refocusing our small molecule work, moving to profile-based design versus screening and selection. We have also revamped our target strategy to focus on discovery of new resistance-breaking MoAs and have deprioritized “me-too” chemistry and research targets with narrow use cases.

In breaking with traditional R&D paradigms, we are:

- // Going beyond conventional approaches, looking for entirely new MoAs and methods, as well as new formulations and application systems
- // Going beyond benchmarks to elevate safety and sustainability, ensuring 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)
- // Going beyond traditional innovation pathways, not by incremental improvements to old chemistry, but trying to unlock new biological and chemical solutions by leveraging data science and digital technologies
- // Going beyond Bayer, expanding opportunities and knowledge, and accelerating innovation through partnerships and collaborations

All the while, we strive to deepen our molecular and mechanistic understanding of complex biological systems to seek opportunities for integrating new technologies into sustainable crop protection solutions. This allows for a more targeted and far-reaching optimization of our crop protection chemistries for the future. As a result, we understand the efficacy and safety aspects of our projects early on and guide projects to create highly innovative products with an outstanding safety profile for humans and the environment.

Biologicals

Agricultural biologicals are crop production and protection tools that are largely 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 crop nutrition and complement our portfolio of products.

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. Ag biologicals are an important part of our commitment to encourage diversity in modern agricultural practices by providing a broad range of solutions to support farmers. Our collection of more than 125,000 microbial strains allows us to use genetic diversity to develop new and beneficial products for farmers all over the world.

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 in 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 to proceed because of our extensive global R&D and commercial infrastructure. Also, our expertise and experience across every aspect of agricultural inputs delivers effective integration of biologicals into fully tailored packages combining other technologies, practices and digital tools.

Formulations

Formulation technology involves usage of different adjuvants (surfactants, emulsifying agents, solvents, stabilizers, defoamers, etc.) to provide efficacious, effective and safe products. Formulation technology improves storage stability, safe handling and effective application and needs to ensure that a product can be registered and produced at the lowest cost and best quality.

Changes in application technologies, grower expectations for efficacious solutions, properties of the active ingredients, including new modalities such as biologics, as well as increasing regulatory expectations for safe and sustainable solutions, are major drivers for innovation in the formulation space. We are focusing on innovating formulations to be applied via existing and future crop protection tools to reduce the amount of active ingredient required and applied and mitigate environmental risk. This aligns with Bayer’s commitment to reducing environmental impact of crop protection by 30% by 2030. Evolving trends in the application space are informing our innovation priorities, e.g., the rapid adoption of drone applications in recent years – particularly in Asia – replacing labor-intensive knapsack sprayer application. Increasing farm sizes in other parts of the world are also driving the need for increasing spray efficiency, i.e., by reducing spray volumes. Therefore, we focus on testing our existing crop protection products for precision and low-volume application systems, including Very-Low Volume (VLV) applications by aerial systems, such as drones, and consider VLV features in the design of new formulations.

Tighter regulations of chemicals based on hazard criteria are impacting the availability of co-formulants or formulation inserts and have triggered replacements while spurring the development of new solutions. An example of regulatory-driven innovation is the replacement of durable polymer-based microcapsules or polymeric seed coatings with biodegradable solutions, in anticipation of upcoming European microplastics regulation. Bayer is currently exploring different biodegradable encapsulation technologies and polymers for these important uses. We also expect to see further diversification in agricultural production systems, from intensification and increased farm sizes to specialization, such as indoor/vertical farming systems, as well as expansion of organic farming. Together with changes in application systems, the emergence of new modes of action or active ingredients based on peptides, proteins, and biologicals, such as fungi, microbes, and plant extracts, will further push the need for new, innovative and sustainable solutions in formulations and application ensuring optimal biodelivery, efficacy and stability of products.

Open Innovation, Partnerships and Collaboration

We have adopted a collaborative, “open innovation” approach to foster innovation, surface new possibilities, incubate new ideas and accelerate the development and delivery of sustainable chemistry and crop protection. This proactive, collaborative approach helps broaden Bayer’s reach in innovation, and allows us to expand beyond our core competencies and areas of expertise.

This open innovation approach includes:

Grants4Ag and Testing4Ag initiatives

- #Grants4Ag provides financial awards to researchers furthering sustainable solutions to agricultural challenges. In addition to funding, winners are mentored by industry leaders. Intellectual property (IP) generated through the program remains with the winner.
- #Testing4Ag offers researchers the opportunity for experimental compounds to be tested against plant pathogens, weed species, insect and nematode pests, or vectors using Bayer’s state-of-the-art biological assays. IP generated during testing remains with the originating individual or institution.

Externally, we are collaborating with these research organizations:

// **iMEAN** (France (FR)) – Combining data, modelling and advanced algorithms to accelerate discovery of new environmentally friendly products.
// **Kebotix** (U.S.) – Combining data, artificial intelligence (AI) and robotics to accelerate the synthesis of new molecules.
// **KREATiS** (FR) – Whose technology delivers computer-based ecotoxicology predictions based on the “Mechanisms of Toxic Action” decision tree, boosting R&D time- and cost-efficiency.
// **Vivent SA** (Switzerland) – Whose technology (biosensors) provides farmers with insights into crop stressors prior to the appearance of visual symptoms.

Embracing open innovation, partnerships and collaboration enriches our portfolio opportunities; helps to address unmet needs, accelerate discovery and development; and brings new thinking, knowledge and approaches into our R&D processes. It also helps us identify potential technology partners and use our resources most efficiently.

3. Safety Evaluations

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, which we will describe here, and pursue only product ideas that present no safety concerns for humans when used according to the label instructions. In addition to the regulatory requirements of countries where our products are registered, Bayer applies its own voluntary internal standard for consumer and operator risk assessment. This is particularly important in geographies where pesticide regulations are still under development.

Bayer applies 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 tests 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 according to risk, e.g., PPE and equipment requirements on labels, use restrictions on labels, farmer trainings, formulation changes, product substitutions. We don't just add protective equipment to our labels, we ensure that the necessary protections are available and affordable and consider if they will be used in an appropriate manner. By accounting for local practices and environments, we make sure our risk management is realistic and appropriate. We also frequently review scientific information and farmer practices.[12]
- Data collection to determine the nature and magnitude of residues on food.

When a new use concept is proposed for a country where regulations are still under development or do not cover consumer and operator risk assessments, Bayer's own voluntary internal standard is applied. This standard also reflects the guidance documents of international organizations, such as Codex Alimentarius[a], and the OECD, the FAO international code of conduct on pesticide management, as well as those of reference regulatory authorities around the world. Bayer's standard is continuously evolved by our scientists based on the latest scientific consensus.

The characterization of any potential hazard of an active ingredient is done via a series of standardized toxicological studies, which are conducted under Good Laboratory Practices (GLP) and according to standardized protocols described in international guidelines. To be sure that all possible effects are characterized, these tests use several laboratory animal species, different routes of administration, different dose levels – mostly beyond those to which humans would be exposed, and different durations of exposure (short- to long-term). The evaluations examine the main organs and systems (e.g., hormonal, respiratory, immune, reproductive, etc.) for effects, such as toxicity, neurotoxicity, carcinogenicity, reproductive toxicity and hormone disruption.

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

[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.

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.

In the mid- to long-term future, traditional animal methods for safety testing will be more and more replaced by New Approach Methods (NAMs) that aim to reduce animal usage and increase predictivity of testing for humans. Bayer is actively engaging in developing NAMs and approaches on how to use these for Next Generation Risk Assessment to prepare for the future of Safety Testing and 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.[13,14] 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 or metabolism products in metabolism studies, as well as the magnitude of residues in field trials. To derive an estimation of exposure, the consumer risk assessment combines the level of residues in food with the food intake by each specific population (e.g., babies, 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 intervene to reduce risk by not applying for additional crop uses or reducing the maximum application rates on the labels.

Bayer routinely applies for Maximum Residue Levels (MRLs) in the countries of use of our products and import of treated goods. 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 each regulatory authority and per active ingredient and crop. MRLs are important to enable trade of agricultural commodities and ensure safe and nutritious food for all.

For an operator risk assessment, we gather information to understand local practices, product formulation the type of equipment used, and operator behavior. We attempt to collect as much data as possible from actual field use to ensure the highest reliability of our assessments of risk, and use exposure models that are built from empirical exposure data considering a variety of use scenarios during the handling and application of a product. 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 protective equipment to our product labels. We ensure that the necessary protections are available and consider if they are realistic under local agronomic and climatic conditions. Full detail on our extensive operator safety standards may be found here: https://www.bayer.com/en/agriculture/information-about-operator-safety-standards.

Environmental Safety

Environmental safety has become a critical success factor for our new compounds. As part of our CropKey strategy, we have included these parameters into the design process for these molecules in Research using a toolbox of predictive assays and models. Therefore, a lot of information is available about these molecules when the development decision is taken, and which is considered to generate the thorough regulatory data package to be generated for the registration of the active ingredients. The regulatory environmental safety assessments for our crop protection products are conducted by groups of experts trained in the fields of ecotoxicology and environmental chemistry. The fields have rapidly evolved over the past 50 years and combine knowledge and techniques from both ecology and toxicology

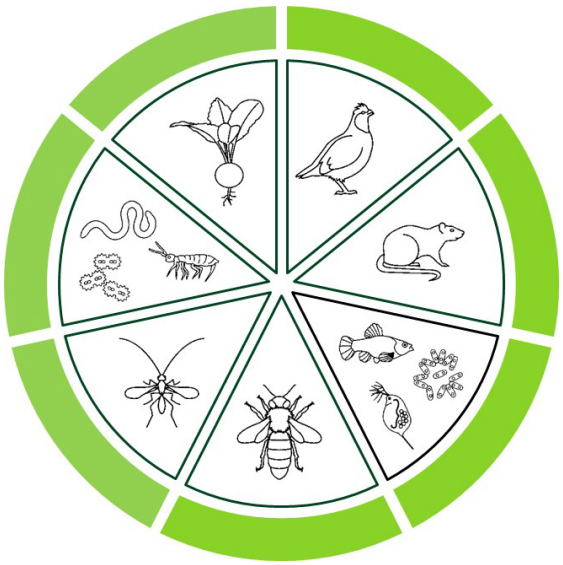
along with an understanding of the environmental fate of substances after they are applied for crop protection. Testing the potential impact of a crop protection product to non-target organisms is very important, as one of our key goals is to protect the organisms that are not targeted by the crop protection product to preserve biodiversity. In addition, an extensive battery of studies is performed to characterize the fate and exposure to the active ingredient and its relevant environmental metabolites in aquatic and terrestrial environments. The results from these studies are used to characterize how quickly the active ingredient degrades and the formation and fate of metabolites in aquatic and terrestrial environments. By combining the results from effect and exposure level testing on both, the active substance and the respective metabolites, we can assess the potential for risk to non-target organisms for the intended uses of our products. All our safety studies needed for this assessment are conducted according to internationally harmonized test guidelines and strict GLP quality assurance (QA) regulations.

At the start of understanding the potential risk to the environment from the use of a crop protection product, the intrinsic hazard of an active ingredient and relevant metabolites are characterized for a wide range of non-target organisms. The groups of non-target organisms that are tested have been defined by authorities and were selected based on the ecosystem functions they provide. It is impossible to test the universe of species; therefore, surrogate non-target organisms that represent key ecological services are tested (e.g., pollination services, biological control of pests, soil services). Representative non-target organisms from the terrestrial environment that are tested include avian species, wild mammals, bees, beneficial insects, soil macro- and micro-organisms, and non-target plants. Representative non-target organisms from the aquatic environment that are tested include different non-target organisms that comprise an aquatic food web, such as primary producers (e.g., algae and plants), primary consumers (invertebrates), and secondary consumers (e.g., fish). To characterize the magnitude and duration of environmental exposure for a pesticide to non-target organisms, laboratory and field experiments are conducted to elucidate the physico-chemical properties and the fate and distribution of substances between the different environmental compartments (e.g., soil, air and surface water), how they degrade and which metabolites they form. Based on our understanding of the environmental fate (e.g., degradation, metabolism and mobility) of the active ingredient and its use pattern, we can predict the concentrations in different environmental compartments after the compound is applied by the farmer. These predicted environmental concentrations are calculated with established and validated scientific models that are approved by regulatory authorities to be used in specific countries or regions.

When a commercial formulated product is developed that contains more than one active ingredient, an assessment of acute toxicity is evaluated to demonstrate that there is an acceptable margin of exposure. There are well established procedures for predicting the combined additive toxicity of two or more active ingredients to non-target organisms (e.g., fish, bees). In many cases, the formulation containing two or more active ingredients is directly tested with the appropriate battery of non-target organisms. The results from the formulation studies are then evaluated within an ecological risk assessment to support a registration with safe uses.

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 of pest species 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 and fish). In addition, a study is performed to understand the potential for a substance to bioaccumulate in organisms and through the food web.

The 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. In some cases, measurements from real-world monitoring programs are collected to further our understanding of the range of environmentally realistic exposures to 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 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.

Internal Safety Standards

Since 2021, we have shared our crop protection operator safety standards on our website. These voluntary standards reflect the guidelines and standards of international organizations, such as the FAO,

the WHO and the OECD, as well as those of reference regulatory authorities around the world. These safety standards use information on the toxicological profile of the active ingredients and crop protection products, their behavior during and after use, and potential exposure of humans or the environment. They evolve continuously based on the latest scientific knowledge and we invite internationally respected researchers from academia and other expert groups to review them. As part of our commitment to ensure globally consistent safety standards for our crop protection products, we also published our Bayer Safety Standard for Operator Safety, which we apply in the risk assessment of our crop protection products. The operator safety standards and the associated data acquisition exceed local regulations in many countries that have less regulation in place for crop protection products. We hereby particularly consider specific use and application scenarios that are mostly relevant in LMICs.

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 protecting the environment and contributing to food security. That's why, as the world's leading provider of crop protection products, we are committed to 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 only company within our industry to make such a measurable commitment across the entire crop protection portfolio with publicly available models.[15]

We have adopted a scientific, data-driven approach, Crop Protection Environmental Impact Reduction (CP EIR), which is based on two independently developed external models (PestLCI and USEtox®). These models, developed externally in academia, 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 for the ability to look beyond volumes per hectare, which is assessed by the models. Broadly speaking, the environmental impact of crop protection is determined by three main variables: the environmental profile of the crop protection, the volume applied per hectare and the emissions of crop protection into the environment.

Through CP EIR, we are aiming to reduce the environmental impact of crop protection while maintaining or even increasing the benefits of crop protection products in securing yields. We have identified a number of different technologies that can be deployed to help progress towards our commitment. These technologies fall into four main categories: improving the chemistry of crop protection products, reducing the amount of crop protection products needed per hectare, reducing crop protection emissions into the surrounding environment, and ensuring safe, responsible use of crop protection products. We have integrated our holistic methodology into the governance of our research and development decisions.

The evolution of our crop protection innovation strategy and the efforts outlined in this report contribute towards these four categories. Therefore, our reduction in crop protection environmental impact should be seen as a consequence of our product development standards, stewardship and Bayer's ability to combine crop protection products with tailored solutions from Seeds & Traits or digital technologies.

Based on the data from 2018-2022, Bayer has reduced the treated-area-weighted environmental impact per hectare of its global crop protection portfolio by 12% against the 2014-2018 baseline. The reduction was mainly the result of changes in our crop protection product portfolio in recent years. For the reporting period 2017 to 2021, we must restate our progress as 11% as opposed to the previously reported 14%, due to model enhancements and newly identified data corrections.[16]

[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®.

4. Regulation of Crop Protection Products

Crop protection products are among the most stringently regulated products. Regulations safeguard that crop protection products manufactured and placed on the market are effective for their intended purpose and do not pose risks to human or animal health or unacceptable risks to 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.

Crop protection products are thoroughly regulated to ensure they are safe when used according to label instructions. Before plant protection products can enter the market and be used by farmers, they need to undergo country-dependent strict evaluation and approval by local authorities for each targeted country to ensure that they may be used safely by humans under local conditions and pose no unacceptable harm to the environment. For this purpose, we conduct hundreds of metabolism, residue, toxicological, eco-toxicological, environmental, physio-chemical, and efficacy studies. All this scientific information is compiled in registration dossiers complying with the local regulatory requirements, containing active ingredient and formulated product composition, individual study reports, summaries, and risk assessments, including proposals for risk mitigation. These dossiers are submitted to regulatory authorities around the world who review the submitted data and risk assessments, and grant or deny approval of active substances and products based on their specific regulations and conclusions.

The global regulatory landscape is diverse and constantly evolving, with different countries and regional organizations frequently setting and updating their regulations based on scientific advancement and local political, environmental, and agronomical priorities. In all countries where we sell our products, Bayer pays utmost importance to compliance that our products fulfil applicable regulatory requirements through an extensive internal global network of experts who monitor and understand regulatory trends and developments in order to update Bayer’s dossiers as and when required.

The Global Landscape of Regulatory Frameworks

Bayer operates in highly regulated regions and countries, and we take the various regulatory approaches and requirements into account when evaluating the safety of our products.

In North America, risk-based regulation is the standard. Regulatory requirements to complete a risk assessment are complex and sophisticated and continue to increase. A global export marketing orientation in obtaining license to operate (LtO) requires global regulatory strategies. In the U.S., for example, pesticides are regulated by the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which is a comprehensive statute that regulates the manufacture, distribution and use of pesticides and stipulates 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 new requirements that must be applied to all food commodities through stricter safety standards, endocrine disruption testing, aggregate exposure and cumulative effects. Aggregate exposure, leading to a risk cup including all dietary sources of potential exposure, ensures that consumers are not exposed to unsafe levels of pesticide due to use on multiple crops. The Endangered Species Act (ESA) ensures that any action authorized by a federal agency will not likely jeopardize the continued existence of any listed species and is managed by services outside of the EPA. In addition to that, state pesticide laws govern the use of pesticides at state level and all federally approved pesticides must also be approved at the state level.

In the EU, crop protection products must pass hazard-based criteria followed by a highly sophisticated risk assessment. As in North America, regulatory requirements of crop protection products are high and constantly evolving, with the imposition of new guidelines. In the EU, Regulation 1107/2009 is the key regulation concerning the placing of plant protection products on the market. 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, 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) legislation 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 legislation Regulation EC 396/2005. Public sector experts from the Member States who represent the scientific views of the Member States carry out peer reviews for EFSA through written comments or participating in expert consultations. Based on EFSA's scientific risk assessments of active substances, the Risk Managers, who are 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 this active) and respective uses at zonal and national levels. Outside of the EU, the regulatory systems and requirements 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, for example, is moving towards a risk-based regulatory framework, with many other countries in LATAM also having increasing regulatory standards. Those standards are often driven by export requirements and, in general, their regulatory frameworks are evolving. In addition, we experience science-based discussions in the context of plant protection product evaluations in most of the LATAM region, approvals within our labels for the use of drones (UAV) and new regulations for biological products.

The regulatory standards across the Asia-Pacific (APAC) region are also very varied. In many APAC countries, increased regulatory scrutiny is being directed at crop protection chemistries because of food safety and environmental concerns, leading to regulatory restrictions and in some cases prohibited uses, influenced by their observation of the globally evolving regulatory landscape and sometimes without full application of the international standards, such as FAO guidelines. As an example, effective from January 2021, China adopted a unique procedure where it no longer accepted international OECD GLP studies and, as a consequence, such internationally conducted and accepted study packages can currently not be used to register new active ingredients in China. The Indian regulatory framework primarily relies on hazard assessment, although there are no defined hazard cut-off criteria. Regulators instead 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 (EU/EPA) are also considered when creating regulatory frameworks and reaching regulatory decisions.

In today's highly globalized world, the ability to export crops to international markets is an important factor for the farmer when considering which crop protection products to employ. Barriers to trade can occur when residues are present in traded commodities, and the export destination has regulations in place to limit the magnitude of these residues – MRLs – in imported goods. Differing MRL and import tolerance legislation between countries can therefore complicate trade. While some countries and regions accept FAO's Codex MRL rules, many have adopted their own, including the U.S., Canada, the EU, UK, Japan, Taiwan, Korea, the Russian Federation, and Australia. Consequently, if MRLs commonly vary between countries, it can be complicated for the farmer to plan which product to use to enable export to all potential global customers.

To overcome these potential trade barriers, Bayer ensures that the development and launch of each new product is accompanied by a robust trade enablement strategy. Examples of such a strategy are 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 approach ensures that the farmer has confidence

in the marketability of the crops, and that the full market potential (as a new tool for farmers, but also in terms of peak sales) of the new product is reached at its earliest opportunity.

Dossier Compilation and Submissions

To secure product registrations in various countries, Bayer must compile and submit to regulatory authorities a data package, or dossier, that includes the results of animal and environmental testing of the product. The data package for a crop protection active ingredient also contains studies on product chemistry, environmental fate, residue chemistry, toxicology and ecotoxicology, and typically includes 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.

Bayer's product development process and the vast array of animal and environmental safety studies conducted throughout this process are designed to comply with the requirements of mature regulatory systems and OECD standards. While the OECD attempts global coordination of required studies, and similarities in requirements exist among various regulatory authorities, significant differences still exist. Some countries require studies on specific species, soil types and crops unique to that country, as examples. Level of detail in the dossier is another variance: while many require full study details from design to results, others, only a summary or endpoints of each study. The dossier format also varies; most regulatory authorities have online submission portals to accept digital dossiers, but others still require paper, which, for a typical dossier, could be tens of thousands of pages.

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

// **QA and compliance colleagues** 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. As many as 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 as many as 80,000 pages, including several hundred pages or more 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 the regulatory authority issues its decision.
// **Submission management specialists** support Crop Science colleagues in preparing, coordinating, compiling and submitting dossiers. These specialists employ dedicated digital tools for dossier submissions and to 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. Since biopesticides tend to originate in nature, some regulatory agencies may require less data to register a biopesticide than to register 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. Like our safety commitments for 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

Our global product labels are prescribed by regulatory authorities as part of the product authorization. The format and content of each label are country specific, in the local language, and are based on

regulators' evaluation of all available data, including the outcome of safety assessments. 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 the conditions of use that are safe, based on the detailed safety assessments, including the use of personal protective equipment (PPE) when needed. The product label also specifies mitigation measures that must be applied, such as keeping a certain distance between the treated area and neighboring water bodies, using drift-reducing nozzles, or incorporating the product into soil after application. Label instructions are legally binding for farmers when using plant protection products.

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

Our product labels are created in accordance with our internal Group Regulation on Product Stewardship Commitment, Principles and Key Requirements.[17] We comply with local regulatory requirements for labelling with a decentralized artwork creation process. The respective Bayer country organizations are responsible for the label artwork, including branding and content, connected with the production process to ensure the use of valid artwork versions. In countries where there are no specific regulatory requirements, our products 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[18], which we use to advocate for label improvements when local regulations deviate from this guideline.

Bayer and the industry are committed to continuously improving label communication techniques. For example, a new pictogram was developed by CropLife International to be used as precautionary icon on pesticide labels to protect pollinators from unintended side effects. In 2022, the new label pictogram was endorsed by FAO. Bayer is currently incorporating the pictogram in our pesticide labels.

In-Licensed Active Ingredients and Formulated Products

Bayer pursues in-licensing of competitors' registered active ingredients and formulated products that we determine may be beneficial additions to our portfolio of crop protection solutions, either to expand into new crops, new regions, or new countries or to complement proprietary products, providing a more convenient solution for the grower or to serve an unmet need in the market place. 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 vigorous 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.

All available published data on a candidate, including chemical composition of the active ingredient, elements of the formulated product, application methods, approved crops, etc., are considered in the evaluation of new in-license candidates. This evaluation indicates which aspects of a candidate meet our standards and flags those that partially meet or do not yet meet our standards, specifying the need for more or additional safety data and further risk assessment. Evaluating this information then guides our decision whether it is viable to make the necessary investment in filling any data gaps to meet our safety standards.

5. Product Stewardship

Stewardship During Product Development

Sustainability is an essential component of our strategy, our business activities, our values and the way in which we conduct our business. Stewardship is a key enabler of sustainable agriculture: product stewardship practices help support the availability of high-quality products, services and best practices by promoting compliance with statutory and regulatory requirements, as well as good agricultural practices. They can also help maximize product potential and sustainability and minimize risk. We are committed to developing new products and services with favorable toxicological human and environmental safety profiles, that enhance the use of resources and are suitable for integrated pest management (IPM).

We are also committed to substituting higher risk profile formulants with materials that have lower risk profiles and minimizing the risk of unintended release and exposure to non-target areas. We seek to develop products, services and technologies that reduce the need for PPE, to support programs that enhance the availability and affordability of PPE, and to align PPE with user education and abilities in the country of sale. We are developing and supporting improvement of application technologies and implementation of best practices to minimize occupational and environmental exposure.[19]

Where required, we obtain and follow country-specific import approvals and testing permits or authorizations for non-registered products or materials. We institute safeguards when performing trials to prevent non-registered products from entering the food or feed chain or result in an uncontrolled environmental release, unless approved by regulators.

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. Experimental products are clearly labelled to identify the material, to meet applicable regulatory requirements and include information on safe handling. We assess and implement processes to help avoid unintended co-mingling or cross contamination of any product. Crops and harvests from trials with non-registered products and uses are destroyed unless regulation and/or laws permit other means of disposal.

Bayer obtains registrations where our products are sold and import tolerances or authorizations in key import countries with functioning regulatory systems. Our data packages are developed and submitted to comply with national and international regulatory requirements before commercialization. Studies are conducted under high testing standards and, at a minimum, under 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. These tests must, at a minimum, be in accordance with Codex Alimentarius Commission[20] 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 Sustainable Pesticide Management at Bayer report,[21] as well as the Bayer corporate 2022 Sustainability Report.[22]

Compliance and Quality During Production

Stewardship of our crop protection products focuses on the entire life cycle, from invention to discontinuation. Effective stewardship requires a multistakeholder approach. Through multistakeholder collaborations under the umbrella of CropLife International, for example, we help build capacity, especially in countries that do not have efficient local structures in line with the FAO-WHO Code. Capacity building includes effective structures for risk-based regulatory assessments of existing and innovative technologies, incident reporting and management, farmer/operator safe use trainings and certifications, professional applications (e.g., via drones), the availability and use of PPE, empty container management, and Anti-Counterfeit and best practice exchange between authorities – to name only a few.

Bayer has instituted mandatory quality management systems that include standards and ongoing assessments to help us ensure the consistent high quality of our products. We also apply specified processes and industry-standard analytical methods to test each product batch before release, sale or transport.

When a new product is introduced in a new market, Regulatory Affairs works closely with Product Supply to ensure that manufactured products comply with the regulatory requirements. The Crop Science Division uses the RegPrime database, an internal information system, wherein key relevant regulatory information is captured in a structured way and made available worldwide to other Bayer Crop Science key systems and databases. RegPrime is the sole source of regulatory information used across the division to ensure full compliance and transparency on national, regional and global levels.

Our global manufacturing sites, as well as our laboratories, have earned the International Organization for Standardization (ISO) certification. ISO standards are independent, internationally recognized criteria that focus on process improvement to ensure quality, safety and efficiency. The standards also significantly contribute to continuous evaluation of our quality system management, which includes identifying and implementing improvements. ISO certification is voluntary, and an independent, external body certifies that standards are met.

Through annual reviews and assessments of potential quality risks, we continuously improve our products as part of our internal Corrective Actions or Preventative Actions (CAPA) and our Plan-Do-Check-Act (PDCA) procedures. Our incident, complaint and safety performance reporting systems keep us up to date on any issues related to the quality of our products. We can promptly take corrective actions to ensure compliance with regulatory and customer requirements. Twice a year, as part of a mandatory Quality Management Review, we report and review quality performance risks and necessary improvements with management and executive leadership. 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 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, among others.

Production, Product Stewardship, Regulatory Affairs and other Crop Science business functions rely upon access to relevant and current regulatory information to earn and maintain regulatory approval, as regulatory authorizations vary from nation to nation and, in some countries, at the state level. Our robust database, RegPrime, captures and retains in a structured way the necessary regulatory information for the markets in which we have license to operate, and is interconnected worldwide with other Bayer Crop Science key systems and databases. RegPrime is our primary source for regulatory information across the Bayer Crop Science business on national, regional and global levels, and is our guidebook for sustaining full regulatory compliance.

Monitoring and Portfolio Screening

For our internal risk assessments, we systematically collect and include information from our own local experts on area agronomic conditions, particularly in LMICs. This can include, but is not limited to, these examples: the local crop structure, the type of application equipment, access to and use of personal protective equipment (PPE), and cultivation and product application practices. In our operator risk assessments, the minimum requirements for PPE are aligned to FAO and WHO recommendations. In certain growing situations, advanced PPE may not be accessible or realistically expected to be used, and in those instances, we also do not consider advanced PPE as a mitigation measure.

In the past, Bayer identified multiple exposure scenarios in LMICs and in Europe that were not adequately addressed in local guidelines and risk assessment approaches. For example, we have developed exposure models that consider hand-held product application in densely grown crops, and addressed other exposure scenarios that are common in LMICs. With sugar beet fields, workers are exposed to treated crops in some varieties due to their tendency under certain conditions to “bolt” or focus energy on producing seed stalks versus beets. Bolts must be removed by workers exposed to the plants. To determine exposure, Bayer conducted a study whose results were published in a peer-reviewed journal and submitted the raw data to regulators for evaluation.[23] The exposure scenario was taken up by binding European regulations.[24]

In-field surveys or other farmer surveillance on product use are the responsibility of governments and their authorities, according to the FAO and WHO Code of Conduct. For example, Bayer currently conducts such surveys where they are mandated by the U.S. EPA (along with training on safe product use) with U.S. farmers who use our herbicide dicamba in dicamba-tolerant soybean and cotton crops.

We also help to drive technological and other advances that not only further reduce the risk to humans and the environment but also enhance productivity, such as partnering with major drone manufacturing companies and local professional drone spray service providers to promote product application by drones, improving efficacy and replacing handheld applications. We also help to create guidance documents in association with regional CropLife organizations, conduct continuing training courses for our employees and our research partners, examine potential new exposure sources, such as frequent refills or battery exchanges, and encourage the development of professional spray service providers, which holds great potential in LMICs.

Under our high internal safety standards and sustainability commitments, we are continually monitoring and evaluating our current portfolio against relevant social, environmental and economic parameters to help us to identify areas that need attention and develop action plans to encourage the development of new, innovative solutions that can contribute to sustainable farming. These action plans may include research projects, reformulations or replacing one product with an alternative product. We work with regulators and other stakeholders to ensure effective and predictive science- and risk-based regulatory systems that enable this innovation, using our high safety standards to substantiate these discussions.

Incidents Management

A key aspect of the FAO-WHO International Code of Conduct on Pesticide Management – to which Bayer is committed – is managing adverse incidents. It is our desire to avoid any kind of incident with our products, and to make this a reality, we need reliable data that tells us how, when, where and the frequency with which incidents occur. Solid data is a prerequisite for product monitoring and the source of effective product stewardship measures.

We collaborate with partners outside of Bayer – an important step towards understanding current global events and overcoming the challenges posed by the lack of coordinated worldwide monitoring systems. We already work jointly with various universities and environmental and regulatory authorities to gain reliable monitoring data on product residues in water and agricultural produce. We are expanding our database through a network of partnerships with poison control centers and rural doctors, equipping them with tools to facilitate reporting of poisonings related to crop protection products.

We track incidents related to our crop protection products worldwide through an internal management system, whose backbone is a software solution, CAIRnew, instituted in 2014. Data includes both information we receive from poison control centers and incidents we record through our network of Bayer colleagues and external partners. CAIRnew improves our risk mitigation, enabling efficient and consistent reporting, managing, documenting, and analyzing of external adverse incidents, complaints and, if necessary, product recalls in keeping with our Product Stewardship Commitment, Principles and Key Requirements.[25]

To achieve our goal of increasing awareness and strengthening reporting channels, our global internal network of Crop Protection Stewardship 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 other sources, like verified media reports, and collaborate with medical professionals and poison control centers. Our incident management system and continuous review of product use form key reference points to both monitor the safety of our products and identify any necessary improvements. We analyze the collected data to understand issues associated with the use of our products, identify hotspots, and collect learnings on how to implement and optimize targeted stewardship measures. These measures may be a response not only to human health incidents but also to those involving domestic animals, pollinators or the environment. In general, steps to mitigate risks can vary from enhanced training efforts, change of a formulation and 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. We believe that through a collective effort at all levels, true positive impact can be achieved in the safe management of crop protection products around the world. 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.

Stewardship During Commercialization

For products in the market, stewardship maximizes product potential and minimizes risk by implementing and monitoring asset and regional specific measures to ensure full compliancy. This includes sustainable Integrated Weed Management (IWM), Integrated Pest Management (IPM) and Integrated Disease Management (IDM) programs and extensive trainings in compliance with FAO to ensure safe product use throughout their life cycle, from spraying to safe disposal of empty packages, containers or obsolete product inventory or waste in accordance with local regulations.

Training

We conduct targeted training courses in which we show farmers, seed treatment professionals, product distributors, and other users, such as applicators, the safe handling of our products during use, transport, storage and disposal; the correct use of protective clothing and equipment; and first aid measures in the event of an emergency. The courses are adapted to meet specific requirements for the situation, for example, the target group's location, crop variety, locally required products and other specifics. Our training materials are available in various formats, including on-site presentations, manuals, brochures, videos and live chats. We also conduct training sessions during events, such as product launches or field days to extend our outreach.

We offer additional training and engagement in LMICs under the umbrella of the Bayer Safe Use Ambassador initiative,[26] launched in 2017. To date, in concert with 53 agricultural universities in 13 countries, we have provided student training in the safe use of crop protection products with a focus on user safety and the environment. These students then share their new knowledge with farmers during internships on farms. In mid-2022, we expanded the Bayer Safe Use Ambassador initiative to medical doctors in rural areas, training more than 1,000 that year. Doctors are trained not only on preventing unintended exposure to crop protection products, but also on treatment in the event of chemical poisoning, snake bites or heat strokes, aiming to expand the positive impact of our program on farmers' health. As part of the training, we also encourage medical doctors to report to us any incidents related to the use of our crop protection products.

6. Anti-Counterfeit

Counterfeit crop protection products pose an increased risk to human health and the environment because their contents do not correspond to the products we formulate and are not approved by regulatory authorities. Many counterfeit products may not contain approved active ingredients. Counterfeit products also take an economic toll on the crop protection industry. With the global pesticide market valued at over USD 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.

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. The App provides reliable information about the product´s authenticity conveniently and in local language. The Bayer Safety Seal is found on all Bayer crop protection products filled in bottles in EMEA and LATAM regions.

In 2021, the Bayer Safety Seal technology was expanded to include selected solid crop protection products in some high-risk markets. And from 2022, row crop seeds in Europe are also protected against counterfeits by using this technology.

In addition, we have a zero-tolerance position toward illegal activities and 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, allowing a reliable differentiation between counterfeits and original Bayer products.

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

Safety Seal as an Enabler for Digital Transformation in Agriculture

As a next step, the Safety Seal technology will be used to provide farmers with 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, amongst others.

Combining the physical product with digital information will increase customer confidence and customer experience significantly. Moreover, broadening the data behind the QR code of the Bayer Safety Seal also avoids the need to scan multiple codes for different purposes and provides convenient digital access to use instructions and other information, for example on sustainable use.

Combining physical products with digital information means enabling digital transformation in agriculture.

7. Governance

Sustainability and Stewardship Governance Internal Committees

Throughout the process of product development and continuing through product commercialization, several committees that include and/or ladder up to the senior leadership of Bayer ensure that we fulfil our corporate sustainability commitments.

The **ESG Committee** of the Supervisory Board focuses on integrating sustainability into our business strategy and establishes sustainability targets and non-mandatory ESG reporting and governs overarching sustainability updates. If applicable, the ESG Committee audits opportunities and risks and organizational structures and processes in ESG areas outside those for which the corporate Audit Committee is responsible.

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 Executive Leadership Team (ELT) 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 **ELT LtO Sub-Committee**, a dedicated ELT sub-committee 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 to Bayer's product safety and sustainability commitments, and defines structures of topic-related sub-committees and processes.

The following sub-committees report into the Regulatory LtO & Product Safety Committee:

// The **Regulatory Policy & Issues Committee,** ensures that important topics or problems involving or impacting regulatory authorities or scientific processes which may impact Bayer's LtO are addressed and elevated to the RLSC when needed.
The **Product Safety & Stewardship Committee** whose scope includes new technologies in seeds and traits, crop protection and biological products, as well as 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.

Business Unit Committees (BUCs) 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 Crop 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.

The **Crop Science Sustainability & Business Stewardship** function, which steers overarching sustainability commitments like CP EIR, GHG emissions, water conservation, and biodiversity, and holds responsibility for Product Stewardship and Anti-Counterfeit. The function reports to Crop Science management on our current performance in these focus areas, as well as their strategy.

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

Our R&D innovation pipeline for crop protection is comprised of six phases:

- **Phase 0:** Discovery of research targets
- **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

Our governance committees apply 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 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.

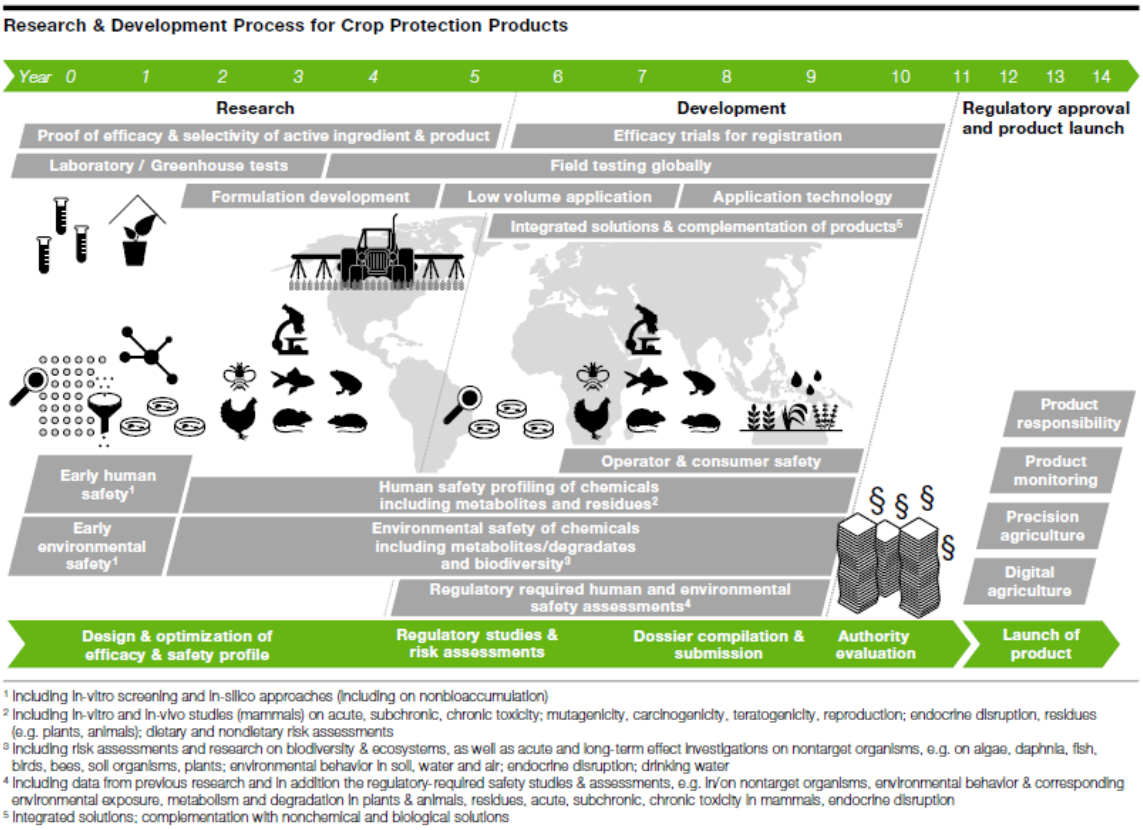
To enter **Phase 2**, concepts must demonstrate probability of technical and regulatory success and business potential, and the first assessment of potential for development of tailored solutions is conducted. Small molecules must further confirm high biological activity in comparison to market standards 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 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 development of 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 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” has been 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). In addition, a core formulation concept has been established and “free for registration,” a technical profile for the new active ingredient has been defined, a launch sub-team established as part of a global project team, and a product supply strategy in place.

To enter **Phase 5**, projects must have progressed into the Business Development phase based on following criteria: product has launched in the first countries, global registration is secured, launch plans are ready, and the product supply plan 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 prohibitive findings that would jeopardize regulatory approval.



Within Crop Science R&D, three committees 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 Research Portfolio Committee (RPC) steers 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. The RPC is also involved in deciding on candidates that will enter the next phase of development and resource commitments. The RPC includes the Head of R&D, the Head of R&D Operations, the Head of Technology Functions, Crop Technology Leads, Head of Regulatory Science and Head of Field Solutions, as well as other optional functions.

The Development Project Committee (DPC) recommends candidates for promotion to Phases 2 and 3 and 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 DPC includes: the Head of R&D Operations, the Head of Field Solutions, the Head of Regulatory Science, the Head of Breeding, the Head of Plant Biotechnology, the Head of Biologics, the Heads of Crop Technology Teams, the Head of Agronomic Solutions, the Head of Reg. Affairs Crop Protection, the Head of Human Safety, Head of Environmental Safety, the Head of Formulation Technology, the Head of Seeds & Traits Safety, the Head of Reg. Affairs Seeds & Traits, and the Head of Strategy & Sustainability – Strategic Portfolio Analysis.

The Strategic Portfolio Committee (SPC) steers cross-crop strategies, our research target pipeline and associated resources in continuing development and business phases. Members of the SPC implement crop overarching strategies across functional teams, serve as arbiter between crops with cross-crop perspective when required, approve updated target product profiles for Phase 3 promotion, and prioritize and promote New Business Model (NBM) and tailored solution projects. The SPC includes

representatives of Strategy & Sustainability, R&D, Finance, IT, Commercial Operations, Digital Farming Solutions and Product Supply.

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. GLP principles are mandatory and must be followed by test facilities carrying out studies to be submitted to regulatory authorities for the purposes of assessing the health and environmental safety of chemicals and chemical 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 are the foundation of all safety studies submitted for regulatory approval. GLP violations can lead to criminal sanctions.

GLP principles to which we adhere direct our test facility organization and study personnel, 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 the Group (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

The FAO and WHO have defined criteria to identify products and substances calling them Highly Hazardous Pesticides (HHP). There is a specific guidance for sound HHP management, including risk assessment and mitigation, published by the FAO and WHO. As for every Crop Protection Product, the risks of an HHP shall be properly assessed. As a result, mitigation measures are defined and the product can be used safely according to its product labels.

The FAO and WHO define HHPs as:

1. Pesticidal formulations that are acknowledged to present particularly high levels of acute toxicity or chronic hazards of active ingredients to human health or the environment according to internationally accepted classification systems, such as WHO or GHS, or their listing in relevant binding international agreements or conventions.
2. Pesticides that appear to cause a high incidence of severe or irreversible harm to health or the environment under conditions of use in a country conducting the assessment. Please consult the FAO website for more information about the eight criteria set forth by the FAO and WHO for identification of HHPs.[27]

As an innovation company with high safety standards, we have successfully phased out and replaced – where possible – several old chemistries, including HHPs. For example, we committed in 2012 to stop selling acutely toxic products of WHO Class 1. Today, we have only a few HHPs – as defined by FAO and WHO – in our portfolio. All of them are managed based on a clear, globally consistently applied approach that is grounded in the FAO and WHO 'Guidelines on Highly Hazardous Pesticides' – from the identification of HHPs in our portfolio, a needs and risk assessment for the registered uses, to any required, subsequent global and local risk mitigation measures through stewardship. Risk assessments must also consider local application scenarios and PPE requirements, availability and use under actual climatic conditions. Stewardship can include use limitations or safe use training, for example.

Because of the specific needs in LMICs, we have many collaborations with industry partners through CropLife International to build local knowledge and capacity for sustainable pesticide management in line with the FAO and WHO Code of Conduct. The "Sustainable Pesticide Management Framework" (SPMF) is our 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.

Through innovation we continuously enhance our portfolio and, thus, the farmer's toolbox.

8. Bayer's Transparency Commitments

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.

Trust and Transparency

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 for the world. 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:[28]

- 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 on 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.[29]
- We are opening our doors via our Crop Science OpenLabs program, allowing people to connect with our scientists and watch them carry out a crop protection safety study live in our labs and in the field under GLP conditions. We also perform periodic webinars, which allow interested parties to connect with our scientists and ask questions about safety testing of crop protection products.
- Since 2021, we have shared our crop protection operator safety standards on our website. 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.
- 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.
- The independent external Sustainability Council[30] advises the Board of Management and performs other functions on sustainability initiatives, 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.[31]

// An external panel of experts is independently performing an assessment of how Bayer Crop Science measures performance against its CP EIR commitment, along with additional methodological considerations. To ensure that the external panel can perform a full assessment, the panel members have received access to confidential information, 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 dedicated webpage: Results and Progress Reviewed by External Experts | Bayer Global.[32]

// In support of our ambition to raise the bar on safety standards for crop protection products globally, we openly share our approaches and risk assessment principles with recognized external experts from academia, former regulators and research organizations. We invite these expert panels to engage in an open dialogue with our scientists to further improve our approaches by including their thorough reviews in further evolutions of our safety objectives and voluntary risk assessment methods. Corresponding minutes and panel protocols are publicly accessible.[33]

Engagement with Stakeholders

We seek common ground with critical stakeholders and listen carefully to diverse points of view and engage in thoughtful dialogue. This requires that all engagements and communications be truthful and transparent. We respect the independence of journalists and media representatives. Our interactions with media are governed by the Bayer Societal Engagement (BASE) principles, set out in a publicly available Board of Management-approved Group regulation, which establishes how we interact worldwide – not just with our employees, but also with patients, customers, consumers, business partners, political stakeholders, scientists, critics, and our stockholders. In this way, we want to live up to our social responsibility as a sustainably acting and transparent company that is respected for its contribution to progress in healthcare and agriculture. We want to listen, understand, take concerns seriously and engage in respectful dialogue – especially where this is difficult or uncomfortable.[34] This means that we engage openly and transparently with media and provide accurate information. Sometimes a scientific article makes claims or provides new information that merits a response or further enquiries, or it may be the origin of a media report where journalists approach Bayer for comment. They have often raised their concerns about crop protection products and have questions about the impacts on the environment, farmers and consumers. Some critics continue to repeat broad claims without additional substantiation. Although we cannot provide comprehensive responses to all unsubstantiated claims, we try to engage in a scientific and constructive dialogue whenever we can. Our scientists assess new studies and reports and their methodologies thoroughly on their scientific merit, and we aim to provide science-based answers to the questions they raise.

Ongoing dialogue with our farmer customers and related value chain stakeholders is vitally important to us. After all, their needs, expectations, and viewpoints affect our credibility, reputation, and public acceptance and, thus, our commercial success. Dialogue that is regular, constructive and transparent helps us to recognize important trends and developments in society and our markets at an early stage and take this information into account when shaping our business. In strategic decision-making processes that demonstrate our commitment to governance, stewardship and responsible use practices, Bayer proactively approaches our customers and key social and political players right from the start of a new project. Such open dialogue modeled on industry leadership and transparency enables us to identify opportunities and address any perceived risks early on. This process is in line with our Stakeholder Engagement Guideline and is supplemented by an internal information platform.

9. Conclusion

Crop protection products are a topic of interest for our stakeholders, and this report attempts to answer some of the questions that arise. Bayer strives to meet the expectations for transparency from investors and others and appreciates the opportunity to engage in productive dialogue. We hope this report can deepen the quality of our engagement and improve mutual understanding.

Endnotes

[9] https://www.nifa.usda.gov/about-nifa/blogs/researchers-helping-protect-crops-pests
[10] https://www.fao.org/3/a0884e/a0884e.pdf
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[34] https://www.bayer.com/en/commitments/our-values