

QUESTIONS AND ANSWERS CONCERNING THE TOPIC:

PERSONAL PROTECTIVE EQUIPMENT IN EUROPEAN PESTICIDE RISK ASSESSMENT – AN INDUSTRY PERSPECTIVE

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INTRODUCTION

Pests and diseases can significantly reduce harvest yield, which in turn jeopardizes global food security. Plant Protection Products (PPPs), better known as pesticides, are designed to get rid of pests, like crawling or sucking insects, or fungal infestation. Like effective medicines for humans, effective PPPs can also have unwanted side effects if used incorrectly. Misuse of PPPs can have negative impacts both on human health and the environment, especially if label restrictions are not followed adequately.

To ensure that the main effects (fighting pests and diseases) outweigh the risk of side effects, a thorough risk assessment is conducted to define a safe use of a PPP. The term "safe use" is used to define a scenario where the risk of an unwanted side effect is considered acceptable. It's important to note that there is no such thing as a zero-risk scenario, but the risk can be minimised if the PPP is applied under the "safe use" conditions.

The use of Personal Protective Equipment (PPE) that operators wear during the use of PPPs can significantly reduce exposure to PPPs and therefore minimise the risk of side effects. Effective PPE are, for example, certified working coveralls or chemical resistant gloves that protect the body and the hands. For PPPs that are produced as powders, a particle filter can also significantly reduce exposure via the inhalation route.

The following document provides information in a Q&A format on how PPE effectively reduces exposure, how PPE are considered during the pesticide authorisation process, and how farmers are trained to use PPE properly so that it can help minimise exposure to PPPs.



OPERATOR RISK ASSESSMENT IN EUROPE

HOW IS OPERATOR RISK TO PESTICIDES BEING ASSESSED IN THE EUROPEAN UNION?

ANSWER IN A NUTSHELL

A safe use corridor for operators must be demonstrated under realistic field conditions to get a registration for a pesticide product in Europe.

Paracelsus, known as the father of toxicology, expressed the classic toxicology maxim: "All things are poison, the dosage alone makes it so a thing is not a poison". In simpler words, "The dose makes the poison", meaning that for most chemical substances on earth, a toxicological threshold can be determined under which there is negligible risk for adverse effects in humans. As an example, the World Health Organization defines a concentration of 250 μ g/l lead in blood as not critical and negligible. All humans have traces of arsenic or lead in their blood, but as long as they don't exceed the critical concentration, they are not relevant and are therefore considered an 'acceptable risk'. Plant Protection Products (PPPs), generally known as pesticides, can have side effects if used incorrectly - like the majority of human medicines. To ensure that there is a 'safe use corridor'1 in which the desired outcome (control of pests and diseases) outweighs the likelihood that negative side effects occur, a thorough risk assessment is conducted.

In order to sell a PPP on the EU market, applicants 1A scenario in which the risk of unwanted side effects is considered to be acceptably low 2 N.B. There are other risk definitions, e.g. in engineering, such as the probability of the occurrence of an event and its impact. 3 Kluxen FM, Felkers E, Baumann J, et al. (2021) Compounded conservatism in European re-entry worker risk assessment of pesticides. Regul Toxicol Pharmacol; 121: 104864 4 European Safety Authority, A. Charistou, T. Cola et al. (2021), Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products, EFSA Journal 2022 7032, pp. 60. need to demonstrate a 'safe use corridor' for operators for their products. This term may be incorrectly understood as a use that is not associated with any risk. However, in a regulatory context, one needs to demonstrate that a use is associated with no unacceptable risk. Acceptable risk relates to a health-based reference value, which is usually generated by vertebrate studies, called an uncertainty factor (or a 'safety factor') of at least 100 in European risk assessments. Hence, a reference value relates to a 1/100th fraction of a tested dose that elicits no observable adverse effects in an acceptable animal study (supported by a larger set of studies). Thus, risk in chemical safety assessments is defined as the ratio between the exposure dose and the reference value, and usually expressed as a percentage.²

The concept of risk can be simply captured in the equation: **"Risk = Hazard x Exposure"**.

An exposure value is usually a point estimate of an underlying distribution of values, e.g. from actual exposure data, a product of several default values or a model prediction. When such a value is generated, the current European approach is to consider high percentile values, i.e. low exposure events are not considered in risk assessment. Accordingly, European risk assessment can be considered conservative ^{3, 4}.

Only if a safe use corridor is identified under realistic use conditions is a registration granted. Furthermore, instructions on how to minimize risk are provided on the label of each pesticide product.

HOW IS OPERATOR EXPOSURE TO PESTICIDES ESTIMATED IN EUROPE?

ANSWER IN A NUTSHELL

Operator exposure is estimated by using exposure models that are based on field studies conducted under realistic field conditions. These models are then used by regulators to decide, if a safe-use corridor for a plant protection product can be determined.

Operators, i.e., farmers who apply pesticides, can be exposed to pesticides in multiple ways. For example, when operators are mixing the neat product with water, during the filling of the tank, during the application when, e.g., fixing a blocked nozzle. To conduct a realistic operator risk assessment and to identify the abovementioned safe use corridor, it is important to estimate the exposure as accurately as possible. Operator exposure estimations are based on models built from experimental data conducted with Plant Protection Products (PPPs) under realistic field conditions. As an example: real farmers were monitored for one working day in a defined scenario, e.g., tractor-mounted ground boom application using a wettable powder (WP) formulation, after which the residues on clothing and skin as well as potential inhalation exposure were analysed in a laboratory. Results from multiple studies conducted under the actual use conditions of the products were compiled in a large database, which is publicly available.



Given the number of variables (type of application, equipment, formulation type, total amount of active substance handled) the data is statistically analysed and evaluated so that a generic model can be developed that allows estimations of operator exposure for certain use scenarios. The current European Food Safety Authority (EFSA) guidance⁵ on non-dietary exposure and risk assessment, which is routinely considered for the registration of a plant protection product in Europe, relies on the Agricultural Operator Exposure Model (AOEM) to determine exposures for operators during mixing and loading of Plant Protection Products and applying them as spray using a tractor or handheld equipment. This model was jointly developed by a working group led by the German regulatory body, Bundesinstitut für Risikobewertung (BfR)⁶ and based on the evaluation of over 40 operator exposure studies, involving 595 operators, carried out by the Plant Protection Product industry between 1994 and 2009. The products were applied by experienced individuals who operated in their habitual fashion with no more instructions than the product label. A range of behaviours was sampled, providing exposures which are reflective of real-world exposure scenarios. The outcome is a well-acknowledged operator exposure model that balances realistic use conditions and precautionary principles.

One issue of a generic risk assessment is that only defined use scenarios or prescribed scenarios according to Good Agricultural Practice can be assessed along with the hazard endpoints that are suitably health protective to cover repeat exposure over several consecutive days during the application season. Accordingly, accidents or non-labelled use cannot be covered by risk assessments and cannot be addressed by operator exposure models like the AOEM.



Model Development

Product:	Product 1	
Active Substance:	Substance 1	
Formulation Type (FT):	Liquid	
Equipment (EQUIP):	Tractor Boom (with and without cabin)	
Application rate (AR):	1	kg a.s./ha
Treated area (AREA)	50	ha/day
Dermal absorbtion: concentrate	25.0	%
Dermal absorbtion: dilution	70	%
Bodyweight	60	kg
ADEL	0.1	mg/kg bw/day
Mask during M&L	No	
Mask during Application	No	

Operator exposure estimations for products and scenarious that are covred by the model



Product:	Product 1	
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Mask during M&L Mask during Application	No	
	No	

Operator exposure estimation for product X for scenario Y

Figure 1: Illustration of the development of an operator exposure model: Numerous field exposure studies are statistically analyzed and checked for parameters that can influence operator exposure. The derived model is then used by regulators to decide, if a safe-use corridor for a Plant Protection Product can be determined.

⁵ EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P, Martin S, Sanvido O, Chiusolo A, Colas M and Istace F. 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. https://doi.org/10.2903/iefsa.2022.7032

⁶ BfR (Bundesinstitut fuer Risikobewertung, German Federal Institute for Risk Assessment), 2013. Joint development of a new Agricultural Operator Exposure Model, BfR, Berlin, 259 pp. Available online: https://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf

THE ROLE OF PERSONAL PROTECTIVE EQUIPMENT FOR OPERATOR SAFETY

CAN PERSONAL PROTECTIVE EQUIPMENT PREVENT EXPOSURE SO THAT THERE IS NO RISK FOR OPERATORS?

ANSWER IN A NUTSHELL

Personal protective equipment can significantly reduce exposure of operators to pesticides, but there will never be a 'no-risk' scenario.

Personal Protective Equipment, commonly referred to as PPE, is equipment worn by operators to minimise the risk of adverse effects caused by pesticides. The use of PPE can significantly reduce exposure to operators when handling a pesticide or when being exposed indirectly to residues on the crop or application machinery. However, wearing PPE does not mean that exposure is 100% prevented. PPE reduces operator exposure so that the dose is within acceptable limits, which means that exposure is mitigated and below the toxicological threshold under which no adverse effects for the operator are likely. The risk to the operator, therefore, can be considered acceptable, and allows for a safe use corridor - a scenario in which the risk of unwanted side effects is considered to be acceptably low. To be clear: in any activity in life, for example driving a car, having a glass of wine, cleaning your home, or applying Plant Protection Products, there is no such thing as a zero-risk scenario. However, the risk associated with the use of PPPs can be managed to acceptable levels if they are applied under the defined conditions.



Misuse of pesticides, particularly if label instructions are not followed properly, risks causing negative impact on human health and/or the environment. Pesticides are chemicals and, as for all chemicals, should be handled properly to minimise risk.

WHAT KINDS OF WORKING COVERALL ARE AVAILABLE AND HOW IS THE PROTECTION EFFICIENCY TESTED?

ANSWER IN A NUTSHELL

A new generation of PPE garments for pesticide use significantly improves comfort, adaptation to agricultural tasks and protection efficiency.

Personal Protective Equipment (PPE) is tailored equipment for specific use, and their efficiency. comfort and production must meet specific criteria in the European Union in order to be considered effective⁷. PPE is designed to protect hands, feet, face, and respiratory tract specific to a farmers' tasks. Previously, PPE followed 'general' chemical protection norms: a single use garment whose comfort and design were not really suited to open air and long, specific agricultural tasks. Based on this feedback, new specific norms⁸ to test for protection against PPPs were developed in specific laboratory methods for operators in a realistic agricultural context (involved in mixing, loading, spraying PPP, maintaining, and cleaning equipment, etc.) and for workers during re-entry activities (manually working on recently treated plots). This norm describes a performance standard, based on laboratory and operator exposure study data. It defines criteria for three levels of protection (C1, C2, C3), with C1 being certified PPE with performance similar to the coveralls commonly used for operator exposure studies that regularly proved their efficiency.



7 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. 8 ISO 27065:2017 https://www.iso.org/obp/ui/#iso:std/iso:27065:ed-2:vlien



C1: basic protective clothing to which other items can then be added if needed (apron, etc.) when the potential risk is relatively low (e.g., when handling diluted products). Level C1 is close to an uncertified "classic" workwear (effectiveness of which has nevertheless been observed).



C2: protective clothing above level C1, which generally still offers a good balance between comfort and protection.



C3: protection for the most significant risk situations like handling of concentrated products and could be recommended for spraying tasks at risk of increased exposure (confined to greenhouses, backpack sprayers, etc.). Precautionary measures, such as short-term use, are necessary as these suits may generate significant discomfort or heat.

Figure 2: Example of certified clothing according to ISO 27065, marked with either C1, C2 or C3, depending on the level of protection. Crédits : RAS PRODUCTION / Astrid Loren, reproduction illicite

Contrary to previous general chemical protection norms, EN/ISO 27065:2017 dictates tests are done with a specific "pesticide" test formulation and not with generic compounds like acids, bases, etc. This specific test formulation was chosen to be easily used in laboratories, and without hazardous or commercially complicated procedures to obtain compounds. Further tests were conducted to mimic the specific penetration behaviour of the worst-case PPPs, that were evaluated from a range of 67 real international commercialized PPPs, with a diversity of representative active ingredients and formulation types.

The new generation of PPE for PPP use would benefit from better recognition and use as they bring a real added value in terms of comfort, adaptation to agricultural tasks and efficiency, in particular since they are tested with a formulation that reflects worst-case scenarios of PPP penetration.

HOW DOES PERSONAL PROTECTIVE EQUIPMENT PROTECT THE FARMER UNDER REALISTIC FIELD CONDITIONS?

ANSWER IN A NUTSHELL

The outcome of many field studies has demonstrated the effectiveness of Personal Protective Equipment. In particular a certified working coverall and chemical resistant gloves can significantly reduce operator exposure.

The use of Personal Protective Equipment (PPE) can significantly reduce exposure when handling a pesticide product. The extent of exposure reduction from wearing a working coverall or chemical resistant gloves has been demonstrated in numerous operator exposure studies under realistic field conditions. A European project has compiled exposure data from more than 40 operator exposure studies involving over 595 operators. The objective was to create a refined operator exposure model, the AOEM, that can effectively predict operator exposure for various exposure scenarios. And the results were clear: using Personal Protective Equipment is an effective way of reducing operator exposure. The following figures show the level of protection measured in the different studies for hand and body protection. For example, in study LCTM_19, when wearing chemical resistant gloves during mixing and loading the provided hand protection on average is 94% (range 83%-99%).



The AOEM data also show variability in the level of protection, both within individual studies and overall. This variation is covered by the use of sufficiently conservative exposure centiles (75th/95th-centiles) in the European operator exposure model. Data outliers are considered in the statistical analysis - and not "taken out", as occasionally claimed.

Please note that this analysis contained only values above a certain exposure threshold (total hand exposure > 100 μ g/operator). Otherwise, ultra-low exposure values would have led to artificial protection factors.

9 BfR (Bundesinstitut fuer Risikobewertung, German Federal Institute for Risk Assessment), 2013. Joint development of a new Agricultural Operator Exposure Model, BfR, Berlin, 259 pp. Available online: https://www.bfr.bund.de/cn/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf









Figure 4: Protection factor achieved by of wearing a working coverall comparable to C1 certification during mixing and loading (A) and during the application of pesticides (B).

PPE IMPROVEMENTS IN THE PAST YEARS & WHAT WE CAN EXPECT IN THE FUTURE

WHAT HAPPENED IN THE PAST YEARS IN TERMS OF PPE IMPROVEMENTS?

ANSWER IN A NUTSHELL

Significant progress was made in the past years to make personal protective equipment more efficient to reduce operator exposure, and to increase the comfort of PPE.

The development of safer Plant Protection Products (PPPs) and more efficient Personal Protective Equipment (PPE) is a collective and continuous process to improve operator safety. A few years ago (around 2000), the framework for personal protection against chemical risks in the agricultural sector was published, following the international standardisations of general chemical protection. These chemical protection standards were written with the primary objective of protecting workers in factories.

The working conditions of a factory worker, however, do not necessarily reflect the working conditions of a farmer and their specific constraints (comfort, freedom of movements, thermal amplitude during the year, duration, and specificities of the tasks). This opinion has been shared by many different European stakeholders such as local authorities, occupational health and safety specialists, farmers and industry experts. The gradual collective awareness led to a significant progression in the field of agricultural personal protection.



More than 10 years of progress, admittedly still not widely communicated, has made it possible to take steps forward in terms of international standardisation relating to agricultural chemical protection, training and certification of PPP users/advisors, as well as information on the PPE to be used, according to the agricultural tasks undertaken and the types of PPP handled. The mentioned developments have also led to the creation of new innovative ranges of PPE dedicated to chemical protection in the agricultural context. One example is the introduction of specific working gloves where only the palm pads are coated with nitrile. These types of gloves were developed to protect workers during re-entry activities. Particularly when exposed to dry pesticide residues, these gloves are almost as effective in exposure reduction as common nitrile gloves, but are much more comfortable to wear, which has led to more farmers using them. Full nitrile gloves are, however, still recommended to protect operators from liquids during mixing & loading or during the application of Plant Protection Products.



Figure 5: a) Common nitrile gloves recommended for tasks like mixing and loading of a plant protection product. b) Working gloves that are semi-coated with nitrile. They provide good protection to dry residues with an increased comfort factor.

In 2019, Germany's BVL (Federal Office for Consumer Protection and Food Safety) published a database of Personal Protective Equipment suitable for PPP protection that are in compliance with BVL requirements¹⁰, including easily available and affordable garments certified in accordance with the new PPE norms (ISO 27065 or ISO 18889). The listing on the BVL website (last update in December 2021) is a sound source to access updated information, certificates and normative pictograms on available protective suits (reusable & disposable), certified work clothing, long-sleeved aprons, gloves (reusable, disposable and partial gloves for re-entry workers).



10 https://www.bvl.bund.de/DE/Arbeitsbereiche/04_Pflanzenschutzmittel/04_Anwender/03_Schutzaus-

WHAT CAN BE EXPECTED IN THE FUTURE TO FURTHER IMPROVE EFFICACY, COMFORT AND SPECIFICITY OF PPE?

ANSWER IN A NUTSHELL

A new generation of more comfortable, more protective, and more aesthetically attractive personal protective equipment is currently being developed to increase take-up among farmers.

Based on new Personal Protective Equipment (PPE) international norms, PPE manufacturers developed a new generation of PPE dedicated to farmer's protection. The outcome of several projects recently reached the European market. New and more adapted designs, in terms of fabrics and colours, as well as more comfort, including under hot climate conditions, will help to increase the acceptance of farmers to wear reusable PPE.

By being aware of the special responsibility, the PPP industry has been a driving force behind these changes for many years. In 2010, the European 'Safe Use Initiative' project was launched", including research in France, with the objective of comparing recommended good practices with the reality in the field. Various agricultural stakeholders were involved in this exercise to find technical and organisational approaches to increase the efficiency and acceptance of PPE by farmers. During the project, the first avenues for the development of better adapted PPE emerged.



Several tests in real conditions in Gironde, Marne and the north of France (2014 to 2016) and specific exposure studies (in 2015 and 2017) have made it possible to develop and assess prototypes of innovative PPE that guarantees a high level of protections in combination with a higher comfort and a better adaptation to real agronomic work conditions. For the moment, lots of farmers are still reserved about the use of agricultural PPE because they think that only uncomfortable, old-generation chemical PPE are available to them, and they are not aware of the new generation PPE.

II https://croplife.org/crop-protection/stewardship/responsible-use/

HOW TO IMPROVE TAKE-UP OF PERSONAL PROTECTIVE EQUIPMENT AMONG FARMERS

WHO IS RESPONSIBLE THAT PLANT PROTECTION PRODUCTS CAUSE NO UNACCEPTABLE RISK TO OPERATORS?

ANSWER IN A NUTSHELL

Together, industry, farmers, and regulators ensure safe application of pesticides.

A seatbelt in a car does not protect the driver if they do not buckle up during the ride. The same is true concerning the use of Personal Protective Equipment during pesticide application. For implementing a safe use corridor, a scenario where the risk of unwanted side effects is considered to be acceptably low involves contributions from three key responsible parties:



Figure 6: The safe use triangle for plant protection products

- The manufacturers of Plant Protection Products 1 (PPPs). The industry must provide products that are effective and safe under realistic local use conditions. Hereby, the industry needs to generate data on the toxicity of the PPPs as well as data on the potential for exposure in order to estimate whether the expected level of exposure under a defined scenario lies sufficiently below the toxicity threshold. The defined use scenario can also consider the use of Personal Protective Equipment (PPE), to reduce exposure for example, wearing gloves and coveralls while mixing a product with water and loading into a sprayer. In addition, the manufacturers of PPPs can offer safe-use trainings for farmers.
- 2. Operators and farmers applying a PPP. It is the farmer's (PPP user) responsibility to follow the label instructions that defines the safe use and to apply PPPs according to Good Agricultural Practices. In many European countries, exclusively certified operators are allowed to spray professional Plant Protection Products. The certification usually also ensures that operators are able to properly and responsibly use Personal Protective Equipment during mixing & loading of the concentrated product, during the application or during re-entry activities.

3. Use regulations set up by authorities.

Regulators need to provide a regulatory environment that defines the framework for setting product authorisation, the safe use of those products and controls the proper use of the products by the farmer.

WHAT HAS BEEN DONE TO IMPROVE RISK AWARENESS AND TO INCREASE THE ACCEPTANCE OF PPE BY FARMERS?

ANSWER IN A NUTSHELL

Trainings and certifications help to improve farmer acceptance of wearing PPE when handling pesticides.

In Europe, agricultural courses and trainings are constantly improving. They aim to inform farmers about the risks involved when applying Plant Protection Products (PPP) and how they can mitigate the risk with proper use of Personal Protective Equipment (PPE). In 2009, a European Union Directive¹² established a framework of community actions aimed at using pesticides compatible with safe use and sustainable development. Through a national action plan, each Member State had to set itself quantitative objectives and develop measures to reduce the risks and effects of PPPs on human health and the environment, and to encourage the implementation of integrated pest management. Following this Directive, Member States had to ensure that all professional users, distributors, and advisers have access to appropriate training through certification. Several schemes have been set up in different Member States.

For example, in France, it has resulted in the establishment of Certiphyto¹³. Since 2009, all professionals carrying out activities related to PPP, whatever their status or their sector of activity, are required to hold a Certiphyto license to deliver, advise and/or purchase and use PPP. Each Certiphyto is valid for up to five years and needs to be renewed. The license is to be obtained through training or exam and it covers three themes: 1-Regulations and environmental safety; 2-Health and safety (including PPE); and 3-Reduction of use and alternative methods.

Such national schemes are set to be harmonised under the Proposal for a Regulation on the Sustainable Use of Plant Protection Products¹⁴. This regulation will require Member States to clearly ensure initial and continuous training for professional PPP users and distributors, practical training for professional PPP users and in-depth training for PPP advisers. In the Commission proposal, training certificates will be valid for a maximum of ten years for distributor and professional user, and five years for advisers. Trainings will include in particular "hazards of and risks associated with Plant Protection Products. and how to identify and control them", and include information on risks to human health, safe working practices, measures to minimise risks and appropriate first aid measures in case of poisoning.

12 Diractive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides 12 bits of Vication basis.

14 DRAFT Regulation: Proposal for a Regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115. Brussels, 22.6.2022, COM(2022) 305 final, 2022/0196 (COD).

WHAT CAN BE FURTHER DONE TO IMPROVE RISK PERCEPTION AND RISK AWARENESS OF FARMERS?

ANSWER IN A NUTSHELL

Stakeholders are undertaking public awareness campaigns to improve knowledge and understanding.

Recently, awareness of the risks and hazards related to PPP is increasing due to recognised health effects based on previous exposure to both obsolete PPPs and outdated use behaviours. European Union regulations, societal, NGO and media attention as well as questions from scientific publications have also led to a growing risk perception amongst farmers.

At the same time, many initiatives from different stakeholders have been carried out by authorities, farmers' associations, preventers, PPP advisors, PPP industry associations, PPP distributors, or PPE manufacturers, which all aim at delivering stewardship and prevention messages to increase awareness and good practices. In 2020, all stakeholders in France came together to deliver a collective prevention campaign on PPE. This multistakeholder initiative was the first time all stakeholders in a country decided to work together, and gathered together the Ministry of Agriculture, farmers' associations, agricultural advisors' representatives, distribution associations, agricultural medical experts, PPP and PPE industries.

The tagline for the campaign was:

"THE NEW GENERATION OF PPE REVEALS THE PROFESSIONAL YOU ARE":

la nouvelle génération d'**EPI*** révèle le **PRO** qui est en **VOUS**



Figure 7: The key image of the collective prevention campaign

Pedagogic tools and information such as prevention messages, new regulations/ requirements, new PPE norms, availability of a wide range of PPE, and disposal of contaminated PPE is available in French on a website¹⁵. This prevention campaign covered print and web French agricultural media for two years (2020 and 2021). One of the key points of this initiative was that all public and private stakeholders were involved, which enables to build a "common language" to facilitate farmers' understanding.

For the first time farmers simultaneously got the same information from all relevant stakeholders. Moreover, to find new ways to reach farmers, social media was also used, with a creative web series that addressed preconceived ideas about PPE and illustrated good practices. Eight episodes, plus a final episode as part of a national video competition for agricultural students, was recorded. Those episodes were viewed on different platforms more than 280,000 times¹⁶.

PPE requirements vary considerably around the globe. General statements on the labels such as "wear suitable protective clothing", which still exists in some countries, make it difficult for PPP users to identify the genuine PPE they should wear to protect themselves. European Regulations¹⁷ indicates that the manufacturer has to provide general PPE information on the PPP label: "Member States may identify suitable personal protective equipment for operators and prescribe specific elements of this equipment (e.g. coveralls, apron, gloves, sturdy shoes, rubber boots, face protection, face shield, tightly fitting glasses, hat, hood or respirator of a specified type). [...] Member States may further identify the specific tasks which require particular protective equipment, such as mixing, loading or handling the undiluted product, applying or spraying the diluted product, handling recently treated materials like plants or soil or entering recently treated areas." European countries and industry associations have generated several initiatives to ameliorate PPE information and readability of the requirements.



15 https://epiphyto.fr/

16 https://epiphyto.fr/webseries/

17 Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products The first major initiative was done in France in 2016 with the publication of an official text from Ministry of Agriculture¹⁸, intended for PPP manufacturers. It exhaustively lists the most appropriate PPE recommendations for farmers/ operators that have to be put on French PPP labels: the different areas of the body (eyes, respiratory, body, hands, feet), the phases of use/tasks involved, the types of crops (high, low, greenhouses, etc.), the type of treatment equipment used (tractor with or without cabin, manual spraying, etc.) as well as the toxicological and physico-chemical characteristics of the PPP used. This official document made it possible to standardize the requirements and proposes more detailed information to users. Following this regulatory initiative, the French pesticide industry association (Phyteis) took the opportunity to redesign and unify all national PPP labels and especially how the safety information would be presented. The long official text was translated into didactic tables with pictograms.



* EN CAS D'INTERVENTION À L'EXTÉRIEUR; DANS CE CAS, LES GANTS DOIVENT ÊTRE STOCKÉS ET PORTÉS À L'EXTÉRIEUR DE LA CABINE.

Figure 8: An example of PPE table according to Phyteis national labeling guideline.

Another example, in Germany , was the BVL (Federal Office of Consumer Protection and Food Safety) publication in 2020 of PPE guidelines, "Personal protective equipment when handling Plant Protection Products"¹⁹ which helps determine which PPE is suitable for different PPP and situations. It covers not only uncertified workwear and certified PPE for body protection but also hands, eyes, respiratory tract, head and feet protection. Also in Germany, the IVA (German Crop Protection Association) initiated a campaign to implement harmonised pictogram tables to replace the text on PPP labels²⁰.

Another initiative that can be highlighted is from Switzerland. The SECO (State Secretariat for Economic Affairs) in charge of these topics built a tool kit²¹ and a web application²² for agricultural extension and practice, based on their operator and re-entry workers safety standards and guided by a three level color-coded set of PPE requirements, the objective is to help PPP users quickly identify the necessary protective measures depending on the PPP used, the crop type and the work steps (mixing & loading, application, re-entry work). The grouping strategy is based on the level of risk of PPPs, according to their evaluation results. Due to the grouping, the protective measures can be stricter than those specified in the approval of the PPP, but with only three groups, the number of possible combinations of different protective measures required is thus reduced, and so easier to assimilate by farmers. With the digitalisation of labelling, it is expected access to information will become even easier in the future and help guide them on the use of mitigation measures.

These examples from France, Germany and Switzerland are a sound starting point, and it is hoped that these initiatives could lead to a more common European and global approach. Discussion is currently ongoing to build a "Roadmap for a partnership in Europe" from these initiatives and will be presented during the 7th International Akademie Fresenius Conference "Worker, Operator, Bystander and Resident Exposure and Risk Assessment", December 2022.



20 IVA (2021), "Einheitliche Piktogramme erleichtern Auswahl von Schutzausrüstung / IVA-Handbuch Anwendungssicherheit jetzt auch zum Bestellen", <u>Sichere Anwendung von Pflanzenschutzmitteln |</u>

21 https://www.gutelandwirtschaftlichepraxis.ch/index.php?id=97

22 https://www.gutelandwirtschaftlichepraxis.ch/bonnes-pratiques/protection-sante-environnement

Figure 9: Example of the PPE requirements depending on the risk level of the PPP (yellow, orange, red), for mixing & loading, application and, last column, for re-entry work. The red classified PPPs are exceptions due to their specificities (like respiratory hazard PPP). For those, the farmer must consult the PPP specific instructions, based on the PPP label.



