



Product Stewardship

Commitment, Principles and Key Requirements





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Introduction

Product Stewardship is the responsible and ethical management of a product, throughout its life cycle, from invention through ultimate use and finally discontinuation. Product Stewardship ensures the availability of high quality products and services and best practices to ensure compliance with all legal and regulatory requirements, facilitate trade, maximize product potential and sustainability, and minimize risks to human and animal health and the environment.

Bayer's Crop Science division, (referred to as Bayer), has adopted a life cycle approach that addresses all major aspects of responsible product management. Bayer Product Stewardship activities include: investing in safety and quality testing of its products and services; understanding and maintaining compliance with regulatory requirements; facilitating trade and commodity marketing; continually improving development, manufacturing, distribution, and crop production techniques; promoting responsible product use; and implementing initiatives against production, import, trade and use of counterfeit and illegal products and services.

This document outlines Bayer Product Stewardship Commitment, Principles and Key Requirements throughout the life cycle for all products and services worldwide and is intended to support all Bayer employees to ensure the responsible and ethical development, management and use of Bayer products and services. It forms the basis for securing Bayer business operations through the implementation of stewardship measures and by demonstrating quality management and compliance throughout the product life cycle. This also strengthens partnerships and opens dialogue with our key stakeholders creating lasting trust in Bayer products and services, maintaining our business foundation over the long term and, ultimately, enhancing public confidence.

The Bayer Stewardship Commitment relates to the life cycle of all seeds and traits, biologics, and crop protection products, as well as to services in the Bayer portfolio. The established industry views on life cycles by Excellence Through Stewardship (ETS) for seeds and traits and by Crop Life International (CLI) for crop protection are reflected in the Bayer Product Life Cycle (see Figure: Product Life Cycle).



Figure: Product Life Cycle

Commitment

Bayer, as an industry leader, is committed to Product Stewardship as an integral part of its activities, ensuring that its products, services and technologies are safe and sustainable, and their use is environmentally responsible, while meeting customer expectations and needs.

Bayer endorses the Food and Agriculture Organization of the United Nations (FAO) Code of Conduct on Pesticide Management, the CropLife International Plant Biotechnology Code of Conduct, and the Universal Declaration of Human Rights. These guidance documents, together with participation in industry initiatives – such as Excellence Through Stewardship (ETS) and Responsible Care programs – in conjunction with regulatory considerations, provide the basis for Bayer Product Stewardship Commitment.

Bayer is committed to:

- Utilizing a life cycle approach to manage products and services.
- Implementing training activities around the whole life cycle for our staff, customers and other stakeholders.
- Developing and selling only safe products and services that do not pose an unacceptable risk to users, consumers and the environment when used according to the label.
- Developing quality products and services that deliver solutions to help farmers protect and/or enhance crop sustainability.
- Evaluating key markets and import activities prior to commercial sale of a product in a country.
- Manufacturing products using efficient, safe and environmentally sound production processes.
- Maintaining product quality and genetic integrity.
- Ensuring products and services are packaged appropriately for the market and with clear guidance on proper use.
- Making detection methods for our products available to stakeholders when and where appropriate.
- Complying with all relevant legislation and regulations where a product is developed and commercialized/ marketed by or on behalf of Bayer.
- Having open dialogue with key stakeholders prior to, during and after sale or use of the product.
- Using ethical sales and marketing practices.
- Supporting and promoting the implementation of safe and sustainable practices (e.g., training, educational materials).
- Requiring the adoption of equivalent Product Stewardship by those working on behalf of Bayer or distributing or licensing Bayer products and services.
- Assessing and recording incidents and complaints related to Bayer products and services to limit reoccurrence.
- Combating the trade and use of counterfeit and illegal crop products and services.
- Working in partnership with various stakeholders to promote the responsible use of Bayer products and services.



Rodrigo Santos

Member of the Board of Bayer AG and
President of the Crop Science Division



Implementation

This document covers the Commitment of Bayer to Product Stewardship and provides the fundamental Principles and Key Requirements for implementation.

Bayer will bring Product Stewardship to the attention of all employees within the company and relevant external partners.



It is the responsibility of all Bayer employees to actively promote the appropriate development and use of Bayer products and services internally and externally.

Bayer will require all employees to follow the Product Stewardship Commitment, Principles, and Key Requirements and to promote them within their field of activity.



Individual employee responsibility – for specific aspects of Product Stewardship that apply to their field of activity – is a clear expectation by Bayer management.

Independent of any measures taken with respect to compliance with our Product Stewardship Commitment, Principles, and Key Requirements document, all applicable binding statutes, laws, ordinances, rules, regulations, orders or codes of any governmental entities that deal with product safety, occupational health/safety, consumer protection, conservation of landscape, pollution control and other related subjects, must be complied with.

To continuously improve its Product Stewardship approach, Bayer will regularly assess the effectiveness of implementation and execution of the Principles and Key Requirements contained in this document. Key Requirements are considered to be dynamic and will be updated as required, taking into account technical, economic, regulatory and societal changes.

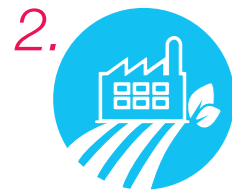
Information:

Throughout this document, a colored background highlights the Product Stewardship Principles. The Key Requirements are indicated by an arrow and are numbered (e.g., [KR 1.6]) giving the number of the Principle and the running number of the Key Requirement.

For explanations of technical terms, please refer to section: Definitions.

Overview

of the Product Stewardship Principles



2. Production

Bayer production facilities and sites will be of an appropriate standard in all countries in which products are manufactured or seeds are produced to minimize risks to health, safety and the environment, as well as to use resources efficiently and in compliance with applicable regulations or industry standards. Where third parties produce on behalf of Bayer, contractual agreements will include stewardship requirements consistent with Bayer internal requirements.



3. Packaging, Storage and Transport

Bayer will ensure that packaging is qualified for use with products and that products are stored and transported according to applicable legal and regulatory requirements in a manner that is appropriate for the market and intended use, including guidance on use, storage, and handling consistent with FAO or ETS Guidelines and internal Bayer standards.



4. Marketing, Branding, Intellectual Property, Sales and Distribution

Bayer will adhere to ethical sales and marketing practices that meet applicable regulations, as well as internal Bayer standards. Responsible marketing and sales also involves monitoring the implementation of procedures, systems and processes by all relevant Bayer legal entities and distributors of Bayer products and services.



5. Integrated Pest Management/Resistance Management

Bayer will support the implementation of Integrated Pest Management (IPM) measures, including resistance management tools for all Bayer products and services.



6. Responsible Use

Bayer will ensure that appropriate programs are implemented to train and instruct Bayer employees and customers regarding the responsible management of Bayer products and services throughout their life cycle.



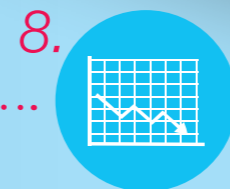
7. Container Management

Bayer will actively support programs to safely recycle and, if not feasible, encourage safe disposal of empty packages and containers in accordance with local regulations.



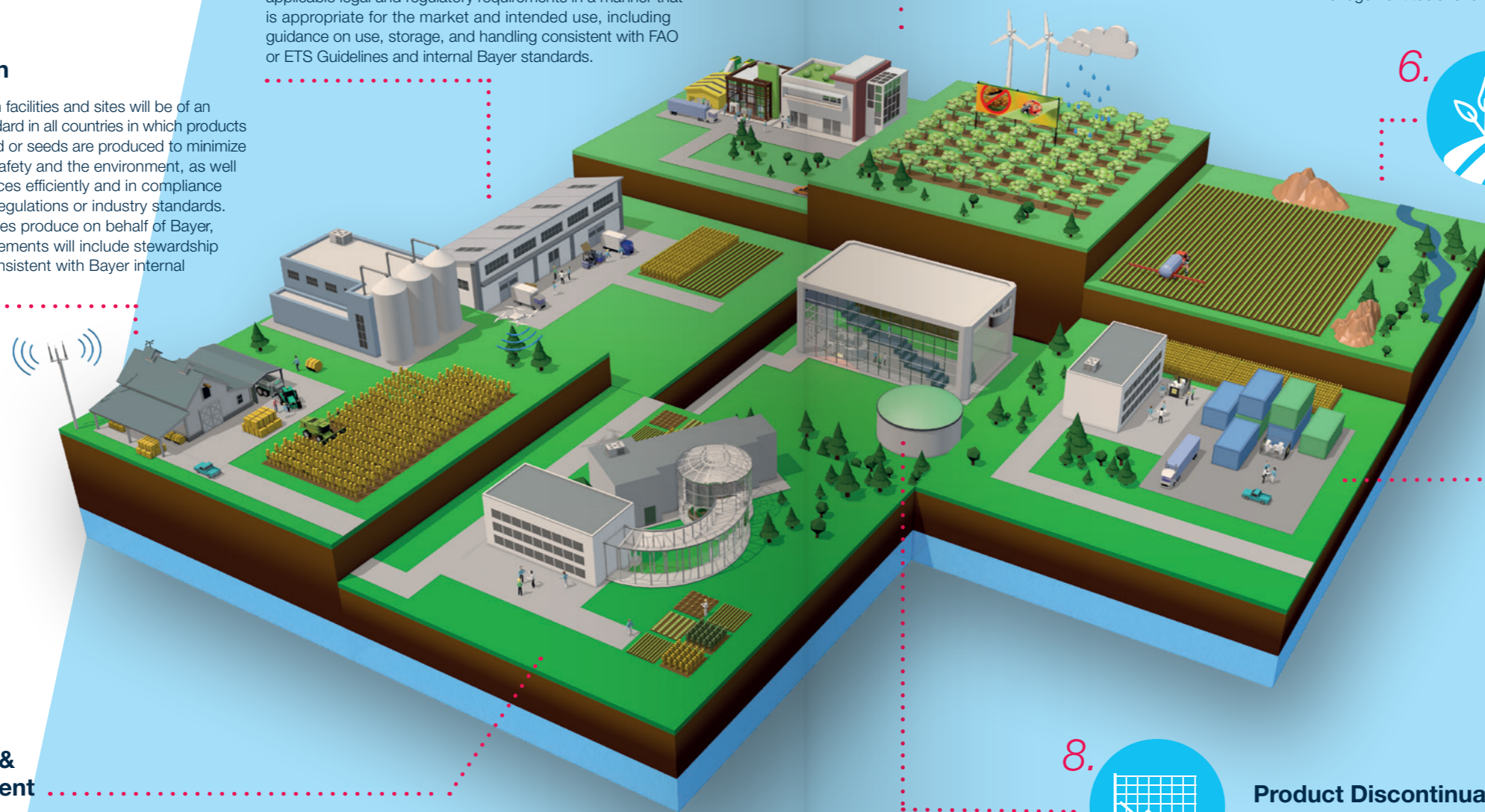
1. Research & Development

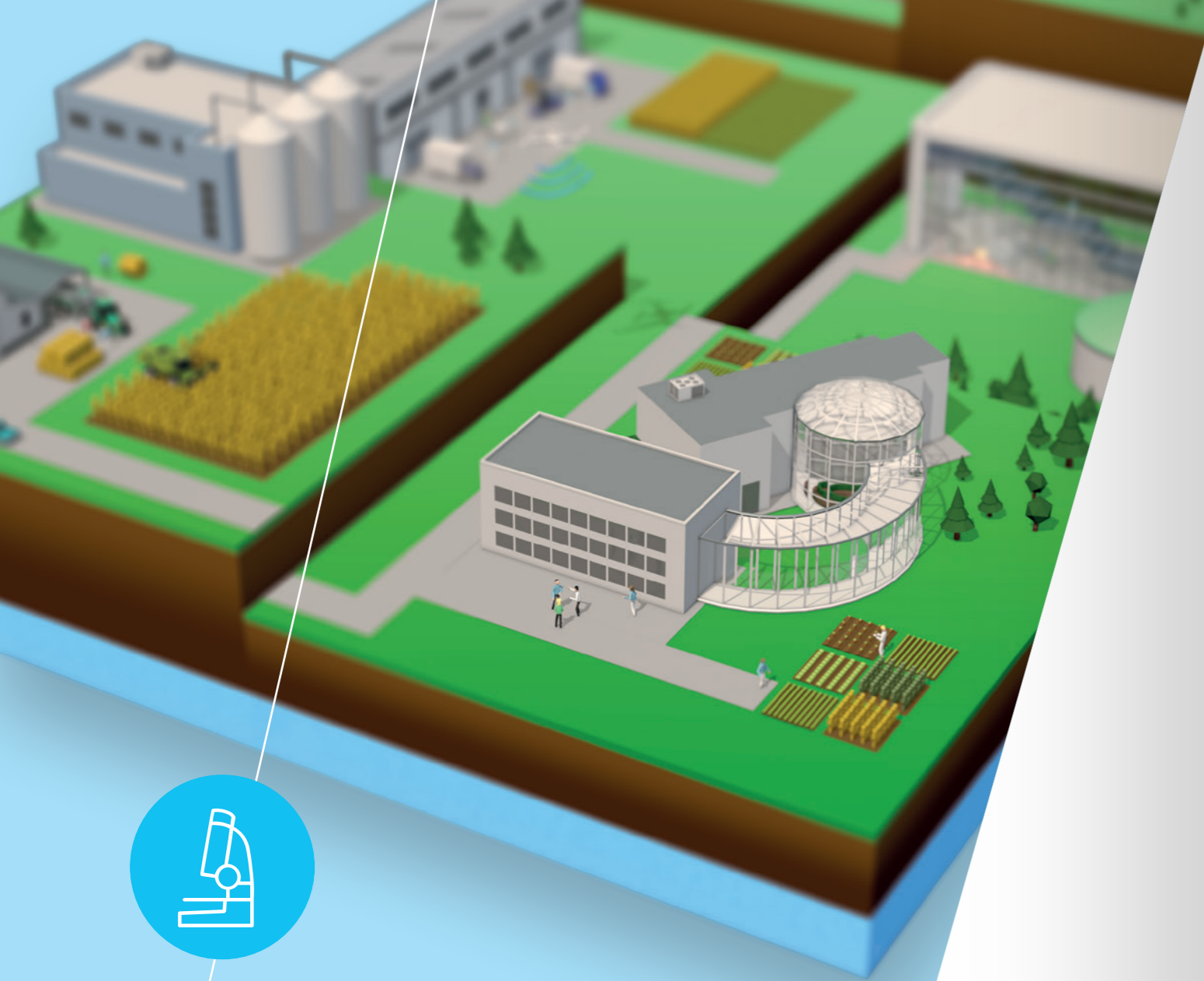
Bayer aims to develop sustainable products and services with improved efficacy, productivity, environmental and human safety profiles. Bayer will test products and services according to applicable regulations and perform robust and comprehensive risk assessments in accordance with sound scientific procedures and applicable regulatory requirements. Bayer will obtain product authorizations in the country where the product is to be cultivated, sold or used, as well as import tolerances/authorizations for key import countries with functioning regulatory systems and will follow accepted industry standards.



8. Product Discontinuation/Disposal of Obsolete Stocks

Bayer will have policies and procedures in place to ensure safe and effective discontinuation of products and services throughout the life cycle, including disposal of obsolete product inventory or waste.





1. Principle

Research & Development

Bayer aims to develop sustainable products and services with improved efficacy, productivity, environmental and human safety profiles. Bayer will test products and services according to applicable regulations and perform robust and comprehensive risk assessments in accordance with sound scientific procedures and applicable regulatory requirements. Bayer will obtain product authorizations in the country where the product is to be cultivated, sold or used, as well as import tolerances/authorizations for key import countries with functioning regulatory systems and will follow accepted industry standards.



KEY REQUIREMENTS:

Bayer will strive to develop improved products, services and technologies

- > All business units involved in the Research and Development of new products and services will strive to [KR 1.1]:
 - Develop new products and services with improved toxicological human, environmental and safety profiles.
 - Develop new products and services that improve the use of resources.
 - Develop new products and services with safety profiles suitable for IPM.
 - Improve plants to enhance crop production methods, improve nutritional and health profiles, or increase overall yield.
 - Substitute higher risk profile formulators with materials that have lower risk profiles.
 - Minimize the risk of unintended release and exposure to non-target areas.
- > Develop products, services and technologies that reduce the need for Personal Protective Equipment (PPE). [KR 1.2]
- > Support programs that enhance the availability and affordability of PPE; and align PPE with user education and abilities in the country of sale. [KR 1.3]
- > Develop and support improvement of application technologies and implementation of best practices to minimize occupational and environmental exposure. [KR 1.4]

Bayer will test adequately and effectively, ensuring quality and genetic integrity

- > Products and services developed will be thoroughly tested and evaluated using recognized, sound scientific procedures and test methods in accordance with or exceeding regulatory requirements and industry standards. [KR 1.5]
- > Information and data from reliable external sources, including peer-reviewed scientific publications, will be considered for the assessment of product performance and safety. [KR 1.6]
- > Results of safety-related studies will be made available to external experts and the public according to the Bayer Transparency Initiative. [KR 1.7]
- > Safe handling requirements will be developed and followed for all new molecules, biological materials and formulations. These include the highest standards of PPE and biosafety considerations when handling material derived from new technologies. [KR 1.8]



1. Principle

Research & Development



- > Where required, country-specific import approvals and testing permits or authorizations for non-registered products or materials will be obtained and followed. [KR 1.9]
- > Procedures will be in place when performing trials to prevent non-registered products from entering the food or feed chain or result in an uncontrolled environmental release, unless appropriate regulatory approvals are in place. [KR 1.10]
- > Research and development of seed, biological, or chemistry technologies, including the use and application of experimental products and services or materials in trials, will only be performed by trained personnel. Experimental product, seed and plant materials will be labeled to clearly identify the material, meet applicable regulatory requirements and include information on safe handling. [KR 1.11]
- > Processes will be assessed and implemented to help avoid unintended comingling or cross contamination of any product. [KR 1.12]
- > Crops and harvests from trials with non-registered products and uses will be destroyed, unless other disposition is allowed by regulations and/or laws. [KR 1.13]

Bayer will obtain registrations where the product is sold and import tolerances or import authorizations for key import countries with functioning regulatory systems

- > Regulatory data packages will be developed and submitted to comply with national and international regulatory requirements before commercialization. [KR 1.14]
- > Regulatory studies will be conducted where high testing standards are in place and, at a minimum, the International FAO Code of Conduct (for plant protection products), or regulatory standards of Organisation for Economic Co-operation and Development (OECD) countries (for biotechnology products) are applied, unless local regulations require otherwise. [KR 1.15]
- > Residue trials for crop protection products will be conducted in accordance with national/regional regulatory requirements prior to marketing. These tests must – at the minimum – be in accordance with Codex Alimentarius and FAO guidelines on good analytical practice and crop residue data in order to provide a basis for establishing appropriate maximum residue limits. [KR 1.16]

- > The potential impact on global import and export trade will be considered; key country import tolerances or import authorizations will be obtained to minimize trade disruptions arising from commercialization of its products. [KR 1.17]
- > Work with relevant stakeholders to ensure that information concerning product authorizations in other countries is communicated. [KR 1.18]
- > Validated methods and training for analysis that ensure identity and key attributes of products (including the respective analytical standards for any active ingredient, or formulation, traits or micro-organisms) will be made available at an appropriate time to regulatory authorities or other relevant stakeholders on request. [KR 1.19]
- > Regulatory authorities will be provided with new or updated product-specific information that could reasonably impact regulatory conditions or the regulatory assessment and status of the product in a timely manner and consistent with regulatory requirements. [KR 1.20]



1. Principle

Research & Development



Bayer will provide transparent and accurate information for product use

- > Proposed use pattern, label claims and directions, packages, and technical literature in local languages will reflect the outcome of scientific tests and assessments and at a minimum comply with all conditions of the applicable authorization and internal minimum requirements, including clarity on the type of application. [KR 1.21]
- > Product containers and related outer packaging will be clearly labeled with adequate and accurate information in accordance with registered or approved uses. [KR 1.22]
- > Product labels will comply with local regulatory requirements for classification and labeling. [KR 1.23]
- > In countries where there are no specific requirements for labeling, crop protection products will be labeled in accordance with the Global Harmonized Systems Codes (GHS) and the FAO Guideline on Good Labeling Practice of Plant Protection Products. [KR 1.24]
- > Specific claims on the safety of a product when used as directed are permitted only when local legislation allows and scientific evidence is available to support the claim. [KR 1.25]
- > Product labels will be written in an appropriate language and understandable to end users. [KR 1.26]
- > Product labels will include symbols and pictograms as appropriate. [KR 1.27]
- > Information and instructions will be provided with each product package in adequate language and format to ensure effective risk management during handling, according to local regulations. [KR 1.28]
- > Product labels, use instructions and packaging will include safety text where relevant that includes [KR 1.29]:
 - Information on appropriate PPE.
 - Information on first aid and medical advice.
 - Warnings against the inappropriate use of empty containers/seed bags.
 - Instructions on cleaning and safe disposal of empty containers/seed bags and excess product.
 - Instructions on re-entry timelines with or without PPE to areas where product(s) have been used.



- > Product packaging will clearly identify contents and include lot or batch of the product to allow traceability. [KR 1.30]
- > Where relevant, product labels and/or bags/tags will clearly show the identity of the registrant/supplier, including a telephone contact number in case of an emergency. [KR 1.31]
- > Product packaging will carry the release date (month and year) of the lot or batch and provide relevant information on appropriate storage conditions for the product in accordance with national labeling rules and requirements. [KR 1.32]
- > Products sold under specific trademarks and/or brand names will only contain the active ingredient(s), trait(s) or variety approved by Bayer for use under that name in accordance with applicable quality standards. [KR 1.33]
- > The same product trademarks/brand names will not be used simultaneously in a country for crop protection formulations containing different active ingredients. [KR 1.34]
- > Contracts and agreements will be completed with Business Partners to define key requirements or restrictions on product use and include appropriate stewardship and quality provisions that are equivalent to internal Bayer requirements for the applicable product(s). [KR 1.35]



2. Principle

Production

Bayer production facilities and sites will be of an appropriate standard in all countries in which products are manufactured or seeds are produced to minimize risks to health, safety and the environment, as well as to use resources efficiently and in compliance with applicable regulations or industry standards. Where third parties produce on behalf of Bayer, contractual agreements will include stewardship requirements consistent with Bayer internal requirements.

KEY REQUIREMENTS:

Bayer production sites, company-owned or contracted, will be of a suitable safety standard

- > Each site/location will take all necessary precautions to protect workers, bystanders, nearby communities and the environment during its operations. [KR 2.1]
- > Each site/location will establish and implement an integrated and process-oriented quality, health, safety, and environment management system suited to its particular needs, based on Bayer internal standards, as well as industry standards, such as Responsible Care. It will focus on the systematic identification and mitigation of site risks and supported by sharing of knowledge, learning and technology solutions within Bayer. [KR 2.2]
- > Bayer will ensure the proper siting of manufacturing and formulation plants, as well as their storage areas, and will adequately monitor and control waste, emissions and effluents in accordance with national regulations, where available, or in accordance with relevant international guidelines. [KR 2.3]
- > Each site/location will adopt engineering standards and operating practices appropriate to the nature of the production operations and the hazards involved and ensure the availability of appropriate PPE. [KR 2.4]





2. Principle

Production



- > Formal hazard identification and risk assessment will be conducted at a site level for all existing activities, modifications, substances, new processes and projects. [KR 2.5]
- > Processes will be designed such that potential risks are minimized, as appropriate, through the selection of materials and process parameters. [KR 2.6]
- > Each site/location where Bayer products are handled will have access to current Safety Data Sheets (SDS). [KR 2.7]
- > Safety Data Sheets (SDS), when applicable to a product, will be provided with Bayer product samples when supplied to a third party. [KR 2.8]

Bayer will ensure product integrity through sound quality assurance and quality control measures

- > Quality and genetic integrity will be maintained by a clearly defined chain of custody. [KR 2.9]
- > Product identification and traceability procedures will be followed to allow the unique identification of products and raw materials through relevant stages of production, starting with receipt of raw materials, until storage and delivery of the final product. [KR 2.10]
- > Product manufacturing will ensure that the quality meets the registered specification. When Bayer becomes aware that a product does not meet specifications, corrective actions in accordance with relevant regulations will be taken. [KR 2.11]
- > Production by Business Partners – on behalf of Bayer – conducted under contract is evaluated prior to and during production to ensure compliance with regulatory and/or industry standards, agreed upon quality assurance and quality control measures and is consistent with Bayer stewardship requirements. [KR 2.12]
- > Formal changes to materials, process and/or equipment at Bayer sites or Business Partners producing Bayer products will follow a management of change process, which is reviewed and approved by Bayer prior to implementation. [KR 2.13]
- > Every reasonable precaution will be taken to ensure that Bayer products do not contain residual impurities in the form of additional active ingredients, microbial contaminants, or other impurities at levels that will impact safety, efficacy, customer acceptance, usability, or render the products non-compliant with applicable country laws. [KR 2.14]
- > Micro-organisms from Master Cell Banks representing the active ingredient of biological products will be supplied by Bayer to manufacturing sites and Business Partners and preserved in a manner to protect genetic integrity. [KR 2.15]
- > Product quality standards will be defined to ensure that the product produced meets and conforms with applicable regulatory, industry and internal Bayer standards. [KR 2.16]
- > Quality control methods will be followed to ensure that product quality standards are being met. [KR 2.17]



3. Principle

Packaging, Storage and Transport

Bayer will ensure that packaging is qualified for use with products and that products are stored and transported according to applicable legal and regulatory requirements in a manner that is appropriate for the market and intended use, including guidance on use, storage and handling consistent with FAO or ETS Guidelines and internal Bayer standards.



KEY REQUIREMENTS:

Bayer will ensure safe storage and transport

- > Storage and transport will be in approved containers and in compliance with international and/or national standards on the transport of dangerous goods by air, sea, road, rail or inland waterways when applicable for the product. [KR 3.1]
- > Products, excluding untreated seeds, will not be transported in the same container or compartment as food, drugs, toys, clothing, cosmetics or household goods. [KR 3.2]
- > Will promote the implementation of measures to ensure suitability of vehicles and safe storage and securing, as well as traceability of the load, including contamination prevention requirements. [KR 3.3]
- > Storage and transportation requirements of products will be based on the properties of the materials and will comply with applicable local requirements and regulations. [KR 3.4]
- > Business Partners who provide transport and storage facilities will be contractually obligated to follow procedures consistent with the procedures at Bayer facilities and in compliance with applicable local regulations. [KR 3.5]

Bayer packaging materials will be in accordance with applicable legal requirements, FAO guidelines and internal standards

- > The development and use of packaging materials for purchased goods, intermediates and finished products must take the following aspects into account [KR 3.6]:
 - Quality
 - Resource conservation
 - Transport safety
 - Interactions between the product and packaging
 - Adequate barrier properties to protect the quality and genetic integrity
 - Safety in operation (filling, handling and application)
 - Use of combinations of packaging materials that support recycling
 - Use of packs that allow complete emptying and rinsing to support recycling in a manner that is safe for the handler
- > Containers for products intended for or supplied to the general public will not have either a shape or design likely to attract or arouse the curiosity of children or have a presentation or a design similar to that used for foodstuffs, animal feed, or medicinal or cosmetic products, which could confuse consumers. [KR 3.8]
- > A reasonable range of pack sizes and types will be provided that are appropriate to the needs of customers. [KR 3.9]
- > Ready-to-use packages or format will be used for Bayer products when reasonably possible and consistent with our sustainability commitments. [KR 3.10]
- > Products of adequate quality, packed and labeled as appropriate for each specific market will be supplied. [KR 3.11]
- > Containers for crop protection products that can be easily opened by children will not be used. [KR 3.7]



4. Principle

Marketing, Branding, Intellectual Property, Sales and Distribution

Bayer will adhere to ethical sales and marketing practices that meet applicable regulations, as well as internal Bayer standards. Responsible marketing and sales also involves monitoring the implementation of procedures, systems and processes by all relevant Bayer legal entities and distributors of Bayer products and services.

KEY REQUIREMENTS:

Bayer will comply with laws, regulations and good business practices

- > Comply with all applicable laws and regulations dealing with marketing practices, the applicable global, regional and local industry codes of conduct relevant for our business, and all Bayer internal standards. [KR 4.1]
- > Ensure trading and/or shipments of products and services comply with the relevant international regulations and conventions. [KR 4.2]
- > Take reasonable efforts to combat counterfeit activities related to the production and formulation, export and import, any kind of transportation, distribution, sale and use of products and services. [KR 4.3]
- > Evaluate demand for a product in the country of sale prior to providing the product to avoid building up obsolete stocks. [KR 4.4]
- > Follow legal and regulatory requirements, as well as industry and internal Bayer standards, when introducing products and services in countries of sale. [KR 4.5]
- > Recommend, advertise and promote only products/product uses that have been registered or authorized in the country of sale. Additionally, these products may be subjected to a directed use or stewarded program if use of the product is not yet authorized for import of food and feed commodities in applicable import countries. [KR 4.6]
- > Use appropriate business practices and industry standards for products and services that do not need a registration or authorization. [KR 4.7]
- > Recommend only lawful uses of a product. All promotion and brand communication claims will comply with applicable laws and will be technically substantiated. [KR 4.8]
- > Make announcements of expected regulatory decisions or technical/educational publications on a product prior to authorization for sale in a country, provided they comply with national rules and regulations. In countries where no national rules or regulations exist, it will be made clear in the announcement/publication that the sale/use of the product is not yet allowed. [KR 4.9]





4. Principle

Marketing, Branding, Intellectual Property, Sales and Distribution

Bayer will be honest and reliable

- > Advertising, promotion and informational materials will be understandable, clear and consistent irrespective of form or forum. They will not contain any statement or visual presentation, which, directly or by implication, omission, ambiguity or exaggerated claim, is likely to mislead or create misunderstandings by buyers/users. [KR 4.10]
- > Advertising of products and services that are legally restricted to be used only by trained or registered operators will not be publicly advertised through journals other than those catering to such operators, unless the restricted availability is clearly and prominently mentioned. [KR 4.11]
- > Advertising material will only contain representations that reflect the proper use of the product and not contain any visual presentation of potentially dangerous practices. [KR 4.12]
- > Statements on efficacy, yield and performance will not be made without a qualifying phrase, such as "when product is used as directed." [KR 4.13]
- > Statements on intrinsic product safety for crop protection products will generally not be made in advertising or promotion. [KR 4.14]
- > Advertising material will not include comparison with brand names of competitors unless this is allowed by national laws. False or misleading comparisons with competitor products and services will not be made. [KR 4.15]
- > All advertising and promotional materials will undergo internal review for accuracy, appropriateness and compliance before being released outside the company. [KR 4.16]



Bayer will listen attentively and communicate appropriately

- > Proper information about any risk associated with Bayer products and services will be transparently communicated in accordance with industry practices and relevant legal requirements. [KR 4.17]
- > Interactions with stakeholder groups will be responsible and transparent. [KR 4.18]
- > Outside views and feedback will be actively sought and considered in Bayer daily work. [KR 4.19]

Bayer cares about people, safety, quality and the environment

- > Systems and processes, including complaint management, will be 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. [KR 4.20]
- > Reasonable market monitoring, entry and control will be implemented to mitigate risk related to counterfeit and illegal products and services. [KR 4.21]
- > Marketing of products, including those identified as highly hazardous products (HHPs) will be adapted to the extent required by risk evaluations. If necessary, labels, promotion activities and sales will be adapted accordingly, including targeted sales restrictions. [KR 4.22]
- > Sales will be stopped and products recalled, if handling or use according to label is found to pose an unacceptable risk to human health, the environment or product quality, and these risks cannot be mitigated through stewardship or other appropriate measures. [KR 4.23]
- > Recall procedures will be in place for all businesses/products at global and local level, so that any recalls that become necessary are run efficiently and in a timely manner. [KR 4.24]
- > Corrective actions will be implemented where improvements to systems and processes are identified. [KR 4.25]



4. Principle

Marketing, Branding, Intellectual Property, Sales and Distribution

Bayer will enable Business Partners to fulfill the Stewardship requirements for Bayer products and services

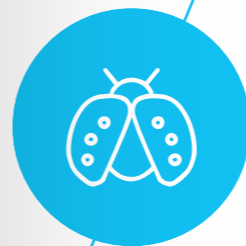
- > Business Partners who handle Bayer products and services will contractually be required to implement Product Stewardship that is equivalent to Bayer internal standards and that meet relevant regulatory requirements and industry standards. [KR 4.26]
- > Business Partners who license Bayer technologies will agree to adhere to Bayer contractual stewardship requirements and to produce products and services containing Bayer technologies that meet Bayer quality assurance standards. [KR 4.30]
- > When commissioning relevant Business Partners as suppliers, Bayer will endeavor to ensure that they apply the same quality standards that are applied by Bayer. [KR 4.27]
- > Steps will be taken to avoid child labor at Bayer and Business Partner operations, consistent with the International Labour Organization's (ILO) 2 core labor standards and the United Nations Global Compact principles. The term "child" refers to any person under the age of 15 (or lower according to the applicable local laws), or under the minimum age for completion of compulsory education, or under the minimum age for employment in any particular country, whichever is the highest. [KR 4.31]
- > New Business Partners contracted to toll manufacture Bayer products will have an evaluation of their equipment, quality control, and qualification of personnel against existing industry standards, applicable regulatory requirements and internal Bayer standards, and may need to have a site inspection to ensure these are understood and capable of being followed. [KR 4.28]
- > Employees under the age of 18 must not perform hazardous work. [KR 4.32]
- > Business Partners who toll, supply, handle and transport Bayer products agree to implement an efficient due diligence process to prevent participation in activities related to counterfeit and illegal products. [KR 4.29]
- > Technical and commercial Bayer staff will provide the appropriate advice, support and training to their Business Partners, such that they are adequately qualified to present accurate information on Bayer products and services to their customers. [KR 4.33]



- > Business Partners who are asked to supply analytical-grade standards to third parties conducting studies on Bayer products, must utilize a Bayer authorized source. [KR 4.34]
- > The privacy and data protection of customer or consumer information supplied to Bayer by Business Partners will be observed and meet the applicable legal requirements. [KR 4.35]

Bayer supports strong and effective intellectual property protection

- > Innovation within Bayer will effectively be protected by patents, plant variety protection rights, trade secret or other means. Details on innovation at Bayer will be considered confidential and not disclosed unless relevant agreements and applicable Bayer internal approvals are in place. [KR 4.36]
- > When made aware of intellectual property infringements by third parties or those related to counterfeit and illegal products and services, Bayer will take appropriate actions to stop the infringing or illegal activities. [KR 4.38]
- > Intellectual property rights of third parties will be reviewed and monitored by Bayer to assess if they are relevant to Bayer products and services or activities and require negotiation to access the innovation or require action to prevent infringement on protected Bayer innovation. [KR 4.37]



5. Principle

Integrated Pest Management/ Resistance Management

Bayer will support the implementation of Integrated Pest Management (IPM) measures, including resistance management tools for all Bayer products and services.

KEY REQUIREMENTS:

Bayer will support resistance management

- > Bayer will develop, position and promote IPM solutions in the market for its products and services. [KR 5.1]
- > Bayer will undertake research to understand how resistance mechanisms work, how resistance evolves, and how it can be managed to optimize the discovery of new modes of actions and to create integrated solutions. [KR 5.4]
- > Bayer will develop, communicate and implement resistance management guidance based on the mutually agreed principles of CropLife and Resistance Action Committees to prolong the effectiveness of products and limit the impact should resistance occur. This includes the consideration of all available technologies, such as chemical and biological products and traits, as well as beneficial insects. [KR 5.2]
- > Bayer will collaborate with other stakeholders (e.g., universities) to better understand local resistance dynamics, and together, craft the best product strategies and tailor solutions for farmers. [KR 5.5]
- > Bayer will train farmers and other stakeholders on Resistance Management and on IPM within the framework of Good Agricultural Practice and ETS Insect Resistance Management. [KR 5.3]
- > Bayer will communicate our knowledge internally and externally in a collaborative way to raise the level of awareness and competence on all levels in agriculture. [KR 5.6]





6. Principle

Responsible Use

Bayer will ensure that appropriate programs are implemented to train and instruct Bayer employees and customers regarding the responsible management of Bayer products and services throughout their life cycle.

KEY REQUIREMENTS:

Bayer will implement training programs for staff and customers

- > The use of Bayer products and services, and the occurrence of any problems arising from the use of the products and services, will be actively monitored to potentially identify the need for changes in labeling, directions for use, formulation or product availability. [KR 6.1]
 - > Where compulsory country training and accreditation requirements are absent or inadequate to ensure safe and responsible use of products and services, Bayer will support the responsible use of its products and services through the implementation of appropriate training measures, either through its own activities and/or those of industry associations, and through collaboration with various stakeholders, including governments and extension services. [KR 6.2]
 - > Training programs will emphasize proper use of Bayer products and services and, as appropriate and relevant, include information on [KR 6.3]:
 - Hazard and risks
 - Symptoms of product-related poisoning
 - Actions to take in case of emergency
- Use of recommended personal protective clothing
 - Clean-up of product spills
 - Personal hygiene
 - Risks associated with the handling and use of counterfeit and illegal products and services, and how to distinguish original from counterfeit and illegal products and services to avoid unintended purchase
 - Correct transportation and storage of products during distribution
 - Correct way to prepare products and services for use
 - Recommended application techniques
 - Calibration, use, cleaning and maintenance of equipment
 - Correct cleaning of empty containers
 - Correct disposal of waste products and empty/cleaned containers
 - Measures to protect the environment, sensitive crops and water sources
 - Minimizing exposure and risk to people and animals





6. Principle

Responsible Use



> All staff involved in marketing, promotion, selling or giving advice on Bayer products and services will be adequately trained to present accurate and valid information on the products and services sold, as well as understand laws, regulations, internal standards relevant to the commercial use, and marketing of the product. [KR 6.4]

> Best management practices for the safe handling and proper application of Bayer products and services will be actively promoted by Bayer staff to customers and users of the products and services, including support for the availability of PPE. [KR 6.5]

Bayer will not support, encourage or tolerate any unapproved use of Bayer products and services or technologies

> When aware of an unapproved use, Bayer will promptly take steps to correct the situation, prevent reoccurrence and, as relevant, report to external stakeholders or regulatory authorities. [KR 6.6]

> To detect, control and prevent the production, transport, trade and use of counterfeit and illegal products and services, Bayer will support governments and authorities through national and international cooperation and information exchange. [KR 6.7]

Bayer will take measures to prevent and manage incidents

> Reasonable and practical measures will be taken by Bayer to prevent incidents involving Bayer research and development and commercial activities. [KR 6.8]

- Address reported incidents in a comprehensive and timely manner.
- Implement measures to reduce the likelihood of recurrence.
- Report them to corporate leadership as required by internal Bayer standards.

> Should an incident occur, the country/country cluster organization will [KR 6.9]:

- Assess all reported accidental or intentional exposures in which Bayer products and services may be implicated and if they are found to have been involved, and as appropriate, complete an incident report in accordance with internal Bayer standards.

> Procedures and trainings will be in place with Business Partners to promptly respond to incidents involving Bayer products and services and report to the Bayer country organizations where the incident occurred. [KR 6.10]

> Procedures for incidents will include possible communications to potentially impacted stakeholders, such as downstream partners, regulators and industry associations. [KR 6.11]

> The Bayer country organization will inform and cooperate with national authorities, users and Poison Control Centers to enable prompt remedial action. [KR 6.12]

> Updated SDS for products will be provided in an appropriate language to Poison Control Centers or other responsible organizations, to regulatory authorities, transport companies, distributors, retailers and, if requested, end users. This applies to all Bayer products sold or supplied by, or on behalf of Bayer. [KR 6.13]



7. Principle

Container Management

Bayer will actively support programs to safely recycle and, if not feasible, encourage safe disposal of empty packages and containers in accordance with local regulations.

KEY REQUIREMENTS:

Bayer will support container management

- > Container design will support safe disposal in accordance with [KR 7.1]:
 - National rules and regulations where they exist.
 - FAO Code of Conduct on Pesticide Management, if national rules and regulations do not exist.
 - CropLife International (CLI) guidelines, if not covered by the FAO Code of Conduct on Pesticide Management.
- > Cleaning steps will be defined in product use guidance for Bayer products to enable empty, cleaned product containers to be treated as non-hazardous waste. [KR 7.2]



8. Principle

Product Discontinuation/ Disposal of Obsolete Stocks

Bayer will have policies and procedures in place to ensure safe and effective discontinuation of products and services throughout the life cycle, including disposal of obsolete product inventory or waste.

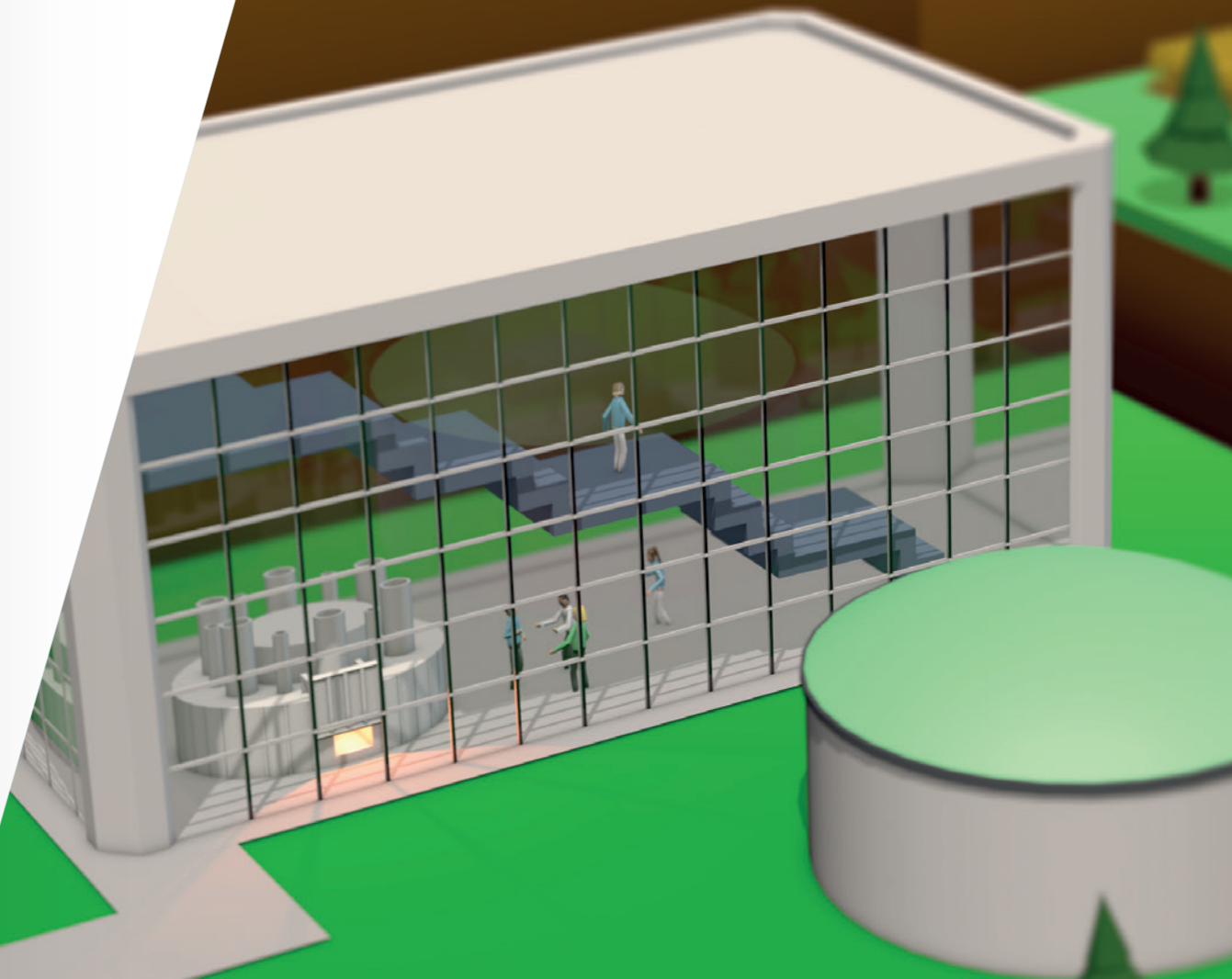
KEY REQUIREMENTS:

Bayer will discontinue products and services at the end of their life cycle

- > Processes will be in place to ensure a smooth discontinuation of Bayer projects and/or products and services. [KR 8.1]
- > Throughout the discontinuation phase, Bayer will comply with and ensure that appropriate regulatory permits, conditions and/or approvals are maintained and, as appropriate, continue for a defined period after commercial discontinuation to sufficiently mitigate the issue of unintended presence that could lead to trade disruption. [KR 8.2]
- > Discontinuation activities will comply with commitments by Bayer to industry stakeholders or other non-governmental entities. [KR 8.3]

Bayer will support safe disposal of obsolete product stocks

- > Dispose of excess and obsolete internal materials consistent with regulatory and industry standards. [KR 8.4]
- > Assist in disposing of obsolete stocks of Bayer products in an environmentally sound manner through multilateral cooperations and/or through industry associations. [KR 8.6]
- > Participate in programs together with other stakeholders, such as retailers, farmers and authorities, to prevent products supplied by Bayer from becoming obsolete stocks. [KR 8.5]



Definitions

Active Ingredient

means the biologically active part of the product.

Advertising

means the promotion of the sale and use of products via printed and electronic media, signs, displays, gifts, demonstration, or word of mouth.

Application

means the actual physical delivery by a technical aid, equipment or machinery of a product to the target organism, or to the place where the target organism comes into contact with the product.

Biologics

means products that are manufactured from or containing materials isolated from nature. Examples include bacteria, fungi, inoculants, natural products, and double stranded RNA.

Business Partners

include suppliers, toll manufacturers, distributors, agents, retailers, formulators, co-marketers, licensees, and seed producers.

Container

means any object used to hold a crop protection, treated seed or biologics product.

Compliance

means full adherence to, and implementation of, legal, regulatory and company requirements.

Crop Protection Product

is a product that protects crops from pests during crop production.

Disposal

means any operation to recycle, neutralize, destroy or isolate product waste, obsolete stocks, used containers and contaminated materials.

Distribution

means the process by which products are supplied through trade channels to national or international markets.

Environment

means surroundings, including water, air, soil and their interrelationship, as well as all relationships between them and any living organisms.

Excellence Through Stewardship (ETS)

is a global not-for-profit organization that promotes the universal adoption of stewardship programs and quality management systems for the full life cycle of agricultural biotechnology products.

Extension Services

means the entities in a country that are responsible for the transfer of information, technology advice and training regarding the improvement of agricultural practices, including the production, handling, storage and marketing of agricultural commodities.

Facilities

mean any place or operation where active ingredients or products are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed of, or where records relating to such activities are maintained.

Food and Agriculture Organization of the United Nations (FAO) International Code of Conduct on Pesticide Management

means the framework on pesticide management for all public and private entities engaged in, or associated with, production, regulation and management of pesticides. The new International Code of Conduct on Pesticide Management was approved by the 38th FAO Conference in June 2013. The Code provides standards of conduct that serve as a point of reference in relation to sound pesticide life cycle management practices, in particular for government authorities and the pesticide industry.

Formulation

means the combination of various ingredients designed to render the active ingredient useful and effective for the purpose claimed; it is the form of the product purchased by end users.

Good Agricultural Practice (GAP)

in the use of plant protection products comprises the officially recommended or nationally authorized uses of plant protection products under actual conditions necessary for effective and reliable performance and safety of the product. It encompasses a range of levels of plant protection applications up to the highest authorized use rate and/or frequency, applied in a manner which leaves a residue that is consistent with that authorized by a competent regulatory authority.

Globally Harmonized System (GHS)

establishes new classification criteria for physical, health and environmental hazards, along with associated hazard communication elements, notably pictograms, signal words and hazard statements for use on labels. It is an international system created by the United Nations and based on harmonizing major existing systems for classifying and labeling.

Hazard

means the inherent property of a product related to its physico-chemical and toxicological properties towards human beings and the environment.

Highly Hazardous Pesticides (HHPs)

means pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment, according to internationally accepted classification systems, such as WHO or GHS, or to their listing in relevant binding international agreements or conventions. In addition, plant protection products that appear to cause severe or irreversible harm to human health or the environment under conditions of use in a country may be considered to be, and treated as, highly hazardous.

Incident

means an unintended event or occurrence that disrupts or has the potential to disrupt operations, commerce, health and safety, the environment, and/or result in non-compliance with relevant regulations or standards for the industry or product.

Integrated Pest Management (IPM)

means the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human and animal health and/or the environment.

Label

means the written, printed or graphic matter on, or attached to, the product or the immediate container thereof and also to the outside container or wrapper of the retail package of the product that provides use requirements and required product information.

Life Cycle

means all the stages a product might pass through from initial invention through to final product discontinuation. The life cycle includes research and discovery, manufacture, formulation, packaging, distribution, storage, transport, use, degradation in the environment, and final disposal of obsolete stocks and/or used containers.

Manufacturer

means a corporation or other entity in the public or private sector or any individual engaged in the business or function of manufacturing components of a product and/or a final product.

Marketing

means the overall process of product promotion, including advertising, product public relations and information services, as well as the distribution and sale on national or international markets.

Master Cell Bank (MCB)

is defined as an aliquot of a single pool of cells that generally has been prepared from a selected clone under defined conditions, dispensed into multiple containers, and stored under defined conditions. An MCB typically originates from a research cell bank that is the “end point” of cell-line development.

Maximum Residue Limit (MRL)

means the maximum concentration of a residue that is legally permitted or recognized as acceptable in or on a food or agricultural commodity or animal feedstuff. The MRL is set at a value that is unlikely to be exceeded if the product creating the residue is used according to product label.

Monitoring

means collection and analysis of information on the status of, for example, compliance, environmental conditions, or public health events, such as poisoning incidents.

Packaging

means the container together with the protective wrapping to carry products via wholesale or retail distribution to users.

Personal Protective Equipment (PPE)

means any clothes, materials or devices that provide protection from product exposure during manufacture, handling and application. In the context of the International Code of Conduct on the Distribution and Use of Pesticides, it includes both specifically designed protective equipment and clothing reserved for product application and handling.

Pest

means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products, materials, or environments and includes vectors of parasites or pathogens of human and animal disease, and animals causing a public health nuisance.

Poison

means a substance that can cause disturbance of structure or function, leading to injury or death when absorbed in relatively small amounts by human beings, plants or animals.

Poisoning

means occurrence of damage or disturbance caused by a substance and includes intoxication.

Product

means a plant protection product, seeds, trait technology, biological materials, and other components, in the form in which they are sold.

Quality and Genetic Integrity

means characterized by approved methods at the phenotypic and genotypic level to ensure quality, purity and identity to agreed standards.

Registration

means the process whereby the responsible national government or regional authority approves the sale and use of a plant protection or seed trait product following the evaluation of scientific data aimed at demonstrating that the product is effective for its intended purposes and does not pose an unacceptable risk to human or animal health or the environment under the conditions of use in the country or region.

Regulations

mean the more detailed implementing provisions usually issued by the administrative authorities to describe the specific means by which the regulated community is required to carry out the provisions of legislation.

Residue

means any specified substances present in or on food, agricultural or other types of commodities, or animal feed, as well as in environmental media, including soil, air and water deriving from the use of a plant protection product. The term includes any derivatives of a plant protection product, such as conversion products, metabolites, breakdown products, reaction products and impurities considered to be of toxicological or ecotoxicological significance. The term “pesticide residue” includes residues from unknown or unavoidable sources (e.g., environmental contamination), as well as known, authorized uses of the chemical.

Resistance

means the naturally occurring, inheritable adjustment in the ability of individuals in a pest population to survive a treatment with or exposure to a plant protection product that would normally give effective control.

Responsible Care

is a worldwide initiative by the chemical industry where all employees are requested to act in line with corporate environmental protection and safety objectives and implementing innovative solutions with the aim of achieving continual improvements in health care, safety and environmental protection.

Key Contacts

Anna Pueschel, Monheim/Germany

Tel.: +49 175 301 3073
Email: anna.pueschel@bayer.com

Diane Re, Chesterfield/USA

Tel.: +1 636 737 9486
Email: diane.re@bayer.com

References

- > International Code of Conduct on the Distribution and Use of Pesticides (revised version), Food and Agriculture Organization of the United Nations; Rome, (revised version of 2014)
- > CropLife International Plant Biotechnology Code of Conduct
- > Responsible Care initiative of the International Council of Chemical Associations
- > Universal Declaration of Human Rights
- > Excellence Through Stewardship Guides



Risk

is the probability of occurrence of an undesirable event resulting from the use of a product, taking into account implemented mitigation measures.

Seed Product

is a product that can be planted to produce a crop and is the end result of research, development and/or plant breeding.

Seed Technology

means techniques and methodologies utilized during the research and development and/or breeding of a plant to produce a desired seed product.

Trait

is a genetically determined characteristic.

Unapproved Use

means the use of a product that is not as per label or country registration requirements or in a location where it is not authorized for use.

Use Pattern

means the combination of all factors involved in the use of a product, including the concentration of active ingredient in the preparation being applied, rate of application, timing of treatment, number of treatments, interval between treatments, use of adjuvants, and methods and sites of application, which determine the quantity applied, timing of treatment and interval before harvest.

Variety

is a subdivision of a species for taxonomic classification, used interchangeably with the term cultivar to denote a genetically uniform, stable group of plants.



Bayer

Bayer AG
Alfred-Nobel-Str. 50
40789 Monheim
Germany

<https://www.cropscience.bayer.com/>