

TECHNICAL DOCUMENTATION Bayer Safety Standard for Operator Safety

MARCH 2021

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IMPORTANT NOTICE

This document details the voluntary safety standard that Bayer applies regarding operator safety. It concerns the baseline standard that Bayer plant protection products must at least meet for operator safety. It contains the associated dataset, the models and methods used.

This document is not an announcement of a new standard; rather it is an outline of the standard that already underpin our decision-making as it relates to product safety for operator exposure worldwide.

The voluntary standard laid out in this document is the baseline standard observed by Bayer. Any potentially stricter, deviating or additional requirements from national authorities (if applicable) have to be met in addition to any voluntary safety standard in this document.

DEFINITIONS (EXTENDED FROM FAO GUIDELINE)

A.I (Active Ingredient) is the biologically active ingredient of a plant protection product.

AOEL (Acceptable Operator Exposure Level) is a systemic endpoint relevant for non-dietary risk assessment.

Co-formulant means a non-active ingredient component of a formulated product, added for various purposes (e.g., to stabilize the mixture of active ingredients).

Exposure to pesticides means any contact between a living organism and one or more pesticides.

FAO (Food and Agriculture Organization) is an agency of the United Nations leading international efforts to defeat hunger, improve nutrition and ensure food security.

Formulation means the combination of various ingredients (active ingredients, co-formulants and solvents) designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application.

GLP (Good Laboratory Practice) is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products through analytical tests.

Hazard means the inherent property of a substance, agent or situation having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property).

Mode/mechanism of action describes a functional or anatomical change, resulting from the exposure of a living organism to a substance.

NOAEL (No Observed Adverse Effect Level) is a dose level in toxicological animal testing studies at which no adverse effects have been observed.

OECD (Organization for Economic Co-operation and Development) is an intergovernmental economic organization with 37 member countries to stimulate economic progress and world trade.

Operator is a professional who is involved in activities relating to the application of a PPP; such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the PPP and emptying/cleaning the machinery/containers after use.

Pesticide means any substance or mixture of substances of chemical or biological ingredients intended for repelling, destroying or controlling any pest or disease, weeds or regulating plant growth.

Pesticide management means the regulatory and technical control of all aspects of the pesticide life cycle, including production (manufacture and formulation), authorization, import, distribution, sale, supply, transport, storage, handling, application and disposal of pesticides and their containers to ensure safety and efficacy and to minimize adverse health and environmental effects and human and animal exposure.

PPP (Plant Protection Product) means a formulated product, containing one or more pesticides and often co-formulants. Plant protection products are usually ready-to-use liquids or solid formulations, like granules.

Risk is the probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to a pesticide.

1. PREFACE

The application of a safety standard as consistent baseline for all of the plant protection products created by Bayer is a key element for a safe and sustainable crop protection portfolio. Bayer endorses 'The International Code of Conduct on Pesticide Management' of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). In addition to the regulatory requirements in countries where we register our products, we apply our own internal safety standard for risk assessment that ensures a globally consistent baseline for product safety. This standard reflects the guidelines and standards of international organisations like FAO, WHO and the Organisation of Economic Cooperation and Development (OECD), as well as those of reference regulatory authorities around the world. It continuously evolves based on the latest scientific knowledge.

We apply a risk-based approach by following the three pillars of a reliable safety standard: data collection to determine the hazard of the product and the exposure of operators, risk assessment to compare hazard and exposure as well as risk management to check if the assumptions of the risk assessment meet the reality.

In this document, we describe the internal baseline operator safety standard we apply to our products. Details, such as the hazard determination for an active substance, and which algorithms are used to identify the absorption behaviour of each substance, are presented. Information on the operator exposure models applied are provided, as well as strategies to implement certain risk mitigation measures.

We will continue to work together with multiple internal and external stakeholders on operator safety. We encourage any stakeholders to join an open dialogue and acknowledge suggestions for improvement.

We will listen, we will learn.

2. BAYER SAFETY STANDARD FOR OPERATOR SAFETY - INTRODUCTION

For operator safety evaluation (e.g. safety of farmers applying a PPP), Bayer follows the FAO code of conduct¹ and its rationale to determine a risk for operators applying a plant protection product. Based on this guidance, we assess both hazard and exposure using conservative and realistic information to reliably determine potential operator risk. We then use risk management tools to ensure operator safety.

The following figure illustrates in three pillars how we apply our operator safety standards to our product.



Figure 2.1: Generic illustration of the operator safety standard framework

I. Safety data collection: We conduct tests to understand the toxicity properties of our products to characterize their hazard and behavior in the body. In addition, we determine routes of exposure and how a substance can enter the human body (dermal/inhalation/oral absorption).

II. Exposure and risk assessment principles: We conduct tests and gather information to understand local practices, equipment used, operator behavior and potential sources of exposure to our products during their application. The more data we can collect from actual field use, the more reliable our assessments of risk.

III. Risk management activities: We don't just add protective equipment to our labels, we ensure that the necessary protections are available and affordable and consider if they will be used in an appropriate manner. By accounting for local practices and environments, we make sure our risk management is realistic and appropriate.

The following chapters provide a deeper insight into each pillar and how we translate our commitments and general safety standard into real actions.

3. SAFETY DATA COLLECTION FOR OPERATOR SAFETY ASSESSMENT

IN A NUTSHELL

To understand the (operator) safety requirements of our products, we conduct tests, collect data and use information to determine any potential risks from use of our products. We assess potential risks from accidental high exposures to regular exposures that occur over days, months, or years of using our products. As a first critical step, we test for the toxicity (hazard) of our products.

The extent and types of animal studies are clearly defined in internationally agreed test guidelines and global or regional regulations and frameworks. We strictly comply with regulatory and ethical requirements:

- // Studies are conducted under good laboratory practice (GLP).
- // All studies are in accordance with applicable OECD (or similar) test guidelines. If tests are performed to generate additional data where test guidelines are not available, methods and results are carefully described, documented and reported.
- // The study designs are carefully considered for statistical relevance and reproducibility, but also include the scope for reduction, refinement and replacement of animal tests.

The results of these studies are used to determine the exposure threshold below which operator or consumer exposures are considered safe.

3.1 Human safety: determination of hazard

The pesticidal effect of a chemical plant protection product is driven by the active substance. Therefore, a hazard assessment of the active substance (as well as for the corresponding plant protection product) and its potential residues is performed. Both short-term and long-term toxicity studies are conducted to determine potential adverse effects. Since the operator is also exposed to the formulated product, these are also routinely tested for acute and local effects, to identify potential hazards posed by exposure when using (mixing, loading and applying) the product.

Toxicological studies with the active substances are conducted to determine the potential for:

- // Short- and long-term adverse effects on all major organs/systems including liver, brain, kidney, thyroid, reproductive organs, nervous system etc.
- // Carcinogenicity (C), mutagenicity (M), reproductive toxicity (including embryotoxicity and teratogenicity) (R) and endocrine disrupting (ED) properties of the active substance. These effects are often referred to as CMR-ED.
- // The absorption, distribution, metabolism and excretion (ADME) pathways in the mammalian system including a toxicological characterization of relevant metabolites (break-down products).
- // The maximum dose at which No Adverse Effects (NOAEL) were observed in at least three mammalian species (mouse, rat, dog).

For human health effects, Bayer complies with section 4 of the OECD Guideline for the Testing of Chemicals.²

As an orientation, this would comprise around 50 different tests to characterize the properties of one single active substance.

The following studies are conducted to get a full toxicological profile of an active substance.

3.1.1 Toxicological studies

3.1.1.1 Acute toxicity studies

Acute toxicity describes the adverse effects of a substance that result either from a single exposure or from multiple exposures in a short period of time (usually less than 24 hours). Active substances, as well as formulated products, are tested for acute systemic and local effects, using in silico, in vitro and in vivo test methods, to assess the main routes of exposure and endpoints:

- // Acute oral toxicity
- // Acute dermal toxicity
- // Acute inhalation toxicity
- // Skin irritation/corrosion effects
- // Skin sensitization effects (allergic reactions)
- // Eye irritation/corrosion effects

The purpose of acute toxicity studies is to provide information of adverse effects of a substance (or a formulation) resulting from exposure in a short period of time. In most acute toxicity tests, relatively high doses of a test substance is given. The studies provide information on toxic effects and the potential of recovery, help to determine possible target organs that may be scrutinized in repeated dose tests and support dose selection for repeated dose studies, when no other toxicological data is available.

The results of these studies provide indication of the hazard of an active substance or the formulated product, which is translated in classification and labelling phrases to be included in the package and on the Material Safety Data Sheet (MSDS), following the GHS labeling (Global Harmonization System).

3.1.1.2 Short-term toxicity (sub-acute and sub-chronic)

In the assessment and evaluation of the toxic characteristics of a chemical, the determination of sub-chronic oral toxicity using repeated doses is usually carried out after initial information on toxicity has been obtained from acute toxicity tests. The 28-day (sub-acute) and 90-day (sub-chronic) study provides information on the possible health hazards likely to arise from repeated exposure and from repeated exposure over a prolonged period of time covering post-weaning maturation and growth into adulthood. The studies provide information on the major toxic effects, indicate target organs and the possibility of accumulation of test chemical and can provide an estimate of a no-observed-adverse-effect level (NOAEL) of exposure which can be used in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. Sub-acute and sub-chronic toxicity studies will thus provide useful data on the risks for operators who are handling and using the pesticide, as well as for other persons who may be exposed sub-chronically. Usually, these toxicity studies are conducted in rats, mice and dogs. This is important to cover potential interspecific variability in mammals, which is needed to judge the hazards for humans. In some cases, short-term studies can also be conducted to assess potential effects from dermal and or inhalation exposure.

3.1.1.3 Long-term toxicity (chronic) and carcinogenicity (C)

When acute, sub-acute and sub-chronic toxicity studies reveal a favorable toxicological profile, long-term (chronic) studies with two mammalian species (rats, mice) are conducted. Chronic toxicity studies provide information on the possible health hazards likely to arise from repeated exposure over a considerable part of the lifespan of the species used. They provide information on the toxic effects of the substance, indicate target organs and the possibility of accumulation.

Chronic toxicity studies are often combined with carcinogenicity studies in order to reduce the number of animals tested. The purpose of these studies, which are conducted in mice and rats, is to identify the carcinogenic properties of a chemical, including an increased incidence of neoplasms, increased proportion of malignant neoplasms or a reduction in the time to appearance of neoplasms, compared with concurrent control groups.

3.1.1.4 Neurotoxicity studies

Neurotoxicity is defined as an adverse change in the structure or function of the nervous system that results from exposure to a chemical, biological or physical agent. Neurotoxicity studies are conducted to detect potential neurobehavioral and neuropathological effects. These studies are not conducted routinely. They are only conducted if the agent under evaluation

belongs to certain chemical classes which are known to have neurotoxic potential, or if findings in acute or sub-acute studies suggest a neurotoxic effect. A developmental neurotoxicity study is carried out, if potential effects on the nervous system and behavioral development following exposure in utero, during lactation and early phase of life until adulthood need to be investigated.

3.1.1.5 Mutagenicity/genotoxicity (M)

Genotoxicity describes the potential of chemical agents to damage the genetic information within a cell causing mutations, which may lead to cancer. The aim of these tests is to predict the potential of a chemical to cause genetic damage, identify and exclude genotoxic carcinogens at an early stage and elucidate the mechanism of action of some carcinogens. The genotoxic potential is tested *in vitro*, *in vivo* in somatic cells and *in vivo* in germ cells.

3.1.1.6 Reproductive toxicity (R)

Reproductive toxicity studies assess the potential for adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring. Developmental toxicity pertains to adverse toxic effects to the developing embryo or fetus. Reproductive toxicity studies are multi-generational and evaluate effects on the integrity and performance of the male and female reproductive systems, including gonadal function, the oestrus cycle, mating behavior, conception, gestation, parturition, lactation, and weaning, and the growth and sexual development of the offspring. In addition, developmental toxicity testing is designed to provide information concerning potential effects of prenatal exposure on the pregnant test animal and on the developing offspring.

3.1.1.7 Endocrine disrupting properties

Endocrine disruptors are chemicals that can directly interfere with endocrine systems in the body controlled by hormones. Adverse effects are monitored and described in all toxicity studies. In addition, in some countries and regions a more detailed investigation is required to better understand the underlying mode/mechanism of action and to provide sufficient evidence whether the observed effect is mediated by an endocrine mode of action or it is a consequence of altered homeostasis due to systemic toxicity. These studies also assess whether the effects seen is animals is relevant to humans (e.g. will the chemical effect occur in humans in the same way as in animals).

3.1.2 Derivation of the AOEL

For operator risk assessment, we follow a systemic risk approach. This means, the toxicological threshold used for operator risk assessments (Acceptable Operator Exposure Level = AOEL) represents the internal (absorbed) dose derived from any route of exposure and is expressed as an internal level (mg/kg body weight/day). The lowest NOAELs (No Observed Adverse Effect Levels), usually determined from sub-chronic animal testing studies, are typically used to set human-relevant endpoints. To determine the Acceptable Operator Exposure Limit (AOEL), the NOAEL from the most-sensitive species identified in sub-chronic studies is divided by a safety factor of 10 to account for possible differences between humans and animals, and an additional factor of 10 to cover differences within the human population. Sometimes further additional safety factors are applied if there is uncertainty in the quality of data or severity of effects. In other words, the AOEL is at a minimum 100 times lower than the dose that produced no effects in animals. The determination of the endpoint is based on the following equation:

AOEL_{systemic} (mg/kg bw/day) = (NOAEL_{oral} x A) / 100

Where:

- // NOAELoral is the No-Observed-Adverse-Effect-Level from the most relevant oral study.
- // A is the fraction of the substance that is taken up by the body after oral administration (e.g. 60% oral absorption: A = 0.6). The AOEL will be routinely corrected, if the measured oral absorption is < 70%.</p>
- // **100** is the assessment factor (10 x 10).

The main routes of exposure for operators are usually via the dermal and inhalation routes, and not via the oral route. To compare a systemic endpoint (AOEL) with systemic exposure, it is important to know what fraction of initial external exposure (e.g. what lands on the hand) becomes bioavailable, i.e. absorbed into the body. Therefore, the behavior of the substance on skin and via the respiratory tract needs to be determined to estimate systemic exposure properly. This is described in the next chapter.

3.2 Behavior (dermal and inhalation absorption)

IN A NUTSHELL

Operators are mainly exposed to plant protection products (PPPs) via two routes: (i) dermal exposure to the concentrated product and the diluted spray mix and, (ii) inhalation exposure to dust particles (for solids) or aerosols (for liquids). Besides the risk evaluation of local effects on skin, eyes and lung, like skin and eye irritation or lung inflammation, it is important to determine the fraction that may enter the circulatory systems of the operator by systemic exposure and potentially cause adverse systemic effects in other parts of the body (e.g. organs like liver or kidney). A substance can only cause systemic effects if it is absorbed and distributed to other parts of the body where it can interact with cells, tissues and organs. In other words, systemic effects can only occur if there is systemic exposure.

Dermal absorption is the transport of chemicals from the outer surface of the skin both into the skin and into the bloodstream. The skin is a multi-layered organ that forms a natural barrier to absorption of foreign substances, including PPPs. Therefore, the amount of dermal absorption is a key parameter used in operator risk assessments for agrochemicals. In internal risk assessment, Bayer uses absorption values from dermal absorption studies with human skin (*in vitro*). If no measured data are available, we use default absorption values which are generally more conservative, i.e., they assume higher levels of absorption than is normally obtained from absorption studies. The operator's systemic exposure via the dermal route is estimated by correcting the operator's dermal exposure for the dermal absorption. For example, if we know from studies that only 10% of a compound applied to the skin is absorbed, then only 10% of an operator's dermal exposure is absorbed and becomes systemically available.

For exposure via the inhalation route, a worst-case is assumed that 100% of the exposure is absorbed via the respiratory system, i.e., all fractions that are inhaled are assumed to be taken up systemically.

The dermal absorption of a substance in a formulated product is usually determined using results of *in vitro* human skin studies. These studies are conducted with real product, where the active substance will be radio labelled. Radioactivity found in the skin and in the receptor fluid, mimicking the blood, provides valuable information on the actual penetration behavior of the substance of interest.

Alternatively, if no data on skin absorption are available, conservative default dermal absorption values are used.

3.2.1 Default dermal absorption values

In case no measured data are available for a certain active substance to determine substance-specific dermal absorption values, default values according to Aggarwal et al 2015³ are used:

- // Dermal absorption default values of 6% for liquid and 2% for solid concentrates, irrespective of the active substance concentration.
- // Dermal absorption default values of 30% for all spray dilutions, irrespective of the formulation type. That corresponds to approximately the 95th percentile of the analyzed dataset, which consisted of data from 190 GLP- and OECD guidelinecompliant human *in vitro* dermal absorption studies (concentrate and dilution).

M.Aggarwal, P.Fisher, A.Hüser, F.M.Kluxen, R.Parr-Dobrzanski, M.Soufie, C Strupp C.Wiemanng, R.Billington: Assessment of an extended dataset of *in vitro* human dermal absorption studies on pesticides to determine default values, opportunities for read-across and influence of dilution on absorption, Regulatory Toxicology and Pharmacology, Volume 72, Issue 1, June 2015, Page 58-70

3.2.2 Substance-specific dermal absorption values

3.2.2.1 Internal Bayer interpretation of study results

For the derivation of appropriate substance-specific dermal absorption⁴ values, data from *in vitro* human skin studies are generally used. These studies are conducted with formulated products under GLP and in accordance with OECD guideline No. 428.5 The dermal absorption is hereby calculated as:

Dermal absorption = Directly absorbed + skin + (Stratum corneum (tape strip 3...X))

In the European Union, the EFSA guidance on dermal absorption proposes for in vitro studies that permeation is considered essentially complete when > 75% of the amount that has permeated into the receptor fluid at the end of sampling (usually at 24 h) has reached the receptor fluid at the half time of the sampling period (usually at 12 h). In this case, it is proposed to exclude all stratum corneum tape strips and not only the first two strips ($\leq 75\%$).

In principle, we follow a similar approach. However, for some substances, where < 75% of the total amount has permeated at the half time, the consideration of the tape strips leads to an artificial increase of the dermal absorption value, because absorption behavior indicates that the substance gets trapped in the stratum corneum and never reaches the receptor fluid.

	Residues in chamber swab (%, not absorbed	Residue in skin (%, defined as absorbed	Residue in stratum corneum (%, dependent on quotient if considered as absorbed	Directly absorbed dose (%, absorbed)	Recovery (%)	Quotient (directly absorbed/ stratum corneum)	Dermal absorption in risk assessment (%)
Pyrethroid X ₁	79.36	0.17	18.7	0.35	98.58	1.9%	0.52
Pyrethroid X_2	89.66	3.99	2.94	0.01	96.6	0.3%	4
Pyrethroid $X_{_3}$	90.67	1.27	2.73	0.01	94.68	0.4%	1.28
Pyrethroid X_4	81.32	2.13	9.94	0.14	93.53	1.4%	2.27
Pyrethroid X_5	97	1.9	0.4	0.9	100.2	225.0%	3.2
Pyrethroid X_6	95.96	0.75	0.24	0.01	96.96	4.2%	0.76

Table 3.1: Example pyrethroids. The proportion of a pyrethroid which remains in the stratum corneum never reaches the receptor fluid. Therefore, it is justified to exclude the entire stratum corneum. However, for Pyrethroid X5, the stratum corneum (tape strip 3...X) was added to the absorbed fraction (quotient > 20%).

Therefore, we used an additional approach: if the quotient between directly absorbed and stratum corneum (tape strip 3...X) is < 0.2 after 24 hours, then all tape strips are excluded. The threshold of 0.2 was based on an expert judgement and has no direct reference.

To avoid unnecessary compounded conservatism, Bayer decided to consider solely the mean value, and not a higher percentile value or the addition of the standard deviation as it is proposed in other guidance documents.

3.2.2.2 The determination of substance-specific dermal absorption values

In a first-tier approach, we decided to define substance-specific dermal absorption values in a multi-to-one approach when measured data from in vitro human skin studies are available. Some regulations claim that co-formulants have a major impact on the dermal absorption of an active substance, which trigger the conduct of product-specific dermal absorption studies. However,

^{4.} EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. https://doi.org/10.2903/j.efsa.2017.4873

^{5.} OECD Guideline for the Testing of Chemicals, Guideline 428. Skin Absorption: in vitro Method (April 2004)

based on our dermal absorption database, which contains values from more than 250 dermal absorption studies, we cannot verify this assumption and consider the influence of co-formulants on the dermal absorption of an active substance as rather negligible (especially for typical in-use dilutions). The observed intrinsic variability caused by the study design is higher than the influence of other parameters. Therefore, for each substance three data pools were established:

- // Dermal absorption of the concentrate (liquid)
- // Dermal absorption of the concentrate (solid)
- // Dermal absorption of the dilution (it is assumed that solid and liquid formulations act similarly once diluted in water)

Depending on the number of independent studies which are available for each substance, the following workflow is used to define substance-specific default dermal absorption figures for each data pool.

Number of independent studies (n=)	Approach taken	Comment
1	Study result -> max value * 2	The safety factor of 1.5 or 2 is needed to
2	The highest study result, max value * 1.5	cover potential variability. If the so derived value exceeds the defined default dermal absorption, the used value is limited to 30%.
> 3	The highest study result	



In conclusion, the following decision tree was followed:



Figure 3.1: Workflow to determine substance-specific default dermal absorption values

In a second-tier approach, when a product-specific *in vitro* dermal absorption study exists for the active substance in the formulation of concern, product-specific measured values can be used.

3.2.3 The determination of dermal absorption values for 3rd party substances

For the derivation of dermal absorption figures for 3rd party substances, we often do not have access to the individual study reports. In these cases, we rely on the data interpretation of the corresponding authorities in a first-tier assessment.

4. EXPOSURE AND RISK ASSESSMENT PRINCIPLES

IN A NUTSHELL

The main principles of risk assessments are described as follows:

- // Estimation of operator exposure taking into consideration the actual exposure as well as the behavior described in the previous chapter.
- // Comparison of exposure to the defined toxicological threshold (AOEL).
- // Decision making by risk assessor, if risk can be considered as safe (safe use) or not.

Operator exposure estimations are based on models built from experimental data conducted with PPP's under realistic field conditions. As an example: real farmers (also called monitoring units in technical terms) were monitored for one working day in a defined scenari, o e.g., tractor mounted groundboom application using a wettable powder (WP) formulation, and the residues on clothing and skin as well as potential inhalation exposure were analyzed. Results from multiple studies were compiled in a large database. In context with a lot of variables (type of application, equipment, formulation type, total amount of active substance handled) the data are statistically analyzed and evaluated so that a model can be developed which allows estimations of operator exposure in certain scenarios.



Figure 4.1: Principle of operator risk assessment based on generic model approaches

The equipment type used to apply a PPP is one of the most important factors that drives the operator exposure. Even though a farmer can treat dozens of hectares using a tractor mounted boom sprayer, he is often significantly less exposed than an operator treating only one hectare but using a manual handheld device like a motorized knapsack.

Bayer compared existing model approaches set by international bodies around the globe to decide which model fits best for our operator exposure assessments. The quality and transparency of the underlying exposure database and the reliability of the statistical analysis were important scientific criteria for this decision. We opted to use mainly US- and European-model approaches for the different scenarios, due to the extent of their existing exposure data and transparent statistical analyses. However, for some use scenarios like pesticide application via handheld devices, we developed an operator exposure model using handheld data from various regions around the globe. The reason for this decision is two-fold. On the one hand, we considered the quality of the statistical analysis of existing handheld models to be insufficient. On the other hand, use scenarios that are common in developing countries are not covered by exposure models developed in the US and Europe. For instance, a handheld application in a dense crop scenario, like a fully developed cotton field in Asia, is not a common use scenario in highly industrialized Western countries (where in broad acre crops a tractor mounted groundboom would be used), but we believe it's important to account for such local practices. Therefore, we closed this gap by developing an exposure estimation approach to also cover this type of use.



Figure 4.2: Handheld application in a dense rice field

4.1 Exposure

Operator exposure estimations are usually linear or log-linear correlated to the amount of active substance handled in one working day. In addition, other side parameters also have an influence on the exposure. The following questions need to be answered thoroughly to conduct a reliable operator exposure assessment.

4.1.1 Questions to be answered to conduct a reliable risk assessment

4.1.1.1 How is the product formulated?

We distinguish between 'Wettable Powders' (WP), 'Wettable Granules' (WG) and 'Liquids'. This is important, because different formulation types can lead to higher or lower operator exposure during mixing and loading of the product. As an example, the use of dusty formulations (WP) result in higher inhalation exposure than the use of liquid or granule formulations. Alternatively, exposure to the hands is higher when using liquids as opposed to WGs.

4.1.1.2 What is the application rate per hectare?

As already mentioned, exposure is often correlated to the amount of active substance handled: the higher the application rate per hectare, the more likely the chance of higher operator exposure to the active substance.

4.1.1.3 What is the treated area per day?

Similarly, this holds true for the treated area per day: the larger the area, the more active substance is handled per day and the more likely the chance of higher operator exposure.

4.1.1.4 What kind of equipment is used?

The type of equipment used to apply pesticides is one of the most important factors influencing operator exposure. Operators are usually less exposed to the PPP during groundboom application than during handheld application. On the other hand, an operator using a tractor mounted sprayer can treat more hectares per day, i.e., he handles more active substance per day. However, the tractor operator's exposure may still be less than that of an operator using handheld equipment owing to the greater physical distance between the spray nozzle and the operator. The question, which equipment scenario can be

considered as the worst case, cannot be answered in general. It's a case-by-case decision. Therefore, if many equipment scenarios per use are realistic, multiple exposure assessments for each equipment type need to be conducted. In addition to the standard equipment for the various application scenarios new as well as modified equipment tools are under development or are already developed. In some cases, an expert judgement may be helpful to estimate operator exposure. In others, however, experimental data have to be generated. Currently, we cover the following equipment/use scenarios in our risk assessment:

- // Tractor mounted boom sprayer
- // Airblast without cabin
- // Speed sprayer
- // Airblast with cabin
- // Aerial (airplane)
- // Handheld (lance, (motorized) Knapsack, hand pressurized devices)
- // Drip irrigation
- // Manual granule application
- // Solid Broadcast spreader for granules

In addition, we are currently working on exposure models for greenhouse uses, seed treatment (high tech facility, on-farm large scale equipment but also small batch treaters), seed sowing and drone applications.

In general, Bayer is prepared to support authorities to establish trial programs for new technologies, like drone application of PPPs.

4.1.1.5 What kind of personal protective equipment (PPE) is worn by the operator?

The protection of the operator by using appropriate PPE is a key element to reduce exposure significantly. During mixing and loading of the PPP, mainly the hands are exposed. The use of chemical resistant gloves during mixing and loading can therefore reduce exposure to a large extent. Another example is the mixing and loading of 'Wettable Powders'. Operators can significantly reduce their exposure via inhalation by wearing a particle filtering mask (FFP1 type).

Hereby, we will consider local agronomic conditions in developing countries to estimate the exposure under local standards. Besides specific crop, climate and equipment-conditions, this also includes a realistic view on the use of appropriate protective clothing during pesticide application. For instance, Bayer will not assume the use of unrealistic protective clothing, like the use of impervious clothing. under hot and humid weather conditions.

4.1.1.6 Which crop is treated at which growth stage?

The combination of crop and growth stage hints at a specific exposure scenario with consequences based on the level of exposure. As an example, exposure during handheld application in a developed rice field (dense crop) is higher than during handheld application in a corn field at an early growth stage (normal crop). In addition, the differentiation between a dense crop and a normal crop scenario is also important for operator exposure assessments. If operators are in contact with contaminated foliage, exposure is usually increased. To distinguish in a first-tier whether a crop can be considered as 'dense' or 'normal,' the following flow chart is applied. Detailed crop and culture condition information from regions can serve as tier 2 refinements.





Figure 4.3: Dense crop decision tree relevant for handheld uses. Remarks: Herbicide application is considered as a use in a normal crop scenario. For crop group 1 the BBCH (growth stage) was chosen to distinguish between dense and normal crop: at BBCH38 or higher, the crop height is usually more than knee height. For group 2 and 3 the use of the BBCH is not useful anymore. Therefore, information on the crop height were used as a parameter: (\leq 50 cm: normal crop; > 50 cm: dense crop). In Group 4, mainly trees, a dense crop scenario is always considered as tier 1. Crops were mainly grouped according to US EPA policy 3.⁶

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4.1.2 The selection of operator exposure models

Once the above-mentioned questions are answered, operator exposure assessments are conducted assuming different model approaches. The following exposure models are used in internal risk assessments by Bayer:

Use scenario	Equipment used	Model used	Assumed treated area/day	
Spray application	Tractor mounted boom sprayer	Europe: AOEM*	50 ha	
	Airblast without cabin	Europe: AOEM*	10 ha	
	Airblast with cabin	Europe: AOEM*	10 ha	
	Aerial (airplane)	CLI – PoR OPEX (AHED**-based model)*	500 ha	
	Handheld, normal crop***	Bayer model	1-4 ha	
	Handheld, dense crop***	Bayer model	1 ha	
	UAV (drone)	Bayer model, under development	4-8 ha	
	Greenhouse	EFSA model, under dev.		
Irrigation	Drip irrigation	Europe: AOEM M&L tank	50 ha	
Granule application	Manual granule application	CLI – PoR OPEX (AHED3-based model)*	2 ha	
	Solid broadcast spreader	CLI – PoR OPEX (AHED3-based model)*	80 ha	
Seed growth	Professional facility	Bayer model, under development		
	On-farm, high throughput	Bayer model, under development		
	Small-scale equipment	Bayer model, under development		

Table 4.1: Use scenarios that are currently covered in Bayer internal risk assessment

- * Model recommended by FAO⁷
- ** AHED = American Handler Exposure Database
- *** Operator exposure data from publicly available European and US handheld datasets were used in the development of the model. In addition, we used operator exposure data from non-disclosed studies conducted in South Korea and the US with kind permission of the College of Agriculture and Life Sciences Seoul National University and the Agricultural Handlers Exposure Task Force (AHETF), respectively.

Technical details on the European model (AOEM) can be found on EFSA's website.⁸ Technical details on the CLI PoR OPEX model as well as a download link to the model can be found CropLife International's website.⁹

For many scenarios, EU- and US-model approaches were selected depending on the availability of data. In case a scenario is covered by both models, the EU-model was chosen because the specific agronomic conditions in the US are considered less representative for many other countries. Moreover, the EU-model shows a high transparency of the underlying data as well as a thorough statistical analysis and evaluation. Some scenarios of the US-model (included in the CropLife OPEX Tool) as well as the EU-model are part of the recommendations by FAO in the Pesticide Registration Toolkit. However, for hand-held applications, there are only a few data available in the EU- and US-models, respectively. Therefore, the decision was made to improve the quality of this data set by collecting global handheld data and developing a new handheld model, which can also be used for exposure scenarios that are typically common in developing countries, like handheld application in arable crop.

8. https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2014.3874&file=3874Ax1-sup-0001.zip - as available on 29/10/2020

9. https://croplife.org/downloads/#accessForm%0D

^{7.} http://www.fao.org/pesticide-registration-toolkit/registration-tools/assessment-methods/method-detail/en/c/1187029/

4.1.3 Technical details on the development of the Bayer handheld model

As for many other models, we developed a two-step approach, considering exposure during mixing and loading separate from exposure during the application. For the exposure during mixing and loading, we used the exposure figures from the European AOEM model. For operator exposure during the application, we distinguished between three application scenarios:

- // Handheld application in normal crops
- // Handheld application in dense crops, spray direction: upwards
- // Handheld application in dense crops, spray direction: downwards

We defined a dense crop scenario as follows: if the operator cannot avoid contact with the treated crop, the scenario is defined as "dense". Spraying sideward or walking backwards during the application may reduce the contact to contaminated foliage but was deemed often impractical under realistic use conditions. Whether a use scenario can be considered "dense" is dependent on the crop, the cultivation type and the growth stage at the time of application. For more information, please refer to the chapter "4.1.1.5 Which crop is treated at which growth stage?" and Figure 4.3.

4.1.3.1 Handheld application in normal crops

We compiled more than 200 monitoring units (farmers) in one database. The underlying studies were conducted in Europe and the US¹⁰, in the field and in greenhouses. For the statistical analysis, the non-parametric method of 75th quantile regression (Koenker, 2005)¹¹ was used for modelling, because it is more robust with respect to measurements below the limit of quantification and does not assume the variability to be independent of the amount of active substance handled. This was also the statistical approach used to develop the European AOEM. Two different clothing scenarios were modelled:

4.1.3.1.1 Operator wearing one layer of clothing, no gloves

225 independent data points were used for quantile regression. The analysis revealed that the exposure is log-linear correlated with the total amount (TA) of active substance handled per day. A pre-analysis revealed that the spray direction (upward or downward) does not have a significant effect on the overall exposure.

Assuming an outdoor scenario in a normal crop the equation to calculate operator exposure during spraying (not including mixing and loading) is as follows:

Dermal operator exposure:

Operator dermal exposure in μ g/person = 10^(0.63602*LOG(TA) + 4.03613)

Inhalation operator exposure:

Operator inhalation exposure in μ g/person = 10^(0.80252*LOG(TA) + 1.95944)

4.1.3.1.2 Operator wearing one layer of clothing, with gloves

216 independent data points were used for quantile regression. The analysis revealed that the exposure is log-linear correlated with the total amount (TA) of active substance handled per day. A pre-analysis revealed that the spray direction (upward or downward) does not have a significant effect on the overall exposure.

Assuming an outdoor scenario in a normal crop the equation to calculate operator exposure during spraying (not including mixing and loading) is as follows:

Dermal operator exposure:

Exposure μ g/person = 10^(0.42129*LOG(TA) + 3.54578)

Inhalation operator exposure:

Operator inhalation exposure in µg/person = 10^(0.80252*LOG(TA) + 1.95944)

^{10.} Operator exposure data from study report AHE400 were considered in the development of the model with kind permission of the Agricultural Handlers Exposure Task Force (AHETF)

^{11.} Koenker, R.: Quantile regression; Econometric society monographs No. 38, ed.: Chesher, A. and Jackson, M., Cambridge university press 2005. Koenker, R.: quantreg: Quantile Regression; R package version 4.81 (2012), http://CRAN.Rproject.org/package=quantreg





4.1.3.2 Handheld application in dense crops, downward spraying

For downward application in dense crop scenarios, we used 31 monitoring units from independent studies conducted in South Korea¹² on rice. A statistical analysis using quantile regression with the total amount of active substance handled per day like it was used for the normal crop scenario was technically not possible due to the variability of the study results and the small range of active substance handled. As an alternative, we defined the scenario "handheld downward application in dense crops" (e.g. rice from BBCH 38 onwards) as a sum of two sub-scenarios for the exposure during application (excluding mixing and loading):

- // Exposure from the actual spraying: It is reasonable to assume that the exposure from spraying is indeed like the exposure in a normal crop. Therefore, we considered exposure calculations using the same exposure figures as for the normal crop scenario.
- // In addition to the exposure from the actual spraying, an additional exposure from contact to the treated crop while walking through contaminated foliage can be assumed. Hereby, mainly the lower body part is exposed. Therefore, mean normalized leg and hip exposure values from the 31 low crop dense studies were taken into consideration. The maximum total amount of active substance handled per day in these studies were 0.12 kg a.s./day. As no clear correlation was observed, we used the mean value up to the maximum amount handled per day (0.12 kg a.s./day). Over 0.12 kg/day a linear extrapolation was used as a rather conservative approach, since without data we could at least not exclude a correlation for higher amounts handled. The mean value was deemed appropriate, because of the addition of two exposure scenarios. The use of a higher centile would have led to an unnecessary compounded conservatism.

We assume that the inhalation exposure is not dependent on the cultivation type (dense or non-dense). Therefore, the formula for both scenarios is identical.

Dermal operator exposure, no gloves (TA=total amount of active substance handled per day):

Exposure in µg/person = 10^(0.63602*LOG(TA) - 0.50321 + 4.53934) + if((TA) < 0.12; 5110; (TA)/0.12 * 5110))

Dermal operator exposure, with gloves:

Exposure in µg/person = 10^(0.42129*LOG(TA) + 3.54578) + if((TA) < 0.12; 5110; (TA)/0.12 * 5110))

Inhalation exposure:

Exposure in µg/person = 10^(0.80252*LOG(TA) - 0.5792 + 2.53864)



Figure 4.5: Exposure of the legs and hips during handheld applications in a dense crop scenario (downward spraying) **Picture left:** Example of operator applying PPP in a dense crop scenario (rice)

4.1.3.3 Handheld application in dense crops, upward spraying

40 Monitoring units from two European studies were used to determine operator exposure during upward spraying in dense high crops. The use of quantile regression was technically not possible, because no statistical correlation between exposure and TA was found. In contrast to the dense crop values for downward spraying, the total absolute amount of active substance handled per day was quite high, up to 2-5 kg a.s./day). Therefore, we decided to normalize the data in mg/kg a.s./day for both dermal and inhalation exposure but using a higher centile value (95th) in a conservative approach.



Figure 4.6: Exposure during handheld applications, dense crop scenario, exposure of different body parts **Picture top-left:** Example of operator applying PPP in a dense crop scenario: upward spraying

Dermal operator exposure, no gloves (TA = total amount of active substance handled per day):

Exposure in µg/person = 17666*(TA) + 49869*(TA) + 1363*(TA)

Dermal operator exposure, with gloves:

Exposure in µg/person = 357*(TA) + 49869*(TA) + 1363*(TA)

Inhalation exposure:

Exposure in μ g/person = 186*(ta)

4.1.3.4 Handheld application in normal and dense crops: summary

The handheld models developed by Bayer are described in the following:

	Normal crop Upward + Downward (µg/operator)	Dense crop, Downward (µg/ operator)	Dense crop, Upward (µg/operator)
Exposure during mixing and loading	Europe: AOEM	Europe: AOEM	Europe: AOEM
Dermal exposure during application, one layer of clothing, no gloves	= 10^(0.63602*LOG(TA) + 4.03613)	= 10^(0.63602*LOG(TA) - 0.50321 + 4.53934) + if((TA) < 0.12; 4727; (TA)/0.12 * 4727))	= 17666 µg/kg*TA (hand) + 49869* TA (body) + 1363 µg/kg * kg a.s. / ha * ta (head)
Dermal exposure during application, one layer of clothing, with gloves	10^(0.42129*LOG(TA) + 3.54578)	= 10^(0.42129*LOG(TA) + 3.54578) + if((TA) < 0.12; 4727; (TA)/0.12 * 4727))	= 357μg/kg*TA (hands+gloves) + 49869 μg/kg*TA (body) + 1363 μg/kg*TA (head)
Inhalation exposure	10^(0.80252*LOG(TA) + 1.95944)	10^(0.80252*LOG(TA) + 1.95944)	= 186 µg/kg*TA

Table 4.2: Exposure algorithms of the Bayer handheld models used for operator risk assessments

TA = total amount of active substance handled per day (kg/day): kg a.s. / ha * area treated Depending on the equipment either "Mixing and loading – tank" or "Mixing/loading – knapsack"

4.1.4 Personal protective equipment

The operator risk assessment answers the question "*under which conditions is the exposure of the operator considered without risk to the operator*"? The estimated systemic exposure has to be lower than the Acceptable Operator Exposure Level (AOEL). To this end, the operator exposure, which has been introduced in the previous chapter, is corrected for the absorption rate (discussed in fate and behavior, so what enters the biosystem) according to the route of exposure to derive the systemic operator exposure and this value is then compared to the toxicological endpoint relevant for operators (AOEL). The risk of operators during the application of PPP is only considered safe if the systemic operator exposure is below the AOEL.

Besides specific crop, climate, and equipment-conditions, an appropriate operator risk assessment also includes a realistic view on the use of personal protective equipment (PPE) during pesticide application. We only assume protective clothing for operators that can be considered realistic under local use conditions and even assuming hot and humid weather conditions. In most of the countries in scope we consider the use of one layer of clothing. In addition, chemical resistant gloves and a simple particle filter mask (FFP1) can be considered, which is directly reflected either as protection factor (mask: 80% protection for inhalation exposure) or distinct exposure figures in our models.

More sophisticated PPE, like engineering control or impervious clothing, can only be considered in a limited number of countries. The assumption of these high-level PPE in the assessment always requires additional concrete stewardship actions. Besides the already mentioned normal PPE (gloves and a particle filter mask), the following clothing combinations could be assumed in selected countries and crops (only connected with concrete stewardship measures to ensure the use of these special PPE):

Advanced/Special PPE



Apron during mixing and loading: 50% additional protection of the body (hand, head and inhalation exposure excluded)

Impervious clothing during mixing and loading and/or application: 95% additional protection of the body (hand, head and inhalation exposure excluded)

Closed Transfer System (CTS) during mixing and loading: Only for liquid formulations, 95% additional protection of all body parts and routes of exposure (dermal + inhalation)

4.2 Apply risk assessment models

In the previous chapters, the minimum safety standard determined by Bayer was introduced to assess operator risk to PPP and to allow a level of operator safety it responsibly considers necessary for its products, even when country regulations do not specifically require this level of assessment. For countries that meet the below criteria, Bayer relies on its regulatory guidelines based on uses in its country-specific risk assessment methods to ensure operator safety:

- // The registration follows a transparent and consistent evaluation process and there is a legal requirement for any registration that:
 - // an operator risk assessment is performed,
 - // the outcome is transcribed,
 - $\ensuremath{\prime\prime}\xspace$ and the intended uses pass the risk assessment.
- // The risk assessment follows a scientific, risk-based approach.
- // The model and assumptions used ensure sufficient protection for the operator.

As an example, and among others, in the regulatory environment in the US and EU27 meet the above-mentioned criteria.

Even though these countries all act responsibly in terms of operator safety, this does not necessarily mean that they all conduct a comparable operator risk assessment. The coverage of exposure scenarios that will be considered in risk assessment is highly variable. While some exposure scenarios, such as a PPP application with a handheld device in a normal crop structure, are addressed in almost all registration processes, some scenarios are currently not in the focus of regulators. This can have multiple reasons, starting from the non-relevance of certain exposure scenarios in certain countries to the fact that for certain new technologies the data necessary to conduct a reliable risk assessment is not yet available (see Table 4.3).

As a globally acting company, it is our objective to cover all possible use scenarios compliant with Good Agricultural Practice to close modelling gaps – either by creating data (e.g. conducting exposure studies) or by developing new risk assessment approaches. Currently, we are working on the assessment of operator exposure during drone application and during seed treatment with small scale equipment like concrete- or drum-mixers.

Our overarching goal is to support authorities to develop or refine regulations for operator safety and develop harmonized safety standards. For instance, operator exposure studies, which were conducted by Bayer, were provided free of charge to PROHUMA, a local industry association in Brazil that collaborates closely with Brazilian regulators, to support their work on the development of an operator exposure model. In addition, Bayer supports an initiative by FAO for the development of a global harmonized operator exposure model for developing countries.

We actively support the scientific dialogue with authorities and academic key opinion leaders that will allow application of a bestpractice standard for assessing exposure and risk.

	Spray application								Granule application		Seed growth		
	Ground- boom	Airblast	Handheld (normal crop)	Handheld (dense grop)	Aerial (airplane)	Drone	Drip irrigation	Green- house	Manual applica- tion	Applica- tion via tractor	Professio- nal facility	On-farm high troughput	Small- scale equip- ment
									<u>+ + 4</u> +				
Operational status	 Image: A second s	~	~	~	~		~		 Image: A second s	~			
Origin of the approach	Europe	Europe	Bayer	Bayer	FAO	Bayer	Europe	Europe	FAO	FAO	Europe	Bayer	Bayer
			•										

routinely addressed

work in progress

Table 4.3: Bayer operator risk assessment approach

4.3 Uncertainties

IN A NUTSHELL

"All models are just simplifications of the reality and only as good as the data and the assumptions from which the model is built". This statement is an alternative variant of the famous sentence by the British statistician George E.P. Box, "all models are wrong, but some are useful". It means that more data and more solid assumptions lead to better predictions. When constructing a model, you leave out all the details which you, with the knowledge at your disposal, consider inessential. Models may not be absolutely true, but it is important that they are applicable, and whether they are applicable for any given purpose must, of course, be investigated. This also means that a model is never final, only on trial.¹³ This general perception of modelling also holds true for our current operator risk assessment approach, which is by far not perfect, but we are working on it.

4.3.1 Missing data

In the safety standard created by Bayer, the most common pesticide application scenarios are already covered or will be covered in future versions. We hereby cover more exposure scenarios than considered by many leading regulatory authorities, because we also consider local requirements and practices, which can be often high exposure drivers. However, it must be said in all honesty that our current model approaches do not cover all possible ways to work with plant protection products, either because we are not aware of some rare use scenarios or don't have enough data to appropriately estimate operator exposure. If a use scenario is not covered by our model approach, we may also consider a bridging from a more conservative scenario (handheld -> drone).



A PPP application according to the label results in a safe use scenario for operators. Thus, it is our objective that farmers work according to Good Agricultural Practice by following the individual use restrictions on the label of each PPP. However, many use scenarios are not supported by us, because they are not according to Good Agricultural Practice and often lead to high exposure scenarios. It's our overarching objective to train farmers to effectively reduce theses high exposure scenarios by further professionalizing the application of plant protection products according to the label.

4.3.2 Compounded conservatism or science vs. regulatory science

In the safety standard approach created by Bayer, exposure models were developed a priori based on the best scientific knowledge and the clear objective to estimate operator exposure in a realistic manner. We are aware that pesticide risk assessments are uncertain by nature, based on assumptions in the absence of data, such as estimating exposure and extrapolating toxicity across species. Regulatory agencies usually resolve those uncertainties in a health protective (conservative) manner; however, only inter- and intraspecific uncertainties when setting the toxicological threshold are explicitly addressed by a safety factor (SF). Other uncertainties are also addressed (e.g., by consistently using "worst case" or conservative assumptions and figures like high exposure percentiles), but here a safety factor cannot be enumerated. Cochran and Ross (2017)¹⁴ developed a methodology to quantify those hidden uncertainty factors, which are routinely applied by many leading authorities globally. This quantification leads to the conclusion that adding multiplicative factors are not only not scientifically useful, but also not helpful to risk manager's policy decisions and to a comprehensive risk-benefit analysis.

The presented approaches in the area of endpoint setting, dermal penetration and exposure estimates may be less conservative than those routinely applied by some regulators, but they all follow strict scientific criteria. Our objective is to estimate the operator exposure as realistic as possible and to consider the nature/severity of the hazard of a substance in a second step to finally judge whether the risk for operators to a certain substance is acceptable or not.

Our risk assessment approaches are an evolving system, meaning that any new data will be thoroughly evaluated and used to refine existing decision. This may lead to the situation that formerly taken decision can be underpinned or revised.

5. RISK MITIGATION

5.1 Product-specific measures

Bayer aspires to obtain registrations only for product uses that meet the Bayer safety standard. Bayer checks that currently registered products also meet the standard and gives guidance for their safe use.

Depending on use-specific circumstances, this ongoing review may identify a requirement for additional risk mitigation measures, such as a reduction in the product application rate or application frequency, or the use of non-standard personal protective equipment such as a mask. In some markets, additional engineering measures such as drift-reducing nozzles, a closed cabin on a tractor, dust extraction during seed treatment or the use of a closed transfer system during loading into a spray tank may be necessary for some uses in order to further reduce operator exposure.

Precautionary statements on product labels are basic measures to mitigate health risks for operators. In this context, Bayer has established a Good Labeling Practice initiative which makes sure that the label information is compatible with the Bayer safety standard. The labels relate to product composition and quality as guaranteed by Bayer. It is vital that counterfeit products (the composition of which is uncertain) are avoided.

5.2 General measures

5.2.1 Safe use trainings

Safe use trainings for operators handling PPPs play an important role in limiting human exposure to health hazards. In some jurisdictions, this is covered by national certification programs for users of PPPs. Bayer offers targeted trainings worldwide with a focus on countries where no, or only limited legal requirements are in place. This includes dedicated trainings for farmers, as well as training activities embedded in events such as product launches or field days run together with retailers. These trainings are tailored to enabling an increased understanding of safe use related topics, such as: product label information; the purchase, transport, and storage of products; mixing, loading and safe application of products; empty container management; and the use of personal protective equipment (PPE). Given the importance of PPE, Bayer has started an initiative to ensure the availability of PPE for purchase by ensuring that it can be ordered via the Bayer sales channel in specific countries. In addition to face-to-face trainings, Bayer is extending its outreach to operators via online trainings.

Furthermore, under the Safe Use Ambassador program observed by Bayer, partnerships with Asian universities offer trainings in the safe use of PPPs. The students who receive the training are then encouraged to share their knowledge with farmers during internships on farms. In 2019, Bayer trained students at 29 universities in seven Asian countries.

5.2.2 License to spray

Operator exposure can be reduced significantly if operators are properly trained in the safe use of PPPs. For countries with no mandatory training or licensing requirements, professional spray services (e.g. Spray Service Providers), offer an effective way of avoiding unsafe use. This approach is being pioneered in several African countries. Bayer supports any initiative or partnership project that aims to ensure that PPPs are only handled by trained operators.

5.2.3 Innovation in application technology

In countries with small agricultural units which typically feature backpack spraying, innovations in application technology such as the use of unmanned aerial vehicles (UAVs/drones) or mechanized ground spraying for the application of PPPs offer the opportunity for more precise application and significantly reduced operator exposure. Proper use of appropriate PPE is required when mixing/loading PPPs for drone use, as for other modes of application. When flying the drones, the pilot does not require PPE, but it must be adopted again when contact with the drone resumes after the application. Stewardship guidance for use of UAVs is available on CropLife International's website.¹⁵

5.2.4 Monitoring

Monitoring and evaluation of product use, either through publicly-available data or user feedback, provides the opportunity to reassess the risks associated with a product in specific markets. Bayer has an established external adverse incident management system and cooperates in many countries with national Poison Control Centers, which provide the basis for understanding and addressing the root causes of unacceptable exposure events.

