# Development of a harmonized risk mitigation toolbox dedicated to environmental risks of pesticides in farmland in Europe: outcome of the MAgPIE workshop

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# Abstract

Risk mitigation measures are a key component in designing conditions of use of pesticides in crop protection. A 2-step workshop was organized under the auspices of SETAC and the European Commission and gathered risk assessors and risk managers of 21 European countries, industry, academia and agronomical advisors/extension services, in order to provide European regulatory authorities with a toolbox of risk mitigation measures designed to reduce environmental risks of pesticides used in agriculture, and thus contribute to a better harmonization within Europe in the area.

The workshop gathered an inventory of the risk mitigation tools for pesticides being implemented or in development in European countries. The inventory was discussed in order to identify the most promising tools for a harmonized toolbox in the European area. The discussions concerned the level of confidence in the technical data on which the tools identified rely, possible regulatory hurdles, expectations as regards the implementation of these tools by farmers and links with risk assessment. Finally, this workshop was a first step towards a network gathering all stakeholders, *i.e.* experts from national authorities, research sector, industry and farmers, to share information and further develop this toolbox. This paper presents an outline of the content of the toolbox with an emphasis on spray drift reducing techniques, in line with the discussions ongoing in the SPISE workshop.

**Key Words:** pesticides, risk management, risk mitigation, Regulation (EC) No 1107/2009, spray drift reducing technologies.

#### Introduction

Risk mitigation measures are a key component in defining the conditions of use of pesticides in crop protection<sup>1,2</sup>. Risk mitigation tools are therefore of increasing importance in modern agricultural practices as well as in the revised legislation regarding their placing on the market<sup>1</sup>. In Europe, risk mitigation measures are recommended for ca. 95% of active substances during the regulatory peer review, and range from special protections while handling the product to conditions of use that allow to minimize transfers to groundwater, for example<sup>1</sup> (Tab. 1). These risk mitigation measures derive directly from the evaluation of pesticide products and the risk assessment conducted for each use, and are thus reported in the approval regulations for an implementation in European Member States<sup>3</sup>. For example, the registration regulation for the active substance spinosad dating 2007 recommends that Member States, in their assessment to authorize plant protection products containing the substance, to "*pay particular attention to the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate*".

Nature of the risk to be mitigated	% of active substances concerned	
Operator	42	
Consumers	15	
Groundwater	37	
Surface water	26	
Air	2	
Terrestrial vertebrates	29	
Non target arthropods	8	
Soil organisms	8	
Honey bees	8	
Non target plants	9	

Tab. 1. Recommendation for risk mitigation measures as an outcome of the European risk assessment of pesticides. Compilation based on 290 active substances approved, excluding micro-organisms<sup>3</sup>

The implementation of risk mitigation measures thus raises multiple exchanges between regulatory authorities, and a number of initiatives have been undertaken in order to develop and implement risk mitigation measures and where possible take them into account in risk assessment procedures. The harmonization of the risk mitigation measures implemented amongst countries is the primary issue, as the measures taken often relate to national policies in first place, as for example in France with the management of spray drift<sup>4</sup>. National policies also inform about the implementation routes for risk mitigation measures, which range from incentive measures, flexible for regulators and usually preferred by farmers, to legal enforcement, less flexible but perceived as more persuasive and therefore efficient in some countries. Finally, the interpretation of a recommendation in a regulatory text and on product's labelling varies among farmers as well as in the regulatory population and more harmonization and or clarity is deemed necessary in the wording associated to risk mitigation tools.

In this context, a 2-steps workshop was organized in 2013 under the auspices of the Society of Environmental Toxicology And Chemistry (SETAC) and the European Commission, in order to provide European regulatory authorities with a toolbox of risk mitigation measures designed for the use of pesticides for agricultural purposes, and thus contribute to a better harmonization within Europe in the area. The workshop gathered risk assessors and risk managers of 21 European countries including Norway and Switzerland, industry, academia and agronomical advisors/extension services. The discussions focused on environmental risks, of all nature: wildlife including vertebrates and invertebrates, flora and microorganisms, biodiversity as well as surface- and groundwater quality, identified as protection goals in the European regulation on pesticides<sup>1</sup>.

During this workshop, an inventory of the risk mitigation measures used to reduce spray drift in European countries was performed and discussed as regards their effectiveness, their implementation in European countries and margin of improvement, and future developments. This paper presents an outline of the content of the toolbox with an emphasis on spray drift reducing techniques, in line with the discussions ongoing in the SPISE workshop.

# **Experimental methods**

During the pre-workshop period an inventory of existing risk mitigation measures in European countries was undertaken. Eleven questionnaires were sent to participants, in order to collect feedback on the risk mitigation tools already implemented, their legal status (*i.e.* enforced via a dedicated legislative text, incentives or as part of good practices) and where relevant the piece of legislation involved (European, national or both). Additional questions allowed to address the technical knowledge on which each tool relied, and the related data were collected and referenced. Feedback of Member States on the success of implementation of the tools was also collected. The consultation finally covered risk mitigation options being in development in each country, as well as the "wish list" of respondents on the risk mitigation measures they were "dreaming of" or at least considered as the most promising in the future.

The measures inventoried were classified into categories based on their nature, *i.e.* related to products application conditions, application equipment or farming practices. The benefits they represented were listed and the piece(s) of legislation where they belong was (were) reported.

The risk mitigation tools listed in the inventory were further discussed and ranked to reflect their importance as a risk mitigation tool as for today or for the future. This ranking was performed using the following criteria, for each tool:

Implementation/advancement level: from well implemented tools in countries to tools on which insufficient knowledge or confidence were available;

Regulatory aspects: regulatory status of the tool, from the straight implementation of a legislation in place to simple good farming practices, possible regulatory hurdles associated to a tool as well as options to resolve them;

Possibility to measure the efficacy of the tool;

Possibility to relate to the risk assessment, *i.e.* to develop a risk assessment that accounts for the risk mitigation tool quantitatively or qualitatively.

The areas of research and of future development of these tools were discussed and accounted for in the ranking exercise.

## **Results and discussion**

The inventory listed a number of risk mitigation measures already implemented in European countries. It also revealed diversity in the tools in use, as illustrated in Tab. 2 below.

Tab. 2. Risk mitigation tools inventoried in European countries, Norway and Switzerland as a result of the MAg-PIE workshop, together with their benefits and related regulatory framework

Category	<b>Risk mitigation Measure</b>	Benefits	Regulatory framework
Product application rate, timing, fre- quency	Application rate, applica- tion frequency and interval between applications	Lower transfers to groundwater and	
		surface water	Regulations 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup>
		Reduces exposure of organisms in-crop and off-crop	
Application equip- ment	Low drift nozzles, shields, precision treatment etc	Reduces exposure of organisms in-crop and off-crop	Regulation 1107/2009 <sup>1</sup> , Directives 2009/128 <sup>5</sup> and 2009/127 <sup>6</sup>
Buffer zones	Non sprayed zone at the edge of a crop	Reduces exposure of organisms in-crop and off-crop	Regulations 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup> , Directi- ve 2000/60 <sup>7</sup> , Directive 92/43 <sup>8</sup>
Field margins	Vegetated buffer zone	Reduces exposure of or- ganisms in-crop and off- crop and provide habitat and food resource	Regulation 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup> , Directi- ve 2000/60 <sup>7</sup> , Directive 92/43 <sup>8</sup>
	Multifunctional field margin	Reduces exposure of organisms in-crop and off-crop and provide habitat and food re- source and mitigate effects on biodiversity	Regulations 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup> , Directi- ve 2000/60 <sup>7</sup> , Directive 92/43 <sup>8</sup>
Compensation areas	Recovery areas (ecological focus areas)	Provide habitat and food resource and reduce exposure of organisms in-crop and pending on location in the farmland may reduce exposure of organisms off-crop	Regulations 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup> , Direc- tive 2000/60 <sup>7</sup> , Directive 92/43 <sup>8</sup> , CAP <sup>9</sup>
Dust drift reduction technologies	High quality coating, low dust drillers	Reduces exposure of organisms in-crop and off-crop	Regulations 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup>
Bee management	Bee hive removal or protec- tion, application periods, information to beekeepers	Managed bees	Regulations 1107/2009 <sup>1</sup> and 547/2011 <sup>2</sup>

Content of the toolbox and current implementation

Modifications of the application conditions (rate, number, frequency and in some cases interval between applications) are often cited as the first measure that may be recommended to reduce pesticide exposure and Member states confirmed their use to reduce exposure levels in environmental compartments (soil, water) and various non-target organisms. The reason for this is that such modifications may easily be taken into account in risk assessment and then check if a simple modification of the conditions of use would be sufficient to mitigate risks. The nature of the modification to be considered, however, depends on the needs derived from the risk assessment. A reduction of the application rates

or of the application frequency may limit the exposure of in-crop organisms as well as the amount of pesticide residues leaching from the treated area to groundwater, since the level of exposure is directly dependant on the amount of pesticide applied. Transfer routes off-crop involve more factors associated to the off-crop area itself (such as interception by vegetated areas, transfer of soil-bound or water soluble residues for example) that may significantly impact transferable residue amounts. Also, modifications of the application rate are difficult to recommend without a proper assessment of the product's efficacy at a lower rate, particularly with regards to resistance management. Thus recommendations as regards maximum applications rates remain limited and have often been decided at a national level for all uses of the product, or a European level<sup>3</sup>. Reductions of exposure of off-crop organisms, terrestrial or aquatic, when required, more often consider buffer zones, vegetated strips or drift reduction techniques.

The most common measures implemented in Member States are buffer zones, which aim to mitigate transfers via spray drift in the off-crop area. Buffer zones consist in non-sprayed bands of variable width, to be respected in the vicinity of the area to be protected. Buffer zones are defined during the evaluation process of pesticides according to Regulation (EC) No 1107/2009. They are thus product-specific and defined for the different uses/use rates of the product by a quantitative risk assessment. Countries either determine the exact buffer width that is necessary to get the safe level of spray drift deposition, or most often fixed buffer zone widths (e.g. 10, 20, 50 meters) are defined and attributed to the product and its uses. The buffer zones are then reported on the labeling<sup>2,3</sup> using a harmonized set of phrases describing the precautionary measures (SPe phrases) that must be respected during pesticide application.

As mentioned above, buffer zones are defined to specifically protect an off-crop area. This area may be a water body or any area hosting non-target organisms (in the context of Regulation (EC) No 1107/2009, non-target arthropods or non-target plants) located at the edge of the crop on which products are sprayed. Our inventory revealed a wide recommendation of buffer zones at the edge of water bodies in European countries (27 out of 27 feedback), whereas the use of buffer zones to protect other non-target areas such as non-target arthropods habitat and/or non-target plants, remains more limited (20 out of 27 feedback to protect non-target arthropods, 12 out of 27 feedback to protect non-target plants). The reason for this probably relies in the somehow different nature of these buffer zones. Buffer zones to protect water bodies are measured from the edge of the water body (usually the top of the bank of a stream) to the last boom of the sprayer, and are therefore partly or entirely outside of the crop. In comparison, the habitat of off-crop non-target organisms usually "starts" at the edge of the crop (although strictly speaking this habitat may also include the crop area itself) and therefore implies to locate the buffer zone inside the crop. The main hurdle to the implementation of in-crop buffer zones by farmers is the potential for side-effects of leaving a band of crop untreated with regards to potential pests/weeds' impact to the crop, and our inventory counted two countries only reported their implementation.

Field margins, composed of simple grass margins or of more complex plant mix composition, were identified as a promising tool although they remain poorly recommended in spite of their potential benefits (Tab. 2). Vegetated buffer strips dedicated to the reduction of run-off are reported in 12 out of 27 countries. Other types of vegetated areas exist that may provide habitat to wildlife, including vertebrates (birds) and invertebrates and seed mixes have been commercially developed. In the UK and Switzerland, guidance has been developed for the implementation and management of these margins by farmers<sup>10</sup>. The benefit of these margins is increasingly documented particularly as regards the multiple benefits that may be provided by each type of margin. An increased implementation of these margins in the future is expected, as a mean to specifically mitigate transfers of pesticides, enhance structural and functional biodiversity, but also because they are part of the recommendations of the CAP reform<sup>9</sup>. The description of the "ecological focus area" provided in the CAP reform list field margins, hedges, trees, fallow land, landscape features, biotopes, buffer strips, afforested and other relevant areas. These ecological focus areas should represent at least 5% of the arable area of the holding for farms with an area larger than 15 hectares (excluding permanent grassland), and rise to 7% in 2017. Some of these tools are already implemented in European countries as part of Agro Environmental Schemes (AES) and feedback on their efficacy to provide the benefit aimed for has been reviewed in the workshop. The implementation of the CAP is ongoing in European countries and the ways it complements/overlaps with the AES already in place are variable among countries. Further optimization of the land use by farmers has been researched during the workshop, particularly on the options to elaborate on the recommendations already in place with the CAP as regards land use when developing recommendations being more specific for the mitigation of pesticide transfers.

Specific protection areas are also defined in other pieces of legislation, such as the "Habitat" directive (Directive 92/43/EEC)<sup>8</sup> and the Water framework directive (Directive 2000/60/EC)<sup>7</sup>, where pesticide applications should be avoided. Directive 92/43/EEC defines protection areas for the protection of wildlife. This directive may complement the risk mitigation measures derived according to Regulation (EC) No 1107/2009 in the case where the use of a product is restricted to certain periods in an area in order to avoid the reproductive period of birds, for example, while Directive 92/43/EEC defines areas where the use of products in general is to be avoided. Directive 2000/60/EC specifically deals with the protection of surface and ground water quality. The list of measures includes the implementation of protection areas that are recommended in the conditions of use of pesticide products. The main difference relies in the fact that the restrictions to be applied in a protection area according to the Water framework directive concern all pesticide products while such recommendation is derived from Regulation (EC) No 1107/2009 it is product-specific and derive from a risk assessment.

The risk mitigation tools to reduce exposure to seed dusts during the sowing of coated seeds or pelleted/granular formulations are being developed by the European Commission and have been referred to during the workshop<sup>11</sup>. This dedicated toolbox involves specific driller equipments and formulation technologies to improve coating quality and reduce dust formation and drift.

Our inventory finally revealed a wide implementation of additional risk mitigation tools aiming at protecting managed bees, mainly honey bees, from exposure to pesticides. These measures are listed in Regulation (EU) No 547/2011<sup>2</sup> and were reviewed during the workshop. They involve restrictions during pesticide application particularly during the flowering period of the crop as well as beekeepers awareness and intervention to e.g. cover hives or take them away from the sprayed area. The workshop discussed these measures as regards their effectiveness in reducing risks to other pollinating insects and also

on the possible overlaps/contradictions with other measures, such as the promotion of flowering species in the farmland for the benefit of biodiversity, which will be included in the proceedings.

#### Outcome of the inventory as regards spray drift reduction technologies

Application equipment such as low drift nozzles, shields and precision treatment remain scarcely recommended at the European scale, and are country-specific (12 out of 27 feedback). Overall, they aim to reduce transfers via spray drift and thus the exposure of organisms and environmental compartments around the crop that receives the treatment. The main reasons for the current limited use of low drift spraying equipment are an insufficient knowledge on their efficacy among users and regulatory authorities, as well as questions about possible reduced efficacy of products when applied with low spray drift nozzles. The lack of availability of some of these equipments on the market also limits their use locally. Communication campaigns have been initiated to facilitate access to knowledge on these equipments as for example on low spray drift nozzles in Italy and the UK, with the first visible results<sup>12</sup>.

On a regulatory point of view, the buffer zones defined to limit deposits of spray drift in the off-crop areas are most often defined without taking into account additional risk reduction technologies, such as low spray drift nozzles or special equipments. In part, data are lacking to take into account quantitatively the level of transfer reduction reached by the use of a shielded sprayer or by using precision applications, in a risk assessment. Low spray drift nozzles constitute the exception as they are being tested and certified for drift reduction rate they provide, and methods are available that measure the effect of the nozzle on droplet distribution size and deposition reduction in tunnels or in the field<sup>13</sup>. Low spray drift nozzles may therefore be considered in a risk assessment on the basis of the transfer reduction they allow to reach, as it is the case in Germany, where buffer zones recommendations take into account the utilization of low spray drift nozzles as part of the mitigation techniques. The drivers in Germany were that the contribution of each mitigation measure to risk reduction is well described based on experimental measurements and the use of these tools by farmers is monitored. This confirms that a more widespread implementation of low spray drift nozzles by farmers is also a key element to their quantitative inclusion in the risk assessment. It is likely that the verification of the effectiveness of low spray drift nozzles in use will eventually enter in the scope of the recommendations of Directive 2009/128/EC as regards technical inspection of sprayers. The benefits of the risk reduction technologies have been discussed during the MAgPIE workshop, together with the possible ways of optimization when using several of these tools concomitantly.

## Conclusions

The MAgPIE workshop reached the following objectives: (1) gather a state of the art of the current knowledge and developments of risk mitigation measures for pesticides in EU countries and if available beyond Europe; (2) discuss risk mitigation practices and their future implementation and development together with experts from national authorities, research sector, industry and farmers; (3) discuss the links between risk assessment and risk management and on how to account for risk mitigation options in risk assessment and (4) build a network to share information to feed their respective actions.

A number of risk mitigation tools may be implemented in the context of Regulation (EC)

No 1107/2009 and multiple references in the text of the regulation allow this at the European and National levels. Regulation (EU) No 547/2011 may be expanded in future in order to account for the risk mitigation measures that have been identified during the workshop and for which no dedicated Specific Precautionary phrase (SPe) is available yet.

With regards to spray drift reduction technology, the MAgPIE inventory highlighted the important technological developments invested by manufacturers in this area and reviewed their potential effectiveness at reducing transfers and thus risks. These important technological progresses need to be transferred to the field and to users, so that users gain experience and confidence in these tools, and to facilitate the inclusion of these tools in the risk assessment models. An important communication effort towards farmers to encourage the use of drift reducing technologies in the field is needed, as well as concerted actions, involving all stakeholders to build on the feedback from the field and further develop these tools, so that they become part of good agricultural practices in future. Detailed recommendations are being developed in the proceedings of the MAg-PIE workshop, together with implications and recommendations as regards monitoring, modelling, the protection of biodiversity and practical and regulatory implementation, to be published in 2015.

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