An approach to fulfill art 8 of directive 2009/128: procedure of risk assessment 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 order to fulfill Article 8.3, a risk assessment protocol was developed in Belgium within the framework of the SIRA-APESTICON project. Risk is now evaluated for the human health and the environment on all Belgian equipment. It will offer guidelines about the necessity to carry out an inspection of every PAE in use. The protocol is based on technical parameters subject to inspections, their occurrences and severities, but also on national scale of use of the PAE types. Results are expressed at different scale levels: the defect, the machine and the country.

Keywords: pesticide application equipment, inspection, risk assessment, guidelines, exemption.

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. The RA 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. The Belgian method from the SIRA-APESTICON project defines the risk by a combination of two factors: 1. the severities of harm on exposed subjects and 2. the occurrences of hazard. In the context of this work, harm is the consequence of technical defects: over-dosage, under-dosage, or injuries induced by the use of PAE during the pesticide applications. Occurrences of defects are defined by PAE technical inspection. Risk is calculated for the health of the operator, the health of the consumer and for the environment. This paper shows an overview of the results for Belgium.

Materials and methods

A RA protocol was developed on basis of literature review and expert opinions. According to literature, risk is the result of the combination of occurrence and severity of harm: In this case, occurrence is

relative to PAE technical defect. They were extracted from the data of the Belgian inspection services. Harms result of the hazard and of the way of exposure. It can be over- or under-dosages or injuries induced by the use of PAE. Values of severities of harm were defined based on an international enquiry submitted in particular to European experts from the SPISE community.

Risk is calculated using two ways to combine the severity of harm and the occurrence: "Defects only" or "Defects + residual risk". Formulations are given in Table 1. The "residual risk" is the risk induced by potential undetectable (at the inspection) small deficiencies combined with the risk inherent to the use of PAE even without any defect. Three different scales are considered: 1. the defect individually, 2. the entire machine (sum of defect's risks) and 3. the country or for all machines of a given PAE type on the national territory (factor of scale of use) (Figure 13). These scales of use were based on a combination of the frequencies of use of the different PAE types and the weight (Kg) of pesticide potentially applied. Sales of active substances in Belgium (Kg) were selected from the Eurostat database. An estimation of the human part of risk (behaviour of the operator) can be added to the technical risk to obtain a total risk of pesticide application (Figure 13). Therefore, the partition between the technical part and the human behaviour part of risk was determined by a European enquiry. Each risk calculation is performed "before" and "after inspection". In one hand, "Before inspection" illustrates the presence of a defect, above tolerance level of inspection and without defect correction. In another hand, "After inspection" illustrates a defect repaired regarding the inspection tolerance level or an absence of defect. Results allow evaluating the potential risk reduction induced by the inspection.

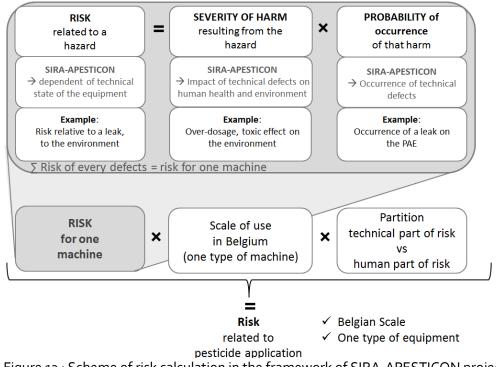


Figure 13 : Scheme of risk calculation in the framework of SIRA-APESTICON project

Table 1: Calculations used to apply the RA in Belgium. Two methods: Defects only and Defects+residual risk. Scales: defect, machine, Belgium, Belgium+human part. Two situations: before technical inspection and after technical inspection

Method / scale	Before technical inspection	After technical inspection
"Defects only" /	occurrence* severity _{before}	occurrence* severity _{after}
scale of the defect	= Risk _{defect.before}	= Risk _{defect.after}
"Defects only" /	∑ Risk _{defect.before}	$\sum Risk_{defect.after}$
scale of the machine	= Risk _{machine.before}	= Risk _{machine.after}
"Defects + residual	(<i>SRisk_{defect+resi.before}</i>)*scale_of_use	(∑ Risk _{defect+resi.after})*scale_of_use
risk" / scale of	= Risk _{Belgium.before}	= Risk _{Belgium.after}
Belgium		
"Defects + residual	(Risk _{defect+resi.before})*scale_of_use*partitio	(<i>Risk_{defect+resi.after}</i>)*scale_of_use*partitio
risk" / scale of	n_human_vs_technical_part	n_human_vs_technical_part
Belgium, + human	= Risk _{Belgium+human.before}	$= Risk_{Belgium+human.after}$
part	-	-

Results and discussions

Defects without residual risk, scale of the defect

Risk values are very useful to elaborate new inspection protocols at the scale of the defect. Defined before and after inspection, they inform about the risk reduction of every individual parameter by the way of inspection. Differences in risk values are observed between defects (then between parameters). That means that some defects give harms more severe than others and/or that some defects occur more often than other. For a given defect, the risk varies from a PAE type to another with the variation of occurrences between PAE types. The defects for which the risk before inspection is close to zero could be exempted from inspection. The defects that present the biggest risks should be inspected. The decision about inspection of a defect can also be influenced by the risk reduction induced by inspection. For example, the risk reductions induced by the replacement of an absent tank filling strainer are among the most important (-67% for the operator).

Defects without residual risk, scale of the machine

The method at the scale of the machine offers results illustrating direct effects of inspection. First, analysis at the machine's scale could be useful to evaluate the risk for the operator who is exposed to only one machine at a time. An illustration is given for knapsack sprayers in Figure 14. It can be observed that of risk values vary between subjects at risk. Relative risk reduction are calculated on the risk "after inspection" as a percentage of the risk value "before inspection". The type of defects listed influences the final risk value. When this RA method is applied to the case of Belgium, a clear effect of inspection is observed: risk reduction is about 63% (Figure 14).

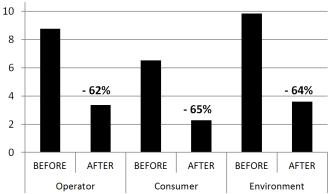


Figure 14: Results of risk calculation in absolute values for Knapsack sprayers. Risks for the operator, for the consumer and for the environment. Scale of the machine, method "defects only". BEFORE=before inspection; AFTER=after inspection. Risk reduction between BEFORE and AFTER are indicated in percentage.

Defects with residual risk, scale of Belgium

The analysis at Belgian scale has the advantage of obtaining a global view on the total technical risk for one PAE type or to compare different PAE types (Figure 3). The differences of results (risk values) between PAE types are mainly due to the scales of use. Indeed, they are specific to each PAE type. In Belgium the field crop sprayers have the biggest scale of use with 78% of the total (all types of sprayers combined) scale of use. The orchard and knapsack sprayers have scales of use corresponding respectively to 5% and 7% of the total. Percentages of risk reductions with the method ("Defect with residual risk") are smaller (~10%) than with the method "Defects without residual risk" (~65%). This is explained by the fact that "residual risks" is equally distributed between "before" and "after inspection" and take a big part in the total risk. Absolute values of risk are above 10.000 (results of calculation haven't standard unit). National scale is interesting concerning the risk for the consumer and the risk for the environment because they are targeted by pollution related to broad crop surfaces.

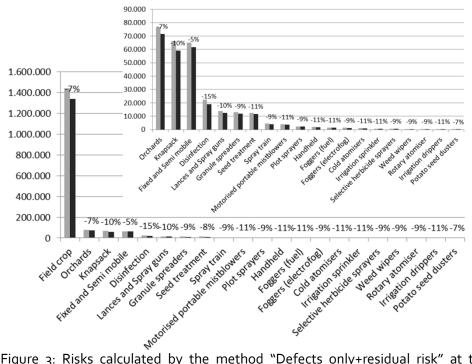


Figure 3: Risks calculated by the method "Defects only+residual risk" at the scale of Belgium for different PAE types (technical risk). Risk values are average of risk for the operator, risk of the consumer and risk for the environment. Grey: risk values before technical inspection; Black: risk values after technical inspection; Values in percentage: risk reductions between the risk before and risk after technical inspection

Defects with residual risk, scale of Belgium plus the human part of risk

This last method of risk calculation can be used to compare pesticide application of the different PAE types. That is the most complete, including defects and residual technical risks, scale of use and human behaviour part of risk. As previously, differences in risk values between PAE types are mainly due to the scale of use. However, risks related to pesticide application are, for some PAE types as knapsack sprayers, more dependent of user's behaviour. For other PAE types, as spray train or irrigating systems, the technical part of risk is more dominating. The percentage of risk reduction is very low (5%) because the residual risk and the human part of risk are added equally to the risks value before and after inspection. The partition between human and technical part of risk could justify the inspection in order to significantly reduce the total risk.

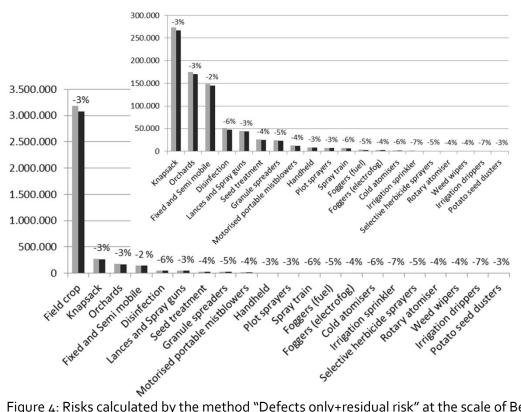


Figure 4: Risks calculated by the method "Defects only+residual risk" at the scale of Belgium for different PAE types and added to the human part of risk (technical risk + human risk). Risk values are average of risk for the operator, risk of the consumer and risk for the environment. Grey: risk values before technical inspection; Black: risk values after technical inspection; Values in percentage: risk reductions between the risk before and risk after technical inspection

Conclusion

The risk assessment method developed in Belgium is successfully applied on the case of Belgium. It illustrates the effects of inspection of each PAE type and the variation of scales of uses between all of them. Risk reductions give indication on efficiencies of inspection for all PAE types. It distinguished different targets (operator, consumer, and environment) and the results can be obtained at different scales of calculation (the technical defect, the machine or the scale of the country). Risk reductions expressed in percentage are similar trough all PAE types but absolute values of reduction are proportional to absolute value of risks that vary between PAE types. These last are mainly due to the complexity of the PAE and its inspection protocol when analysis is made at the scale of the machine. On the other hand, differences between absolute values are mainly due to scale of use when analysis is made at the scale of Belgium. Risk values and risk reduction values at every step of the risk assessment are strong theoretical basis to support decision making. For example, for the method "Defects without residual risk, scale of the machine," a maximum level of risk could be defined for the operator safety

and another maximum level of risk can be defined for exclusion of inspection. Regarding risk results, PAE types already inspected in Belgium are those for that inspections are the most useful (field crop, orchard, fixed and semi mobile, disinfection equipment). Inspections of the others have to be discussed with the results of this work as a support.

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