Appendix C - Evaluation of data concerning the necessity of clofentezine as acaricide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

In the framework of the peer review of the renewal of approval of the active substance clofentezine under Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, during the clock stop period the applicant submitted data concerning the necessity of clofentezine as an acaricide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, in accordance with Article 4(7) of Regulation (EC) No 1107/2009.

In this context, EFSA organised a commenting phase with Member States in order to collect and validate the data submitted by the applicant. The current scientific report summarises the outcome of the evaluation of 9 crop groups/pest combinations in 6 Member States.

The evaluation demonstrated that a wide range of alternative acaricide active substances to clofentezine are not available for chemical control in the following crop group/pest combinations, for which derogation is scientifically supported: bulb mites in flower bulbs and flower tubers (open field and protected uses); spider mites in stone fruit (sweet and sour cherry), raspberry (open field and protected use) (Spain), cucumber (open field and protected use), tomato (protected use); *Eutetranychus* sp. in boxwood. Chemical alternatives of the same mode of action (hexythiazox and in some cases also etoxazole) are available for the control of spider mites in 5 crop groups i.e. pome fruit in Belgium and Poland, strawberry (open field, protected) in Belgium, blackberry (open field, protected), ornamentals in Belgium, and citrus in Spain. Hexythiazox is authorised for pome fruit (*Panonychus ulmi*) and ornamentals (open field, protected) in Germany. For all these uses, derogation is not scientifically supported since at least one chemical alternative (hexythiazox) is available.

In two cases (strawberry/spider mites, field tomato/spider mites), etoxazole has been the only alternative of the same mode of action. However, based on the evaluation on E.U. level, only uses on ornamental plants in permanent greenhouses shall be authorised for etoxazole (Commission Implementing Regulation (EU) No 2020/2105; Official Journal of the European Union, L425/96, 16.12.2020). Therefore, etoxazole was not considered as an alternative and derogation is scientifically supported for use in strawberry against spider mites. Derogation may be scientifically supported for use in field tomato against spider mites depending on the availability and feasibility of alternative non-acaricide methods.

In 2 crop groups/pest combinations, i.e. tulip bulbs/*Aceria tulipae* and plum/spider mites, derogation may be scientifically supported, therefore the available non-acaricide methods should be considered very carefully. The assessment of non-chemical alternatives for the presented uses showed that the available non-chemical methods often have moderate efficacy or have certain limitations. A combination of both chemical and non-chemical methods seems often possible.
Summary

Clofentezine was included in Annex I to Directive 91/414/EEC by Commission Directive 2008/69/EC as amended by Commission Directive 2010/39/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) 2019/1589.

The applicant, ADAMA Agriculture BV, applied for renewal of approval in line with the provisions of Commission Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659.

Clofentezine is an acaricide active substance (a.s.) and the representative uses applied for the renewal are spray applications for the control of Panonychus ulmi, Tetranychus urticae (and related species) in citrus, pome fruits, strawberries and tomatoes.

In the framework of the process for renewal of approval according to Article 13 of Regulation (EU) No 844/2012, the applicant ADAMA Agriculture BV requested derogation under Article 4(7) of Regulation (EC) No 1107/2009, submitting evidence regarding the necessity of clofentezine to control a serious danger to plant health. In January 2016, the European Commission (EC) requested EFSA to provide scientific assistance as regards the consideration of evidence that the application of 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. In order to address this request EFSA set up a working group (WG) to develop a specific methodology for the assessment of insecticide active substances (a.s.). The protocol on the methodology was finalised on 29 March 2017 (EFSA, 2017).

In April 2020, following the EFSA request for additional information on the endocrine disruption potential of clofentezine, the applicant forwarded to the Rapporteur Member State (RMS), Spain and EFSA, the submission for derogation consisting of a data collection set and a report (Adama, 2020). The applicant included claims that the use of clofentezine is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 in relation to the uses authorised in one Member State (MS).

Subsequently, EFSA launched a commenting phase in April – May 2020 asking all MS to confirm that the uses for which the applicant requested Article 4(7) derogation are authorised, and if the use of clofentezine is considered essential to control a serious danger to plant health, giving clear justification for each use that is considered as essential. In addition, all MS were invited to submit information related to respective national authorisations for different crops or non-agricultural uses, evidence on resistance risk and uses that were not covered by applicant’s submission (e.g. minor uses).

Overall, more than 9 different crop group/pest combinations in 6 MS (AT, BE, DE, ES, NL, PL) were evaluated to assess the applicant’s claims or information directly provided by MS on the necessity of clofentezine to control a serious danger to plant health. The evaluation demonstrated that not a wide range of alternative acaricide active substances to clofentezine are available for chemical control in the following crop group/pest combinations, for which derogation is scientifically supported: bulb mites in flower bulbs and flower tubers (open field and protected uses); spider mites in stone fruit (sweet and sour cherry), raspberry (open field and protected use) (Spain), cucumber (open field and protected use), tomato (protected use); Eutetranychus sp. in boxwood.

Chemical alternatives of the same mode of action (hexythiazox and in some cases also etoxazole) are available for the control of spider mites in 5 crop groups i.e. pome fruit in Belgium and Poland, strawberry (open field, protected) in Belgium, blackberry (open field, protected), ornamentals in Belgium, and citrus in Spain. Hexythiazox is authorised for pome fruit (Panonychus ulmi) and ornamentals (open field, protected) in Germany. For all these uses, derogation is not scientifically supported since at least one chemical alternative (hexythiazox) is available. In two cases (strawberry/spider mites, field tomato/spider mites), etoxazole has been the only alternative of the same mode of action. However, based on the evaluation on E.U. level, only uses on ornamental plants in permanent greenhouses shall be authorised for etoxazole (Commission Implementing Regulation (EU) No 2020/2105; Official Journal of the European Union, L425/96, 16.12.2020). Therefore, etoxazole was not considered as an alternative and derogation is scientifically supported for use in strawberry against...
spider mites. Derogation may be scientifically supported for use in field tomato against spider mites depending on the availability and feasibility of alternative non-acaricide methods.

In 2 crop groups/pests, i.e. tulip bulbs/Aceria tulipae and plum/spider mites, derogation may be scientifically supported, therefore the available non-acaricide methods should be considered very carefully. Available non-chemical alternatives were also evaluated for the different uses, however these methods often do not have the same efficacy as chemical control or have restrictions. A combination of both chemical and non-chemical methods seems often possible.
Evaluation of data on clofentezine to control a serious danger to plant health

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1. Introduction

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

Clofentezine was included in Annex I to Directive 91/414/EEC on 1 January 2009 by Commission Directive 2008/69/EC as amended by Commission Directive 2010/39/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) 2019/1589.

The applicant, ADAMA Agriculture BV, applied for renewal of approval in line with the provisions of Commission Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. Clofentezine was evaluated by Spain as rapporteur Member State (RMS). The RMS delivered its initial evaluation of the dossier in the Renewal Assessment Report (RAR), which was received by EFSA on 6 March 2018 (Spain, 2018). In accordance with Article 13(1) of Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, EFSA finalised the conclusion on the peer review for clofentezine on 28 July 2021 (EFSA, 2021b).

Clofentezine is an acaricide active substance (a.s.) and the representative uses applied for the renewal are spray applications for the control of *Panonychus ulmi*, *Tetranychus urticae* (and related species) in citrus, pome fruits, strawberries and tomatoes.

In the framework of the process for renewal of approval according to Article 13 of Regulation (EU) No 844/2012, the applicant ADAMA requested derogation in accordance with the provisions of Article 4(7) of Regulation (EU) 1107/2009, submitting evidence regarding the necessity of clofentezine to control a serious danger to plant health which cannot be contained by other available means. In January 2016, European Commission (EC) requested by a general mandate to EFSA to provide scientific assistance as regards the consideration of evidence that the application of 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. In order to address this request EFSA set up a working group (WG) to develop a specific methodology for the assessment of insecticide active substances (a.s.). The protocol on the methodology was published on 5 April 2017 (EFSA, 2017).

In April 2020, following the EFSA request for additional information on the endocrine disruption potential of clofentezine, the applicant forwarded to the Rapporteur Member State (RMS), Spain and EFSA, the submission for derogation, consisting in a data collection set and a report (ADAMA, 2020). The applicant included claims that the use of clofentezine is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 in the NL.
On 28 April 2020 EFSA launched a 4-week commenting phase asking all MS to confirm that the uses for which the applicant requests Article 4(7) derogation are authorised and if the use of clofentezine is considered essential to control the serious danger to plant health, giving clear justification for each use that is considered as critical. In addition, all MS were invited to supplement the information provided by the applicant with information from their own MS uses also considering other uses not presented by the applicant (e.g. minor uses). During the commenting phase NL validated the information provided by applicant and AT, BE, DE, ES, PL submitted new information in relation to the uses *Panonychus ulmi* in pome fruit and *Tetranychus urticae* (and related species) in citrus, pome fruit, stone fruit, strawberries, small berries, cucumber and tomatoes.

As a follow up, EFSA ensured that the methodology was consistently applied by MS and summarised the evaluation of clofentezine (See Appendix D) in the current scientific report. A consultation process on the draft scientific report with MS was launched in November 2020, and a final consultation at the end of the peer review took place in June 2021.

2. Data and methodologies

2.1. Methodologies

The assessment was conducted in line with the methodology 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, finalised by EFSA on 29 March 2017 (EFSA, 2017). To be noted that the Insecticide evaluation protocol is followed and applied for acaricide active substances. The submission provided by the applicant in the form of a collection data set and a report, was also in line with the EFSA methodology (EFSA, 2017).

The role of EFSA is to act as the co-ordinator of the process, ensuring that the methodology is applied consistently and providing a scientific report on the evaluation of clofentezine. EFSA considered the information provided by Member States such as the full list of authorised acaricide active substances and the non-chemical methods as reliable and no further research was conducted to validate these data. Thus, Member States had 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 applicant report on clofentezine (ADAMA, 2020), and additional information and data provided by MS after the commenting phase launched by EFSA in April – May 2020. Table 1 provides an overview of the authorised uses of clofentezine for which derogation under Art. 4(7) was claimed by the applicant and were modified/verified by Member States, including their additional uses.

EFSA provides the collection data set as validated by MS and evaluated by EFSA (i.e. complete list/s of authorised a.s. in the relevant Member States in combination with the specific controlled pest), as an Appendix to this scientific report (Appendix D).

**Table 1**: Authorised uses of clofentezine in Europe for which derogation under Art. 4(7) was claimed by the applicant and were modified/verified by Member States, including their additional uses.

| Country       | Pest/crop combination(a)                                                                 |
|---------------|-------------------------------------------------------------------------------------------|
| Austria (AT)  | Bulb mites/ Flower bulbs and flower tubers (propagation)                                 |
| Belgium (BE)  | Tetranychidae/ Pome fruit (apple, pear)                                                   |
|               | Tetranychidae/ Stone fruit (sweet cherry, sour cherry, plum)                             |
|               | Tetranychidae/ Strawberry (F, P)                                                         |
|               | Tetranychidae/ Blackberry (F, P)                                                         |
|               | Tetranychidae/ Raspberry (F, P)                                                          |
|               | Tetranychidae/ Ornamentals                                                               |
|               | Tetranychidae - *Eutetranychus* sp./ Boxwood (*Buxus* sp.)                               |
| Germany (DE)  | Tetranychidae/ Ornamentals (F, P)                                                        |
|               | Tetranychidae- *Panonychus ulmi*/ Pome fruit (apple, pear)                               |
| Netherlands (NL)| Bulb mites (*Rhizoglyphus* spp., *Aceria tulipae*)/ Flower bulbs and flower tubers    |
|               | (propagation/forcing) (F, P)                                                             |
In addition, key supporting documents to this scientific report are:

- the applicant submission in the form of a Report (ADAMA, 2020) and collection data set;
- the comments received on the Applicant Report (EFSA, 2020);
- the comments received on the draft scientific report (EFSA, 2021a).

The applicant submitted the information in relation to one (1) Member State (NL); NL verified the information submitted by the applicant. Five (5) additional MS (AT, BE, DE, ES, PL) submitted information in relation to authorised uses in 28 crop/pest combinations.

3. Evaluation and assessment

3.1. Evaluation of chemical and non-chemical alternatives

The detailed evaluation of applicant’s claims on the necessity of clofentezine to control a serious danger to plant health according to Article 4(7) of Regulation (EC) No 1107/2009 concerning acaricide and non-acaricide alternatives is provided in the data collection sheets reported in Appendix D. The results for the different crop group/pest combinations are presented after taxonomic (family) or non-taxonomic grouping (EPPO global database)9.

Etoxazole (sharing the same mode of action (MoA) with clofentezine, different subgroup) has been under evaluation at EU level for its renewal. Based on the evaluation, only uses on ornamental plants in permanent greenhouses shall be authorised for etoxazole (Commission Implementing Regulation (EU) No 2020/210510). Therefore, etoxazole was not considered as an alternative to uses other than on ornamental plants in permanent greenhouses.

A separate evaluation was performed for greenhouse and field situations, wherever the number of available chemical alternatives differed between the two situations.

For reasons of completeness, an analysis of available non-chemical alternatives was carried out for each crop group/pest combination, even if this information does not affect the outcome of the evaluation in any practical way (as derogation is finalised at previous steps of the EFSA methodology). Information on main factors preventing or limiting the application of non-acaricide alternatives (scientific, technical, economic, others) were provided by the applicant and some of the concerned MS.

3.1.1. Flower bulbs and tubers/ bulb mites

Table 2 summarises the outcome for ‘Flower bulbs and tubers/bulb mites’, provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

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9 European and Mediterranean Plant Protection Organization (EPPO) Global Database (https://gd.eppo.int/)
10 Commission Implementing Regulation (EU) 2020/2105 of 15 December 2020 renewing the approval of the active substance etoxazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 425, 16.12.2020, p. 96–100.
Table 2: Outcome of the evaluation ‘Flower bulbs and tubers/bulb mites’ in 3 Member States.

| Crop(group)/pest | Country | Alternative acaricide(s) sharing the same MoA | Score$^{(a)}$ | Derogation scientifically supported |
|------------------|---------|---------------------------------------------|--------------|------------------------------------|
| Flower bulbs and tubers (propagation/forcing) (F, P)/Rhizoglyphus spp. | NL | No | 2.0 | Yes |
| Flower bulbs except tulip (propagation/forcing) (F, P)/Aceria tulipae | NL | No | 2.0 | Yes |
| Tulip bulbs (propagation/forcing) (F, P)/Aceria tulipae | NL | No | 2.67 | Yes |
| Flower bulbs/bulb mites | ES | No | n.a.$^{(b)}$ | Yes |
| Flower bulbs and flower tubers (propagation)/bulb mites | AT | No | n.a.$^{(b)}$ | Yes |

(a): $z/x$ scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions(MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

(b): n.a. = not applicable as no chemical alternatives are available.

Abamectin is only authorised in tulip (bulb dipping) and NL reports that it is effective against Aceria tulipae but not against Rhizoglyphus spp. Spirotremat has a post treatment secondary effect against A. tulipae in tulip after foliar application in outdoor crops but no effect against Rhizoglyphus spp. No alternative acaricide is authorised for flower bulbs against bulb mites in Spain and Austria.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D.

Non-acaricidal methods in the MS include only one practice (warm water treatment) that is highly effective but it has certain restrictions (not applicable in all species of flower bulbs, possible risk of viruses and diseases transmission, possible crop damage) and can only be used in combination with pesticides. There are also some methods of moderate effectiveness and feasible with restrictions: release of commercially available phytoseid mites have inconsistent results and combination with acaricides is necessary; the Ultra Low Oxygen treatment during storage has low cell capacity and other measures are necessary; Crop/cultivar combination is restricted by the fact that the choice of cultivars is dictated by the market. Other methods have low effectiveness and feasibility.

3.1.2. Pome fruit/ spider mites

Table 3 summarises the outcome for ‘Pome fruit/spider mites’, provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

Table 3: Outcome of the evaluation ‘Pome fruit/spider mites’ in 3 Member States.

| Crop(group)/pest | Country | Alternative acaricide(s) sharing the same MoA | Score$^{(a)}$ | Derogation scientifically supported |
|------------------|---------|---------------------------------------------|--------------|------------------------------------|
| Pome fruit (apple, pear)/Tetranychidae | BE | Yes$^{(c)}$ | n.a.$^{(b)}$ | No |
| Pome fruit (apple, pear)/Panonychus ulmi | DE | Yes$^{(c)}$ | n.a.$^{(b)}$ | No |
| Apple/Panonychus ulmi | PL | Yes$^{(c)}$ | n.a.$^{(b)}$ | No |

(a): $z/x$ scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions(MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

(b): n.a. = not applicable as derogation is finalised in a previous Step of the EFSA methodology.
(c): Hexythiazox

For the uses against Tetranychidae in pome fruit, at least one acaricide (hexythiazox) with the same MoA (10A) is authorised. Hence, derogation is not scientifically supported.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D.

Introduction of predatory mites (Typhlodromus pyri) is available in Belgium, Germany and Poland. This non-acaricide method is highly effective in Poland but is applied in small scale. Moreover, the same method is applied in small scale with inconsistent results in Germany and is moderately effective in Belgium, where it is applied in large scale. In addition, conservation biological control, through planting selected plants around the orchard, is moderately effective in Poland. Another measure of moderate effectiveness, applied in a small (Poland) or larger (Belgium) scale, is growing at moderate vigour through controlled nitrogen fertilization.

3.1.3. Stone fruit/spider mites

Table 4 summarises the outcome for 'Stone fruit/spider mites', provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

Table 4: Outcome of the evaluation 'Stone fruit/spider mites' in one Member State.

| Crop(group)/pest                  | Country | Alternative acaricide(s) sharing the same MoA | Score\(^{(a)}\) | Derogation scientifically supported |
|----------------------------------|---------|-----------------------------------------------|-----------------|---------------------------------|
| Sweet cherry, sour cherry/Tetranychidae | BE      | No                                            | 1.50            | Yes                             |
| Plum/Tetranychidae               | BE      | No                                            | 1.00            | Maybe                           |

\(^{(a)}\): \(z/x \text{ scores} > 1.25\): derogation is scientifically supported as there are not enough alternative mode of actions(MoA); \(0.75 < z/x \text{ scores} < 1.25\): derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; \(<0.75\): derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

Derogation is scientifically supported as there are not enough alternative MoA against Tetranychidae in sweet cherry and sour cherry (Insecticide Resistance Action Committee (IRAC) MoA 23, substance with unknown or uncertain MoA). In plum, an extra MoA is available (IRAC MoA 21A) and derogation may be scientifically supported depending on the availability and feasibility of alternative non-acaricide methods.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D.

As reported by Belgium, inoculative biological control through the release of *T. pyri* is highly effective in stone fruit (sweet cherry, sour cherry, plum) and it is practised in large scale (> 50% of the acreage). When inoculative biological control is combined with clofentezine application, the application of the acaricide should be performed no later than 6 weeks before and 6 weeks after the introduction of *T. pyri*.

3.1.4. Strawberry/spider mites

Table 5 summarises the outcome for 'Strawberry/spider mites', provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.
Table 5: Outcome of the evaluation “Strawberry/spider mites’ in 2 Member States.

| Crop(group)/pest       | Country | Alternative acaricide(s) sharing the same MoA | Score(a) | Derogation scientifically supported |
|------------------------|---------|---------------------------------------------|---------|----------------------------------|
| Strawberry (F, P)/Tetranychidae | BE      | Yes(d)                                      | n.a.(b) | No                               |
|                         | ES      | No                                          | n.a.(c) | Yes                              |

(a): $z/x$ scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions(MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.
(b): n.a. = not applicable as derogation is finalised in a previous Step of the EFSA methodology.
(c): :n.a. = not applicable as no chemical alternatives are available.
(d): Hexythiazox
F: Open field; P: Protected

For the use against Tetranychidae in strawberry (open field and protected) in Belgium, one acaricide (hexythiazox) with the same MoA and chemical sub-group (10A) is authorised. Hence derogation is not scientifically supported. For the use against Tetranychidae in strawberry (open field and protected) in Spain, etoxazole (IRAC group 10B) belonging to the same main group (10) is authorised for this use. However, based on the evaluation of etoxazole on E.U. level, only uses on ornamental plants in permanent greenhouses shall be authorised (Commission Implementing Regulation (EU) No 2020/21051). Therefore, clofentezine remains the only available chemical solution for this use in Spain and derogation is considered as scientifically supported.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D.

Introduction of T. pyri against spider mites is practised in 10% - 50% of the crop acreage in Belgium and it is moderately effective. In case of protected crop, greenhouse/tunnel clean-up is a highly effective practice, while avoidance of low relative humidity is moderately effective. No information was provided for available non-acaricide alternatives in Spain.

3.1.5 Small berries/ spider mites

Table 6 summarises the outcome for ‘Small berries/spider mites’, provides information on the number of acaricide a.s. alternatives, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

Table 6: Outcome of the evaluation ‘Small berries/spider mites’ in 2 Member States.

| Crop(group)/pest       | Country | Alternative acaricide(s) sharing the same MoA | Score(a) | Derogation scientifically supported |
|------------------------|---------|---------------------------------------------|---------|----------------------------------|
| Blackberry (F, P)/Tetranychidae | BE      | Yes(d)                                      | n.a.(b) | No                               |
| Raspberry (F, P)/Tetranychidae | ES      | No                                          | n.a.(c) | Yes                              |

(a): $z/x$ scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions(MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.
(b): n.a. = not applicable as derogation is finalised in a previous Step of the EFSA methodology.
(c): :n.a. = not applicable as no chemical alternative is available.
(d): Hexythiazox

11 Commission Implementing Regulation (EU) 2020/2105 of 15 December 2020 renewing the approval of the active substance etoxazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 425, 16.12.2020, p. 96–100.
For the use against Tetranychidae in blackberry and raspberry (open field and protected) in Belgium, hexythiazox with the same MoA (10A) is authorised. Hence derogation is not scientifically supported. No other acaricide is authorised in Spain for the use against Tetranychidae in raspberry.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D.

Introduction of _T. pyri_ against spider mites in blackberry and raspberry is practised in 10%-50% of the crops acreage in Belgium and it is moderately effective. In case of protected crops, glasshouse/tunnel clean-up is highly effective, while avoidance of low relative humidity is moderate effective. No information was provided for available non-acaricide alternatives in raspberry in Spain.

### 3.1.6 Ornamentals/ spider mites

Table 7 summarises the outcome for ‘Ornamentals/spider mites’, provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

**Table 7: Outcome of the evaluation ‘Ornamentals/spider mites’ in 2 Member States.**

| Crop(group)/pest | Country | Alternative acaricide(s) sharing the same MoA | Score(a) | Derogation scientifically supported |
|------------------|---------|---------------------------------------------|----------|-----------------------------------|
| Ornamentals (F, P)/Tetranychidae | BE      | Yes(d)                                      | n.a.     | No                                |
|                   | DE      | Yes(d)                                      | n.a.     | No                                |
| Boxwood ( _Buxus sp._)/ _Eutetranychus sp._ | BE      | No                                          | n.a.     | Yes                               |

(a): z/x scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions(MoA); 0.75 ≤ z/x ≤ 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

(b): n.a. = not applicable as derogation is finalised in a previous Step of the EFSA methodology.

(c): n.a. = not applicable as no chemical alternative is available.

(d): Hexythiazox

F: Open field; P: Protected

For the use against Tetranychidae in ornamentals (open field and protected) in Belgium and Germany, at least one acaricide (hexythiazox) with the same MoA is authorised. Regarding the use against _Eutetranychus sp._ in boxwood, no other acaricides are authorised, hence the derogation is scientifically supported.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D.

Introduction of _T. pyri_ against spider mites is practised in Belgium (10-50% of the acreage) and Germany (up to 10% of acreage) and it is moderately effective. In case of protected crops in Belgium, glasshouse/tunnel clean-up (including crop residues) is a highly effective practice, while avoidance of low relative humidity is moderate effective.

### 3.1.7 Cucumber/ spider mites

Table 8 summarises the outcome for ‘Cucumber/spider mites’, provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.
Table 8: Outcome of the evaluation ‘Cucumber/spider mites’ for in one Member State.

| Crop(group)/pest          | Country | Alternative acaricide(s) sharing the same MoA | Score(a) | Derogation scientifically supported |
|---------------------------|---------|-----------------------------------------------|----------|------------------------------------|
| Cucumber (F, P)/Tetranychidae | ES      | No                                            | 3        | Yes                                |

(a): z/x scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions (MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

Derogation is scientifically supported as there are not enough alternative mode of actions (MoA) against Tetranychidae in cucumber (IRAC MoA 21A).

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D. No information was provided for available non-acaricide alternatives in cucumber/spider mites in Spain.

3.1.8 Tomato/spider mites

Table 9 summarises the outcome for ‘Tomato/spider mites’ provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

Table 9: Outcome of the evaluation ‘Tomato/spider mites’ in one Member State.

| Crop(group)/pest          | Country | Alternative acaricide(s) sharing the same MoA | Score(a) | Derogation scientifically supported |
|---------------------------|---------|-----------------------------------------------|----------|------------------------------------|
| Tomato (F)/Tetranychidae  | ES      | No                                            | 1.09     | Maybe                              |
| Tomato (P)/Tetranychidae  | ES      | No                                            | 1.71     | Yes                                |

(a): z/x scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions (MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

For the use against Tetranychidae in field tomato in Spain, etoxazole (IRAC group 10B), belonging to the same main group (10), is authorised for this use. However, based on the evaluation of etoxazole on E.U. level, only uses on ornamental plants in permanent greenhouses shall be authorised (Commission Implementing Regulation (EU) No 2020/2105). The computed z/x is between 0.75 and 1.25. Hence derogation may be scientifically supported in field tomato/spider mites depending on the availability and feasibility of alternative non-acaricide methods. In case of protected tomato, derogation is scientifically supported as there are not enough alternative MoA (IRAC MoA 21A, 6).

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D. No information was provided.
for non-acaricide alternatives in tomato/spider mites in Spain as no documentation was available on specific non-chemical methods, their effectiveness and feasibility in tomato crop.

### 3.1.9 Citrus/ spider mites

Table 10 summarises the outcome for ‘Citrus/spider mites’, provides information on the available alternative acaricide a.s. sharing the same MoA, the numerical scores for the acaricide/pest resistance management strategy based on the remaining acaricide and non-acaricide alternatives and indicates if a derogation of the a.s. under consideration is scientifically supported or not. Further details on the evaluation are reported in Appendix D.

#### Table 10: Outcome of the evaluation ‘Citrus/spider mites’ in one Member State.

| Crop(group)/pest | Country | Alternative acaricide(s) sharing the same MoA | Score(s) | Derogation scientifically supported |
|------------------|---------|---------------------------------------------|----------|------------------------------------|
| Citrus/Tetranychidae | ES | Yes, (b) | n.a. (b) | No |

(a): z/x scores > 1.25: derogation is scientifically supported as there are not enough alternative mode of actions(MoA); 0.75 and < 1.25: derogation is maybe scientifically supported depending on the availability and feasibility of alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

(b): n.a. = not applicable as derogation is finalised in a previous Step of the EFSA methodology.
(c): Hexythiazox

For the use against Tetranychidae in citrus, one acaricide (hexythiazox) of the same MoA and chemical sub-group (10A) is authorised in Spain. Hence, derogation is not scientifically supported.

The evaluation of non-acaricide alternatives and detailed information on possible reasons preventing or limiting the applicability of each method for the above outlined crop(group)/pest combinations in the respective MS are provided in the data collection sheets in Appendix D. No information was provided for available non-acaricide alternatives in citrus/spider mites in Spain.

### 4. Conclusions

The applicants’ claim that the use of clofentezine is considered essential in accordance with Article 4(7) of Regulation (EC) No 1107/2009 for each authorised use in the considered MS or information directly provided by MS was evaluated following the methodology proposed in the EFSA protocol for evaluation of insecticide active substances under Art. 4(7) (EFSA, 2017). Overall, 9 different crop(group)/pest combinations in 6 MS (AT, BE, DE, ES, NL, PL) were evaluated.

An overview of the outcome of chemical alternative substances to clofentezine is provided in Table 11.

#### Table 11: Overview of the evaluation of chemical alternative substances to clofentezine.

| Crop group (crops)/pest combination | Number of crop (group)/pest combination(a) | Number of MS | Derogation scientifically supported (open field) | Derogation scientifically supported (protected use) |
|-------------------------------------|-------------------------------------------|--------------|-----------------------------------------------|-------------------------------------------------|
| Flower bulbs and tubers/ bulb mites | 6                                         | 3            | Yes                                           | Yes                                             |
| Flower bulbs (tulip)/Acacia tulipae | 1                                         | 1            | Yes                                           | Yes                                             |
| Pome fruit/ spider mites            | 4                                         | 3            | No                                            | n.a. (b)                                        |
| Stone fruit (sweet cherry, sour cherry)/spider mites | 2 | 1 | Yes                                           | n.a. (b)                                        |
| Stone fruit (plum)/ spider mites    | 1                                         | 1            | Maybe                                         | n.a. (b)                                        |
| Strawberry/ spider mites            | 2                                         | 2            | BE: No ES: Yes                                | BE: No ES: Yes                                  |
| Small berries (blackberry)/ spider mites | 2 | 1 | No                                            | No                                              |
| Small berries (raspberry)/ spider mites | 2 | 2 | BE: No ES: Yes                                | BE: No ES: Yes                                  |
The evaluation demonstrated that not a wide range of alternative acaricide active substances to clofentezine are available for chemical control in the following crop group/pest combinations, for which derogation is scientifically supported: bulb mites in flower bulbs and tubers; tulip/Aceria tulipae; spider mites in stone fruit (sweet and sour cherry), raspberry (open field and protected use) (Spain), cucumber (open field and protected use), tomato (protected use); Eutetranychus sp. in boxwood. In one crop groups/pest combination, i.e., plum/spider mites, derogation may be scientifically supported, therefore the available non-acaricide methods should be considered very carefully below.

Chemical alternatives of the same mode of action (hexythiazox and in some cases also etoxazole) are available for the control of spider mites in 5 crops (group) i.e. pome fruit in Belgium and Poland, strawberry (open field, protected) in Belgium, blackberry (open field, protected), ornamentals in Belgium, and citrus in Spain. Hexythiazox is authorised for use against Panonychus ulmi in pome fruit and against spider mites in ornamentals (open field, protected) in Germany. For all these uses, derogation is not scientifically supported. Furthermore, etoxazole is authorised for use against spider mites in protected strawberry and field tomato in Spain (Table 12). However, based on the evaluation of etoxazole on E.U. level, only uses on ornamental plants in permanent greenhouses shall be authorised (Commission Implementing Regulation (EU) No 2020/2105\(^{13}\)). Therefore, derogation is scientifically supported for use against spider mites in strawberry since clofentezine remains the only available chemical while it may be scientifically supported in field tomato/spider mites depending on the availability and feasibility of alternative non-acaricide methods.

Table 12: Summary of the evaluation where chemical alternative substances of the same MoA to clofentezine were available.

| Crop group (crops)/pest combination | Number of crop (group)/pest combination\(^{(a)}\) | Number of MS | Derogation scientifically supported (open field) | Derogation scientifically supported (protected use) |
|-------------------------------------|-------------------------------------------------|--------------|-----------------------------------------------|-----------------------------------------------|
| Ornamentals/ spider mites           | 2                                               | 2            | No                                            | No                                            |
| Ornamentals (Buxus sp.)/Eutetranychus sp. | 1                                               | 1            | Yes                                           | n.a.\(^{(b)}\)                                 |
| Cucumber/ spider mites              | 2                                               | 1            | Yes                                           | Yes                                           |
| Tomato/ spider mites               | 2                                               | 1            | Maybe                                         | Yes                                           |
| Citrus /spider mites                | 1                                               | 1            | No                                            | n.a.\(^{(b)}\)                                 |

\(^{(a)}\): Uses for a crop(group)-pest combination in open field and protected use are considered separately uses for (in open field and under protected use).

\(^{(b)}\): n.a. Not applicable, as use was not requested or use is related to tree crops (open field).

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\(^{13}\) Commission Implementing Regulation (EU) 2020/2105 of 15 December 2020 renewing the approval of the active substance etoxazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 425, 16.12.2020, p. 96–100.
alternative non-acaricide methods; <0.75: derogation is scientifically not supported as there are enough alternative MoA. Further details see EFSA, 2017.

(b) Hexythiazox

The evaluation included an assessment of non-chemical alternatives for the presented uses. A narrow range of non-chemical methods are available and often these methods have moderate efficacy or have certain limitations. More specifically:

Only one practice (warm water treatment) is highly effective for the control of bulb mites in the MS but it has several restrictions (not applicable in all species of flower bulbs, possible risk of viruses and diseases transmission, possible crop damage) and can only be used in combination with acaricides. Release of commercially available phytoseiid mites, Ultra Low Oxygen treatment during storage, and crop/cultivar combinations are some additional measures of moderate effectiveness and restricted feasibility.

Inoculative releases of predatory mites (mainly _T. pyri_) is of moderate to high effectiveness in orchards, depending on the crop and the country. The introduction of _T. pyri_ against spider mites in pome fruit is highly effective in Poland, although applied in small scale, but of moderate effectiveness in Belgium where applied in large scale; it shows inconsistent results in Germany. Release of _T. pyri_ is highly effective in all examined stone fruit (sweet cherry, sour cherry, plum) and it is already used in large scale (> 50% of the acreage). Two other practices of moderate effectiveness are available for the control of spider mites in apple: conservation biological control, through planting selected plants around the orchards in Poland; growing at moderate vigour through controlled nitrogen fertilization, used in small (Poland) or larger (Belgium) scale.

In open field and protected crops of strawberry, blackberry and raspberry and ornamentals, introduction of _T. pyri_ against spider mites is practised in 10-50% of the acreage in Belgium and up to 10% of acreage in Germany, and it is moderately effective. In case of protected crops, greenhouse/tunnel clean-up is a highly effective practice, already applied in 10-50% of the acreage, while avoidance of low relative humidity is moderately effective.

No information was provided for available non-acaricide alternatives against spider mites in strawberry, raspberry, cucumber, tomato and citrus in Spain.
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Abbreviations
a.s. active substance
AT Austria
BBCH growth stages of mono- and dicotyledonous plants
BE Belgium
DAR Draft Assessment Report
EC European Commission
ES Spain
EU European Union
IPM Integrated Pest Management
IRAC Insecticide Resistance Action Committee
MoA Mode of Actions
MS Member State
NL The Netherlands
PL Poland
RAR Renewal Assessment Report
RMS Rapporteur Member State
WG Working Group
Appendix D

Validated Excel files submitted by MS (Austria, 2020; Belgium, 2020; Germany, 2020; Spain, 2020; Netherlands, 2020; Poland, 2020) and evaluated by EFSA.