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Evaluation of the emergency authorisations granted by Member State France for plant protection products containing imidacloprid or thiamethoxam

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was requested by the European Commission to provide technical assistance in accordance with Article 53(2) of Regulation (EC) No 1107/2009 to examine the emergency authorisations granted in 2021 by the competent national authority in France for plant protection products containing the neonicotinoid active substances (a.s.) clothianidin, imidacloprid or thiamethoxam for uses on sugar beet which were restricted when all outdoor uses were prohibited in May 2018. EFSA was asked to assess whether the granting of this emergency authorisation and its wide scope was necessary because of danger which cannot be contained by any other reasonable means. In this context, EFSA collected and evaluated the information in relation to the emergency authorisation for imidacloprid and thiamethoxam in France in line with the EFSA insecticide protocol developed in the framework of a mandate concerning the application of Article 4(7) of Regulation (EC) No 1107/2009. The current technical report summarises the outcome of the evaluation of four crop/pest combinations considered in France in 2021. The evaluation demonstrated that for the examined pests (*Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus* and *Myzus persicae*) vectors of the quarantine virus BYV (beet yellows virus) no alternative active substance to neonicotinoids is currently authorised in France on sugar beet for seed treatment. Foliar spraying applications against the aphid vectors of BYV can't be considered as sufficient alternative method to the seed treatment, because they can't control the early proliferation of aphids. The evaluation included an assessment of non-insecticide alternatives for the presented uses. Seven non-chemical methods are available, but they are only moderately effective. For this reason, EFSA concluded when considering the methodology of the EFSA Article 4(7) insecticide protocol, that the emergency authorisations were scientifically supported.

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Keywords: pesticide, insecticide, imidacloprid, thiamethoxam, Article 53(2) of Regulation (EC) No 1107/2009

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Summary

In 2013, the uses of clothianidin, thiamethoxam and imidacloprid were restricted by Commission Implementing Regulation (EU) No 485/2013 to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances (a.s.) to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid have been prohibited for crops attractive to bees and for cereals (sown from January to June) except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing these a.s. have been prohibited for crops attractive to bees and for cereals except for uses in greenhouses and uses after flowering. Subsequently in May 2018, all outdoor uses were prohibited.

In 2021, France notified the European Commission of two 120-day emergency authorisation for neonicotinoids (imidacloprid & thiamethoxam) covering the uses on sugar beet against aphids *Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus* and *Myzus persicae* granted in accordance with Article 53 of the Regulation (EC) No 1107/2009.

Subsequently, the European Commission requested EFSA to provide technical assistance in accordance with Article 53(2) of Regulation (EC) No 1107/2009 to examine the emergency authorisations granted by Member State France for uses of imidacloprid and thiamethoxam which were restricted in accordance with Commission Implementing Regulation (EU) No 485/2013. In particular, EFSA was asked to assess whether the granting of these emergency authorisations and their wide scope were necessary because of danger which cannot be contained by any other reasonable means. In performing this exercise, EFSA should make use of the EFSA protocol for the evaluation of data concerning the necessity of the application of insecticide a.s. to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. This protocol was developed in the framework of a mandate concerning the application of Article 4(7) of Regulation (EC) No 1107/2009 and was published by EFSA on 5th April 2017.

On 31st May 2021 France was requested to update its emergency notifications in line with the data requirements and methodology proposed in the related EFSA insecticide protocol. France provided the updated documentation on 22nd June 2021. France provided further information on 20th September 2021. In the following steps, EFSA considered the information submitted by France in order to discuss whether the provided justifications indicated the need for the emergency authorisations due to a danger which cannot be contained by any other reasonable means.

Overall, five pests were evaluated to assess France's claims on the necessity of imidacloprid, and thiamethoxam to control a serious danger to plant health in sugar beet, specifically the vectors of the quarantine virus BYV (beet yellows virus), i.e. the aphids *Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus* and *Myzus persicae*. The evaluation demonstrated that for the vectors of the quarantine virus BYV (beet yellows virus), no alternative a.s. to neonicotinoids is currently authorised in France on sugar beet for seed treatment. Foliar spray applications against the aphid vectors of BYV cannot be considered as a sufficient alternative method to the seed treatment, because they can't control the early proliferation of aphids. Initially information was not provided by France on any alternative non-insecticide methods for controlling BYV. In September 2021 information on this was provided. Seven non-chemical methods are available, but they are only moderately effective. For this reason, EFSA concluded when considering the methodology of the EFSA Article 4(7) insecticide protocol, the emergency authorisations were scientifically supported.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

In 2013, the uses of clothianidin, thiamethoxam and imidacloprid were restricted by Commission Implementing Regulation (EU) No 485/2013¹ to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid have been prohibited for crops attractive to bees and for cereals (sown from January to June) except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing these active substances have been prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering (all details are provided in Annex I of Commission Implementing Regulation (EU) No 485/2013). Specific conclusions have been issued by EFSA in 2013 on the risk assessment for bees as regards the authorised uses of clothianidin, imidacloprid and thiamethoxam applied as seed treatments and granules (EFSA, 2013a,b,c). EFSA reviewed the risk to bees from these uses in February 2018 (EFSA, 2018a,b,c). EFSA also finalised its conclusion on the risk assessment for bees as regards all uses other than seed treatments and granules for the three neonicotinoids in July 2015 (EFSA, 2015a,b,c). Subsequently in May 2018 all outdoor uses of these three neonicotinoids were prohibited

In 2021, France notified the European Commission of two 120-day emergency authorisations covering the use of thiamethoxam & imidacloprid on sugar beet against aphids vectors of BYV (beet yellows virus) i.e. *Aphis fabae* (APHIFA), *Aulacorthum solani* (AULASO), *Macrosiphum euphorbiae* (MACSEU), *Myzus ascalonicus* (MYZUAS) and *Myzus persicae* (MYZUPE) granted from 06/02/2021 until 06/06/2021, in accordance with Article 53 of the Regulation (EC) No 1107/2009².

On 17th May 2021, the European Commission requested EFSA to provide scientific assistance in accordance with Article 53(2) of Regulation (EC) No 1107/2009 to examine the emergency authorisations granted by Member State France for the following uses of imidacloprid and thiamethoxam which were restricted by Regulation (EU) No 485/2013. EFSA was asked to assess whether the granting of these emergency authorisations and their wide scope were necessary because of danger which cannot be contained by any other reasonable means.

In this exercise, EFSA may consider making use of the 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, which was published on 5 April 2017 (EFSA, 2017). This protocol was developed in the framework of a mandate concerning the application of Article 4(7) of Regulation (EC) No 1107/2009, providing an exemption from the application of some cut-off criteria in cases of a serious danger that cannot be contained by other available means.

As a following step, on 31st May 2021 France was requested to update its emergency notifications in line with the data requirements and methodology proposed in the related EFSA insecticide protocol.

France provided the updated documentation to EFSA on 22nd June 2021. EFSA considered the information provided by France and drafted a Technical Report in order to examine whether the provided justifications indicate the need for the granted emergency authorisations for thiamethoxam due to a danger which cannot be contained by any other reasonable means.

EFSA ensured that the methodology of the protocol developed for the evaluation of insecticide active

1 Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.5.2013, p. 12-26.

2 Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

substances under Art. 4(7) (EFSA, 2017) was consistently applied by France and summarised the evaluation of imidacloprid and thiamethoxam in a draft report. On 6th September 2021 EFSA consulted France via written procedure on the draft Technical Report. Subsequent to the comments and additional information received on 20th September 2021 EFSA updated its assessment including incorporating updates in Appendix A.

2. Data and methodologies

2.1. Methodologies

The assessment was conducted in line with the 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, 2017). The submission provided by France in the form of data collection forms (see Appendix A) and report (France, 2021), was in line with the EFSA methodology (EFSA, 2017) with the notable exception that initially an assessment of alternative non-insecticide methods for controlling BYV vectors or BYV was not provided. France also submitted two supportive documents on the action plans against beet yellows (INRAE ITB 2020), and on the risk mitigation measures from the use of neonicotinoids (ANSES 2020). On 20th September 2021 a further document (Efficacité des traitements disponibles pour lutter contre les pucerons de la betterave (ANSES 2021)) and an updated data collection form was provided (see Appendix A). These additions provided a consideration of alternative non-insecticide methods for controlling BYV vectors / BYV.

The role of EFSA is to ensure that the methodology has been applied consistently. EFSA should review the summary provided by the concerned Member State and produce a Technical Report on the Member State notifications regarding their considerations justifying the need due to a danger which cannot be contained by any other reasonable means. Therefore, EFSA considered the information provided by France, such as the list of authorised insecticide active substances for each crop/pest combination, the evaluation of risk of resistance of pests, the evaluation of risk of resistance of insecticides and the presentation regarding non-insecticide alternatives as fully reliable and no further research was conducted to validate these data. Thus, France has the full responsibility for the accuracy and correctness of the data provided to EFSA to perform the assessment.

2.2. Data and information

This report presents the information contained in the report France (2021) and in the data collection forms on thiamethoxam and imidacloprid (Appendix A), prepared by France in order to align the information contained in its emergency notifications to the data requirements and methodology proposed in the EFSA insecticide protocol (EFSA, 2017). Table 1 provides an overview of the 120-day emergency authorisations granted by France for imidacloprid and thiamethoxam on sugar beet from 06/02/2021 until 06/06/2021.

Table 1: Emergency authorisations granted by France for imidacloprid and thiamethoxam uses in 2021

Active substance	Crop/pest combination ^(a)
Imidacloprid	Sugar beet /aphids (<i>Aphis fabae</i> , <i>Aulacorthum solani</i> , <i>Macrosiphum euphorbiae</i> , <i>Myzus ascalonicus</i> , <i>Myzus persicae</i>), vectors of BYV
Thiamethoxam	Sugar beet /aphids (<i>Aphis fabae</i> , <i>Aulacorthum solani</i> , <i>Macrosiphum euphorbiae</i> , <i>Myzus ascalonicus</i> , <i>Myzus persicae</i>), vectors of BYV

(a): Further information on the taxonomy of the pest is provided in Appendix B to this Technical Report

The data collection forms as submitted by France and evaluated by EFSA (i.e. list/s of alternative authorised a.s. in combination with the specific controlled pest), are presented as an Appendix to this Technical Report (Appendix A).

In addition, key supporting documents to this Technical Report are:

- the Member State submission in the form of a report (France, 2021).
- three supporting documents (ANSES 2020, ANSES 2021, INRAE ITB 2020),
- the comments received on the draft Technical Report by the concerned Member State (EFSA, 2021).

3. Evaluation and assessment

3.1. Emergency authorisations granted for plant protection products containing imidacloprid and thiamethoxam

Sugar beet / Aphids (*Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus*, *Myzus persicae*), vectors of BYV (beet yellows virus)

Table 2 indicates whether there are alternative a.s. authorised with the same Insecticide Resistance Action Committee (IRAC) MoA as the a.s. under consideration (i.e. IRAC group 4A neonicotinoids) and the information provided on alternative non-insecticide methods to control the vectors of the quarantine virus BYV (beet yellows virus), i.e., the aphids *Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus*, *Myzus persicae*, in sugar beet. Table 2 provides the outcome for the insecticide pest resistance management strategy based on the remaining insecticides and non-insecticide alternatives and indicates if a derogation for the use of the a.s. under consideration is supported or not by the information provided by France in accordance to the protocol. According to the French Reporting Template (France, 2021), in 2019, BYV was successfully controlled by authorised PPPs via treatment of the aerial parts against the aphid vectors, but in 2020 weather conditions and early proliferation of aphid vectors could not contain virus spread. To protect sugar beet in 2021 from the virus, the use of neonicotinoids for seed treatment of sugar beet was deemed necessary. In case that climatic conditions favour the early proliferation of aphid vectors, the sugar beets need to be protected at the first stages of the biological cycle, before the crop stage that foliar treatments against aphids can be applied. Therefore, foliar spraying applications against the aphid vectors of BYV cannot be considered as a sufficient alternative method against virus spread in sugar beet. Hence, a z/x score was not calculated. Further details on the evaluation are reported in Appendix A. EFSA concluded when considering that *Myzus persicae* has a very high resistance risk and the methodology of the EFSA Article 4(7) insecticide protocol, that the emergency authorisations were scientifically supported.

Table 2: Outcome of the evaluation of data concerning the emergency authorisations granted by France for plant protection products containing imidacloprid or thiamethoxam to control aphids (*Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus*, *Myzus persicae*) in sugar beet.

Authorised a.s. with same MoA	Alternative non-insecticide methods ^(a)	Evaluation of insecticide alternatives (z/x score) ^(b)	Derogation scientifically supported
No	Yes	N.A.	Yes

a.s.: Active substance.

MoA: Mode of action.

(a): Further information regarding the effectiveness, practised usage and feasibility of the available non-insecticide methods is provided in the text.

(b): N.A. = not applicable. There is no need to calculate the z/x score as chemical alternatives to neonicotinoids for seed treatment are not available and foliar sprays are only possible at later plant growth stages.

The evaluation of non-insecticide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop/pest combination is provided in the data collection forms in Appendix A. In summary, the possible non-insecticide methods listed to control the aphids in France are: biological control with macro- and micro- organisms; cultural methods, i.e. organic fertilisation (to reduce palatability of host plants to aphids), mulching (to impede identification of host plants by aphids), use of plants associated with “bottom-up” and “top-down” effect (use of plants to attract aphids away from the crop and use of plants that attract/host aphid natural

enemies); physical methods (applications with mineral or organic oils). These methods are of restricted feasibility and moderately effective against aphids and are not practiced. Moreover, regarding virus transmission by aphids, the vector population must be kept at a low level, unlike aphids that do not transmit viruses where a certain level of infestation can be tolerated. Table 3 provides an overview of the research activities and action plans on alternative processes which are currently ongoing in France. Research includes action plans for the substitution of seed treatment with neonicotinoids and development of sugar beet varieties resistant to viruses, which will gradually give results in the following five years.

Table 3: Research programs and action plans on alternative processes in France

Title of research programme and short description of research efforts undertaken and/or in progress	Funding	Expected date of results	State of works of the research project
French research program conducted by INRAe with an implementation followed by a managing board	20 million Euro Funding for 3 years	In 3 years	
Action plan for the substitution of seeds treated with neonics: - Agronomic research led by the French institutes INRAe and ITB, - Pilot farms to conduct the results of research and innovations, - AKER research program on sugar beet varieties resistant to neonics		Between 2021 and 2025 depending on the research program	500 ha of pilot farms in 2021

4. Conclusions

EFSA assessed whether the 120-day emergency authorisations for plant protection products containing the neonicotinoid a.s. imidacloprid and thiamethoxam for uses on sugar beet granted by the competent national authority in France in 2021 were necessary because of danger which cannot be contained by any other reasonable means by applying the protocol for evaluation of insecticide a.s. under Art. 4(7) of Regulation (EC) No 1107/2009 (EFSA, 2017).

Overall, five pests were evaluated to assess France’s claims on the necessity of imidacloprid and thiamethoxam to control a serious danger to plant health in sugar beets, specifically the vectors of the quarantine virus BYV (beet yellows virus), i.e., the aphids *Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus*, *Myzus persicae*. An overview of the outcome of the evaluation of chemical alternative substances to imidacloprid and thiamethoxam in France is provided in Table 4.

Table 4: Outcome of the evaluation of the granted 120-day emergency authorisations by France for the use of imidacloprid and thiamethoxam applying the Art. 4(7) protocol (EFSA, 2017)

Active substance	Crop/pest combination	Derogation scientifically supported
Imidacloprid	Sugar beet / aphids (<i>Aphis fabae</i> , <i>Aulacorthum solani</i> , <i>Macrosiphum euphorbiae</i> , <i>Myzus ascalonicus</i> , <i>Myzus persicae</i>), vectors of BYV (beet yellows virus)	Yes
Thiamethoxam	Sugar beet / aphids (<i>Aphis fabae</i> , <i>Aulacorthum solani</i> , <i>Macrosiphum euphorbiae</i> , <i>Myzus ascalonicus</i> , <i>Myzus persicae</i>), vectors of BYV (beet yellows virus)	Yes

The evaluation demonstrated that for the vectors of the quarantine virus BYV (beet yellows virus), i.e. the aphids (*Aphis fabae*, *Aulacorthum solani*, *Macrosiphum euphorbiae*, *Myzus ascalonicus*, *Myzus persicae*), no alternative a.s. to neonicotinoids are currently authorised in France on sugar beet for seed treatment. Foliar spraying applications against the aphid vectors cannot be considered as sufficient alternative method against virus spread compared to the seed treatment, because they cannot control the early proliferation of aphids. The evaluation included an assessment of non-insecticide alternatives for the presented uses. The methods listed are biological control with macro and micro-organisms, cultural methods, i.e. organic fertilisation, mulching, plants associated with "bottom-up" and "top-down" effects of natural enemies and aphids, respectively, and physical methods (applications with mineral or organic oils). These methods are characterised of restricted feasibility, they are moderately effective and are not practiced. Moreover, regarding virus transmission by aphids, the vector population must be kept at a low level, unlike aphids that do not transmit viruses where a certain level of infestation can be tolerated. Therefore, when considering the methodology of the EFSA Article 4(7) insecticide protocol, the emergency authorisations were scientifically supported. Research on alternative processes against BYV are currently ongoing in France.

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Abbreviations

a.s.	active substance
EC	European Commission
EU	European Union
IRAC	Insecticide Resistance Action Committee
MoA	Mode of Action
MS	Member State

Appendix A – Data Collection Forms

Validated data collection form (Excel file) submitted by France and evaluated by EFSA, in order to examine the emergency authorisations granted by France in accordance with Art. 53 of Regulation (EC) No 1107/2009 and their necessity to control a serious danger to plant health which cannot be contained by other available means including non-insecticide alternatives.

Appendix A can be found in the online version of this output ('Supporting information' section):

<https://doi.org/10.2903/sp.efsa.2021.EN-6968>

Appendix B – Pest classification

Information on the taxonomy of the pests under consideration in this Technical Report.

Species	Order	Family
<i>Aphis fabae</i>	Homoptera	Aphididae
<i>Aulacorthum solani</i>	Homoptera	Aphididae
<i>Macrosiphum euphorbiae</i>	Homoptera	Aphididae
<i>Myzus ascalonicus</i>	Homoptera	Aphididae
<i>Myzus persicae</i>	Homoptera	Aphididae