



# Demystifying Science: Enabling access to safety studies

## Background

Crop protection products are among the most thoroughly researched and strictly regulated chemicals in the world. They are an important tool for farmers all over the world and enable the production of safe, healthy and affordable food. **On average, approximately 1,200 studies are required to gain market authorization for an active substance.** In accordance with the registration process, the results of these studies are then submitted to the relevant authorities, who then evaluate the data.

**Companies do not typically share their study results with the general public, as much of the content is considered to be confidential business information.** This has often been a point of contention. Some authorities, such as the European Food Safety Authority (EFSA) make study summaries available on their website. However, information remains largely inaccessible to the public.

In 2016, **the European Court of Justice (ECJ) established principles throughout the EU for authorities, regarding public access to information concerning crop protection product studies.** Bayer supports this development as long as confidential data, such as product composition and manufacturing processes, are safeguarded. We intend to offer support to the authorities in dealing with requests for access to safety-relevant crop protection data as needed.

In addition to this, Bayer wants to improve the ease and speed with which human and environmental safety studies featuring its products can be accessed.

## Bayer's Transparency Initiative

Established in 2017, [crops-science-transparency.bayer.com](http://crops-science-transparency.bayer.com) is an initiative to pro-actively share safety-relevant regulatory information about Bayer's crop protection products with non-commercial interested parties. By sharing safety data, Bayer is taking a leading role in breaking down barriers to build public trust and foster a fair, science-based dialogue around crop protection products.

*"We want non-commercial interested parties – from the general public to members of the scientific community – to be able to access safety relevant information in a way that is fast and easy to understand. We also want the public to understand why and how we perform safety studies. By sharing this information, we hope to connect the public with our scientific community in a way that builds trust and shows our desire to create transparency."*

**Adrian Percy, Global Head Research & Development at Bayer Division Crop Science**

## Why do we care?

Even though crop protection products are among the most heavily-regulated products in the world, there is a huge gap between what Bayer knows, and what the public knows.

We want to close this information gap, and enable access to our safety studies.

We understand that not everybody is a scientist. We want to make these often-complex studies accessible to non-commercial stakeholders.

The public debate should be based on scientific data and interested stakeholders should be able to base their opinion on scientific data – just like we do.

## Enabling access to safety studies

On a dedicated website, Bayer will provide:

- **Human and environmental safety-related study summaries for download** concerning those active substances that are currently used in products on the market. With respect to ownership rights, Bayer can only disclose documents in those cases where disclosure would not violate the ownership rights of third parties.
- **Interactive tutorials and ‘explainers’ to ensure that this information is accessible to all.** These will help non-experts to develop a better understanding of the regulatory science used to assess the safety of crop protection products.
- As of 2018, non-commercial users will also be able to request **access to the full in-depth safety study reports** behind these summaries.

As a first step, this project will focus upon a selection of active substances that have been approved for use in the EU.

## Decision of the European Court of Justice

In November 2016, the European Court of Justice published judgements for two cases (C-673/13 and C-442/14) concerning the rights of public access, under regulations based on the Aarhus convention, to documents filed with authorities in the course of authorization procedures relating to the market authorization of certain crop protection products. Among other things, the court ruled that information from studies to assess **actual or foreseeable emissions under normal or realistic conditions** of use need to be disclosed by the authorities.



See for yourself:  
[cropscience-transparency.bayer.com](http://cropscience-transparency.bayer.com)

### Have a question?

Send an email to [cropscience-bayer@bayer.com](mailto:cropscience-bayer@bayer.com)  
Or visit the FAQ section on [cropscience-transparency.bayer.com](http://cropscience-transparency.bayer.com)