Agvocacy Program

Our Commitment to Transparency

Streamlined messaging to guide communications on Transparency at Crop Science

This document is intended to support internal questions. Please do not share this document externally.

The Background

As a leading life science company, we recognize and embrace our responsibility to be more transparent about how we innovate, test and develop our products. Over the last few generations, our society has become increasingly disconnected from the farm, leading to a growing "innovation disconnect" when it comes to food production and the benefits that science and innovation can deliver in agriculture. We wish to bridge this disconnect by talking openly about the challenges we face and the innovative solutions we pursue. But most importantly, while we respect that views on the use of agricultural innovations can differ, we want to reiterate that safety is our top priority – because people deserve to feel confident about what they put on the table.

About Bayer's commitment to transparency in Crop Science: the program's origins

- Our transparency commitments are meant to establish a conversation around science, which means listening and responding to questions and concerns from our internal and external stakeholders. We also aim to foster an open and informed dialogue on agricultural innovations by enhancing public access to the process used to assess the safety of our products, so that everyone can see the integrity of our results for themselves. Through our transparency-focused platform, both interested consumers and the scientific community can access the insights of our work and connect with us and our science. Visitors to our platform can download summarized test results and evaluations that provide information on the human and environmental safety of active substances used in our crop protection products as well as on the safety of GM Crops. We have also provided access to full in-depth study reports[1] evaluated by regulators for the authorization of our products, alongside informational materials to help put regulatory science into context. This commitment not only makes product safety studies accessible, but also has an educational component through the platform where users can learn more about Good Laboratory Practices (GLP), regulatory bodies, the overall process our products go through before they are authorized to be sold and what Bayer does beyond the officially required measures.

What Bayer is making available through this program

- We have made safety study data available for download for 32 active substances used in our crop protection products[2] .This data has been submitted to the European Food Safety Authority (EFSA) for substance approval in the European Union.
- We've enabled online-access to key submission documents for 16 traits of our GM crops that have been assessed by regulators in the United States – the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). We also provide the Study Index, the list of studies provided to the Environmental Protection Agency (EPA).
- Upon request, we provide access to full in-depth study reports[1] evaluated by regulators for the authorization of our marketed crop protection and GM crop products.
- In addition to providing downloadable and requestable regulatory safety study documents, our transparency platform also includes large amounts of educational materials that help put regulatory science into context. Our goal is to transform the way we communicate about science so that we can cultivate trust about our products, practices, and innovations.

Since launching the program and enabling access to safety study results, we have continued to expand our efforts, including:

- Launching our OpenLabs Program, in which technical observations and conversations with scientists and experts will offer visitors the chance to learn how Bayer ensures the reliability, consistency and integrity of results through Good Laboratory Practices (GLP).
- Providing access to Bayer's Operator Safety Standards and soon also Bayer's dietary and environmental safety standards.
- Adding information about the rigorous process for granting Emergency Authorization of crop protection products in the European Union as well as our views as Bayer on the topic.

We will continually add new topics update the content of the website as we bring new products to the market.

References
1 Access to the full safety studies is limited to non-commercial users.
2 The safety study data available for active substances used in crop protection substances covers studies submitted to EFSA for substance approval in the European Union.

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Bayer´s disclosure rules for public availability of its studies

- At Bayer, we are committed to continually enhancing transparency standards around the process used to assess the safety of our products, while protecting confidential business information and personal data. Public disclosure of data is therefore based on specific guidelines:
  - Substances/products/studies must be fully Bayer-owned, and substances/products must already be on the market.
  - Always pre-evaluated by a regulatory authority.
  - Personal data and confidential business information redacted.
  - Public disclosure for non-commercial use and access to full study reports based on a license agreement.

Bayer Transparency website updates

- The disclosure of safety-related information regarding our products is a continuous process. In addition to expanding the initiative to include additional topics such as GM crops, breeding and safety standards, we continuously listen to our stakeholders to determine which additional topics to include.

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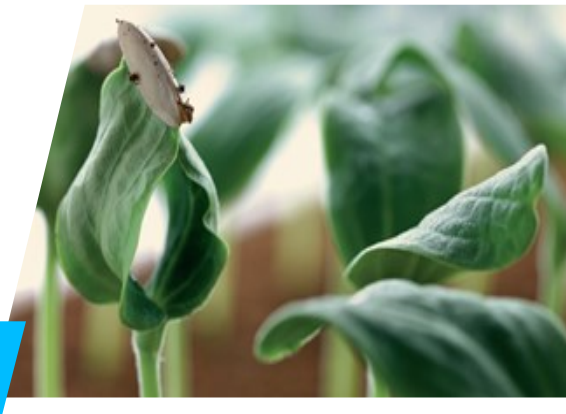
The Highlights

Crop Protection

- We are proud to have been the first in the industry to proactively enable access to our crop protection safety study results. Bayer´s dedicated transparency platform offers access to safety-relevant information on our crop protection products. To date, we have made safety study summaries for 32 active substances accessible on our platform for download. Visitors to our website will find study summaries concerning the human and environmental safety of many of our active substances that have been evaluated by the European Food Safety Authority (EFSA). This list is updated on a rolling basis. Non-commercial access to full study reports can be requested by submitting a dedicated request-form on the Transparency website.
- The science and processes leading to safety study data can be found in our "Learn More" section, covering Human Safety, Residues in Food, Environmental Safety, Benefits of Crop Protection, Regulatory Process for Crop Protection and Good Laboratory Practices
- Crop protection products are among the most thoroughly researched and strictly regulated in the world. On average, it takes 11 years to bring a new crop protection product to market. For every 160,000 molecules that are tested by scientists, only one will ever make it into a crop protection product sold on the market[3].

GMOs

- At Bayer we believe in the safety and science behind Genetically Modified crops – and we understand that consumers might have questions around how we develop these products. We want to provide consumers with information behind the safety and science of our GM crops.
- To do this, we:
  - Enabled access to key submission documents for our GM crops that have been assessed by regulators in the United States via our transparency platform. We will continually update this list of crop traits as we bring new products to the market.
  - We have further extended this effort and now also provide access to full GM crop study reports. Non-commercial access can be requested by submitting a dedicated request-form on the Transparency website.
  - We have also provided scroll stories (Safety of GM Crops, Benefits of GM Crops, Regulatory Process for GM Crops), infographics and other materials so that consumers have access to the information they need to help put regulatory science and policy around GMOs into context.



Plant Breeding

- On the transparency website, we invite our stakeholders to learn more about innovation in plant breeding, which helps farmers provide the world with enough food, using fewer resources and fewer pesticides. The potential of plant breeding could lead to an improvement in the variety, nutrition and quality of our food.

References
3 Phillips McDougall, 2016. The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014. R&D expenditure in 2014 and expectations for 2019. Accessible from: https://croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf [last accessed 26 February 2019]

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OpenLabs

- In 2020, we were excited to launch our OpenLabs program, in which individuals can visit our Monheim labs and field-testing stations to see how our scientists work, following stringent, internationally recognized procedures as they carry out regulatory safety studies. OpenLabs offers visitors the unique opportunity to engage with our scientists and see and connect with science in action.

  - **What is OpenLabs?** OpenLabs is a unique opportunity for those who wish to learn about the details of Good Laboratory Practice (GLP) and how we conduct GLP studies to ensure the integrity of our study results. As part of the program, visitors will be able to see the science – and the safety behind it – in action in the lab and out on the fields. Visitors can observe Bayer technicians conducting a laboratory study to generate data that will be used in a regulatory substance review process. Technical observations and conversations with scientists and experts will offer visitors the chance to pose their questions and to learn how Bayer ensures the reliability, consistency and integrity of results.

  - **When is the next OpenLabs visit happening?** Due to the COVID-19 pandemic, we've taken the OpenLabs program virtual for the near future, where we will host small groups for an intensive and engaging virtual event covering the same topics as the in-person visits. Looking forward, we will evaluate the COVID-19 situation for in-person OpenLabs visits in Monheim. Please check our website periodically for updates.

  - **How are you selecting the participants for the virtual OpenLabs program?** Due to the depth and detail of the information provided, we will give priority to participants that have a high level of interest in the subject matter. Depending on the registrations, we will arrange groups in such a way that the participants "fit together" as well as possible due to their stated interests and background.

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Crop Protection Safety Standards

- Bayer's safety standards are the evaluation criteria we apply to ensure that our crop protection products can be used without risks to human health or unacceptable risks to the environment when following label instructions.
- Our internal crop protection safety standards reflect the guidelines and standards of international organizations like the Food and Agriculture Organization (FAO), the World Health Organization (WHO) and the Organisation of Economic Cooperation and Development (OECD), as well as those of regulatory authorities around the world, to ensure a globally consistent baseline for product safety. These safety standards continuously evolve based on the latest scientific knowledge.
- As a first step, in March 2021, we posted our Operator Safety Standards to the transparency website. These lay out the detailed scientific approach we use when assessing the risks for operators (applicators) of our crop protection products and show how.

Emergency Authorizations

- Crop protection products are usually approved via the standard regulatory process. However, there can be exceptions – called 'emergency authorizations' – in exceptional situations.
- Emergency authorizations are a vital component of several countries' regulations which allows farmers to swiftly protect their crops against otherwise unavoidable losses in exceptional situations and according to specific and stringent considerations. This helps to secure the farmer's livelihood, while also contributing to providing enough food for our growing world population.
- That said, we understand that people might have concerns around emergency authorizations and why they are needed. Therefore, we have added a designated section on emergency authorizations to our transparency platform, providing information about the rigorous process to grant an emergency authorization specifically in the EU but also in other countries, as well as Bayer's views on the topic.

Key Things to Remember

- At Bayer, we recognize and embrace our responsibility to be more transparent about how we innovate, test and develop our products. Our aim is to bridge the communication gap between farm and society by talking openly about the challenges we face and the innovative solutions we pursue. But also, by reiterating that safety is our top priority – because people deserve to know that our products are safe when used as directed.
- Our transparency commitments aim to foster an open and informed dialogue on agricultural innovations. We enabled public access to the process used to assess the safety of our products through our transparency-focused platform, where both, interested consumers and the scientific community, can access the insights and integrity of our work and connect with us and our science.
- Our commitment is not only making our product safety studies accessible, but also has an educational component through the platform where users can learn more about Good Laboratory Practices (GLP), regulatory bodies, the overall process our products go through before they are authorized to be sold and what Bayer does beyond the officially required measures