CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for aquatic organisms for the active substance imidacloprid[1]

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ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to perform an evaluation of imidacloprid as regards the risk to aquatic organisms. In this context the conclusions of EFSA concerning the risk assessment for aquatic organisms for the active substance imidacloprid are reported. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. The conclusions were reached on the basis of the evaluation of the representative uses of imidacloprid authorised at the time of approval of the substance. The proposed endpoints concluded as being most appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data, are presented. Missing information identified as being required to allow for a complete risk assessment is listed.

KEY WORDS

Imidacloprid, peer review, risk assessment, pesticide, insecticide

[1] On request from the European Commission, Question No EFSA-Q-2014-00028, approved on 17 September 2014.

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Suggested citation: EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment for aquatic organisms for the active substance imidacloprid. EFSA Journal 2014;12(10):3835, 49 pp. doi:10.2903/j.efsa.2014.3835.

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC, 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) No 541/2011 and Commission Implementing Regulation (EU) No 485/2013.

In accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data, in January 2014 the European Commission requested the EFSA to perform an evaluation of imidacloprid and provide conclusions as regards the risk to aquatic organisms following consideration of a new study on the toxicity of imidacloprid on aquatic organisms.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing studies that were submitted by the applicant in support of the original approval of imidacloprid, the recent study on the toxicity of imidacloprid on aquatic organisms together with its evaluation undertaken by the Netherlands. In addition, higher tier microcosm/mesocosm studies not available for the original approval of imidacloprid were submitted by the applicant and three other companies and were taken into account, as well as any other data that were judged to be relevant to the assessment. For the latter purpose, EFSA requested the applicant to conduct a systematic literature review in accordance with the EFSA Guidance on the submission of scientific peer-reviewed open literature (EFSA Journal 2011;9(2):2092). The EFSA guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290) was considered in the current evaluation.

Definitive Regulatory Acceptable Concentrations (RACs) to be used for the acute and chronic risk assessment for aquatic organisms could not be established on the basis of the available data. However, in the absence of further data, the provisional tier-2 RACs should be considered currently as the most suitable approach for addressing the risk to the most sensitive aquatic species. Overall, based on these provisional tier-2 RACs and by following a conservative approach, a high acute and chronic risk could not be excluded for the representative uses in apple and field tomato and a high chronic risk could not be excluded for the representative use in glasshouse tomato, while a low risk may be concluded for the representative use in sugar beet based on a weight of evidence approach. Overall, further data would be needed to draw a firm conclusion and/or to refine the risk assessment.

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BACKGROUND

Imidacloprid was included in Annex I to Directive 91/414/EEC[3] on 1 August 2009 by Commission Directive 2008/116/EC[4], and has been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7] and Commission Implementing Regulation (EU) No 485/2013[8]. The peer review leading to the approval of this active substance was finalised on 29 May 2008 as set out in the EFSA Scientific Report (2008) 148 (EFSA, 2008). In addition, a specific Conclusion was issued on 19 December 2012 concerning the risk assessment for bees (EFSA, 2013) and on 17 June 2014 following the submission of confirmatory data concerning the risk assessment for operators and workers, and the risk to birds and mammals (EFSA, 2014a).

In view of an evaluation carried out by the Netherlands based on a recent study on the toxicity of imidacloprid on aquatic organisms (Roessink *et al.*, 2013), a new chronic toxicity threshold regarding aquatic organisms was derived for imidacloprid. Following the review of the article by the rapporteur Member State Germany it was proposed that the new study can be considered useful for regulatory purposes.

In accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data, on 13 January 2014 the European Commission requested the EFSA to perform an evaluation of imidacloprid and provide conclusions as regards the risk to aquatic organisms.

A consultation on the evaluation and preliminary conclusions of EFSA on the risk assessment for aquatic organisms was conducted with Member States via a written procedure in May - June 2014. The draft conclusions drawn by EFSA, together with the points that required further consideration in the assessment, as well as the specific issues raised by Member States following the consultation were discussed at the Pesticides Peer Review Experts' Meeting 116 on ecotoxicology in June 2014. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report. A further consultation on the final conclusions arising from the peer review of the risk assessment for aquatic organisms took place with Member States via a written procedure in August 2014.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing studies that were submitted by the applicant in support of the original approval of imidacloprid, the recent study on the toxicity of imidacloprid on aquatic organisms (Roessink *et al.*, 2013) together with its evaluation undertaken by the Netherlands (EFSA, 2014b). In addition, higher tier microcosm/mesocosm studies not available for the original approval of imidacloprid were submitted by the applicant and three other companies[9] and were taken into account, as well as any other data

[3] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[4] Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86-91.

[5] 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.

[6] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

[7] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

[8] 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.

[9] Nufarm GmbH & Co KG, Makhteshim Agan Industries group and Sharda Worldwide Exports Pvt. Ltd.

that were judged to be relevant to the assessment. For the latter purpose, EFSA requested the applicant to conduct a systematic literature review in accordance with the EFSA Guidance on the submission of scientific peer-reviewed open literature (EFSA, 2011). In addition, the EFSA guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters was considered in the current evaluation (EFSA PPR Panel, 2013).

A key background document to this conclusion is the Final addendum (compiled version of August 2014 containing all individually submitted addenda (Germany, 2014), and the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised during the peer review. The Peer Review Report (EFSA, 2014b) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the evaluation of the study by Roessink *et al.*, (2013) by the Netherlands,
- the study evaluation notes[10] prepared by EFSA,
- the report of the scientific consultation with Member State experts, including comments received on the preliminary draft EFSA conclusion,
- the Evaluation Table (10 September 2014),
- the comments received on the draft EFSA conclusion,
- the re-evaluation of the outdoor mesocom study from Ratte & Memmert (2003), the summary of the literature data search and the report on systematic literature review provided by the applicant.

[10] As no Draft Assessment Report prepared by the rapporteur Member State was available in the context of this peer review, the studies and available data submitted by the applicant and/or made available by other parties were evaluated by EFSA and summarised in a document titled 'study evaluation notes'.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Imidacloprid is the ISO common name for (*E*)-1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine (IUPAC).

The evaluated representative uses in the original peer review were as an insecticide seed treatment for sugar beet and as a foliar spray for apples and tomatoes. Full details of the GAP can be found in Appendix A.

CONCLUSIONS OF THE EVALUATION

The risk assessment was performed taking into consideration the recommendations of the EFSA PPR Panel (2013).

The EFSA PPR Panel (2013) recommends to follow a stepwise approach for effect assessment that starts with the tier 1 acute and tier 1 chronic toxicity data set, respectively. The tier 1 and tier 2 effect assessments are based on single species laboratory toxicity tests; the tier 3 (population- and community-level experiments and models) and the tier 4 (landscape-level models) may concern a combination of experimental data and modelling to assess population- and/or community-level responses (e.g. recovery, indirect effects) at relevant spatio-temporal scales. According to the effect assessment schemes proposed by the EFSA PPR Panel (2013), Regulatory Acceptable Concentrations (RACs) should be derived and directly compared with the relevant Predicted Environmental Concentration values in surface water (PEC_{sw}). Deriving the RACs, two options may be considered: (1) the ecological threshold option (ETO), accepting negligible population effects only, and (2) the ecological recovery option (ERO), accepting some population-level effects if ecological recovery takes place within an acceptable time period. In principle, all the tiers are able to address the ETO, while only the tier 3 (model ecosystem approach) may be able to address also the ERO. The **tier-1 RACs** are based on standard toxicity endpoints; the **tier-2 RACs** are based on the standard and additional single species laboratory tests to calculate the geometric mean or to construct a Species Sensitivity Distribution (SSD) curve; while the **tier-3 RACs** are based on the microcosm and mesocosm data.

1. Toxicity endpoints

Aquatic toxicity endpoints for imidacloprid were derived from the studies submitted for the EU peer review to support the original approval of imidacloprid and from publicly available literature, including a systematic literature search performed by the applicant. The validity of data available for the original EU peer review was reconsidered by EFSA and all studies were deemed acceptable, except the study of Gagliano (1991) on *Chironomus tentans* reported in the original DAR (Germany, 2005) as additional information (see study evaluation notes, section 1.1; EFSA, 2014b). It has to be noted that the lower tier studies were not in depth re-evaluated, because the EFSA PPR Panel (2013) did not introduce new criteria for the evaluation of these studies.

The acute toxicity to **fish,** reported in the systematic review report, ranged from 170 to 502 mg a.s./L. The lowest endpoint (170 mg a.s./L) was observed in the paper from Chen *et al.*, (2013). This endpoint was related to imidacloprid in a formulated product. In the same study different formulations were tested showing a different toxicity to fish. Therefore, the acute endpoint used in the tier-1 RAC was the one reported in the DAR with imidacloprid technical (>83 mg a.s./L for *Oncorhynchus mykiss*). The chronic toxicity endpoint to fish was 9.02 mg a.s./L, as reported in the original DAR (Germany, 2005) and in the EFSA Conclusion (EFSA, 2008). No relevant chronic data on fish were reported in the systematic literature search.

The acute toxicity to **aquatic invertebrates** ranged from 0.65 to 284 µg a.s./L for insects, and from 2.07 to 90680 µg a.s./L for crustaceans. The chronic toxicity ranged between 0.024 - 4.57 µg a.s./L and 0.47 - 6000 µg a.s./L for insects and crustaceans, respectively. The chronic endpoints were all reported either in the DAR or in the systematic literature review.

The toxicity to **algae** ranges from > 10 to 389 mg a.s./L, as reported in the original DAR, in the EFSA Conclusion (EFSA, 2008) and in a single paper (Tĭsler *et al.*, 2009) available in the systematic literature review report.

The risk assessment for aquatic organisms for imidacloprid was driven by the invertebrates, being the most sensitive organisms. A detailed summary of all the available data for aquatic invertebrates is reported in Appendix B, Tables B1 and B2 for the acute endpoints and Tables B3 and B4 for the chronic endpoints. Furthermore, several microcosm and mesocosm studies were available to derive higher tier toxicity endpoints. A summary and an evaluation of these studies were reported in the study evaluation notes (EFSA, 2014b) and they were further considered in Section 2.3, below).

2. Acute risk assessment

2.1. Tier-1 $RAC_{sw;ac}$ based on acute toxicity tests with standard species

Only acute toxicity data with standard species were considered to derive the tier 1 Regulatory Acceptable Concentration. These data are presented in Table 1. The insect *Chironomus* and the macrocrustacean *Americamysis* are several orders of magnitude more sensitive than other standard test species, including the crustacean *Daphnia magna*.

Table 1: Acute toxicity data for aquatic standard test species

	48–96h L(E)C_{50} (µg a.s./L)	**Taxonomy**
Oncorhynchus mykiss	>83000 (mm)*	Pisces; Salmonidae
Daphnia magna	85000 (mm)	Crustacea; Daphniidae
Chironomus riparius	55.2 (24 h) (n)	Insecta; Chironomidae
Americamysis bahia	34.1 (96 h) (mm)**	Crustacea; Mysidae

* lowest endpoint available for imidacloprid technical
**lower value of results from a test including two assays available in the original DAR.
mm: mean measured concentration
n: nominal concentration

Applying an AF of 100 to the lowest toxicity value of 34.1 µg/L for *Americamysis bahia* the **tier-1 $RAC_{sw;ac}$ is 0.341 µg a.s./L**.

2.2. Tier-2 $RAC_{sw;ac}$ based on Species Sensitivity Distribution (SSD)

The tier 1 data indicate that the representatives of Crustacea (*Americamysis*) and Insecta (*Chironomus*) are several orders of magnitude more sensitive than the other standard test species. The higher tier effect assessment on the basis of additional laboratory toxicity data will focus on aquatic arthropods (crustaceans and insects). Two approaches can be used according to the EFSA PPR Panel (2013) to derive the tier-2 RAC: 1) the geomean approach (tier-2A), and 2) the SSD (tier-2B), depending on the number of data available.

Several additional acute toxicity data were available for the tier 2 effect assessment for insects and crustaceans, indicating that insects are more sensitive than crustaceans (see Appendix B). In line with the recommendations of the EFSA PPR Panel (2013), the geometric mean approach (tier-2A) was not

further considered, since there were enough data to go directly to tier-2B (SSD). To make the best use of the available data, EFSA constructed an acute SSD curve, despite that the data set was not fully adequate for this purpose. Although the PPR Panel (EFSA PPR Panel, 2013) recommends to preferably use the arthropod SSD in the effect assessment, the acute SSD was constructed with the insect toxicity data only, as the insects were more sensitive than crustaceans (Figure 1 in Appendix C).

The SSD curve proposed by EFSA along with the entire dataset used for this SSD and the AF to be applied were discussed at the Pesticides Peer Review Experts' Meeting 116 in June 2014. It was noted that the majority of the toxicity endpoints used in the SSD were derived from literature data, some of them lacking of details regarding the study design. One of the key studies was the paper from Roessink *et al.*, (2013). To be able to conclude on the reliability of this study, taking into account also the EFSA PPR Panel (2013) regarding the assessment of open literature, further information was requested by the experts. Additional information was made available after the meeting by the RMS in the Addendum 9 dated July 2014 (Germany, 2014). However, EFSA noted that this information was insufficient to consider the results of the study robust enough for regulatory use (for further details see the study evaluation notes, sections 2 and 3, published as part of the background documentation to this Conclusion; EFSA, 2014b).

Furthermore, it was noted that a similar laboratory study was available from the same author (report No 29499 (2013), see study evaluation notes, section 5.1; EFSA, 2014b). In this study the acute endpoints derived for the same species were 10 times higher than those from Roessink *et al*., (2013) (EC_{50} of 17 µg a.s./L *vs* 1.7 µg a.s./L for *Caenis horaria*, EC_{50} of 12.1 µg a.s./L *vs* 1.02 µg a.s./L for *Cloeon dipterum*). In the Addendum 9 dated July 2014 (Germany, 2014), the study author argued that the different sensitivity to imidacloprid might have been due to the natural seasonal variation of the tested organisms. EFSA acknowledged that, the slow-growing winter-generation of Ephemeroptera may be less sensitive than the fast-growing summer-generation. However, no data were provided to support this hypothesis, as an explanation of the inconsistent results. For example, EFSA noted that in both studies the organisms tested were at nymph stage. It is unlikely that nymphs collected in October belong only to the winter generation, taking into account that organisms of the summer generation may mate until the end of August and therefore nymphs of the summer generation can still be present in autumn. Furthermore, no information was available indicating that a specific morphological characterisation of the larvae was performed to distinguish whether the organisms belonged to the spring/summer or winter generation. Therefore, it is likely that the organisms tested in the two studies might represent both generations.

Nevertheless, as it was agreed at the meeting, in the absence of further data, EFSA considered that the endpoints from Roessink *et al*., (2013) can be used for risk assessment as a conservative approach. The experts also agreed to use the lowest endpoint where several studies on the same species were available.

The HC_5 value (and 95 % confidence interval) on the basis of acute toxicity **data for insects** (n=15, values in bold in Table B1 of Appendix B) was 0.49 (0.098 – 1.38) µg/L. Consequently, for insect taxa the **median HC_5 was 0.49 µg/L** and the **lower limit HC_5 was 0.098 µg/L**.

The experts discussed the AF by taking into account the criteria in the EFSA PPR Panel (2013). Most of the criteria in the guidance indicate that the appropriate AF should be 6. However, the experts considered that an AF of 5 could be suitable because some criteria triggered the lowest AF recommended in the guidance document and the most sensitive tested species were considered in the SSD.

Therefore, applying an AF of 5 to the median HC_5 of 0.49 µg/L, the resulting **tier-2B $RAC_{sw;ac}$** was **0.098 µg a.s./L**.

However, it has to be noted that this **tier-2B RAC$_{sw;ac}$** may only be used as provisional for risk assessment, due to the limitations related to the data set.

Overall, a data gap was identified for further data to address the acute tier 2 effect assessment.

2.3. Tier-3 RAC$_{sw;ac}$ based on micro/mesocosm studies

Several microcosm and mesocosm studies were available and shortly summarised and evaluated in the **study evaluation notes**: Ratte & Memmert, 2003 (DAR; Germany, 2005); Roessink, I., & E.M. Hartgers, 2014 (see study evaluation notes, section 5.2; EFSA, 2014b); Hammers-Wirtz, Strauss & Memmert (Nufarm), May 2009 (see study evaluation notes, section 5.3; EFSA, 2014b) and Hammers-Wirtz, Strauss & Memmert (Sharda), July 2009 (see study evaluation notes, section 5.4; EFSA, 2014b). Additional microcosm and mesocosm studies (see section 5.5 of the study evaluation notes; EFSA, 2014b) were also included in the literature search performed by the applicant. However, these additional studies, with some exceptions (Alexander *et al*., 2008; Colombo *et al*., 2013 and Pestana *et al*., 2009b), were not considered useful for risk assessment, because either the exposure was not relevant or worst case (e.g. addition of contaminated leaves to the micro/mesocosm, paddy micro/mesocosm or indoor micro/mesocosm), or only one concentration was tested or an endpoint could not be derived, or there were concerns on the representativeness of the environmental conditions in Europe.

The microcosm and mesocosm studies submitted by the applicant and two other companies[11], except Hammers-Wirtz, Strauss & Memmert (Sharda), July 2009, were considered at the Pesticides Peer Review Experts' Meeting 116 in June 2014.

The outdoor microcosm study from Roessink, I., & E.M. Hartgers (2014) was aimed at investigating the potential effects of imidacloprid (applied as IMIDACLOPRID SL 200) on the mayfly *Cloeon dipterum* under outdoor exposure conditions and to establish dissipation DT_{50}water values for imidacloprid under two different light intensities. The authors concluded that the NOEC should be set at 1.52 µg a.s./L (based on nominal concentration).

It is noted that only effects on one species of mayfly, i.e. *C. dipterum* were considered under realistic natural conditions and exposure regimes, and no further effects on population/community level were investigated. Furthermore, under the experimental conditions, *C. dipterum* is reported to be a multivoltine species with approximately three generation per year, therefore species with less possibility to recover were not covered. Overall, the experts at the meeting concluded that this study cannot be used as a tier 3 ecosystem study (i.e. the study is not useful to derive **tier-3 RAC**). The NOEC derived from this study can only be used as additional information.

The mesocosm study from Ratte & Memmert (2003) investigated the impact of imidacloprid SL 200 on freshwater pond communities. The test item was applied twice in May 2001 with a 21-day interval at concentrations ranging from 0.6 to 23.5 µg a.s./L. A DT_{50} for the whole system (water plus sediment) could only be measured at the two highest test concentrations: the average DT_{50} was 14.8 days, which is in agreement with the estimated aqueous degradation rates for imidacloprid under illuminated conditions (1.4 - 10 days as reported in the list of endpoints of the EFSA Conclusion (EFSA, 2008)). On the basis of the most sensitive endpoints (Chironomidae and Baetidae) the overall $NOEC_{microcosm}$ was 0.6 µg imidacloprid/L (nominal concentration). Since the dissipation of imidacloprid in the test system was realistic to worst case compared to that predicted for the field, the NOEC can be expressed as nominal concentration.

Ephemeroptera were very sensitive due to their long larval development. However, it was not possible to draw a clear conclusion on the recovery of sensitive mayfly species since they were present in too

[11] Nufarm GmbH & Co KG and Makhteshim Agan Industries group

low abundance to allow a reliable statistical evaluation. Direct effects on emergence of insects and secondary effects on phytoplankton abundance and chemical parameters were observed at a concentration of 1.5 µg imidacloprid/L. A clear recovery of Chironominae was not shown at this concentration until the end of the study.

A re-evaluation according to the EFSA PPR Panel (2013) was provided by the applicant and considered by EFSA in the study evaluation notes, section 1.2 (EFSA, 2014b).

Based on the re-evaluation, the applicant concluded that the study is suitable for risk assessment without further lines of evidence, at least to derive the ETO-RAC. However, EFSA noted that, for some sensitive taxonomic groups, the statistical power of the study is limited (e.g. the MDD for Ephemeroptera emerged insects is >100[12], indicating that data for this taxon have a low statistical power). Additionally, it was not clear where the so-called MDDs NOEC (the MDD for the NOEC of each endpoint on each sampling date for all taxa) were reported. The experts at the meeting noted that the MDD was assessed only after 63 days. Considering the fast dissipation of imidacloprid in water, the effects after 63 days could have been underestimated due to a low actual exposure. Furthermore, apparently no Ephemeroptera were observed at the beginning of the study up to 63 days (i.e. less overall statistical power of the study). Therefore, the NOEC from the study from Ratte & Memmert (2003) of 0.6 µg a.s./L cannot be considered sufficient to cover sensitive species, such as Ephemeroptera.

The mesocosm study from Hammers-Wirtz, Strauss & Memmert (Nufarm, Report No: B07683, May 2009) investigated the duration and magnitude of adverse impacts of the active substance imidacloprid on a freshwater community. Five different test item concentrations were selected in this study to determine the toxicant effect thresholds for different taxa (NOEC), as well as the No Observed Ecologically Adverse Effect Concentration (NOEAEC) for a pond community after an acceptable recovery period. Since the dissipation of imidacloprid in the test system (mean value over all DT_{50} values of imidacloprid in water in the range of 4.6 - 13 days) was realistic to worst case compared to that predicted for the field (estimated aqueous photolysis DT_{50} in the range 1.4 - 10 days), the NOEC can be expressed as nominal concentration. The authors established an overall NOEC at the concentration of 0.6 µg a.s./L (nominal concentration), taking into account effects on individual taxa that could be quantitatively evaluated in the pond communities and on population parameters.

The experts noted that this study was similar to the study from Ratte and Memmert (2003). The most sensitive group of organisms belonged to Chironominae. Although the abundance of Ephemeroptera was higher than that in Ratte and Memmert (2003), no Ephemeroptera were observed up to 35 days after the first application. As a possible explanation, the experts argued that the sampling could have been conducted improperly or Ephemeroptera were present in the form of neanic stage (compromising the observation due to the small size and the classification due to the absence of specific morphological characteristics). Emergence was observed in the controls at day 42, while in the treatment groups emergence occurred a bit later (day 48), indicating potential treatment-related sublethal effects at the NOEC of 0.6 µg a.s./L.

It should be noted that the data from this mesocosm study was not analysed for statistical significance by using, for example, the MDD concept in order to evaluate the robustness of the NOEC identification.

The mesocosm study from Hammers-Wirtz, Strauss & Memmert (Sharda, Report No B72325, July 2009) was submitted to EFSA at a late stage of the peer review process (16 July 2014) and therefore was not peer reviewed. However, EFSA noted that this is an outdoor mesocosm study very similar to

[12] For the Baetidae captured with the MASS the calculated % MDD_{abu} is > 100 in 5 samplings out of a total of 8 samplings for which a MDD can be calculated.

the mesocosm study submitted by Nufarm (Report No: B07683) (see study evaluation notes; EFSA, 2014b). Taking into account the effects on individual taxa that could be quantitatively evaluated in the pond communities and on population parameters, the authors concluded that the overall lowest NOEC for the emerging insects would be below the lowest test concentration (< 0.5 µg a.s./L, nominal). The EFSA noted that the same deficiencies as those highlighted for the Nufarm study at the experts' meeting can be observed also for this study (i.e. no Ephemeroptera were observed in the samples up to 49 days after the first application). Also in this case, a statistical and ecological evaluation of concentration - response relationship for this mesocosm experiment was not performed (lack of MDD analysis). However, this study supports the conclusion of the peer review that a NOEC endpoint cannot be used to derive the tier-3 RAC.

Overall, on the basis of the available mesocosm studies, the experts concluded that a tier-3 $RAC_{sw;ac}$ to cover more sensitive aquatic species cannot be derived due to the lack of information on more sensitive species, such as Ephemeroptera. Furthermore, this conclusion was also supported by the additional information derived from the publicly available mesocosm studies, which indicated effects on Ephemeroptera at concentrations below the mesocosm NOECs (Alexander *et al*., 2008 and Colombo *et al*., 2013; see the study evaluation notes, section 5.5; EFSA, 2014b).

The experts at the meeting agreed that a possible approach to make use of the available data would be to derive a pseudo tier-3 RAC_{sw} by extrapolating the sensitivity of Ephemeroptera from the available data on Chironomids, as suggested by the RMS. This extrapolation was documented by the RMS in the Addendum 9 of July 2014 (Germany, 2014) and was further considered by EFSA after the meeting. Average 10-day NOEC values for Chironomids were calculated based on laboratory data. The worst-case estimated 10-day NOEC (about 0.6 µg a.s./L) was compared with the laboratory data on Ephemeroptera from Roessink *et al*., (2013) (i.e. 28-day EC_{10} of 0.024 µg a.s./L, *Caenis horaria).* This comparison showed a difference in sensitivity of about a factor of 20 between Chironomids and Ephemeroptera. However, EFSA noted that the available data cannot be considered adequate to support such an extrapolation factor. The factor of 20 was based on the comparison between laboratory data on Chironomids and a single laboratory study on Ephemeroptera (Roessink *et al*., 2013). This may be considered as a relevant source of uncertainty. In addition, the experimental conditions in the studies were similar (i.e. constant exposure), but the exposure duration was shorter in the Chironomid studies (10 days) than in Roessink *et al*., (2013) (28 days). Moreover, one of the studies on Chironomids (Gagliano, 1991; Germany, 2005), could not be considered as valid due to the control contamination with the test material (see study evaluation notes, section 1.1; EFSA, 2014b). These considerations indicate that a robust extrapolation factor based on the available data cannot be derived. In addition, it has to be noted that the sensitivity of Ephemeroptera in the field can vary depending on the environmental conditions, as it was for example observed for *C. dipterum* in the outdoor microcosm study (Roessink, I., & E.M. Hartgers, 2014, see above). Therefore, the quantitative extrapolation of sensitivity to imidacloprid from Chironomids to Ephemeroptera and from laboratory to field should be further investigated.

Therefore EFSA considered the pseudo tier-3 RAC, as derived by the RMS, not suitable for risk assessment purposes. However, the difference in sensitivity showed by the analysis of the available data can be used as a weight of evidence approach.

Overall, a data gap was identified for further data to address the acute tier 3 effect assessment.

3. Chronic risk assessment

3.1. Tier-1 $RAC_{sw;ch}$ based on chronic toxicity tests with standard species

The chronic toxicity data for standard test species are presented in Table 2. As for the acute assessment, the insect *Chironomus* is several orders of magnitude more sensitive than other standard test species.

Table 2: Chronic toxicity data for aquatic standard test species

	Chronic ECx/NOEC (µg a.s./L)	**Taxonomy; Family**
Oncorhynchus mykiss	9020 (91 d, NOEC)	Pisces; Salmonidae
Daphnia magna	1800 (21 d, NOEC)	Crustacea; Daphniidae
Chironomus riparius	2.09 (28 d, EC_{10})	Insecta; Chironomidae
Scenedesmus subspicatus	> 10 000 (72 h) (n)	Green alga (chronic study)

n: nominal concentration

By applying an AF of 10 to the lowest toxicity value of 2.09 µg/L for *Chironomus riparius* the **tier-1 chronic $RAC_{sw;ch}$ is 0.209 µg a.s./L**.

3.2. Tier-2 $RAC_{sw;ch}$ based on standard and additional single species laboratory tests

Besides the endpoints for *Daphnia magna*, chronic toxicity endpoints for three other crustaceans (Table B3 in Appendix B) and seven insect species (Table B4 in Appendix B) were available from the literature data. These data included mainly chronic endpoints from the paper by Roessink *et al*., (2013). However, as reported in Section 2.2 above and in the study evaluation notes (section 2; EFSA, 2014b), the information made available by the author was considered insufficient to consider the results of the study robust enough for regulatory use. Moreover, the data set included two 28-day EC_{10} values extrapolated from graphics reported in Stoughton *et al.*, (2008). Although the robustness of this data set might be questionable, it was used for deriving tier-2 RACs which may only be used as provisional for risk assessment.

3.2.1. Tier-2A $RAC_{sw;ch}$ based on geomean approach

According to the EFSA PPR Panel (2013), toxicity data based on similar endpoints should be selected when applying the geomean approach. Since only 2 similar endpoints were available (EC_{10} immobilisation, see Table B3 in Appendix B) for crustaceans, the geomean approach was only applied to the insect endpoints (i.e. a total of 5 EC_{10} immobilisation endpoints, as reported in Table B4 in Appendix B). The geometric mean insect endpoints (n = 5) was 0.393 µg a.s./L.

Applying an AF of 10 to this geomean value (insects) a tier-2A chronic RAC of 0.0393 µg a.s./L could be derived. Since this value is higher than the lowest chronic toxicity value presented in Table B4 in Appendix B, the final **tier-2A chronic RAC should be <0.024 µg a.s./L.** In other words, an assessment factor > 1 and ≤ 10 should be applied to the lowest chronic toxicity value presented in Table B4 in Appendix B. As mentioned above, it has to be noted that this **tier-2A $RAC_{sw;ch}$** may only be used as provisional for risk assessment, due to the limitations related to the data set used to calculate the geomean. It has also to be noted that, when enough data are available to construct a SSD, according to the EFSA PPR Panel (2013), the latter approach should be applied for risk assessment rather than the geomean.

3.2.2. Tier-2B $RAC_{sw;ch}$ based on Species Sensitivity Distribution (SSD)

A SSD approach was carried out by the Netherlands (NL) based on some literature data (n=10, values in bold in Tables B3 and B4 in Appendix B). EFSA evaluated the NL approach in the **study evaluation notes** (see section 3; EFSA, 2014b). The chronic SSD and the endpoints used to construct this curve were discussed at the Pesticides Peer Review Experts' Meeting 116 (June 2014).

The chronic SSD curve provided by the NL and agreed at the meeting has been included in Appendix C of this Conclusion. The **HC_5 value** (and 95 % confidence interval) was **0.027** (0.0031 – 0.092) **µg a.s./L**.

The experts agreed to apply an AF of 3 to the median HC_5, as recommended by the EFSA PPR Panel (2013). Therefore, the **tier-2B $RAC_{sw;ch}$** was **0.009 µg a.s./L**. This RAC is more relevant than the **tier-2A,** above. However, as already mentioned, it is noted that this **tier-2B $RAC_{sw;ch}$** may only be used as provisional for risk assessment, due to the limitations related to the data set used to construct the SSD.

Overall, a data gap was identified for further data to address the chronic tier 2 effect assessment.

3.3. Tier-3 $RAC_{sw;ch}$ based on micro/mesocosm studies

The mesocosm studies for deriving the tier-3 RAC were considered in Section 2.3. No tier-3 RAC could be derived for the acute risk assessment. This is the case also for the chronic RAC.

According to the EFSA PPR Panel (2013), to evaluate chronic risks (triggered by the tier 1 chronic core data), either the peak concentration or a TWA concentration of the active substance in the relevant matrix (water, sediment) may be used as estimate of $RAC_{sw;ch}$ and/or as PEC estimate.

When the exposure regime tested in the mesocosm studies are realistic to worst case relative to the predicted exposure profiles for edge-of-field surface waters, the ETO-RAC based on nominal concentrations from these studies can be linked with $PEC_{sw;max}$. For imidacloprid this would be the case for all the scenarios (Figures 1 - 28 of Appendix D), except the pond scenarios D4, D5 and R1 for the representative use in apple, as these exposure profiles are characterised by periods with more or less constant exposure (Figures 3 - 4, 7 - 8 and 11 - 12 of Appendix D). For these specific cases, the EFSA PPR Panel (2013) offers the possibility to express the endpoints from the micro-/mesocosm experiments in terms of TWA concentrations measured in these test systems. This should be taken into account in case the available mesocosm studies will in future be reconsidered for deriving tier-3 RACs.

Overall, a data gap was identified for further data to address the chronic tier 3 effect assessment.

4. PEC_{sw} and exposure profiles on the basis of FOCUS scenarios and modelling

The aquatic PEC values for imidacloprid available in the EFSA Conclusion (EFSA, 2008) were reconsidered and the exposure profiles for each scenario/crop were reproduced by EFSA in order to accurately characterise the exposure regimes when addressing time-variable exposures in higher-tier effect studies (Appendix D).

FOCUS SW modelling step 3 calculations resulted in $PEC_{sw;max}$ values in the range of 0.330 - 6.187 µg/L (apple, single application) and 0.627 – 3.037 µg/L (tomato, two applications except for the D6 scenario). The lowest $PEC_{sw;max}$ is calculated for the R1 pond/apple scenario and the highest $PEC_{sw;max}$ for the R3 stream/apple. When the maxima mitigation measures considered reliable and recommended for regulatory assessments in the FOCUS Landscape and Mitigation Report (FOCUS, 2007) are implemented (i.e. 95 % spray drift reduction, equivalent to a no-spray buffer zone between 35 and 40 m, in combination with 90 % run-off reduction), the re-calculated $PEC_{sw;max}$ values were in

the range of 0.204 µg/L (R1 pond) – 0.373 µg/L (R3 stream) for the apple uses, and 0.171 µg/L (D6 ditch) – 0.712 µg/L (R4 stream) for the tomato uses.

As regards the representative use on sugar beet, the aquatic exposure reported in the EFSA Conclusion (EFSA, 2008) was confirmed. Due to soil incorporation (to a depth of 4 cm), maximum PEC_{sw} due to run-off are < 0.0005 µg/L. From the relevant FOCUS step 3 drainage scenario D4 stream a maximum PEC_{sw} of 0.01 µg/L and a maximum PEC_{sed} of 0.01 µg/kg was obtained.

In addition, for the representative use on tomato in glasshouse, initial PEC_{sw} were calculated using the FOCUS (2001) step 1 and step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator), which were then modified by post processing the spray drift input results (option no run-off or drainage was selected) to obtain a 0.2 % emission of imidacloprid from greenhouses being re-deposited on adjacent surface water bodies. This approach has been accepted by Member State experts as an assumption that can be used in EU level surface water exposure assessments for greenhouse uses and is referred to in the FOCUS (2008) guidance.

5. Overall conclusion - linking exposure to effects in the risk assessment

Definitive Regulatory Acceptable Concentrations (RACs) to be used for the acute and chronic risk assessment for aquatic organisms could not be established. However, a summary of tier-1 RACs and provisional tier-2 RACs that could be derived from the available data, are reported in Table 3. The tier-1 RACs have to be considered as less conservative because they did not cover more sensitive species than the standard tested species, therefore they are not appropriate for risk assessment. The tier-2 RACs cover the species that according to the scientific information available were more sensitive. However, they can only be considered as provisional due to the qualitative and quantitative limitations of the data set. No tier-3 RACs could be derived. In the absence of further data, the provisional tier-2 RACs should be considered as the most suitable approach for risk assessment for the representative uses. It was acknowledged at the meeting that further field investigations on Ephemeroptera are currently ongoing. When available, the RAC derivation can be reconsidered.

A comparison of the provisional tier 2 acute and chronic RACs with the PEC_{sw} values is reported in Table 4.

Table 3: Summary of the provisional Regulatory Acceptable Concentrations (RACs) and the PEC_{sw} values

	Acute RAC	**Chronic RAC**
Tier 1	0.341 µg a.s./L (not appropriate for risk assessment)	0.209 µg a.s./L (not appropriate for risk assessment)
Tier-2B (SSD)	0.098 µg a.s./L (to be used only as provisional for risk assessment)	0.009 µg a.s./L (to be used only as provisional for risk assessment)
Tier 3	Not available	Not available

Table 4: Risk assessment based on comparison of the provisional tier-2 RACs with the PEC_{sw} values

$PEC_{sw;max}$		**Provisional acute tier 2 RACs**	**Provisional chronic tier 2 RACs**
Apple	FOCUS STEP 4 0.204 µg/L (min., R1 pond) 0.373 µg/L (max., R3 stream)	**0.098** µg a.s./L	**0.009** µg a.s./L
Tomato (field)	FOCUS STEP 4 0.171 µg/L (min., D6 ditch) 0.712 µg/L (max., R4 stream)	**0.098** µg a.s./L	**0.009** µg a.s./L
Tomato (glasshouse)	FOCUS STEP 2 0.055 µg/L	0.098 µg a.s./L	**0.009** µg a.s./L
Sugar beet (seed treatment)	FOCUS STEP 3 0.01 µg/L (max., D4 stream)	0.098 µg a.s./L	**0.009 µg a.s./L**

Values in **bold** indicate a high risk not excluded

Based on the comparison between the tier-2 RACs and the PEC_{sw} values in Table 4 the following conclusions can be drawn:

- for the representative uses in apple a high acute and chronic risk could not be excluded, being the PEC_{sw} step 4 higher (2 - 4 and 23 - 41 times, respectively) than the RACs for all the situations covered by all the FOCUS scenarios, even including mitigation measures.

- for the representative uses in field tomato a high acute and chronic risk could not be excluded, being the PEC_{sw} higher (2 - 7 and 19 - 79 times, respectively) than the RACs for all the situations covered by all the FOCUS scenarios, even including mitigation measures.

- for the representative use in tomato in glasshouse a high chronic risk could not be excluded with PEC_{sw} step 2 (6 times higher than the RAC), while a high acute risk was not indicated.

- for the representative use in sugar beet as seed treatment a high chronic risk could not be excluded with PEC_{sw} step 3 (1.1 times higher than the RAC), while a high acute risk was not indicated. However, by considering that the RAC is very close to the PEC_{sw} step 3 and that it is a provisional and conservative RAC, the chronic risk for this representative use could be considered as low, based on a weight of evidence approach.

Overall, based on the available data a high acute and chronic risk could not be excluded for the representative uses in apple and field tomato and a high chronic risk could not be excluded for the representative use in glasshouse tomato, while a low risk may be concluded for the representative use in sugar beet based on a weight of evidence approach. However, it has to be noted that only provisional tier-2 RACs could be established which, based on a conservative approach, were considered currently as the most suitable approach for addressing the risk to the most sensitive aquatic species. Further data would be needed to draw a firm conclusion and/or to refine the risk assessment.

6. Metabolites

In this Conclusion, the aquatic risk assessment for the metabolites of imidacloprid was not further considered. A low risk for all the metabolites was concluded in the EFSA Conclusion (EFSA, 2008), except for metabolite M14. The additional data submitted in the context of this mandate did not

contain any further information to address the risk from this metabolite and/or the other metabolites of imidacloprid. Therefore, the data gap identified in the EFSA Conclusion (EFSA, 2008) for metabolite M14 is still valid.

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a list of the data gaps identified during this focussed peer review process.

- Further acute and chronic data would be needed to further address the risk to aquatic organisms. These further data may be needed to address the tier 2 and/or tier 3 effect assessments for the most sensitive species (relevant for all representative uses).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- None

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[13], and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

None.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

No critical areas of concern are identified.

[13] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Apple**	**Tomato (field)**	**Tomato (glasshouse)**	**Sugar beet, fodder beet**
Risk to aquatic organisms	Risk identified	X	X	X	
	Assessment not finalised				
Comments/Remarks					

The superscript numbers, if any, in this table relate to the numbered points indicated in Section 9.

REFERENCES

ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

Agatz, A.; Ashauer, R.; Brown, C.D., 2014. Imidacloprid perturbs feeding of Gammarus pulex at environmentally-relevant concentrations. Environmental Toxicology and Chemistry, March 2014, Volume: 33, Issue: 3, Pages: 648-653, http://onlinelibrary.wiley.com/doi/10.1002/etc.2480/abstract

Alexander, A.C.; Culp, J. M.; Liber, K.; Cessna, A.J., 2007. Effects of insecticide exposure on feeding inhibition in mayflies and oligochaetes. Environ. Toxicol. Chem., August 2007, Volume: 26, Issue: 8, Pages: 1726-1732, DOI: 10.1897/07-015R.1

Alexander, A.C.; Culp, J. M.; Liber, K.; Cessna, A.J., 2008. Emergent body size of mayfly survivors. Freshwater Biology, Volume: 53, Issue: 1, Jan 2008, Pages: 71–180, doi:10.1111/j.1365-2427.2007.01880.x

Ashauer, R.; Caravatti, I.; Hintermeister, A.; Escher, B. I., 2010. Bioaccumulation kinetics of organic xenobiotic pollutants in the freshwater invertebrate Gammarus pulex modeled with prediction intervals. Environmental Toxicology and Chemistry, July 2010, Volume: 29, Issue: 7, Pages: 1625-1636, DOI: 10.1002/etc.175

Azevedo-Pereira, H. M. V. S.; Lemos, M. F. L.; Soares, A. M. V. M., 2011. Behaviour and growth of Chironomus riparius meigen (Diptera: Chironomidae) under imidacloprid pulse and constant exposure scenarios. Water, Air, Soil Pollut., Volume: 219, Issue: 1-4, Pages: 215-224, DOI 10.1007/s11270-010-0700-x

Boettger, R.; Schaller, J.; Mohr, S., 2012. Closer to reality - the influence of toxicity test modifications on the sensitivity of Gammarus roeseli to the insecticide imidacloprid. Ecotoxicol. Environ. Saf., May 2012, Volume: 81, Pages: 49-54, http://dx.doi.org/10.1016/j.ecoenv.2012.04.015

Chen Ai-mei; Wang Jin-hua; Xia Xiao-ming; Wang Juan; ZHU LUsheng; Fan Yan-yan, 2013. Acute toxicity of imidacloprid with different formulation on earthworms and zebrafish. Journal of Agro-Environment Science 32 (9): 1758-1763. doi:10.11654/jaes.2013.09.008

Chen, X. D.; Culbert, E.; Hebert, V.; Stark, J. D., 2010. Mixture effects of the nonylphenyl polyethoxylate, R-11 and the insecticide, imidacloprid on population growth rate and other parameters of the crustacean, Ceriodaphnia dubia. Ecotoxicol. Environ. Saf., 2010, Volume: 73, Issue: 2, Pages: 132-137, doi:10.1016/j.ecoenv.2009.09.016

Colombo, V.; Mohr, S.; Berghahn, R.; Pettigrove, V.J., 2013. Structural changes in a macrozoobenthos assemblage after imidacloprid pulses in aquatic field-based microcosms. Arch Environ Contam Toxicol, Volume: 65, Pages: 683–692, Nov 2013, DOI 10.1007/s00244-013-9940-2

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid. EFSA Scientific Report (2008) 148, 1-120, doi:10.2903/j.efsa.2008.148r. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2010; Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. [90 pp.]. doi:10.2903/j.efsa.2010.1637. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092. Available online: www.efsa.europa.eu.

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid. EFSA Journal 2013;11(1):3068, 55 pp. doi:10.2903/j.efsa.2013.3068. Available online: www.efsa.europa.eu/efsajournal

EFSA, (European Food Safety Authority), 2014a. Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance imidacloprid. EFSA Journal 2014;12(7):3741, 20 pp. doi:10.2903/j.efsa.2014.3741. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2014b. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment for aquatic organisms for the active substance imidacloprid. Available online: www.efsa.europe.eu

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.1 dated March 2012

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2007. Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2008. Pesticides in Air: Considerations for Exposure Assessment. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008

Germany, 2005. Draft assessment report on the active substance imidacloprid prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, December 2005. Available online: www.efsa.europa.eu

Germany, 2014. Final Addendum to the Draft Assessment Report on imidacloprid, procedure under Article 21 of Regulation (EC) No 1107/2009, compiled by EFSA, August 2014. Available online: www.efsa.europa.eu

Hayasaka, D.; Korenaga, T.; Suzuki, K.; Sanchez-Bayo, F.; Goka, K., 2012. Differences in susceptibility of five cladoceran species to two systemic insecticides, imidacloprid and fipronil. Ecotoxicology, March 2012, Volume: 21, Issue: 2, Pages: 421-427, DOI 10.1007/s10646-011-0802-2

Jemec, A.; Tĭsler, T.; Drobne, D.; Sepcic, K.; Fournier, D.; Trebse, P., 2007. Comparative toxicity of imidacloprid, of its commercial liquid formulation and of diazinon to a non-target arthropod, the microcrustacean Daphnia magna. Chemosphere, Aug 2007, Volume: 68, Issue: 8, Pages: 1408-1418, doi:10.1016/j.chemosphere.2007.04.015

Ieromina, O.; Peijnenburg, W. J. G. M.; de Snoo, G.; Mueller, J.; Knepper, T. P.; Vijver, M. G., 2014. Impact of imidacloprid on Daphnia magna under different food quality regimes. Environmental Toxicology and Chemistry, March 2014, Volume: 33, Issue: 3, Pages: 621 -631, DOI: 10.1002/etc.2472

Key, P.; Chung, K.; Siewicki, T.; Fulton, M., 2007. Toxicity of three pesticides individually and in mixture to larval grass shrimp (Palaemonetes pugio). Ecotoxicology and Environmental Safety, Nov 2007, Volume: 68, Issue: 2, Pages: 272-277, doi:10.1016/j.ecoenv.2006.11.017

LeBlanc, H. M. K.; Culp, J. M.; Baird, D. J.; Alexander, A. C.; Cessna, A. J., 2012. Single versus combined lethal effects of three agricultural insecticides on larvae of the freshwater insect Chironomus dilutus. Archives of Environmental Contamination and Toxicology, Oct 2012, Volume: 63, Issue: 3, Pages: 378-390, DOI 10.1007/s00244-012-9777-0

Overmyer, J. P.; Mason, B. N.; Armbrust, K. L., 2005. Acute toxicity of imidacloprid and fipronil to a nontarget aquatic insect, Simulium vittatum Zetterstedt cytospecies IS-7. Bull. Environ. Contam. Toxicol., May 2005, Volume: 74, Pages: 872–879, DOI: 10.1007/s00128-005-0662-7

Pavlaki, M. D.; Pereira, R.; Loureiro, S.; Soares, A. M. V. M., 2011. Effects of binary mixtures on the life traits of Daphnia magna. Ecotoxicology and Environmental Safety, Jan 2011, Volume: 74, Issue: 1, Pages: 99-110, doi:10.1016/j.ecoenv.2010.07.010

Pestana, J. L.T.; Loureiro, S.; Baird, D. J.; Soares A. M.V.M., 2009a. Fear and loathing in the benthos: Responses of aquatic insect larvae to the pesticide imidacloprid in the presence of chemical signals of predation risk. Aquat. Toxicol., June 2009, Volume: 93, Issue: 2-3, Pages: 138-149, doi:10.1016/j.aquatox.2009.04.008

Pestana, J. L. T.; Alexander, A. C.; Culp, J. M.; Baird, D. J.; Cessna, A. J.; Soares A. M. V.M., 2009b. Structural and functional responses of benthic invertebrates to imidacloprid in outdoor stream mesocosms. Environ. Pollut., Volume: 157, Issue: 8-9, March 2009, Pages: 2328-2334, doi:10.1016/j.envpol.2009.03.027

Pestana, J. L.T.; Loureiro, S.; Baird, D. J.; Soares, A. M. V. M., 2010. Pesticide exposure and inducible antipredator responses in the zooplankton grazer, Daphnia magna Straus. Chemosphere, Volume: 78, Issue: 3, January 2010, Pages: 241-248, http://dx.doi.org/10.1016/j.chemosphere.2009.10.066

Roessink, I.; Merga, L. B.; Zweers, H. J.; Van Den Brink, P.J., 2013. The neonicotinoid imidacloprid shows high chronic toxicity to mayfly nymphs. Environ. Toxicol. Chem., May 2013, Volume: 32, Issue: 5, Pages: 1096-1100, DOI: 10.1002/etc.2201

Stoughton, S. J.; Liber, K.; Culp, J.; Cessna, A., 2008. Acute and chronic toxicity of imidacloprid to the aquatic invertebrates Chironomus tentans and Hyalella azteca under constant- and pulse-exposure conditions. Archives of Environmental Contamination and Toxicology, May 2008, Volume: 54, Issue: 4, Pages: 662-673, 10-1007/s00244-007-9073-6

Tĭsler T.; Jemec, A.; Mozetic, B.; Trebse, P., 2009. Hazard identification of imidacloprid to aquatic environment. Chemosphere, July 2009, Volume: 76, Issue: 7, Pages: 907-914, doi:10.1016/j.chemosphere.2009.05.002

APPENDICES

APPENDIX A – SUMMARY OF REPRESENTATIVE USES EVALUATED IN SUPPORT OF THE ORIGINAL APPROVAL: IMIDACLOPRID*

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g a.s./hL min - max (l)	water L/ha min - max	g a.s./ha min - max (l)	(m)	
Apple	Northern and Southern Europe	Confidor	F	*sucking and biting insect pests*	SL	200	SPI	1.BBCH 10 2.BBCH 69/71 or latest 14 d prior to harvest	1 1	--	7	500 - 1500	1st 70 2nd 105	14	
Tomato	Southern Europe	Confidor	F	*aphids, white flies, leaf beetle*	SL	200	SPI	BIF	2	14	5	1000	100	3	
Tomato	Southern Europe	Confidor	G	*aphids, white flies, leaf beetle*	SL	200	SPI	BIF	2	14	5	1500	150	3	
Sugar beet, fodder beet	Northern Europe	Gaucho	F	*soil-dwelling and early leaf-feeding and sucking insect pests*	FS	600	BEZ/PIL	seed	1	--	n.a.	n.a	117	n.a.	Seed rate 1.3 U/ha 1 U = 100,000 pelleted seeds

n.a. not applicable (fixed with time of seeding); SPI = high volume spraying (foliar application); BEZ/PIL = seed treatment; BIF = at infestation

* It is noted that this GAP table does not take into account changes to the representative uses occurred as a consequence of risk management decisions / regulatory measures taken since the original approval of the substance.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

APPENDIX B - TOXICITY ENDPOINTS

Acute toxicity endpoints

Table B1: Acute toxicity data for standard and additional aquatic test species of Insecta

Species	24-96 h L(E)C_{50} (µg a.s./L)	Taxonomy; Family	Source
Chironomus riparius	55.2	Insecta; Chironomidae (Nematocera)	Draft Assessment Report (Germany, 2005)
Chironomus riparius	**12.94**	**Insecta; Chironomidae (Nematocera)**	**Pestana *et al.*, (2009a)[1]**
Chironomus riparius	19.9	Insecta; Chironomidae (Nematocera)	Azevedo-Pereira et al (2011)[1]
Chironomus tentans	**5.75**	**Insecta; Chironomidae (Nematocera)**	**Stoughton *et al.*, (2008)[1]**
Chironomus dilutus	**2.65**	**Insecta; Chironomidae (Nematocera)**	**LeBlanc *et al.*, (2012)[1]**
Caenis. horaria	17	Insecta; Caenidae (Ephemeroptera)	R-29499 (study evaluation notes section 5.1; EFSA, 2014b)
Caenis horaria	**1.77**	**Insecta; Caenidae (Ephemeroptera)**	**Roessink *et al.*, (2013)[2]**
Chaoborus obscuripes	**284**	**Insecta; Chaoboridae**	**Roessink *et al.*, (2013)[2]**
Cloeon dipterum	12	Insecta; Baetidae (Ephemeroptera)	R-29499 (study evaluation notes section 5.1; EFSA, 2014b)
Cloeon dipterum	**1.02**	**Insecta; Baetidae (Ephemeroptera)**	**Roessink *et al.*, (2013)[2]**
Coenagrionidae	**150**	**Insecta**	**R-29499 (study evaluation notes section 5.1; EFSA, 2014b)**
Epeorus longimanus	**0.65**	**Insecta; Heptageniidae (Ephemeroptera)**	**Alexander *et al.*, (2007)[1]**
Limnephilidae	**1.79**	**Insecta; Limnephilidae (Trichoptera)**	**Roessink *et al.*, (2013)[2]**
Micronecta	**10.8**	**Insecta; Corixidae (Hemiptera)**	**Roessink *et al.*, (2013)[2]**
Notonecta	**18.2**	**Insecta; Notonectidae (Heteroptera)**	**Roessink *et al.*, (2013)[2]**
Plea minutissima	**35.9**	**Insecta; Pleidae (Heteroptera)**	**Roessink *et al.*, (2013)[2]**
Simulium vittatum	**6.75**	**Insecta; Simuliidae (Diptera)**	**Overmyer *et al.*, (2005)[1]**
Sialis lutaria	**50.6**	**Insecta; Sialidae (Megaloptera)**	**Roessink *et al.*, (2013)[2]**
Sericostoma vittatum	**47.22**	**Insecta; Sericostomatidae (Trichoptera)**	**Pestana *et al.*, (2009a)[1]**

[1] The study was included in the literature search done by the applicant. The literature search is not considered reproducible and transparent at each of its stage. For further details see the study evaluation notes (section 4; EFSA, 2014b).

[2] The study of Roessink *et al.*, (2013) is not considered fully reliable. For details see the study evaluation notes (section 2; EFSA, 2014b).

Values in **bold** were used in the SSD.

Table B2: Acute toxicity data for standard and additional aquatic test species of Crustacea and Oligochaeta

Species	24-96 h L(E)C_{50} (µg a.s./L)	Taxonomy; Family	Source
Daphnia magna	85000	Crustacea; Daphniidae	Draft Assessment Report (Germany, 2005)
Daphnia magna	90680	Crustacea; Daphniidae	Pestana *et al.*, (2010)[1]
Daphnia magna	56600 (30000 Formulation)	Crustacea; Daphniidae	Tĭsler *et al.*, (2009)[1]
Daphnia magna	53265	Crustacea; Daphniidae	Hayasaka *et al.*, (2012)[1]
Daphnia pulex	36872	Crustacea; Daphniidae	Hayasaka *et al.*, (2012)[1]
Ceriodaphnia dubia	572	Crustacea; Daphniidae	Hayasaka *et al.*, (2012)[1]
Ceriodaphnia dubia	2.07	Crustacea; Daphniidae	Chen *et al.*, (2010)[1]
Ceriodaphnia reticulata	5553	Crustacea; Daphniidae	Hayasaka *et al.*, (2012)[1]
Gammarus pulex	5.34 (Feeding inhibition)	Crustacea; Gammaridae	Agatz *et al.*, (2014)[1]
Gammarus pulex	3857	Crustacea; Gammaridae	Ashauer, *et al.*, (2010)[1]
Gammarus pulex	18.3	Crustacea; Gammaridae	Roessink *et al.*, (2013)[2]
Gammarus roeseli	14.2	Crustacea; Gammaridae	Boettger *et al.*, (2012)[1]
Hyalella azteca	65.43	Crustacea; Hyalellidae	Stoughton *et al.*, (2008)[1]
Hyalella azteca	526	Crustacea; Hyalellidae	Draft Assessment Report (Germany, 2005)
Palaemonetes pugio	563.2 (adult)	Crustacea; Palaemonidae	Key *et al.*, (2007)[1]
Palaemonetes pugio	308.8 (larvae)	Crustacea; Palaemonidae	Key *et al.*, (2007)[1]
Americamysis bahia	35.9	Crustacea; Mysidae	Draft Assessment Report (Germany, 2005)
Asellus aquaticus	119	Crustacea; Asellidae	Roessink *et al.*, (2013)[2]
Moina macrocopa	45271	Crustacea; Moinidae	Hayasaka *et al.*, (2012)[1]
Lumbriculus variegatus	6.2	Oligochaete; Lumbriculidae	Alexander *et al.*, (2007)[1]

[1] The study was included in the literature search done by the applicant. The literature search is not considered reproducible and transparent at each of its stage. For further details see the study evaluation notes (section 4; EFSA, 2014b).
[2] The study of Roessink *et al*., (2013) is not considered fully reliable. For details see the study evaluation notes (section 2; EFSA, 2014b).

Chronic toxicity endpoints

Table B3: Chronic toxicity data for standard and additional aquatic test species of Crustacea

Species	Chronic ECx/NOEC (µg a.s./L)	Taxonomy; Family	Source
Daphnia magna	6000 (NOEC, reproduction)	Crustacea; Daphniidae	Jemec *et al.*, (2007)[1]
Daphnia magna	1800 (NOEC, reproduction)	Crustacea; Daphniidae	Draft Assessment Report (Germany, 2005)
Daphnia magna	2000	Crustacea; Daphniidae	Ieromina *et al.*, (2013)
Daphnia magna	6000	Crustacea; Daphniidae	Pavlaki *et al.*, (2011)
Gammarus pulex	64 (NOEC, swimming/behaviour)	Crustacea; Gammaridae	Draft Assessment Report (Germany, 2005)
Gammarus pulex	**2.95 (EC_{10}, immobilisation)**	**Crustacea; Gammaridae**	**Roessink *et al.*, (2013)[3]**
Hyalella azteca	**0.47 NOEC, survival)**	**Crustacea; Hyalellidae**	**Stoughton *et al.*, (2008)[1,2]**
Asellus aquaticus	**1.71 (EC_{10}, immobilisation)**	**Crustacea; Asellidae**	**Roessink *et al.*, (2013)[3]**

[1]The study was included in the literature search done by the applicant. The literature search is not considered reproducible and transparent at each of its stage. For further details see the study evaluation notes (section 4; EFSA, 2014b).
[2] From this study, the EC_{10} values were derived from the dose-response curve by means of a digitizing program for converting hard copy graphs (TechDig) and by visual observation. The NOEC as reported in the study are not considered valid. For further details see the study evaluation notes (section 3; EFSA, 2014b).
[3] The study of Roessink *et al.*, (2013) is not considered fully reliable. For details see the study evaluation notes (section 2; EFSA, 2014b).
Values in **bold** were used in the SSD.

Table B4: Chronic toxicity data for standard and additional aquatic test species of Insecta

Species	Chronic ECx/NOEC (µg a.s./L)	Taxonomy; Family	Source
Chironomus riparius	2.09 (EC_{10}, Emergence)	Insecta; Chironomidae (Nematocera)	Draft Assessment Report (Germany, 2005)
Chironomus riparius	< 2.15 (10-day NOEC, recovery after 4 days exposure)	Insecta; Chironomidae (Nematocera)	Azevedo-Pereira *et al.*, (2011)[1]
Chironomus riparius	**0.4 (NOEC, Emergence, growth)**	**Insecta; Chironomidae (Nematocera)**	**Pestana *et al.*, (2009a)[1]**
Chironomus tentans	**0.42 (EC_{10}, survival)**	**Insecta;Chironomidae (Nematocera)**	**Stoughton *et al.*, (2008)[1,2]**
Caenis horaria	**0.024 (EC_{10}, immobilisation)**	**Insecta; Caenidae (Ephemeroptera)**	**Roessink *et al.*, (2013)[3]**
Chaoborus obscuripes	**4.57 (EC_{10}, immobilisation)**	**Insecta; Chaoboridae**	**Roessink *et al.*, (2013)[3]**
Cloeon dipterum	**0.033 (EC_{10}, immobilisation)**	**Insecta; Baetidae (Ephemeroptera)**	**Roessink *et al.*, (2013)[3]**
Sialis lutaria	**1.28 (EC_{10}, immobilisation)**	**Insecta; Sialidae (Megaloptera)**	**Roessink *et al.*, (2013)[3]**
Plea minutissima	**2.03 (EC_{10}, immobilisation)**	**Insecta; Pleidae**	**Roessink *et al.*, (2013)[3]**

[1] The study was included in the literature search done by the applicant. The literature search is not considered fully reproducible and transparent at each of its stage. For further details see the study evaluation notes (section 4; EFSA, 2014b). The endpoints from this study was used to construct the SSD.

[2] From this study, the EC_{10} values were derived from the dose-response curve by means of a digitizing program for converting hard copy graphs (TechDig) and by visual observation. The NOEC as reported in the study are not considered valid. For further details see the study evaluation notes (section 3; EFSA, 2014b).

[3] The study of Roessink *et al.*, (2013) is not considered fully reliable. For details, see the study evaluation notes (section 2; EFSA, 2014b). The endpoints from this study are used to construct the SSD.

Values in **bold** were used in the SSD.

APPENDIX C - SPECIES SENSITIVTY DISTRIBUTIONS

Acute Species Sensitivity Distribution

Sufficient acute insect toxicity data (> 8 endpoints) are available to construct a SSD curve (see Table B1 in Appendix B). Many of these data are both from the literature search done by the applicant or from the publication of Roessink *et al.*, (2013). Although all these endpoints cannot be considered as fully reliable (see further details in the study evaluation notes, sections 2 and 4; EFSA, 2014b), the ones in bold were used to construct the SSD.

The PPR Panel (EFSA PPR Panel, 2013) in the new aquatic guidance recommends to preferably use the arthropods SSD (crustaceans and insects) in the effect assessment. However, as insects resulted to be more sensitive than crustaceans to imidacloprid, the SSD curve was only constructed with the insect data.

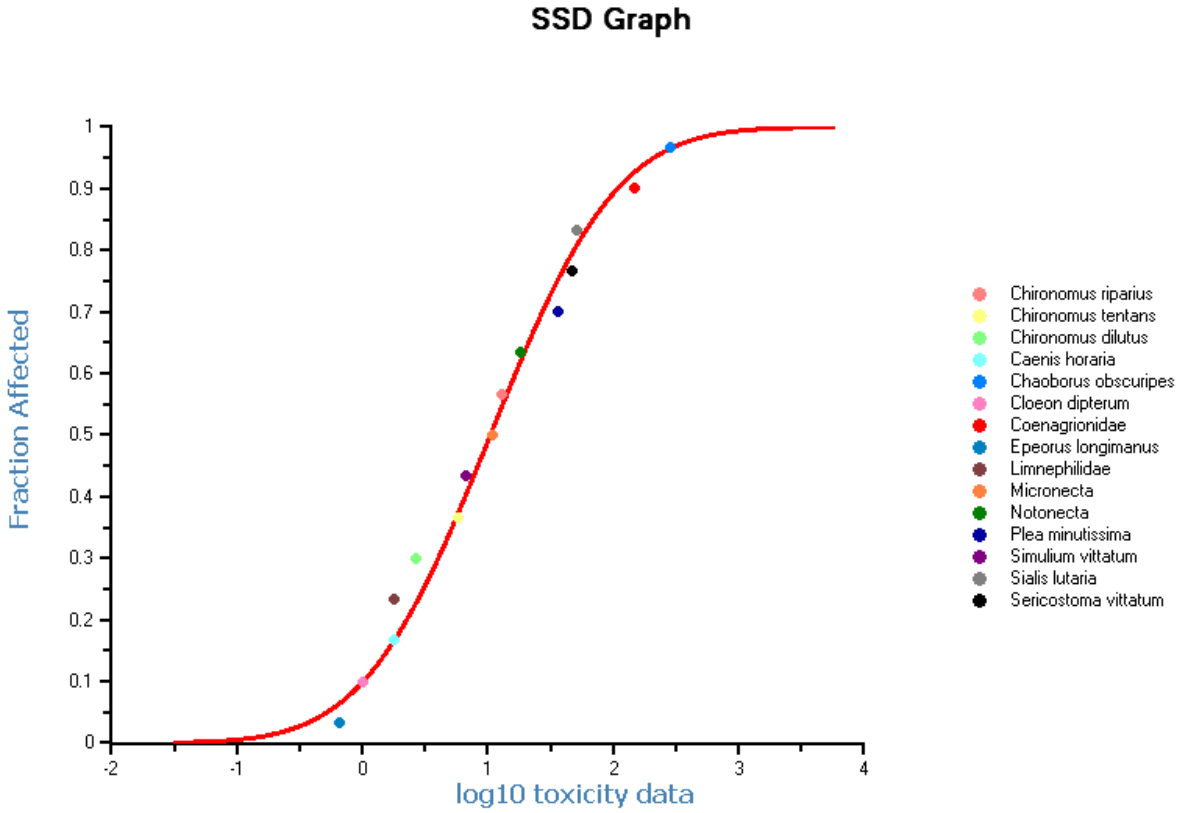

Figure 1: Species Sensitivity Distribution (SSD) curve for imidacloprid constructed with acute toxicity data from aquatic insects

The Anderson-Darling test for normality is accepted at all levels. The HC_5 value (and 95 % confidence interval) on the basis of acute toxicity **data for insects** (n=15) was 0.49 (0.098 – 1.38) µg/L. Consequently, for insect taxa the **median HC_5 was 0.49 µg/L** and the **lower limit HC_5 was 0.098 µg/L**.

Chronic Species Sensitivity Distribution

Sufficient chronic toxicity data are available for arthropods, but not for crustaceans or insects only (see Tables B3 and B4 in Appendix B). Many of these data are both from the literature search done by the applicant or from the publication of Roessink *et al.*, (2013). In addition, from the paper of Stoughton *et al.*, (2008), EC_{10} values (0.42 µg/L for *Chironomus riparius* and 0.47 µg/L for *Hyalella azteca*) were derived from the dose-response curve by means of a digitizing program for converting hard copy graphs (TechDig) and by visual observation. Therefore, although all these endpoints cannot be considered as fully reliable (see further details in the study evaluation notes, sections 2, 3 and 4; EFSA, 2014b), the ones in bold were used to construct the SSD.

Chronic values for aquatic arthropods (crustaceans and insects) listed in bold in Tables B3 and B4 are combined to construct a SSD curve and to calculate HC_5 values. The endpoints for *Daphnia* spp. were not considered in the SSD because *Daphnia* was relatively insensitive compared to other crustaceans or insects. The corresponding SSD curve for arthropods is presented in Figure 2 below. The Anderson-Darling test for normality is accepted at all levels. The HC_5 value (and 95 % confidence interval) on the basis of chronic toxicity **data for arthropods** (values in bold in Tables B3 and B4 in Appendix B (n=10) is 0.027 (0.0031 – 0.092) µg/L.

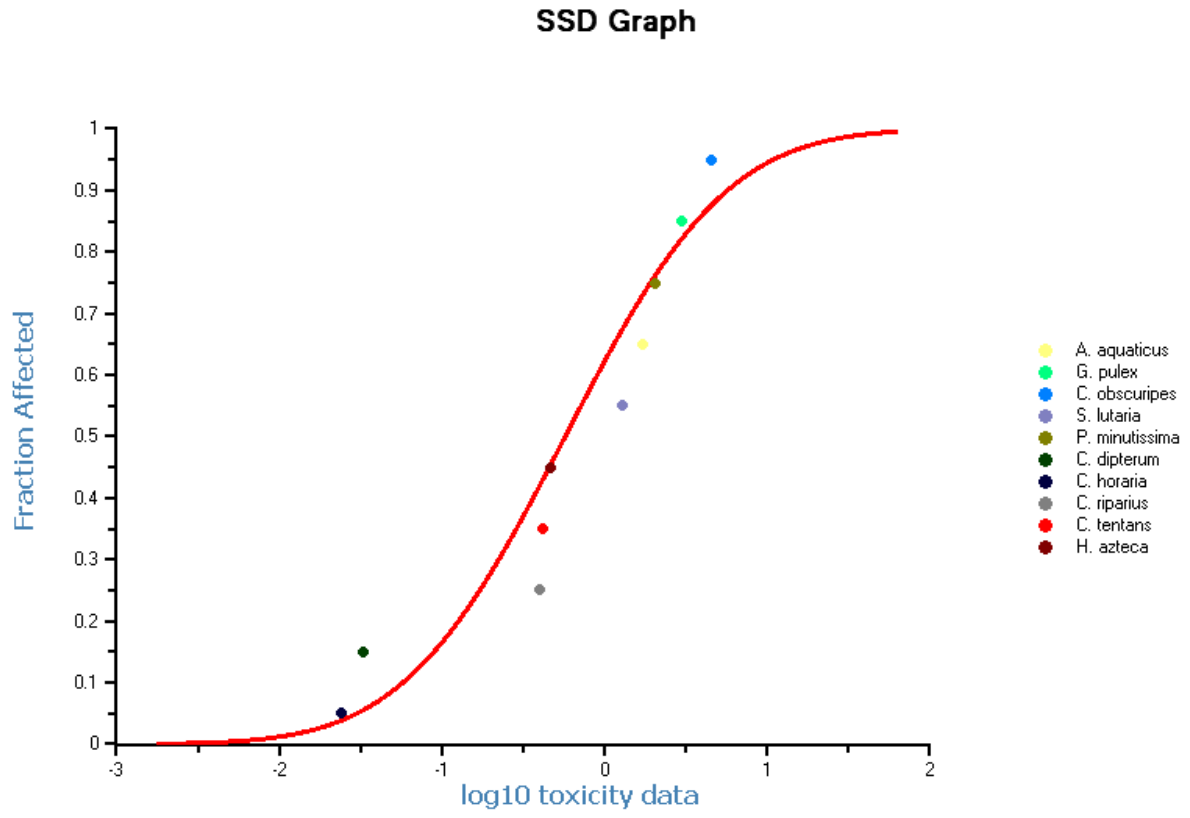

Figure 2: Species Sensitivity Distribution (SSD) curve constructed with chronic toxicity data for aquatic arthropods (values in bold in Tables B3 and B4 in Appendix B)

APPENDIX D – PREDICTED ENVIRONMENTAL CONCENTRATIONS OF IMIDACLOPRID IN SURFACE WATER BODIES BASED ON THE FOCUS SW STEP 3 AND STEP 4 APPROACHES AND EXPOSURE PROFILES PREDICTED FOR EDGE-OF-FIELD SURFACE WATERS

The aquatic PEC values for imidacloprid available in the EFSA Conclusion (EFSA, 2008) were reconsidered and the exposure profiles for each scenario/crop were reproduced by EFSA in order to accurately characterise the exposure regimes when addressing time-variable exposures in higher-tier effect studies.

In the new simulations performed by EFSA (step 3 and step 4 according to the FOCUS guidance (2001), the input parameters used were as agreed by the peer review and reported in the list of endpoints of the EFSA Conclusion (EFSA, 2008). The only exception was the application rate of the second application for the use in apple. In fact, the GAP for imidacloprid is based on the representative uses reported in Table D1.

Table D1: Summary of the representative uses evaluated for the first EU approval of imidacloprid

Crop and/or situation	**Member State or Country**	**Field (F) or greenhouse (G) application**	**Application**			
			growth stage & season	**number min/max**	**interval between application**	**application rate per treatment (g a.s./ha)**
Apple	Northern and Southern Europe	F	1.) BBCH 10 2.) BBCH 69/71 or latest 14 d prior to harvest	1 1	-**	1st 70 2nd 105
Tomato	Southern Europe	F	at infestation	2	14	100
Tomato*	Southern Europe	G	at infestation	2	14	150
Sugar beet, fodder beet*	Northern Europe	F	seed	1	-	117

* Not further considered in the present evaluation as the risk assessment of this representative use is considered covered by the other uses.
** A time interval of 40 days was considered.

For the field use on apple two applications are considered: the first application at leaf development and the second application at a late stage (end of flowering/beginning of fruit development). As the FOCUS SWASH shell does not allow performing a simulation which combines an early application and a late application for pome/stone fruit at the same time, the second application was then adjusted in order to take into account the lower mass loading per drift event estimated for application at BBCH 69/71. A summary of key input data is given in Table D2.

Table D2: Summary of key input data for the aquatic PEC calculations

Parameter	Value
Application Crop, application rate	Apple (spray) – 2 applications as follows: ditch: 70 g a.s./ha + 45.62 g a.s./ha stream: 70 g a.s./ha + 43.92 g a.s./ha pond: 70 g a.s./ha + 35.04 g a.s./ha Tomato, field (spray) – 2 x 100 g a.s./ha
Substance data	
K_{Foc} value	225 mL/g
Freundlich exponent 1/n	0.80
DT_{50} in soil	76.8 days for apple; 82.0 days for tomato
DT_{50} in aquatic system	90 days (water phase); 1000 days (sediment phase)
DT_{50} on tomato leaves	10 days (default)

The software tools STEPS in FOCUS SWASH 3.1 were used for the step 3 PEC calculations (MACRO 4.4.2, PRZM 1.1.1 and TOXSWA 3.3.1). Step 4 calculations taking mitigation into account were performed with the help of the SWAN program version 3.0.0, using the original FOCUS surface water models and scenarios (FOCUS, 2001).

FOCUS Step 3 calculations

EFSA carried out new simulations at step 3 with both single and two applications, in line with the FOCUS guidance (2001) recommendations. The resulting maximum PEC_{sw} of the FOCUS step 3 simulation runs for the relevant scenarios for the uses in apple and tomato are summarised in Table D3 and Table D4. In these tables the FOCUS step 3 $PEC_{sw;max}$ values as calculated in the EFSA Conclusion (EFSA, 2008) and by the applicant in 2014[14] are also reported for a comparison. The new simulations performed by EFSA for apples confirmed that, when single applications were defined (early application timing that gave the highest aeric mass deposition via spray drift), maximum concentrations were always higher compared to those when 2 applications had been defined (Table D3). The maximum step 3 PEC_{sw} for the use of imidacloprid on apple is 6.187 µg/L for the R3 stream scenario. However, it should be noted that, when selecting the appropriate exposure regimes to address time-variable exposures in higher-tier effect studies, the shapes of the predicted exposure profiles based on FOCUS step 3 are quite different between 1 and 2 applications (Figures 1 to 28). In fact, the pulse durations and intervals between pulses characterised by 2 applications seem to be worst case when compared with those with 1 application, as periods with more or less constant exposure can be identified. For the field use on tomato, the step 3 $PEC_{sw;max}$ values were obtained for both simulations based on 2 applications (R2 and R3 scenarios) and 1 application (D6 scenario). The R4 stream scenario resulted to be the worst case, with a $PEC_{sw;max}$ of 3.037 µg/L.

[14] Lubos Vrbka, 2014 – Exposure patterns from the surface water risk assessment as presented in EFSA conclusion 2008. Submitted to EFSA on 26 May 2014 upon request from EFSA.

Table D3: FOCUS step 3 $PEC_{sw;max}$ values of imidacloprid for all calculated scenarios for the use in apple

Scenario	WB	Application date	Appl. rate (g/ha)	PECsw EFSA 2008 (µg/L)	PECsw applicant (2014) (µg/L)	PECsw EFSA 2014* (µg/L)
D3	ditch	4 Apr (94)	70	5.431	5.433	5.429
		4 Apr (94) + 17 May (137)	70 + 45.62	-	-	4.668
D4	pond	18 Apr (108)	70	0.371	0.340	0.334
		18 Apr (108) +30 May (150)	70 + 35.04	-	-	0.320
D4	stream	18 Apr (108)	70	5.206	5.209	5.204
		18 Apr (108) +30 May (150)	70 + 43.92	-	-	4.445
D5	pond	7 Mar (66)	70	0.388	0.372	0.357
		7 Mar (66) + 22 Apr (112)	70 + 35.04	-	-	0.330
D5	stream	7 Mar (66)	70	5.177	**7.904**	5.173
		7 Mar (66) + 22 Apr (112)	70 + 43.92	-	-	4.420
R1	pond	21 Mar (80)	70	0.363	0.330	0.330
		21 Mar (80) + 22 Apr (120)	70 + 35.04	-	-	0.314
R1	stream	21 Mar (80)	70	4.425	4.427	4.425
		21 Mar (80) + 22 Apr (120)	70 + 43.92	-	-	3.778
R2	stream	5 Mar (64)	70	5.771	5.824	5.821
		5 Mar (64) + 22 Apr (104)	70 + 43.92	-	-	4.970
R3	stream	10 Mar (69)	70	**6.187**	6.190	**6.187**
		10 Mar (69) + 22 Apr (112)	70 + 43.92	-	-	5.283
R4	stream	2 Mar (61)	70	4.378	4.397	4.395
		2 Mar (61) + 23 Apr (113)	70 + 43.92	-	-	3.753

* To be used for risk assessment
Values in **bold** indicate the max PEC_{sw} value

Table D4: FOCUS step 3 $PEC_{sw;max}$ values of imidacloprid for all calculated scenarios for the use in tomato

Scenario	WB	Application date	Appl. rate (g/ha)	PECsw EFSA 2008 (µg/L)	PECsw applicant 2014 (µg/L)	PECsw EFSA 2014 (µg/L)*
D6	ditch	7 May (127) + 31 May (151)	100 + 100	0.628	0.627	0.555
		7 May (127)	100			0.627
R2	stream	22 Apr (112) + 7 May (127)	100 + 100	1.298	0.979	1.298
		22 Apr (112)	100			0.627
R3	stream	2 Jun (153) + 18 Jun (169)	100 + 100	**4.070**	**3.001**	2.856
		2 Jun (153)	100			1.926
R4	stream	11 May (131) + 27 May (147)	100 + 100	2.908	2.541	**3.037**
		11 May (131)	100			3.037

* To be used for risk assessment
Values in **bold** indicate the max PEC_{sw} value

Predicted exposure profiles for imidacloprid used in apple and tomato on the basis of FOCUS step 3 modelling

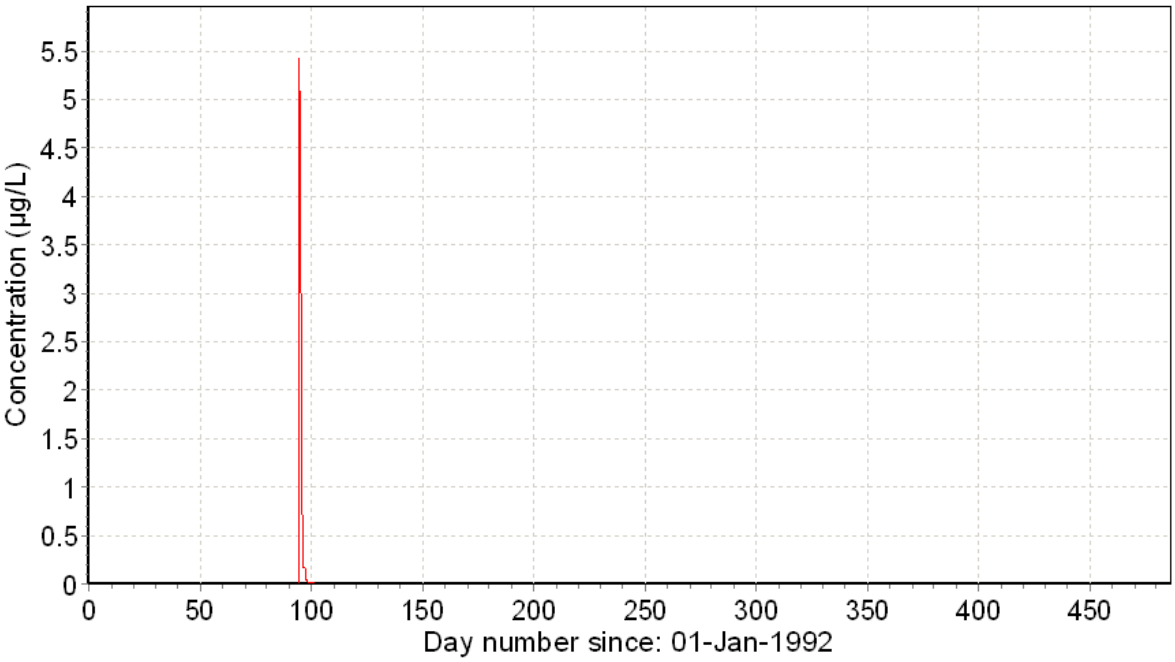

Figure 1: FOCUS PECsw at Step 3 for apple, D3 scenario (ditch), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 5.429 µg/L).

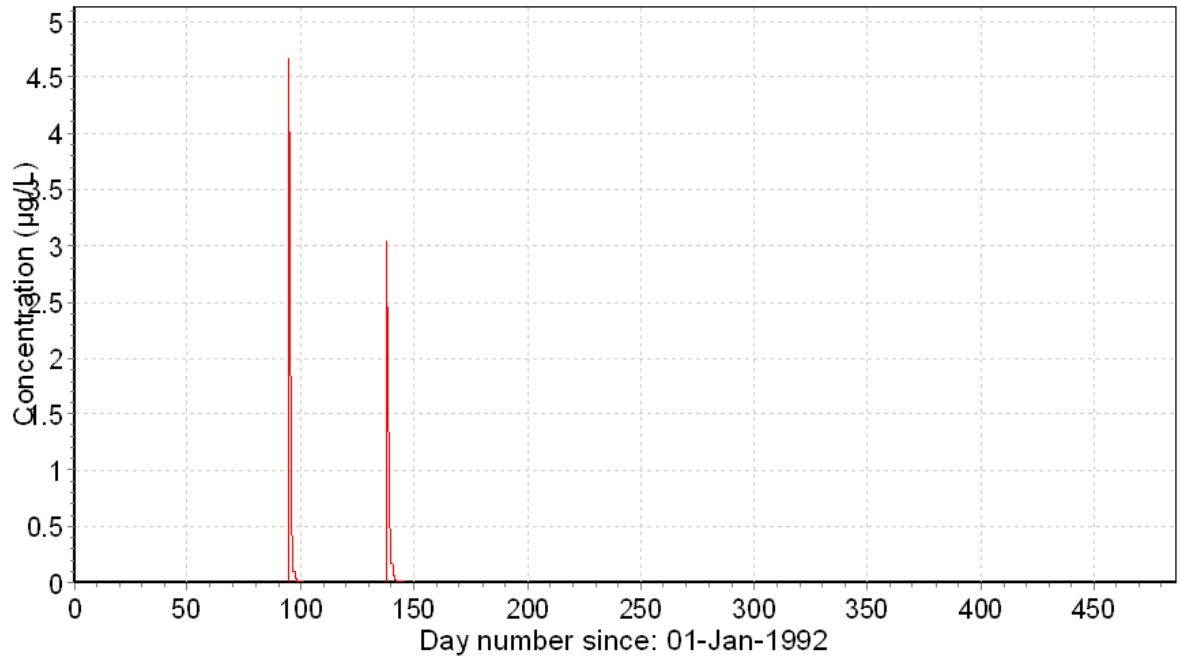

Figure 2: FOCUS PECsw at Step 3 for apple, D3 scenario (ditch), with 2 applications of 70 g a.s./ha and 45.62 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 4.668 µg/L).

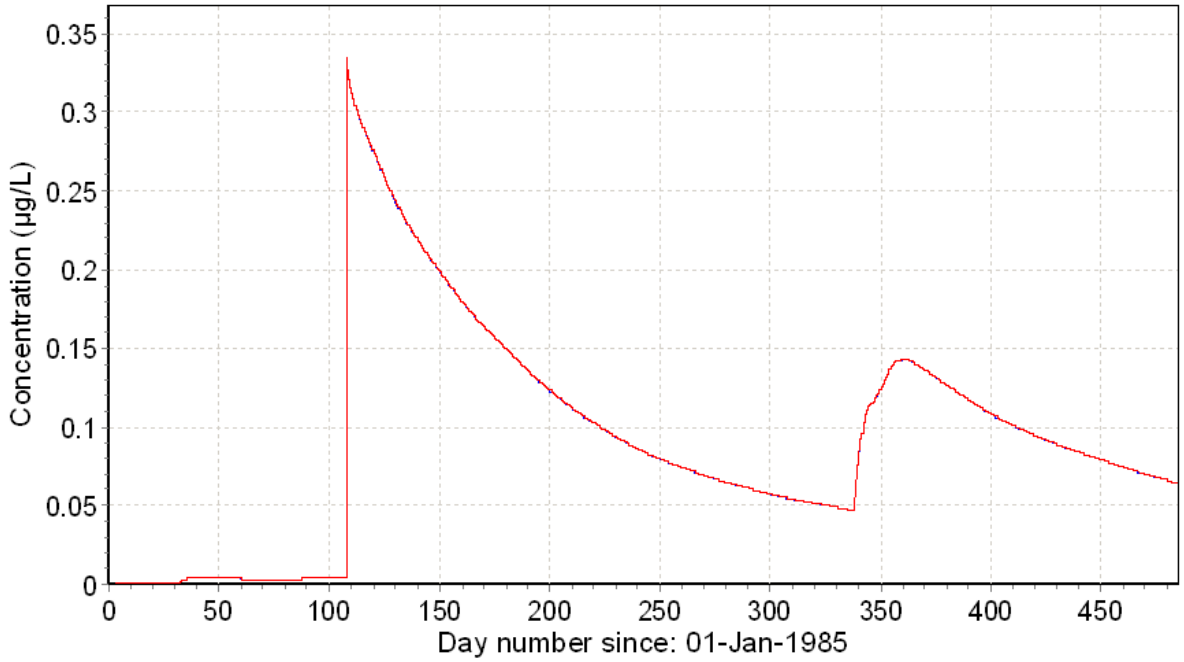

Figure 3: FOCUS PECsw at Step 3 for apple, D4 scenario (pond), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 0.334 µg/L).

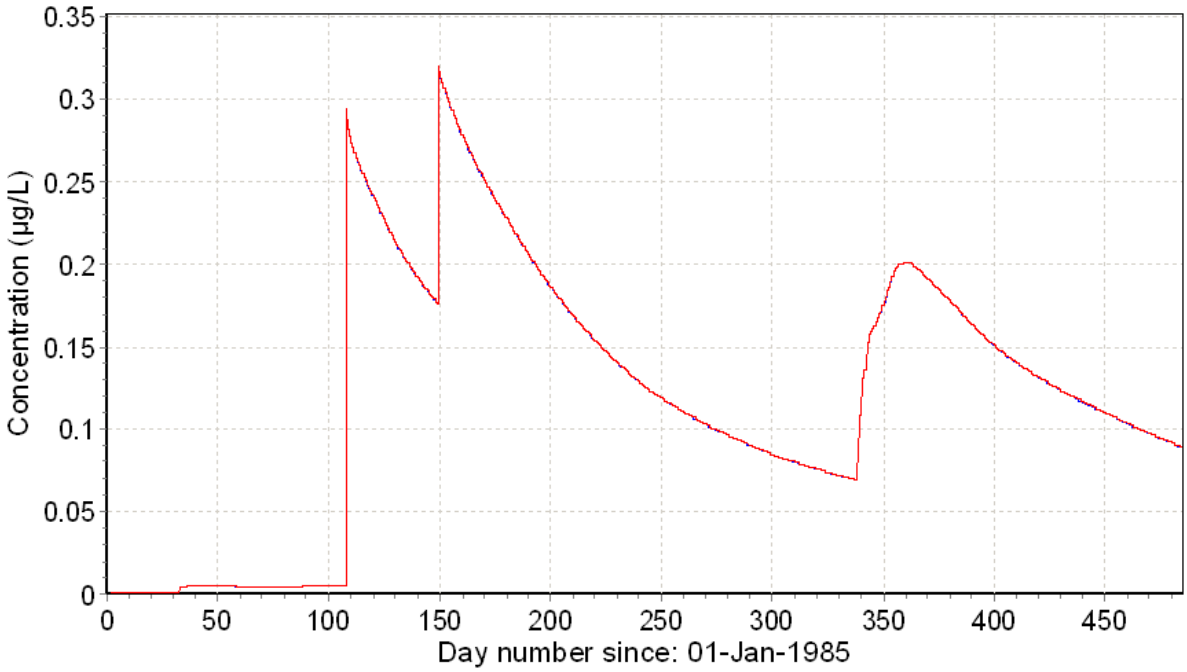

Figure 4: FOCUS PECsw at Step 3 for apple, D4 scenario (pond), with 2 applications of 70 g a.s./ha and 35.04 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 0.320 µg/L).

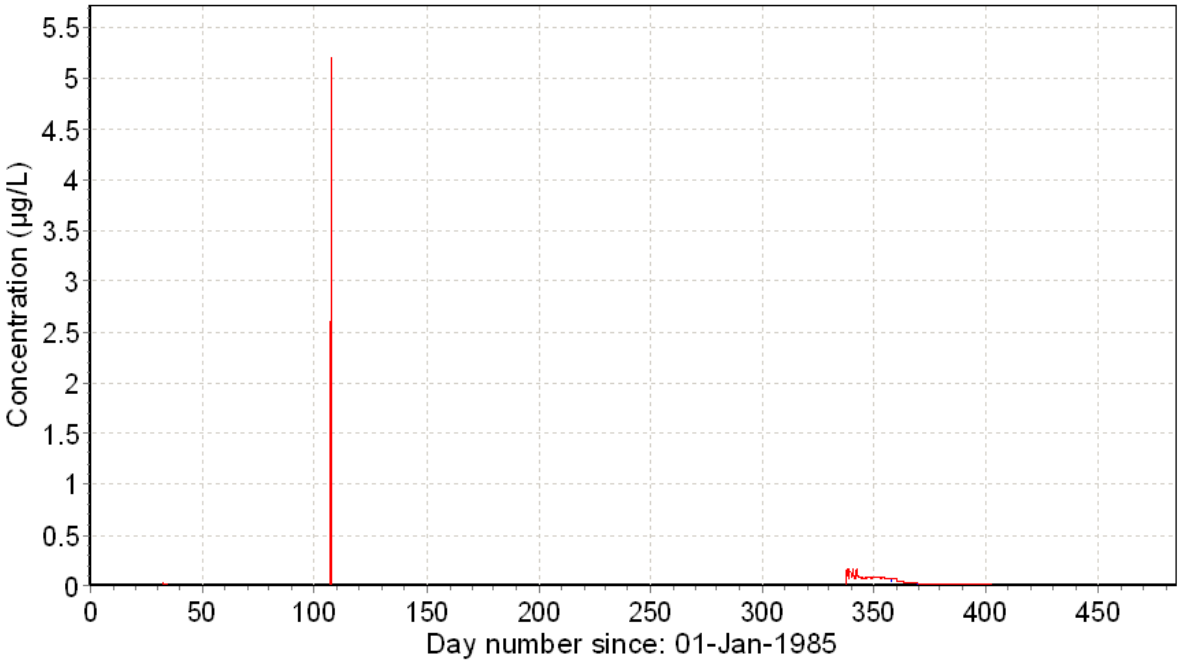

Figure 5: FOCUS PECsw at Step 3 for apple, D4 scenario (stream), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 5.204 µg/L).

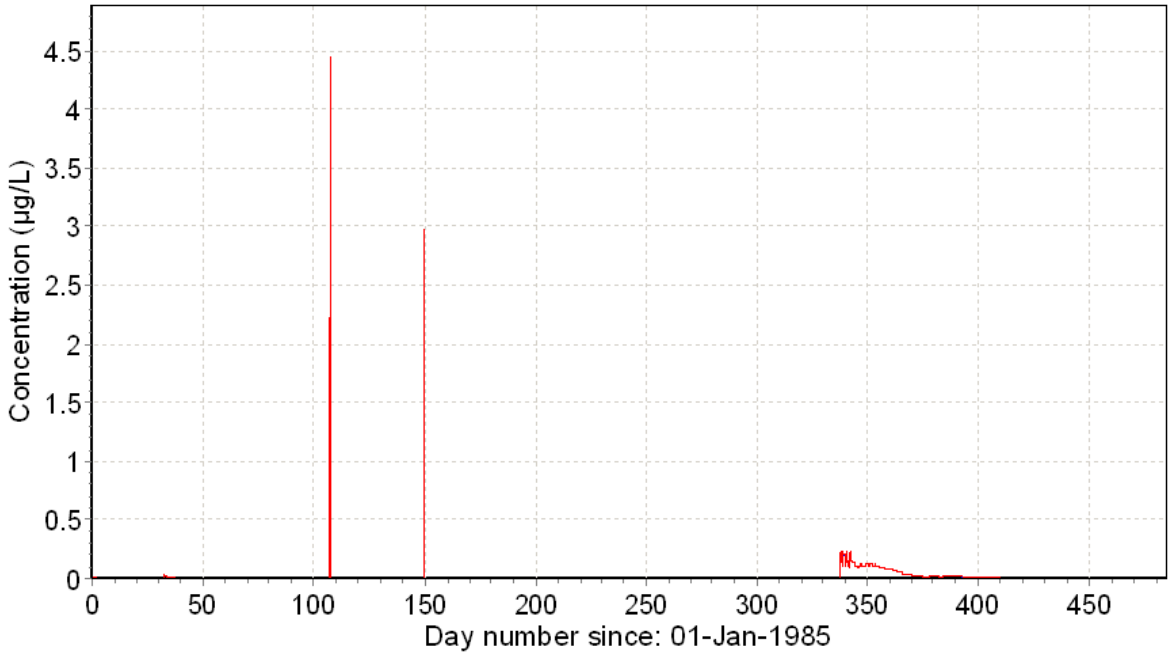

Figure 6: FOCUS PECsw at Step 3 for apple, D4 scenario (stream), with 2 applications of 70 g a.s./ha and 43.92 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 4.445 µg/L).

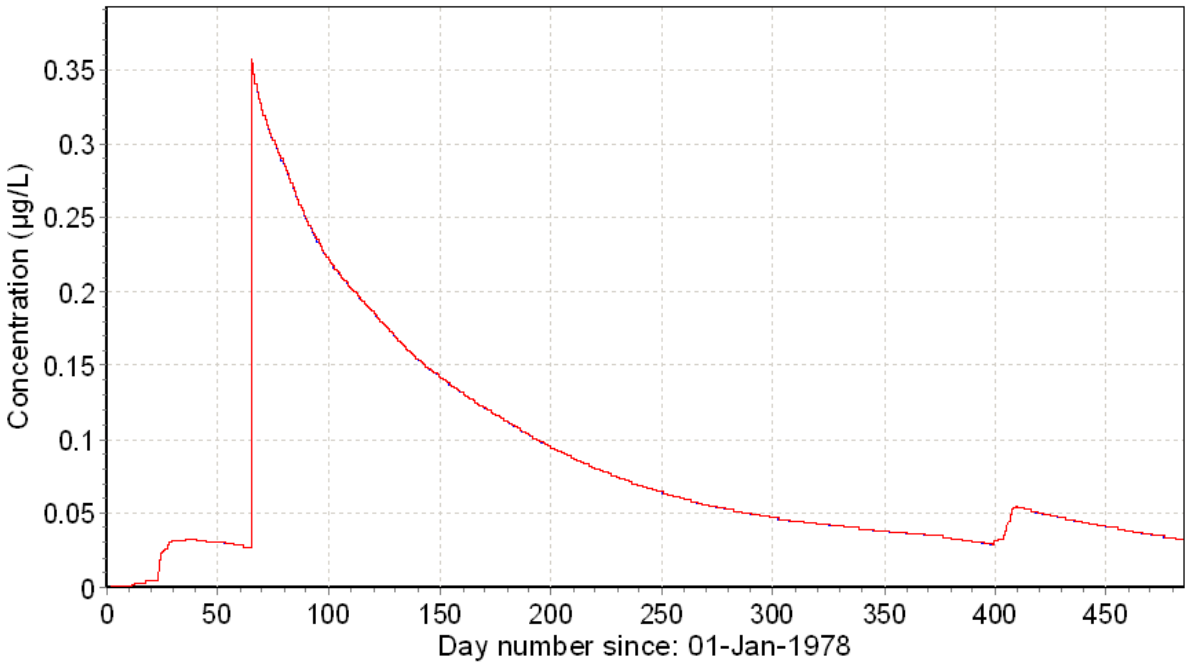

Figure 7: FOCUS PECsw at Step 3 for apple, D5 scenario (pond), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 0.357 µg/L).

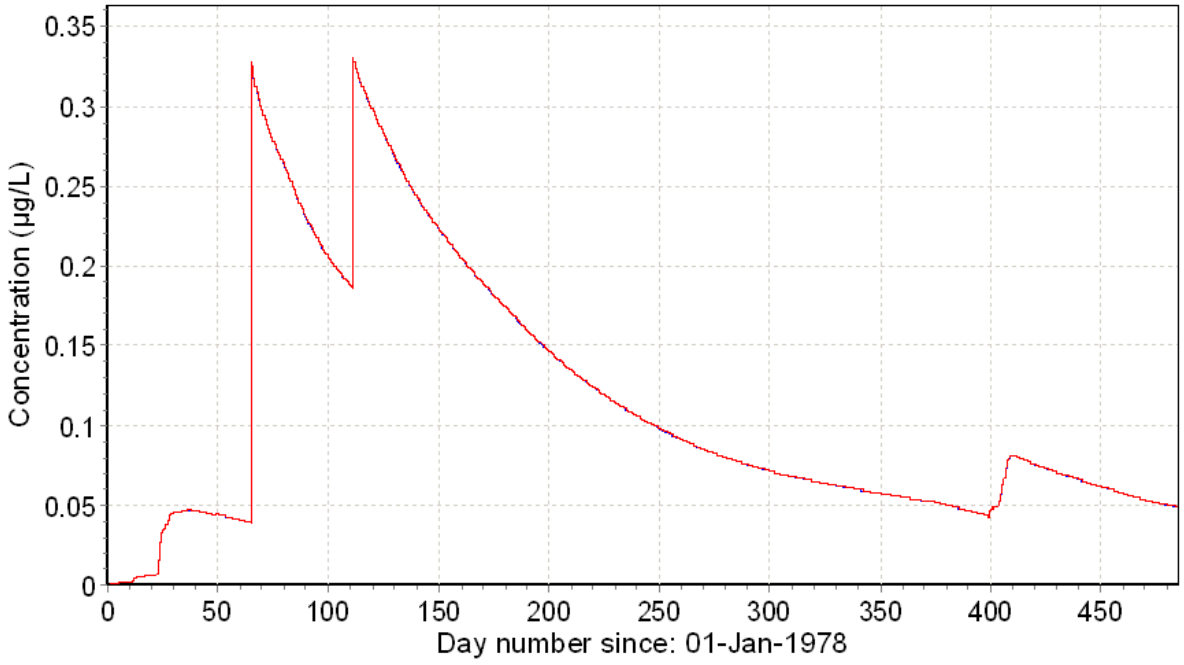

Figure 8: FOCUS PECsw at Step 3 for apple, D5 scenario (pond), with 2 applications of 70 g a.s./ha and 35.04 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 0.330 µg/L).

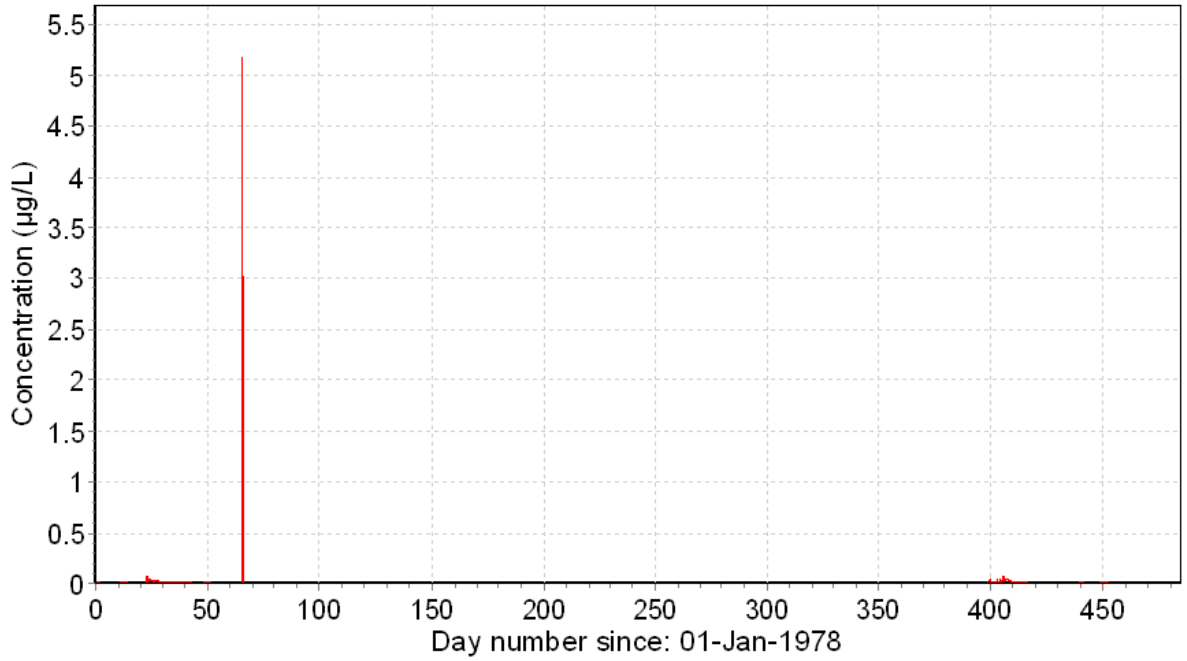

Figure 9: FOCUS PECsw at Step 3 for apple, D5 scenario (stream), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 5.173 µg/L).

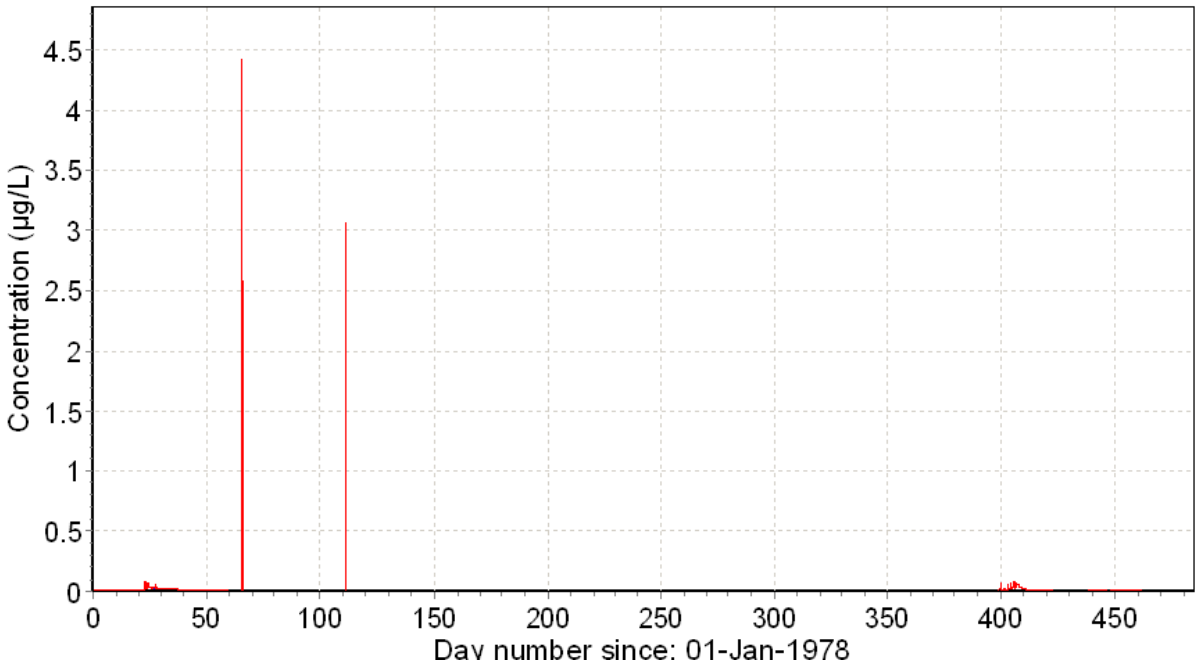

Figure 10: FOCUS PECsw at Step 3 for apple, D5 scenario (stream), with 2 applications of 70 g a.s./ha and 43.92 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 4.420 µg/L).

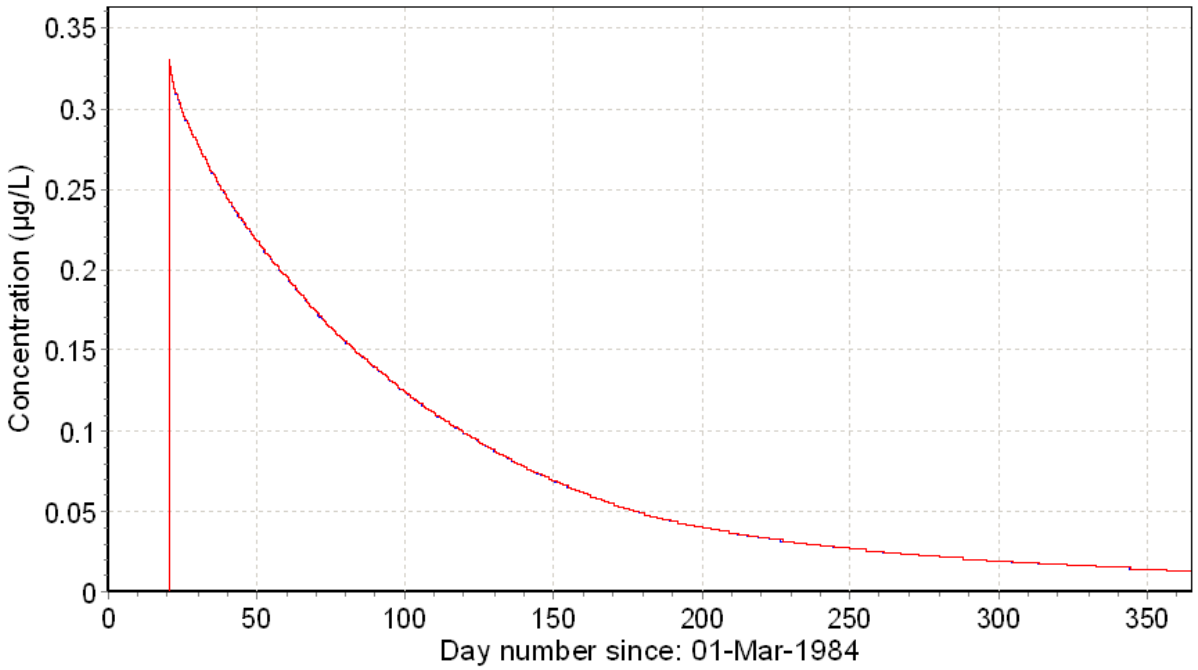

Figure 11: FOCUS PECsw at Step 3 for apple, R1 scenario (pond), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 0.330 µg/L).

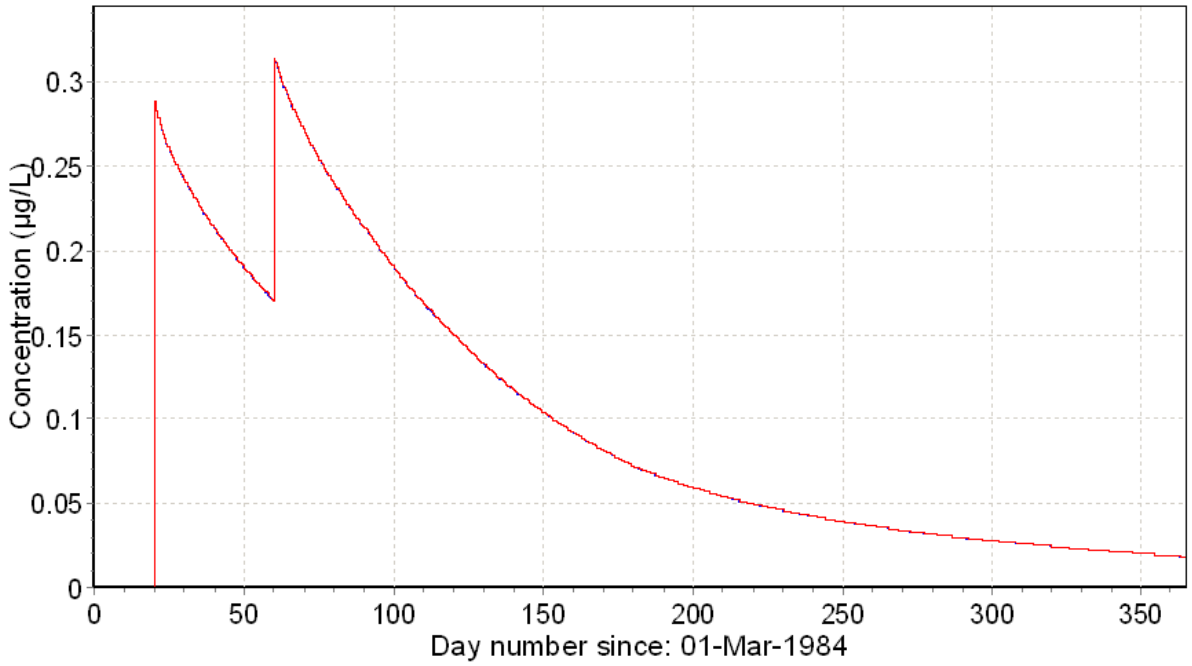

Figure 12: FOCUS PECsw at Step 3 for apple, R1 scenario (pond), with 2 applications of 70 g a.s./ha and 35.04 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 0.314 µg/L).

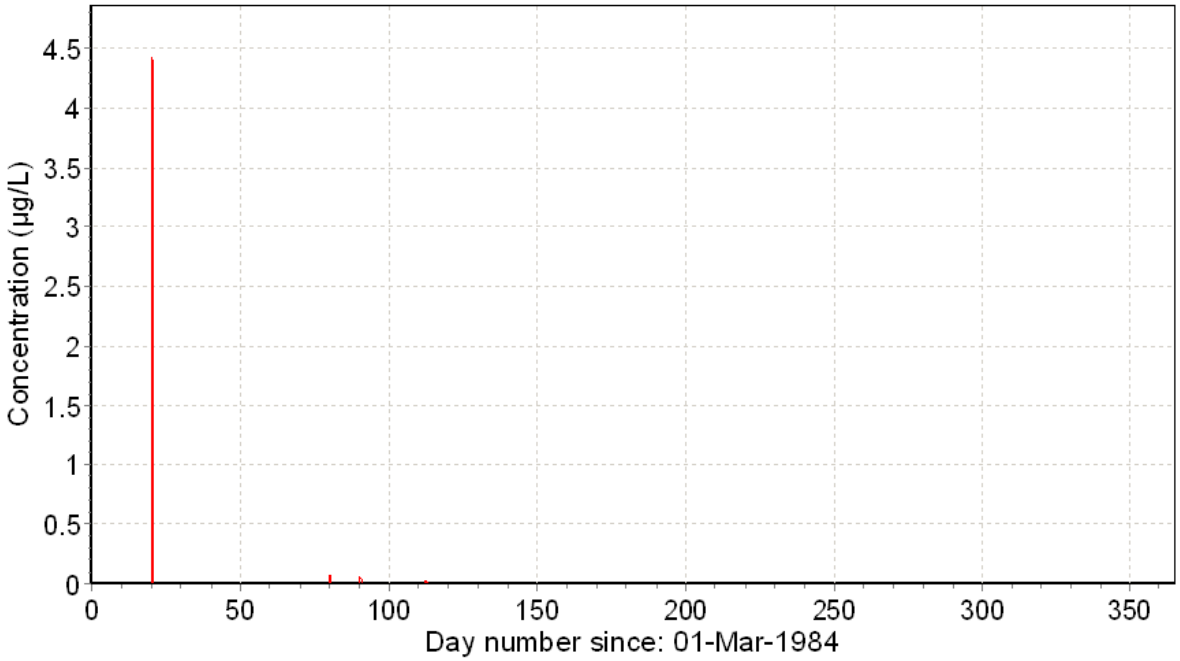

Figure 13: FOCUS PECsw at Step 3 for apple, R1 scenario (stream), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 4.425 µg/L).

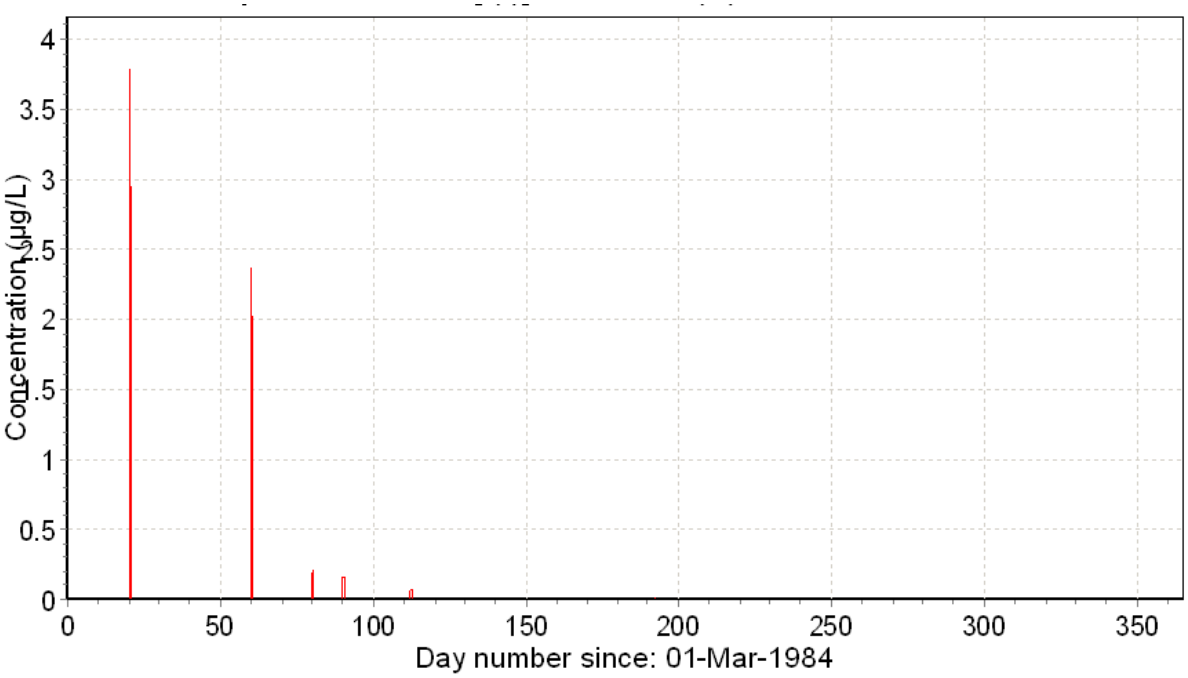

Figure 14: FOCUS PECsw at Step 3 for apple, R1 scenario (stream), with 2 applications of 70 g a.s./ha and 43.92 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 3.778 µg/L).

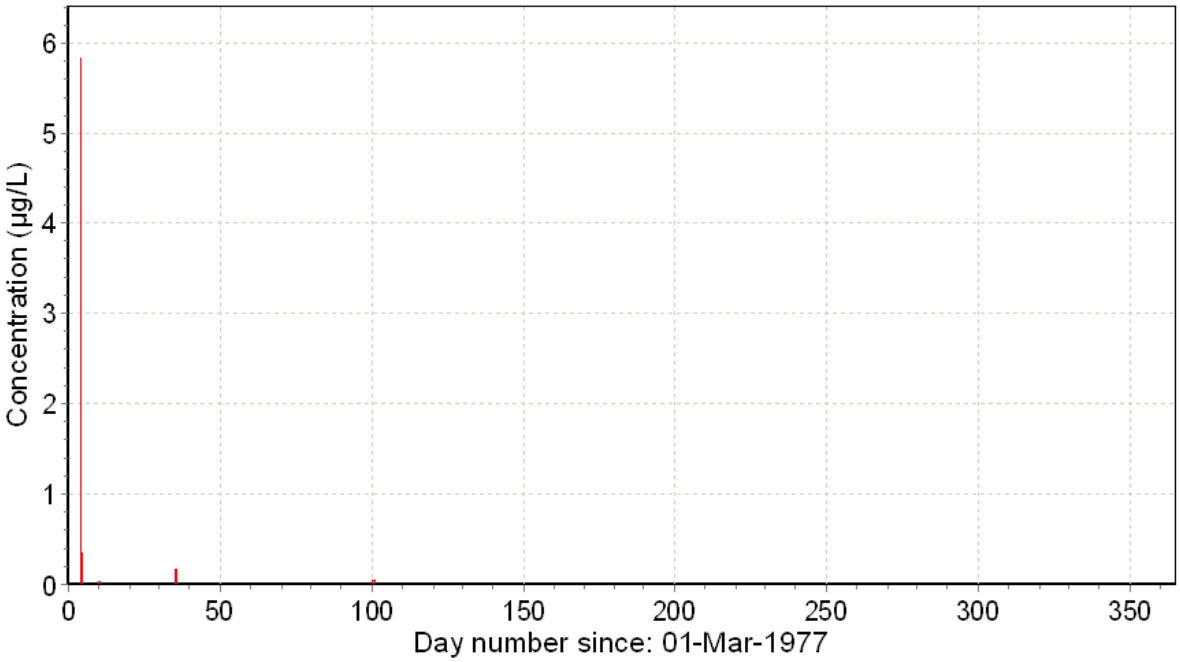

Figure 15: FOCUS PECsw at Step 3 for apple, R2 scenario (stream), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 5.821 µg/L).

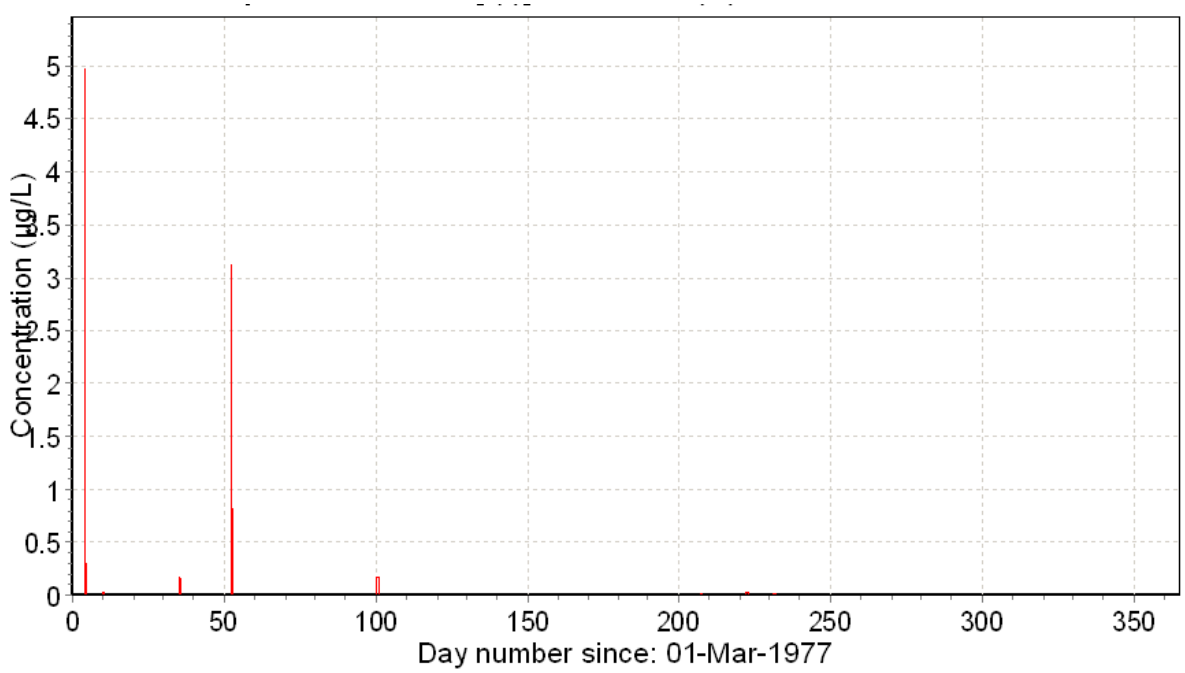

Figure 16: FOCUS PECsw at Step 3 for apple, R2 scenario (stream), with 2 applications of 70 g a.s./ha and 43.92 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 4.970 µg/L).

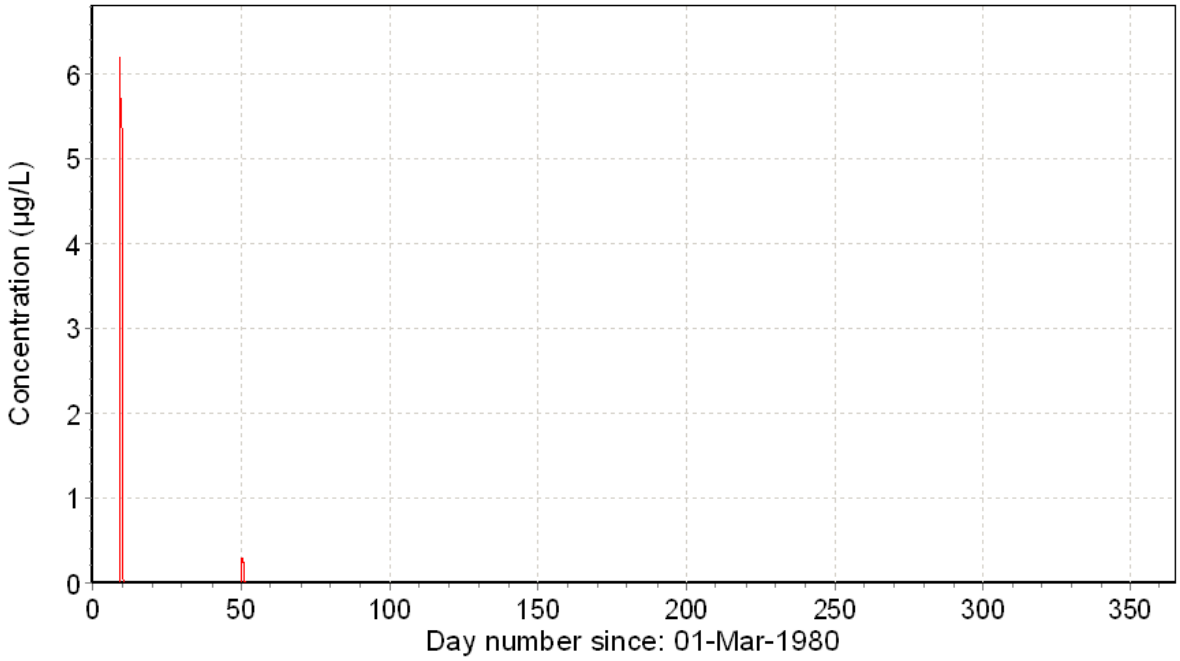

Figure 17: FOCUS PECsw at Step 3 for apple, R3 scenario (stream), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 6.187 µg/L).

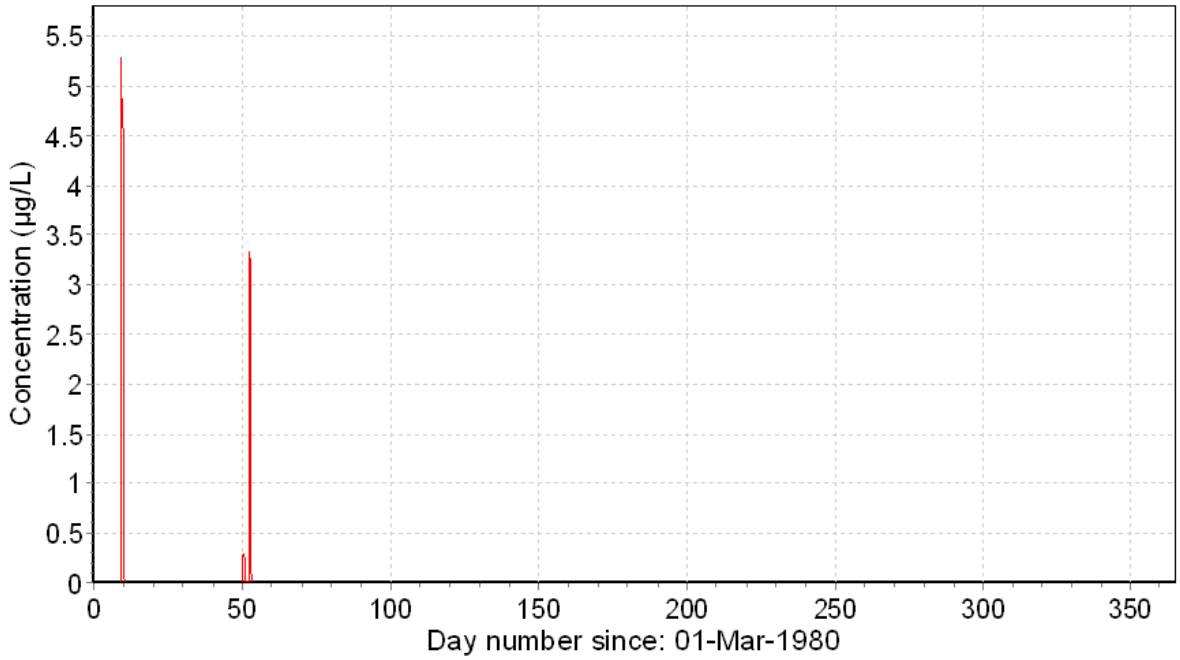

Figure 18: FOCUS PECsw at Step 3 for apple, R3 scenario (stream), with 2 applications of 70 g a.s./ha and 43.92 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 5.283 µg/L).

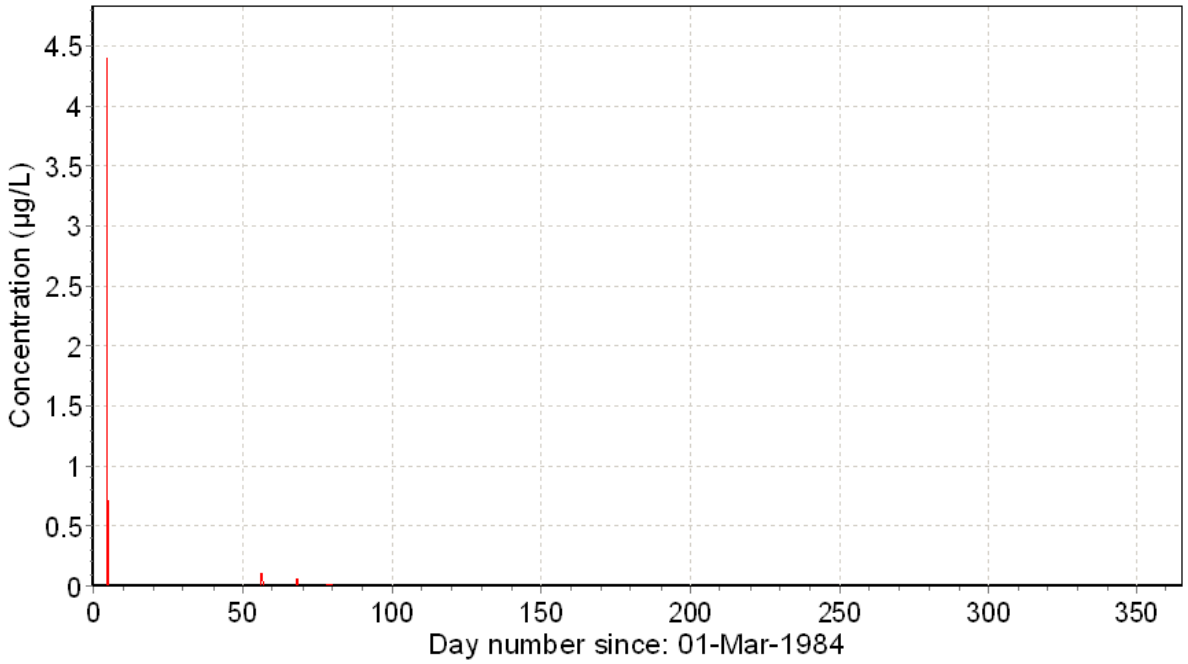

Figure 19: FOCUS PECsw at Step 3 for apple, R4 scenario (stream), with 1 application of 70 g a.s./ha ($PEC_{sw;max}$ = 4.395 µg/L).

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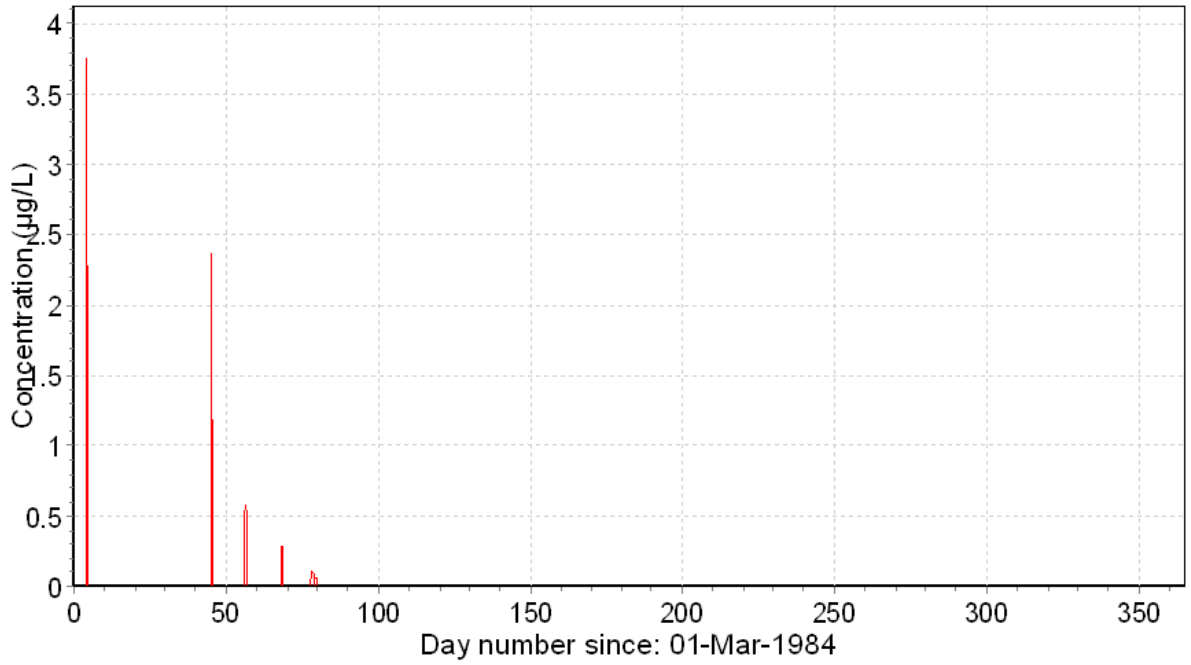


Figure 20: FOCUS PECsw at Step 3 for apple, R4 scenario (stream), with 2 applications of 70 g a.s./ha and 43.92 g a.s./ha (second rate of 105 g a.s./ha corrected to take into account the late BBCH for the second application) ($PEC_{sw;max}$ = 3.753 µg/L).

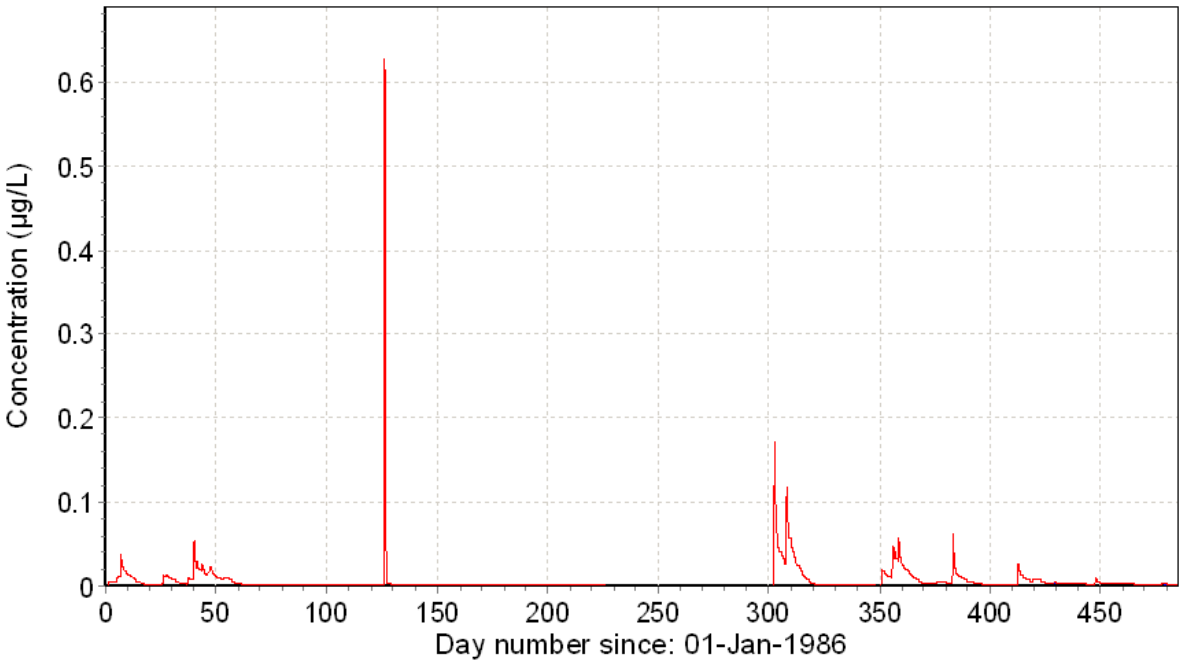


Figure 21: FOCUS PECsw at Step 3 for tomato, D6 scenario (ditch), with 1 application of 100 g a.s./ha ($PEC_{sw;max}$ = 0.627 µg/L).

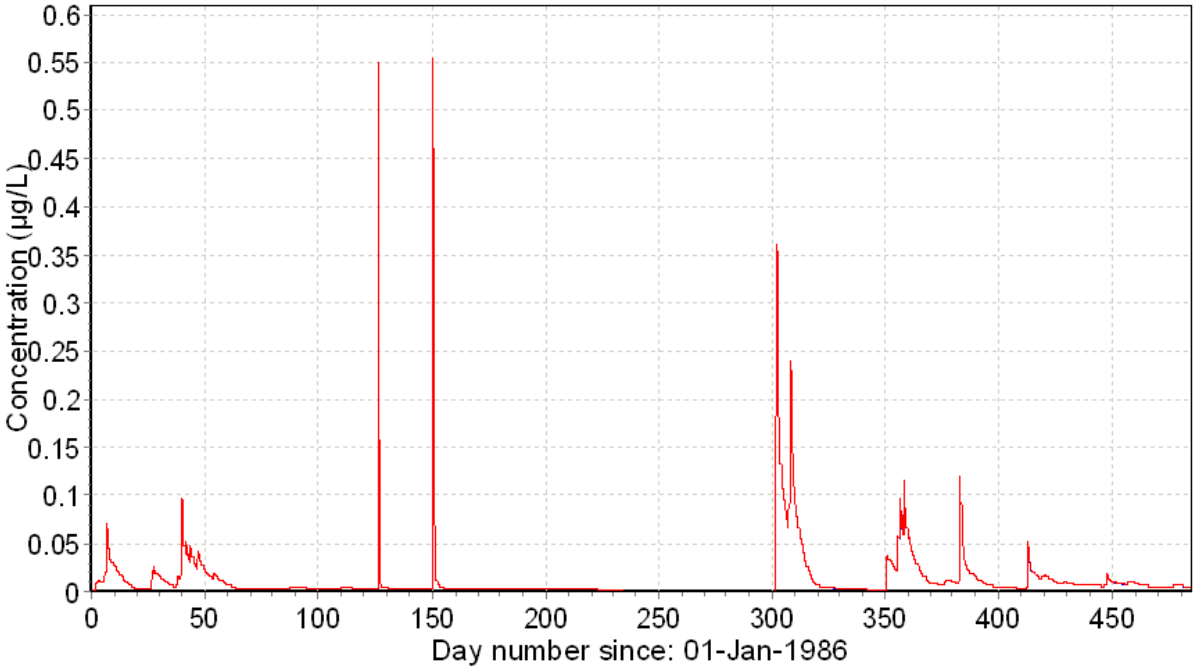


Figure 22: FOCUS PECsw at Step 3 for tomato, D6 scenario (ditch), with 2 applications of 100 g a.s./ha ($PEC_{sw;max}$ = 0.555 µg/L).

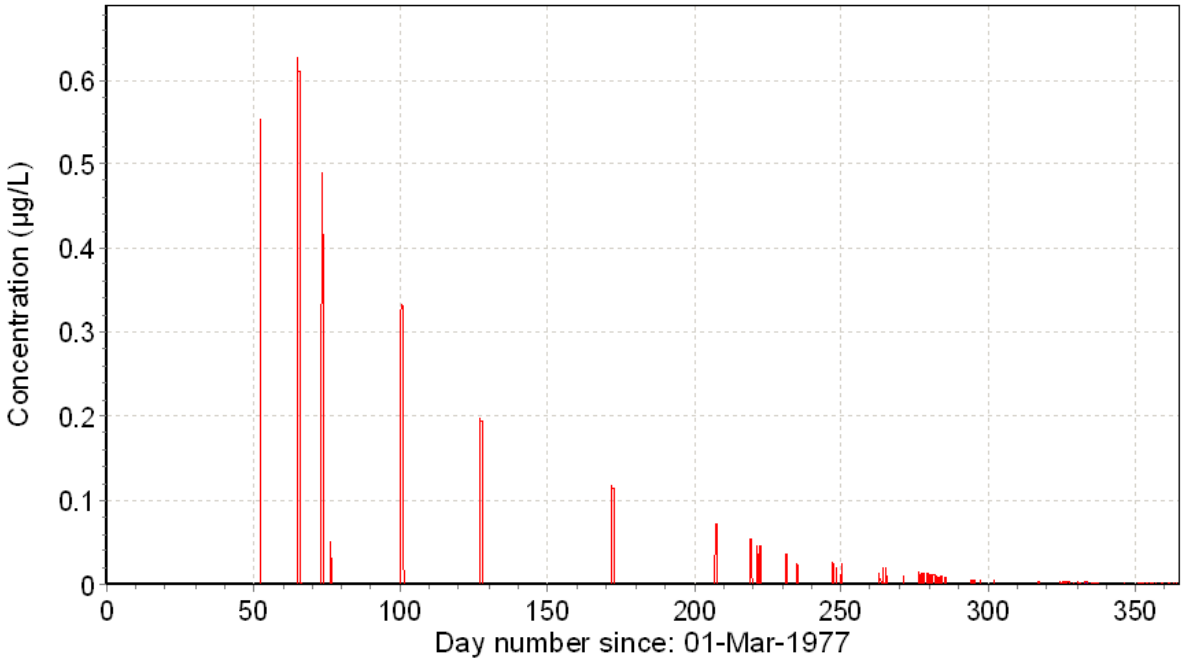


Figure 23: FOCUS PECsw at Step 3 for tomato, R2 scenario (stream), with 1 application of 100 g a.s./ha ($PEC_{sw;max}$ = 0.627 µg/L).

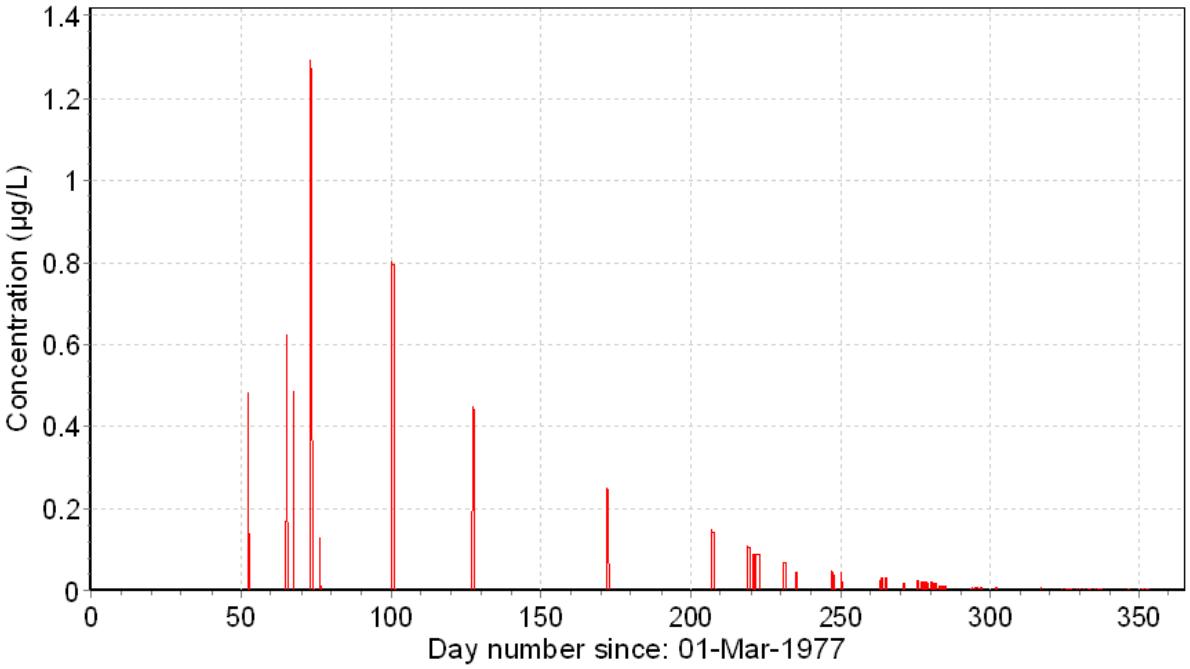


Figure 24: FOCUS PECsw at Step 3 for tomato, R2 scenario (stream), with 2 applications of 100 g a.s./ha ($PEC_{sw;max}$ = 1.298 µg/L).

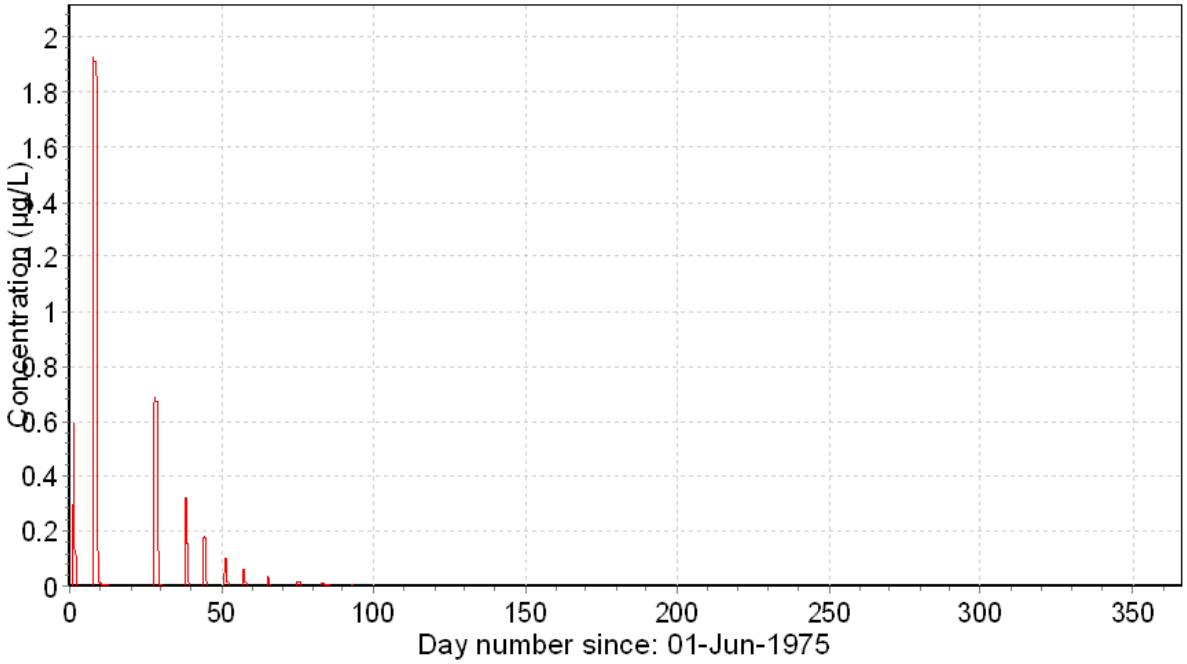


Figure 25: FOCUS PECsw at Step 3 for tomato, R3 scenario (stream), with 1 application of 100 g a.s./ha ($PEC_{sw;max}$ = 1.926 µg/L).

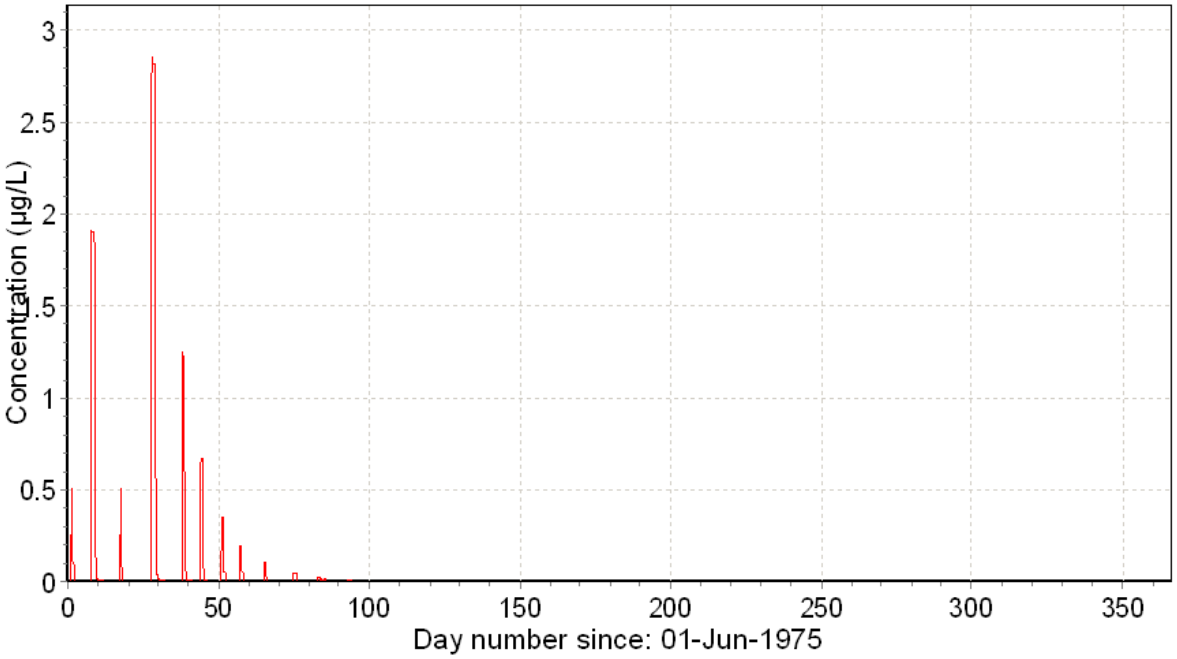


Figure 26: FOCUS PECsw at Step 3 for tomato, R3 scenario (stream), with 2 applications of 100 g a.s./ha ($PEC_{sw;max}$ = 2.856 µg/L).

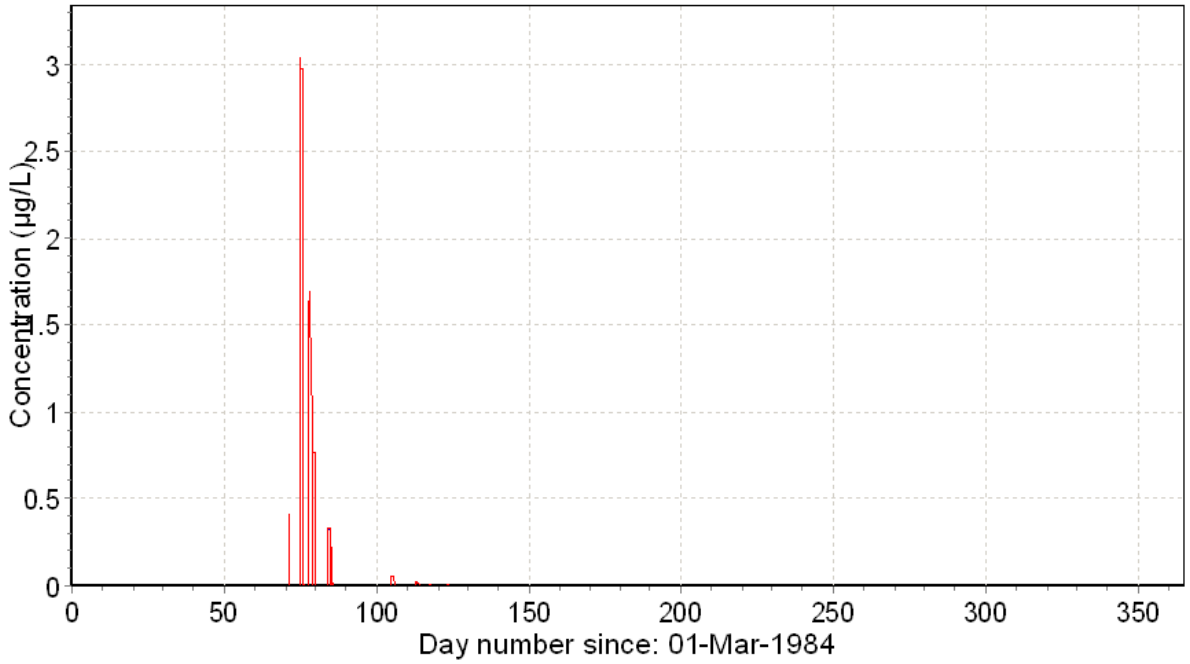


Figure 27: FOCUS PECsw at Step 3 for tomato, R4 scenario (stream), with 1 application of 100 g a.s./ha ($PEC_{sw;max}$ = 3.037 µg/L).

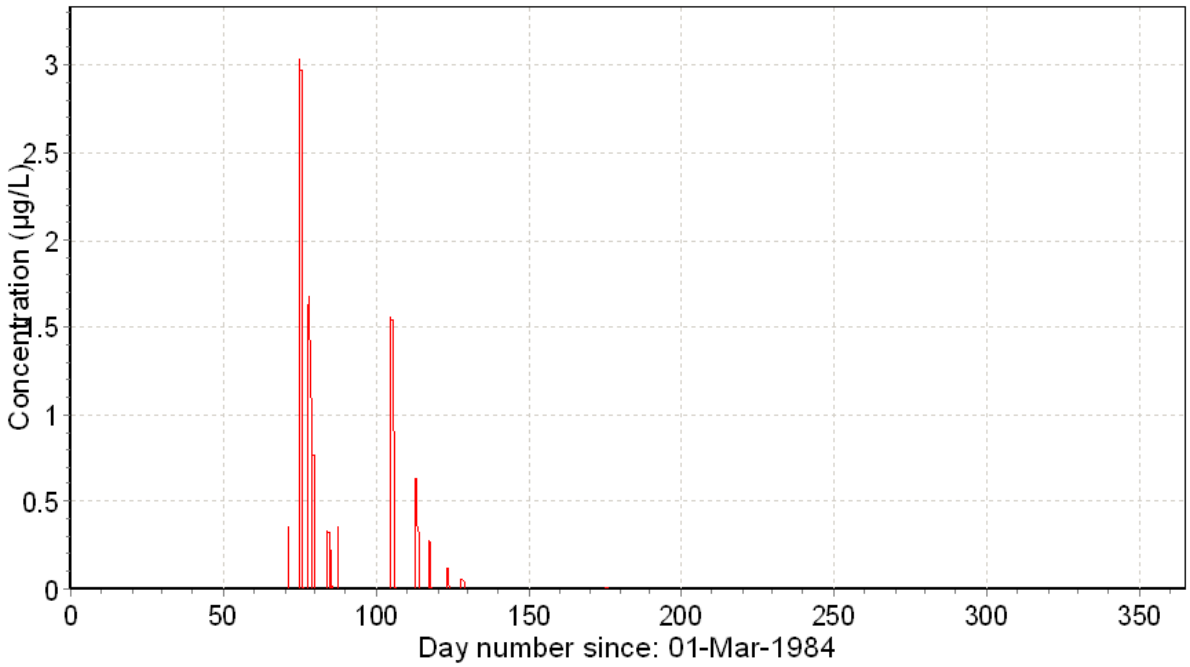


Figure 28: FOCUS PECsw at Step 3 for tomato, R4 scenario (stream), with 2 applications of 100 g a.s./ha ($PEC_{sw;max}$ = 3.037 µg/L).

FOCUS Step 4 calculations

The effect of spray drift and run-off mitigation was also investigated in the new simulations completed by EFSA. Step 4 calculations were performed assuming the same mitigation measures adopted in the original calculations presented in the EFSA Conclusion (EFSA, 2008). In particular, 90 % run-off reduction and 95 % spray drift reduction were implemented for apples, these being the maxima considered reliable and recommended for use in regulatory assessments in the FOCUS Landscape and Mitigation Report (FOCUS, 2007). The estimated 95 % spray drift mitigation values tabulated in Table D5 are the values reported for the combination of a 20 m no-spray zone and a 50 % drift mitigation technology as reported in the original PEC_{sw} calculations (EFSA, 2008). For the use on tomato, a 95 % spray drift reduction, equivalent to a no-spray buffer zone between 35 and 40 m, was considered for the D6 scenario. For the simulation of the R scenarios a 90 % run-off reduction in combination with 95 % spray drift reduction were implemented. The results are presented in Table D6.

Table D5 – FOCUS step 4 $PEC_{sw,max}$ values of imidacloprid for the use in apple

Scenario	WB	EFSA (2008)	EFSA (2014) Step 4 PECsw*		
		Step 4 PECsw (µg/L)	10 m buffer zone (µg/L)	50 % spray drift reduction technology + 20 m buffer zone (µg/L)	90 % Run-off reduction + 50 % spray drift reduction technology + 20 m buffer zone (µg/L)
D3	ditch	0.300		0.299	
D4	pond	0.252	0.208		
D4	stream	0.316		0.316	
D5	pond	0.258	0.234		
D5	stream	0.318		0.316	
R1	pond	0.226	0.204		
R1	stream	0.267			0.267
R2	stream	0.348			0.351
R3	stream	**0.373**			**0.373**
R4	stream	0.264			0.265

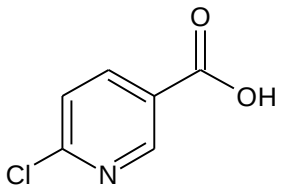
* To be used for risk assessment
Values in **bold** indicate the max PEC_{sw} value

Table D6 – FOCUS step 4 $PEC_{sw,max}$ values of imidacloprid for the use in tomato

Scenario	WB	Step 4 PECsw EFSA (2008) (µg/L)	Step 4 PECsw EFSA (2014)*	
			95 % spray drift reduction technology (µg/L)	90 % Run-off reduction + 95 % spray drift reduction (µg/L)
D6	ditch	**0.447**	0.171	-
R2	stream	0.152		0.296
R3	stream	0.429		0.693
R4	stream	0.313		**0.712**

* To be used for risk assessment
Values in **bold** indicate the max PEC_{sw} value

APPENDIX E - USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
M14 6-chloronicotinic acid NTN33893-6-CNA	6-chloronicotinic acid OC(=O)c1cnc(Cl)cc1	

* The metabolite name in bold is used in the Conclusion
**ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

µg	microgram
a.s.	active substance
AF	assessment factor
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
d	day
DAR	Draft Assessment Report
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EAC	environmentally acceptable concentration
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
EC_x	concentration where x % effect was observed/calculated
EEC	European Economic Community
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
ERO	ecological recovery option
ETO	ecological threshold option
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GM	geometric mean
GS	growth stage
h	hour(s)
ha	hectare
HC_x	hazardous concentration for x % of the species of a SSD
L	litre
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
m	metre
MAF	multiple application factor
MASS	Macro-invertebrate Artificial Substrate Samplers
MDD	minimal detectable difference
MDD_{abu}	MDD for the abundance
mg	milligram
mL	millilitre
mm	millimetre
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
ng	nanogram
NOAEC	no observed adverse effect concentration

NOAEL	no observed adverse effect level
NOEAEC	no observed ecologically adverse effect concentration
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
$PEC_{sw;max}$	the maximum predicted environmental concentration in surface water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
$PEC_{sw;twa}$	the predicted time-weighted average concentration in surface water
PER	proboscis extension reflex
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
ppb	parts per billion (10^{-9})
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RAC	Regulatory Acceptable Concentration
$RAC_{sw;ac}$	RAC in surface water for adverse effects of pesticide exposure occurring within a relatively short period after exposure
$RAC_{sw;ch}$	RAC in surface water for adverse effects of pesticide exposure that develop slowly and/or have a long-lasting course and that are caused by short- or long-term exposure
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SL	soluble (liquid) concentrate
SSD	species sensitivity distribution
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TLV	threshold limit value
TRR	total radioactive residue
TWA	time weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WHO	World Health Organization
wk	week
yr	year