

A close-up, high-angle photograph of a person's eye. The eye is looking slightly to the right. The iris is a light, hazy blue. In the reflection of the eye, a globe of the Earth is visible, showing continents and oceans. The background is a soft, out-of-focus blue and white. A green curved shape is on the left side of the image.

Product Stewardship Policy and Key Requirements





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Introduction



Product Stewardship is the responsible and ethical management of a product throughout its life-cycle, from its invention, through to its ultimate use and beyond. Product Stewardship has the following main objectives: to ensure best practices and maximise the benefits from product use, to provide beneficial, quality products that gain consumer and stakeholder confidence and to minimise potential risks to human health and the environment.

Bayer CropScience has adopted a life-cycle approach that addresses all major aspects of responsible product management. This includes research, development, registration, plant breeding, production, packaging, labelling, distribution, handling, application, storage and transport including empty product containers and product/waste disposal.

Bayer CropScience's Product Stewardship activities include extensive investment in safety testing of its products, the development of improved packaging design and crop production techniques, the development of new technologies for improved seed varieties and the provision of support services to promote responsible product use.

This document outlines Bayer CropScience's Crop Protection, BioScience and Environmental Science Product Stewardship Policy and Key Requirements throughout the life-cycle of its products world-wide.

It is based on the International FAO Code of Conduct on the Distribution and Use of Pesticides (revised version of 2002), the Croplife International Plant Biotechnology Code of Conduct and the Guidelines referred to therein and the "Excellence Through StewardshipSM" programme.

This Bayer CropScience Product Stewardship Policy and Key Requirements are intended to support all Bayer CropScience employees, who have to ensure the responsible use of our products.

Benefits for Bayer CropScience generated by a strong commitment to product stewardship include:

- ▶ Greater public confidence, by demonstrating our ability and expertise in technology improvement and by consistent documentation of research and development activities.
- ▶ Sustainable business operations, founded upon a reputation as an ethical company with high quality standards.
- ▶ Keeping existing and gaining new customers through their positive experience with our products and services.
- ▶ Maintaining and extending the life of our products in their respective markets.
- ▶ Strengthening relations and partnerships with a variety of stakeholders, including regulatory bodies, governments, researchers, farmers and the entire food chain.
- ▶ Differentiating ourselves from our competitors.
- ▶ Generating and strengthening own employee pride and support.



Policy



Bayer CropScience, as an industry leader, is committed to Product Stewardship as an integral part of its activities, in line with the principles of Sustainable Development and Responsible Care®. Bayer CropScience fully endorses the International FAO Code of Conduct on the Distribution and Use of Pesticides and the Croplife International Plant Biotechnology Code of Conduct together with the “Excellence Through StewardshipSM” programme and has used these as the basis for its Product Stewardship Principles.

Bayer CropScience will:

- ▶ Adopt the life-cycle approach to stewardship, ensuring that for each phase: research, development, commercialisation and product discontinuation a stewardship programme is in place.
- ▶ Comply with all relevant legislation and regulations in individual countries affecting the research, development, registration, production, distribution, sale, use and disposal of our products.
- ▶ Develop and sell products that do not pose an unacceptable risk to human and environmental safety when applied in the appropriate manner and for the intended uses.
- ▶ Develop quality varieties which will offer greater choice and improvements in crop production. Through sound scientific techniques new seed technologies will further advance this offering providing useful and improved seed products to customers.
- ▶ Manufacture products in compliance with Bayer AG's Sustainable Development Principles on the use of efficient and environmentally sound manufacturing processes.
- ▶ Maintain product integrity by quality assurance and quality control of products which ensures they are fit for their intended purpose.
- ▶ Support and promote the implementation of Sustainable Agriculture including Integrated Crop Management (ICM) through provision of appropriate products, techniques and services.
- ▶ Have an open dialogue with key stakeholders, during the development of (and prior to selling) seed products, and take into account import and export regulations in order to minimise trade disruptions.
- ▶ Work in partnership with various stakeholder groups to promote the responsible use of Bayer CropScience products.
- ▶ Promote the adoption of product stewardship by our contract or toll manufacturers and Licensees of Bayer CropScience technologies.
- ▶ Base stewardship activities and decisions on ethical behaviour which seeks to balance economic prosperity, environmental protection, public health and social need.

Friedrich Berschauer
Chief Executive Officer

Franz-Josef Placke
Head of Development

Implementation



Bayer CropScience will bring Product Stewardship to the attention of all employees within the Company and related groups. It is the responsibility of all Bayer CropScience employees to promote the correct use of our products. Bayer CropScience will ask all employees to follow the Product Stewardship Policy and Key Requirements and to promote them. Individual responsibility for specific aspects of Product Stewardship is clearly required by management.

Independent of any measures taken with respect to the compliance with this guidance document, all relevant statutes, laws, ordinances, rules, regulations, orders or codes of any governmental entities, dealing with product safety, occupational health / safety, consumer protection, conservation, pollution control and other related subjects, must be strictly applied.

The content of this Document is the minimum requirement from which each affiliate company of Bayer CropScience can derive its own Product Stewardship operational procedure, best suited to its national conditions, for implementation in the context of all applicable rules and regulations within the country while observing the basic commitment of Bayer CropScience to Product Stewardship.

To continuously improve its Product Stewardship approach, Bayer CropScience will monitor compliance with the defined Key Requirements and review progress. This monitoring and progress review will be done by the Product Stewardship functions. They will also issue a separate Guideline on the details of "Monitoring and Progress Review".

The relevance and applicability of the Key Requirements will be periodically reviewed by Management as they are considered to be a dynamic system which must be adapted as required, taking into account technical, economic, regulatory and social changes.

INFORMATION:

- ▶ Throughout this GUIDANCE DOCUMENT a coloured background highlights the PRODUCT STEWARDSHIP PRINCIPLES. Principles only valid for Crop Protection and Environmental Science will be highlighted with orange colour, all others with blue colour.
- ▶ 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.

See references



Overview of the principles

1. Product Integrity and Testing:

Bayer CropScience will test products adequately and effectively in accordance with sound scientific procedures and applicable regulatory requirements. Utmost care will be taken to avoid exposure during handling and when conducting bio-efficacy, crop selectivity and safety evaluations with new molecules, formulations or traits for which only limited toxicological and/or environmental information is available. Bayer CropScience will ensure the product integrity of its seed through sound quality assurance and quality control measures.

2. Product Authorisation:

Bayer CropScience will obtain product authorisation for products in the country where the product is to be sold. Bayer CropScience will take a consistent approach to research and development of products regardless of where in the world this may be. Where a regulatory system is not in place best international knowledge and accepted practices will be used.

3. Labels for Commercial Products:

Bayer CropScience labels for commercial Crop Protection and Environmental Science products will contain appropriate information on registered/recommended uses, first aid and medical advice, precautions for storage, handling and safe use, and instructions for handling and safe disposal of empty packages. Seed labels for commercial products will provide clear identity of the product, mention the applicable intellectual property rights and where necessary possible use restrictions and comply with the international and local regulatory requirements for labelling.

4. Products and/or Application Techniques:

Bayer CropScience will make every reasonable effort to develop products with further improved biological, toxicological, ecotoxicological and environmental profile and support improvement of application technologies.

5. Training:

Bayer CropScience will ensure that appropriate programmes are implemented in order to train, instruct and, as necessary, update our own staff and customers in all aspects of the responsible management of our products during their entire life-cycle from research to product discontinuation.

6. Production:

Bayer CropScience own production facilities will be of a suitable standard in all countries, where product is manufactured. Where third parties produce product on-behalf of Bayer CropScience contractual agreements will impose adequate stewardship requirements.

7. Packaging, Transport, Storage and Disposal of Crop Protection and Environmental Science Products:

Bayer CropScience will organise qualified packaging, transport, storage and disposal of its Crop Protection and Environmental Science products in accordance with applicable legal requirements, the respective FAO Guidelines and the Bayer CropScience Quality, Health, Safety and Environment Key Requirements.

8. Brand Communication:

Bayer CropScience will advertise and promote only products/product uses that have been registered or authorised in the country in which the product is sold and will ensure that all brand communication claims are technically substantiated. Announcements of regulatory decisions or technical articles for pre-launch of products that are not yet authorised can be made, provided they comply with national rules and regulations.

9. Business Partners:

Bayer CropScience will require that its business partners apply the same level of Product Stewardship to our products as is expected within our own Company.

10. Unapproved Uses:

Bayer CropScience will only endorse responsible use of its products. Therefore, it will not support, encourage or tolerate any unapproved use of our products or new seed technologies, nor the unapproved growing of seed products.

11. External Incident Prevention and Investigation:

Bayer CropScience will take all practicable measures to prevent any external accident or incident involving our R&D activities and products but should such accidents or incidents occur, they will be reported and fully investigated by the country organisation. Measures will be implemented to reduce the likelihood of recurrence. Potential incidents will be communicated and managed in a timely way to ensure that impact to the company and stakeholders, including trade disruptions, is minimised.

12. Intellectual Property:

Bayer CropScience will support strong and effective intellectual property protection for innovation in crop production technology and for Crop Protection and Environmental Science products. Bayer CropScience will procure adequate legal protection for its innovations. Bayer CropScience will not intentionally infringe valid intellectual property rights of third parties.



1. Principle

Product integrity and testing

Bayer CropScience will test products adequately and effectively in accordance with sound scientific procedures and applicable regulatory requirements. Utmost care will be taken to avoid exposure during handling and when conducting bio-efficacy and crop selectivity and safety evaluations with new molecules, formulations or traits for which only limited toxicological and/or environmental information is available. Bayer CropScience will ensure the product integrity of its seed through sound quality assurance and quality control measures.



KEY REQUIREMENTS:

- ▶ It must be ensured that each product is adequately tested by using recognised procedures and test methods so as to fully evaluate efficacy, behaviour, fate, hazard and risk with regard to the various anticipated conditions in the countries of use. Testing of crop protection products also includes a crop tolerance evaluation. [KR 1.1]
- ▶ It must be ensured that such tests are conducted in accordance with sound scientific procedures and all legal requirements, as e.g. the principles of Good Laboratory Practice. [KR 1.2]
- ▶ Bayer CropScience must ensure that procedures are in place designed to prevent seed derived from new technologies and crops treated with non registered products from entering the human food chain or animal products, unless appropriate regulatory approvals are in place to allow such practices. [KR 1.3]
- ▶ Experimental product samples/seed samples must be appropriately labelled including safe handling requirements. [KR 1.4]
- ▶ Research and development with new seed technologies and the application of new molecules or experimental formulations must only be made by trained personnel. Where required, permission to conduct field trials must first be obtained. [KR 1.5]
- ▶ All safe handling requirements for new molecules and formulations (such as personal protective equipment), and bio-safety considerations when handling material derived from new seed technologies, (such as use in appropriate containment or confinement facilities), must be followed. [KR 1.6]
- ▶ Bayer CropScience must develop, implement and communicate resistance management guidance to prolong effectiveness of its products and to limit the impacts should resistance occur. [KR 1.7]
- ▶ Product stewardship packages/programmes must be developed and implemented to support the best use of products so that they are sustainable and that benefits will be fully realised by stakeholders. [KR 1.8]

INFORMATION:

- ▶ The guidelines issued by CropLife International (CLI, formerly GCPF) Fungicide, Herbicide, Insecticide and Rodenticide Resistance Action Working Group provide information on anti-resistance concepts. A list of relevant information issued by CLI is attached. The Agricultural Biotechnology Stewardship Technical Committee provides comparable resistance management concepts for Bt-containing seed products.

[See references](#)



2. Principle

Product Authorisation

Bayer CropScience will obtain product authorisation for products in the country where the product is to be sold. Bayer CropScience will take a consistent approach to research and development of products regardless of where in the world this may be. Where a regulatory system is not in place best international knowledge and accepted practices will be used.



KEY REQUIREMENTS:

- ▶ A regulatory package based on international and national regulatory requirements must be developed before commercialisation. [KR 2.1]
- ▶ Bayer CropScience prefers to conduct studies in countries with an established regulatory system. Whenever it is necessary to conduct studies in countries without an established regulatory system, the International FAO Code of Conduct and, for biotechnology products, regulatory standards of OECD countries must apply. [KR 2.2]
- ▶ Bayer CropScience must consider the potential impact on global import and export trade by ensuring key country authorisations are obtained to minimise trade disruptions arising from commercialisation of seed products. [KR 2.3]
- ▶ It must be ensured that the proposed use pattern, label claims and directions, packages and technical literature truly reflect the outcome of scientific tests and assessments and comply with all conditions of authorisation. [KR 2.4]
- ▶ Residue trials for crop protection products must be conducted in accordance with national regulatory requirements prior to marketing. These tests must at 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 2.5]
- ▶ Methods for the analysis of any active ingredient or formulation and the identity of genetic modifications once validated, as well as the respective analytical standards, will be made available to regulatory authorities on request. [KR 2.6]
- ▶ Analytical grade standards of Bayer CropScience compounds must be supplied only to third parties conducting relevant research known to Bayer CropScience, e.g. official residue trials, environmental monitoring or authorised customers formulating with Bayer CropScience compounds. [KR 2.7]
- ▶ Seed confirmed to be of a quality fit for purpose, must be supplied only to third parties conducting relevant research and/or development known to Bayer CropScience e.g. for analytical testing by regulatory authorities or commercial testing partners. [KR 2.8]
- ▶ Training and assistance must be available to the technical staff involved in the relevant analytical work. [KR 2.9]
- ▶ Bayer CropScience must work with downstream partners to ensure product identity where necessary and that information concerning product authorisations is communicated. [KR 2.10]
- ▶ Regulatory authorities must be provided with new or updated information that could impact regulatory conditions or the regulatory status of the product, as soon as it becomes available. [KR 2.11]

INFORMATION:

- ▶ There are specific guidelines related to the development and evaluation of data considered in the registration process.

[See references](#)

3. Principle

Labels for Commercial Products

Bayer CropScience labels for commercial Crop Protection and Environmental Science products will contain appropriate information on registered/recommended uses, first aid and medical advice, precautions for storage, handling and safe use, and instructions for handling and safe disposal of empty packages. Seed labels for commercial products will provide clear identity of the product, mention the applicable intellectual property rights and where necessary possible use restrictions and comply with the international and local regulatory requirements for labelling.

KEY REQUIREMENTS:

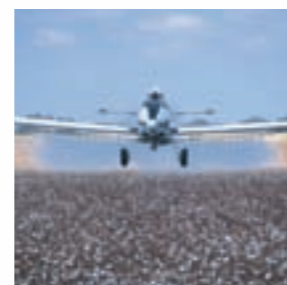
- ▶ All product containers and related outer packaging must be clearly labelled with adequate and accurate information in accordance with registered or approved uses. [KR 3.1]
- ▶ Specific claims on the safety of a product to bees, beneficial insects, fish, etc., when used correctly, are permitted, provided scientific evidence is available to support the claim. [KR 3.2]
- ▶ Product labels must be understandable to end users, written in an appropriate language and in compliance with national regulations. [KR 3.3]
- ▶ Product labels must include symbols and pictograms, if appropriate. [KR 3.4]
- ▶ Product packaging must clearly identify each lot or batch of the product. [KR 3.5]
- ▶ Product labels must clearly show the name, address and telephone number of the registrant as well as the name and telephone contact in case of an emergency regarding Crop Protection and Environmental Science products. [KR 3.6]
- ▶ Crop Protection and Environmental Science product packaging must contain the release date (month and year) of the lot or batch and contain relevant information on appropriate storage conditions for the product in accordance with national labelling rules and requirements. [KR 3.7]
- ▶ The safety text of Crop Protection and Environmental Science labels must cover relevant protective clothing. [KR 3.8]
- ▶ Crop Protection product labels must contain a re-entry time for each use, where appropriate. [KR 3.9]
- ▶ Crop Protection and Environmental Science product labels must clearly identify whether an application is allowed for ground and/or aerial application. [KR 3.10]
- ▶ Crop Protection and Environmental Science product labels must include a warning against the inappropriate use of empty containers. [KR 3.11]
- ▶ Crop Protection and Environmental Science product labels must include indication on decontamination of empty packages and safe disposal. [KR 3.12]
- ▶ With each product package, information and instructions must be provided in an adequate form and language to ensure effective risk management during handling according to local regulations. [KR 3.13]
- ▶ Products sold under specific trademarks must only contain the active ingredients or trait or variety approved for use under that name in accordance with normal quality standards. [KR 3.14]
- ▶ The same trademark must not be used simultaneously in a country for formulations containing different active ingredients. Finished products for sale by Environmental Science or BioScience utilising the same brand name can be excluded from these provisions. [KR 3.15]
- ▶ In the absence of specific government guidelines on labelling, crop protection products must be labelled in accordance with the Global Harmonized Systems Codes (GHS). [KR 3.16]
- ▶ Chemically treated seed requires a different approach, since the standard seed bag or sack is not a pesticide container and only carries information of the nature, weight and perhaps origin of the content. Therefore, Bayer CropScience must ask seed treatment companies to apply the following (or equivalent) warning phrases to the outside of the container:
This seed has been chemically treated – minimise handling and always wear gloves
 - do not reuse sacks for food or animal feed
 - do not use treated seed as food or animal feed
 - dispose of sacks safely [KR 3.17]
- ▶ The appropriate business team must ensure that before launch each Bayer CropScience product is appropriately labelled subject to relevant Bayer CropScience intellectual property rights and that the Bayer CropScience Patent and Licensing [PL] department is contacted in a timely way in this regard. [KR 3.18]
- ▶ An active interest must be retained in following on-farm use of Bayer CropScience products, keeping track of main uses and the occurrence of any problems arising from the use of the products, as a basis for determining the need for changes in labelling, directions for use, formulation or product availability. [KR 3.19]



4. Principle

Products and/or Application Techniques

Bayer CropScience will make every reasonable effort to develop products with further improved biological, toxicological, ecotoxicological and environmental profile and support improvement of application technologies.



KEY REQUIREMENTS:

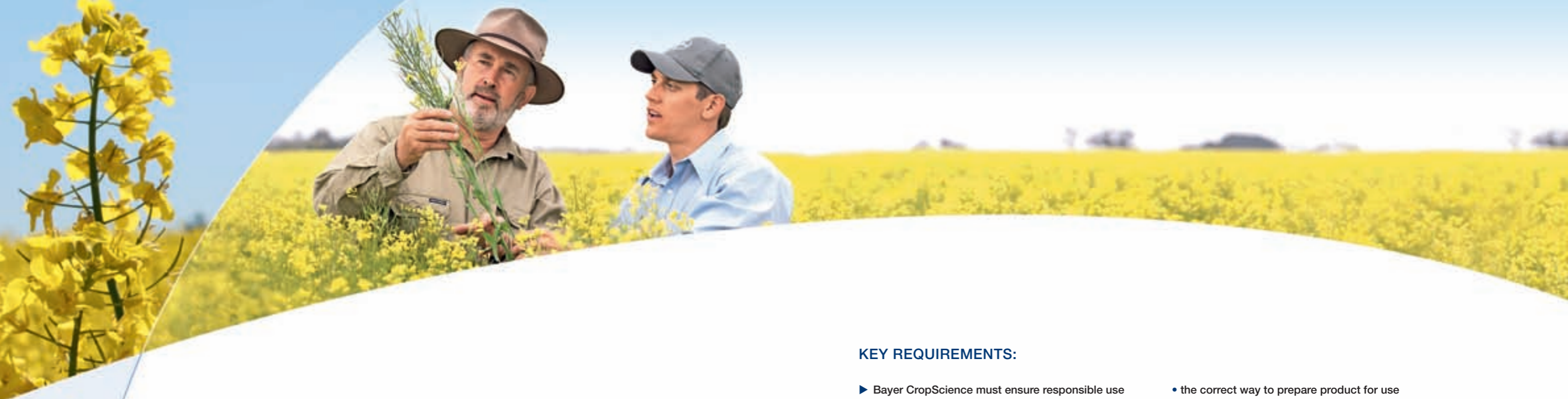
- ▶ Bayer CropScience Crop Protection and Environmental Science must make every reasonable effort to develop products with improved biological as well as user protection and environmental profiles. [KR 4.1]
- ▶ Bayer CropScience BioScience must make every reasonable effort to strive in their research and development activities for improvements of plants that can enhance crop production methods, product profile and/or end use. [KR 4.2]
- ▶ Bayer CropScience Crop Protection and Environmental Science must make every reasonable effort to substitute high risk profile formulants with materials with lower risk profiles. [KR 4.3]
- ▶ Preference must be given to products whose use requires personal protective and application equipment that are more easily available and affordable and to procedures that are well matched with user education and abilities. [KR 4.4]
- ▶ Bayer CropScience must make every reasonable effort to develop/support introduction of application methods and equipment that minimise user and environmental exposure to Crop Protection and Environmental Science products. [KR 4.5]
- ▶ Bayer CropScience Crop Protection and Environmental Science must make every reasonable effort to introduce products in ready-to-use packages where appropriate. [KR 4.6]

INFORMATION:

- ▶ FAO Agricultural Engineering Branch provides information on pesticide application equipment for use in agriculture.

[See references](#)





5. Principle

Training

Bayer CropScience will ensure that appropriate programmes are implemented in order to train, instruct and, as necessary, update our own staff and customers in all aspects of the responsible management of our products during their entire life-cycle from research to product discontinuation.



KEY REQUIREMENTS:

- ▶ Bayer CropScience must ensure responsible use of its products through the implementation of appropriate training measures, e.g. through own activities and/or industry associations and through collaboration with various stakeholders, including governments. [KR 5.1]
- ▶ Emphasis must be given to risk associated with improper use of Bayer CropScience products and how to minimise adverse effects on the environment (water, soil and air) and on non-target organisms. [KR 5.2]
- ▶ Training programmes must include, as appropriate and relevant to the product, information on:
 - hazard and risks
 - recognition of the symptoms of product-related poisoning
 - actions to take in case of emergency
 - use of recommended protective clothing
 - clean-up of product spills
 - personal hygiene
 - product integrity
 - correct on-site storage of products
- the correct way to prepare product for use
- recommended application techniques
- calibration, use, maintenance and repair of application equipment
- correct empty and rinse of containers for decontamination
- correct disposal of waste product and empty/decontaminated containers [KR 5.3]
- ▶ Where relevant, training must include resistance management strategies in the framework of Good Agricultural Practice and Integrated Pest Management. [KR 5.4]
- ▶ Personal safety precautions for the safe handling and application of Bayer CropScience products must be actively promoted by our field staff, e.g., when visiting farmers or other customers, at product launch meetings, etc.. [KR 5.5]
- ▶ All staff involved in sales promotion must be adequately trained to present accurate and valid information on the products sold. [KR 5.6]

INFORMATION:

- ▶ 'Safe use initiatives' initiated by CROPLIFE INTERNATIONAL and conducted in different countries can be found on the following web page: <http://www.croplife.org/issue>.
- ▶ CropLife International and FAO guidelines provide information on good practice for use of plant protection products in agriculture.

See references



6. Principle

Production

Bayer CropScience own production facilities will be of a suitable standard in all countries, where product is manufactured. Where third parties produce product on-behalf of Bayer CropScience contractual agreements will impose adequate stewardship requirements.

KEY REQUIREMENTS:

- ▶ Each site/location must establish and implement an integrated and process-oriented Quality Health Safety and Environment (QHSE) Management System suited to its particular needs. It must focus on the systematic identification and mitigation of site risks. [KR 6.1]
- ▶ Crop protection production sites must monitor and comply with national legislation, regulations and permit requirements. [KR 6.2]
- ▶ A formal Hazard Identification and Risk Assessment must be conducted for existing activities, modifications, substances, new processes, and projects at site level. [KR 6.3]
- ▶ Each site/location, where Bayer CropScience Crop Protection and Environmental Science products are handled must be equipped with up-to-date Material Safety Data Sheets. [KR 6.4]
- ▶ New processes must be designed so that potential risks are minimised by the proper selection of materials and process parameters. [KR 6.5]
- ▶ Knowledge and technology must be offered and transferred to all Bayer CropScience-sites/locations to enable them to develop, implement and improve the Quality Health Safety and Environment system according to Bayer CropScience Principles and Standards or the equivalent thereof. [KR 6.6]

- ▶ Every precaution must be taken to ensure that our Crop Protection and Environmental Science products do not contain residual impurities in the form of additional active ingredients or other impurities at levels which will prejudice safety or efficacy, (for detailed information see "QHSE Key Requirements, Product Integrity). [KR 6.7]
- ▶ Crop Protection and Environmental Science product manufacturing must ensure that the quality of Bayer products meets the registered specification. [KR 6.8]
- ▶ An updated Material Safety Data Sheet must be provided with Crop Protection and Environmental Science product samples when supplied to a third party (e.g., for registration trials). [KR 6.9]
- ▶ Seed quality standards must be defined to ensure seed is fit for its intended purpose. [KR 6.10]
- ▶ Quality control methods must be available in order to assure that seed quality standards have been met. [KR 6.11]
- ▶ Chemical seed treatment quality standards must be defined to ensure the treated seed is fit for its intended purpose and the impact on humans and the environment is minimised. [KR 6.12]
- ▶ Quality control standards must be available in order to assure that chemical seed treatment quality standards have been met. [KR 6.13]
- ▶ Seed cleaning, conditioning, bagging and storage facilities of Bayer CropScience must be operated in compliance with local regulations. [KR 6.14]
- ▶ Seed production done on behalf of Bayer CropScience by third parties must be in accordance with good agricultural practice following similar stewardship requirements as those undertaken by Bayer CropScience. [KR 6.15]
- ▶ Seed produced on behalf of Bayer CropScience by third parties must comply with agreed quality assurance and quality control measures ensuring that the seed is fit for its intended purpose. [KR 6.16]
- ▶ Product integrity must be ensured by a clear defined chain of custody. [KR 6.17]
- ▶ Product identification and traceability procedures must be established for unique identification of products and raw materials through relevant stages of production (including receipt of raw materials) until storage and delivery. [KR 6.18]
- ▶ Sales must be stopped and products have to be recalled when handling or use pose an unacceptable risk for the environment or human health. [KR 6.19]

8. Principle

Brand Communication

Bayer CropScience will advertise and promote only products / product uses that have been registered or authorised in the country in which the product is sold and will ensure that all brand communication claims are technically substantiated. Announcements of regulatory decisions or technical articles for pre-launch of products that are not yet authorised can be made, provided they comply with national rules and regulations.

KEY REQUIREMENTS:

- ▶ Advertising and promotion materials must be understandable and must encourage the user to read and follow the product label. [KR 8.1]
- ▶ Advertising material must not contain any statement or visual presentation, which, directly or by implication, omission, ambiguity or exaggerated claim, is likely to mislead the buyer/user. All advertising materials and visual presentations of products must be free of inappropriate statements and visuals. [KR 8.2]
- ▶ Statements on efficacy or effect on yields (i.e., use of this product has resulted in x % yield increase in our tests) must only be given when backed by scientific evidence. [KR 8.3]



- ▶ Claims of product safety (i.e., “safe”, “non-poisonous”, “harmless”, “non-toxic”) must not be made without a qualifying phrase such as “when used as directed”. [KR 8.4]
- ▶ Claims of product safety must comply with national rules and regulations and must be backed by scientific evidence. [KR 8.5]
- ▶ Advertising material must contain only representations which demonstrate the proper use of the product (including necessary protective clothing) and must not contain any visual presentation of potentially dangerous practices, such as mixing or application of crop protection products without recommended protective clothing, use near food, or use by or near children. [KR 8.6]
- ▶ Advertising or promotional material must, when appropriate, draw attention to warning phrases and symbols as provided in the FAO Labelling Guidelines and/or required by national regulations. [KR 8.7]
- ▶ Advertising material must not include comparison with brand names of competitors unless it is allowed by national laws. [KR 8.8]
- ▶ False, misleading or technically irrelevant comparisons with competitor products must not be made. There must be no misinterpretation of research results or technical or scientific literature to promote Bayer products. [KR 8.9]
- ▶ In countries where no national rules or regulations exist on how to make announcements of regulatory decisions or technical articles for products that are not yet registered, it has to be made clear in the announcement/article that for the time being it is still not allowed to sell and/or use the product. [KR 8.10]

INFORMATION:

- ▶ FAO Guideline on branding.

[See reference](#)



9. Principle

Business Partners

Bayer CropScience will require that its business partners apply the same level of Product Stewardship to our products as is expected within our own Company.



KEY REQUIREMENTS:

- ▶ When commissioning relevant supplier companies, Bayer CropScience must endeavour to ensure the same Quality Standards as in its own Company. [KR 9.1]
- ▶ The approval process concerning a newly contracted toll manufacturer of Crop Protection and Environmental Science products must include a site visit to evaluate equipment, QHSE Standards, the quality control laboratory, the qualification of personnel, etc. to ensure that Bayer CropScience QHSE requirements are understood. [KR 9.2]
- ▶ Licensees working with Bayer CropScience seed technologies must agree to adhere to similar stewardship requirements and ensure that seed products which they produce containing Bayer technologies meet similar quality assurance standards in order that they are fit for the intended purpose. [KR 9.3]
- ▶ When treatments (seeds, storage areas, in-house applications) with our products are to be done by specialised companies, reasonable measures must be taken to ensure compliance with Bayer CropScience Product Stewardship Policy and Key Requirements. [KR 9.4]
- ▶ Bayer CropScience must not engage in child labour (i.e. any work by children below the age of 15 years that:
 - Is mentally, physically, socially or morally dangerous and harmful and/or
 - Interferes with their schooling by
 - Depriving them of the opportunity to attend school
 - Obliging them to leave school prematurely; or
 - Requiring them to attempt to combine school attendance with excessively long and heavy work) For whatever purpose, nor should their agents or contractors do so in the course of fulfilling any obligations under any agreement they are performing for Bayer CropScience. [KR 9.5]
- ▶ Distributor, retailer, formulator or co-marketing staff involved in sales promotion must be adequately qualified to present accurate information on the products sold. [KR 9.6]
- ▶ Agents for Bayer CropScience in a country, where the company has no local organisation must follow the Product Stewardship programmes of Bayer CropScience. [KR 9.7]
- ▶ For crop protection tender business the national requirements must be followed and the respective FAO Guideline must be taken into account. Before providing the product, its demand must be evaluated in the country to avoid building up obsolete stocks. [KR 9.8]
- ▶ Bayer CropScience technical and commercial staff must provide the appropriate advice, support and training to its business partners. [KR 9.9]
- ▶ When affiliated companies are asked to supply analytical grade standards to third parties conducting studies on our active ingredients, seed or products, the analytical grade standards must be provided from an authorised source. Bayer CropScience must have an agreement with the third party and, where possible, monitor the work conducted and be provided with a copy of the study report. [KR 9.10]

Unapproved uses

10. Principle

Unapproved uses

Bayer CropScience will only endorse responsible use of its products. Therefore, it will not support, encourage or tolerate any unapproved use of our products, or new seed technologies nor the unapproved growing of seed products.



KEY REQUIREMENTS:

- ▶ Where an unapproved use is known to occur, it must be promptly addressed and appropriate steps taken to correct the situation. [KR 10.1]
- ▶ Bayer CropScience affiliate companies must cooperate with the appropriate partners, including authorities to correct unapproved use. [KR 10.3]
- ▶ Each observed unapproved use must be reported to the respective local, regional and global function. [KR 10.2]
- ▶ Personal misuse or encouraging or tolerating unapproved uses of a product by a Bayer CropScience employee is grounds for disciplinary action. [KR 10.4]

INFORMATION:

- ▶ Encouraging or tolerating unapproved uses can result in poor bio-efficacy, phytotoxicity, human and environmental risks, trade disruption or illegal or excessive product residues beyond established MRL's in commodities sold in national and/or international trade and must therefore be strictly avoided.
- ▶ Encouraging or tolerating unapproved uses in one country may lead to an "incident" which can have serious negative implications on the continued use of the product in that country and other countries.
- ▶ A serious incident as a result of a misuse may lead to a ban or severe restriction being placed on a crop protection product by a national authority. Under the UNEP/FAO "Prior Informed Consent" (PIC) policy, national authorities world-wide are informed of a decision taken to ban or severely restrict the use of a crop protection product in a country, which can lead to negative publicity and the potential for similar decisions to be taken in other countries.
- ▶ Unapproved cultivation, import or consumption of genetically modified seeds or plants may be illegal if not all regulatory approvals have been obtained. Severe financial implications by way of imposed fines, product recall and impacts on trade, as well as damage to the Company reputation, can result.

11. Principle

External incident Prevention and Investigation

Bayer CropScience will take all practicable measures to prevent any external accident or incident involving our R&D activities and products but should such accidents or incidents occur, they will be reported and fully investigated by the country organisation. Measures must be implemented to reduce the likelihood of recurrence. Potential incidents will be communicated and managed in a timely way to ensure that impact to the company and stakeholders, including trade disruptions, is minimised.

KEY REQUIREMENTS:

- ▶ Bayer CropScience affiliate companies or the Bayer CropScience division in any given country must have a procedure in place to report and promptly respond to external incidents such as fatalities, human over-exposure, environmental impact, unusual intervention by the media or authorities involving Bayer CropScience products. [KR 11.1]
- ▶ Personnel within each Bayer CropScience affiliated company or Bayer CropScience division in a country must be nominated to respond to, and manage external incidents. This includes reporting to regional functions and to global headquarters. [KR 11.2]
- ▶ For unauthorised products potential incidents should be reported as defined by local regulatory requirements. [KR 11.3]
- ▶ For potential incidents involving seed or grain products procedures should include communications to appropriate stakeholders, such as downstream partners and industry associations. [KR 11.4]
- ▶ Co-operation between national authorities and Poison Control Centres must be established to enable prompt action to be taken to control the situation and give immediate and accurate advice in case of an acute poisoning. [KR 11.5]
- ▶ Updated Material Safety Data Sheets (MSDS) must be provided in the appropriate language for all Bayer CropScience Crop Protection and Environmental Science products sold by, or on behalf of Bayer CropScience to each local Poison Control Centre, to regulatory authorities, transport com-

panies, distributors, retailers and if requested, end users. Bayer CropScience affiliate companies must provide the Poison Control Centres in each country with a list of contact details. Where a poison control centre does not exist in a given country, the Material Safety Data Sheets must be made available to other organisations or individuals that may need them. [KR 11.6]

- ▶ Poison-control centres and if appropriate nominated doctors must be provided with information about product hazards and on suitable treatment of product poisoning. [KR 11.7]
- ▶ At local level, the following actions must be followed in cases of accidental or intentional over-exposure:

- investigate all reported over-exposures in which Bayer CropScience Crop Protection products may be implicated and if so, complete an over-exposure report in accordance with the Bayer CropScience External Adverse Incident Guideline.
- depending on the product, collect an urine or blood sample from the patient as soon as possible to confirm if a Bayer CropScience product was involved. Where such samples are taken, ensure proper labelling and storage. If required, the samples have to be sent to a laboratory named by Global Product Stewardship.
- conduct a review of the factor(s) contributing to the incident to prevent recurrence. [KR 11.8]

INFORMATION:

- ▶ Emergency Measures in Cases of Crop Protection Product Poisoning. CropLife International, 1997.

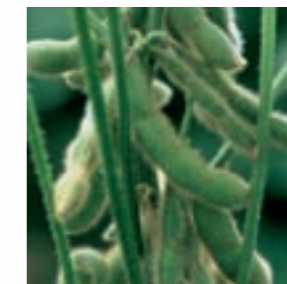
[See reference](#)



12. Principle

Intellectual Property

Bayer CropScience will support strong and effective intellectual property protection for innovation in crop production technology and for Crop Protection and Environmental Science products. Bayer CropScience will procure adequate legal protection for its innovations. Bayer CropScience will not intentionally infringe valid intellectual property rights of third parties.



KEY REQUIREMENTS:

- ▶ Bayer CropScience must ensure that innovation within Bayer CropScience is promptly brought to the attention of the Bayer CropScience Patents and Licensing (PL) department as soon as possible so that it can be effectively protected by patents, plant breeder's rights or otherwise. [KR 12.1]
- ▶ Bayer CropScience must ensure that confidential information is not disclosed to third parties without explicit approval of the Bayer CropScience Patents and Licensing department. Information should be considered to be confidential unless there is clear indication otherwise. [KR 12.2]
- ▶ Bayer CropScience must ensure that intellectual property rights of third parties that could be potentially relevant with respect to Bayer CropScience products or activities is brought immediately to the attention of the Bayer CropScience Patents and Licensing department. [KR 12.3]
- ▶ Bayer CropScience must ensure that the Bayer CropScience Patents and Licensing department will identify and monitor potentially relevant intellectual property rights of third parties and analyse the relevance and validity of such rights with respect to Bayer CropScience products or activities, and inform the relevant business of its findings so that appropriate licenses can be negotiated if necessary. [KR 12.4]
- ▶ Bayer CropScience must ensure that any product activities with Bayer CropScience products that might violate Bayer CropScience intellectual property rights, or might be illegal, are analysed, and that if needed appropriate action is undertaken to try to stop infringing or illegal activities. [KR 12.5]



Definitions

Accident or Incident includes, but is not restricted to

- product spillage due to a road or rail accident during transport;
- accidental or intentional over-exposure of humans (e.g. misuse, attempted suicide)
- accidental or intentional over-exposure of non-target species (e.g. fish kill caused by incorrect application of a plant protection product, spillage or dumping)
- accidental or intentional misapplication of a product leading to illegal crop residues and restriction on consumption

Active Ingredient

means the biologically active part of the product.

Advertising

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

Analytical Grade Chemical Standard

is a purified chemical substance (e.g. active ingredient, metabolite or impurity) supplied with GLP certification.

Application Equipment

means any technical aid, equipment or machinery, which is used for the application of products.

Application Technology

means the actual physical delivery and distribution process of a pesticide to the target organism or to the place where the target organism comes into contact with the plant protection product.

Authorisation

means the process whereby the responsible national government or regional authority authorises a product for use and sale following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose an unacceptable risk to human or animal health or the environment. The regulatory process should be fully functioning.

Bayer CropScience Products (or products)

include own and third party products sold by Bayer CropScience.

Business Partners

are Suppliers, Toll Manufactures, Distributors, Retailers, Formulators, Co-marketers.

Compliance

means full adherence to and implementation of legal requirements.

Compliance Monitoring

means collecting and analysing information on compliance status of an entity or facility or of an industry or economic sector.

Crop Protection Product

is a product that protects crops from pests during crop production and is the end-result of research and development.

Crop Tolerance Evaluation

means the assessment of (potential) adverse effects of the plant protection product on the crop that is to be treated, such as phytotoxicity, adverse effects on crop yields and quality, and effects on plants or plant parts used for propagation.

Disposal

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

Distribution

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

Efficacy Evaluation

means the assessment of the effectiveness of a plant protection product, against the target pest, which may include an assessment of its agronomic sustainability and economic benefits.

Environment

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

Experimental Product Samples

are those based on new molecules or new formulations to which only limited toxicological or ecotoxicological data are available.

Facility

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

Formulation

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

Good Agricultural Practice (GAP)

in the use of plant protection products includes the officially recommended or nationally authorised uses of plant protection products under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of plant protection applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable.

Globally Harmonized Systems (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 based on harmonising major existing systems for classifying and labelling.

Hazard

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

Integrated Crop Management

means achieving a balance between efficient, profitable production of high-yielding, quality crops, using fertilisers and modern seeds, with or without improved traits and crop protection inputs, but without depleting natural resources or damaging the environment.

Integrated Pest Management

means a pest management system that, in the context of the associated environment and the population dynamics of the pest species, utilises all suitable techniques and methods in as compatible a manner as possible and maintains the pest population at levels below those causing economically unacceptable damage or loss.

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.

Manufacturer

means a corporation or other entity in the public or private sector or any individual engaged in the business or function of manufacturing active ingredients and/or products.

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.

Maximum Residue Limit (MRL)

means the maximum concentration of a residue that is legally permitted or recognised as acceptable in or on a food or agricultural commodity or animal feedstuff.

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

means any clothes, materials or devices that provide protection from product exposure during 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.

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 poison, and includes intoxication.

Premises

are land and buildings together considered as a property.

Product

means the pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.

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 in or on food, agricultural commodities or animal feed resulting from the use of a product. The term includes any derivatives of a product, such as metabolites and impurities considered to be of toxicological significance. The term includes residues from unknown or unavoidable sources (e.g. environmental) as well as known 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 plant protection products that would normally give effective control.

Responsible Care

is a world-wide initiative by the chemical industry. It means all employees acting 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.

Risk

of an undesirable event is assessed according to its Probability of occurrence and its Severity of consequence. (Harm/damage is the outcome of an actual exposure to a particular hazard of a product.)

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 within BioScience.

Seed Technology

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

Sustainable Agriculture

is a concept laid down in the Agenda 21 of the Rio de Janeiro conference in 1992. Sustainable Agriculture needs to be economically viable, environmentally responsible and socially acceptable and must:

- satisfy human food, animal feed and fibre needs
- optimise natural resources utilisation
- integrate the optimal use of available technologies
- maintain or enhance the economic viability of farms and the rural community

Sustainable Development

is a development that meets the needs of the present without compromising the ability of future generations to meet their own needs.

Tender

means request for bids in purchasing of products.

Trader

means anyone engaged in trade, including export, import and domestic distribution.

Trait

is a genetically determined characteristic.

Unapproved Use

primary refers to:

- use on a non-registered crop;
- use at a non-registered location;
- use for a non-registered pest;
- use of a non-registered formulation;
- use at a higher dose or/and with later timing (non-compliance with recommended pre-harvest intervals), or/and frequency of application, or/and different methods of application compared with the recommendations on the product label
- use of a non-registered seed and seed technology

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, time of treatment, number of 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 classifications. Used interchangeably with the term cultivar to denote a uniform, stable group of plants.

Key Contact

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Abbreviations

BCS	<u>Bayer CropScience</u>
CLI	<u>CropLife International</u>
FAO	<u>Food and Agriculture Organisation of the United Nations</u>
GCPF	<u>Global Crop Protection Federation (now CropLife International)</u>
GHS	<u>Global Harmonized System</u>
ICM	<u>Integrated Crop Management</u>
IPM	<u>Integrated Pest Management</u>
MSDS	<u>Material Safety Data Sheets</u>
QHSE	<u>Quality, Health, Safety and Environment</u>



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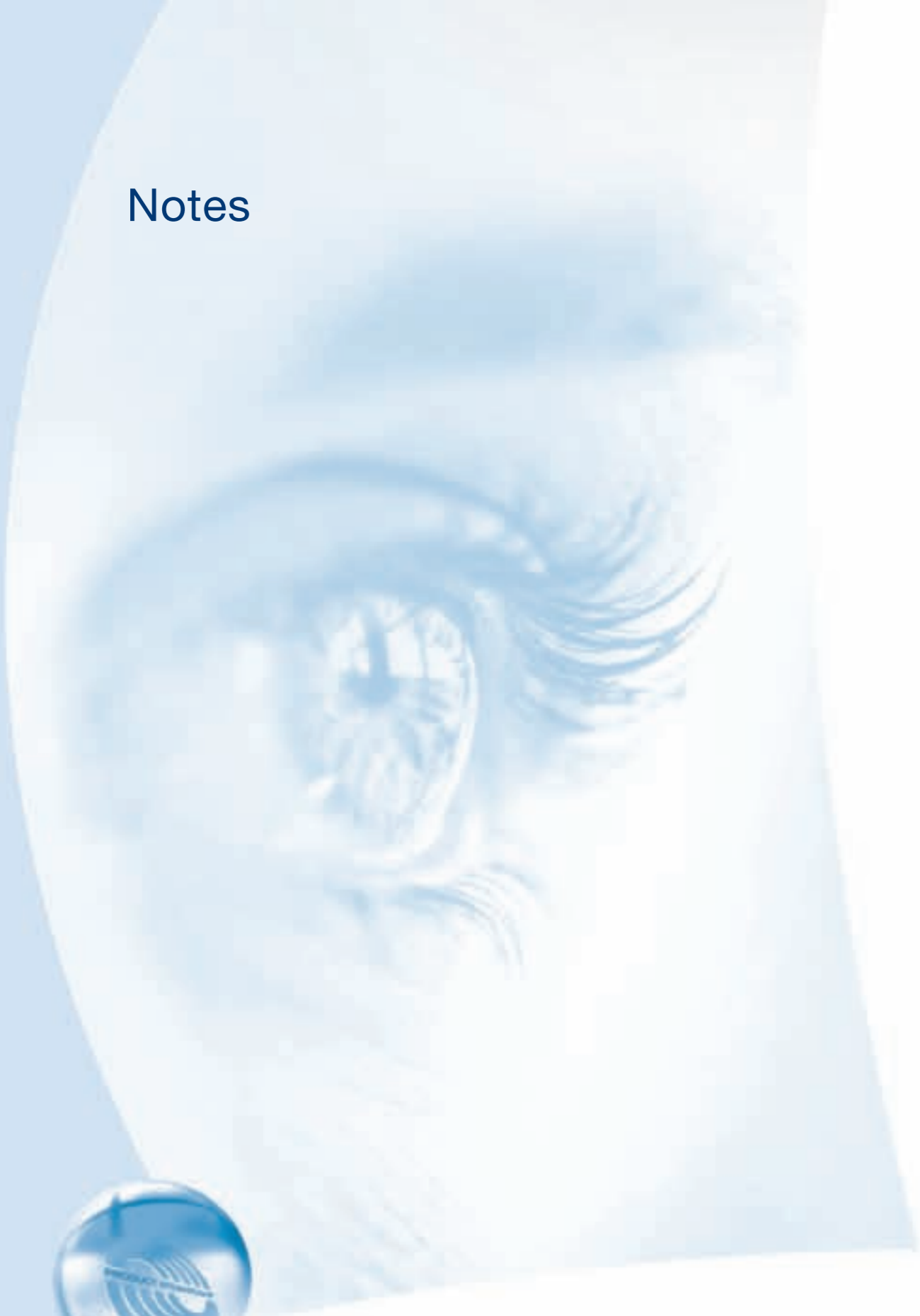
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Notes





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