

Session 2: Common procedures for Pesticide Application Equipment (PAE) risk assessment and for the evaluation of environmental benefit of the inspection

Advise for risk assessment concerning the inspection of pesticide application equipment in use according to article 8 (3) of Directive 2009/128/EC

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Introduction

Article 8 (3) of Directive 2009/128/EC (Sustainable Use Directive) demands a Risk Assessment (RA) for human health and the environment including an assessment of the Scale of Use (SU) of the equipment in order to apply different time tables and inspection intervals in selected cases for the inspection of pesticide application equipment (PAE) in use. These exemptions in regard to different time tables and inspection intervals are concerning PAE

- not used for spraying pesticides,
- which are handheld application equipment,
- knapsack sprayers,
- or additional PAE that represent a very low scale of use.

Furthermore, Directive allows derogations from the mandatory inspection for knapsack or handheld sprayers, also based on a Risk Assessment for human health and environment and an assessment of Scale of Use.

This considered, we believe it is necessary to provide a **SPISE advice** on how to make such a Risk Assessment and an assessment of the Scale of Use in a practical and harmonized way on European level.

Considering literature review, most publication about risk assessment methods agree on the general concept: *Risk depends on the exposure of a "target" to a hazard (then to an impact) and on the exposure frequency (Figure 1).*

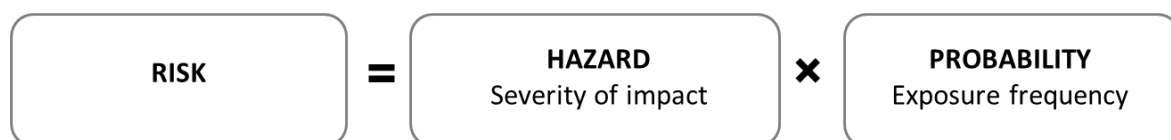


Figure 1: Parts of the Risk related to a hazard

Therefore to develop a RA process, some questions have to be precisely answered: (i) What is/are the hazard situation(s); (ii) who/what is concerned by the hazard situation(s); (iii) which impacts have to be taken into consideration; (iv) what is the exposure frequency of the subject at risk.

In the context of the PAE inspection, the risk related to the use of a PAE is clearly based on the technical dysfunctions or technical defects of this PAE, occurring during the pesticide application.

Even though the major part of the risk linked to the use of PAE is due to the pesticides itself; it is not practically possible to take into account the intrinsic toxicity of the applied pesticides. Indeed, a given PAE can apply different pesticides (active ingredients) presenting each different levels of toxicity. For that reason, the applied pesticide toxicity will be considered as an invariable factor.

In the framework of the Directive 2009/128/EC, the targets considered at risk are clearly the human health and the environment.

Impacts on human health or environment depend on the hazard source and of the way of exposure. In this case, hazards mostly are from wear or accident. They can be over- or under dosages or injuries induced by the use of PAE presenting technical defects.

The exposure is linked to the occurrence of a technical dysfunction. Depending on the RA method used, it can be determined by a statistical approach based on available data of the sprayer inspection scheme, or it can be determined by a linear scale relative to PAE number.

Thereby, in the context of PAE inspection, a technical risk is the product of probability of occurrence of a certain technical defect and the severity or extent of the subsequent impact (Figure 2).

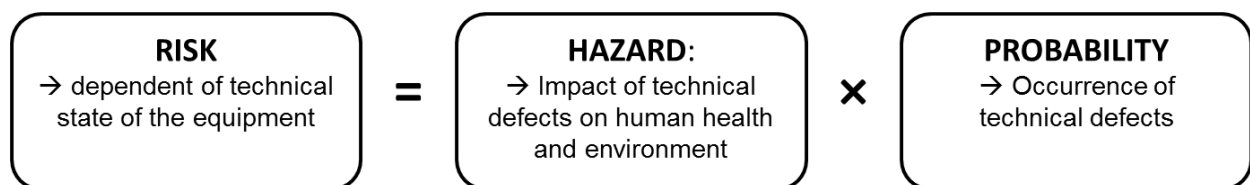


Figure 2: Part of Risk related to the use of PAE

The present SPISE Advice proposes two different approach to develop a Risk Assessment related to the use of PAE and their inspection: the Zurich method and the Apesticon method.

The first methodological basis is the risk matrix according to Nohl and Thiemecke (1988). This is a common method for technical risk assessment also known as Zürich-methodology. It is applied for the assessment of safety risks e.g. of aerial railways or for the assessment of risks arising from the operation of nuclear power plants. In SPISE context, it focusses on the risk evaluation of using different categories of PAE. Its advantage is to give results very quickly. It is accessible to every nation thanks to a simple process using little data that could be harvested by each country.

According to Stas et al (2016), the second method 'Apesticon' not only focusses on the risk evaluation of using PAE, but also on the risk reduction which can be achieved by inspecting different categories of PAE. This methodology offers a precise and complete risk assessment. Results are closer to reality and can be interpreted in several useful ways.

The results given by the two methods are not objectively equivalent and the degree of completeness of the results is different. The choice of one method to the other should be based on the available data in the country. Nevertheless, both approaches have been tested successfully in Germany and Belgium.

Zürich methodology

Concepts and assumptions of the methodologies

Aim of the matrix is to define how high a risk might be. Concerning the risk assessment of PAE in use the advantage of this methodology is that the risk assessment can be reduced to those technical parameters which are in the focus of the inspection of PAE in use (Wegener 2014).

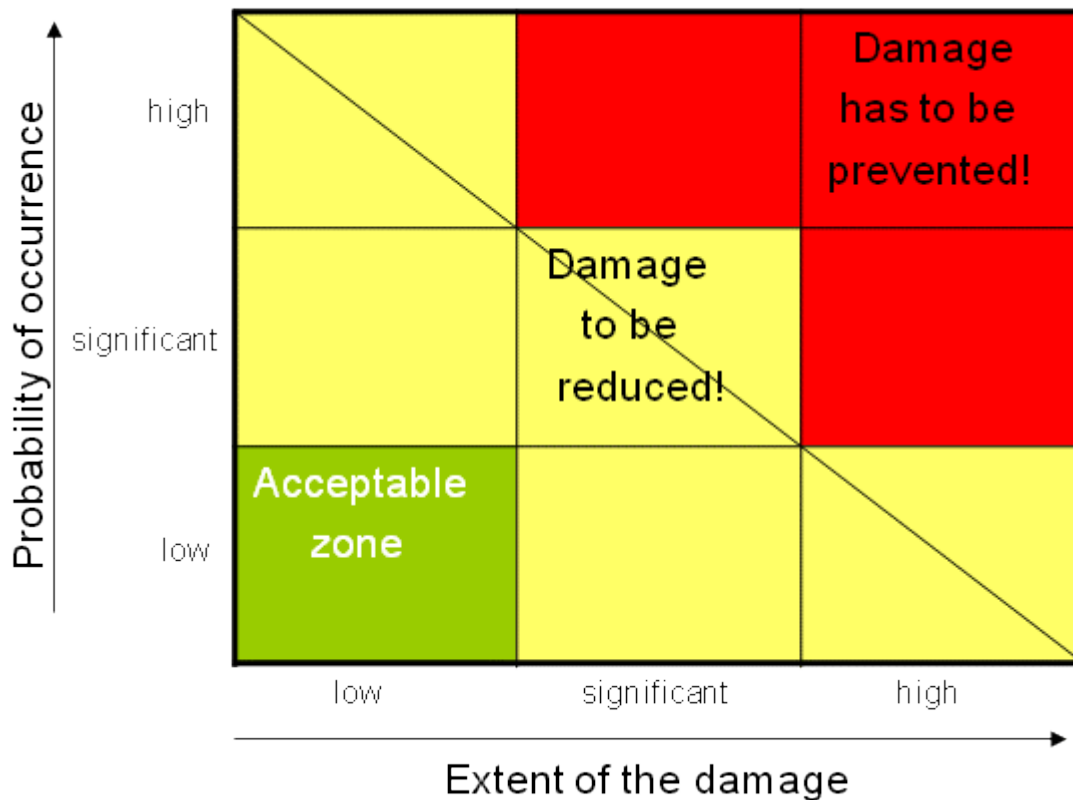


Figure 3: Risk matrix according to Nohl and Thiemecke (1988)

The extent of damage is discharged by a qualitative analyses of equipment components being part of the inspection (acc. ISO 16122) and their impact on human health and the environment in case of technical disorder.

Technical parameters – equipment

To apply the Zurich methodology, each category of PAE was judged by nine different experts of SPISE by using qualitative measures (++; +; 0; -; --) for the following equipment components: Power transmission parts; Pump; Agitation; Spray liquid tank; Pipes and hoses; Spray boom; Filter; Nozzles; Controls; Regulation System; Distribution / drift; Cleaning; Blowers. The qualitative measures were then transformed into a point system: ++ = 20 points, + = 15 points, 0 = 10 points, - = 5 points and -- = 0 points. Afterwards the judgment of each expert was added together for each category of PAE. Table 1 shows the average figures of judgment made by all experts for each category of PAE. These components correspond mostly to those of some spray application techniques. For other techniques which can potentially be exempted (PAE not used for spraying pesticides, handheld application equipment, knapsack sprayers or additional PAE that represent a very low scale of use) additional components need to be analyzed.

Table 1: Different categories of Pesticide Application Equipment and the proposed impact of their components on human health and the environment (Wehmann 2015a)

Pesticide Application Equipment (PAE)								
Equipment components	Handheld sprayers	Knapsack sprayers	Not used for spraying	Additio nal/ low scale use	Hand operated	Additio nal/ aircraft	Additio nal/ train	Spraying incl. fogging
Power transmission parts	0	3	12	13	9	12	9	16
Pump	8	8	11	11	13	13	11	15
Agitation	4	4	4	10	14	13	11	16
Spray liquid tank	9	8	8	12	13	14	11	18
Pipes and hoses	9	9	11	12	18	14	13	16
Spray boom	2	9	11	12	12	13	12	14
Filter	6	8	5	11	11	13	11	13
Nozzles	12	9	9	13	16	16	13	16
Controls	9	9	9	9	13	13	11	13
Regulation systems	7	8	10	11	12	15	12	14
Distribution/ drift	9	12	9	12	13	17	16	18
Cleaning	9	9	8	11	13	14	13	18
Blowers	2	6	7	7	4	1	2	13
Sum	87	105	114	143	161	170	184	199
Priority sum	by 1 th	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th

Probability of occurrence and scale of use

The probability of occurrence is normally figured out by taking the number of incidents of each group of PAE into account. Since there are no such statistics available on a national level of all Member States (SPISE 2014) this lack of information can be solved in the Zürich methodology by taking the number of different PAE in professional use in practice into account. For this method, it should be supposed that these numbers are proportional to the frequency of incidents. Another expert survey was made to find out about the numbers of PAE in different Member States (Wehmann 2015b). In order to make the reported numbers comparable on a supranational level they were divided by the total sum of arable land per Member State according to national figures (Table 2)

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Table 2: Reported numbers of PAE in professional use sorted by category and accounted per million hectare.

Member State	PAE per million hectare							
	Handheld	Knapsack-sprayer	Not used for spraying	Additio nal/ low scale use	Hand operated	Additio nal/ aircraft	Additio nal/ train	spraying (incl. fogging)
Belgium	22.091	14.728	74	147	2.946	*	1	16.281
Czech Republic	57.405	57.405	287	57	57	9	11	3.444
Germany	13.170	23.946	808	299	1.916	0	2	10.297
Italy	1.128	2.722	544	389	3.889	1	2	50.560
Luxemburg	534	22.901	382	1.527	1.527	*	*	10.053
The Netherlands	2.671	53.419	1.068	2.671	2.137	1	3	10.417
Norway	50.454	10.091	10.091	5.045	3.027	1	3	20.182
Spain	*	*	*	*	2.105	*	*	12.041
Sweden	2.935	24.462	326	294	326	1	1	5.219
United Kingdom	*	2.741	*	*	*	0	1	2.295
Average	15.039	21.242	1.358	1.043	1.793	1	2	14.709

*not reported

In a next step the risk matrix is established by using different levels for the probability of occurrence in a linear scale with an increment of 5,000 PAE per million hectares (Figure 4). Within the first level the sum of the extent of damage for each category is used. The figures within the next lines of the matrix are in each case just the first ones multiplied by the mentioned level.

Results integration and application

According to Article 8 (3) of Directive 2009/128/EC the categories of PAE being exempted from inspection, if operators are trained, are marked in green, the ones where the inspection is mandatory are marked in red and the ones where different time tables and inspection intervals can be applied are marked in yellow.

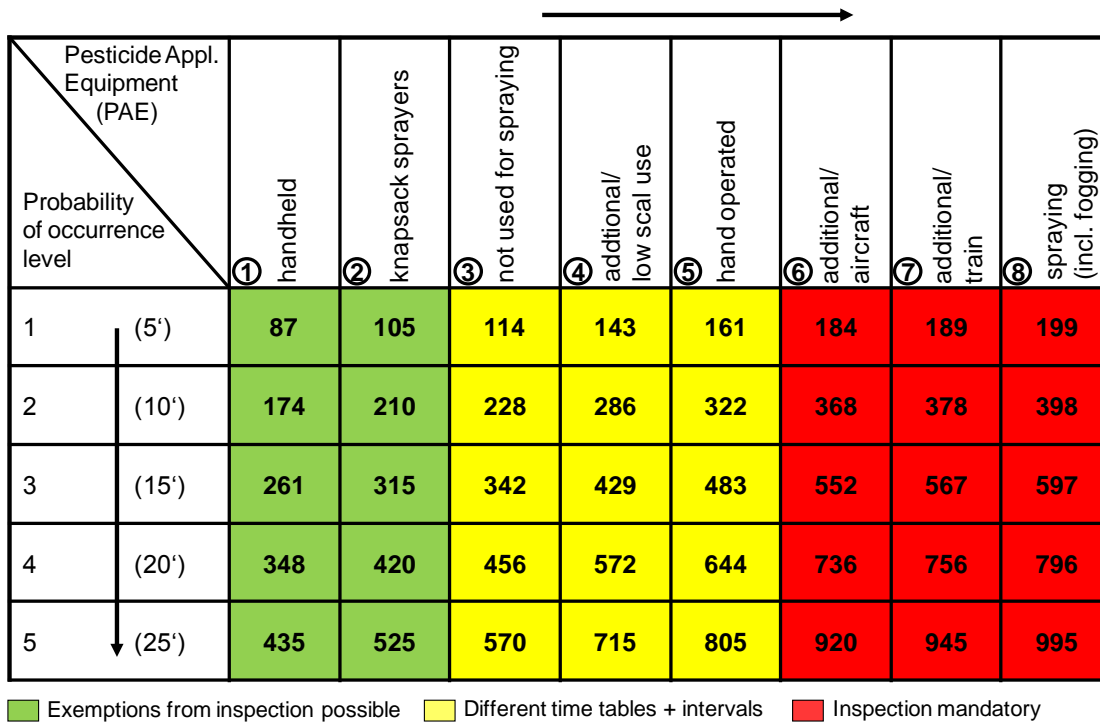


Figure 4: Risk matrix

Next the risk tolerance line has to be defined, which is a measure for what kind of risks are still acceptable or not. Therefore, the average numbers of PAE reported in

Table 2 are integrated into the risk matrix in a qualitative manner. To have an equal treatment of all PAE categories considered, the highest acceptable risk is the baseline for the risk tolerance which has to be applied (Wegener 2015). In this case, the numbers of “handheld” and “knapsack sprayers” are basis for the definition of the risk tolerance being acceptable.

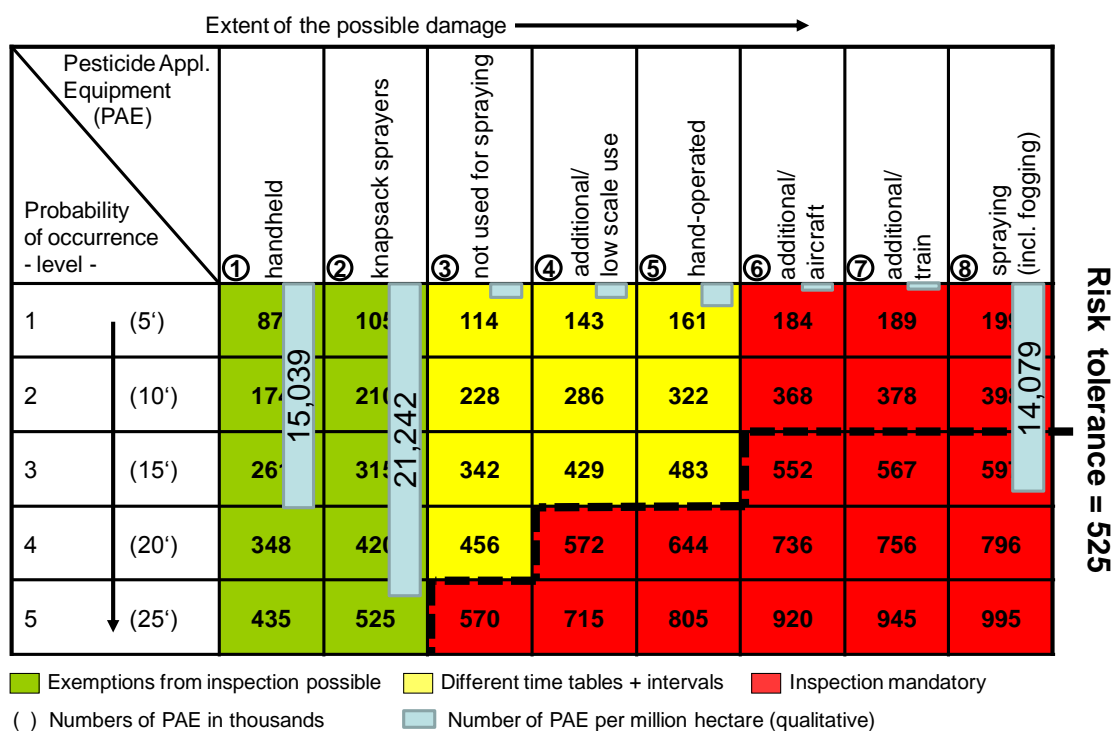


Figure 5: Risk matrix including the average figures of PAE per million hectare of nine Member States and the derived risk tolerance line

Following Figure 5 the highest acceptable risk is defined by the number of knapsack sprayers which is within the 5th probability of occurrence level. For this reason the risk tolerance line is 525.

Results interpretation

To apply the risk assessment on Member State level national figures for each category of PAE have to be integrated into the risk matrix presented in Figure 5. Different time tables and inspection intervals can be applied for those of the categories “not used for spraying”, “hand-operated” and “additional – low scale use” where the histograms does not intersect the risk tolerance line. According to Article 8 (3) of Directive 2009/128/EC the categories “additional/train”, “additional/aircraft” and “spraying incl. fogging” must be inspected even if the mentioned histograms does not intersect the risk tolerance line.

Apesticon risk assessment method (or Belgian method)

Concepts and assumptions of the methodologies

The Apesticon risk assessment is performed “before inspection” (presence of a defect, above inspection tolerance level and without defect correction) and “after inspection” (all defects are repaired regarding the inspection tolerance level). The general objective is to evaluate the potential risk reduction induced by the inspection. This process in two steps allows performing a complete RA according the ISO 12100 (2010). At the end for the authorities, only a notable risk reduction could justify the necessity to inspect the PAE type concerned.

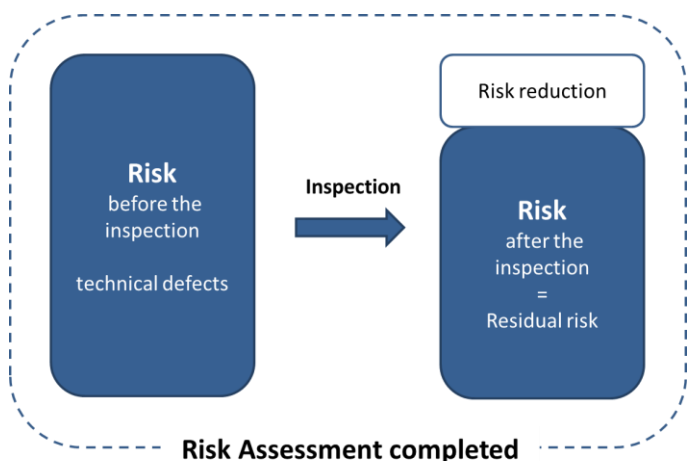


Figure 6: Complete Risk assessment related to the use of PAE and its inspection according to Stas et al. (2016).

The Apesticon methodology is based on actual data and experts judgment to gather data at the national level:

One makes uses of the database of the inspection results and the amount of pesticides used (Eurostat).

Survey of stakeholders can be used to determine the scale of use of the different types of PAE, the technical and human contribution in the the risk, and the risk reduction potential of the inspection.

It is considered that PAE are used following the Good Agricultural Practices. Because of their independence from the technical aspects, the local external conditions (as weather or cultural practices) are considered as invariable.

Considering the output and depending of the level of aggregation, this approach is able to provide the Risk (R) and the Risk Reduction (RR) caused by the inspection for: one defect, one PAE, one type of PAE at the national level, one type of PAE at national level taking account the human contribution in the risk and finally the distribution of the risk for the different types of PAE used at the national level (Figure 7). R and RR can be calculated separately and also aggregated for the different compartments considered at risk (human health, consumer, environment).

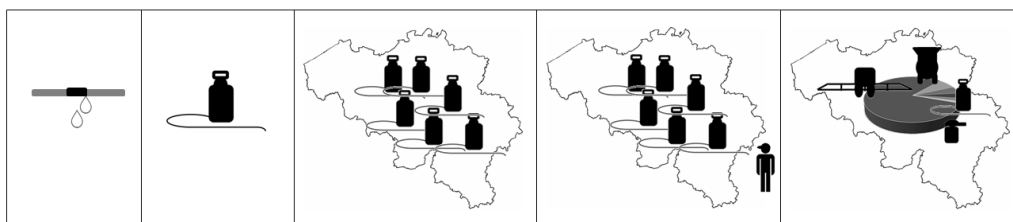


Figure 7: Different levels of aggregation for the calculation of Risk and Risk Reduction: one defect, one machine, one PAE type at national scale (only technical risk), one PAE type at national scale (technical+human risk), different PAE types at national scale (Stas et al., 2016).

Technical parameters - equipment

Based on the inspection protocol of each PAE type, the inspection parameters and the corresponding technical defects are listed. The basic rule of this method is to consider that one “defect” corresponds to each inspected parameters of the PAE. Since the consequences of the defects are the basis of the hazard and of the impact definition, the list was elaborated with the descriptions of the four data:

- Items
- Parameter
- Consequence
- Extent of the risk

"Items" are the requirements which are potentially subject to inspection. They are mostly components of the PAE, such as "filter" or "spray boom" but it also can be a direct defect such as "leaks" for example. "Parameters" are descriptions that refer to what is really inspected. These descriptions may contain the tolerance levels. "Consequences" are descriptions of the impacts on Environment and on Human Health. These are mostly under- and overdosages but they also can be injuries caused to the operator. "Extents" are evaluations of the surfaces impacted by the under- or overdose. They can be "point" (one isolated place), "localized" (a strip) or "global" (on the whole parcel treated).

The list is available in a table called "inspection table". It was elaborated based on Belgian data. As the PAE types in use are not necessarily exactly the same through the different countries, the list should be reviewed before application in other countries.

In theory, impact is the consequence of the hazard on the exposed subject. In the context of this paper, 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 impact need to be evaluated to estimate the risk. In Belgium, a questionnaire was submitted for experts' judgment (mixed panel of Belgian experts). "Severity" is presented as a relative value between 1 and 10, when 0 = no impact and 10 = maximum severity of impact, defined for each situation impacting human health or environment. Every potential technical defect corresponds to a specific situation of impact. Values (1-10) are defined by experts' opinion.

Severity is evaluated in two situations: "before inspection" and "after inspection". This evaluation is of a great importance to determine the Risk Reduction due to the inspection. In the case "before inspection", the parameter is deficient and the level of deficiency is above tolerance level of inspection. In the case "after inspection", the level of deficiency is below the tolerance level defined by inspection. It should be notice that it is absolutely possible that the Severity of impact of a defect "after inspection" (after reparation) can be different from 0. For example, a Severity is estimated at 7 for the impact of a leak on the operator (before inspection) and is estimated at 2 after inspection and reparation of that leak. Even after reparation, an inspected parameter can present a residual hazard.

The Severity values are defined to be valid for all PAE types. For example, a Severity value of 7 defined for a leak will remain "7" for field crop sprayers, knapsack sprayers, spray train, handheld sprayers and all other PAE.

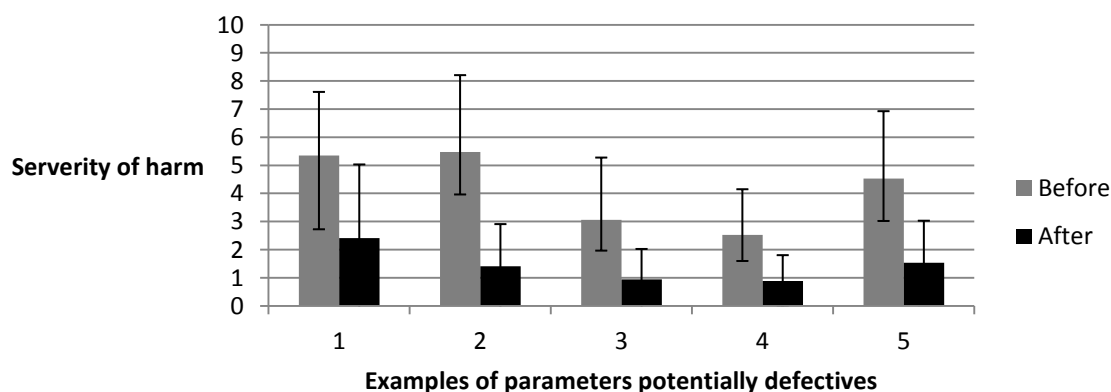


Figure 8: Examples of severities of harm on the environment. Grey=Before inspection ; Black=After inspection. Parameters: 1=General condition of the sprayer; 2=Presence and readability of the tank

content indicator; 3=Presence and condition of the tank filling strainer; 4=Presence and condition of the suction filter; 5=Presence and condition of the discharge filter

Belgian data are available in the “inspection table”. They can be used for the risk calculation of other countries. In this case it should be assumed that Severity values are the same whatever the PAE type and that the ways of exposure (to the operator, the consumer or the environment) are the same whatever the country.

Probability of occurrence and scale of use

The Belgian method takes into account the number of incidents (number of technical dysfunctions in a given interval of time) of each group of PAE. Occurrence illustrates the frequency of defect emergence during a complete inspection cycle. In Belgium it is three years. Therefore, the occurrences values given in this paper are obtained on that basis. They are defined for each inspected parameter thanks to the available data from the sprayer inspections in Belgium (Field crop sprayers, Orchards, Fixed and semi mobile sprayers). Since these data are expressed in percentage, they could be used in risk calculation whatever the country and its inspection cycle duration. It should be supposed that frequencies of defect emergence are the same for a machine in Belgium and for a machine in the country of study. If occurrence needs to be reconsidered in another country, it should be calculated based on the inspection data of that country and the inspection cycle duration.

The occurrence is combined with the Severity of impact of each defect in order to calculate the risk.

The scale of use reflects the amount of utilization of a specific type of PAE at national scale. It is based on 3 factors:

1. Amount of pesticides sold per year in the country of study. In the same way as for occurrences, for Belgium the scale of use is calculated every three years corresponding to the last complete inspection cycle (2011-2013). Important: These data should be specific to the country of study, so that the scale of use reflects the country scale.
2. Repartition of active substances potentially used among PAE types. This repartition was realized by Belgian experts specialized in pesticides and in PAE inspection and could be used for other countries. In that case, it should be supposed that a given PAE type is used with the same potential products in Belgium and in the country of study.
3. Frequency of use of each PAE type. In Belgium, a national enquiry allowed evaluating the number and frequencies of use of the PAE types in Belgium. It was conducted by professionals and farmers. 42 professional and more than 300 farmers answered. A similar national enquiry should be conducted in the country of study. Frequency of use of each PAE should be specific to the country, because farmers will use differently the PAE types regarding their activity.

Results of scale of use can be expressed in absolute values or in relative values (percentages) as in Figure 9.

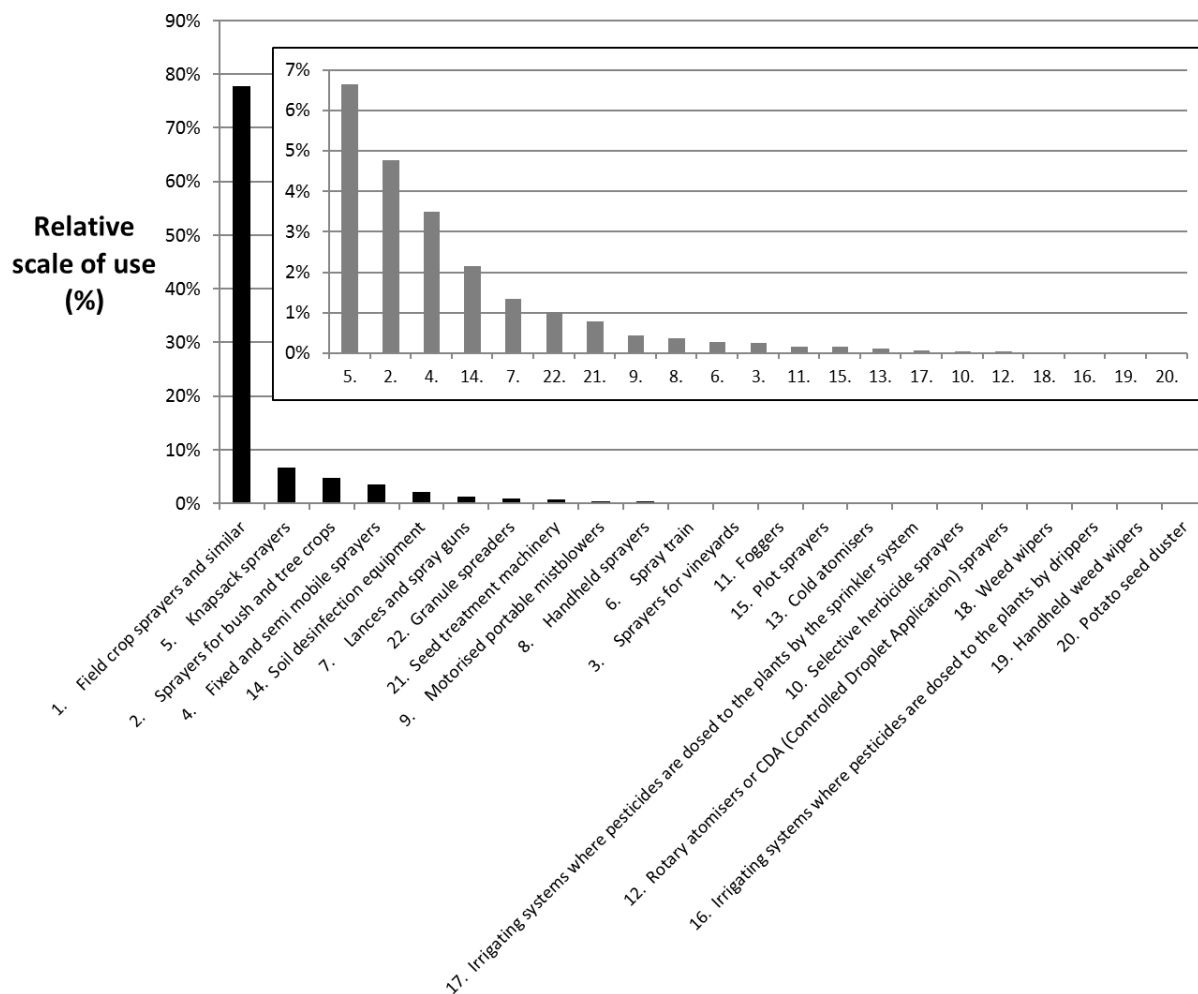


Figure 9: Scale of use of the different PAE types, calculated for Belgium. Results are expressed in percentage from the sum of scales of uses of all PAE types

Results integration and application

Within the whole risk assessment, risk is then calculated in different steps (Figure 10), as described below.

At the scale of the defect, the Severity of impact (to the environment, the operator or the consumer; before and after inspection) is combined with the probability of occurrence by two methods described below. The two methods are named "defects only" and "defects+residual risk":

1: "Defects only"

Risk (before/after inspection)	Calculation
Before inspection	occurrence*Severity before
After inspection	occurrence*Severity after

This method represents the risk, considering that all parameters studied are defectives.

2: "Defects + residual risk"

Risk (before/after inspection)	Calculation
Before inspection	Severity before *occurrence + Severity after*(1-occurrence)
After inspection	Severity after *occurrence + Severity after*(1-occurrence) = Severity after

This method represents the total risk (risk of defect + residual risk). The risk is calculated for the defective parameters and also for the correct parameters (for which a residual risk can remain).

→Risk for one defect is obtained.

- Risks of all defects of one machine (one PAE type) are summed.

→Total technical risk for one single and entire machine is obtained.

- The risk for one machine is extrapolated, by multiplying the scale of use (corresponding to the PAE type concerned) to the result.

→Technical risk for one type of PAE is obtained at the national scale.

- The technical risk for one type of PAE in the country can be completed by a human part of risk.

In this work, we assume that pesticide application is more dangerous when there are technical defects on PAE. By this RA method, only the risk due to technical defects is calculated. However, another source can cause an imperfection on the application: human mistake (or human behaviour). Those two sources of suboptimal application (technical defects part and a human behaviour part) can be gathered in a total risk for pesticide application.

In order to determine the size (% of the total) of each part, an enquiry was launched with experts, including inspection managers from 11 countries. Human behavior and technical defects parts were determined for every PAE type. Results are expressed in percentage.

→Then the total risk related to pesticide application for one PAE type at the scale of Belgium is obtained

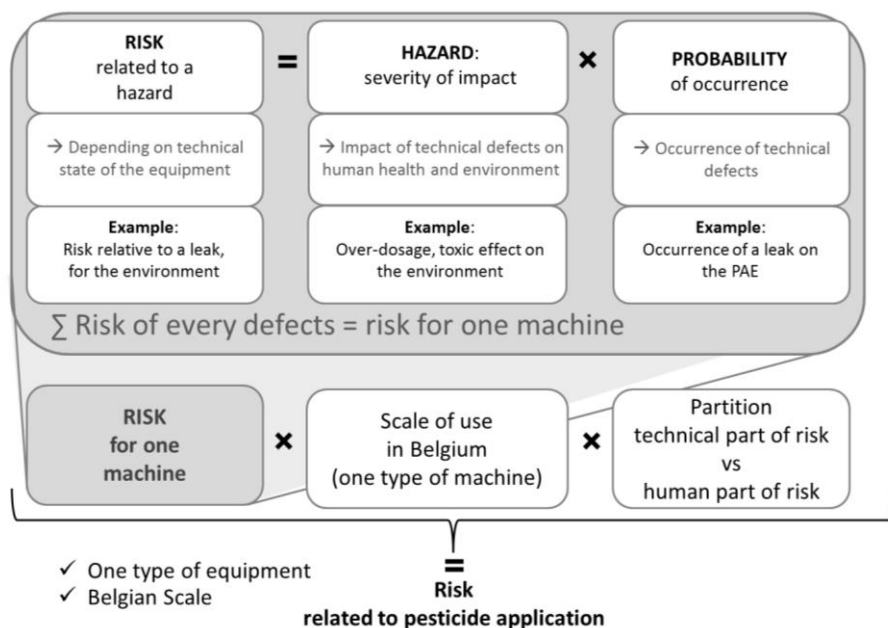


Figure 10: Risk Assessment, method of calculation

Results interpretation

The Apesticon method has been specially developed to realize a complete Risk Assessment according to the article 8 (3) of Directive 2009/128/EC. This method was developed within the Belgian case study, but can be quite easily transposed in other Member States. It can support decision making. The numerous results can be expressed in charts. Decision can be made by common sense rules, taking into account the levels of risks and the magnitudes of risk reductions, at every step of the risk assessment:

Scale of defects

The risks at the scale of the defect are useful to elaborate new inspection protocols. The defects for which the risk is almost zero could be exempted of 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 after inspection.

Scale of the machine

The risks at the scale of the machine have to be subjects of attention concerning the risk reductions because they directly reflect the effects of technical inspection when the “defects only” are analyzed. A maximum level of risk could be defined for the operator safety and a maximum level of risk can be tolerated in an exclusion of inspection. But it will be subject of discussion by taking account of the other analyzes of risk (with scale of Belgium) and for example the toxicity of substance applied and the partition between human and technical risk. Figure 11 gives an example with risk and risk reduction values for knapsack sprayers.

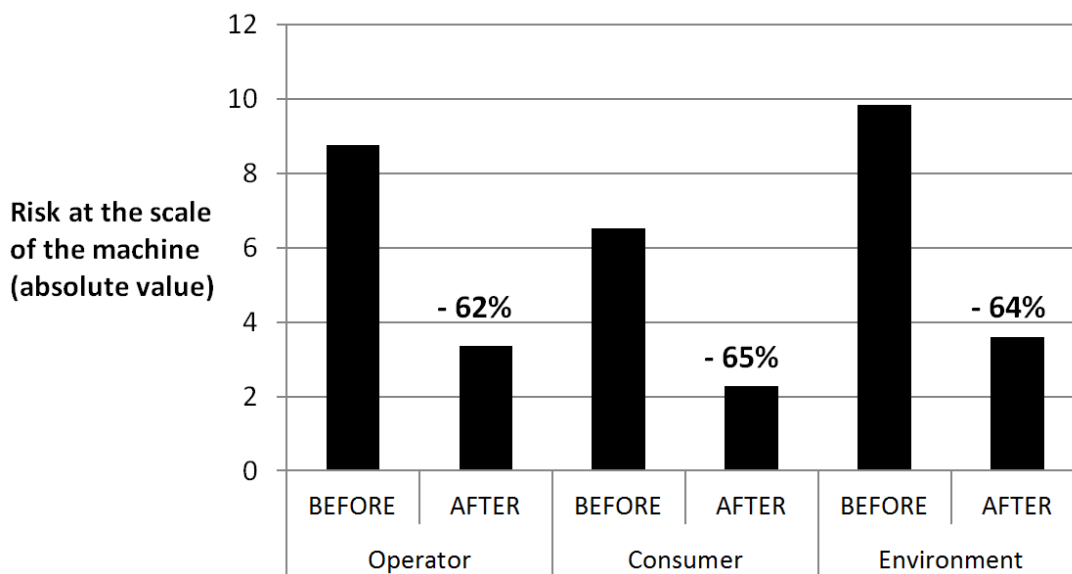


Figure 11: Results of risk calculation in absolute values for Knapsack sprayers. Risks for the operator, for the consumer and for the environment. Scale of the machine, method “defects only”. BEFORE=before inspection; AFTER=after inspection. Risk reduction between BEFORE and AFTER are indicated in percentage.

Scale of the country (technical)

The advantage here is the global vision offered by the total technical risk. The great differences in risk values between PAE types are due to the scales of use that are specific to each PAE type. In order to define the necessity (and the intervals) of technical inspection, a focus on the technical risk should be more relevant than the total “technical+human” risk. Indeed, the technical risk answers more directly to the question of inspection effect. Then, a maximum level of risk can be defined as tolerance level for an exclusion of inspection at the Belgian scale.

A maximum level of risk could be defined for the consumer and for the environment. Indeed, the consumer and the environment are targeted by a global pollution of the Belgian surfaces. An example of Belgian results is given in Figure 12.

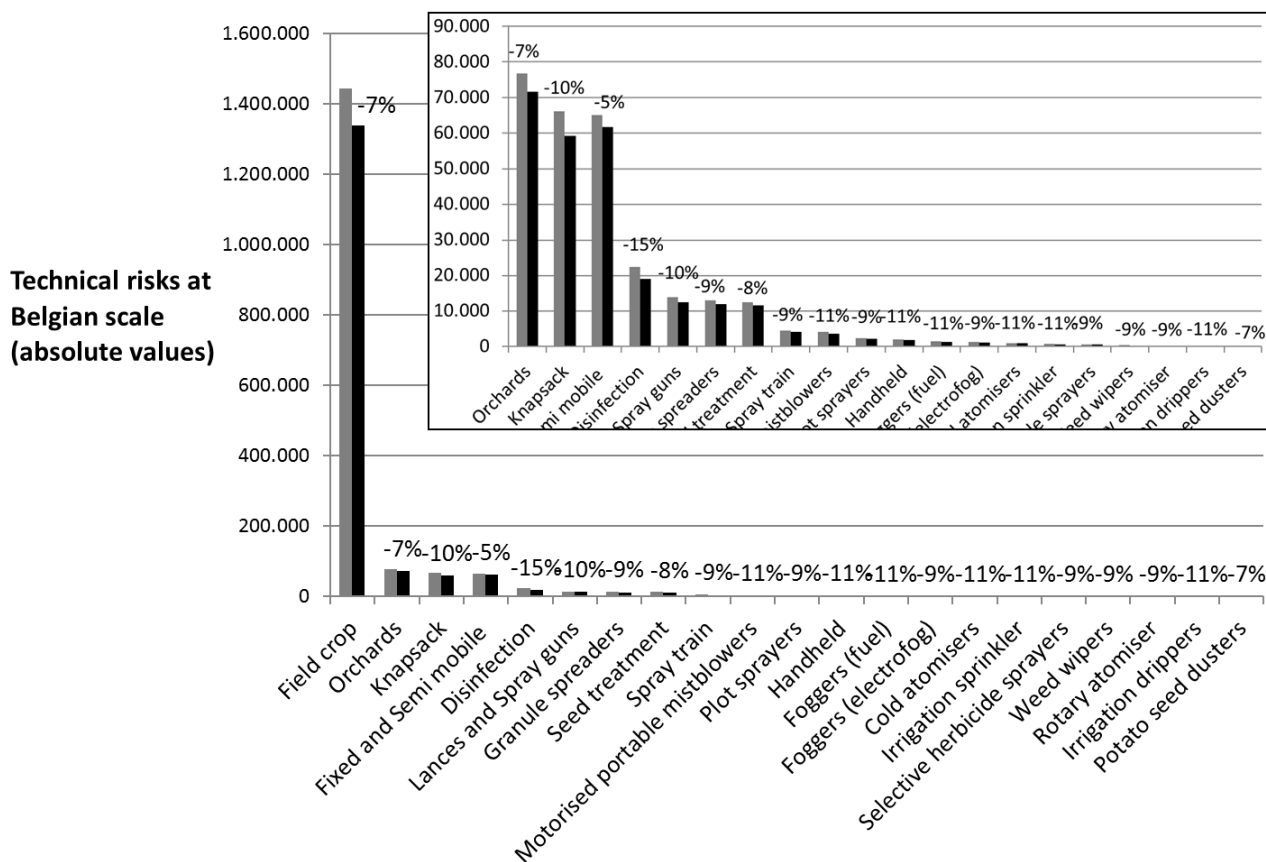


Figure 12: Results of risk calculation in absolute values for different PAE types. In this chart, risk for the operator, risk for the consumer and risk for the environment are gathered in an average. National (Belgian) scale, method “defects + residual risk”. Grey=before inspection; Black=after inspection. Risk reductions between before and after inspection are indicated in percentage.

Scale of the country (technical + human)

The total risk “technical+human” offers an overview about the risk of pesticide application in Belgium. It is interesting in terms of comparison of PAE types.

The partition between human and technical part of risk, in percentage of total risk, offers additional information very useful in decisions about mandatory inspection. That could justify the necessity (or not) to reduce the technical risk by the way of an inspection, in order to reduce significantly the risk total of pesticide application.

Conclusions for the two methodologies

The risk matrix according to Nohl and Thiemecke (1988), or the Zürich methodology has the advantage to be accessible to every nation thanks to a very simple process using data that could be easily harvested by each country. Results can be available quickly and limits of decisions are putted (imposed) clearly. Risks of 8 PAE types are evaluated for all target combined by the way of 13 technical components. Details of the method are available in a publication (Wegener, 2015).

A risk assessment can also be implemented following Belgian method (Stas et al., 2016). It requires some data gathering in the country of study: the sales or the use of pesticide active substances (in Kg); the frequency of use of each PAE type by professionals (this data can be obtained by a national

enquiry). According to the cultural practices of the country concerned, an update of the list of PAE and parameters associated should be achieved. By this method, risks can be calculated for an unlimited number of PAE types. It distinguishes different targets: operator, consumer, and environment. Risk reductions give an indication on the effect of an inspection for the different PAE types. Results can be obtained at the scale of the technical component, of the machine or the scale of the country. Risk values and risk reduction values at every step of the risk assessment deliver a strong theoretical basis to support decision making.

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