

**Bayer Operator Safety Standard Virtual Science Review Panel**  
**April 21-22, 2021**  
**Virtual Microsoft Teams Meeting**

## **I. INTRODUCTION AND OBJECTIVES**

In March 2021, Bayer published its Operator Safety Standard on the Bayer transparency homepage. The Bayer safety standard is a written commitment to ensure that Bayer's crop protection products are used safely, if applied in accordance with the label instructions. As a result, Bayer applies additional safety requirements in addition to those set by regulatory authorities in many countries where Bayer registers its products. The safety of the applicator (operator) is at the center of efforts for product safety and hence the definition of the internal operator safety standard as a global consistent baseline is of particular importance for Bayer.

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). The Safety standard reflects the guidelines and standards of international organizations like FAO, WHO and the Organization 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.

The Bayer Safety standard applies a risk-based approach by following the three pillars of a reliable safety standard: safety data collection to determine the hazard of the product and the exposure of operators, risk assessment to integrate the information from the hazard and exposure to characterize the risk, as well as risk management to check if the assumptions of the risk assessment meet the reality. Details, such as the hazard determination for an active substance, and the algorithms used to identify the absorption behavior of each substance, are presented in technical details. Information on the operator exposure models applied are provided, as well as strategies to implement certain risk mitigation measures are presented.

As part of the commitment, Bayer invites multiple internal and external stakeholders to discuss the Bayer Safety Standard and join an open dialogue to provide suggestions for improvement.

Subsequently, Bayer approached several independent experts from academia, regulatory authorities and industry with expertise in toxicology, exposure assessments and risk management and invited them to comment independently on the Bayer Operator Safety Standard. After collecting the comments, Bayer with the support of an external consultant, organized a two-day panel discussion in April 2021 to further discuss with those experts the Bayer safety operator standard and elaborate options for improvement. The outcome of this panel discussion is summarized in this document.

Please note for transparency, all experts who reviewed the operator safety standard, regardless of their participation in the two-day panel discussion, were offered an honorarium. The honorarium was offered after all participants provided their initial detailed feedback of the safety standard, because Bayer recognized that this process would be time intensive and wanted to ensure that the experts were able to give their full attention to their review, as developing a quality standard is of the utmost importance. Feedback provided is the reviewers' individual expert opinions.

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### III. PARTICIPANTS

<b>Name</b>	<b>Further information</b>	<b>Role in Panel Discussion</b>
<b>John P. Worgan</b>	MSc. Retired Pest Management Regulatory Agency Regulator (Canada), Experience in Environmental Assessment, Occupational Exposure, Risk Assessment and Management for Pesticides, Canada	External expert
<b>Jeff Evans</b>	Retired US Environmental Protection Agency Regulator, Experience in Risk assessments and non-dietary exposure, USA	External expert
<b>Mary Gulumian. PhD</b>	Professor, South Africa's National Institute for Occupational Health, Head of Toxicology Research Projects and the University of the Witwatersrand, South Africa	External expert
<b>Anugrah Shaw, PhD</b>	Professor and Director, International Center for PPE for Pesticide Operator and Re-entry Workers, University of Maryland Eastern Shore, USA	External expert
<b>Hugh Dawick</b>	Director, Pesticides, Australian Pesticides and Veterinary Medicines Authority (APVMA).	External expert
<b>Selma Kaasinen, PhD</b>	Senior Toxicologist, Australian Pesticides and Veterinary Medicines Authority (APVMA)	External expert
<b>Alistair Morriss</b> (commented on the Safety standard, but was not present at the panel discussion)	Principal Consultant, Blue Frog Scientific, Scotland (reviewed the Operator Safety Standard but was unable to attend the panel discussion)	External expert
<b>Rhian Cope, PhD</b> (commented on the Safety standard, but was not present at the panel discussion)	Principal Toxicologist, Australian Pesticides and Veterinary Medicines Authority (APVMA) (reviewed the Operator Safety Standard but was unable to attend the panel discussion)	External expert
<b>Greg Watson. PhD</b>	Crop Protection Regulatory Policy Manager / Analyst, Bayer CropScience. Saint Louis, MO, USA	Bayer representative
<b>Aimee Hood</b>	Regulatory Science Engagement Lead, Bayer CropScience in Saint Louis, MO, USA	Bayer representative
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<b>James Messina</b>	Principal Scientist, Exponent, Inc., Washington, DC, USA	Exponent
<b>Shannon Owings</b>	Scribe, Scientist, Exponent, Inc., Washington, DC, USA	Exponent
<b>Matthew Feinberg</b>	Managing Scientist, Exponent, Inc., Bowie, MD, USA	Exponent, Moderator
<b>Neil Byron</b>	Senior Managing Scientist, Exponent, Inc., Harrogate, UK	Exponent, Moderator

## IV. AGENDA

<b>DAY 1 – Wednesday, 04/21</b>	
<b>2:00 – 2:10</b>	Set-up
<b>2:10 – 2:30</b>	Introductions
<b>2:30 – 2:40</b>	Background of Project (Bayer)
<b>2:40 – 4:00</b>	Overall discussion
<b>2:40 – 3:05</b>	Risk vs Hazard based approach
<b>3:05 – 3:30</b>	Importance of Hazard, Exposure/Risk Assessment, Risk Management
<b>3:30 – 4:00</b>	Which requires more investment from Bayer?
<b>4:00 – 4:15</b>	Break
<b>4:15 – 5:15</b>	Hazard discussion – Dermal absorption – determination of appropriate data, reducing compounded conservatism
<b>DAY 2 – Thursday, 04/22</b>	
<b>2:00 – 2:10</b>	Set-up
<b>2:10 – 2:40</b>	Discuss local exposure scenarios
<b>2:40 – 3:25</b>	Improving operator assessment
<b>3:25 – 4:00</b>	Discuss uncertainties and over-conservatism
<b>4:00 – 4:15</b>	Break
<b>4:15 – 5:15</b>	Risk management discussion
<b>4:15 – 4:45</b>	Improving communication
<b>4:45 – 5:15</b>	Awareness of hazards and risks and ensuring use of PPE
<b>5:15 – 6:00</b>	Closing thoughts and comment

## V. EXECUTIVE SUMMARY

The Bayer Operator Safety Standard was developed as a written commitment to ensure that Bayer's crop protection products are used safely, if applied in accordance with the label instructions. It is written to comply with the FAO code of conduct and align with the FAO pesticide registration toolkit using a risk-based approach.

The Bayer Safety standard targets different audiences by covering three levels of complexity. Level 1 is summarized in a separate one-pager and contains a simplified high-level overview. Level 2 ("in a nutshell") and level 3 (deep technical insight) are both compiled together in the technical document. This safety standard was provided to several subject matter experts who then reviewed and provided comments and suggestions for the document, and several of the experts participated in the follow up virtual panel discussion. Bayer emphasizes its willingness to further improve the safety standard by considering the comments from this panel discussion as well as comments that arrives to Bayer via other channels.

The Bayer Operator Safety Standard utilizes a risk-based approach, and risk assessment to integrate the information from the hazard and exposure to characterize risk. This type of approach is complex and requires more expertise and technical knowledge from regulators than a hazard-based approach. The standard focuses on operators, with the intended audience to be all involved in agriculture around the world, including regulators, operators, farmers, risk assessors, technical experts, trade associations, governments, etc. and to be inclusive of all countries involved in agricultural practices. This scientific panel discussions were held to improve the focus of the document as well as to provide other considerations that could be incorporated into the document to improve its application.

Operators are mainly exposed to Plant Protection Products (PPPs) via two routes: dermal and inhalation. Bayer recognizes that the assigned amount of dermal absorption is a key parameter used in operator risk assessments for dermal exposures to agrochemicals. The absorption factors, in particular the dermal absorption, are key parameters for operator risk assessments. In risk assessments, the dermal absorption value used is typically generated from dermal absorption studies using human skin (*in vitro*) or rat skin (*in vitro* or *in vivo*). However, if no measured data are available, default absorption values are typically used in a regulatory context: in the US and Canada up to 100% dermal absorption is often used, and in Europe values between 10% and 70% are proposed, dependent on the concentration and type of formulation. The Bayer safety standard uses default values, as proposed by Aggarwal, *et al.* (2014), which are between 2% and 30%. Bayer is aware that the selection of appropriate dermal absorption values, particularly default values, is a controversial topic which may require further discussion.

First tier operator exposure estimations are based on exposure models developed from experimental data conducted with PPPs under realistic field conditions. However, it is recognized that these data have often been generated under conditions representative of developed countries such as the EU, US, Canada, Australia, etc. Exposure scenarios that are common in emerging regulatory countries (ERCs) can significantly differ from those covered by available exposure models. The key point to consider when promoting and developing the Bayer Operator Safety Standard document is that Bayer is reliant on scenarios and practices with which they are familiar. It is recognized that a

greater understanding of application practices used in ERCs is also required to ensure that the safety standard is equally applicable to these countries.

Improving operator exposure and risk assessments is the goal of this safety standard; especially for those scenarios that are insufficiently covered by existing regulatory exposure models, such as handheld pesticide applications in ERCs. While there is a wealth of data for numerous exposure scenarios that exist in developed regulatory countries, there is significant lack of realistic exposure data for ERCs, especially for those scenarios that only occur in those countries. However, conducting exposure studies involves a significant investment of time, and human and monetary resources. Two main issues with exposure assessment uncertainty are the existing regulatory models that do not provide a quality statistical analysis of real-world operator exposure scenarios and the use of default assumptions instead of actual study data which will lead to over-conservatism. To help mitigate issues associated with models not developed and designed for ERC application scenarios, Bayer developed an exposure estimation approach. In trying to understand ways to improve the models and to eliminate (or minimize) the uncertainties, options for how to better understand the ERC exposure scenarios was discussed. The experts recognized the challenges in conducting new studies in ERCs and suggested novel approaches might be warranted. This was also seen as an opportunity to see what improvements to local practices could be implemented and what their impact might be. Promoting safe use through outreach with farmers was highlighted by the experts as an important part of improving standards.

Risk management is one of, if not the most, important aspect for operator safety standards. Exposure models, statistical analyses and experimental data are only tools used to help identify the actual risks. If the outcome of risk assessments is not properly implemented or managed, they become irrelevant in terms of protecting operators. In the initial written feedback from the panelists, the experts indicated that working alongside grassroots organizations is the most effective way to improve risk management; however, national organizations/governments also need to play their part. Improving the clarity of product labels, as well as identifying the appropriate personal protective equipment (PPE) and application methods for applying the product, are excellent ways to manage risk, but any such improvements must be effectively communicated to the user. Managing risk is something that is within the control of pesticide companies, regulators, and local stakeholders, although ensuring applicators are aware of those risks and how they can be managed can be a significant challenge. Improving operator awareness to the risks when using PPPs and ensuring the appropriate PPE is available, worn correctly and properly maintained, are all areas that need significant improvement. Education through effective product stewardship programs has an important role in helping achieve this.

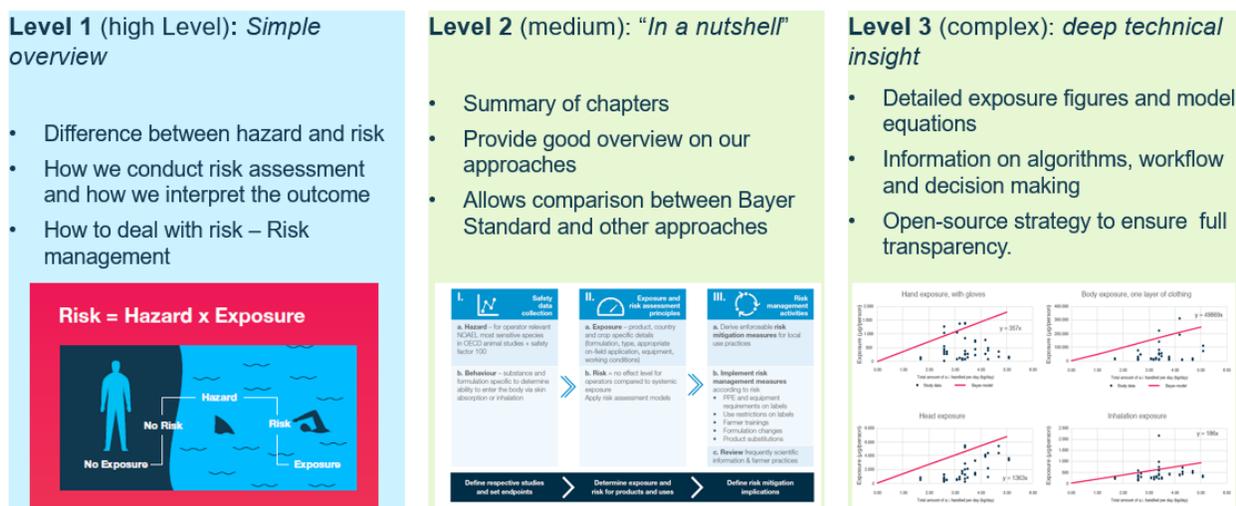
## VI. DAY 1 OF DISCUSSIONS FOR THE SCIENTIFIC REVIEW PANEL

### A. Background of Project and Overall Discussion

Bayer presented an introduction slideshow of the Bayer Operator Safety Standard. Bayer reiterates that the Bayer safety standard complies with the FAO code of conduct and aligns with the FAO pesticide registration toolkit. It follows a risk-based approach considering three main pillars:

1. Collection of sufficient safety data
2. Realistic risk assessment
3. Sensible risk management

The Bayer Safety standard targets different audiences by covering three level of complexity:



Level 1 is summarized in a separate one-pager and contains a simplified high-level overview. Level 2 (“in a nutshell”) and level 3 (deep technical insight) are both compiled together in the technical document, which were provided to the experts. Bayer emphasizes their willingness to further improve the safety standard by considering the comments from this panel discussion as well as comments that arrives Bayer via other channels. As an example, for future improvements, Bayer indicated that they will implement seed treatment uses and seed sowing processes as well as greenhouse uses in the future updates of the standard.

#### i. Feedback from the panels:

- **Complexity of the document:** The experts were in consensus that the safety standard in its current form attempts to target too many audiences at once. i.e. the document seemed merged between the audiences. The depth of technical details varies a great deal in the document, which makes it hard to follow the rationale and increases the possibility of the reader to lose the thread of the content as well as understand the underlying principles. The experts therefore propose to divide the document into two sections based on key target audiences:

- One broader section for those with a practical understanding of the use of pesticides (level 2), and
- One technical section for those highly experienced in risk assessment and data evaluation (level 3).

Bayer response: Bayer’s motivation to drafting such a broad document was to include not only the risk assessors, but others as well, including regulators, farmers, and applicators. Bayer agrees that the intention to meet all requirements was possibly too ambitious and ultimately lead to confusion. Bayer plans to consider the option to divide this document into two or increase the complexity consecutively in the document.

- **Include operators/farmer as target audience:** Currently, the users/operators are not included in the intended audiences. It is not evident from the document, if a farmer was reading the document in search of what kind of PPE was needed, the farmer would not be able to find the information. It was suggested that at the beginning of the document an explanation could be provided about the importance of PPE – why gloves, masks, etc. are needed.

Bayer response: Agreed. In a future revision of the standard, Bayer will include a section covering the importance and effectiveness of PPE. In addition, information should be provided where PPE can be found on product labels by applicators.

- **Option to provide general feedback on the Bayer Safety Standard:** Panelists stated that it would be good to also have a mechanism (e.g. feedback button or link) for any stakeholders to provide comments, feedback, issues, etc.

Bayer response: Anyone can provide feedback and comments on the safety standard by contacting the dedicated transparency email: [crops-science-transparency@bayer.com](mailto:crops-science-transparency@bayer.com).

## **B. Risk vs Hazard Based Approach**

### **i. Background:**

The Bayer Operator Safety Standard applies a risk-based approach: data collection to determine the human-relevant toxicological threshold (hazard) of the product/active substance and to determine the exposure of operators. A risk assessment integrates information from hazard and exposure to characterize risk. If the exposure is below the toxicological threshold, the use can be considered as safe under the assumed use conditions. The panelists were asked in particular: “*How can the industry switch to a risk-based approach especially for ERCs?*” noting that ERCs may not have the knowledge/experience/infrastructure to implement these guidelines; further, ERCs would likely prioritize food securities over worker protections.

## **ii. Feedback from the panelists:**

The experts suggest that industry works together with FAO to improve the regulatory situation in ERCs. The pesticide registration toolkit is of major importance in this regard. It needs to be ensured that by revising the toolkit the usability and simplicity of this tool is continued, due to limited expertise by regulators in ERCs in the completion of operator risk assessments.

However, the need for a cost-effective chemical solution might outweigh the operator risks in certain countries and specific conditions (example: Fall Armyworm or the emergence of an invasive pest that threatens food security). Also risk management solutions need to be considered in the context of what is available to the user (e.g., PPE may be too costly or not available). ERCs in general might have different motivations for the registration of pesticide uses. Food security and operator safety both needs to be adequately considered and balanced.

Bayer response: Agreed that the best way to strengthen the regulatory environment in ERCs is to approach FAO. Bayer will use different channels, including CropLife International, to invite different stakeholders to collaborate in the improvement of operator safety globally. Currently, the Bayer Safety Standard only addresses operator safety. Balancing both food security and operator safety is quite challenging and needs additional consideration. Herein, Bayer seeks advice how to consider this in the decision-making process. A follow-up discussion with a broader audience is needed, because this is a very sensitive topic, and it requires reflection and consideration of the societal contract between government regulators and the constituents it serves.

## **C. Bayer Operator Safety Standard Audience**

### **i. Background:**

The Bayer Safety Standard is a document focused on operators, with the intended audience to be all involved in agriculture around the world, including regulators, operators, farmers, risk assessors, technical experts, trade associations, governments, etc. The scientific panel discussions are meant to help improve the document's focus to be inclusive of all countries involved in agricultural practices, as well as to provide other considerations that could be incorporated into the document to improve its application. The panelists were then asked: *“To provide input on how to prioritize/score different categories”*.

### **ii. Feedback from the panelists:**

The experts commented that when collecting data in ERCs on realistic use patterns, it is likely that actual exposures could exceed reference doses because of inappropriate operator practices. In these situations, attempting to quantify exposures is likely to be of secondary importance compared to promoting better practices to reduce exposure. In situations where Bayer thinks or suspects a product will be misused due to a lack of regulatory oversight and/or poor training/knowledge by applicators, the experts felt that Bayer should not continue to supply product to those countries. Acting as a liaison with the regulators and FAO to establish an understanding/agreement to improve best practices and operator safety was suggested as the way forward in these situations. Generally, it was agreed this was an important issue which needed across industry support, including

engagement from the local stakeholders who may be involved. It was noted that this issue would need to be handled sensitively, so that ERCs did not feel they were being dictated to by outside parties. The experts agreed that the FAO's ambitions for improving standards need to be supported, and that the various training resources already available need to be promoted.

Bayer response: Agreed that certain use scenarios cannot be appropriately considered in risk assessments, either because industry is not aware that such practices exist or those uses violate good agricultural standards or practices. If Bayer identifies uses that are primarily considered as unacceptable, either based on risk assessments or the identification of generally unacceptable practices, Bayer follows a stepwise approach to improve the farmer's situation and operator safety. If Bayer does not see the possibility to act appropriately, it will work with local affiliates to mitigate the situation or potentially halt sales of a product for this use of concern in a certain country. One example for generally unacceptable uses is the common practice to apply a seed treatment product by so-called rolling sheets, where seeds are placed on a plastic foil and then turned over multiple times to coat the seeds with product. This leads to high operator exposures, which is considered unacceptable. In addition, Bayer continues to commit to provide ongoing support to FAO in their ambitions to improve operator safety standards.

## **D. Hazard discussion – Dermal absorption – determination of appropriate data, reducing compounded conservatism**

### **i. Background:**

Operators are mainly exposed to plant protection products 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). Bayer recognizes that the amount of dermal absorption is a key parameter used in operator risk assessments for agrochemicals. In risk assessments, the first absorption value used is generated from dermal absorption studies, typically with human skin (*in vitro*) or in the rat (*in vivo*), which is still standard in the US and Canada. (Please note that recent communications from both US EPA and Pest Management Regulatory Agency (PMRA) indicated that their new science policy will be to use the *in vitro* human data on its own for risk assessment purposes. While EPA still intends to accept the *in vivo* rat study, PMRA will eventually phase out this requirement.) However, if no measured data are available, default absorption values are used, which are generally more conservative (e.g., in the US and Canada up to 100% dermal absorption is used). Given the range of comments received from the panelists concerning the use of dermal absorption data and the impact these values (can) have on predictions of systemic exposure, the panelists were asked: “*Discuss the impact of moving away from rat in vivo studies.*”. Further, the panelists were asked “*How do you consider compounded conservatism in risk assessment?*”

### **ii. Feedback from the panelists:**

The experts noted that although the EU has moved towards accepting human *in vitro* testing alone, the PMRA had been reluctant in the past to accept *in vitro* dermal absorption data on its own, unless it was part of a “triple pack” approach for the purpose of risk assessment. The experts were in agreement that it is important to have the option of using realistic default values where product specific data were not available. Using overly conservative default values may result in risk mitigation measures which are overprotective and could then potentially lead to noncompliance

with PPE recommendations due to hyposensitization (risk of dulling effects, if there are constant warnings without differentiation). The experts asked Bayer why the default values recommended in the Bayer Safety standard were not in line with those currently given in EFSA's guidance on dermal absorption, even though they were based on the same underlying data. This difference could be perceived as potentially lowering safety margins. It was agreed that there needed to be greater transparency around the default values used by different regulatory authorities, which would help to build confidence, particularly in those regulators who have little or no experience with agrochemical risk assessment. The experts were interested to hear about the *in-silico* approach which Bayer had been developing but remarked that such an approach was yet to be validated and gain regulatory acceptance.

Bayer response: Supported the decision by EFSA to focus on *in vitro* human skin data instead of continuing animal testing studies to derive *in vivo* data. With regard to the used default values in the Bayer Safety Standard, Bayer agrees that a more thorough explanation is needed to justify the applied dermal absorption values in case they are different to what is currently applied by regulators, in particular when the chosen defaults are less conservative. Now that an initial review and discussion of the safety standard was completed, Bayer intends to improve the risk assessment and to reduce the resources in conducting *in vitro* skin study, by introducing novel *in silico* methods that can predict dermal absorption based on physico-chemical properties of the tested substance, concentration, and formulation type. Bayer aims to publish this approach along with the prediction tool in peer-reviewed journals, so that all stakeholders including regulators, competitors and academia will be provided an opportunity to comment and engage in the dialogue on the appropriate utilization of data derived using these *in silico* methods.

## VII. DAY 2 OF DISCUSSIONS FOR THE SCIENTIFIC REVIEW PANEL

### A. Discussing Local Exposure Scenarios

#### i. Background:

Operator exposure estimations are based on models built from experimental data conducted with PPPs under realistic field conditions. However, these realistic field conditions are all from conditions in developed countries such as the EU, US, Canada, Australia, etc. Exposure scenarios in ERCs are not accounted for in these studies, which can differ drastically. The key aspect to consider when promoting and developing the Bayer Operator Safety Standard document is that Bayer is relying on scenarios they know. The panelists were asked: “*What information is needed to establish data gaps?*”; furthermore, “*What are the data gaps for these ERCs?*” and “*How do we go about collecting this data?*”.

#### ii. Feedback from the panelists:

The Bayer Safety standard is currently focused on spray applications. Farmers in ERCs typically apply pesticides using hand-held (i.e., knapsack) equipment, and this was seen by the experts as the key application method for gathering suitable data. Surveys of local farmers were recommended to identify the main application techniques and exposure scenarios, as well as what operators routinely wore in terms of clothing and PPE. Regarding PPE, the panelists felt that it is also important to understand how well it is maintained, cleaned, and if it is continued to be used after its recommended lifespan. Poison information centers could also provide information on which application scenarios are leading to adverse incidents. It was suggested by the experts that additional scenarios to be considered might include fumigation, fogging and misting. In addition, the inclusion of vertebrate control agents (e.g. rodenticides) was also recommended.

Bayer response: Agreed that hand-held applications are the most common application technique in ERCs. For example, an application in a dense rice field, where the operator is exposed to the pesticide both through applying the product and from the treated crops while walking through the treated field, is currently not covered by European and US based model approaches. In the Safety Standard, Bayer has introduced a particular model for these application methods. However, the underlying dataset used to establish the models is still quite small and needs improvement. Bayer hopes to further improve the model by collecting additional available data both globally, and through collaborations with stakeholders, including industry, regulators, farmer associations and academia. The consideration of appropriate data from poison control centers to obtain more information on “hidden” exposure scenarios is an excellent idea, which Bayer will certainly implement to gather additional information. With regard to the use of rodenticides, additional aspects need to be considered, such as food security, human hygiene as well as security on infrastructures like in airports.

## **B. Improving Operator Assessment**

### **i. Background:**

Improving operator assessments was the goal of this operator safety standard; especially those scenarios that are insufficiently covered by existing models, such as handheld pesticide applications. As discussed above, while there is a wealth of data for numerous exposure scenarios that exists in developed regulatory countries, there is significant lack of realistic exposure data for ERCs, especially for those scenarios that only occur in those countries. However, conducting exposure studies involves a significant investment of time, and human and monetary resources. If Bayer attempted to “go it alone” and wanted to be transparent, that would likely require the review and approval of study protocols by an established federal regulatory agency to minimize any potential regulatory acceptance or perception issues. The panel was then asked: “*What does the panel think of Bayer working with regulators and other companies to develop something analogous to the independent Human Studies Review Board (HSRB)?*”

### **ii. Feedback from the panelists:**

The experts suggested exposure studies could be conducted through local Universities in partnership with industry and/or regulatory authorities. It was recognized that conducting studies outside of the US and Europe, e.g. in ERCs, would be beneficial to address any local differences in operator practices and behaviors. Data sharing was also highlighted by the experts as a company issue, with companies often not willing to share data or work together. This issue is further complicated by the local ‘generic’ companies who would also be involved. There is also an issue around who provides funding for the studies and will they be conducted to a recognized standard and follow established approaches.

The inherent variability of exposure typically seen in exposure studies was noted by the experts, and this was often higher in hand-held application studies than seen in those involving mechanized application. Differing local operator practices and working conditions were expected to further increase the variability in exposure levels in these studies. A small number of studies was therefore unlikely to provide a sufficiently robust dataset, although it was recognized having some data generated in ERCs was better than having none at all. The experts agreed that whilst Bayer’s suggestion to generate these data was well intentioned, the scale of the dataset needed required an industry wide response.

Bayer response: Agreed that a collaboration between multiple stakeholders is needed to collect sufficient data for model development, particularly for handheld models. The collection of data from industry partners on behalf of CropLife international, as well as government-owned studies, such as data that available from China, is the biggest challenge. Bayer will invite all stakeholders to work together on improving the current situation, by offering a trustful and transparent working environment, with the aim to develop better models that can predict operator exposure more realistically.

## **C. Discussing Uncertainties and Over-Conservatism**

### **i. Background:**

Two main issues with exposure assessment uncertainty are that the existing models do not provide a quality statistical analysis of real-world operator exposure scenarios. Also using default assumptions in place of actual study data leads to over-conservatism. To help mitigate issues with models not developed and designed for ERC application scenarios, Bayer developed an exposure estimation approach. In discussing uncertainties, the panelists were asked: “*What about considering long term exposures (i.e. pesticide sitting on the skin, not wearing waterproof clothing, possibly wearing clothes that absorb the chemicals, etc.)?*”

### **ii. Feedback from the panelists:**

The experts enquired what exposure data was currently available to Bayer, and if Bayer was working with other companies/organizations to fill the known data gaps. The experts were aware of exposure data generated in China and South Korea, which should be included in Bayer’s data list, although it was recognized there could be issues in gaining full access to some of these data. The experts were in agreement that it would be beneficial to do a systematic review of the available data, including any published data, before conducting any new experimental work. Regulatory authorities could also assist in compiling the data list. It was noted that EFSA has recently conducted a data call-in to update its own guidance document and that the US may also have data available, i.e. older studies, but open ownership concerns may still be overcome to access these data. The experts remarked that from their own experiences the data generated as part of a data call-in typically end up being much less than what was identified.

The experts recognized the challenges in conducting new exposure studies in ERCs and suggested novel approaches might be warranted. This was also seen as an opportunity to see what improvements to local practices could be implemented, and what their potential impact might be. These improvements could be considered in the study design and might reasonably lead to simple solutions that are most effective in reducing exposure.

Regarding the use of PPE, the experts drew attention to the balance between comfort and protection. This makes it important to understand which aspect of operator exposure need to be most protected: whether partial body garments such as aprons or impermeable trousers, instead of an entire coverall/suit, could provide the required level of protection.

### **iii. Follow-up questions:**

In trying to understand ways to improve the models and to eliminate (or minimize) the uncertainties, options for how to better understand, the ERC exposure scenarios was discussed. The panelists were asked about surveys that were conducted in Canada a few years ago: “*How did PMRA conduct the surveys, and what was the intent of the surveys. Specifically, what information was PMRA looking to gather?*”

### **i. Feedback from the panelists:**

PMRA conducted an extensive survey of farmers in Western Canada on their use practices and their beliefs with respect to pesticides, including compliance with the label, (e.g. PPE recommendations) and what motivated them to read and follow the label advice. The survey included both farmers and pesticide applicators, when these were separate individuals rather than the farmer/farm owner. Distributors and farmers' spouses were also involved in the outreach activities. Guidance based on the behavioral trends identified in the survey was incorporated into pesticide labelling language. Data gathered through this exercise was also used by PMRA regional staff as part of their outreach and education efforts. Overall, the surveying was perceived to have been successful and PMRA continues to conduct safe use outreach with farmers. It was also noted that a similar initiative has also been conducted in China.

### **iv. Follow-up questions:**

Bayer then asked the panel for advice on how to consider manual exposures (e.g., the use of bare hands or minimal PPE for seed treatment) in the Bayer Operator Safety Standard document: *“Exposure data on manual exposure scenarios are not possible, so how do we account for these exposure scenarios?”* More importantly, if Bayer knows their chemicals are used in this way: *“Is it worth thinking about revoking these products from the market if the potential hazard is severe? Should this be a hazard assessment?”* *“How does Bayer address these uses and potentially hazard exposures?”*

### **ii. Feedback from the panelists:**

The experts stated that in these scenarios it is very likely the reference dose will be exceeded. Instead of focusing on quantifying what is expected to be a very high exposure, the goal should be to address how to bring the exposure down. This will involve considering what are the best achievable practices which can be properly implemented. The experts identified using available expertise at the local level as an important resource to support this initiative, as these experts could help to identify what would be the most impactful changes to help minimize the exposures. The experts re-emphasized the importance of training, together with Product Stewardship, as the best way to improve application practices and thereby minimize exposures.

Bayer response: The exposures during manual treatment of pesticide products (e.g., seed treatments) is hard to estimate. Bayer agrees that stewardship initiatives, providing a more sophisticated infrastructure (like the use of drums for seed treatment applications), or market segmentation, are better tools to improve the current situation. However, this is a multi-stakeholder project where Bayer needs support from the regulators in ERCs, FAO, industry, and farmer associations.

## **D. Risk Management Discussion**

### **i. Background:**

Risk management is one of, if not the most, important aspect for operator safety standards. Models, statistical analyses, and data are only tools used to help identify the risks. If the results are not properly implemented or managed, then they are irrelevant. In the initial written feedback from the panelists, they indicated that grassroots organizations are the best way to go to improve risk management; however, national organizations/governments need to do their part. The panelists were asked: “*What would be the options (or best approach) for Bayer to work with countries to improve risk management?*”

## **ii. Feedback from the panelists:**

The experts emphasized the importance of working together with other stakeholders to achieve operator safety, which is a complex issue requiring the "magic triangle" of industry, regulators, and farmers/growers to work together with academia as catalysts. The experts suggested a top-down approach to strengthen the regulatory environment, and a bottom-up approach to make it easier for farmers/operators to understand the recommendations and advice given on pesticide product labels, including PPE requirements. France was cited as an example of how the industry and French regulatory authorities cooperated to improve and standardize product labelling advice. However, it was recognized by the experts that different strategies will be needed in different countries, and that there was no simple or single solution to this issue. In terms of how Bayer might best engage with stakeholders directly, the experts suggested talking with grower’s spouses or searching for influencers in the community that might also be other useful channels of communication.

Regarding the option to not allow products into certain countries where Bayer is aware of improper use. The experts asked if, in these instances, there is a minimum standard of practice to promote the proper use of their products in those countries.

Bayer response: Education is key to improving operator safety, as is the implementation of improved operator handling and application practices. This also holds true for regulator experience in performing operator risk assessments, as well as farmer behavior when handling plant protection products. If Bayer identifies use patterns where safe uses are unrealistic to assume under local conditions, it will work with local affiliates to initiate the withdrawal of the product from the market or stop the registration process. However, withdrawing a product from the market could potentially lead to farmers switching to alternative solutions that often present an even worse hazard potential. Therefore, Bayer agrees that it is necessary to address the status quo from two directions: 1. strengthen the farmers knowledge on and implementation of safe use behaviors, like the use of appropriate PPE during and after applications; and 2. improve the overall regulatory environment in those regions. Bayer’s aim is to not only have its own safe product portfolio, but rather to raise the bar of operator safety in general.

## **E. Improving Communication**

### **i. Background:**

Improving product labels by altering application rates and application methods to minimize risk, as well as identifying the appropriate PPE, are excellent ways to manage risk, but these improvements must all be effectively communicated. To help identify ways to improve communication, especially in ERCs, the panelists were asked: “*Is it reasonable to assume*

*operators have the necessary knowledge for these products.” After some discussion, follow-up questions were asked of the panelists: “Would there be a benefit for a training or school sponsored by industry for these ERCs using manual methods? Is there value in something like this?”*

## **ii. Feedback from the panelists:**

The experts stated there is a case for adopting a more simplified label system, which could include pictograms and visuals, rather than standard text. The example pictograms of PPE shown by Bayer were seen as a good starting point, although these may need to be further simplified. It was also recommended that the label should make it clear that operators need to wash their hands after using pesticides. The experts generally felt product labels have become too long, overly complicated, and the text is often too small to be readable. The use of interactive labels (QR codes) is seen to be gathering momentum, but would require significant global cooperation to implement, and would be of little use in countries with limited technology. Literacy levels also need to be taken into account in ERCs, hence the use of pictograms had obvious benefits. In summary, the experts thought this was a good opportunity to ‘reinvent’ what product labels should look like, the labelling needing to be simplified, and globally harmonized labels are necessary. Thought should also be given to the pictograms that are used, as these need to be tested because there can be different interpretations of images globally.

Regarding the use of industry sponsored training, the experts thought this was an interesting concept, especially since children are often the ones reading and learning in ERCs. Young people are also typically the ones that are enthusiastic and receptive to learning new ideas. It was recommended Bayer looks at the training programs being operated in Kenya, which give training in pesticide application, as well as provide equipment and PPE.

Bayer response: Agreed that label language needs to be improved significantly. However, Bayer can only initiate a discussion on this, as the ultimate responsibility to change labels is often in the hands of local authorities. An initiative started by the European Commission is currently ongoing to improve labels to facilitate the improved readability and comprehensibility of pesticide labels. Further, CropLife Europe has initiated a project (with Bayer’s support) on creating a digital label system.

## **F. Awareness of Hazards and Risks and Ensuring Use of PPE**

### **i. Background:**

Managing risk and communicating those risks to operators is something that is in the control of pesticide companies, regulators, and local stakeholders, but ensuring that applicators are aware of what those risks are and use the appropriate PPE can be a bigger challenge. Improving operator awareness of the risks and ensuring that the appropriate PPE is available, and worn, are areas that need significant improvement. To identify ways to improve operator awareness and the use of PPE, the panelists were asked: “*Who/what are the best ways to get the outreach to grassroots?*”. The panelists were also asked to provide specific options for improvement: “*Is there a way to follow up/promote if operators are using these products properly? Not a policing strategy, but a follow up? Is there value or a way to do this?*”

## **ii. Feedback from the panelists:**

The experts commented that training in ERCs is often organized through CropLife International. In Canada, there is a developed training activity, whereby PMRA, along with Provincial regulators, developed national standards for various application scenarios, which included aerial application and fumigation. This training was developed through liaison with local farmers. Product stewardship is implemented in tandem with the provincial pesticide regulators, who prepare and deliver the training and certify the applicators. Product specific stewardship programs were also implemented, where the use of a certain product or products required a reduction in applicator exposure in order to manage the associated risk.

In Australia, there was a heavy reliance on the product label to instruct users how to apply the product; however, there was no established national code of practice covering the safe use of pesticide products. Having an established training and certification program for pesticide applicators, supported by a national code of practice, was seen as a way of improving standards and reducing reliance on product labels. Because people tend to quickly forget what they are taught, continuous training rather than one-off training was needed to ensure standards were maintained. It was recognized by the experts that compliance monitoring of operators was difficult to undertake and that successful regulatory systems are based on a mixture of incentives and enforcement. The experts remarked that risk assessors and risk managers have a very different understanding of processes and priorities.

## **G. Closing thoughts and Comment**

### **i. Background:**

After a very fruitful discussion over the course of two days, Bayer was asked to provide its thoughts on the feedback that was presented. The panelists also provided their opinions, as well.

### **ii. Feedback from the Bayer:**

Bayer felt that the panel structure of having individuals from multiple countries leading to multi-regional input, with various expertise and backgrounds, was very important. This diversity led to a variety of viewpoints being presented, including new and important ideas that were previously not considered. Bayer indicated that they consider the drafting and developing of the Operator Safety Standard to be an iterative process and will incorporate any feedback in future versions. Ultimately, Bayer intends to review and improve the standard on the basis of stakeholder by stakeholder. The first version of the Operator Safety Standard is already available on Bayer's transparency website:

<https://www.cropsience.bayer.com/who-we-are/transparency/information-about-our-crop-protection-safety-standards>