

Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

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Published PDF deposited in [Curve](#) September 2016

Original citation:

European Food Safety Authority , Dehnen-Schmutz, K. , Bastiaans, L. , Chauvel, B. , Gardi, C. , Heppner, C. and Koufakis, I. (2016) Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. *EFSA Supporting Publications*, volume 13 (8): EN-1060

URL: <http://dx.doi.org/10.2903/sp.efsa.2016.EN-1060>

DOI: 10.2903/sp.efsa.2016.EN-1060

Publisher: European Food Safety Authority

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APPROVED: 1 July 2016

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Abstract

Following a request of the European Commission (EC), the European Food Safety Authority (EFSA) initiated a procedure for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health within the context of Article 4(7) of Regulation (EC) No 1107/2009. EFSA established an ad hoc working group (WG) who proposed a methodology for conducting such type of evaluation. The draft methodology was circulated among European Union Member States (MS) for commenting, and was discussed with MS and EC (DG SANTE) representatives during a meeting of the Pesticide Steering Network on 10 March 2016. At the meeting, it was agreed that the WG would draft a protocol for carrying out this type of evaluation. In this technical report, a protocol developed after consultation with MS for providing data and information and their evaluation is presented. The aim of this protocol is to enable a consistent and transparent evaluation of submissions made by applicants in accordance with the derogation detailed in Article 4(7) of Regulation (EU) No 1107/2009 to confirm the lack of other available means capable of controlling an identified serious danger to plant health. The methodology comprises four steps. The starting point for the evaluation is the full list of active substances (a.s.) that are authorised as herbicides for a particular crop or non-agricultural use in the MS. These a.s. need to be classified according to the targeted weed spectrum and time of application. Step one leads to a shortlist of a.s. that are authorised as herbicides for a particular crop or non-agricultural use. Step two involves a herbicide resistance risk classification, which is based on the mode of action of the a.s., and results in a three-level classification of the risk of resistance (high, moderate or low). Step three leads to the evaluation of chemical alternatives. Step four comprises the evaluation of non-chemical alternatives.

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Key words: pesticide, herbicide, weed spectrum, weed resistance, integrated weed management, Article 4(7) of Regulation (EC) No 1107/2009

Requestor: European Commission

Question number: EFSA-Q-2016-00377

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Acknowledgements: EFSA wishes to thank the hearing expert Vaya Kati, EFSA staff members Benedicte Vagenende for the support provided to this scientific output, members of the pesticide steering network and Trond Rafoss who reviewed this output.

Suggested citation: EFSA (European Food Safety Authority), 2016. Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA supporting publication 2016:EN-1060. 18 pp.

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Summary

Following a request of the European Commission (EC), the European Food Safety Authority (EFSA) initiated a procedure for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods within the context of Article 4(7) of Regulation (EC) No 1107/2009. EFSA established an ad hoc working group (WG) who proposed a methodology for conducting such type of evaluation. The methodology proposed by EFSA and the methodologies proposed by Member State Authorities were discussed at a dedicated meeting of the Pesticides Steering Network on 10 March 2016. At this meeting, it was agreed that the WG would develop a draft protocol outlining the data to be provided by the applicant and evidence needed to substantiate that the application of an active substance is necessary to control a serious danger to plant health that cannot be contained by other available means, including non-chemical methods, as well as a methodology for conducting the actual evaluation. The aim of this protocol is to enable a consistent and transparent evaluation of submissions made by applicants in accordance with the derogation detailed in Article 4(7) of Regulation (EC) No 1107/2009 to confirm the lack of other available means capable of controlling an identified serious danger to plant health. EFSA will act as the co-ordinator of the process, will ensure that the methodology is applied consistently, and will issue a scientific report on the evaluation of each herbicide for which derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested. The protocol takes into account relevant international standards (from European and Mediterranean Plant Protection Organization), as well as experiences and suggestions expressed by European Union Member States (MS).

The applicant requesting a derogation under Article 4(7) of Regulation (EC) No 1107/2009 should include information, data and evidence to demonstrate that the substance is necessary to control a serious danger to plant health that cannot be contained by any other available means including non-chemical methods in their dossier, following the methodology and harmonised template presented in this report. MS verify the information provided by the applicant and provide supplementary information, data and evidence from their respective countries and may include other uses that were not requested by the applicant e.g. minor uses. MS evaluate the overall information based on the following methodology comprising of four steps. The starting point for the evaluation is the full list of active substances (a.s.) that are authorised as herbicides for a particular crop or non-agricultural use in the MS where the applicant is requesting a derogation. These a.s. need to be classified according to the targeted weed spectrum and time of application. Step one leads to a shortlist of a.s. that are authorised as herbicides for a particular crop or non-agricultural use. This shortlist is created based on the targeted weed spectrum and the herbicide application time retaining the a.s. having characteristics similar to that of the herbicide under consideration. Exclusion of a.s. from the shortlist (e.g. due to the lack of efficacy against certain weed species contained in the targeted weed spectrum) is possible provided that this is supported by evidence from MS. Step two involves a herbicide resistance risk classification, which is based on the mode of action (MoA) of the a.s., and results in a three-level classification of the risk of resistance (high, moderate or low). This classification is based on the number of unique resistance cases for the specific MoA, reported in the International Survey of Herbicide Resistant Weeds (Heap, 2016). MS reported cases of herbicide resistance for a particular MoA will automatically result in a high-risk classification. Step three leads to the evaluation of chemical alternatives. For each of the three categories of resistance risk, the number of unique MoA will be counted, and this number will be multiplied by a weighing factor (high = 1.5; moderate = 2; low = 3). The scores for each category will be added and, if the total score is higher than 8, this suggests that sufficient chemical alternatives for sustainable herbicide resistance management are available. However, if the total score is lower or equal to 6, it is assumed that there are insufficient chemical alternatives available. Step four comprises the evaluation of non-chemical alternatives. Information on preventive and non-chemical curative methods according to a proposed classification has to be provided by applicants (and MS where appropriate), as well as information on the possible reasons preventing or limiting their applicability leading to an evaluation of non-chemical methods.

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1. Introduction

1.1. Background and terms of reference as provided by the requestor

In May 2015, the European Commission asked the European Food Safety Authority (EFSA) to provide scientific assistance as regards data on evidence that application of the herbicide flumioxazin is necessary to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, within the context of Article 4(7) of Regulation (EC) No 1107/2009.

EFSA set up a working group (WG) on flumioxazin and plant health to prepare a methodology for this assessment because no clear instructions about how to handle Article 4(7) mandates were available to the Member States and EFSA.

On 10 March 2016, EFSA organised a dedicated meeting of the Pesticide Steering Network (PSN) with participation of Member States (MS), the European Commission (EC), EFSA, and the members of the WG on flumioxazin presenting and discussing the methodology proposed by EFSA and the methodologies proposed by Member State Competent Authorities and seeking agreement regarding the methodology to be used in such assessments. The PSN meeting concluded that EFSA shall develop a protocol comprising a methodology to be agreed by all MS for the evaluation of data concerning the necessity of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods and a harmonised template outlining what kind of information, data and evidence need to be presented and evaluated by MS during such an assessment.

There are two possible situations in which applicants may submit information to demonstrate that Article 4(7) can be applied:

1. When a substance already has harmonised classification in accordance with Regulation (EC) No 1272/2008¹ such that one or more of the approval criteria in Annex II, points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 to Regulation (EC) No 1107/2009² are not satisfied
or
2. When the peer review of the active substance proposes a substance classification in accordance with the provisions of Regulation (EC) No 1272/2008 such that one or more of the approval criteria in Annex II, points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 to Regulation (EC) No 1107/2009 are not satisfied.

The process to be followed under situation 1 is as follows: the applicant should include information, data and evidence to demonstrate that the substance is necessary to control a serious danger to plant health that cannot be contained by any other available means including non-chemical methods in their (renewal of) approval dossier following the methodology and harmonised template proposed by EFSA. The rapporteur Member State (RMS) should evaluate the applicant's submission when preparing the Renewal Assessment Report or Draft Assessment Report (RAR/DAR). The RMS can supplement the information provided by the applicant with information from their country and other MS where the applicant requests a derogation, and the RAR/DAR then enters the peer review process.

The process to be followed under situation 2 is as follows: following receipt of the EFSA Conclusion on the peer review of the active substance, the EC requests information from the applicant that demonstrates that Article 4(7) can be applied. The applicant should take note of the protocol prepared by EFSA and provide information, data and evidence outlined in the harmonised template proposed by EFSA. Following the applicant's submission, the EC requests the RMS to consider the information provided. As a following step the RMS asks all MSs to confirm that the uses for which the applicant requests Article 4(7) derogation are authorised and that the use is considered essential to control the serious danger to plant health, giving clear justification for each use that is considered as critical. In

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

² 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. OJ L 309, 24.11.2009 p. 1–50.

addition, all concerned MS can supplement the information provided by the applicant with information from their own country. The RAR/DAR is updated with the evaluations from Member States. Member States may also consider other uses that were not requested by the applicant e.g. minor uses at this stage.

The agreed protocol will be used by all MS when assessing applications for herbicide active substances within the context of Article 4(7) of Regulation (EC) No 1107/2009. EFSA will act as the co-ordinator of the process, will ensure that the methodology is applied consistently and will issue a scientific report on the evaluation of each herbicide a.s. for which derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested.

The process to consider whether an active substance can be approved under the provisions of Article 4(7) is distinct from the comparative assessment of plant protection products under the Guidance document on Comparative Assessment and Substitution of Plant Protection Products³ in accordance with Regulation (EC) No 1107/2009. A decision in accordance with Article 4(7) is taken at Union level for the active substance, whereas comparative assessment is performed at MS level for individual products containing substances that are candidates for substitution. However, EFSA has been asked to take into account the principles of the Guidance on Comparative Assessment when developing the protocol to assess Article 4(7) submissions.

A general mandate for scientific assistance related to the data concerning the necessity of the application of an active substance to control a serious danger to plant health that cannot be contained by other available means including non-chemical methods was sent to EFSA in January 2016. EFSA will provide the methodology and a protocol for each type of pesticide (e.g. herbicide, insecticide, fungicide) separately and afterwards the protocols will be merged to form a single guidance document, taking into consideration the experience gained through the application of the individual protocols to real cases. Before finalising the guidance, EFSA envisions a public consultation in addition to the consultation with the risk assessment organisations in the Member States. The final guidance will be sent to the European Commission for consideration by risk managers.

EFSA is requested, in accordance with Article 31 of Regulation (EC) No 178/2002, to provide a protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods within the context of Article 4.7. of Regulation (EC) No 1107/2009.

1.2. Additional information

1.2.1. Legislation

Regulation (EC) No 1107/2009⁴ lays down the rules for the placing of plant protection products on the market. Articles 4 to 13 of this Regulation outline the requirements, the conditions for approval, including the approval criteria (details given in Article 4 and under points 3.6, 3.7, 3.8, 3.9 and 3.10 of Annex II), and the procedure for the approval or non-approval at EU level of active substances contained in plant protection products. Under Article 4(7) of Regulation (EC) No 1107/2009, derogation from the requirements and conditions for approval for an active substance is provided.

This means 'where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005. This derogation shall not apply to active substances which are or

³ http://ec.europa.eu/food/plant/docs/pesticides-approval_active_substances-guidance_documents-comparative_assessment_substitution_rev_1107-2009.pdf

⁴ 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. OJ L 309, 24.11.2009, p. 1–50.

have to be classified in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A. Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory. At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.'

Complementary to Regulation (EC) No 1107/2009, is Directive 2009/128/EC⁵ establishing a framework for Community action to achieve the sustainable use of pesticides as outlined in Article 1 'by *reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides*'. Recital 19 of Directive 2009/128/EC reminds that 'on the basis of Regulation (EC) No 1107/2009 and of this Directive, implementation of the principles of integrated pest management is obligatory and the subsidiarity principle applies to the way the principles for integrated pest management are implemented. Member States should describe in their National Action Plan how they ensure the implementation of the principles of integrated pest management, with priority given wherever possible to non-chemical methods of plant protection and pest and crop management'.

The recent legislation on invasive alien species (Regulation (EC) No 1143/2014) contains also indications relevant for weed management, especially referring to the cases of alien weed species.

1.2.2. 'Plant health'

In the mandate, reference is made to a 'serious danger to plant health'. In a strict sense, weeds do not directly pose a threat to plant health, but rather affect crop performance indirectly mainly through competition for water, nutrients, light and space. It is however theoretically possible that weeds could host pests and diseases or be parasitic plants.

The European Weed Research Society defines a weed as 'any plant or vegetation, interfering with the objectives or requirements of people' (EWRS, 2008). Therefore, plant health in the context of this report is understood in the sense of the technical definition of the EFSA mission to provide scientific opinions on issues having direct or indirect impact on plant health (Regulation (EC) No 178/2002⁶). Weeds are included in the objectives of national and international plant protection agreements (Schrader & Unger, 2003), and the control of weeds is an important component of crop protection. Plant protection products are regulated by Regulation (EC) No 1107/2009, which also authorises their usage in non-agricultural areas. Therefore, the proposed methodology should also be applicable for assessment of the necessity of a given herbicide in non-agricultural areas such as railways.

On the scale of possible impacts caused by weeds, it does not seem feasible to set a defined measure or threshold for defining these impacts as 'serious' as they will vary depending on crops and other factors affecting crop performance. Therefore, the decision on the classification of impacts on plant health as 'serious' should be taken by the risk managers (e.g. European Commission) on a case by case basis.

1.2.3. 'Herbicide resistance'

The use of herbicides is a major strategy for controlling weeds. This strategy faces increasing problems from the development of herbicide resistances, and alternating the use of herbicides with different modes of action (MoA) is therefore commonly recommended to avoid (or slow down) the development of herbicide resistance (Powles & Yu, 2010; Mortensen et al., 2012). In the proposed methodology for the evaluation of the availability of alternative herbicides, this is taken into account, by securing that a sufficient number of alternative MoA is available for a sustainable herbicide resistance management strategy.

⁵ 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. OJ L 309, 24.11.2009, p. 71–86.

⁶ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

Herbicide resistance is defined as the inherited ability of a plant to survive and reproduce following exposure to a dose of a herbicide normally lethal to the wild type (WSSA-Weed Technology, 1998). Herbicide resistance can also be defined at the plant population level and then refers to the situation where the frequency of herbicide resistant mutants is such that herbicide application in the standard dose does not provide adequate weed control anymore. Different types of mechanisms are involved in herbicide resistance (Délye et al., 2015) and confer different agronomic situations. Once a weed field population contains a too high fraction of herbicide resistant individuals, it is very difficult to reverse this situation. For that reason, the evaluation of alternative strategies (chemical and non-chemical) serves two purposes: the first is to find out if the gap that is left by withdrawing the active substance (a.s.) under consideration can be filled; the second is to find out if a sufficient spectrum of alternatives is left for preventing the development of resistance against the remaining a.s.

In this evaluation, two important notions are considered in determining the 'risk of herbicide resistance'. The first one is that past experience suggests that the likelihood of herbicide resistance development differs widely among the various categories of herbicides. This is what Rotteveel et al. (2011) referred to as the inherent resistance risk of an active substance. They suggested three classes of inherent risk for the active substance (low, medium and high), but did not specify an objective procedure for categorising the different compounds. The European and Mediterranean Plant Protection Organization (EPPO) (2015) argues that, for established MoA's, the best option is to base the risk of resistance on a historical analysis of resistance cases. The Herbicide Resistance Action Committee (HRAC) supports the establishment of a worldwide herbicide resistance database and is suggested as a suitable source for such a historical analysis (HRAC, 2016). The International Survey of Herbicide-Resistant Weeds (Heap, 2016) is located at www.weedscience.org. According to Heap (2016), there are currently 470 unique cases (species × site of action) of herbicide resistant weeds with about 250 species. Twenty-three of the 26 known herbicide sites of action are affected and 160 different herbicides are now reported to have a reduced efficacy. According to this website, herbicide resistant weeds have presently been reported in 86 crops in 66 countries. In the current procedure, the global number of unique cases of herbicide resistance will be used as a proxy for the inherent risk of resistance. In line with the suggestion of Rotteveel et al. (2011), three categories (high, medium and low) are discerned. For specific cases, the classification based on the global data base might be overruled. Particularly for relatively new MoA's this is considered relevant, as in such cases the past history is not likely to reflect their actual risk of resistance. Therefore, if resistance against a MoA has been reported in the Member State, this MoA will be put in the high-risk category, irrespective of the global classification.

The second notion is that frequency of application of a specific herbicide is an important determinant for the development of herbicide resistance. Repeated use of the same MoA will (depending on the MoA type, frequency of use, weed species, plant density), select weed individuals which have a higher ability to survive that specific MoA. This kind of risk deriving from the conditions of use of a herbicide is generally referred to as agronomic risk (EPPO 1/213(4) (2015)). Conditions of use that have the specific purpose of minimizing the appearance of resistance in the field are termed modifiers. Alternating the application of herbicides belonging to different herbicidal classes is an important means for reducing the risk of herbicide resistance (e.g. EPPO 1/213(4)(2015)). To make use of this modifier, sufficient alternative compounds should be available. Nauen et al. (2008) reasoned that at least three MoAs are necessary, of which at least one should ideally be of low inherent risk. They considered four MoAs to be desirable. Rotteveel et al. (2011) provided a more detailed attempt to estimate the number of different MoA's necessary for sustainable control of a pest in which the evaluation of resistance is prevented. They argued that, depending on inherent risk factors and other factors related to the agronomic system in which the compound is used, two, three or four MoAs are necessary. Obviously, the number of remaining MoAs is an important parameter for determining the agronomic risk of herbicide resistance and is thus included in this analysis.

1.2.4. 'Non-chemical methods'

Apart from chemical control, weeds can be managed by different non-chemical means. In conventional cropping systems, the application of non-chemical means can help in reducing the dependency on chemical weed control and thus help in reducing the frequency of use of a specific herbicide. Therefore, next to their direct effect on the management of a weed population, non-chemical measures are also considered modifiers of the agronomic risk of herbicide resistance (EPPO

1/213(4)). Two important categories of non-chemical alternative weed control measures can be discerned. The first category consists of preventive measures, which can be defined as any adjustment to the general management of the crop or cropping systems that contributes to the regulation of weed populations and reduces the negative impact of weeds on crop production (Bastiaans et al., 2008). Examples of this category are numerous and include, among others, an increased seeding rate, competitive cultivars, false seedbed technique, mulching, stimulation of weed seed predation, and weed seed removal during harvest. The second category consists of alternative curative control measures, such as mechanical and biological control.

Crop rotation is an important element of any weed management strategy. By avoiding the continuous cultivation of a single crop, or a too narrow rotation, the development of a weed species that is perfectly tuned with the growing cycle of a particular crop is prevented. In this regard, crop rotation can be considered as an important cultural control measure. Growing a range of crops also creates opportunities for using a much wider spectrum of herbicides, which, as indicated in the previous section, is an important modifier of the agronomic risk for the development of herbicide resistance. However, many other factors (pedoclimatic, economic, etc.) determine whether a wide crop rotation is preferred over a monoculture or a narrow rotation.

As indicated in the Directive for the sustainable use of pesticides (2009/128/EC), and according to the National Action Plans for the sustainable use of PPP, non-chemical methods of plant protection and pest and crop management should be given priority wherever possible. However, compared to chemical control, the general applicability and reliability of most alternative measures is often just moderate (Bastiaans et al. 2008). In addition, the effectiveness is usually below that of herbicides, for which the efficacy (percentage of dead weed plants) can be extremely high (up to 100%). For that reason, often only combinations of these alternatives will result in adequate weed control. This generally results in an increased systems complexity and any success often greatly depends on the skills of individual farmers. For that reason, it is difficult, even before economic considerations are included, to provide a reasonable general estimate on how much these alternative measures can contribute to the control of weeds in a specific crop in a specific country. For the same reason, the information on the application/applicability of the non-chemical methods should be provided by MS. An example is the review on non-chemical pest control prepared by Defra, UK (Defra, 2012).

2. Data and methodologies

2.1. Data and evidence

This section outlines the agreed data to be provided, as well as the template and methodology for assessing the need for a herbicide a.s. (called the 'a.s. under consideration' in this protocol) to control a serious danger to plant health to be provided by MS. This protocol will be applied when evaluating the necessity of the application of the a.s. under consideration within the context of Article 4(7) of Regulation (EC) No 1107/2009.

The applicant requesting a derogation under Article 4(7) of Regulation (EC) No 1107/2009 should include information, data and evidence to demonstrate that the substance is necessary to control a serious danger to plant health that cannot be contained by any other available means including non-chemical methods in their dossier using the agreed methodology and the harmonised template presented in Appendix B. MS verify the information provided by the applicant and provide supplementary information, data and evidence from their respective countries and may include other uses that were not requested by the applicant e.g. minor uses.

EFSA will consider the information provided by MS such as the non-chemical methods and the full list/short list of authorised herbicide a.s. as reliable and no further research will be done for the validation of these data. Thus, MS have the full responsibility for the accuracy and correctness of the data provided to EFSA to perform the assessment. In providing the supporting information, the MS should take into account that all the information provided will be made publicly available as background documents to the EFSA Scientific Report.

2.1.1. Full list of authorised herbicide active substances

The MS is requested to check the information submitted by the applicant and provide the full list of authorised herbicide a.s. for each crop or non-agricultural use where the applicant is requesting a derogation, using the template provided by EFSA (see Appendix B). If a registered product consists of two or more a.s. (a mixture), the information should be provided for each a.s. in the mixture separately. In addition to the list of authorised herbicide a.s. (column 'herbicide authorised'), MS are asked to include further information regarding each a.s. on target weed spectrum (column 'weed spectrum'; annual or perennial, broadleaved or grasses), exceptions (column 'exceptions'; weeds that belong to this spectrum, but that are not controlled with a sufficient efficacy by the specific a.s.), time of application (column 'time of application'; pre-emergence, early post-emergence, or post-emergence) and MoA (column 'HRAC group/MoA'; HRAC group).

2.1.2. Short list of authorised herbicide active substances

From the full list, only the authorised herbicide a.s. that have the same spectrum of weed control and time of application will be retained in a shortlist (column 'herbicide shortlisted'). MS have the possibility to provide a 'justified' shortlist, where some of the authorised herbicide a.s. present in the full list can be excluded even if the shortlisting criteria described above would be valid. For example a justification can be a case of specific weed (i.e. *Alopecurus myosuroides* or *Ambrosia artemisiifolia*), that is controlled efficiently by the a.s. under consideration and that is not controlled by a potential shortlisted herbicide a.s. In such a case, the exclusion should be justified by evidence (column 'Evidence/supporting data for non-inclusion in the shortlist'; e.g. scientific or technical papers, field trial report in any language, including expert judgement).

2.1.3. Data on herbicide resistance

The MS is asked to classify the authorised herbicide a.s. on the short list according to herbicide resistance risk, based on Table 1 (column 'Resistance risk/global'). If, at national level, documented cases of herbicide resistance for any of the shortlisted herbicides a.s. exist, MS should state this by indicating the weed species (column 'Resistance risk/national') and by providing the respective evidence. In this case, the overall classification will be set to high (column 'Overall classification').

Table 1: Classification of herbicide resistance risk based on the number of unique cases reported in the International Survey of Herbicide Resistant Weeds⁷ (modified after Heap, 2016)

	Mode of action	HRAC group	Example of a.s.	Dicots	Monocots	Total	Risk
1	ALS inhibitors	B	Chlorsulfuron	97	62	159	High
2	Photosystem II inhibitors	C1	Atrazine	50	23	73	High
3	ACCase inhibitors	A	Sethoxydim	0	47	47	High
4	EPSP synthase inhibitors	G	Glyphosate	18	17	35	Moderate
5	Synthetic auxins	O	2,4-D	24	8	32	Moderate
6	PSI electron diverter	D	Paraquat	22	9	31	Moderate
7	PSII inhibitor (ureas and amides)	C2	Chlorotoluron	10	18	28	Moderate
8	Microtubule inhibitors	K1	Trifluralin	2	10	12	Low
9	Lipid inhibitors (thiocarbamates)	N	Triallate	0	10	10	Low
10	PPO inhibitors	E	Oxyfluorfen	9	1	10	Low
11	Carotenoid biosynthesis (unknown target)	F3	Amitrole	1	3	4	Low
12	PSII inhibitors (nitriles)	C3	Bromoxynil	3	1	4	Low
13	Carotenoid biosynthesis inhibitors	F1	Diflufenican	3	1	4	Low

⁷ The risk of resistance is expressed as the ratio between the unique cases of resistance per group and the total number of unique cases of resistance (for all the groups - i.e. group B: $159/470 = 0.34 \rightarrow 34\% \rightarrow$ High risk). Based on this ratio the risk is classified as: High: > 10%; Moderate: 5-10%; Low: <5%. Data accessible at: <http://www.weedscience.org>.

	Mode of action	HRAC group	Example of a.s.	Dicots	Monocots	Total	Risk
14	Long chain fatty acid inhibitors	K3	Butachlor	0	5	5	Low
15	Cellulose inhibitors	L	Dichlobenil	0	3	3	Low
16	Antimicrotubule mitotic disrupter	Z	Flamprop-methyl	0	3	3	Low
17	HPPD inhibitors	F2	Isoxaflutole	2	0	2	Low
18	Glutamine synthase inhibitors	H	Glufosinate-ammonium	0	2	2	Low
19	Mitosis inhibitors	K2	Propham	0	1	1	Low
20	Unknown	Z	Endothall	0	1	1	Low
21	Cell elongation inhibitors	Z	Difenzoquat	0	1	1	Low
22	Nucleic acid inhibitors	Z	MSMA	1	0	1	Low
23	Inhibition of DOXP synthase	F4	Clomazone	0–	2	2	Low
24	Inhibition of DHP (dihydropteroate) synthase	I	Asulam	–	–	–	No records
25	Uncoupler (membrane disruption)	M	Dinoseb	–	–	–	No records

ACCase: acetyl CoA carboxylase; ALS: acetolactate synthase; a.s.: active substance; DHP: dihydropteroate; DOXP: 1-deoxy-d-xylulose 5-phosphate; EPSP: 5-enolpyruvylshikimate-3-phosphate; HPPD: 4-hydroxyphenylpyruvate dioxygenase; HRAC: Herbicide Resistance Action Committee; PPO: protoporphyrinogen oxidase; PS: photosystem

Some of the herbicide a.s. listed in table 1 are no longer authorised in Europe (European Commission, 2016).

2.1.4. List of non-chemical alternatives for weed management

The MS is requested to comment on the non-chemical alternatives for weed management, reported in Table 2, using the Excel file provided in Appendix B. A list of common methods, compiled based on a literature search (e.g. Barberi, 2002; Bond & Grundy, 2001) is provided, but additional methods can be added.

For each of the methods, the following information should be provided:

- Is the method considered a valid alternative contributing to weed management in this crop or non-agricultural use? – Column header 'Is it an alternative?'
 - Response: yes (1) or no (0)
 - If the answer is no, an explanation by the MS is required.
- Practiced:
 - Is this method used on a large scale in different cropping systems of the MS?
 - 0: not applied
 - 1: applied on up to 10% of the acreage of crop or non-agricultural use
 - 2: applied on 10–50% of the acreage of crop or non-agricultural use
 - 3: applied on more than 50% of the acreage of crop or non-agricultural use
- Availability:
 - Is this method commonly available to farmers (machinery available, sufficient expertise among farmers)?
 - 0: not available
 - 1: available
- Effectiveness:
 - Is the method providing an effective contribution to weed management?
 - 0: not effective
 - 1: moderately effective
 - 2: highly effective
- Feasibility:
 - Are the conditions (e.g. pedoclimatic, economic) permitting the use of this method?
 - 0: not feasible
 - 1: feasible with restriction
 - 2: feasible

Table 2: Classification of non-chemical methods for weed control.

Non-chemical methods for weed control	
Main categories	Types
Preventive methods	Primary tillage (e.g. ploughing)
	False seedbed
	Late sowing dates
	Increased crop competitiveness
	Weed seed removal during harvest
	Cover crops/mulching
	Crop rotation
	Others
Curative methods	Mechanical weeding
	Hand weeding
	Thermal weed control
	Biological weed control
	Others

2.2. Methodologies

A flow chart with the proposed methodology is shown in Appendix A. The starting point of the methodology is the full list of herbicide a.s. authorised for a particular crop or non-agricultural use in a MS where the applicant is requesting a derogation. The methodology can be divided into four steps, which are described below.

2.2.1. Step 1: Shortlisting of herbicide a.s.

The shortlist of herbicide a.s. is created based on the targeted weed spectrum and the herbicide application time retaining the a.s. having characteristics similar to that of the herbicide under consideration. In addition, MS have the possibility to exclude herbicide a.s. from the shortlist (e.g. due to the lack of efficacy against certain weed species). Such exclusions have to be supported by evidence provided by MS.

2.2.2. Step 2: Herbicide resistance risk classification

The herbicide a.s. are classified based on their MoA. If one of the shortlisted herbicide a.s. has the same MoA as the a.s. under consideration, withdrawal of the a.s. under consideration has no implications for herbicide resistance management. Consequently, justifying derogation based on a reduced number of MoAs no longer holds, and steps 2 and 3 are not needed, unless the site of action⁸ of the a.s. under consideration differs from that of the shortlisted herbicide a.s.

If the a.s. under consideration has a different MoA than any of the shortlisted herbicide a.s., the inherent risk of resistance of the shortlisted herbicide a.s. will be classified in three categories 'high', 'moderate', or 'low' according to their MoA, in accordance with Table 1. In case of reported resistance in the MS for a specific herbicide a.s. the classification of this a.s. will be 'high', and MS are asked to provide written evidence for such cases.

⁸ Some MoA (i.e. ALS) includes herbicides a.s. belonging to different chemical families (i.e. sulfonylurea, pyrimidinylthio-benzoates, imidazolinones), having in turn different site of action.

2.2.3. Step 3: Evaluation of herbicide resistance (HR) management strategy based on remaining chemical alternatives

For each of the three categories of resistance risk, the number of unique MoA will be counted. The number of available MoA per category will be multiplied by a weighing factor based on the risk resistance classification:

- Low: weighing factor 3
- Moderate: weighing factor 2
- High: weighing factor 1.5

The scores for each category will be added. If the total score is lower or equal to 6 (two MoA's with low risk; three MoA's of moderate risk; four MoA's with high risk), it is assumed that there are insufficient chemical alternatives available. Addition of one MoA with moderate resistance risk is assumed to sufficiently improve this situation. Therefore, it is assumed that a score higher than 8, represents a situation where there are sufficient chemical alternatives for sustainable HR management available. A value ranging between 6 and 8 indicates an intermediate situation. The procedure provides an objective quantitative estimate of the value of the risk modifier consisting of the alternate use of remaining chemical alternatives.

2.2.4. Step 4: Evaluation of non-chemical alternatives

The information provided for each of the listed non-chemical alternatives (or additional methods that are not listed), will be evaluated and summarised.

- This summary will show the number of available non-chemical methods;
- It also provides insights into possible reasons preventing or limiting their applicability.

If, for instance, a given non-chemical method is available, effective and feasible, but not practiced, this could be related to lack of knowledge transfer, a cultural obstacle or other reasons.

Evaluation: the information provided shows to what extent non-chemical measures are used. Together these measures also form a modifier of the agronomic risk of herbicide resistance. Furthermore, the information allows the interpretation of the main factors preventing or limiting the application of non-chemical methods. In the evaluation column, these limiting factors were coded as:

- S: scientific, if the method is not available.
- T: technical, if the method is available but not effective.
- E: economic, if the method is available but costly.
- C: other reasons, lack of knowledge, cultural obstacle.

3. Conclusions

EFSA has provided a protocol for the evaluation of data concerning the necessity of the application of a herbicide a.s. to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods within the context of Article 4(7) of Regulation (EC) No 1107/2009. The protocol can be used objectively and transparently by applicants when preparing their dossiers/submissions and by MS when assessing applications for herbicide a.s. for which a derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested by the applicant.

EFSA will act as the co-ordinator of the process, will ensure that the methodology is applied consistently and will issue a scientific report on the evaluation of each herbicide a.s. for which derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested.

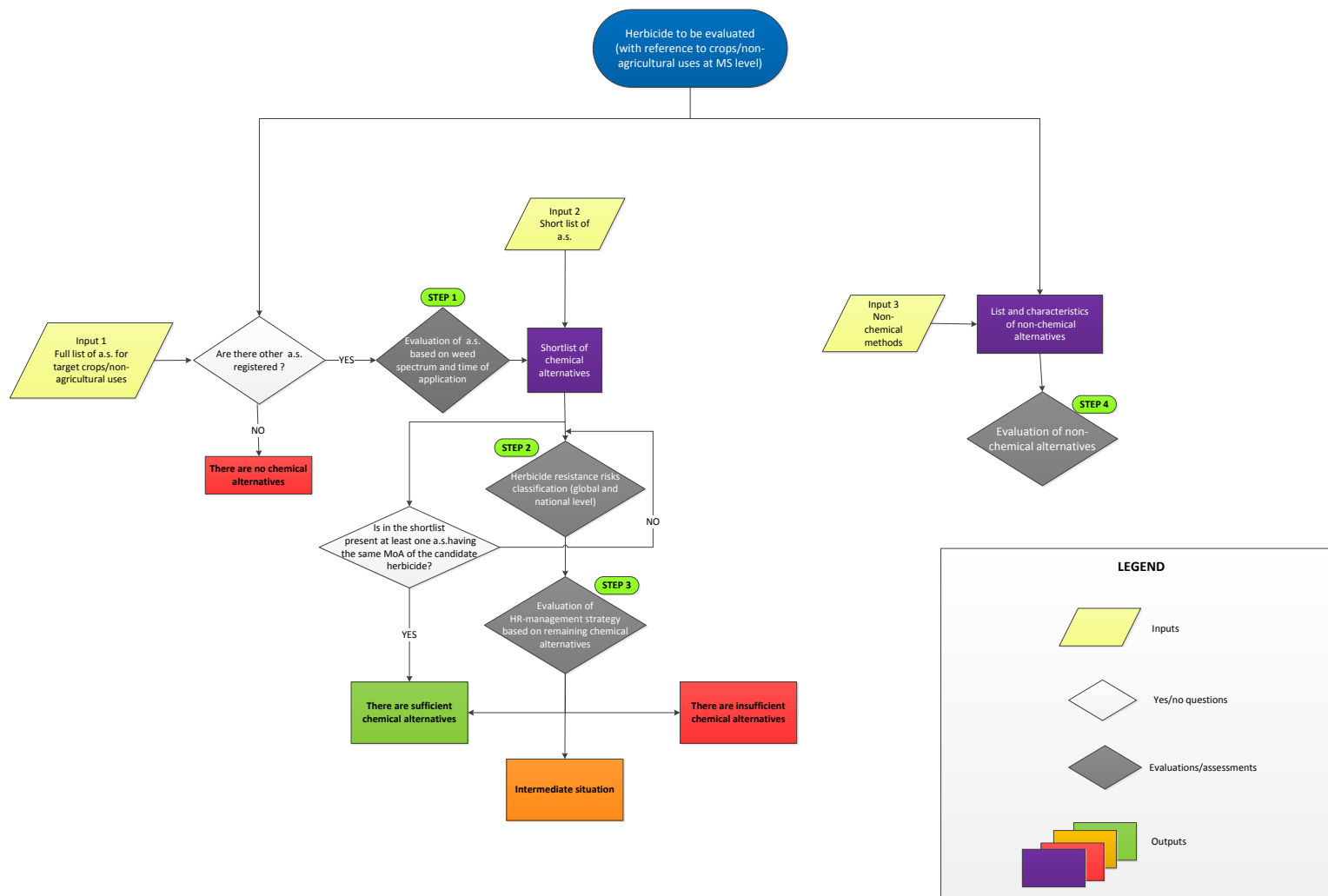
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Abbreviations

a.s.	active substance
EC	European Commission
EPPO	European and Mediterranean Plant Protection Organization
HR	Herbicide resistance
HRAC	Herbicide Resistance Action Committee
MoA	mode of action
MS	Member State
PPP	Plant Protection Product
PSN	Pesticide Steering Network
RAR/DAR	Renewal Assessment Report or Draft Assessment Report
RMS	rapporteur Member State
WG	working group

Appendix A – Flow chart of the methodology proposed for the evaluation of the necessity of given herbicide (start at the top-left of the flow chart)



Appendix B – Data collection form

This worksheet can be found as an Excel file (Appendix B) in the online version of this publication ('Supporting information' section): <http://dx.doi.org/10.2903/sp.efsa.2016.EN-1060>.

Crop or non agricultural use											Resistance risk ⁴			Chemical alternatives/unique MoA (class of risk of resistance)			Notes	Number of chemical alternatives/unique MoA - weighted score
Herbicide authorised ¹	Weeds spectrum	Exception	Time of application	Herbicides shortlisted ²	Evidence/supporting data for non inclusion in the shortlist	HRAC group/MoA ³	Global	National	Overall classification	Low	Moderate	High			0			
Non-chemical alternatives ⁵								Evidence/supporting data for non applicability of non-chemical alternatives	Notes	Number of non-chemical alternatives								
Main group	Type	Is it an alternative?	Practised	Availability	Effectivity	Feasibility	Evaluation											
Preventive methods	Primary tillage (e.g. ploughing)																	
	False seed beds																	
	Late sowing dates																	
	Increased crop competitiveness																	
	Weed seed removal																	
	Cover crops/mulching																	
Curative methods	Crop rotation																	
	Others																	
	Mechanical weeding																	
	Hand weeding																	
	Thermal weed control																	
	Biological weed control																	
	Others																	
Practiced: 0) no practiced; 1) up to 10% of the acreage; 2) 10-50% of the acreage; 3) above 50% of the acreage								Data to be entered by MSs										
Availability: 0) no; 1) yes																		
Effectivity: 0) not effective; 1) moderate effective; 2) high effective								Data to be entered by EFSA										
Feasibility: 0) no; 1) feasible with restrictions; 2) feasible																		
Evaluation of implementation obstacles: S) scientific; T) technical; E) economic C) cultural - this column should be filled by EFSA WG								Data to be entered by MSs										
NOTES								Data to be entered by EFSA										
¹ Full list of herbicide a.s. authorised for the specific crop/non agricultural use, with the exception of the herbicide a.s. under evaluation																		
² Herbicides shortlisted are the effective alternative to the candidate a.s. based on weed spectrum and application timing																		
³ Classification of Mode of Actions according to HRCA (Herbicide Resistance Action Committee)																		
⁴ Supporting information justifying the exclusion from the shortlist (can be scientific/technical literature, reports from field trials, etc). Also expert judgement can be considered as supporting evidence.																		
⁵ Non-chemical alternatives: include all agronomic, physical, biological means to control weeds. The use of non synthetic chemical substances can be also listed (i.e. allelopathic plant extracts).																		

Appendix C – Member States' comments on the draft EFSA technical report

This Table of comments can be found as a Word file (Appendix C) in the online version of this publication ('Supporting information' section): <http://dx.doi.org/10.2903/sp.efsa.2016.EN-1060>.

Member States' comments on the draft EFSA technical report on "Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods" and EFSA responses to the comments.