The Belgian approach to fulfill art 8 of directive 2009/128: Development of a risk assessment procedure for pesticide application equipment

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Summary

The EU Directive 2009/128/EC on the sustainable use of pesticides requires that Member States (MS) shall ensure that all Pesticide Application Equipment (PAE) in professional use shall be subject to inspection at regular intervals. Article 8.3 of the Directive allows the MS to derogate from the mandatory inspection at regular intervals or to apply different timetables and inspection intervals for certain types of PAE based on a Risk Assessment (RA) for human health, food safety and environment and an assessment of the scale of use.
In Belgium, a risk assessment protocol is being developed within the framework of the SIRA-APESTICON project. It will be applied on the equipment in use and will offer guidelines about the necessity to carry out an inspection of every PAE in use. Risk will be evaluated for the health of the operator, for the health of the consumer and for the environment. The protocol is supported by a literature review and by experts' opinion. It is based, among others, on technical parameters subject to inspections and on scale of use of the PAE types. Description of the risk assessment method and first results will be presented at the SPISE workshop.

Keywords: pesticide application equipment, inspection, risk assessment, protocol, inventory, exemption, intervals, scale of use.

Introduction

The EU Directive 2009/128/EC on the sustainable use of pesticides requires that Member States (MS) shall ensure that all Pesticide Application Equipment (PAE) in professional use shall be subject to inspection at regular intervals (Article 8.1 and 8.2).

The inspection of the material requested by the Directive concerns all types of PAE for all types of pesticides formulations (liquid, solid, gas, etc.) without any distinction. However, Article 8.3 of the Directive allows the Member States to derogate from the mandatory inspection at regular intervals or to apply different timetables and inspection intervals for certain types of PAE based on a Risk Assessment (RA) for human health and environment and an assessment of Scale of Use. MS have to provide a list of PAE subject to exemption. The Risk Assessment process should demonstrate the usefulness of the inspection to significantly decrease the risk of the use of the PAE. The SPISE Technical Working Group 2 (Spise TWG 2) developed a first protocol based on the Zurich method (Wegener, 2015). For the moment no standardized protocol of Risk Assessment is available in what concerns the risk decrease after PAE technical inspection for PAE types potentially concerned by the derogation.

A preliminary EU enquiry has been realized with the representatives of the sprayer inspection in all the MS of the SPISE Community. With 19 responses, the results from the enquiry show a large variation in the inspection situation of the different PAE types over

the different MS. The main risks and the possible impact of PAE technical defects estimated by the experts also differ greatly. Furthermore, the results indicate that by the end of 2016 practically no MS will have fully implemented the requirements of the EU Directive 2009/128/EC concerning the inspection of PAE.

In Belgium, a project called SIRA-APESTICON, started in 2015, aims at developing a scientific solution to these issues. Among others, objectives are to develop and validate a RA protocol and apply the RA protocol on the PAE in use in Belgium. Results should help to provide a list of PAE subject to exemption based on Risk Assessment (human health and environment).

Material and methods

The RA protocol was developed on basis of literature review and expert opinions. Most RA published in the literature were elaborated in order to fit with case studies (Bach M. R.-G., 2005; Choi H. M.-K.-H., 2013; Reus J. L., 2002; Roussel O. C., 2000). So, for this work, the protocol has been adapted thanks to pragmatism, experts' judgment, and by taking into account available data.

First, with literature content, concept of RA has been defined. Risk factors, context and limitations of the RA were subject of discussion and debates before to be determined. All data available were gathered. All parts of the RA (list of defects, list of harm situation, calculation of occurrences, calculation of scale of use, etc.) were progressively readapted to the context and the limitations during the method development.

Results and discussion

Inventories: PAE types, inspection protocols and test equipment protocols

Types of PAE used in Belgium have been inventoried based on a review of the literature, an internet search and a national enquiry with 366 responses. In total, 29 PAE types have been defined and described[2]:

Field crop sprayers and similar; Sprayers for bush and tree crops; Sprayers for vineyards; Fixed and semi mobile sprayers; Knapsack sprayers; Spray train; Lances and spray guns; Handheld sprayers; Motorized portable mistblowers; Selective herbicide sprayers; Foggers; Rotary atomizers or CDA (Controlled Droplet Application) sprayers; Cold atomizers; Soil disinfection equipment; Plot sprayers; Irrigating systems where pesticides are dosed to the plants by drippers; Irrigating systems where pesticides are dosed to the plants by the sprinkler system; Weed wipers; Handheld weed wipers; Potato seed duster; Seed treatment machinery; Granule spreaders; Seeders (not considered as PAE by European Commission); Sulphur evaporator; Tree trunk implantation/injection; Tree painting; Post harvest treatment system; Post harvest ripening systems using ethylene; Aerial spraying.

Concept of Risk assessment

The first step to develop a RA protocol is to define what the risk is. RA's methodologies generally are so adapted to case studies that there are as many protocols as case studies. Nevertheless, a lot of authors agree on the main concept: Risk is a combination of a

2. More information: Inventory of pesticide application equipment used in Belgium – a practical approach (Nuyttens, Zwertvaegher, Declercq, Mostade, Stas, Defays, Dekeyser, Huyghebaert). Session 2, SPISE meeting 2016.

hazard, an exposure and a probability of occurrence. For example, FAO (2015), the IPCS (2010) and other authors (Cox J. , 2009; Johansen I. , 2010; Touche D. a., 2012) and in the ISO 31000 (2009) provides principles and generic guidelines for a lot of Risk managements and assessment. In the context of this work, several methods of RA evaluation have been raised from publications as interesting sources of information. They include PRIBEL index (Vergucht S. C., 2006), Fuzzy Expert System (Roussel O. C., 2000; van der Werf H. Z., 1998; Zhang Y. Z., 2013), Zurich methodology (Ganzelmeier H. , 2012; Wegener J. , 2013; Wegener J. , 2015), the classification of Parkin et al. (Parkin, 1994), Risk index of Spugnoli et al. (Spugnoli, 1998), and the EOS tool (Doruchowski, 2014). Some specific points have been retained from the different methods for de development of the RA protocol within this study. For instance, the matrix concept of the Zurich methodology is useful to associate the scale of use and hazard exposure; experts' opinion from the fuzzy logic application is appropriate to define the severity of harm and the human behavior part of risk…

A risk depends of the severity of harm resulting from the hazard on the exposed subject, and on the probability of occurrence of that harm. Then to develop the risk assessment, some questions have been precisely answered: What is/are the hazard situation(s); who/what is concerned by the hazard situation(s) and which harms have to be taken into consideration.

In the framework of the project, the risk related to the use of a PAE is based on the technical dysfunctions or technical defects of this PAE, occurring during the pesticides application. Thereby, for every type of PAE, risks to human health and to environment are evaluated. Risk should be evaluated as well at the scale of one machine as at national (Belgian) scale. In both situations, it has to be evaluated "before inspection" and "after inspection". Between the "before" and the "after inspection", a diminution of risk should be observed. This diminution could justify the necessity to inspection. The whole process evaluation of the risk "before" and "after inspection" constitutes the complete RA of a given PAE type.

Hazard definition

In this project, it is considered that the hazard is only related to the technical dysfunctions, or defects of the PAE. It is limited to the use of the PAE: preparation of the equipment, pesticide application and cleaning of the equipment. One assumes that applied pesticide toxicity is an invariable factor. Indeed, a given PAE can apply different pesticdes (active ingredients) presenting each different levels of hazard. Therefore, it is nearly impossible to determine the hazard presented by the use of a PAE taking into account the pesticides/active ingredients and their related toxicity. Moreover, because of their independence from the technical aspects, the local external conditions (as wheater, cultural practices, human behavior...) are considered also as invariable. Therefore, one assumed that PAE are used following the Good Agricultural Practices.

All defects/dysfunctions of a single machine allow calculating the technical risk for this entire and single machine by the way of the severity of harm.

Severity of harm

In theory, harm is the consequence of the hazard on the exposed subject. In the context of this project, it is the consequence of technical defects on human health and environment: over-dosage, under-dosage, or injuries induced by the use of PAE during the pesticide applications. Severities of harm need to be evaluated to estimate the risk. In order to do it,

a questionnaire has been submitted to experts' judgment. Severities of harm are evaluated for every inspected parameter, in the situation of defect "before inspection" and in the situation of repaired defect "after inspection". The severity is defined as a relative value between 0 and 10 (10 being the most severe harm). It should be notice that it is absolutely possible that the severity of harm of a defect after inspection (reparation) can be different than 0. Even after reparation, an inspected parameter can present a residual hazard.

Nature and severity of harm are different regarding the exposed subject (operator, consumer and environment). For this reason, there are different evaluations for each of these three subjects.

Dysfunctions/defects table

In practice, the defects correspond to the parameters that are inspected. Since the consequences of the defects are the basis of the hazard definition, then a list of the parameters, consequences and extent of consequences has been elaborated. Inspected parameters are sometimes described with tolerance levels. Consequences are descriptions of the harm on environment and on human health. Extents are evaluations of the surface impacted. They can be one isolated place, a strip or a global contamination (e.g.: the whole parcel treated). Parameter, consequence and extent descriptions help to determine the severity of harm from a defect.

Occurrence

In the context of PAE inspection, probabilities are the occurrences of technical defects. They are defined for each inspected parameter due to the available data from the Belgian sprayer inspections (Field crop sprayers, Orchards, Fixed and semi mobile sprayers). They are calculated from last complete cycle of inspection (the three years 2011, 2012 and 2013) and are expressed in percentage. Occurrence is combined with the severity of harm of each defect in order to calculate a risk, at the level of a single machine.

Scale of use

Scale of use should reflect the amount of utilization of a specific type of PAE at Belgian scale. It would be estimated on basis of amount of pesticides applied by each group of PAE (Vergucht et al. (2006) did it a little differently for the "PRIBEL index") and on basis of the number of PAE (as done in the Zurich methodology (Wegener, 2015)).

In this work, the scale of use is based on 3 factors:

- Amount of pesticides sold in Belgium each year. National data are available. In the same way as for occurrences, the scale of use is calculated on the last complete inspection cycle.
- Repartition of active substances potentially used among PAE types. This repartition was realized by experts specialized in pesticides and in PAE inspection.
- Frequency of use of each PAE type. A national enquiry allowed evaluating the number and frequencies of use of the PAE types in Belgium. It was conducted with professionals and Flemish farmers. 42 professional and more than 300 farmers answered.

Thereby, the number of machines in use in Belgium and the amount of pesticide potentially applied by this type of PAE on Belgian territory are taken into account in the risk evaluation. Results of scale of use are expressed by relative values.

Subjects exposed

The human health and the environment are exposed to hazard situations. In this work, the operator, the consumer and the environment are considered as exposed subjects. All compartments of the environment (soil, water, air, wildlife...) were gathered together because expert opinions about severities of harm don't vary enough between these compartments. On the other hand, the operator and the consumer are distinguished. Indeed, the ways of exposure (then the severity of harm) and the scales of use are very different. The bystander will not be part of the RA calculation. Indeed, inspection does not look at equipment components that specifically concern risk to bystander. Moreover, variations of risk due to external conditions like weather or operator behavior are too big compared to the inspection impact on the bystander.

The three subjects exposed are taken into account in the whole risk assessment from the evaluation of severity of harm.

Partition technical part of risk vs human part of risk

This project focus on techical sources of hazard. Indeed, pesticide application become more dangerous with occurrence of PAE technical defects. However, another source can cause an imperfection on the application: human mistake (or human behavior). Therefore one considered that total risk of suboptimal application is divided into a technical part and a human part.

In order to determine the size of each part, an enquiry was lounched with experts. Human and technical parts were determined for every PAE type. Results are expressed by a percentage on the total risk relative to the suboptimal pesticide application.

Risk assessment calculation

Risk is calculated by the way of some steps (Figure 1). First, severity of harm of a defect is combined with the probability of occurrence of the defect. Second, results from all defects are added to evaluate a global risk of one single and entire machine. Third, the risk related to one machine is extrapolated at the concerned PAE type in Belgian territory thanks to a national scale of use. Finally, in case of relevance, the risk relative to technical part of the equipment can be compared to a global risk of pesticide application, also concerned by human behavior. All calculations are made once with data of "before inspection" and once with data of "after inspection". Thereby, risk related to pesticide application "before inspection" can be compared to risk related to pesticide application "after inspection" and a risk reduction can be observed.

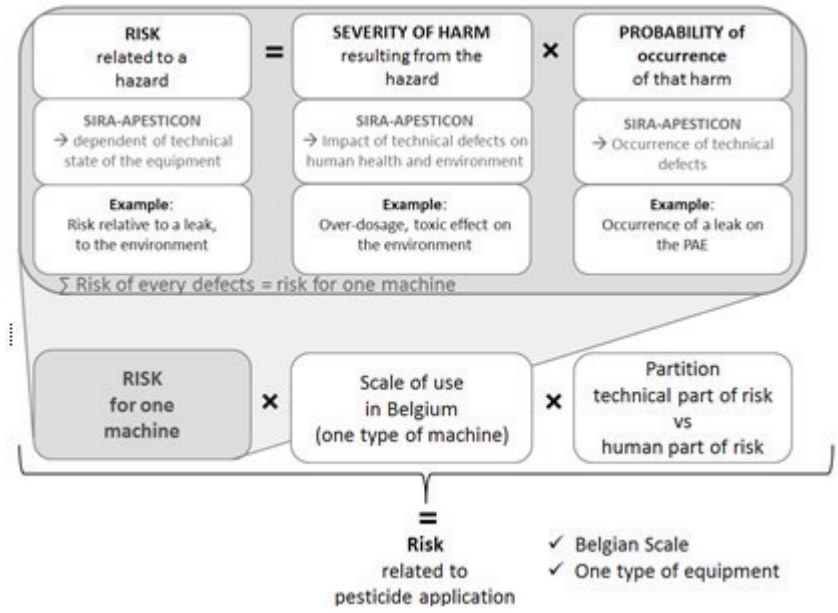

Fig.1 *Scheme of risk calculation in the framework of SIRA-APESTICON project*

Conclusion

The method focuses on PAE types that potentially are concerned by derogation from the EU Directive 2009/128/EC requirements. Flexible, it could be improved by the future increasing knowledge about these PAE types, not yet inspected and not much studied until now. To our knowledge, this method is the first RA method that considers a maximum of available parameters involved, in the context of PAE technical inspection. Occurrences are representatives of the reality of inspection, as they are defined with data of the country studied. Judgment by experts from different disciplines offers also a more complete analysis of the risk.

According to the Directive requirements, some PAE types will soon be inspected for the first time. For them and for PAE types already inspected, new inspection protocols adapted to the risk are needed. Results of risk variation between all defects, results of the scales of use, literature and expert knowledge should help to elaborate these future protocols.

The complete RA including the scale of use study can serve as decision support tool to apply Article 8.3 of the Directive 2009/128/EC. In particular, the risk reduction from "before" to "after" inspection should help in the decision about mandatory inspection and about inspection intervals.

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