

3 Regulatory framework for setting risk mitigation measures under Regulation (EC) No. 1107/2009

Wolfgang Reinert and Martin Streloke

Anne Alix, Burkhard Golla, Gerhard Goerlitz, Volker Laabs, and Veronique Poulsen for the updated set of safety precaution phrases

3.1 Legislative aspects

3.1.1 Regulation (EC) No. 1107/2009 and the placing of plant protection products on the market

Plant protection products (PPP) are recognized as an important tool for producing high quality food in a sufficient amount and at an affordable price. Despite their benefits, their application may also lead to harmful effects on human or animal health or on the environment if the application does not follow the recommended risk mitigation measures (RMM) set out on the label of the applied product. These risk mitigation measures are an important part of Good Agricultural Practice (GAP).

Regulation (EC) No. 1107/2009 defines the legislative framework for the authorization and the placing on the market of PPP in the EU. It is based on the principle of a sequenced pre-marketing authorization: active substances, safeners, and synergists for the use in PPP must be approved at the EU level and placed on a positive list. The PPP themselves are authorized by Member States (MS).

Regulation (EC) No. 1107/2009 reflects the separation of risk assessment and risk management: Approval and authorization are legislative acts based on a scientific assessment of the potential risk from the use of a PPP. Risk assessors and risk managers represent widely separate entities.

According to Article 4(3) of the Regulation, a PPP shall only be authorized if, among other requirements, it is expected that, consequent to realistic conditions of use, there will be:

- No immediate or delayed harmful effects on human health or animal health or on groundwater
- No unacceptable effects on plants
- No unacceptable effect on the environment, under particular consideration of its fate and distribution as well as its impact on non-target species, biodiversity, and the ecosystem

The term "realistic conditions of use" entails two main elements: good practices (e.g., good agricultural practice, good plant protection practice) and risk mitigation measures.

For reasons of efficiency, risks assessment schemes follow a tiered approach. Products that show no risk under a simple set of generic and very conservative criteria are quickly sorted out as "acceptable" and do not have to undergo a detailed and more sophisticated higher-tier risk assessment. Where the lower-tier risk assessment predicts unacceptable risks, this does not necessarily lead to a non-authorization decision. The use of appropriate risk mitigation measures can result in a reduction in the theoretical risk identified following the application to the GAP towards an acceptable level. Clearly, risk mitigation measures may also be applied subsequently to a higher-tier risk assessment.

Risk mitigation measures are mainly risk management tools. However, as they are part of the risk assessment (in order to prove that a risk identified can be effectively mitigated), Regulation (EC) No. 1107/2009 requires that risk mitigation measures are identified in the draft assessment report (DAR) for a PPP made by the rapporteur Member State (RMS) and addressed in the conclusion on the peer review of an active substance by the European Food Safety Authority (EFSA) (Art. 12[2]), for further adaptation and implementation at national level.

As risk mitigation measures are necessary to assure that a PPP is being used according to the requirements of Article 4(3) (i.e., without harmful or unacceptable effects), they are also part of the authorization of a PPP (Article 31[2]). Risk mitigation measures are displayed on the label of the product (Article 65) and users are obliged to apply them (Article 55); Member States shall promote high levels of compliance and, where necessary, prosecute and sentence cases of non-obedience (Articles 72, 73).

Article 65 (1) and (3) of Regulation (EC) No. 1107/2009 refers to different types of phrases to be put on the label of a PPP in order to advise the user on any necessary risk mitigation measures:

- Safety provisions are laid down in Directive 1999/45/EC (transitional until 1 June 2015, afterwards phrases from Regulation (EC) No. 1272/2008 apply). These are common for all chemicals falling under the REACH Regulation.
- Safety provisions laid down in Annex III to Regulation (EU) No. 547/2011. These provisions are specific for PPPs and are harmonized (SP-phrases, which are reproduced in [Chapter 3.2](#)).
- Any additional specific phrase considered necessary by a Member State to protect human or animal health or the environment. Any such additional phrase must be notified, together with an explanation, to the Commission and all other Member States, in order to consider them for an inclusion into Annex III to Regulation (EU) No. 547/2011.

The zonal system of mutual recognition can only work if risk mitigation measures are harmonized between Member States as far as possible. This does not necessarily mean that all Member States must exclusively use the same set of phrases, but the degree of risk reduction needed should be determined at zonal level and a common understanding of the effectiveness of single risk mitigation measures has to be developed. A classification of measures according to their effectiveness would ease their harmonized use. Article 36(3) explicitly recognizes the role of risk mitigation measures, which address specific needs in a certain Member

State. The purpose of risk mitigation measures is mitigating the possible risk of PPPs so, that there is no harmful or unacceptable effect from the use of these products. They must be concrete enough to assure that the protection goal is achieved and flexible enough to allow users to apply the right measures in a practical use situation. Member States shall describe the degree of risk reduction expected when using a specific risk mitigation measure.

3.1.2 The Sustainable Use Directive (SUD)

Directive 2009/128/EC on the sustainable use of PPPs is a piece of legislation that is not dealing with the authorization and placing on the market of PPP, but covers the use phase of these products. It provides measures that are complementary to those foreseen in other areas of EU legislation.

The SUD strives to integrate a high level of protection with the principle of sustainable development (recitals 3, 22, 23). With these objectives, it goes beyond the concept of "no harmful or unacceptable effect," which is the basis for granting authorization and its objectives are the reduction of the impact of PPP use and the promotion of alternatives to conventional phyto-protection practices.

Measures to be taken under this Directive are not related to single products, but follow rather a generic approach to reduce the overall risk and impact of PPP use. Requirements for application machinery, sales of products, or training and licensing of farmers are outlined in this document. Other items like aerial application or use of PPP in specifically protected areas (Water Framework Directive 2000/60/EEC and 2006/118/EC; Biodiversity in Directives 79/409/EEC and 92/43/EEC) are regulated, too. Rules for integrated pest management (IPM) are laid down. A national action plan (NAP) must be implemented by each Member State summarizing all measures to be taken for reducing risks, goals to be reached in a specific period are set, and results must be reported to the European Commission. Ideally, all stakeholders work together to focus their activities and efforts to reach specific goals outlined in the NAP. All these activities must be implemented by the national plant protection acts.

3.1.3 Contribution of industry and farmer organizations

Article 7 of the SUD requires Member States to raise the awareness of the general public about possible risks coming from the use of PPPs. However, as most of the PPPs are applied by professional users, farmers and authorization holders have an important role for the proper implementation of risk mitigation measures. Hence, authorization holders share the responsibility for a safe use of their products. Beside a correct labeling of products, generic awareness-raising campaigns for risks are a risk mitigation measure, and as such must comply or reflect the conditions of approval and use of products. For example, reducing exposure of surface water from point sources is one such important industry project (see references to TOPPS in [Chapter 4](#) and examples of Stewardship actions in [Chapter 10](#)). Specific awareness-raising campaigns for company advisers and users of a specific compound are another tool. Companies can refrain from selling products in vulnerable areas (e.g., groundwater protection). Other examples include stewardship projects for specific PPPs. Model projects (farms) are run by a few companies where, for example, farming practices for improving the status of biodiversity or to reduce runoff are demonstrated.

In a few Member States farmer organizations play an important role in finding effective risk mitigation measures. They are most important in awareness-raising and increasing acceptance among practitioners. More support to farmers and farmer organizations would increase acceptance of risk mitigation measures among regulators and subsequently availability of products on the market. Appropriate risk mitigation measures are an important element to be considered in assessing whether there is a "significant difference in risk" between a candidate for substitution and an alternative product (Annex IV to Regulation [EC] No. 1107/2009).

3.1.4 Other regulatory frameworks

Ideally, the measures taken under different legislations and by authorization holders and farmers are harmonized as far as possible to reduce risks in the most efficient way. Furthermore, acceptance of risk mitigation measures by practitioners should benefit from harmonized

approaches under different pieces of legislation. Measures to be taken under Directive 2000/60/EC (WFD) to control erosion can have a direct effect on reducing exposure of surface waters by active substances. The articulation of risk mitigation measures to protect non-target terrestrial life, and especially biodiversity, is more complex. Nature conservation and providing habitats in the agricultural landscape does not fall under regulation (EC) No. 1107/2009, but RMM under this regulation may have unintended consequences for nature conservation and habitat provision. As an example, buffer zones applied to hedgerows as a risk mitigation measure to protect insects may prevent laying out new hedgerow habitats, even if money from subsidy programs is available. The more habitats there are in a landscape the higher the resilience of communities and populations against any effects of PPPs. In areas where biodiversity is already low, the remaining species are usually not endangered by the use of PPP. However, indirect effects of using pesticides on biodiversity must be avoided. If the use of insecticides leads to an almost complete eradication of insects in an agricultural landscape because only cropped fields are left – in extreme cases only with one crop – no insectivorous birds can live in this area. The use of PPP should not preclude the recolonization of the aforementioned landscapes. Laying out of new habitats to increase the recovery potential and avoid indirect effects on biodiversity or other risk mitigation measures may be needed to avoid indirect effects at least of products posing highest risks. Balancing these issues against the need for efficient food production is a challenge. Joint actions under Regulation (EC) No. 1107/2009, Directive 2009/128/EC (NAPs) together with an intelligent use of subsidy programs are needed to strengthen the carrying capacities of agricultural landscapes.

3.2 Experience from setting risk mitigation measures in Member States

Over the last twenty years, Member States have used mitigation measures to reduce the risk to the environment for several purposes and in different ways. Specific rules for protecting areas of drinking water abstraction, or honey bees and birds, and stipulating buffer zones to surface waters are

well established tools and have been widely used for regulatory purposes. Furthermore, new and more specific, tailor-made measures are in use today – for treated seeds or for new groups of organisms, such as terrestrial invertebrates, for example. In addition, risk mitigation measures are needed where new protection goals are being developed, for example in relation to biodiversity, as this has become important over the last few years.

Under Directive 91/414/EEC rules for Member States existed for setting risk mitigation measures. In part, legally binding label phrases were stipulated under national laws to facilitate enforcement of specific restrictions regarded as very important. The product label is the main communication vehicle by which the user is informed of the requirements for a safe and effective use of a product. The Safety Precautions Phrases (SP-phrases) are among the information that appears on the label, and aim at providing pesticide users with directions for use that effectively mitigate the exposure of and risks to human, animal health, and the environment. These SP-phrases are most often deduced from the conclusions of risk assessments. Details on these risk assessments may be found in guidance documents on the risk assessment, as for example in the EFSA Guidance Document for Birds and Mammals (EFSA 2009), in the SANCO document on terrestrial ecotoxicology (SANCO/10329/2002 rev 2), or guidance documents for non-target arthropods (Candolfi et al. 2002, Alix et al. 2012).

In Annex V of the aforementioned Directive, SP-phrases for protecting the environment were listed and afterwards reproduced in Regulation (EU) No. 547/2011. Table 3.1 reproduces the current SP-phrases with relevance for the protection of the environment, as they may be found in Regulation (EU) No. 547/2011:

Table 3.1: Safety precautions phrases with relevance to the environment as in Regulation (EU) No. 547/2011.

Safety Precaution Phrase	Criteria for Use of EU ‘Safety Precaution’ Phrase
SPe 1:	

<p>To protect groundwater/soil organisms do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (time period or frequency to be specified).</p>	<p>The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.</p>
<p>SPe 2:</p> <p>To protect groundwater/effects on aquatic organisms do not apply to (soil type or situation to be specified) soils.</p>	<p>The phrase may be assigned as a risk-mitigation measure to avoid any potential contamination of groundwater or surface water under vulnerable conditions (e.g. associated to soil type, topography, or for drained soils), if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures are necessary to avoid unacceptable effects.</p>
<p>SPe 3:</p> <p>To protect [aquatic organisms/non-target plants/non-target arthropods/insects] respect an unsprayed buffer zone of (distance to be specified) to [non-agricultural land / surface water bodies].</p>	<p>The phrase shall be assigned to protect non-target arthropods, if an evaluation according to the Uniform Principles shows that, for one or more of the labelled uses, that risk mitigation measures are necessary to avoid unacceptable effects.</p>
<p>SPe 4:</p> <p>To protect [aquatic organisms/non-target plants] do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks, and other situations with a high risk of runoff.</p>	<p>Depending on the use pattern of the plant-protection product, Member States may assign the phrase to mitigate the risk of runoff in order to protect aquatic organisms or non-target plants.</p>
<p>SPe 5:</p> <p>To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.</p>	<p>The phrase shall be assigned to plant-protection products, such as granules or pellets, which must be incorporated to protect birds or wild mammals.</p>
<p>SPe 6:</p> <p>To protect birds/wild mammals remove spillages.</p>	<p>The phrase shall be assigned to plant-protection products, such as granules or pellets, to avoid uptake by</p>

	birds or wild mammals. It is recommended for all solid formulations, which are used undiluted.
SPe 7: Do not apply during bird breeding period.	The phrase shall be assigned when an evaluation according to the uniform principles shows that for one or more of the labelled uses such a mitigation measure is necessary.
SPe 8: Dangerous to bees./To protect bees and other pollinating insects do not apply to crop plants when in flower./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./ Do not apply when flowering weeds are present./ Remove weeds before flowering./Do not apply before (state time).	The phrase shall be assigned to plant-protection products for which an evaluation according to the uniform principles shows for one or more of the labelled uses that risk-mitigation measures must be applied to protect bees or other pollinating insects. Depending on the use pattern of the plant-protection product, and other relevant national regulatory provisions, Member States may select the appropriate phrasing to mitigate the risk to bees and other pollinating insects and their brood.
SPr 1*: The baits must be securely deposited in a way so as to minimise the risk of consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.	To ensure compliance of operators the phrase shall appear prominently on the label, so that misuse is excluded as far as possible.
SPr 2*: Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it shall be mentioned.	The phrase shall appear prominently on the label, so that accidental poisoning is excluded as far as possible.
SPr 3*: Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.	To avoid secondary poisoning of animals the phrase shall be assigned to all rodenticides containing anticoagulants as active substances.

*this phrase applies to rodenticide products.

In spite of this regulatory framework, overall the degree of harmonization among Member States is low and that may slow down the process of working through zonal applications under Regulation (EC) No. 1107/2009 considerably. Developing harmonized and standardized risk mitigation measures is an important prerequisite to ease zonal authorizations and mutual recognition of registrations allowing one Member State to employ the same risk mitigation measures used by another Member State. A common terminology about all aspects of risk mitigation measures is needed. If there is a need to use different SP-phrases, regulators should be able to judge on the equivalence of different (national) measures. Networks amongst regulators responsible for decision-making on risk mitigation measures should facilitate the process of coming to harmonized approaches.

3.3 A step towards harmonization across Europe

The analysis of the survey undertaken in Europe in the context of this workshop highlighted a need for a toolbox of risk mitigation measures offering Member States a certain degree of flexibility to adjust for their specific conditions on the one hand, while ensuring a common and consistent approach for the whole EU on the other. A common understanding about the effectiveness of single measures – the degree of risk mitigation expected – must be developed to enable harmonized decisions in zonal authorization procedures. The Commission, in close cooperation with Member States, may wish to keep an official list of risk mitigation measures available where the SP-phrase, together with the degree of effectiveness of the measure and effective alternatives, are outlined. If Member States need such alternatives to ease plant protection under their specific conditions they should propose the degree of risk reduction together with a scientific reasoning to the Commission and Member States. Such a list would facilitate the use of modern risk mitigation measures in all Member States while harmonizing plant protection practices at the same time.

Voluntary measures are preferred because acceptance for such restrictions among practitioners is much higher than legally binding requirements. All

attempts should be made to increase acceptance. Therefore, it is important to involve representatives of farmer organizations when developing concepts of risk mitigation measures. Easy to understand text on the label, thorough explanations in training courses, and informational material are important tools when familiarizing farmers with risk mitigation measures. On the other hand, experience has shown that economic pressures reduce acceptance by farmers, especially for any measure leading to loss of soil or area for producing crops or complicating farming practices. Therefore, legally binding risk mitigation measures and a control system are needed to enforce the SP-phrases. Attention must be paid to the enforceability of a risk mitigation measure. The wording must be clear from a legal point of view because in a few situations control actions may end up in court cases.

High quality education and advice for (professional) users is crucial, as an effective implementation of risk mitigation measures is only possible if users are willing to comply. However, no enforcement strategy can go without controls of compliance, as otherwise it will lose its credibility over time. As it is very difficult to control farmers when spraying products it should be possible - for example - to take soil samples in the middle of a field and within the buffer zone. A clear difference of the two soil concentrations may indicate that the label restriction was followed. Other approaches to control the appropriate use of PPP should be developed. It is the responsibility of Member States to decide upon the choice of the most appropriate control methods and whether they are relevant for requirements under the cross compliance system (Regulation (EC) No 1122/2009). Member States must report the results of their controls to the Commission.

In the core assessment of registration reports (RR) it should be clearly stated whether there is a need for risk mitigation for fulfilling the requirements of regulation (EC) No. 1107/2009. Furthermore, the degree of risk mitigation needed should be defined. Participants felt that the exact level of risk reduction needed should not be given, but rather a grouping of risk in classes would facilitate the regulatory work and communication with farmers. Classes of 50, 75, 90 and 95% risk reduction are well established. Also 99% might be an acceptable class if it is scientifically based. Classes

may call for a single risk mitigation measure or a combination of different risk mitigation measures; e.g. air-assisted boom sprayer in combination with 90% drift reducing nozzles and end-nozzle.

The reference point or scenario for defining the efficiency of a risk mitigation measure – the degree of risk reduction – should be the same as in the corresponding risk assessment scheme. If runoff PECs are calculated for a field with a length of 100 m the degree of risk reduction should not be determined for one with a length of 10 m. Participants felt that the ongoing use of different exposure models within risk assessments schemes complicates the setting of harmonized risk mitigation measures considerably. Scientific data and a robust scientific reasoning for determining the degree of risk reduction by a single measure is needed, but often complicated by a lack of data and other uncertainties. Furthermore, legal requirements, practicality, acceptance of measures by practitioners, and other non-scientific items are to be considered when setting risk mitigation measures. Therefore, in conclusion, pragmatic approaches need to be found, balancing all important requirements with each other while achieving the legally required safety level.

At least within one zone a common understanding among Member States must be developed regarding the maximum acceptable degree of risk reduction that can be achieved. Otherwise a product or use would be available in one Member State, but not in the other. If a Member State accepts a maximum buffer zone of 100 m to surface waters while another accepts only 20 m, and no other risk mitigation measures are available critical uses can be authorized in the first Member State, but not in the second. For example, in some Mediterranean areas even 500 m could, in principle, be acceptable as there are several crops and uses where no surface waters are around while applying the product.

For all relevant risks (e.g., surface or groundwater, birds and mammals, non-target arthropods, in- and off-crop), exposure routes, and other items, lists can be developed. Such lists might be structured according to the risk reduction class mentioned (e.g., 75%) and, for example, through exposure routes. Member States are free to use and apply the most relevant and suitable measures for their agriculture and conditions. For example, in one

Member State spray drift reducing machinery of class 99% is available while in others even 90% is not.

Using class 75% and the exposure of surface waters via runoff as an example, one measure might be a grassed buffer zone of 10 m, and as an alternative, conservation tillage on the field with a soil cover of 70%. Both measures can be implemented for the same use and reduce the risk respectively. A system of risk reduction points was proposed to ease the use of a combination of risk mitigation measures relevant for the same type of risk and exposure route ([for details see Chapter 4.1](#)). For communication with farmers it might be best to use only these points. The label would contain only the information that use of this product in a specific crop requires the use of a “point/class/star two measure” which could for example correspond to a risk reduction class of 75%.

From a compliance and enforcement point of view, risk mitigation measures that are not use- or product-specific, but rather need to be established before sowing the crop and are effective for the whole season should be handled differently. A grassed buffer zone for reducing runoff must be established when, for example, cereals are sown. Such risk mitigation measures may be regarded as crop-specific.

3.4 Set of possible SP-phrases reflecting the toolbox developed during the MAgPIE workshop

There is no need to change the basic regulatory system of setting risk mitigation measures at the EU-level. However, the investigation of SP-phrases relevant for protecting the environment of regulation (EU) No. 547/2011 as illustrated above, has shown that some might be adjusted to give Member States more flexibility in setting appropriate risk mitigation measures. Furthermore, it should be considered whether an EU Guidance Document on setting risk mitigation measures should be worked out in order to describe a clear framework for Member States facilitating the use of EU-wide harmonized label phrases.

It may be difficult to find the text for an SP-phrase describing the risk mitigation measures to reduce a specific risk in a way that can be used effectively in all Member States. Besides language and translational difficulties, agricultural practices are still different, for example the availability of spray drift reducing machinery varies across Member States. The sensitivity of the public towards effects on the environment is different and may lead to different risk management decisions. Therefore, the SP-phrases should allow Member States some flexibility. Specific parts may be even left open for specifications laid down in official national publications which must be notified to the Commission and other Member States.

During this workshop, participants reviewed existing SP-phrases in order to account for upcoming risk mitigation tools to protect the different compartments of the environment. This led to the proposal of new and revised SPe- or SPr-phrases, so that they better reflect the diversity of the options offered to users to mitigate risks and improve the clarity of the directions provided.

The following table lists these new or revised phrases as deduced from the expert discussions. Where risk mitigation comprises various options, as for example for the reduction of runoff, it is recommended that risk managers communicate with risk assessors in order to implement the options that better reflect their risk management policy.

Workshop participants conducted an initial review of the phrases during the preparation of these proceedings. The wording proposed in these phrases is meant to reflect the diversity of options while reflecting a harmonized language. The proposed SP-phrases have also been reviewed by representative users and farmers and corrected where necessary for more clarity. They are summarized in Table 3.2 below.

Table 3.2: New and revised SPe- and SPr-phrases as deduced from the risk mitigation measures (RMM) toolbox presented in the MAgPIE proceedings. RMM are allocated into the following categories: Buffer Zones (BZ), aimed at reducing exposure of off-crop areas via spray drift; Field Margins (FM) and Compensation Areas (CA), aimed at providing food sources and habitat to off-crop flora and fauna; Spray Drift Reduction Technologies (SDRT),

which involve any technology associated to sprayers, nozzles, or spraying techniques that will reduce the drift; Dust Reduction Technologies (DRT), which involve any technology associated with seed coating, granule manufacture, or drillers to reduce the abrasion of seeds or granules at drilling or to reduce the spread of dust out of the cropped area; Good Agricultural Practices (GAP), which relate to product application (dose and application regime); Crop Management (CM), which relates to agricultural practice in the crop or the field margins aimed at reducing a source of exposure or transfer route; and Bee Management (BM), which relates specifically to measures applied to managed bees to keep them from exposure.

Environmental Area	Risk Mitigation Measure	Category	Related SPe-Phrase in Regulation (EU) No. 547/2001	Proposed New SPe-Phrase in the Context of Regulation (EU) No. 547/2011
Groundwater	Dose of product (reduction/limit) Application frequency (reduction), interval between applications Timing of applications (e.g., overnight; before/after flowering)	GAP	SPe1	Existing phrase – no change: To protect groundwater/soil organisms do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (time period or frequency to be specified).
Groundwater	Soil type	GAP	SPe2	Existing phrase – no change: To protect groundwater/aquatic organisms do not apply to (soil type or situation to be specified) soils.
Groundwater/ drainage	Vulnerable areas	GAP	None	New SPe-phrase: To protect groundwater do not apply this or any other product containing (identify active

				substance or class of substances, as appropriate) in vulnerable areas (areas of drinking water abstraction or other vulnerable conditions).
Groundwater/ drainage	Crop management tools	GAP	None	New SPe-phrase: To protect groundwater the use of this or any other product containing (identify active substance or class of substances, as appropriate) is only allowed if specific management conditions e.g. use of cover crops, band application, others (to be specified) are fulfilled.
Surface water (spray drift) Off-crop	No spray zone Buffer zone of bare soil	BZ	SPe3	Adapted from current SPe3: SPe3: To protect [aquatic organisms/non-target plants/non-target arthropods/ insects] from spray drift respect an unsprayed buffer zone of (distance to be specified) to the edge of the field/surface water bodies]. The edge of the field is either the edge of the crop or, in the presence of a margin strip, the edge of a margin strip (see definition in Chapter 6).
Surface water (spray drift) Off-crop	Wind direction – dependant on spray zone	BZ	SPe3	Additional text to be added to SPe3: The buffer zone may be adjusted as a function of wind speed, wind direction, and temperature conditions based on available recommendations.
Surface water (spray drift) Off-crop	Drift reducing nozzles (incl. adjusted spray pressure, etc.) Special equipment/machinery	SDRT	SPe3	Additional text to be added to SPe3: The buffer zone may be reduced to (distance to be specified) if a combination of spray drift

	(Wings-/Tunnel-/Band sprayer etc.) Directed spraying techniques (one-sided spraying, forward-speed, reflection shield, boom-height adjustment etc.)			reduction technologies such as drift reducing nozzles, special equipment to reduce spray drift or directed spraying technique [is/are] used providing at least (% of drift reduction to be specified).
Surface water (runoff) Off-crop	Vegetated buffer strip	FM	none	<p>In countries where a list of runoff risk mitigation measures provided together with an evaluation of their efficacy (into the form of an official guidance or white book), through e.g., a point-system has been developed, the following phrase could be used:</p> <p>New SPe X1:</p> <p>SPe X1: To protect [aquatic organisms] only apply to fields [adjacent/within Y m to surface water] where approved mitigation measures(s) with [X% reduction of runoff potential/XY runoff mitigation points] are implemented. The official reference for approved mitigation measures is [detail official reference].</p> <p>In countries where recommendations regarding the mitigation of runoff have been derived from modeling or only product-specific mitigation options are intended, the following phrase could be used:</p> <p>New SPe X2:</p> <p>To protect [aquatic organisms/surface water resources] only apply to fields [adjacent /within Y m to surface water] where the following</p>

[measure/measure combinations] were implemented: [detail list of appropriate measures or combinations thereof].

Both phrases could be complemented with the following, to take into account the case of farmlands under a runoff risk diagnosis program, where it is available and accepted by regulatory authorities:

These product-specific runoff mitigation obligations may be superseded by implementing field-specific runoff mitigation measures on the field/farmland, based on the participation in an officially approved national runoff risk diagnosis and management scheme (detail names of officially accepted diagnosis systems).

To tackle the issue of concentrated runoff in agricultural landscapes, the following phrase is proposed:

New SPe Y:

To protect [aquatic organisms/surface water resources] only apply to fields [within Y m to surface water] where concentrated runoff is prevented by appropriate measures (see [detail official reference or whitebook for concentrated flow mitigation measures]).

This sentence could make the prevention of concentrated

				runoff more binding in comparison with relying on good agricultural practice only. A control in the field would be done via the traces of concentrated runoff in-fields (erosion rills or gullies and deposited sediment at field edges).
Surface water (spray drift, runoff) Off-crop In-crop	Multifunctional field margins (e.g., as qualification of a vegetated buffer) Note that in situations where runoff transfers only need mitigation then SPe2-phrases only would be needed	FM	None	New SPe to introduce field margins to protect one or several groups of organisms and mitigate transfers via runoff (multi functional field margins): To protect [birds/mammals/aquatic organisms/non-target arthropods/non-target plants] and limit risks related to situations of runoff, respect a unsprayed non-cropped vegetated buffer zone of (distance to be specified) to [the edge of the field /surface water bodies] which should consist of [wild bird seed mix/wild flower mix/pollen and nectar mix/sown grass] in order to provide the requested benefits.
Surface water (spray drift,) Off-crop In- crop	Landscape-dependant buffer zones	BZ/CA	None	Additional text to be added to a SPe aiming at introducing field margins to protect wildlife: An implementation of this buffer zone for the purpose of wildlife protection may not be needed if recovery area that provide a habitat are already present in the farmland and represent (percentage to be specified) of the farmland surface.
Surface water (spray drift,	Dose of product (reduction/limit)	GAP	None	New SPe proposing adapted Good Agricultural Practices

runoff, drainage) In-crop Off-crop	Application frequency (reduction), interval between applications Timing of applications (e.g., overnight; before/after flowering)			(GAP) to reduce exposure of wildlife or transfers via runoff: To protect [birds/mammals/aquatic organisms/pollinators/non- target arthropods/non-target plants/limit risks related to situations of runoff] respect an application rate of maximum (application rate to be specified)/do not apply this product more than (time period or frequency to be specified)/ do not apply during the bird breeding period (dates may be proposed at MS level)/restrict applications to (dates or growth stages to be specified).
Birds/wild mammals	Incorporation of granules and pellets	GAP	SPe5	Current SPe5 – no change: To protect birds/wild mammals the product must be entirely incorporated in the soil at the end of rows.
Birds /wild mammals	Spillage removal	GAP	SPe6	Current SPe6 – no change: To protect birds/wild mammals remove spillage.
Birds /wild mammals	Restriction with regards to the timing of application	GAP	SPe7	Current SPe7 – no change: Do not apply during bird breeding period (dates may be proposed at MS level).
Birds/wild mammals	Caution with regards to application of repellents	GAP		New SPe-phrase: Add repellents to formulation in order to avoid ingestion by birds and mammals.
Birds/wild mammals	Caution with regards to the application of rodenticides	GAP	SPr1	Current SPr1-phrase – no change: The baits must be securely deposited in a way so as to minimise the risk of

				<p>consumption by other animals. Secure bait blocks so that they cannot be dragged away by rodents.</p> <p>Apply baits in confined places in order to avoid non-target organisms' exposure.</p>
Birds/wild mammals	Caution with regards to the application of rodenticides	GAP	SPr2	<p>Current SPr2-phrase – no change:Treatment area must be marked during the treatment period. The danger from being poisoned (primary or secondary) by the anticoagulant and the antidote against it should be mentioned.</p>
Birds/wild mammals	Caution with regards to the application of rodenticides	GAP	SPr3	<p>New SPr3-phrase:</p> <p>Dead rodents must be removed from the treatment area each day during treatment. Do not place in refuse bins or on rubbish tips.</p> <p>Remove carcasses in order to avoid secondary poisoning of prey birds and carnivorous mammals.</p>
Migratory birds	Caution with regards to application	GAP	none	<p>New SPe-phrase:</p> <p>Do not apply the product on migrant birds resting grounds.</p>
Honey bees Pollinators	<p>Remove or cover bee hive</p> <p>Close hives 1 day before spraying</p> <p>Alert beekeepers</p>	BM	SPe8	<p>Adapted from current SPe8:</p> <p>Dangerous to bees./To protect bees and other pollinating insects do not apply to crop plants when in flower./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./ Do not apply when flowering weeds are present./ Do not</p>

				<p>apply before (state time)./ Respect a flowering strip of [width to be specified] at [distance to be specified] of the treated field.</p> <p>Alert beekeepers prior to applying the product to allow adequate mitigation measures to be taken, and avoid bee colonies' exposure.</p>
--	--	--	--	--

3.5 From the toolbox to the implementation of a procedure in Europe

A toolbox or list of risk mitigation measures must be published by the European Commission in close connection with Member States. National orders specifying the measures to be taken in each Member State must be communicated to the Commission and other Member States to facilitate information exchange and subsequent harmonization among Member States. According to Art. 31 (4.a) of Regulation (EC) No. 1107/2009, Member States are still responsible for setting risk mitigation measures.

To facilitate the implementation of the new type of SP-phrases, these may include a reference to legally binding order that is in force at the Member State-level, in which details of the risk mitigation measure can be stipulated in a way appropriate for each single Member State. As an example for spray drift the following phrase was worked out during the workshop:

SPe3 (new)

To protect [aquatic organisms/non-target plants/non-target arthropods/insects] from spray drift, respect an unsprayed buffer zone of (distance to be specified) to the edge of the [field/surface water bodies]. The edge of the field is either the edge of the crop or, in the presence of a margin strip, the edge of a margin strip.

This new SPe3 can be used for different types of risks, which are mentioned in brackets. Furthermore, the distance to surface waters or hedgerows, or a percentage of risk reduction can be stipulated as appropriate. This new type of SP-phrase would clearly lead to greater harmonization of labels than is currently achievable. At the same time Member States would be able to meet their responsibilities in a flexible and efficient way.

Another example for runoff is given below:

SPe X1 (new):

To protect [aquatic organisms] only apply to fields [adjacent/within Y m to surface water] where approved mitigation measures with [X% reduction of runoff potential/XY runoff mitigation points] are implemented. The official reference for approved mitigation measures is [detail official reference].

With this option harmonization is promoted through an agreement on the level of reduction that needs to be reached. Such a system would move the regulatory focus from the measure itself and primarily put it on the protection goal. It has the potential to achieve a high level of harmonization of risk mitigation between different Member States without forcing a break with current national risk mitigation approaches.

There are legal, technical, or historic reasons why things are defined slightly differently, but harmonization can be achieved in future. Geographical and climatic conditions will prevail and flexibility will be needed when all other items are fully harmonized. The new type of SP-phrases would allow to agree on common protection goals in different national contexts.

3.6 References

Alix A, Bakker F, Barrett K, Brühl CA, Coulson M, Hoy S, Jansen JP, Jepson P, Lewis G, Neumann P, Süßenbach D, van Vliet P eds. 2012. ESCORT 3: Linking Non-Target Arthropod Testing and Risk Assessment with Protection Goal. Pensacola (FL): SETAC Press. 136 p.

Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R and Vogt H eds. 2002. Guidance Document on Regulatory Testing and Risk Assessment

Procedures for Plant Protection Products with Non-Target Arthropods. Pensacola (FL): SETAC Press. 46 p.

- [EC] European Commission. 1979. Council Directive 79/409/EC of 2 April 1979 on the conservation of the wild birds. See Directive 2009/147 below for updated text.
- [EC] European Commission. 1991. Council Directive of 15 July 1991 concerning the placing of plant protection products on the market. L 230/1: 19.08.1991.
- [EC] European Commission. 1992. Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. Official Journal of the European Union. L 206: 22.7.1992.
- [EC] European Commission. 1999. Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of dangerous preparations. L 200/1: 30.07.1999.
- [EC] European Commission. 2000. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. L 327/1: 22.12.2000.
- [EC] European Commission. 2006. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. L 372: 27.12.2006.
- [EC] European Commission. 2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. L 353/1: 31.12.2008.
- [EC] European Commission. 2009a. Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds. L 207/7: 26.01.2010.
- [EC] European Commission. 2009b. Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. L 309/1: 24.11.2009.
- [EC] European Commission. 2009c. Commission Regulation (EC) No. 1122/2009 of 30 November 2009 laying down detailed rules for the implementation of Council Regulation (EC) No 73/2009 as regards cross-compliance, modulation and the integrated administration and control system, under the direct support schemes for farmers provided for that Regulation, as well as for the implementation of Council Regulation (EC) No 1234/2007 as regards cross-compliance under the support scheme provided for the wine sector. Official Journal of the European Union. L 316/65: 2.12.2009.
- [EC] European Commission. 2009d. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides. Official Journal of the European Union. L309/71: 24.11.2009.
- [EC] European Commission. 2011a. Commission Regulation (EU) No. 547/2011 of 8 June 2011 implementing Regulation (EC) No. 1107/2009 of the European Parliament and of the Council as

regards labeling requirements for plant protection products. Official Journal of the European Union. L155/176: 11.6.2011.

[EC] European Commission. 2011. Commission Regulation (EU) No. 547/2011 of 8 June 2011 implementing Regulation (EC) No. 1107/2009 of the European Parliament and of the Council as regards labeling requirements for plant protection products. Official Journal of the European Union. L155/176: 11.6.2011.

[EFSA] European Food Safety Authority. 2009. Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal. 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu.

SANCO. 2002. Draft Working Document Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final, 17 October 2002.