TECHNICAL REPORT

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Protocol for the evaluation of data concerning the necessity of the application of insecticide[1] 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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Abstract

Following a request from the European Commission (EC), the European Food Safety Authority (EFSA) initiated a procedure for the evaluation of data supporting the necessity of the application of insecticide 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 this type of evaluation. The draft protocol was circulated among European Union Member States (MS) for commenting. 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. All the evaluations are made for each specific crop/pest combination separately for which a derogation is requested. Usually, derogation for the use of an insecticide active substance is not scientifically supported if an alternative control programme not requiring the application of an insecticide can manage the specific crop/pest combination under consideration, or if another active substance with the same mode of action (IRAC) as the active substance under consideration is available. If these conditions are not verified, the process moves to the evaluation of: 1) the risk of resistance associated to the different mode of action of all active substances that are authorised in the MS; 2) the risk of resistance associated to the different pests; 3) the availability of non-insecticide alternatives.

Key words: pesticide, derogation, insecticide spectrum, insect resistance, integrated pest management, Article 4(7) of Regulation (EC) No 1107/2009

Requestor: European Commission

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[1] In this protocol, the term "insecticide" refers to both insecticides and acaricides.

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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 insecticide active substances (a.s.) to control serious dangers 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) to develop a methodology for conducting such type of evaluation. The aim of this protocol is to enable 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 coordinator of the process, will ensure that the methodology is applied consistently, and will issue a scientific report on the evaluation of each insecticide a.s. for which derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested. The protocol takes into account relevant international standards from the European and Mediterranean Plant Protection Organization (EPPO). The proposed methodology was also circulated among the EU Member States (MS) for commenting, and hence also their suggestions were assessed by the WG and taken into account where applicable.

The applicant requesting a derogation under Article 4(7) of Regulation (EC) No 1107/2009 should include in their dossier: information, data and evidence to demonstrate that the substance is necessary to control a serious danger to plant health that cannot be sufficiently contained by any other available means including non-chemical methods, following the methodology and harmonised template presented in this report. The information should be provided for each specific crop/pest combination separately, at national level for which a derogation is applied. The MS will verify the information provided by the applicant and will provide supplementary information, data and evidence from their respective countries and may include other uses that were not requested by the applicant e.g. Article 51 extensions of minor use. The MS will evaluate the overall information based on the following methodology applied to each specific crop/pest combination separately, at national level for which a derogation is applied. The process starts by checking whether another a.s. with the same mode of action (MoA) as the a.s. under consideration is available (see MoA definition given in chapter 1.2.3.). In this case, derogation is usually not scientifically supported. Likewise, if a non-insecticide control programme (that can include the use of semiochemicals) is sufficient to manage the pest/crop combination under consideration, derogation would be considered as not being scientifically supported. Otherwise the process moves to the evaluation of: 1) the risk of resistance associated to the different MoA of all a.s. that are authorised in the MS; 2) the risk of resistance associated with the different pests; 3) the non-insecticide alternatives. Data on the combined resistance risk and the evaluation of non-insecticide alternatives will support the risk management decision.

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1. Introduction

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

In January 2016, the European Commission (EC) requested with a general mandate to the European Food Safety Authority (EFSA) to provide scientific assistance as regards the consideration of evidence that 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 within the context of Article 4(7) of Regulation (EC) No 1107/2009[2] because no clear instructions about how to handle Article 4(7) applications were available to the Member States and EFSA.

The EC agreed that EFSA would provide a protocol on the methodology for each type of pesticide (e.g. herbicide (EFSA, 2016), insecticide, fungicide) separately and afterwards the protocols would 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 (collating the three protocols), EFSA envisions a public consultation in addition to the consultation with the risk assessment organisations in the MS. The final guidance will be sent to the European Commission for consideration by risk managers.

In September 2016, EFSA set up a working group (WG) on insecticides Article 4(7) to address the above request of the EC, to provide, in accordance with Article 31 of Regulation (EC) No 178/2002[3], a protocol for the evaluation of data concerning the necessity of the application of insecticide 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.

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

1. When an active substance already has harmonised classification in accordance with Regulation (EC) No 1272/2008[4] 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 at the time of submission of the dossier

or

2. When the peer review of the active substance proposes a 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 active substance is necessary to control a serious danger to plant health that cannot be contained by any other available means including non-insecticide alternatives as part of their (renewal of) approval dossier following the methodology and harmonised template proposed by EFSA. The rapporteur Member State (RMS) should present the applicant's submission as part of the Renewal Assessment Report or Draft Assessment Report (RAR/DAR). At the start of the peer review, Member States will be invited by EFSA to consider the information provided and to complete a standard template. Member States can supplement the information provided by the applicant with information from their own country. Member States may also consider other uses that were not requested by the applicant e.g. Article 51 extensions of minor use at this stage.

[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.

[3] 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.

[4] 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.

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 to demonstrate 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 to EFSA, the EC and RMS, EFSA requests all MS to consider and validate the information provided and to complete a standard template. Member States (MS) can supplement the information provided by the applicant with information from their own country. MS 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 insecticide active substances within the context of Article 4(7) of Regulation (EC) No 1107/2009. EFSA will act as the coordinator of the process, will ensure that the methodology is applied consistently and will issue a scientific report on the evaluation of each insecticide active substance 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 Products in accordance with Regulation (EC) No 1107/2009. A decision in accordance with Article 4(7) is taken at EU 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.

1.2. Additional information

1.2.1. Legislation

Regulation (EC) No 1107/2009 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.

Article 4(7) states that '*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 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, MS 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, Directive 2009/128/EC[5] establishes 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*

[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.

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[6]) also contains indications relevant to insect pest management, especially referring to the cases of alien pest species.

1.2.2. 'Plant health'

The definition of plant health may significantly vary depending on the perspectives and the approaches adopted. According to Döring et al. (2012), either a reductionist or a holistic approach can be adopted, with an anthropocentric or a biocentric perspective, respectively.

In the context of this report, we will adopt a reductionist approach with an anthropocentric perspective, defining plant health as the absence of damage to quality or quantity of plants for use, directly or indirectly by human beings, including non-crop uses.

On the scale of possible impacts caused by pests, 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, including social and cultural factors. 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. 'Insecticide resistance'

Resistance is the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a plant protection product treatment that would normally give effective control. Although resistance can often be demonstrated in the laboratory, this does not necessarily mean that pest control in the field is reduced. 'Practical resistance' is the term used for loss of field control due to a shift in sensitivity (EPPO 1988), cited in (EPPO 2015).

Resistance can evolve in pest populations through different mechanisms The modification of the target site and the changes in the metabolism increasing the breakdown of the a.s. (detoxification) are the most common but there are also many examples of resistance evolution due to behavioural changes, reduced penetration, sequestration or increased excretion of the a.s. (For review see (Ffrench-Constant 2013, Feyereisen et al. 2015)). As resistance is a genetically-based phenomenon, its dynamics will correlate directly with some intrinsic characteristics of the species such as: mutation rate, number of generations per season, type of reproduction, dispersion capacity, etc. The repetitive exposure to pesticides (selection pressure) is the main driving force for selecting resistant individuals in the populations. The more often a single Mode of Action (MoA) is used, the more likely is that the number of resistant individuals increases in the population. IRAC (Sparks and Nauen 2015) defines main groups of MoA as well as sub-groups (see Table 1 and visit http://www.irac-online.org/ for reference). Cross resistance between sub-groups of MoA are likely to occur in case of target site resistance whereas, for metabolic resistance, an alternation of a.s. from some specific sub-groups can be recommended. Therefore, for pests exhibiting metabolic resistance, no cross resistance has to be expected for the sub-groups listed under the main groups 4, 8, 11, 22 and for all active substance listed under the main group UN in Table 1. For the purpose of the methodology presented here, the main groups of MoA are usually used (except for the group UN and groups 4, 8, 11 and 22 in case of metabolic resistance). Currently, there are almost 600 species of insects and mites that have already developed resistance to at least one a.s., with a total number of over 10,900 cases listed in the Arthropod Pesticide Resistance Database for pest species having an impact in agriculture (http://www.pesticideresistance.org/). It should be noted that although the existing database is currently the only available option, it is not optimal to provide the necessary information. Additional information on pesticide resistance in Europe can be found at: https://www.eppo.int/PPPRODUCTS/resistance/resistance.htm.

[6] Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species. OJ L 317, 4.11.2014, p. 35–55

Assessing the likely impact of a requested derogation on the risk of resistance evolution in a pest damaging the specific crop under consideration is a rather difficult task. This process requests to weigh the contribution of both: the current status of the a.s. authorised for pest species in the specific crop according to the previous history of cases of resistance reported in the literature and also the intrinsic characteristics of the pest in a given region and cropping system.

1.2.4. 'Non-insecticide methods'

There are many examples of alternative methods preventing pest occurrence or reducing pest populations under an economic threshold. In a number of cases, these alternative methods have even been proven more effective than insecticide treatments (see e.g. Bale et al. 2008), because of their long-term control (e.g. classical biological control: Caltagirone and Doutt, 1989); varietal resistance: (Sorensen et al., 2008), or because they are less likely than insecticides to select for resistance. Quite often alternative methods are applied in combination, in order to increase their efficacy. These combinations can include insecticidal methods (e.g. insecticide treatment followed by mating disruption or sterile insect techniques). Some methods usually have a long-lasting effect: cultural methods; varietal resistance; conservation or classical biological control, although there are known cases of fast adoption of a pest to changes in cultural methods, e.g. *Diabrotica virgifera* adapting to the use to a simple crop rotation system (Levine et al. 2002). Other methods are applied recurrently when justified by sufficient pest pressure: mating disruption, sterile insect techniques, inoculative or inundative biological control, and physical methods. The following main methods should be considered, though additional ones may also be suitable.

1.2.4.1 **Cultural control** (e.g., change of planting or harvest dates (Alyokhin 2009), cover crop management (Bugg and Waddington 1994), ploughing, mulching, push-and-pull (Cook et al. 2006), use of cultivation in raised beds, cultivar combinations).

1.2.4.2 **Management of varietal resistance** (use of tolerant or resistant plant genotypes, including rootstocks and/or genetically engineered crops as Bt-maize). An example is the grafting of *Vitis vinifera* on North American rootstocks against grape phylloxera (reviewed by Sorensen et al. 2008).

1.2.4.3 **Biological control**:

- Conservation biological control, i.e. habitat management to favour local natural enemies, e.g. by the use of banker plants for the provision of alternative food (nectar, pollen, alternative hosts or prey), the provision of nesting or overwintering sites (Landis et al. 2000; Messelink et al. 2014).
- Classical biological control against exotic pests by introducing natural enemies from their area of origin. An example is the use of the coccinellid *Rodolia cardinalis* against the scale *Icerya purchasi* (reviewed by Caltagirone and Doutt 1989).
- Inoculative biological control by periodically restarting natural enemy populations by limited releases in areas where pests occur recurrently, e.g. launch of predators or parasitoids in greenhouses (van Lenteren 2012).
- Inundative biological control by massive releases of natural enemies that are expected to achieve control in one or two generations. An example is mass releases of *Trichogramma* spp. against the European corn borer, *Ostrinia nubilalis* (Razinger et al. 2016).

1.2.4.4 **Semiochemical**[7] **control**:

- the use of attractants (sex pheromones) for mating disruption (Wizgall et al. 2008; 2010; Ioriatti and Lucchi 2016).

[7] For the purpose of this document semiochemicals are considered as non-insecticides and they refer to naturally occurring chemicals or artificial mimicks of them involved in the interaction between organisms. For more general definition see Nordlund & Lewis (1976).

- the use of attractants (e.g. aggregation pheromones, kairomones) for mass-trapping, for example for controlling forest pests (Raty et al. 1995) or the medfly (Navarro-Llopis et al., 2012).
- the use of repellents to protect crops, e.g. against forest pests (Gillette et al. 2006).

1.2.4.5 **Autocidal control**, in particular the use of the sterile insect technique (SIT), which consists in mass-producing and releasing e.g. male insects sterilised by gamma irradiation or genetic engineering, which will cause wild females to lay sterile eggs (Dyck et al. 2005; Catteruccia et al. 2005).

1.2.4.6 **Physical methods: :** e.g. soil treatment with heat, beating, flooding, netting (Vincent et al. 2003); the use of attractive colours or shapes to lure pests into specifically designed traps (Kirk 1984).

2. Data and methodologies

2.1. Data and evidence

This section outlines the data to be provided by applicants and MS, as well as the template and methodology for assessing the need for an insecticide a.s. (called the 'a.s. under consideration' in this protocol) to control a serious danger to plant health. 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-insecticide alternatives, the resistance situation in their territory (until a valid and up to date resistance data bank has been established such as currently has been planned by EPPO) and the list of authorised insecticide 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. List of authorised insecticide active substances on crop/pest combination

A crop could refer to a single plant species (e.g. wheat - *Triticum aestivum*, oilseed rape - *Brassica napus* or horse-chestnut - *Aesculus hippocastanum*) or to a group of species (e.g. cereals, ornamentals), and can be differentiated depending on whether the cultivation takes place e.g. in open field or, in a greenhouse, etc. In this protocol, crop products (e.g. grains, tubers, fruits, etc.) kept in storehouses, silos, where insecticides can be applied, are also considered to be crops. If relevant, crop destination (fresh consumption, industrial processing, etc.) should also be taken into account.

The MS are requested to check the information submitted by the applicant and provide the list of authorised insecticide a.s. only for each crop/pest combination or non-agricultural use for which derogation is requested, using the template provided by EFSA (see Appendix B). If a registered product consists of two or more a.s. (co-formulation), the information should be provided for each insecticidal a.s. in the co-formulation separately. In addition to the list of authorised insecticide a.s. (column 'insecticide authorised'), MS are asked to include further information regarding each a.s. on other pests controlled (column 'other pest controlled'), exceptions (column 'exceptions'; species or groups of species that belong to this spectrum, but that are not controlled with a sufficient efficacy by the specific a.s.), period of application (column 'period of application';) and MoA (column 'IRAC group/MoA').

2.1.2. Data on insecticide resistance

The applicant/MS is asked to evaluate the risk of resistance of the pest to be controlled towards the authorised insecticide a.s., based on Table 1 and on the instructions given in the section 2.2.4., and report these data using the Excel file provided in Appendix B (column 'Resistance risk/global'). If at MS level, cases of resistance for any of the insecticides a.s. exist, the applicant/MS should state this by indicating the insect species (column 'Resistance risk/national') and by providing the corresponding evidence (e.g. scientific or technical papers, field trial report in any language, including expert judgement). In this case, the overall classification for the risk of resistance will be set to high (column 'Overall classification').

Table 1: Classification of insecticide resistance risk based on the number of cases reported in the Arthropod Pesticide Resistance Database[8]

Main group and primary site of action[9]	Chemical sub-group or exemplifying a.s.	Example of a.s[10].	Resistance cases	Risk of resistance[11]
1 Acetylcholinesterase (AChE) inhibitors	1A Carbamates	Pirimicarb	693	High
	1B Organophosphates	Chlorpyrifos	2898	High
2 GABA-gated chloride channel blockers	2B Phenylpyrazoles (Fiproles)	Ethiprole, Fipronil	146	Moderate
3 Sodium channel modulators	3A Pyrethroids Pyrethrins	Deltamethrin	3085	High
4 Nicotinic acetylcholine receptor (nAChR)	4A Neonicotinoids	Imidacloprid	879	High

[8] Only resistance cases related to the agricultural uses of the a.s. belonging to each MoA are accounted for (resistance cases in vectors for human or animal diseases are excluded) Data available at http://www.pesticideresistance.org/index.php (accessed 24 November 2016)

[9] The classification of pesticides Mode of Action (MoA) is carried out according to the Insecticide Resistance Action Committee. IRAC MoA Classification Version 8.1, April 2016. Data available at http://www.irac-online.org/ (accessed 24 November 2016). The list is corrected according to the EU pesticide databank http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN (accessed 1 December 2016). Only MoA of a.s. accepted in the EU or still pending are left in the list. Be aware that EU listed a.s. may change over time.

[10] Example of representative active substance (a.s.) for each MoA. A complete list is available at http://www.irac-online.org/.

[11] The risk of resistance is expressed as high if there are more than 500 cases reported, as moderate if there are between 100 and 500 cases reported and as low if 100 or less resistance cases have been reported. Data available at http://www.pesticideresistance.org/index.php (Accessed 24 November 2016). Except in cases of metabolic resistance (see chapter 1.2.3.), if several sub-groups are available, the highest "risk of resistance" within the main group should be used.

Main group and primary site of action[9]	Chemical sub-group or exemplifying a.s.	Example of a.s[10].	Resistance cases	Risk of resistance [11]
competitive modulators	4C Sulfoximines	Sulfoxaflor	86	Low
	4D Butenolides	Flupyradifurone	2	Low
5 Nicotinic acetylcholine receptor (nAChR) allosteric modulators	Spinosyns	Spinosad	235	Moderate
6 Glutamate-gated chloride channel (GluCl) allosteric modulators	Avermectins, Milbemycins	Abamectin	357	Moderate
7 Juvenile hormone mimics	7B Fenoxycarb	Fenoxycarb	1	Low
	7C Pyriproxyfen	Pyriproxyfen	56	Low
8[12] Miscellaneous non-specific (multi-site) inhibitors	8C Fluorides	Cryolite (Sodium aluminum fluoride)	1	Low
	8F Methyl isothiocyanate generators	Dazomet	No records	Low
9 Chordotonal organ TRPV channel modulators	9B Pyridine azomethine derivatives	Pymetrozine	17	Low
10 Mite growth inhibitors	10A Clofentezine, Diflovidazin,Hexythiazox	Clofentezine, Diflovidazin, Hexythiazox	29	Low
	10B Etoxazole	Etoxazole	3	Low

[12] Active substances in these MoA are thought not to share a common target site and therefore may be freely rotated with each other unless there is reason to expect cross-resistance. The risk of resistance development is considered as low.

Main group and primary site of action[9]	Chemical sub-group or exemplifying a.s.	Example of a.s[10].	Resistance cases	Risk of resistance[11]
11[13] Microbial disruptors of insect midgut membranes	11A Bacillus thuringiensis and the insecticidal proteins they produce	*Bacillus thuringiensis* subsp. *kurstaki*; *B.t. crop proteins: Cry1Ab*	See footnote 13	Low
15 Inhibitors of chitin biosynthesis, type 0	Benzoylureas	Lufenuron	106	Moderate
16 Inhibitors of chitin biosynthesis, type 1	Buprofezin	Buprofezin	84	Low
17 Moulting disruptors, Dipteran	Cyromazine	Cyromazine	12	Low
18 Ecdysone receptor agonists	Diacylhydrazines	Chromafenozide, Halofenozide, Methoxyfenozide, Tebufenozide	101	Moderate
20 Mitochondrial complex III electron transport inhibitors	20B Acequinocyl	Acequinocyl	2	Low
	20D Bifenazate	Bifenazate	14	Low
21 Mitochondrial complex I electron transport inhibitors Energy metabolism {Good evidence that action at this protein complex is responsible for insecticidal effects}	21A METI acaricides and insecticides	Fenpyroximate	87	Low

[13] Each *B. thuringiensis* strain expresses its own combination and quantity of insecticidal toxins. Different toxins might target the same or different molecules or binding sites in the midgut of larvae. The risk of resistance development is usually considered as low for Bt sprays and the risk of cross resistance among individual toxins will correlate with their ability to share or not the binding site in the midgut of larvae.

Main group and primary site of action[9]	Chemical sub-group or exemplifying a.s.	Example of a.s[10].	Resistance cases	Risk of resistance[11]
22 Voltage-dependent sodium channel blockers	22A Oxadiazines	Indoxacarb	175	Moderate
	22B Semicarbazones	Metaflumizone	12	Low
23 Inhibitors of acetyl CoA carboxylase	Tetronic and Tetramic acid derivatives	Spiromesifen	35	Low
24 Mitochondrial complex IV electron transport inhibitors Energy metabolism {Good evidence that action at this protein complex is responsible for insecticidal effects}	24A Phosphides	Aluminium phosphide	146	Moderate
25 Mitochondrial complex II electron transport inhibitors Energy metabolism {Good evidence that action at this protein complex is responsible for insecticidal effects}	25A Beta-ketonitrile derivatives	Cyenopyrafen	6	Low
28 Ryanodine receptor modulators	Diamides	Chlorantraniliprole	109	Moderate
29 Chordotonal organ Modulators - undefined target site	Flonicamid	Flonicamid	9	Low

Main group and primary site of action[9]	Chemical sub-group or exemplifying a.s.	Example of a.s[10].	Resistance cases	Risk of resistance [11]
UN[12] Compounds of unknown or uncertain MoA and those not classified by IRAC	*Adoxophyes orana* granulovirus, Azadirachtin, *Beauveria bassiana*, Capric acid, Caprylic acid, Carbon dioxide, *Chromobacterium subtsugae*, *Cydia pomonella* granulovirus, Fatty acids, *Helicoverpa armigera* nucleopolyhedrovirus, Hydrolysed proteins, *Isaria fumosorosea*, Kieselgur, Lauric acid, *Lecanicillium muscarium*, Lime sulphur, Maltodextrin, *Metarhizium anisopliae*, Methyl decanoate, Methyl octanoate, Oleic acid, *Paecilomyces fumosoroseus*, Paraffin oils, Pelargonic acid, Plant oils, Pyridalyl, Rescalure, *Spodoptera littoralis* nucleopolyhedrovirus, Sulphur, Terpenoid blend		few cases for many different MoA and a.s.	Low

Please note that some of the insecticide a.s. listed in table 1 are no longer authorised in Europe (European Commission, 2016).

2.1.3. Non-insecticide methods for insect management

The applicant/MS is requested to provide data and comment on the non-insecticide alternatives for insect management, reported in Section 1.2.4 and Table 2, using the Excel file provided in Appendix B. Additional methods, if any, can be added.
For each of the methods, the following information should be provided:

- Is this method commonly available to farmers (e.g., machinery, natural enemies, information, external support, sufficient expertise among farmers)?
  - Column header: 'Availability'
  - Response:
    - 0: not available
    - 1: available

- Does the method or combination of methods (insecticide or non-insecticide) provide a contribution to the effective control of the target pest/s?
  - Column header: 'Effectiveness'
  - Response:
    - 0: not effective
    - 1: moderately effective
    - 2: highly effective

- Is this method used on a large scale in different cropping systems of the MS?
  - Column header: 'Practised Usage'
  - Response:
    - 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

- Do the conditions (e.g. pedoclimatic, economic, social) enable the use of this method?
    - Column header: 'Feasibility'
    - Response:
        - 0: not feasible
        - 1: feasible with restriction
        - 2: feasible

Table 2: Classification of non-insecticide methods for insect control.

Main group	Type
Cultural control	Crop rotations
	Intercropping (mixed crops, row, strip)
	Change in planting/harvesting dates
	Cover crops
	Increased crop competitiveness
	Soil tillage
	Mulching
	Push-and-pull
	Others
Varietal resistance	Tolerant or resistant plant genotypes
	Crop/cultivar associations
	Genetically engineered crops
	Others
Biological control	Conservation biocontrol
	Classical biocontrol
	Inoculative biocontrol
	Inundative biocontrol
Semiochemical control	Mating disruption
	Mass-trapping
	Repellents
	Others
Autocidal methods	Sterile male technique (SIT)
Physical control	Nets, agrotextiles,
	Heat (e.g. steam sterilisation, soil solarisation)
	Cold (e.g. cold storage techniques)
	Water (e.g. flooding)
	Coloured traps; light traps, succion traps
	Others

2.2. Methodology

A flow chart with the proposed methodology is shown in Appendix A. The starting point of the methodology is the list of insecticide a.s. authorised for a particular crop/pest combination or non-agricultural use in a MS where the applicant is requesting a derogation.

The methodology is described below:

2.2.1. Step 1: Evaluation of insecticide alternatives with same MoA:

Are there other a.s. available within the same MoA?

- **If yes** => derogation is probably not scientifically supported and the evaluation should stop here. However, if there are scientific and/or technical evidence to support the different performance of the a.s., provide evidence and go to 2
- **If no** => go to 2

2.2.2. Step 2: Evaluation of alternative non-insecticide program:

Is there at least one practical /acceptable / established non-insecticide effective programme (which could include the use of semiochemicals) to manage the crop against the pest under consideration?

- **If yes** => there are enough alternatives and therefore derogation is not scientifically supported, and the evaluation should stop here.
- **If no and no other a.s. are available** => derogation is scientifically supported
- **If no and other a.s. or non-insecticide alternatives are available** => go to 3

2.2.3. Step 3: Compute the following parameters and perform evaluations:

a) Insecticide risk of resistance (x)
b) Pest risk of resistance (z)
c) Evaluation of non-insecticide alternatives

2.2.3.a. Evaluation of insecticide risk of resistance (x)

Check, count, and rank the number of different MoAs included in the list of a.s. authorized against the target pest in the crop under consideration (**Insecticide risk of resistance value x**). Those MoAs for which relevant loss of efficacy due to resistance is already known for the pest under consideration should not be included in **x,** but should be listed in the excel file and the reason why it is not included has to be motivated. The value **x** is the sum of every alternative MoA multiplied by a weighing factor based on the risk of resistance development intrinsically linked to that MoA (see Table 1). If the MoA is classified as **high risk** multiply by **0.5**, if the risk is **moderate** multiply by **0.75** and if it is **low** multiply by **1.0**. For example: If there are **2 MoAs** classified as high risk, **3 MoAs** classified as moderate and **2 MoAs** classified as low then **x= (2*0.5) + (3*0.75) + (2*1.0) = 5.25.**

2.2.3.b. Evaluation of pest risk of resistance (z)

Assess the intrinsic risk of the pest under consideration developing resistance within a cropping system (see examples below) (**resistance risk value z**: *1-low*, *2-moderate*; *3-high*):

To analyse the inherent risk of resistance development for the pest under consideration on a given crop and to classify this risk as **low, moderate** or **high,** a simplified approach similar to that described in Rotteveel et al. 2011 has been used. This classification may differ among regions because of different climatic, pedobiological and agricultural situations which may influence e.g.: the number of generations of the pest per year or that of applications needed to control them. It will also be influenced by the extent of areas available where no insecticide selection pressure occurs (e.g., insect recreation areas, natural habitats, etc.) as this usually favours the increase of susceptible individuals in the insect population. Therefore, the analysis has to consider case by case and should be carried out separately by applicants and MS for each pest species, crop and country. For instance, the classification of pests in open field versus greenhouse conditions will often differ resulting in higher risks in greenhouses, as pesticide usage in greenhouses is usually higher.

Pests are considered as "low risk" when (1) resistance to the relevant a.s. has not been reported in the EU and (2) selection pressure is low (e.g., the pest in that cropping system is **treated less than once per year** because it rarely exceeds the Economic Injury Level (EIL) and it is rarely exposed to treatments targeting other pests in the same crop). These species often have 1 generation per season, they also occur in high frequency in non-agricultural habitats or in certain types of fields where they are rarely treated.

Examples of such low risk pests are:

- Wireworms (*Agriotes* spp.) which are not treated every season and frequently occur in untreated agricultural and natural habitats.
- Cabbage pod midge (*Dasyneura brassicae*) in oilseed rape which is not regularly exposed to treatments and often only at field boundaries.
- The wood borers *Synanthedon myopaeformis*, *Zeuzera pyrina* and *Cossus cossus* in pome fruit as they also occur in non-crop areas and are usually controlled by mechanical means.
- Leafhoppers in maize, which are not regularly treated.
- The scale *Icerya purchasi* in citrus, which occurs also in non-crop areas and is usually regulated by its natural enemies.

Pests are considered as "moderate risk" when (1) resistance to the relevant a.s. has never or rarely been reported in the country and (2) selection pressure is medium or low, respectively selection pressure is medium. These pests are typically **treated about once per year** in that cropping system because they regularly exceed EIL or are exposed to treatments with the same MoA targeting other pests in the same or in other crops in the region and have limited untreated areas in that region.

Examples of such moderate risk pests are:

- The Colorado potato beetle (*Leptinotarsa decemlineta*) in the north of Europe, which does not need treatment every season and exists in fields where no other insect pests are treated regularly. It is not a low risk pest because there are many resistance reports from the EU, and potato is the only host plant in that region, leaving no refuge areas.
- Cereal aphids (e.g. *Sitobion avenae*) in winter cereals in regions where they are not regularly treated either in autumn to control virus transmission or in summer for controlling direct damage and where there is frequently no need to use the same MoA to control other cereal insect pests exposing also the aphids.
- The southern green stink bug *Nezara viridula* in protected crops.
- The scale *Quadraspidiotus perniciosus* in pome fruit.
- The leafminer *Phyllocnistis citrella* in citrus, which is usually not treated but may be exposed to pesticides targeting other citrus key pests.

Pests are considered as "high risk" when either (1) resistance to the relevant a.s. has been frequently reported in the country or (2) selection pressure is high These pests are **treated (usually) more than once per year in that cropping system**, because (a) they have several generations per year which often exceed economic injury level (EIL), or (b) they are exposed to treatments with the same MoA targeting other pests in that cropping system, or (c) they are treated also in other crops with pesticides with the same MoA because these pests are not host specific, or (d) occur in areas where limited untreated host plants exist.

Some examples of such high risk pests are:

- The green peach aphid (*Myzus persicae*) which is treated frequently within the same crops (e.g. seed potato production) with the same MoA and in addition also in several other crops, though often not being the target of the application.
- Cereal aphids (e.g. *Sitobion avenae*) in winter cereals in regions where they are regularly treated either in autumn to control virus transmission or in summer for controlling direct damage or where there is frequently a need to use the same MoA to control other cereal insect pests exposing also the aphids.
- Most pest insects and mites in greenhouse conditions (see above). However, if the main control strategy is based on biological control and/or other non-insecticide alternatives, which is often the case for fruit vegetables like tomatoes or peppers, the risk for resistance development may be classified as low.
- The pollen beetle (*Meligethes aeneus*) and cabbage stem flea beetle (*Psylliodes chrysocephala*) in oilseed rape, because they are exposed more than once per season to insecticides of the same MoA either as direct targets or by treatments targeting other insect pests. In addition, there are limited refuges areas available in all regions with oilseed rape being an important crop.
- The Colorado potato beetle (*Leptinotarsa decemlineta*) in the center and south of Europe, which often needs treatments and about which many resistance reports from Europe exist. In addition, potato is the main host plant and no refuge areas are available in natural habitats.
- The codling moth (*Cydia pomonella*) in apple in regions with intensive apple production and several insecticide applications needed. However, when this pest can be effectively controlled by mating disruption, it may be then classified as low risk.
- Spider mites (e.g., *Tetranychus urticae, Panonychus ulmi*) which are frequently treated during the same season and exposed to other treatments targeting pests occurring in the same system.
- The western flower thrips (*Frankliniella occidentalis*) for the same reasons as for the spider mites.
- The hop aphid (*Phorodon humuli*) on hops with high treatment frequency and no unsprayed host plants in natural habitats in the regions of hop growing.

2.2.3.c. Evaluation of non-insecticide alternatives

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

Appendix B allow also to provide information on possible reasons preventing or limiting the applicability of each method.

If, for instance, a given non-insecticide 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-insecticide measures are used. Together these measures also form a modifier of the agronomic risk of insecticide resistance. Furthermore, the information allows the interpretation of the main factors preventing or limiting the application of non-insecticide alternatives. In the evaluation column, these limiting factors will be 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.

2.2.4. Evaluation of insecticide/pest resistance management strategy based on remaining insecticide and non-insecticide alternatives

Compute z/x:

- **If z/x < 0.75** => derogation not scientifically supported because there are enough alternative MoAs not to repeat the same MoA within the same season.

- **If 0.75 < z/x < 1.25** => derogation may be scientifically supported depending on the availability and feasibility of alternative non-insecticide methods. In this case, the development of alternative methods (either chemical or not) during the time covered by the derogation may be critical for the future sustainability of the cropping system.

- **If z/x > 1.25** => there are not enough alternative MoAs not to repeat the same MoA within the same season. Derogation may delay the development of resistance, especially if the a.s. under consideration has a low risk for resistance development (see Table 1). In this case, the development of alternative methods (either chemical or not) during the time covered by the derogation would become critical for the future sustainability of the cropping system.

Example: if resistance risk for your pest is moderate (= 2) and for control of this pest 2 MoAs are available the z/x value will be 1.0 if both MoAs are of low resistance risk 2/(1+1)=1, but if the two alternative MoAs have high risk the value will be 2.0 (2/(0.5+0.5)=2).

3. Conclusions

EFSA has provided a protocol for the evaluation of data concerning the necessity of the application of an insecticide 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 insecticide a.s. for which a derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested.

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 insecticide a.s. for which derogation under Article 4(7) of Regulation (EC) No 1107/2009 is requested.

References

Alyokhin, A., 2009. Colorado potato beetle management on potatoes: current challenges and future prospects. Fruit, Vegetable and Cereal Science and Biotechnology, 3.

Bale, J. S., Van Lenteren, J. C., and Bigler, F., 2008. Biological control and sustainable food production. Philosophical Transactions of the Royal Society B: Biological Sciences, 363(1492), 761-776.

Bugg, Robert L., and Waddington, C., 1994. Using cover crops to manage arthropod pests of orchards: a review. Agriculture, Ecosystems & Environment 50.1: 11-28.

Caltagirone, L. E., and Doutt, R. L., 1989. The history of the vedalia beetle importation to California and its impact on the development of biological control. Annual Review of Entomology, 34(1), 1-16.

Catteruccia, F., Benton, J. P., & Crisanti, A., 2005. An Anopheles transgenic sexing strain for vector control. Nature Biotechnology, 23(11), 1414-1417.

Consoli, Fernando L., José RP Parra, and Roberto A. Zucchi, eds., 2010. Egg parasitoids in agroecosystems with emphasis on Trichogramma. Vol. 9. Springer Science & Business Media.

Cook, S. M., Khan, Z. R., and Pickett, J. A., 2006. The use of push-pull strategies in integrated pest management. Annual Review of Entomology, 52(1), 375-400.

Defra, 2012. Non-chemical pest control methods: A review of the literature to establish their efficacy and safety to workers, to inform the process of comparative assessment required by new pesticide legislation. Available online: http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=17861&FromSearch=Y&Publisher=1&SearchText=PS2809&SortString=ProjectCode&SortOrder=Asc&Paging=10%23Description [Accessed:17 May 2016]

Döring, T. F., Pautasso, M., Finckh, M. R., & Wolfe, M. S., 2012. Concepts of plant health–reviewing and challenging the foundations of plant protection. Plant Pathology, 61(1), 1-15.

Dyck, V. A., Hendrichs, J., & Robinson, A. S., 2005. Sterile insect technique. IAEA.

EFSA Plant Health Panel, 2014. Scientific Opinion on the risk to plant health posed by Daktulosphaira vitifoliae (Fitch) in the EU territory, with the identification and evaluation of risk reduction options. EFSA Journal: EFSA Journal, 12(5): 3678 [67 pp.]. doi: 10.2903/j.efsa.2014.3678

EPPO (European and Mediterranean Plant Protection Organization), 2015. Efficacy evaluation of plant protection products. PP 1/213 (4) Resistance risk analysis. EPPO Bulletin 45: 371-387.

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.

Feyereisen R, Dermauw W and Van Leeuwen T, 2015. Genotype to phenotype, the molecular and physiological dimensions of resistance in arthropods. Pesticide Biochemistry and Physiology; 121(61-77 DOI Electronic Resource Number.

Ffrench-Constant RH, 2013. The molecular genetics of insecticide resistance. Genetics; 194(4): 807-815 DOI Electronic Resource Number.

Gillette, N. E., Stein, J. D., Owen, D. R., Webster, J. N., Fiddler, G. O., Mori, S. R., & Wood, D. L., 2006. Verbenone-releasing flakes protect individual Pinus contorta trees from attack by Dendroctonus ponderosae and Dendroctonus valens (Coleoptera: Curculionidae, Scolytinae). Agricultural and Forest Entomology, 8(3), 243-251.

Ioriatti, C., & Lucchi, A., 2016. Semiochemical Strategies for Tortricid Moth Control in Apple Orchards and Vineyards in Italy. Journal of Chemical Ecology, 42(7), 571-583.

Khan, Z. R., Midega, C. A., Pittchar, J. O., Murage, A. W., Birkett, M. A., Bruce, T. J., and Pickett, J. A., 2014. Achieving food security for one million sub-Saharan African poor through push–pull innovation by 2020. Philosophical Transactions of the Royal Society of London B: Biological Sciences, 369(1639), 20120284.

Kirk, W. D. (1984). Ecologically selective coloured traps. Ecological Entomology, 9(1), 35-41.

Koenning, S. R., Schmitt, D. P., Barker, K. R., and Gumpertz, M. L., 1995. Impact of crop rotation and tillage system on Heterodera glycines population density and soybean yield. Plant Disease, 79(3), 282-286.

Landis, D. A., Wratten, S. D., & Gurr, G. M., 2000. Habitat management to conserve natural enemies of arthropod pests in agriculture. Annual Review of Entomology, 45(1), 175-201.

Levine, E., Spencer, J. L., Isard, S. A., Onstad, D. W., & Gray, M. E. (2002). Adaptation of the western corn rootworm, Diabrotica virgifera virgifera LeConte (Coleoptera: Chrysomelidae), to crop rotation: evolution of a new strain in response to a cultural management practice. American Entomologist, 48 (9): 94-117.

Messelink, G.J., Bennison, J., Alomar, O. et al. BioControl, 2014. 59: 377. doi:10.1007/s10526-014-9579-6

Nauen R, Leadbeater A and Thompson A, 2008. Proposal on the Revision of EU Directive 91/41. The impact on resistance management and sustainable crop production in Europe. Outlooks on Pest Management S.19, 150–151.

Navarro-Llopis V., Primo J., Vacas S., 2012. Efficacy of attract-and-kill devices for the control of *Ceratitis capitate.* Pest Management Science 2012; DOI: 10.1002/ps.3393

Nicholls, C. I., Parrella, M. P., and Altieri, M. A., 2000. Reducing the abundance of leafhoppers and thrips in a northern California organic vineyard through maintenance of full season floral diversity with summer cover crops. Agricultural and Forest Entomology, 2(2), 107-113.

Nordlund, D.A. & Lewis, W.J., 1976. Terminology of chemical releasing stimuli in intraspecific and inter- specific interactions. Journal of Chemical Ecology, 2: 211-220.

Raty, L., Drumont, A., De Windt, N., and Grégoire, J. C., 1995. Mass trapping of the spruce bark beetle Ips typographus L.: traps or trap trees?. Forest Ecology and Management, 78(1), 191-205.

Razinger, J., Vasileiadis, V. P., Giraud, M., van Dijk, W., Modic, Š., Sattin, M., & Urek, G., 2016. On-farm evaluation of inundative biological control of Ostrinia nubilalis (Lepidoptera: Crambidae) by Trichogramma brassicae (Hymenoptera: Trichogrammatidae) in three European maize-producing regions. Pest Management Science, 72(2), 246-254.

Rotteveel T, Jorgensen LN and Heimbach U, 2011. Resistance management in Europe: a preliminary proposal for the determination of a minimum number of active substances necessary to manage resistance. Bulletin OEPP/EPPO Bulletin 41, 432–438.

Schrader G and Unger JG, 2003. Plant quarantine as a measure against invasive alien species: the framework of the International Plant Protection Convention and the plant health regulations in the European Union. Biological Invasions, 5(4), 357–364.

Sorensen, C. W., Smith, E. H., Smith, J., & Carton, Y., 2008. Charles V. Riley, France, and Phylloxera. American Entomologist, 54(3), 134-149.

Sparks, T. C., and R. Nauen. 2015. IRAC: Mode of action classification and insecticide resistance management. Pesticide Biochemistry and Physiology 121: 122-128.

Van Lenteren, J. C., 2012. The state of commercial augmentative biological control: plenty of natural enemies, but a frustrating lack of uptake. BioControl, 57(1), 1-20.

Van Lenteren, J. C. (Ed.), 2012. IOBC Internet book of biological control. International Organization for Biological Control.

Vincent, C., Hallman, G., Panneton, B., and Fleurat-Lessard, F. (2003). Management of Agricultural Insects with Physical Control Methods. Annual Review of Entomology, 48(1), 261-281

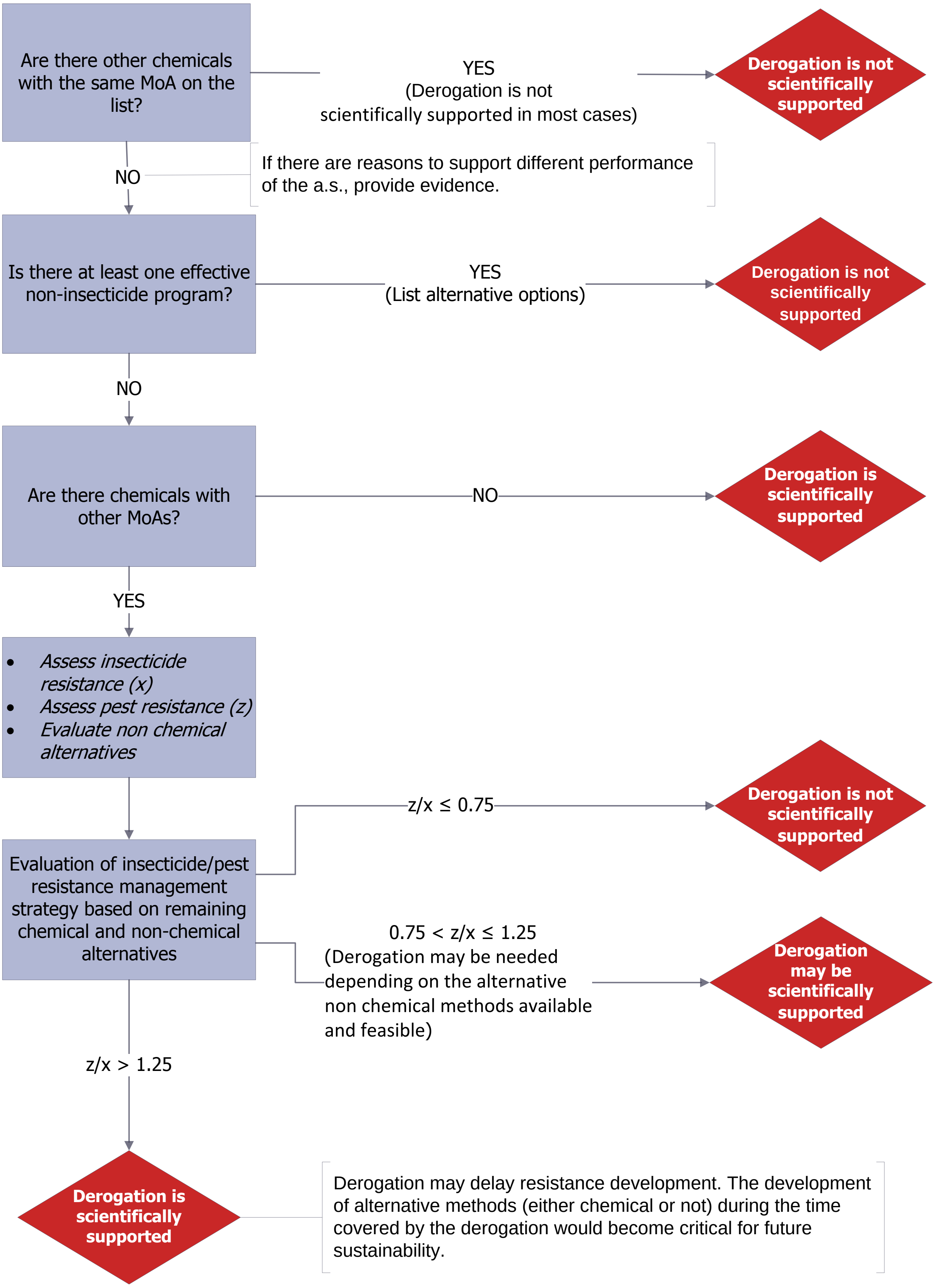
Witzgall, P., Kirsch, P., & Cork, A., 2010. Sex pheromones and their impact on pest management. Journal of Chemical Ecology, 36(1), 80-100.

Witzgall, P., Stelinski, L., Gut, L., & Thomson, D., 2008. Codling moth management and chemical ecology. Annual Review of Entomology, 53, 503-522.

Abbreviations

a.s.	active substance
EC	European Commission
EPPO	European and Mediterranean Plant Protection Organization
EIL	Economic Injury Level
EU	European Union
IRAC	Insecticide 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 insecticide (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://onlinelibrary.wiley.com/wol1/doi/10.2903/sp.efsa.2017.EN-1201/suppinfo

EFSA Journal

Example 2: the insecticides authorized are reported using fictitious names

Appendix B: Data collection form

Appendix to: EFSA (European Food Safety Authority), 2017.
Protocol for the evaluation of data concerning the necessity of the application of insecticide 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 2017:EN-1201

Crop/pests combination : Mandarin, tetranychid mites

Data to be entered by MSs

General info Cosmetic damage on fruit for fresh consumption; important losses for fruit infestations at the end of season
Key species at national level: Tetranychus urticae, Panonychus citri, Eotetranychus orientalis, Eotetranychus banksi
Number of generations/year: Tetranychid mites in citrus are active all year round,; most likely more than 10
Period of occurrence: All year round
Number of application: up to 9

Data to be entered by EFSA
Data to be entered by MSs
Data to be entered by EFSA

Insesticide alternatives

Insecticide authorised [1]	Other pests controlled [2]	Pest risk of resistance (z value)	Exceptions	Period of application	Max number of applications per crop	IRAC group/MoA [3]	Insecticide risk of resistance [4]			Insecticide alternatives MoA (class of risk of resistance) [5]			Insecticide risk of resistance (x value)	Notes			Evaluation of insecticide alternatives (z/x value)
							Global	National	Overall classification	Low	Moderate	High		Agronomic issues	Bee and environmental restrictions	Other information	
ABC	Citrus leafminer, Eriophyies sheldoni	3			3 per season	6	Moderate		Moderate	3	1	0	3.75		Not allowed during bloom; a security margin of 15 m from any water course		0.80
CDF						10 A	Low		Low					Active against immature stages only; should be mixed with oil to target adults as well		Protected use	
GHI					1 per season	10 B	Low		Low						A security margin of 15 m from any water course		
LMN	Leafhoppers				1 per season	21 A	Low		Low								
OPQ	Citrus leafminer					10 A	Low		Low					Active against immature stages only; should be mixed with adulticide to target adults as well			
a.s. under consideration					**2 per season**	**21 A**	**Low**		**Low**						**Avoid treatment during daytime to protect bees**	**Protected use**	

Non-insecticide methods

Main group	Type	Availability	Effectiveness	Practised Usage	Feasibility	Evaluation	Notes
Cultural control	Rotations						
Cultural control	Intercropping (mixed crops, row, strips)						
Cultural control	Change in planting/harvesting dates						
Cultural control	Cover crops	1) Use of cover crops (i.e., Festuca arundinacea)	1) this not a stand alone measure ans should be combined with other	1)	2)		
Cultural control	Increased crop competitiveness						
Cultural control	Soil tillage						
Cultural control	Mulching						
Cultural control	Push-and-pull						
Cultural control	Others						
Varietal resistance	Tolerant or resistant plant genotypes						
Varietal resistance	Crop/cultivar combinations	0) cultivar susceptibility is mediated by the rootstock	1) at present this is not an option as we are learning about the influence of rootstock on above ground pests	0)	0)		
Varietal resistance	Genetically engineered crops						
Varietal resistance	Others						
Biological control	Conservation biocontrol	1) Cover crops increase diversity and abundance of phytoseiid predatory mites 2) Application of pollen to increase abundance of generalist phytoseiid predatory mites 3) Use of pesticdes selective for phytoseiid predatory mites	1) this not a stand alone measure and should be combined with other methods	1)	2)		Use of selective pesticides is a widely adopted tactic in citrus
Biological control	Classical biocontrol						
Biological control	Inoculative biocontrol	1) Commercially available phytoseiid mites can be released as needed	1) unconsistent results so far	1)	2)		
Biological control	Inundative biocontrol						
Semiochemical control	Mating disruption						
Semiochemical control	Mass-trapping						
Semiochemical control	Atttract-and-sterilize						
Semiochemical control	Attract and infect						
Semiochemical control	Repellents						
Semiochemical control	Others						
Autocidal methods	Sterile male technique (SIT)						
Physical control	Nets, agrotextiles, traps			0)	0)		
Physical control	Others						

Aavailability: 0) no; 1) yes
Effectiveness: 0) not effective; 1) moderate effective; 2) high effective
Practiced Usage: 0) not practiced; 1) up to 10% of the acreage; 2) 10-50% of the acreage; 3) above 50% of the acreage
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

FOOTNOTES

[1] List of insecticide a.s. authorised for the specific crop/pest, with the exception of the insecticide a.s. under evaluation.

[2] Other pests controlled, other than the pest under evaluation, that can be controlled with the given insecticides.

[3] Classification of Mode of Actions according to the Insecticide Resistance Action Committee (IRAC). More explanation under Chapter 1.2.3.

[4] Except in case of metabolic resistance (see Chapter 1.2.3), if several sub-groups available, the highest "rsk of resistance" within the main group should be used.

[5] Insert the number of alternative MoA having respectively low, medium and high risk of resistance.

Appendix C – Member States' comments on the draft EFSA Technical Report

This Table of comments can be found as a pdf file (Appendix C) in the online version of this publication ('Supporting information' section):

http://onlinelibrary.wiley.com/wol1/doi/10.2903/sp.efsa.2017.EN-1060/suppinfo

Member State comments on the draft EFSA technical report on "Protocol for the evaluation of data concerning the necessity of the application of insecticide 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.