Session 2: Member States may apply different timetables and inspection intervals with exceptions following a risk assessment and exempt handheld pesticide application equipment or knapsack sprayers

Introduction paper

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DOI 10.5073/jka.2012.439.009

Summary

Article 8/3 of the European Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides allows the Member States to derogate from the mandatory inspection at regular intervals for certain types of pesticide application equipment (PAE).

The derogation is based on a risk assessment for human health and environment and an assessment of scale of use. The FWD does not give any clear instruction and/or indication on these assessments. Nevertheless the MS will have to carry out these ones if they want to introduce derogation and without having a clear protocol, an uneven situation may occur within the MS. Risk assessments should be clarified.

The purpose of this paper is to introduce the notion of risk assessment based on a literature review and to clarify this assessment in regard with the Directive 2009/128/EC.

Key words: sprayer inspection, derogation, risk assessment

Introduction

Article 8/1 and 8/2 establish the main scope of the mandatory inspection in EU. This scope covers all types of Pesticides Application Equipment (PAE). Considering the MS particularities and the unavailability of standards or valuable protocols, the Article 8/3, by introduction derogation possibilities, makes lighter the implementation of the FWD.

Article 8/3 of European Directive 2009/128/EC on the sustainable use of pesticides allows the Member States to derogate from the mandatory inspection at regular intervals of certain types of pesticides application equipment (PAE) based on a risk assessment for human health and environment and an assessment of scale of use.

During the SPISE III (2009), the analysis of article 8/3 of the Directive allowed us to define a classification scheme of the PAE according to their potential of derogation from the mandatory inspection and to conclude on the necessity to go deeper into the risk assessment process. Three years later, we have to notice that we didn't progress so much in that subject. The major problem is that the COM didn't give clear indication/instruction on this risk assessment and that the priority in many Member States is at least to start the inspection of boom and orchard sprayers as soon as possible.

This paper makes the points on the risk assessment and its implication into the sprayer inspection and the fulfilling of the requirement of the Directive 2009/128/EC

Definition of risk related to a hazard and the risk assessment

Following the ISO 12100, the risk assessment is an overall process comprising a risk analysis and a risk evaluation. Although, this definition remains relatively hazy and asks for more explanation, it is interesting to note that the risk assessment isn't limited to an estimation of the risk but includes other concepts as the risk evaluation and the risk analysis.

Before to go further in the analysis of the risk assessment, we have to remind the definition of the risk itself. The risk is the combination of the probability of occurrence of harm and the severity of that harm (ISO 12100).



Fig. 1. Definition of the risk.

The risk associated with a particular hazardous situation depends on the severity of the harm resulting from the hazard and the probability of occurrence of that harm.

Coming back to the Directive 2009/128/EC, we have to understand the term "harm" in the broad sense including "harm" for the Human Health and the Environment. The risk related to the use of a non-in-spected PAE will be estimated for the Human Health and the Environment.

The severity of the harm can be estimated quite easily by taking into account the severity and the extent of the damage. The probability of occurrence of harm is a function of three notions:

- The exposure of the studied target to the hazard: the probability of the occurrence of "harm" could be influenced by factors as the need for access to the hazard zone, time spent in the hazard zone is also an important factor, frequency of access...
- The occurrence of the hazardous event: statistical data and accident history would be helpful to estimate the occurrence of a hazardous event.
- Possibility of avoiding or limiting harm: with this notion we are already much more in the action and the minimizing of the risk. Factors as training of the operator or supplying of information, indication, warning signs...could be taken into account.

Risk assessment as an overall process

Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated, in our case, to the use of a non-inspected PAE (ISO 12100).

To implement risk assessment the designer shall take the following actions (see Fig. 2):

a) Determine the limits of the machinery (PAE): allows to precise the limits where risk assessment will be apply and to avoid any confusion of scope (e.g. : the risk assessment of the use of a non-in-spected PAE is not the risk assessment of the pesticides, or of the user's skill...).

b) Identify of the hazards within the defined limits of the machinery: this essential step consists into the systematic identification of reasonably foreseeable hazards, hazardous situations and/or hazardous events within the defined limits of the machinery.

c) Estimate the risk for each identified hazard and hazardous situation, as define before (see Fig. 1), combining the severity of the harm related to the hazard and its probability of occurrence.

These three first steps constitute the risk analysis which is the first phase of the risk assessment.

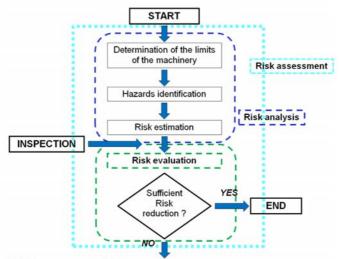


Fig. 2. Risk assessment as an overall process.

After the risk analysis, the overall process of the risk assessment needs two other steps which are determining and indissociable: an action aiming at reducing the risk and the risk evaluation.

The action, in our case, is simply the inspection following the standardized protocol. The risk evaluation consists into a judgment, on the basis of the risk analysis, of whether the risk reduction objectives have been achieved (ISO 12100). A positive risk reduction means that the action, the inspection in our case, is sufficient to reduce the risk under an acceptable and reasonable level.

On the other hand, a negative risk reduction means that the undergone action is useless and cannot reduce the risk. In that case, another more appropriate solution would be developed and applied. Then the risk assessment is followed by a risk reduction process which follows its own protocol and procedure. Iteration of this process (risk assessment + risk reduction process) can be necessary to eliminate hazards as far as practicable and to adequately reduce risks by the implementation of adequate measures.

The described process can be illustrated by the following examples related to the sprayer inspection: a) **Large leakages on orchard sprayers**: leakage is considered in the limits of the machinery. The hazard for the Environment could be the pollution of the surface water (aquatic organism). In Belgium, (Declercq J. & al, 2012) leakages on orchard sprayers in use considered as large (> 30 ml/min) have an occurrence of 9 % of the inspected machines. The risk is then quite high resulting of the combination of a non inconsiderable severity of "harm" for the aquatic organisms (depending on the pesticides, just few droplets of mixture could destroyed these organisms) and a high probability of occurrence considering the percentage of sprayers presenting large leakages. During the inspection, these leakages are determined and afterwards repaired. The risk to pollute the surface water is obviously reduced. We may conclude that the inspection is useful to reduce the risk for the Environment related to the large leakages on orchard sprayers in use.

b) **Overdosage of handheld spray lance/gun**: overdosage is considered in the limits of the machinery. The hazard for the Human Health could be an exceeding of the MRL. These sprayer types are quite common in glasshouses for fresh vegetables (tomato, pepper, salad, strawberry...) and ornamental crops production. One estimate in Flanders shows that more than 2800 glasshouses (70.5 % of total) are sprayed by using a gun (GOOSSENS E. and SONCK., 2006). Moreover a great quantity of active ingredient (a.i.) is used in glasshouses. Following national statistics established in 1997, the growers used on average 27 kg a.i./ha for strawberry, 45 kg a.i./ha for flowers, from 20 to 260 kg a.i./ha for pot plant... which could cause a potentially high risk of pesticides residue on food plants. On the other hand, trials (LANGENAKENS J. & al, 2002) showed that the applicator using a spray lance/gun has a greater influence on the spray quality than the equipment itself. Therefore the inspection of this type of sprayer cannot reduce the risk related to excessive residue on plant. Training the user seems to be the best tools to reduce that risk.

Discussion

The risk assessment is an overall process and should be associated to a risk reduction process in order to reduce adequately the risk related to the considered hazard or hazard situation. Usually for that purpose, experts and designers develop several combined solutions.

Following the Directive 2009/128/EC, the first solution to reduce all risks related to the sprayers in use is the inspection. Secondly, based on a risk assessment, Member States may derogate to the inspection of certain type of PAE and apply other timetable and inspection intervals or may exempt from the inspection handheld pesticide application equipment or knapsack sprayers providing the operator is trained.

To base the derogation on a risk assessment is a good process. That will allow determining the limits of the inspection as a solution to reduce the risks related to the sprayers in use. But, to give as replacement solution the postponement of the inspection or/and the lengthening of the inspection interval is a non-sense, because the risks related to the sprayers in use by inspection normally only are very limited reduced. Additionally, an inspection of a knapsack sprayer in practical use is estimated to cost almost the price of a new sprayer. However, training, self check and calibration are more important tools in order to minimize the level of risk (safety, environment and overdosing)..

The two examples of risk assessment given previously show that the work waiting the Member States is huge. The process would be applied for the PAE under derogation taken into consideration all hazard situations for Human Health and Environment. Sub-targets would be also taken into consideration (e.g. : under Human Health, we could consider the operator, the inspector and the citizen). All these factors will multiply the number of risk assessment that will be realized.

The risk assessment process needs to be fed by statistics, data and expert's views. To find these inputs and to ensure their representativeness is also a great challenge. Fuzzy expert system could help and would be explored. It allows objectivizing expert's views when a lack of raw data is present. This system has already used successfully to define indicator of pesticide environmental impact (Roussel & al, Hayo & al).

Conclusion

Following the ISO 12100, the risk assessment is an overall process comprising a risk analysis and a risk evaluation. The risk analysis combines the specification of the limits of the machine, the hazard identification and the risk estimation. The risk evaluation follows a certain action (e.g.: the inspection) and consists into a judgment, on the basis of the risk analysis, of whether the risk reduction objectives have been achieved.

Article 8/3 of European Directive 2009/128/EC on the sustainable use of pesticides allows the Member States to derogate from the mandatory inspection at regular intervals of certain types of pesticides application equipment (PAE) based on a risk assessment for human health and environment and an assessment of scale of use. Unfortunately, the COM didn't give clear indication/instruction on this risk assessment. Moreover, analyzing the article 8/3 of the Directive, it seems that the COM limited the risk assessment to only the risk evaluation which is the first part of the overall process.

Regarding the deadlines of the Directive 2009/128/EC implementation by the Member States (2016), there is a real need to go forward in the subject of the derogation and the related risk assessment. A common process would be developed while at the end the result would be different from Member State to another considering the local use.

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