

PPE for pesticide operators and reentry workers: achievements in France through national and international collaborations

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Abstract

Plant protection products (PPP) are regulated products that require authorization in the country where they are sold. Operator and reentry worker safety when handling pesticides is one of the safety considerations that must be addressed as part of the registration process. Personal protective equipment (PPE) is one of the options for reducing operator and reentry worker exposure. Quality, comfort, cost, and availability are common constraints in the use of PPE that need to be addressed for it to be used effectively to mitigate risk. This requires stakeholders from the PPP and PPE sectors working together; it cannot be accomplished by any one group or entity alone. This process, which begins with compliance with regulations and ends with the possibility of the farmer/operator/reentry worker to protect themselves, requires a concerted effort. This article shows how international standards and expertise, as well as coordination of PPP and PPE stakeholders in France, resulted in the development and implementation of risk-based PPE requirements, which are acceptable to farmer/operator/reentry worker. The French example could be used by other countries that are governed by EU regulations. Additionally, the development of consistent labels and partnerships to promote clear consistent message has broader implications.

Introduction

The safe and responsible use of pesticide/plant protection products (PPP) includes the protection of individuals and the environment. Regulations mandate that the registered PPP address the occupational health and safety of pesticide operators and reentry workers. To ensure operator and reentry worker safety, personal protective equipment (PPE) may be required to reduce exposure. For PPP products that require PPE to mitigate risk, effective communication is necessary to inform users what they need in order to protect themselves. The PPE requirements

vary considerably around the world, which leads to varying levels of protection for operators and reentry workers. General statements such as “wear suitable protective clothing (coverall)” make it difficult for the users to select the PPE they should wear; specificity is essential to communicate PPE based on risk assessment. A “worst-case” scenario approach that requires individuals to wear all PPE, all the time, especially in hot climates, is also not recommended. Overprotection can affect comfort/heat stress, the ability to perform the work, and cost and possibly cause noncompliance. Thus, the importance of requiring appropriate PPE, when needed, cannot be

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overemphasized. The information in this article is presented primarily in chronological order, with key milestones included in Table 1. It explains the coordination between the stakeholders and shows the work done to effectively communicate the PPE requirements, in compliance with relevant EU and French regulations.

In the EU, PPP regulations provide rules that need to be met for protection of operators and reentry workers. PPP regulations address who must be protected and how to ensure adequate and consistent protection. However, (EU) N° 547/2011 Regulation allows the manufacturer/supplier to provide general PPE statements on the PPP label [1]. Annex III includes the following information for member states regarding PPE statements directed toward member states:

“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). Such supplementary safety precautions shall be without prejudice to the standard phrases applicable according to Directive 1999/45/EC.

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.”

This information is overly general and does little to help provide meaningful information to operators and reentry workers. For example, the statement “Wear appropriate

clothes, gloves and eye and face protection” was in compliance with the regulation, but it did not provide the information needed for the user to determine *which* protective gloves and protective garments need to be worn. In France, similar previous general PPE statements on PPP products and the use of chemical protective clothing raised concerns regarding the protection provided by PPE worn by operators. In 2011, decision was made in France to delay most of the new approvals of PPP while the PPE issue was being resolved. The specificity of and low user acceptance of CE-certified chemical protective clothing had to be addressed for the approval of new PPP products to resume.

Resolving this PPE issue became a priority for the regulatory authorities and PPP industry. In 2014, the French Agency for Food, Environmental and Occupational Health Safety (ANSES), the French Ministry of Agriculture, and Union des Industries de la Protection des Plantes (UIPP) gave presentations at the 3rd International Fresenius Conference “Worker, Operator, Bystander and Resident Exposure and Risk Assessment” that focused on their efforts to address the PPE for PPP issue [2–4]. Each entity approached the issue based on the relevancy of the issue for its organization.

- The ANSES presentation highlighted the regulatory basis for PPE recommendations (Fig. 1). Regulation EU 546/2011 [5] requires member states to consider the obtainability and suitability, including ease of wearing that considers physical stress and climatic conditions, of protective clothing and equipment. The decision-making section of the regulation states “Where the proposed conditions of use require use of items of protective

Table 1. Key milestones listed in chronological order.

Year	Milestone
2007	Study raised questions on efficiency of PPE worn by farmers in France.
2010	Several PPE removed from the market.
2013–2014	French evaluation of PPE standards; studies and surveys. Decision to support ongoing work on ISO 27065 to be revised as EN/ISO standard.
2014	International Consortium for PPE for Pesticide Operators and Re-entry was established as an outcome of a symposium held in 2013.
2015	Master Plan for coordination between International Consortium and international stakeholders on implementation of PPE Requirements for pesticide operators and reentry workers.
2015	UIPP initiative on PPE garment design and color preference. Findings were shared with PPE manufacturers.
2016–2017	Validation of pipette method and development of a generic database to validate the test chemical.
2016	Regulatory changes by French Ministry of Agriculture provided specificity for PPE recommendations for each tasks. This required major changes in PPP labels.
2016–2017	Development of a PPP labelling guideline by UIPP for consistency and readability.
2016	Initial meeting of French Ministry of Agriculture and Ministry of Labor with French certification bodies and PPE manufacturers.
2016	National PPE waste disposal service ECO EPI introduced by ADIVALOR.
2017–2018	Revised EN/ISO 27065 was approved in 2017; the harmonized EN standard was published in 2018.
2018–2019	A new generation of certified garments in compliance with EN/27065 was available in France.
2019	More than 90% of French PPP labels based on UIPP voluntary labeling guideline.
2020	Major safety multistakeholder campaign with consistent message to the farmers.

clothing and equipment, no authorization shall be granted unless those items are effective and in accordance with the relevant EU provisions and are readily obtainable by the user.” Information on survey and laboratory data of studies conducted in France to obtain information on use and performance of protective clothing was included in the presentation. Conclusions and recommendations, based on regulations and studies, were for the following:

- Continuation of the ongoing work for a standard for PPE dedicated to PPP at the European level; revision of ISO 27065 as EN/ISO 27065 [6].
- PPE manufacturers to provide information to users on performance and practices concerning the maintenance (time of wearing, washing practices, etc.) for the CE-certified garments.

- PPP manufacturers to provide test results on the PPE recommended or to justify extrapolation of results from existing products with similar characteristics for each product submitted for an authorization.
- The French Ministry of Agriculture presentation highlighted the need for standardized protective clothing for pesticide operators (and reentry workers). It stated that PPE for protection against PPP is at the crossroads of several regulations; compliance is required with PPE directives, regulations for placement of PPP in the marketplace, and classification, labeling, and packaging regulations. As seen in Fig. 2, the presentation also drew attention to the challenge of implementing working clothing or uncertified cotton coveralls listed as the default

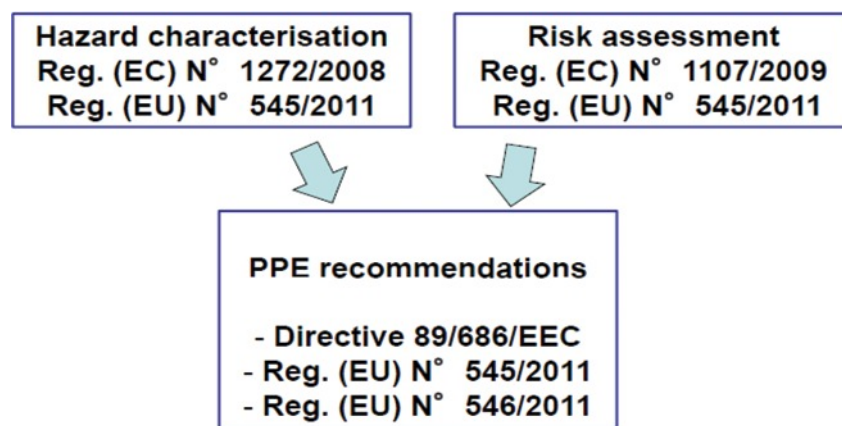


Figure 1. EU mandates for PPE recommendations.
Note: The PPE directive 89/686 is now a Regulation (EU) N° 2016/425.

Table 7: Default personal protective equipment (PPE) (modified from EFSA PPR Panel, 2010, based on Gerritsen-Ebben et al., 2007, van Hemmen, 2008)

Technical control/PPE item	Penetration factor (by which exposure in absence of protection should be multiplied)	Specific exposure value affected
Protective (chemical-resistant) gloves	Operators, liquids 10 %; operators, solids 5 %; workers, solids 10 %	Dermal exposure—hands only
Working clothing or uncertified cotton coverall	Operators 10 %	Dermal exposure—body only
Protective coverall (this is used instead of working clothing/uncertified cotton coverall)	Operators certified protective coverall 5 %	Dermal exposure—body only
Hood and visor (a)	Operators 5 %	Dermal exposure—head only
Hood	Operators 50 %	Dermal exposure—head only
RPE mask type	Filter type	
Half and full face masks	FFP1, P1 and similar	25 %
	FFP2, P2 and similar	10 %
		80 %
		80 %
		Inhalation exposure
		Dermal exposure—head only
		Inhalation exposure
		Dermal exposure—head only

(a): Hood and visor are considered as an alternative to the RPE. RPE, respiratory protective equipment.

Figure 2. EFSA table with highlighted default PPE.

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PPE in the European Food Safety Authority (EFSA) guidelines [7, 8].

At this time, the EU-certified chemical protective clothing showed that the standards failed to predict the performance of PPE against PPP. Additionally, farmer surveys conducted in France identified a lack of comfort and inadequate design as the main reasons for operators not wearing the chemical protective clothing. This is because the chemical protection clothing were mostly designed primarily for use in industrial settings and have not been adapted for use in a farm setting. Based on this feedback, French ministries supported an ongoing revision of performance standard ISO 27065 as an EN/ISO 27065. This PPE performance standard, based on laboratory and operator exposure study data, was developed specifically for protection against PPP products. The standard would also enable implementation of default protective clothing. It specifies requirements for three levels of protection (C1–C3), with C1 being certified PPE with performance similar to coveralls used for operator exposure studies.

- The UIPP presentation provided the French PPP industry perspective on PPE requirements. The presentation included a chronological overview of events and a review of existing standards as well as laboratory and field data. Assigned protection factors were proposed based on the information. In conclusion, the French industry recognized that the PPE used by farmers was not optimal and that the absence of clear communications hindered acceptance of PPE by farmers. Regular work clothing with clear specifications have been shown to provide protection, with additional protection provided by partial body PPE (such as aprons).

All three stakeholders identified a need for a harmonized EN standard for certification of protective clothing for pesticide operators and reentry workers. According to French authorities “[the] draft of revised ISO 27065 is scientifically-data driven, pragmatic and allows answers to major concerns on PPE for PPP.” Moreover, the French authorities anticipated the adoption of Level C1, protection equivalent to garments used in operator exposure studies, as a baseline protection to secure PPP placement on the market for users’ health and safety (notification 2015/084/F). Note: Although they concluded that the revised ISO/EN 27065 could fulfill the need, implementation of the new standard would be challenging, as it would require confirming that PPP and PPE regulation requirements are met. PPP stakeholders would have to work closely with PPE stakeholders to ensure certification and availability of protective clothing that met user acceptance. Since the penetration (pipette) and cumulative permeation test standards required for certification in accordance with ISO 27065 were not being used in the EU, building expertise in conducting the tests required for certification was also needed.

Coordination with international and EU entities

The Ministry of Agriculture played an important role in the coordination at the national level and with EU/international entities on the revision and implementation of EN/ISO 27065. The Ministries of Agriculture and Labour were engaged in the discussions in the CEN Working Group and French mirror committee. The Ministry of Agriculture was also engaged in the ISO 27065 discussion at the ISO meetings. The International Consortium for PPE for Pesticide Operators and Re-entry Workers, a neutral entity to support research and standards development, worked with the French stakeholders on the implementation of EN/ISO 27065. The Consortium, with research and methodology development study data for over two decades, supports initiatives related to PPE for pesticide operators and reentry workers. The first important step was validation of the ISO 22608 (pipette method) in France [9]. Fabrics remaining from previous interlaboratory study were tested in Brazil and France in 2016 with ISO 27065 test chemical. Results were compared with data for the US laboratory that had participated in the previous interlaboratory study. Despite the production of the test chemical approximately a decade apart, the pesticide penetration data for all three labs were similar. Studies and initiatives described below were then conducted to ensure compliance with EU PPP and PPE regulations [10, 11].

- **Verification of the PPE protection level for a specific PPP** (a requirement for PPP Regulation (EU) N° 1107/2009)—Effectiveness of the PPE protection for the PPP product being registered should be verified before it can be placed on the market. To comply with this requirement, a generic database was developed with 67 products from commonly used PPP formulation types. The generic database, published as a refereed paper, provides information on formulation types tested and an analysis that could be used for extrapolations for different formulations [12]. This serves as an effective and efficient process for verification of PPE protection against specific PPP.
- **Testing and certification by notified bodies/independent testing laboratories** (a requirement for PPE Directive 89/686/EEC that was replaced by Regulation (EU) 2016/425)—Notified bodies in EU participated in interlaboratory studies for ISO 22608 (pipette penetration test) and EN/ISO 19918 (permeation test). The PPE directive requirement is met; EU-notified bodies have been authorized to certify in accordance with EN/ISO 27065. Levels C1, C2, and C3 are the three performance levels for EN/ISO 27065:2017. Minimum requirements for Level C1 were based on garments used for operator exposure studies in EU. A brief description of the three levels is included in the Introduction of the published standard [6].
- **Obtainability and suitability of PPE** (a requirement for PPP Regulation (EU) N° 1107/2009)—As mentioned

in the ANSES presentation, survey conducted in France highlighted the need for comfortable protective clothing [2]. ANSES concluded that ISO 27065 Level C1 garments could be considered as the base requirement for most situations. The Consortium members worked together with fabric manufacturers to identify cotton and/or cotton/polyester fabrics sold in EU that met the fabric requirements. French PPP stakeholders then worked closely with PPE manufacturers to develop suitable garments for the French market. Farmer input, part of the R&D initiatives on style and design, resulted in certified garments with higher user acceptance. These garments are better adapted to working in farms and provide a balance between protection and comfort. A garment that met Level C1 requirements was also tested by the industry for exposure and comfort reentry studies in France. The International Consortium assisted with the selection of fabric for that study. Over the years, the availability of C1- and C2-certified garments has increased. Reusable garments that address the suitability requirements are now available in various colors, styles, and sizes for men and women. In 2019, German Federal Office for Consumer Protection and Food Safety (BVL) published a database of personal protective equipment suitable for pesticide protection that are in compliance with BVL requirements, including garments certified in accordance with EN/ISO 27065 [13]. The listing on the BVL website includes the garments produced in France; it is a source to access updated information about certified garments and other PPE. In 2020, information about the PPE database and information about operator and worker safety initiatives were presented by BVL at the 6th International Fresenius Conference “Worker, Operator, Bystander and Resident Exposure and Risk Assessment” in 2020 [14].

- **Avoid a PPE market leader**—To avoid a PPE market leader, in 2015, the Ministry of Agriculture, in coordination with the Ministry of Labour, held several open meetings to communicate the information about ISO 27065 to interested PPE manufacturers and notified bodies. The informational meeting was also attended by some PPP manufacturers. Based on the certified garments available, the issue of no PPE market leader seems to have been addressed.

In a nutshell: Since compliance with EU regulations is applicable to all countries, work done by the Consortium/French stakeholders on validation, generic database, and certification of garment can be adopted by other EU countries. As the demand for garments increases, the supply is expected to increase.

Labelling—PPP industry initiative

New PPE requirements published by the French Ministry of Agriculture provided specificity [15]. However, communicating these requirements on PPP labels would have made the long text difficult to read. Farmers have limited time to read labels when they have to decide for PPP application. Therefore, a table with pictograms and concise PPE requirements was identified as a power tool for communication and implementation. Decision was made by UIPP to redesign how the safety information would be presented on all PPP labels. For the PPE part, a table with pictograms was used to translate the textual official requirements into PPE information that is easier to understand (Fig. 3). Because reading and understanding labels is important for operator and worker safety, UIPP

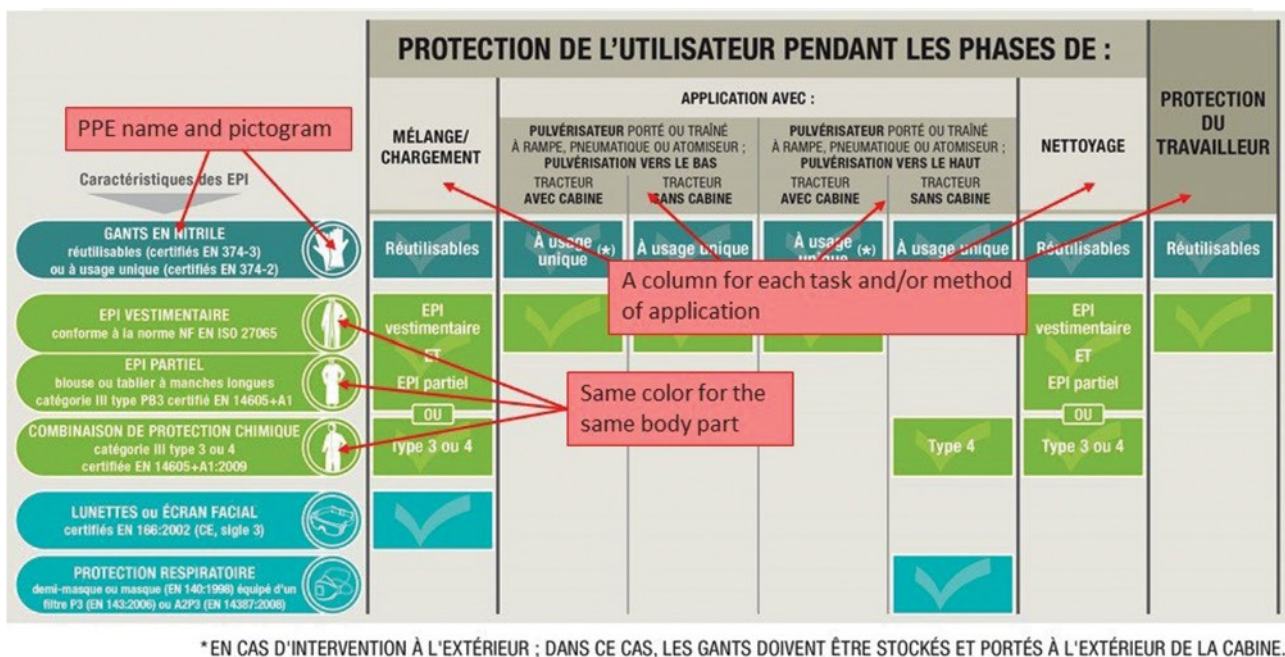


Figure 3. An example of a PPE table with pictograms according to the UIPP labeling guideline.

initiated this complete redesign with input from the farmers during the whole process. Small focus groups with farmers were used to understand farmers' needs, test the proposed options, and finally to fine-tune the labeling guidance document. Coordination was also required with the French competition & consumption administration, ANSES, farmer associations, distribution associations, agricultural medicine experts, and PPE manufacturers. The labeling harmonization project was completed rather quickly (within a year) of collective work [16]. The new visual format for safety information on PPE would enable the user to determine the PPE required, based on the task (mix and loading, spraying, etc.), the pesticide classification, the spraying equipment (closed cabin, backpack, etc.), and the crop height. The new design ensured that farmers could find "the same kind of information presented the same way" regardless of the brand of the pesticide they purchased. The guideline was published in 2017. The transition to the new French PPP labels, printed in accordance with the voluntary labeling guideline, was 40% in year 1, 90% in year 2, and 98% in year 3.

A small survey was conducted on pictogram preference for four sets of pictograms (including FAO and French sets) by the International Consortium. UIPP obtained feedback from French farmers on their preference. The survey indicated that, especially for garments and aprons, French farmers preferred the pictogram designed in France. These pictograms were more representative of the overall style garment and apron with sleeves that are commonly used in France. The farmers' distinct preference for pictograms developed in France supported UIPP's decision to use the French pictograms set in the tables.

In a nutshell: Labeling is crucial for communication—the labeling guideline developed by UIPP could be considered as an example by other PPP associations. Label change would require a major effort; however, it makes it easier to communicate clear, consistent safety information, not only on PPE.

Partnerships at the national level

Partnership for waste disposal

In parallel to the work on PPE and labeling, a project was initiated for the safe disposal of end use and contaminated PPE by **A**griculteurs, **D**istributeurs, **I**ndustriels, pour la **VALOR**isation (ADIVALOR). It is a nonprofit corporation established in 2001 by the French pesticide industry, gathering industry, distributors, and farmers associations to manage empty pesticide containers and expired pesticides. Since then, it has expanded to efficiently recover all agro-supply waste in accordance with framework agreements signed with the French environmental ministry. France is the only country to have a national organization dedicated to recovery of all the following agro-supply waste.

- Empty plastic, metal, cardboard/paper bags of plant protection products, fertilizers and seeds
- Expired pesticides
- Used agricultural films, big bags, strings, and nets
- Hygiene products waste, especially for dairy farming
- PPE waste
- Wine industry waste

The additional PPE waste disposal unit, named "ECO EPI", was created in 2016 and enables farmers to safely dispose of contaminated gloves, protective hoods, face shields & goggles, masks & respirators, tractor filters & cartridges, aprons & nonreusable chemical garments, and chemical protective boots [17]. Note: EPI is PPE in French and ECO EPI is the name of the service provided by ADIVALOR to manage PPE waste. In 2018, the disposal of reusable garments was also included.

Partnership for consistent messaging

In 2019, after the major steps (technical, normative, regulatory, labeling, and availability of PPE), it was time to explain all that is new to farmers. For the communication to be effective, it was co-constructed by several entities working together to send all a consistent message. The first step, as preventors, was to avoid falling into the trap of talking only about PPE. A broad risk prevention approach, of which PPE is just one component, was used to ensure operator and worker safety. The message emphasized that the following risk reduction measures be considered for worker and operator safety:

- **Good information:** Reading PPP and PPE labels is important. It includes information on conditions of use, storage, maintenance, and the precautions to be taken when handling them.
- **Occupational hygiene:** Priority to handwashing before and after intervention. Shower after the end of work. Mastery of dressing/undressing procedures. Do not smoke, drink, eat, or use the telephone when using plant protection products.
- **Work organization:** Prepare the intervention in advance. Dedicated, clean, and well-organized PPP storage and mix & loading zone. Strict segregation between pesticide work zones and contaminated equipment and the family/house.
- **Protective equipment:** This includes engineering controls such as closed cabin, closed transfer systems, and PPE. Garments, gloves, aprons, etc. are used for dermal protection; respirators/filtering facepieces/masks for respiratory protection; and face shields and goggles for eye and face protection.

The development and implementation of the safety messages focused on the health and safety of the farmers and their families. Past experiences in prevention communication have shown that, to be effective, the same message must be conveyed simultaneously by all the

individuals/entities interacting with the farmers. Although this concept seems intuitive, it was nevertheless the first time in France that all agricultural and prevention stakeholders joined forces to co-construct a common public/private prevention campaign. This initiative also received the support of the French Ministry of Agriculture, which provided a large part of the financing for the project.

A French prevention/safety campaign was launched in March 2020. It is a multistakeholder initiative by the Ministry of Agriculture, farmers associations, agriculture counselors' representatives, distribution associations, agricultural medical experts, ADIVALOR, PPP, and PPE industries. The tagline for the campaign is "The new generation of PPE reveals the professional you are." Information such as prevention messages, new regulations/requirements, norms, availability of a wide range of PPE, and disposal of contaminated PPE is available in French on a website [18]. Figure 4 is the key visual of the prevention campaign. In addition, the website includes "PPE, that's it!", a creative web series that addresses preconceived ideas about PPE and illustrates good practices. Eight episodes, plus a final episode as part of a national video competition for agricultural students, have been planned as part of this initiative. The episodes and all downloadable and printable technical tools (in French) are available under "Tools" on the website.

The prevention campaign will be covered by French agricultural print and web media for two years (2020 and 2021). Importantly, all communication channels from each of the campaign partners will also promote the preventive campaign. This collaboration is also an opportunity to build a "common language" to facilitate selection of appropriate

PPE by farmers. Hence, the PPE pictograms and tables are now used not only on PPP labels but also in distribution stores and in PPE manufacturers' catalogs to help farmers recognize and purchase the appropriate PPE. The goal is to inform most of the farmers and agricultural advisers of the new PPE rules and safety information by 2021. Future plans include expansion of the safety/prevention campaign in French West Indies territories. It will build on the EPIDOM project to develop PPE suitable for tropical climate and crops grown in France's overseas territories [19].

In a nutshell: Operator and worker safety requires coordination with all stakeholders working together to send a consistent message.

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Figure 4. Main visual of the PPE campaign.

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