



Bayer Safety Standards

Ensuring Operator Safety

Bayer is committed to providing our customers with the best tools and solutions, while ensuring the safety of our products to those who use them (operators).

Did You Know?

In the effort to define stringent safety standards for the use of crop protection products, at Bayer we apply additional safety standards on top of the regulatory requirements in many countries where we register our products. As an example, since 2016, we only sell products with active ingredients which have a registration for use in at least one OECD country, or for new active ingredients with a complete OECD safety data package.

Our Approach to Operator Safety

Bayer's **operator safety standards** reflect the relevant guidelines and regulations of international organizations such as the Food and Agriculture Organization (FAO) and the Organization on Economic Co-operation and Development (OECD), as well as of country regulatory authorities. And these standards aren't static – we are continuously evolving our operator safety standards, incorporating the latest scientific developments in risk assessments. Our operator safety standards follow the internationally accepted risk-based approach, meaning that we take into consideration not only the **hazards** of a product, but also the potential for **exposure to these hazards**. Both elements are essential to determine whether a product can be used safely. Combined, hazard and exposure assessments help us to assess potential operator risk and to define appropriate risk management tools, measures and actions to further ensure operator safety and minimize risk.

Risk = Hazard x Exposure



A shark in the water is a potential hazard (you could be bitten), but your risk is high only if you go swimming with the shark (exposure).

This example shows why hazard and exposure assessments should be the basis for every risk assessment. Something hazardous might not be a risk if you are not exposed to it. When deciding if and how to use a product, we evaluate risk not hazard.

Risk Assessment

During the risk assessment, data from hazard and exposure assessments are combined to determine under which conditions a product can be safely used. Our objective is to estimate the operator exposure as realistically as possible and to consider the nature and severity of the hazard of a substance, to determine whether the risk for operators to a certain product is acceptable or not. During our risk assessments, we take uncertainties in the data on hazards and exposure into account by adding safety factors and/or using conservative assumptions and figures.



Hazard Assessment

We conduct a variety of **studies** to understand the toxicity properties of our products, allowing us to characterize their behavior and any potential hazards. For example, we look at short and long-term effects on all major organs and bodily systems ranging from the liver and brain to the reproductive and nervous systems. As part of these studies, we assess short term effects like acute toxicity, skin irritation and allergic reactions as well as long term effects like liver damage, carcinogenicity and effects on reproduction. In addition, we look at the behavior of the substance and determine possible exposure scenarios and routes by which a substance can enter the human body – such as through the skin, mouth or nose.

The results of these studies are used to determine the exposure threshold below which operator exposures are considered safe. This threshold is called the **Acceptable Operator Exposure Level (AOEL)**. The AOEL is a very safe value, as it is set 100 times below the level at which no effects could be detected in the toxicity studies.



Exposure Assessment

We conduct studies and gather information to understand aspects like local farm practices, product formulation, the type of crop and operator behavior. Each of these elements influence the exposure of the operator to our products. The type of equipment used to apply a product is very important for operator exposure. For example, even though a farmer might be covering dozens of hectares using a sprayer on a tractor, he is often less exposed than an operator treating only one hectare with a manual sprayer. Additionally, an operator not wearing protective equipment like gloves or a face mask will be more exposed than an operator who does.

Operator exposure estimations are based on models built from empirical exposure data: these are, thousands of data points collected in the field over years as the basis for predictive models. At Bayer, we primarily use US and European model approaches due to the extent of their existing exposure data and transparent statistical analyses. For certain scenarios – such as pesticide application via handheld devices - we supplement these models with additional exposure models using data from various regions around the globe. In this way, we can account for local practices that might not be common in the United States and Europe.

Risk Management

Following our risk assessments, it becomes clear where possible risks can be found, and which measures can be used to prevent them. Risk management may lead to restrictions for certain uses on the label and requirements for the safe use of products. For example, which protective equipment is needed. We only use mitigation measures that are considered realistic under local agronomic and climatic conditions. These measures are clearly communicated, on the label of the product. The labels comply with local regulatory requirements for classification and labeling, and in countries where there are no specific requirements for labeling, crop protection products are labeled in accordance with the Global Harmonized Systems Codes (GHS) and the FAO Guideline on Good Labeling Practice of Plant Protection Products.

Apart from realistic label and practical personal protective equipment requirements, Bayer takes additional measures to support safe product use according to label instructions. This includes the development and implementation of safe use training programs for staff and customers, contributing to spray license programs, driving innovation in application technology and monitoring actual usage to be able to adjust label instructions if necessary.

In 2019, Bayer trained more than
1,000,000 farmers *in the safe*
use of our products.

As part of our Safe Use Ambassador Program we trained students at
29 universities *in seven Asian countries* *in the safe use*
of crop protection products in 2019.