anses
French agency for food, environmental and occupational health & safety

The Director General

Maisons-Alfort, 1 July 2015

Guidelines for issuing decisions on the marketing of plant protection products and adjuvants

These guidelines have been established in the context of activities entrusted to ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, hereafter named "the Agency", through application of Articles L.1313-1 to L.1313-6-1 of the French Public Health Code, last modified by the French Act on the future of agriculture, food and forestry adopted on 13 October 2014. This document presents the principles chosen by the Agency to guide the issuing of decisions on marketing authorisations (MA) for plant protection products (PPP) and adjuvants. It describes the criteria enabling the Agency to exercise its power of judgment leading to individual decisions on the basis of a scientific assessment of authorisation applications taking into account regulations and available supplementary data.

These guidelines were submitted to public consultation in compliance with Articles L. 120-1 and L. 120-2 of the French Environmental Code.

They have been adopted by the Agency and shall be regularly revised after consultation of the committee to monitor marketing authorisations mentioned in Article L. 1313-6-1 of the Public Health Code. They are available on the Agency's website at www.anses.fr.

1. General principles

MA applications for plant protection products shall be assessed in compliance with the uniform principles for assessment of Point 6, Article 29, of Regulation (EC) no. 1107/2009[1], with validated European policy papers and, where appropriate, any national regulations. This assessment leads to a Registration Report written in English and validated by the Member State examining the request in the zone concerned, after consultation of all the Member States in that zone. It also gives rise to a summary document in French giving the conclusions of the assessment: a synopsis of the Agency's assessment or examination of the mutual recognition dossier if the latter was examined by another Member State in the same zone.

Assessment conclusions indicate, for each assessment criterion mentioned in the annex of Regulation (EU) no. 546/2011[2], whether the result complies with EU regulations, complemented by European guidance documents. They include any restrictions on use and/or regulatory risk

[1] Regulation (EC) no. 1107/2009 of the European Parliament and 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.

[2] Regulation (EU) no. 546/2011 of the Commission adopted on 10 June 2011 implementing Regulation (EC) no. 1107/2009 of the European Parliament and the Council as regards uniform principles for assessment and authorisation of plant protection products.

management measures, together with proposed additional management measures that appear necessary in view of assessment results. They also specify, if relevant, the uncertainties arising from missing and/or contradictory data identified during the assessment procedure.

The application is assessed and validated within the Agency by the Regulated Products Assessment Department (DEPR), which acts independently from the Market Authorisations Department (DAMM), responsible for establishing draft decisions, according to the principle of functional separation between risk assessment and management. The Agency's quality management system, certified to ISO 9001 and regularly audited by an independent certifying body, guarantees traceability throughout the process.

In accordance with European regulations, and especially with uniform principles relating to the decision-making process included in Regulation (EU) no. 546/2011, the general principle to be applied to issuing of MAs is to only grant authorisation if, for all or part of the claimed uses, the assessment reveals compliance with all regulatory requirements. In this context, the authorisation will be issued only for uses that comply with these requirements, including in the decision any restrictions and appropriate risk management measures based on assessment results.

These general principles may partially apply to adjuvants covered by Regulation (EC) no. 1107/2009, but for which the authorisation procedures and data and assessment requirements are not yet standardised throughout Europe.

The applicant will be notified of Agency decisions, which are also made public via the electronic register of decisions, rapidly accessible on the Agency's website. The assessment conclusions will also be posted on the website.

Part A of the Registration Report per zone, written by the Agency, shall be made available on the Agency's website. Part B of this same Registration Report, also written by the Agency, will be available on request once confidential items have been rendered unidentifiable.

2. Cases requiring further examination

In certain cases, the DAMM may need an additional examination of the application, depending on the type of application and/or the result of the assessment, in order to prepare the draft decision. The cases identified are as follows:

- When all or some of the risk management measures associated with the results of the assessment raise questions of feasibility in the field guaranteeing efficacy;
- When new data are produced either as a result of the assessment—particularly data from after regulations governing approval of the active substance—or from vigilance or surveillance networks;
- When data on the health and plant health consequences of the absence of PPPs deserve to be taken into account in the decision-making process;

- When the product contains an active substance leading to the implementation of a comparative assessment and when a more detailed analysis of the practical and economic consequences of different possible alternatives is necessary.

In these various cases, the MA monitoring committee covered by the French Act on the future of agriculture may be consulted by the Agency to shed light on decisions to be taken, particularly on the management measures relating to MAs but also on the agronomic benefits to be drawn from the different plant health solutions available, including biocontrol solutions, and their socio-economic impact.

2.1. Examination of the feasibility of proposed risk management measures

The risk management measures related to an MA decision may concern, non-exhaustively, requirements on product labelling, product packaging, storage and preparation, conditions of use (frequency, time intervals with which to comply, weather conditions, incompatibility between treatments, untreated areas, etc.), the protection of human and animal health together with the environment (e.g. water and soil) and resistance management.

Some of these measures are defined by regulations in a general framework then tailored according to the assessment. Others are a direct result of the assessment of a given MA application. By selecting the most common risk management measures, the Agency has drawn up an inventory of these management measures.

The list of the various risk management measures thus inventoried is appended.

With respect to the MA decision-making process:

- If the assessment concludes that the product complies with European regulations with, if applicable, some of the management measures included in the annex, the MA decision will include these management measures.

- If the assessment reveals the need for management measures not included in the annex, their efficacy and practicability shall be specifically examined before any decision is reached. This may cover more appropriate management measures guaranteeing the same efficacy, based on decision trees for example.

The list of risk management measures shall be regularly revised to take into account experience and changes to regulations after consulting the MA monitoring committee. The updated list shall be made public on the Agency's website. The Agency may also put forward recommendations to the ministries concerned for management measures that cut across individual application dossiers.

2.2. Taking into account additional data and uncertainties

Several situations warrant further examination before an authorisation decision is issued:

- When the assessment has identified new scientific and technical knowledge, particularly new toxicology or eco-toxicology data likely to challenge the approval conditions of the active substance, but not yet included in regulations: beyond the assessment carried out

with regulatory values currently in force, the DEPR will perform an additional assessment taking into account the latest data that it considers admissible. For example, in the hypothesis that this additional assessment would reveal an unacceptable risk according to the uniform principles of assessment and authorisation of PPPs mentioned in Point 6 of Article 29 of Regulation (EC) no. 1107/2009, without it being possible to define risk mitigation measures, authorisation will be refused for the uses concerned. The Agency will inform the other Member States. Furthermore, the Agency will ask the ministries to ensure that a request for the rapid re-examination of the active substance and maximum residue limits (MRL) is submitted to the European Commission if the new data are the result of a process other than that of approval under the terms of Regulation (EC) no. 1107/2009.

- Taking into account data from phytopharmacovigilance (PPV) schemes as defined in Article L253-8-1 of the French Rural and Maritime Fishing Code: the scientific assessment of an application and decision include taking into account data from PPV schemes (presence or absence of adverse effects on humans, farm animals—including honey bees—crops, biodiversity and wildlife, presence or absence of impacts on water, soil, air quality and food, or emergence of resistance), particularly during renewal of a currently authorised product. The consequences of these data do not only come under the individual decisions on product authorisation. They may justify other types of risk management measures to be taken by the Agency, ministries or—on a more local scale—prefects, or the revision of current measures.

- Taking into account uncertainties: when new data reveal uncertainties that may call into question authorisation conditions, the Agency shall investigate whether, according to the precautionary principle mentioned in Point 4 of Article 1 of Regulation (EC) no. 1107/2009, it would be advisable to take certain proportionate management measures pending additional data. Data from phytopharmacovigilance schemes may shed light on the decision, along with possible alternatives identified in the context of a comparative assessment.

- When new scientific data may justify a change in or withdrawal of an MA currently in force:

    - When new scientific data arising from PPV schemes or special events indicate that there is no longer compliance with one of the regulatory criteria, the Agency re-examines the authorisation without waiting for expiry of the current MA in application of Article 44 of Regulation (EC) no. 1107/2009. If the non-compliance is confirmed, the Agency withdraws or modifies the authorisation. The Agency first informs the authorisation holder, who is allowed to make observations or provide additional information. When the Agency proceeds to withdraw or change an MA, it immediately informs the authorisation holder, Member States, EFSA and the French Ministry of Agriculture, which informs the European Commission;

    - When new scientific data produced by the PPV scheme or special events reveal a serious risk for human or animal health or the environment, Article 71 of Regulation

(EC) no. 1107/2009 on emergency measures grants a Member State the right to immediately restrict or prohibit use and/or sales of the substance or product when the Commission has not dictated emergency measures in compliance with Articles 69 and 70 of Regulation (EC) no. 1107/2009. In this case, ANSES immediately informs the other Member States and the Commission. These interim protective measures on a national scale may remain in force until EU measures are adopted according to the committee procedure described in the aforementioned regulation.

- When a mutual recognition procedure is submitted to ANSES, should the risk mitigation measures recommended by the Member State examining the authorisation application be considered inapplicable, insufficient or unsuitable in France due to specific environmental or agricultural conditions: the Agency may add other risk management measures to the authorisation, or may decide that some of the requirements based on uniform principles fail to comply. The Agency may investigate whether, under the terms of Article 36.3 of Regulation (EC) no. 1107/2009, the MA should be refused or limited to certain uses. In this case, the Agency immediately informs the applicant and the Ministry of Agriculture, which informs the European Commission. The Agency provides the technical or scientific evidence to back up this decision.

- When uses involve a challenge to human or plant health: health risks (e.g. poisonous plants or mycotoxins) or plant health risks (such as unplanned or minor uses, resistance management, control of emerging pests, diseases, invasive species or of a harmful organism subject to quarantine or mandatory control measures). Particular attention shall be paid to the conditions under which products could be approved while complying with uniform principles to rise to these health or plant health challenges without questioning the requirements needed for risk assessment.

2.3. Implementation of a comparative assessment

For all PPPs containing an active substance on the candidate list for substitution[3] (substances with certain hazardous features justifying a search for substitute solutions whenever possible), the assessment prior to issuing an MA decision shall include a comparative assessment for each use in compliance with the requirements of Article 50 of Regulation (EC) no. 1107/2009, within the specified timeframe with the exception of cases covered by Point 3 of this same Article.

In compliance with the principle of substitution, the Agency shall not authorise or shall limit the use of a PPP for a given crop that contains such a substance when the comparative assessment weighing out the risks and benefits reveals that:

[3] In accordance with Article 80(7), a candidate list of substances for substitution shall be drafted by the European Commission. At the time of writing, this candidate list of active substances for substitution is included in Commission Implementing Regulation (EU) no. 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) no. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution.

- there are already other solutions for the claimed uses (other authorised PPPs or non-chemical methods of prevention or control) that are significantly safer for human or animal health or the environment;
- and that substitution by these alternative solutions has no major economic or practical drawbacks;
- and that the chemical diversity of active substances or crop pest control and prevention practices are able to reduce the emergence of resistance as far as possible;
- and that the consequences on authorisations for minor uses are taken into account.

In exceptional cases and when there is a non-chemical method of prevention or control for the same use, commonly used in France, a comparative assessment may also be carried out when examining the application for authorisation of a product not containing a substance to be substituted nor a low-risk active substance in accordance with Article 50(2) of Regulation (EC) no. 1107/2009.

The comparative assessment of a product shall comply with dedicated European guidance documents:

- document SANCO/11507/2013 rev.12, “Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) no. 1107/2009” published by the European Commission on 10 October 2014;
- document EPPO PP 1/271(1), “Guidance on comparative assessment” published in 2011 by the European and Mediterranean Plant Protection Organisation;

When implemented, the comparative assessment shall be the subject of a specific document retracing the answers provided at different steps of the procedure. This document will be attached to the assessment’s conclusions and made public along with them.

Marc Mortureux

KEYWORDS

Guidelines, decision, marketing authorisation, MA, plant protection products, adjuvants

ANNEX

Risk management measures for plant protection products and adjuvants

This document is an inventory of the risk management measures required for the marketing authorisation of a plant protection product or adjuvant, following risk assessment, and which appear the most frequently. The risk management measures are classified by topic.

They complement the cross-cutting management measures from general regulatory provisions, mentioned in point 1 of the present annex (which may in particular concern residents and non-professional uses, for example).

The restrictions on use resulting from the risk-benefit assessment are not considered as risk management measures. They specify the scope of use. Various reasons may lead to restrictions on use, including a lack of data on residues or efficacy, or a potential or proven risk for the consumer.

This annex will be regularly updated.

1. GENERAL REGULATORY PROVISIONS DETERMINING CROSS-CUTTING RISK MANAGEMENT MEASURES

The cross-cutting risk management measures relating to plant protection products (PPPs) and adjuvants are drawn from various texts named below. This list is given for information only and is likely to change over time.

List of texts from which cross-cutting risk management measures are drawn (for information only):

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 labelling requirements for plant protection products

Act No. 2014-1170 of 13 October 2014 on the future of agriculture, food and forestry

Order of 28 November 2003 on the conditions of use of insecticides and acaricides for agricultural usage with a view to protecting bees and other pollinating insects

Order of 9 November 2004 defining the classification criteria and labelling and packaging conditions for dangerous preparations and transposing Directive 1999/45/EC of the European Parliament and 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 labelling of dangerous preparations

Order of 28 February 2005 modifying the Order of 6 September 1994 implementing Decree no. 94-359 of 5 May 1994 on the control of plant protection products

Order of 12 September 2006 on placing on the market and use of products referred to in Article L. 253-1 of the Rural and Maritime Fishing Code

Order of 5 July 2006 on general conditions of use of certain fumigants for agricultural usage and specific provisions on sulphuryl fluoride

Order of 13 January 2009 modified by the Order of 13 April 2010 on conditions for coating and using seeds treated with the products referred to in Article L. 253-1 of the Rural Code with a view to limiting the emission of dust during factory processing

Order of 7 April 2010 on the use of tank-mixtures of products mentioned in Article L. 253-1 of the Rural Code

Order of 30 December 2010 prohibiting the use of certain plant protection products by non-professional users

Order of 30 December 2010 on packaging conditions for plant protection products able to be used by non-professional users

Order of 27 June 2011 prohibiting the use of certain products referred to in Article L. 253-1 of the Rural and Maritime Fishing Code in areas hosting the general public or groups of vulnerable persons

Order of 15 September 2014 on conditions of aerial crop spraying of products referred to in Article L. 253-8 of the Rural and Maritime Fishing Code

Notice in the *Journal Officiel* of 8 October 2004 for all holders of marketing authorisations for commercial specialties based on glyphosate (or N-(phosphonomethyl)glycine)

2. SPECIFIC RISK MANAGEMENT MEASURES ARISING FROM THE ASSESSMENT THAT COULD BE REQUIRED PRIOR TO ISSUING A MARKETING AUTHORISATION

Specific risk management measures may be required before an MA is issued for plant protection products and adjuvants if the assessment has revealed a risk.

The following tables list the specific risk management measures appearing the most frequently in MA decisions.

Certain standard phrases indicating specific risks and their application criteria are detailed in Regulation (EU) no. 547/2011.

MEASURES CONCERNING PHYSICO-CHEMICAL PROPERTIES OF THE PPP OR ADJUVANT

Topic	Management measures	Regulations	Details
Storage	Do not exceed XX °C during storage	-	This measure is justified when it is expected or cannot be ruled out that the active substance may be degraded and/or the product become unstable at storage temperatures above the given temperature.
Storage	Store at room temperature	-	This measure is justified when it is expected or cannot be ruled out that the active substance may be degraded and/or the product become unstable at storage temperatures above room temperature.
Storage	Protect from freezing	-	This measure is justified when it is expected or cannot be ruled out that the product may be degraded at storage temperatures below or equal to 0°C.
Technical property	Stir during application as per good farming practices	-	This measure is justified when there is a risk of the technical properties of the product changing if the mixture in the tank is not constantly stirred throughout application.
Non-homogeneous preparation before and/or after storage (phase separation)	Stir before application	-	This measure is justified when it is likely that the product's technical properties change should the product not be stirred prior to use.
Pourability	Rinse the packaging at least twice before disposal	-	This measure is justified to avoid any risk of environmental pollution for products that are not easy to pour.

MEASURES CONCERNING EXPOSURE OF THE OPERATOR, BYSTANDERS AND WORKERS

Topic	Management measures	Regulations	Details
Safety of operators / workers	Recommendations on personal protective equipment[4] (PPE). See example below.	-	In the context of risk mitigation measures, the applicant recommends that operators and workers wear PPE. ANSES evaluates the recommendations in terms of comfort, compatibility with the activity, availability on the market and level of protection required in relation to the risk assessment.

Example of applicants' recommendations evaluated by ANSES

Application using an air blast / boom sprayer

- The operator should wear:

- ***when mixing/loading***
  - Nitrile gloves certified to EN 374-3;
  - Working coverall in splash-resistant 65% polyester/35% cotton with a fabric weight of 230 g/m² or more;
  - Partial PPE (long-sleeved overall or apron) of category III and type PB (3) to be worn over the abovementioned coverall;
- ***during application***

  When applied using a tractor with cab
  - Working coverall in splash-resistant 65% polyester/35% cotton with a fabric weight of 230 g/m² or more;
  - Single-use nitrile gloves certified to EN 374-2 in the event of having to work on the equipment during the spraying phase. In this case, the gloves must only be worn outside the tractor cab and stored outside the cab after use;

  When applied using a tractor without cab

  Boom sprayer (spraying downwards):
  - Working coverall in splash-resistant 65% polyester/35% cotton with a fabric weight of 230 g/m² or more;
  - Single-use nitrile gloves certified to EN 374-2 in the event of having to work on the equipment during the spraying phase.

  Air blast sprayer (spraying upwards):
  - Protective hooded coverall of category III and type 4;

  - Single-use nitrile gloves certified to EN 374-2 during application and in the event of having to work on the equipment during the spraying phase;

[4] Action is ongoing concerning personal protective equipment for PPPs. It aims to certify equipment currently considered as work clothes but which may be used under certain conditions to reduce exposure. Their effectiveness needs to be guaranteed. This work should be finalised in the coming months; particularly thanks to international standardisation (ISO standard 27065 currently under review). This project is being monitored by the departments of ministries of agriculture and labour on a national and European scale.

- ***when cleaning the spraying equipment***
  - Nitrile gloves certified to EN 374-3;
  - Working coverall in splash-resistant 65% polyester/35% cotton with a fabric weight of 230 g/m² or more;
  - Partial PPE (long-sleeved overall or apron) of category III and type PB (3) to be worn over the abovementioned coverall.

Topic	Management measures	Regulations	Details
Safety of workers	Re-entry interval (number of hours) in accordance with the Order of 12 September 2006.	French Order of 12 September 2006	This measure applies to all products applied by spraying or dusting with powder an *in situ* crop with the exception of those for amateur gardens. It aims to limit worker exposure. The re-entry interval before returning to the crop depends on the classification following product assessment.
Safety of amateur gardeners	Re-entry interval: wait until the treated zone is completely dry.	-	This measure applies to all products for amateur gardens to limit exposure.
Safety of operators / workers	In accordance with the Order of 9 November 2004, skin contact must be avoided for all products containing pyrethroids, which can lead to paraesthesia.	French Order of 9 November 2004	This measure applies to all products containing pyrethroids and aims to limit exposure.

Topic	Management measures	Regulations	Details
Safety of operators / workers Fumigation with sulphuryl fluoride		Order of 5 July 2006	This measure applies to products containing sulphuryl fluoride for fumigation. It aims to control practices and limit exposure.

Topic	Management measures	Regulations	Details
	For treatment in fumigation chambers or containers: - Use DGAL-approved fumigation chambers (checked for airtightness); - Ensure that the preparation is to be used by somebody qualified for this type of product and wearing self-contained breathing apparatus (SCBA); - Ensure the operator monitors operations of fumigation and off-gassing with a mandatory 10-metre safety perimeter and aeration time enough to maintain an acceptable concentration (below the acceptable operator exposure concentration (AOEC) of 2 ppm); - Measure the concentration of sulphuryl fluoride (below the AOEC of 2 ppm) before authorising outward or inward movement to the treatment chamber; - Wear SCBA during fumigation and aeration operations.”		

MEASURES CONCERNING RESIDUES AND CONSUMER EXPOSURE

Topic	Management measures	Regulations	Details
Possible residues in the following crops (rotation) or replacement crops (should the crop fail)	In the event of crop failure, do not plant/sow (X) less than (X) months after treatment with substance (X).	-	This measure is justified when it is expected or cannot be ruled out that the MRL for the following crop will be exceeded.
Possible residues in the following crops (rotation) or replacement crops (should the crop fail)	For crops in rotation, for which substance (X) is not authorised, observe an interval between the product's last application and sowing/planting the following crop of: - (X) days for (crop X), - (Y) days for (crop Y), - etc.	-	This measure is justified when it is expected or cannot be ruled out that the MRL for the following crop will be exceeded within an interval shorter than those mentioned.
Risk of exceeding the MRL for the replacement crop if treated with a product containing the same active substance	Observe an interval of (X) days before sowing or planting a new crop if crop growth is prematurely interrupted, except for crops for which products containing (X) are authorised. Do not apply products containing (X) on replacement crops.	-	This measure is justified when it is expected or cannot be ruled out that the MRL for the following crop will be exceeded in the case of crops for which the active substance is authorised if this active substance is planned to be used on the following crop.
Risk of exceeding the MRL related to multiple foliar applications of substances generating the same residue	Limit applications of preparations containing active substances able to generate a total of (X) kg of phosphonic acid equivalent per hectare per year on crop (X). "	-	Several active substances can lead to phosphonic acid in the harvested products: e.g. potassium phosphonate, disodium phosphonate and fosetyl. This measure is justified when it is expected or cannot be ruled out that the MRL will be exceeded due to the cumulative use on the same plot of such active substances.
Risk of exceeding the MRL related to applications of the same substance on the same crop by different pathways	Do not apply preparation (X) [or any other preparation containing (X)] by two different methods on the same crop (soil, seed or plant treatment, treatment of aerial parts).	-	This measure is justified it is expected or cannot be ruled out that the MRL will be exceeded following applications of the same active substance on the same crop using different methods of application.

MEASURES CONCERNING RISKS FOR THE ENVIRONMENT (ENVIRONMENTAL MEDIA, FAUNA AND FLORA)

Topic	Management measures	Regulations	Details
Water pollution	SP 1: “Do not contaminate water with the product or its container. [Do not clean application equipment near surface water. / Avoid contamination via drains from farmyards and roads.]"	Regulation (EU) no. 547/2011	This measure applies to all plant protection products and aims to protect the environment.
Groundwater	SPe 1: “To protect groundwater, 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]."	Regulation (EU) no. 547/2011	Frequency, number of applications or period of application determined during the assessment. This measure is justified when a risk of groundwater contamination has been identified relating to the properties of the active substance and its metabolites (i.e. mobility and persistence of the active substance).
Groundwater	SPe 2: “To protect groundwater, do not apply to [soil type or situation to be specified] soil."	Regulation (EU) no. 547/2011	Soil type or situation identified during the assessment. This measure is justified when a risk of groundwater contamination has been identified relating to the behaviour of the active substance and its metabolites influenced by the type of soil (e.g. when the mobility and/or persistence of the active substance are influenced by the soil’s pH).
Soil organisms	SPe 1: “To protect 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]."	Regulation (EU) no. 547/2011	Frequency, number of application or period of application determined during the assessment. This measure is justified when a risk to soil organisms has been identified relating to the properties of the active substance and its metabolites (i.e. persistence of the active substance).

Topic	Management measures	Regulations	Details
Aquatic organisms	SPe 2: “To protect aquatic organisms, do not apply to [soil type or situation to be specified] soils."	Regulation (EU) no. 547/2011	Type of soil or situation determined during the assessment. This measure is justified when a risk for aquatic organisms has been identified relating to the behaviour of the active substance and its metabolites influenced by the type of soil (e.g. when the mobility and/or persistence of the active substance are influenced by the soil’s pH or clay content).
Aquatic organisms	SPe 2: “To protect aquatic organisms, do not apply to [soil type or situation to be specified] soils."	Regulation (EU) no. 547/2011	Situation determined during the assessment. This measure is justified when a risk for aquatic organisms has been identified relating to the properties of the active substance and its metabolites and development of the plot of land. This measure mainly concerns land with effective drains.
Aquatic organisms	SPe 3: “To protect aquatic organisms, respect an unsprayed buffer zone of [distance to be specified] to surface water bodies."	Regulation (EU) no. 547/2011 and Order of 12 September 2006 which determines the distance (5, 20 or 50 m)	Distance determined during the assessment. This measure is justified when a risk for aquatic organisms has been identified relating to spray drift of the active substance or product into surface water and the toxicity of this active substance or product. The maximum distance for the unsprayed buffer zone may be reduced under conditions defined in Annex 3 of the Order of 12 September 2006.

Topic	Management measures	Regulations	Details
Aquatic organisms	SPe 3: To protect aquatic organisms, respect an unsprayed buffer zone of [distance to be specified] to surface water bodies including a strip of permanent, unsprayed plant cover [distance to be specified] metres wide near surface water bodies.	Regulation (EU) no. 547/2011 and Order of 12 September 2006 which determines the distance (5, 20 or 50 m)	Distances determined during the assessment. This measure is justified when a risk for aquatic organisms has been identified relating to spray drift of the active substance or product into surface water or transport by run-off and to the toxicity of this active substance or product. If the value of the unsprayed buffer zone is less than or equal to the value of the strip of permanent plant cover, only the value of the permanent plant cover is taken into account. If the value of the unsprayed buffer zone is greater than the value of the strip of permanent plant cover, the plant cover is included in the unsprayed buffer zone. The maximum distance of the unsprayed buffer zone may be reduced under the conditions defined in Annex 3 of the Order of 12 September 2006.
Aquatic organisms	SPe 4: “To protect aquatic organisms, do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks and other situations with a high risk of run-off."	Regulation (EU) no. 547/2011	This measure is justified for use in non-agricultural areas when a risk for aquatic organisms has been identified relating to transport of the active substance by run-off into surface water and to the toxicity of this active substance.
Non-target arthropods	SPe 3: “To protect non-target arthropods/insects, respect an unsprayed buffer zone of [distance to be specified] to non-agricultural land."	Regulation (EU) no. 547/2011	Distance determined during the assessment. This measure is justified when a risk for non-target arthropods has been identified relating to product spray drift to non-agricultural land and to the toxicity of the product.
Non-target plants	SPe 3: “To protect non-target plants, respect an unsprayed buffer zone of [distance to be specified] to non-agricultural land."	Regulation (EU) no. 547/2011	Distance determined during the assessment. This measure is justified when a risk for non-target plants has been identified relating to product spray drift to non-agricultural land and to the toxicity of the product.

Topic	Management measures	Regulations	Details
Birds and mammals	SPe 5: “To protect birds/wild mammals, the product must be entirely incorporated into the soil; ensure that the product is also fully incorporated at the end of rows."	Regulation (EU) no. 547/2011	This measure applies to plant protection products in granular form or treated seeds incorporated into the soil to avoid birds and wild mammals ingesting the product.
Birds and mammals	SPe 6: “To protect birds/wild mammals remove spillages."	Regulation (EU) no. 547/2011	This measure applies to plant protection products in granular form or treated seeds to avoid birds and wild mammals ingesting the product.
Birds	SPe 7: “Do not apply during the bird breeding period."	Regulation (EU) no. 547/2011	This measure is justified when a risk for birds has been identified for application during their breeding period. The period in question is specified in decisions.
Bees and other pollinating insects	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]."	Regulation (EU) no. 547/2011 and Order of 28 November 2003	All or part of this measure applies systematically to acaricides and insecticides depending on use and other types of plant protection products for the uses for which a risk has been identified for bees.
Pollution of water and amateur gardens	Do not discharge into the sink, gutter or any other surface water body the unused dregs from containers [or water used to wash the sprayer]."	-	All or part of this measure applies to all plant protection products for amateur gardens and aims to protect the environment.
Aquatic organisms and amateur gardens	To protect aquatic organisms, do not apply within 5 metres of a surface water body (such as a well, pond, pool, stream or river).	-	This measure is justified when a risk for aquatic organisms has been identified relating to spray drift of the active substance or product into surface water and to the toxicity of this active substance or product.
Aquatic organisms and amateur gardens	To protect aquatic organisms, do not apply to sloping gardens or impermeable surfaces near surface water bodies such as asphalt, concrete, cobblestones and slabs.	-	This measure is justified when, for use on impermeable surfaces in amateur gardens, a risk has been identified for aquatic organisms relating to transport of the active substance by run-off into surface water and to the toxicity of this active substance.
Non-target plants and amateur gardens	Avoid spray drift and run-off to neighbouring plants.	-	This measure applies to all herbicides for amateur gardens.

Topic	Management measures	Regulations	Details
Bees, pollinating insects and amateur gardens	Do not apply when pollinating and/or auxiliary insects such as bees, bumble bees, ladybirds etc. are foraging in the area.	-	This measure applies to all insecticides and acaricides for amateur gardens.
Earthworms, soil macro-organisms and amateur gardens	Dangerous for earthworms and other soil macro-organisms.	-	This measure applies to products for amateur gardens identified as toxic for earthworms.

MEASURES CONCERNING THE MANAGEMENT OF RESISTANCE

Topic	Management measures	Regulations	Details
Resistance	SPa 1: "To avoid the build-up of resistance do not apply this or any other product containing [identify active substance or class of substances, as appropriate], more than [number of applications or time period to be specified]." Followed by: [or any other preparation with the same active substance having the same mode of action] [whatever the target / not exceeding (X) consecutive applications]. or [In order to control risks of resistance with product (X), it is recommended to follow the restrictions on use per chemical group put forward in [Technical form available for the sector in question].]	Regulation (EU) no. 547/2011	The number of applications is determined during the assessment. This measure is justified when there is a risk of emergence or significant development of resistance relating to product use. In the absence of a technical form, the number of applications is limited depending on the mode of action (see, for example the joint technical memo on managing resistance to fungicides used to control small-grain cereal diseases).