Conclusion regarding the peer review of the pesticide risk assessment of the active substance

imidacloprid.

Finalised: 29 May 2008

SUMMARY

Imidacloprid is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on imidacloprid in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 13 June 2005. The peer review was initiated on 25 January 2006 by dispatching the DAR for consultation of the Member States and the sole applicant Bayer CropScience AG. Subsequently, the comments received on the DAR were examined and responded to by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues which were agreed during a written procedure in March - May 2007. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in October 2007.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in April 2008 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as an insecticide seed treatment for sugar beet and as a foliar spray for apples and tomatoes. Full details of the GAP are in the attached list of end points.
The representative formulated products for the evaluation were “Confidor”, a soluble concentrate formulation (SL) and “Gaucho” a flowable concentrate for seed treatment (FS).

Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. However it

[1] OJ No L 224, 21.08.2002, p. 25, as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

should be noted that the residue definition in plants and surface water for monitoring purposes has not been finalised. In addition to this as the peer review process found that the active substance should be classified as toxic a data gap for a method of analysis for body fluids was identified.
Sufficient data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. A method of analysis is available for the active substance in the FS formulation but not in the SL.

Within the toxicological assessment, imidacloprid is almost completely absorbed by oral administration, does not bioaccumulate and is excreted mainly by the urine. Showing a high acute oral toxicity in mice but a low toxicity after dermal or inhalative exposure, imidacloprid was not irritant to the skin or the eye and had no skin sensitisation potential. The proposed classification for the acute toxicity was T, R25 Toxic if swallowed. In short term studies with rats and mice, the most sensitive parameter was the decreased body weight development. In the dog studies, indications of an effect on the central nervous system were observed (clinical signs). No evidence of genotoxic or carcinogenic effects was observed with imidacloprid. Likewise it did not affect the reproductive parameters in rats, or the embryofoetal development in rats and rabbits. In neurotoxicity studies, effects occurred in the functional observational battery, without histopathological findings in the nervous tissues. The acceptable daily intake (ADI) was 0.06 mg/kg bw/day based on the chronic rat study, the acceptable operator exposure level (AOEL) was 0.08 mg/kg bw/day based on the 90-day dog study supported by the subchronic rat neurotoxicity study, and the acute reference dose (ARfD) was 0.08 mg/kg bw/day based on the 90-day dog study. All reference values were derived with a safety factor of 100.
The agreed dermal absorption values for Confidor SL 200 were 0.3% for the concentrate and 8% for the dilution, whereas the default value of 100% was adopted for Gaucho FS 600 in the absence of experimental data. The estimated operator exposure is below the AOEL for Confidor SL 200 without the use of personal protective equipment whereas it is above the AOEL for Gaucho FS 600 with the use of coveralls and gloves. Similarly the exposure estimates for workers re-entering crops treated with Confidor SL 200 are lower than the AOEL, whereas the estimates for workers loading and sowing seeds treated with Gaucho FS 600 are higher than the AOEL. And finally, the bystander exposure to both formulations is not expected to exceed 6% of the AOEL .

The plant metabolism of imidacloprid has been clearly elucidated after foliar, seed and soil treatments. Considering all information available, the residue definition for risk assessment is proposed to include the active substance and all metabolites containing the 6-chloropyridinyl moiety. A residue definition for monitoring was not agreed under the peer review process. The EFSA is however of the opinion that 2 options are possible (either parent compound or the same residue definition as for risk assessment).
A sufficient amount of field supervised residue trials is available in support of all representative uses. These data allow assessing acute and chronic consumer exposure. They also provide appropriate information for setting MRLs in accordance with the 2 options proposed for the residue definition. No significant transfer of soil residues to rotational crops is expected under practical conditions.

No change in the nature of residues is expected under processing.
Livestock may be exposed to residues of imidacloprid and its metabolites, but the metabolism and feeding studies demonstrate that the transfer of residues to animal commodities is limited and below the limit of quantification of analytical methods.
No risk for the consumer has been identified under acute or chronic exposure to residues resulting from the representative uses of imidacloprid. This conclusion needs however to be consolidated by further information first confirming that the metabolism of the compound in plants does not lead to compounds of particular toxicological concern.

In soil under aerobic conditions imidacloprid exhibits moderate to very high persistence. Mineralisation of the pyridinyl-^{14}C-methylene radiolabel to carbon dioxide accounted for 3.3-17% AR after 91-100 days. The formation of unextractable residues was a sink, accounting for 17-27 % AR after 91-100 days. No metabolite accounted for > 3.4% AR at any sampling time. The soil accumulation assessment for imidacloprid residues under conditions represented by 2 UK soil accumulations studies was not finalised. Under anaerobic soil conditions the metabolite M09[2] was a major metabolite accounting for a maximum of 51% AR after 249 days of anaerobic conditions. Imidacloprid exhibits high to medium mobility in soil. M09 would be expected to exhibit low mobility. There was no indication that adsorption of imidacloprid was pH dependant.

In dark natural sediment water systems imidacloprid exhibited moderate to high persistence. No metabolite accounted > 6.3% AR at any sampling time. The terminal metabolite, CO_2, was a small sink in the material balance accounting for a maximum of 2.5 % AR at 92 days (study end). Unextracted sediment residues were the major sink representing 66 % AR at study end in the system with 4.09% organic carbon (oc). In the lower oc content system (0.89%) unextracted residues accounted for a lower proportion at 15% AR at study end. Photolysis mediates the degradation of imidacloprid in aquatic systems to 4 major identified degradation products with imidacloprid exhibiting low to moderate persistence in a German outdoor mesocosm study (summer application). The necessary surface water and sediment exposure assessments are available using the agreed FOCUS scenarios approach for imidacloprid at steps 3 and 4, with spray drift and runoff mitigation being applied at step 4.

The potential for groundwater exposure from the applied for intended uses by imidacloprid above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. Evidence from the available guideline lysimeter studies indicated that contamination of groundwater by imidacloprid or its minor soil metabolites is unlikely from the applied for intended uses assessed in this conclusion.

The representative uses are spray application in apples (northern Europe and southern Europe) and tomatoes (southern Europe) indoors and outdoors and seed treatment of sugar beet. The risk

[2] M09: 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine

assessment for birds and mammals was conducted for uptake of contaminated food items for the outdoor uses only. No exposure of birds and mammals was assumed for the glasshouse use. The acute, short-term and long-term endpoints used in the risk assessment for birds were discussed in the meeting of experts and the values which were proposed by the RMS in the DAR were confirmed in the meeting of experts. The first-tier TERs the uptake of sugar beet seed pellets as a food item and as grit were significantly below the Annex VI trigger values. The suggested refinements based on the low attractivity as food items and the low availability of sugar beet seed pellets (provided a high drilling efficiency leaving only 0.17% of the seed pellets on the soil surface and seed pelletages are removed from the soil surface) was accepted and the risk to birds was considered as low. However the suggested refinements of the risk assessment for granivorous mammals were not sufficiently supported by data and therefore rejected by the experts. A data gap was identified for the applicant to refine the risk to granivorous mammals. The risk to medium herbivorous mammals from uptake of residues in sugar beet seedlings was assessed as low but the risk assessment for birds for the uptake of residues in sugar beet seedlings needed refinement. Wood pigeon (*Columba palumbus*) was accepted as a focal species. As a refinement step it was proposed that wood pigeons feed in bouts and one filling of the crop with sugar beet seedlings would constitute 20% of the daily food intake. This was used as a crop-filling factor of 0.2 in the exposure calculation. However it was noted by the experts that the birds may feed several times in one day on the same field and considerations of metabolic processes was missing. An open point was identified by the experts for the RMS to include information on the toxicokinetics to support the risk refinement. The RMS noted in addendum 6 (not peer-reviewed) that the available studies on the metabolic processes cannot be used to support the suggested use of the crop limiting factor of 0.2. The RMS proposed using the crop-limiting factor of 0.2 also for the short-term and long-term risk assessment. This was not accepted and it was proposed that real PD data would be a more appropriate refinement step for the short-term and long-term risk assessment. The suggested PT value of 0.1 was rejected by the experts because it was not sufficiently justified by data. The experts concluded that a high risk to birds from uptake of sugarbeet seedlings cannot be excluded for the representative use.

The first-tier TER values were below the triggers for insectivorous birds for the uses in tomatoes and orchards. The applicant suggested a PT of 0.61 for blue tit (*Parus caeruleus*) in orchards and 0.1 for yellow wagtail (*Motacilla flava*) in tomato. An insect residue study was submitted and discussed in the expert meeting. The results of the study were considered as not reliable by the experts. The PD refinements (relative proportion of small and large insects) were accepted by the experts. The suggested PT value for yellow wagtail was not supported by data and hence rejected by the experts as well as the PT to refine the acute risk of blue tit. The TERs based on accepted refinements indicate a low risk to insectivorous birds for the use in tomato but the acute TER for blue tits is below the trigger of 10 requiring further risk refinements for the use in orchards.

The first-tier acute and long-term TERs for herbivorous mammals were below the Annex VI trigger values of 10 and 5. The risk to herbivorous mammals from spray application in tomatoes was considered as low since tomatoes are not attractive as a food source. The risk assessment for herbivorous mammals in orchards resulted in TERs above the trigger taking interception factors into account and also residue decline to refine the long-term risk assessment.

The risk to herbivorous birds and mammals from uptake of plant metabolites is considered as covered by the risk assessment for imidacloprid.

The lowest endpoints from the tested aquatic organisms were observed for *Chironomus riparius*. The spray formulation Confidor SL 200 was tested with *Chironomus riparius*. The toxicity of formulated imidacloprid was similar to technical imidacloprid. Testing with the granular formulation Gaucho FS 600 Uncoloured was considered as not necessary since aquatic organisms are expected to be exposed to the active substance but not to the formulation. The TER values based on maximum PECsw of the worst case FOCUSsw scenario R3 were well above the Annex VI triggers for fish, daphnids and algae. The acute and chronic TER for *Chironomus riparius* were below the Annex VI trigger of 10. The experts agreed that the endpoints from the mesocosm of 0.6 µg imidacloprid/L should be used in the risk assessment. No agreement was reached on the safety factor which should be applied. It was proposed that MSs use a safety factor of 1-3 in combination with the NOEC of 0.6 µg imidacloprid/L. The TER values based on the endpoint of 0.6 µg imidacloprid/L and FOCUS step3 PECsw were in the range of 0.09 and 1 indicating a high risk to aquatic insects for the uses in tomatoes and apples. The TERs for the use as a seed treatment were >3 suggesting a low risk. With no-spray buffer zones of 20 m a TER of ≥1 is achieved in the full FOCUS step4 drainage scenarios (D3, D4, D5) and in the run-off scenarios R1, R2, R3 (without additional run-off mitigation) and R4 (including 50% run-off mitigation) for the use in orchards. A TER of ≥3 was reached in none of the full FOCUS step4 scenarios. The drainage scenario D6 resulted in a TER of ≥1 with spray drift reduction by 95% (equivalent to 35-40 m no-spray buffer zone) but no full run-off scenario resulted in a TER ≥1 for the use in tomatoes. If run-off is mitigated by 90% then the TERs were ≥1. However none of the scenarios except R3 resulted in TERs ≥3. The metabolites M01, M07, were about 1 order of magnitude acutely less toxic and the metabolites M09, M12, M16 and M23 were more than 2 orders of magnitude less chronically toxic to *Chironomus riparius* than imidacloprid. The TER values based PECsw values from FOCUSsw scenario R3 (which resulted in highest PECsw values for imidacloprid) were above the trigger of 100 except for metabolite M07 where a TER of 46 was observed. It is concluded that the risk from metabolites is low for all representative uses and that the risk from metabolite M07 is covered by the risk mitigation required for imidacloprid. No toxicity data were made available for the photolysis metabolite M14. The risk from this metabolite to aquatic organisms needs to be addressed.

The risk of bioaccumulation from imidacloprid and its metabolites which are predicted to reach surface water is considered as low.

Imidacloprid is acutely very toxic to bees. In addition to the standard acute toxicity tests also chronic tests and studies to investigate sublethal effects (bee behaviour) were conducted. The HQ values for oral and contact exposure were far in excess of the HQ trigger value of 50 indicating a high risk to bees from the use as a spray application in orchards and tomatoes. Imidacloprid has a distinct systemic mode of action. Therefore the uptake in plants from soil/seed treatment applications was investigated in different crops. Imidacloprid is preferentially translocated to leaves and shoots and to a much lower extend to the reproductive organs. No major soil metabolites were detected in the soil degradation studies. Bees would therefore only be exposed to imidacloprid residues in succeeding crops. The RMS presented a TER calculation based on NOEC values (acute and chronic lethal

effects, behavioural impacts including bee hive development) and residue levels in nectar and/or pollen of <5 ppb resulting in TER values of >9.2, >10, >4.8 and >4 indicating a low risk to bees from the representative use as a seed treatment. Furthermore sugar beet is harvested before flowering hence the risk to bees is expected to be low from the use as a seed treatment in sugar beet.

The risk from exposure to honeydew excreted from aphids was considered as low based on the argumentation that the acute oral LD_{50} for aphids is several orders of magnitude lower than for bees and hence it would be highly unlikely that aphids would survive exposure to imidacloprid at concentrations in sap which could lead to the excretion of honeydew which is toxic to bees. The line of argumentation was agreed by the experts but it was not clear how the toxicity value for aphids was derived and the experts suggested a data gap for the applicant to clarify this point.

Overall it is concluded that the spray applications of imidacloprid pose a high risk to bees. Risk mitigation is required for the use in orchards. The risk to bees is considered to be low if the product is not applied during flowering and if flowering weeds are removed/mown before the application. However it should be noted that bees potentially foraging in the off-crop area would still be exposed via spray drift and hence not be protected by the suggested risk mitigation measure. Flowering tomato plants are visited by honey-bees and other pollinators. The risk mitigation suggested for orchards is not an option for the use in tomato since the tomato plants flower almost continuously.

The spray application of imidacloprid will cause severe impacts on non-target arthropods in the in-field and off-field area. However in semi-field and field studies it was demonstrated that recolonisation of the in-field area is possible. The available data suggest that ageing of residues of 273 days is required in order not to be hazardous to larvae of *Poecilus cupreus*. A high risk to soil dwelling arthropods cannot be excluded for the seed treatment use. The available semi-field test with *P. cupreus* was conducted at too low concentrations of imidacloprid to allow a conclusion on the risk from the representative use in sugar-beet.

The first tier risk assessment for earthworms resulted in TERs below the trigger. Field studies were submitted. However it was not clear whether the application pattern in the field studies were the same as suggested in the GAP and whether the plateau PECsoil is covered. An open point was set in the meeting for the RMS to check whether the exposure in the field studies were in accordance to the GAP. The RMS confirmed that the application patterns were different from the representative uses but suggest that the application rates of 133 g a.s./ha (seed treatment) and 150 g a.s./ha (spray application) would cover the representative uses. However the estimated PECsoil in the field studies (0.1773 mg a.s./kg and 0.2 mg a.s./kg) are below the accumulated maximum PECs. Therefore uncertainty remains with regard to the long-term risk to earthworms. This uncertainty needs to be addressed further.

Organic matter breakdown was not affected in litterbag studies with the spray formulation Imidacloprid SL 200 and the seed treatment formulation Gaucho FS 600. However the maximum PECsoil values calculated are about 2-3 times higher than the concentrations in the litterbag studies. Therefore it cannot be concluded that the risk to organic matter breakdown is addressed.

No adverse effects were observed in a test with technical imidacloprid and the predatory mite *Hypoaspis aculeifer* at the highest tested application rate of 120 g a.s./ha. The NOEC observed for technical imidacloprid and *Folsomia candida* was 1.25 mg a.s./kg soil The endpoint observed for the

formulations were lower compared to technical imidacloprid and the TERs for the formulations are below the trigger of 5 if the NOECs are compared to the accumulated maximum PECsoil concentrations indicating a potential high risk to soil dwelling arthropods. The risk from the metabolites M06 and M07 was assessed as low.

The risk to non-target soil micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

Key words: imidacloprid, peer review, risk assessment, pesticide, insecticide.

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Imidacloprid is one of the 79 substances of the third stage Part A covered by the amended Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on imidacloprid, hereafter referred to as the draft assessment report, to the EFSA on 13 June 2005. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 25 January 2006 to the Member States and the main applicant Bayer CropScience AG as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA and Member States identified and agreed during a written procedure in March – May 2007 on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier, a scientific discussion took place in expert meetings in October 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in April 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 25 April 2007)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 28 May 2008)

Given the importance of the draft assessment report including its addendum (compiled version of March 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Imidacloprid is the ISO common name for (*E*)-1-(6-Chloro-3-pyridinylmethyl)-N-nitroimidazolidin-2-ylideneamine (IUPAC). Originally the ISO name referred to any mix of the E and Z isomers. However, during the peer review process it became clear that it was only the E isomer and the Z isomer will not be formed. The applicant approached ISO and they agreed to change what the ISO name referred to.

Imidacloprid is a nitroguanidine insecticide; other examples of this class of insecticides are the compounds clothianidin and thiamethoxam. It is a systemic insecticide with translaminar activity and with contact and stomach action. Readily taken up by the plant and further distributed acropetally, with good root-systemic action. It acts as an antagonist by binding to postsynaptic nicotinic receptors in the insects central nervous system.

The representative formulated products for the evaluation were "Confidor", a soluble concentrate formulation (SL) and “Gaucho” a flowable concentrate for seed treatment (FS).

The evaluated representative uses are as an insecticide seed treatment for sugar beet and as a foliar spray for apples and tomatoes. Full details of the GAP are in the attached list of end points.

The RMS included in the draft assessment report an evaluation of import tolerances on bananas, grapes, mangoes, pecans and citrus fruits. These uses were not part of the notified uses and were not peer-reviewed.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of imidacloprid as manufactured should not be less than 970 g/kg this is in line with the FAO specification which is applicable to this compound from the manufacturer Bayer. The technical material contains no relevant impurities. The name imidacloprid was originally allocated to any mix of the E and Z isomers however the applicant have stated and it was accepted by the meeting of experts that in crystalline form only the E isomer is present. The applicant has now got the ISO name to only refer to the E isomer. In the meeting of experts there was still some data gaps proposed for the isomers. Evidence is required that the E isomer is stable and that the Z isomer is not formed. Some information was provided on this in the evaluation table which demonstrated that the Z isomer will not be formed however, this was not peer reviewed. If the Z isomer is formed it would be expected to show up as a separate peak in the chromatograms. There is no evidence in the entire dossier of this happening, therefore the overall conclusion is that the E isomer is stable and the Z isomer will not be formed.

The content of imidacloprid in the representative formulations is 200g/L in the soluble concentrate formulation (SL) and 600 g/L in the flowable concentrate for seed treatment (FS).

The assessment of the data package revealed no issue that needs to be included as a critical area of concern with respect to the identity, physical, chemical and technical properties of imidacloprid or the respective formulation. However, the following data gap was identified:

- Validation data for the method of analysis used to analyse the active substance in the SL formulation.

The main data regarding the identity of imidacloprid and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of imidacloprid in the technical material and in the FS formulation as well as for the determination of the respective impurities in the technical material. As mentioned above there is a data gap for the SL for a validated method of analysis.
Therefore, enough data are available to ensure that quality control measurements for the FS formulation are possible. For the SL formulation all parameters can be controlled apart from the active substance content. However, it should be noted that there is a CIPAC method available for imidacloprid SL formulations but this has never been proposed as an enforcement method by either the applicant or the rapporteur.

For products of plant origin there is a validated LC-MS/MS method that analyses imidacloprid, M01[3] and M06[4] with the following LOQs for each compound 0.02 mg/kg (apple, cabbage head, citrus, cotton seed, potato, tomato, rape seed, wheat grain), 0.20 mg/kg (hop cones, dried) 0.01 mg/kg (sunflower, corn)0.005 mg/kg (honey, rape, sunflower). However, it should be noted that the residue definition for monitoring has not been finalised and therefore further methods may be required in the future. For products of animal origin there is an LC-MS/MS method for imidacloprid, M01 and M06 with an LOQ for each analyte of 0.01 mg/kg for milk and 0.033 mg/kg for all other matrices. For soil there is an LC-MS/MS method with an LOQ of 0.005 mg/kg. Water is analysed by HPLC-UV with an LOQ of 0.03 µg/L confirmation is by HPLC-UV with column switching with an LOQ of 0.05 µg/L. The residue definition for surface water is not concluded on and therefore additional methods may be required in the future. Air is analysed by HPLC-UV with an LOQ of 5 µg/m3.

The meeting of experts mammalian toxicology have changed the classification of the active substance to toxic and therefore the rapporteur has identified a new data gap for a method of analysis for body fluids. The method of analysis for animal products can be used for tissues.

2. Mammalian toxicology

Imidacloprid was discussed by the experts in mammalian toxicology in October 2007 (PRAPeR 34, Round 7).

Further details on the toxicological batches were provided in the addendum 3 to Vol.4 (September 2007). The experts agreed that the toxicological batches were equivalent to the technical specification except for the impurity 1 which was present in a higher amount in the technical specification. Based on the available toxicological information on this impurity (see details in 2.8), the experts agreed that it had a lower toxicity profile than the parent compound and was not relevant.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

Rapidly and almost completely absorbed after oral administration in rats, imidacloprid was distributed to the peripheral tissues and organs without indication of bioaccumulation. The excretion occurred mainly via urine (75%) and also via faeces (mainly by biliary excretion). Up to 90% of the administered dose was metabolised, starting with oxidative cleavage of the methylen-bridge, or hydroxylation of the imidazolidine ring.

2.2. Acute toxicity

Imidacloprid had a moderate acute oral toxicity in rats (combined LD_{50} ~506 mg/kg bw) but exhibited a higher acute oral toxicity in mice (LD_{50} 131 mg/kg bw). The experts agreed to propose the classification **T, R25 Toxic if swallowed** in order to take into account the higher sensibility of mice. Imidacloprid was not toxic after dermal application (LD_{50} >5000 mg/kg bw) as well as after acute exposure by inhalation (LC_{50} >0.069 mg/L for the aerosol, LC_{50} >5.3 mg/L for the dust, both highest

[3] M01: 1[(6-Chloro-3-pyridinyl)methyl]-4,5-dihydro-2-(nitroamino)-1H-imidazol-5-ol
[4] M06: 1[(6-Chloro-3-pyridinyl)methyl]N-nitro-1H-imidazol-2-amine

technically achievable concentrations). It was neither a skin nor an eye irritant, and had no skin sensitising properties.

EFSA notes: The RMS has expressed its disagreement with T, R25 after the experts' meeting. This is an issue to be forwarded to the competent authority for classification and labelling.

2.3. SHORT TERM TOXICITY

In **oral** studies with rats (98-day, 96-day, 91-day neurotoxicity) and mice (107-day), the decreased body weight or body weight gain was the most sensitive parameter and the liver was the main target organ in dogs (28-day, 90-day, 1-year) and rats. From the first two rat studies, the experts agreed on NOAELs in the same order of magnitude (57-61 mg/kg bw/day, respectively) based on decreased body weight development, hepatotoxicity (clinical chemistry changes and histopathological findings) and histopathological degenerative changes in the testes. A lower NOAEL of 9.3 mg/kg bw/day was agreed for the 91-day neurotoxicity in rats (see 2.7) based on decreased body weight, and was considered as the relevant short term NOAEL in rats. Adverse effects observed in the mouse study included mortality, clinical signs and decreased body weight gain. The resulting NOAEL was 86 mg/kg bw/day.

In the range-finding 28-day dog study, the NOAEL was 7.3 mg/kg bw/day based on liver and thyroid effects (hepatocellular hypertrophy and follicular atrophy of the thyroid). Ataxia, tremors and/or mortalities were observed at the high dose (up to 180 mg/kg bw/day), suggesting an effect on the central nervous system. Tremors and trembling were observed in the 90-day dog study and the relevance of the trembling was discussed by the experts. Based on all the uncertainties, the experts agreed to consider the trembling as a relevant effect and set the NOAEL at 7.8 mg/kg bw/day. In the 52-week dog study, no clinical signs were observed but adaptive changes in the liver and clinical chemistry, leading to a NOAEL of 41 mg/kg bw/day.

Effects on the liver were also observed following exposure of rats by **inhalation** during four weeks, resulting in a NOAEC of 30.5 mg/m³ (equivalent to a mean daily oral intake of 11.5 mg/kg bw/day).

No adverse effects were observed in rabbits following repeated **dermal** exposure during three weeks at the limit dose of 1000 mg/kg bw/day.

2.4. GENOTOXICITY

Imidacloprid was tested *in vitro* for point mutations (4 tests with bacterial cells and 1 test with mammalian cells were negative), for chromosome aberrations in human lymphocytes (slight increase at cytotoxic concentration without metabolic activation) and for sister chromatid exchanges (slightly positive at cytotoxic concentration, not confirmed in a second test at lower doses, nor in the *in vivo* test). In *in vivo* tests, imidacloprid did not induce clastogenic effects in bone marrow of mice or hamsters, nor in germ cells of mice. Therefore it was concluded that imidacloprid had not genotoxic potential.

2.5. LONG TERM TOXICITY

In the 24-month **rat** study, the thyroid was the main target organ based on histopathological observations. The increased incidence of mineralisation in the colloid of the thyroid gland follicles was considered adverse, reflecting an effect of imidacloprid resulting in premature biological ageing processes in this organ. Therefore, the agreed NOAEL was 5.7 mg/kg bw/day.

Long term effects of imidacloprid in **mice** (24-month study) included reduction in body weight, weak hepatotoxicity and more frequent mineralisation of the thalamus. Based on these findings, the systemic NOAEL was 208 mg/kg bw/day.

No evidence of an oncogenic potential of imidacloprid was found in both species.

2.6. REPRODUCTIVE TOXICITY

The effects of imidacloprid on the reproductive parameters were studied in a one-generation (range-finding) and a 2-generation rat studies. In the absence of adverse effects, the reproductive NOAEL was the highest dose, i.e. 50 mg/kg bw/day. The parental NOAEL was 20 mg/kg bw/day based on reduced body weight gain, food consumption and liver enzyme induction. The offspring NOAEL was also 20 mg/kg bw/day based on reduced body weight gain in pups.

The embryotoxic effects of imidacloprid were investigated in rats and rabbits. In the rat study, some maternal toxicity (reduced body weight gain) was observed at the highest dose with an increased incidence of wavy ribs in the foetuses. Therefore, the agreed maternal and developmental NOAEL was 30 mg/kg bw/day. In rabbits, total litter losses and a slight decrease in foetal body weight with retarded ossification were found at a maternal toxic dose (where body weight loss was observed). Based on these findings, the developmental NOAEL was set at 24 mg/kg bw/day whereas the agreed maternal NOAEL was 8 mg/kg bw/day based on reduced body weight gain.

Overall, the data showed that imidacloprid had no primary reproductive toxicity and no teratogenic potential.

2.7. NEUROTOXICITY

Neurotoxic effects of imidacloprid were investigated in an acute, a subchronic and a developmental neurotoxicity screening studies in rats.

The agreed acute NOAEL was 42 mg/kg bw/day based on clinical signs and clearly reduced motor/locomotor activity.

In the 13-week neurotoxicity study, the agreed NOAEL was 9.3 mg/kg bw/day based on a decreased body weight, minor effects were observed in the functional observational battery at the high dose but no convincing evidence of neurotoxicity. In the developmental neurotoxicity study, the maternal NOAEL was 30 mg/kg bw/day based on decreased food consumption, and the foetal NOAEL was also 30 mg/kg bw/day based on reduced body weight gain and decreased motor/locomotor activity.

The only indications of neurotoxic effects were behavioural changes in the acute neurotoxicity study (at the high dose) and in the developmental neurotoxicity study.

EFSA notes: despite the occurrence of clinical chemistry changes at the LOAEL (63.3 mg/kg bw/day) in the 13-week neurotoxicity study, the relevance of the body weight changes at the same

level is debatable for the setting of the NOAEL. Therefore, the use of this study as supporting the AOEL might be questionable.

2.8. FURTHER STUDIES

Metabolites

The minor plant metabolite M07[5] was not identified in the excreta of rats from short term studies on the metabolism of imidacloprid. Since nitroso-compounds may exert adverse effects, additional studies were performed and showed that M07 is absorbed, distributed and eliminated similarly to imidacloprid. Furthermore, the formation of M07 was shown in rats after repeated administration of imidacloprid for one year at a high dose level (100 mg/kg bw/day), presumably when enzyme systems involved in the usual degradation reactions are saturated.

The animal and plant metabolites M12[6], M06, M09[7] and M07 were tested for acute oral toxicity in rats and for the induction of point mutations in bacteria. The acute oral toxicity was lower than that of imidacloprid, except for M09 (rat LD_{50} 280 mg/kg bw), and no mutations were induced by any of the metabolites. Because of a structural alert, additional genotoxicity tests were performed with M07. Negative results were obtained in two forward mutations assays *in vitro* (with different cell lines), in two tests *in vitro* for DNA-damaging effects (with Bacillus subtilis and rat hepatocytes), in one chromosome aberration assay *in vitro* (in mammalian cells) and in two micronucleus test *in vivo* (by oral or intraperitoneal administration). Similarly to the parent imidacloprid, M07 also showed an acute oral toxicity in mice higher than in rats (LD_{50} 200 mg/kg bw) in a supplementary study. In a rat 12-week study with administration in drinking water, the NOAEL was 13 mg/kg bw/day, based on increased lymphocyte counts and lower number of polymorphonuclear cells in the blood.

EFSA notes: After the experts' meeting in the Residue section, the possible carcinogenic alert coming from the structure of M07 was investigated further. The available results showed no genotoxicity *in vivo* and *in vitro*, similar toxicokinetics, and the same level of acute and subchronic toxicity. In addition, M07 was found in rat urine after one year treatment with imidacloprid. Therefore a threshold for carcinogenic effects, if any, must exist and is expected to be much higher than the levels the consumers would be exposed to.

Impurities

Experimental data for impurity 1 were presented in the Addendum 2 (September 2007). Rapidly and almost completely absorbed from the gastro-intestinal tract, the **impurity 1** did not accumulate in tissues and was excreted unchanged, mainly by urine. The acute toxicity was low when administered to rats and mice by the oral route (LD_{50} >2000 mg/kg bw) and when administered to rats and rabbits by the dermal route (LD_{50} >2000 mg/kg bw/day). In addition, it was not irritating to skin and eye and not a skin sensitiser. In short term rat studies (14 and 90 days), the relevant NOAEL was 316 mg/kg bw/day based on decreased body weight. However, in a 90-day mouse study, no adverse effect was observed up to the highest dose tested of 1000 mg/kg bw/day. The available tests for genotoxicity

[5] M07: NTN33893-nitrosimine, 1-[(6-chloro-3-pyridinyl)methyl]-, oxohydrazone
[6] M12: NTN33893-urea, 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-one
[7] M09: NTN33893-desnitro, 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine

didn't show any mutagenic potential *in vivo* (an *in vitro* chromosome aberration test showed positive results). In a rat two-generation study with the impurity 1, the fertility and the development of the offspring were not affected at the highest dose level (1000 mg/kg bw/day) whereas the parental NOAEL was 300 mg/kg bw/day based on decreased body weight. Teratogenic effects were not observed in rats and rabbits. In rats, the maternal and developmental NOAEL was 316 mg/kg bw/day based on clinical signs in some dams and decreased body weight gain with delayed ossification in foetuses. Based on the same effects, the same NOAEL of 316 mg/kg bw/day was derived in the rabbit study. Taking into account these toxicological results showing a lower toxicity profile for the impurity 1, the experts agreed that this impurity was not relevant.

2.9. MEDICAL DATA

No adverse health effects have been reported for employees handling imidacloprid during the production of the active ingredient and its formulations. However, mild cases of contact dermatitis in pet owners have been reported following use of veterinary formulations of imidacloprid. From the field tests with imidacloprid formulations, no effects on the health of the operators and workers were reported. No epidemiological studies on the general population were available.

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

Acceptable Daily Intake (ADI)

The agreed **ADI** was **0.06 mg/kg bw/day**, based on the chronic rat study and applying a safety factor of 100. It was noted in the addendum 2 (September 2007) that this is in agreement with the ADI established by the JMPR in 2001.

Acceptable Operator Exposure Level (AOEL)

Based on the 90-day dog study supported by the subchronic rat neurotoxicity study, an **AOEL** of **0.08 mg/kg bw/day** was derived with the use of a safety factor of 100.

Acute Reference Dose (ARfD)

Considering the acute effects observed in the 90-day dog study (trembling), supported by the developmental study in the rabbit, and applying a safety factor of 100, the experts agreed on an **ARfD** of **0.08 mg/kg bw**.

EFSA notes: even though this was the value agreed by all the experts during the meeting, the RMS clearly expressed its disagreement in the addendum 6 of February 2008, adding that their proposal was in line with the JMPR evaluation of 2001 (based on the acute neurotoxicity study).

2.11. DERMAL ABSORPTION

For both representative formulations (Confidor SL 200 and Gaucho FS 600), no experimental data on dermal absorption were available in the original DAR. However, in the addendum 2 of September 2007 were provided the results of an *in vitro* study on human and rat skin with Confidor OD 200 (oil-

based suspension concentrate, similar to the representative Confidor SL 200, soluble concentrate). The agreed values were 0.3% for the concentrate and 8% for the highest dilution.
For the second representative formulation Gaucho FS 600, the experts agreed to apply the default value of 100% in the absence of data.
EFSA notes: this value for Gaucho FS 600 was a very conservative and worst case value agreed by all the experts during the meeting. The RMS clearly expressed its disagreement with it in the addendum 6 of February 2008.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Confidor SL 200 is a formulation containing 200 g of imidacloprid/L, for use on apples (field) and tomatoes (field and greenhouse). The second representative plant protection product Gaucho FS 600 (flowable concentrate for seed treatment) is a formulation containing 600 g of imidacloprid/L to be applied on seed (of sugar beet and fodder beet).

Operator exposure

Confidor SL 200

Crop / Application method	Model	Exposure without PPE (% AOEL)	Exposure with PPE (% AOEL)
Apple / tractor, air blast sprayer	German BBA	14	14* - 2.3**
	UK POEM	15	15° - 10°°
Apple / hand held sprayer	German BBA	8	7* - 2**
Tomato (field) / tractor, boom sprayer	German BBA	6	6* - 0.5**
	UK POEM	7	7° - 1°°
Tomato (greenhouse) / knapsack sprayer	Mich, 1996 (study)*	27	1
Tomato (greenhouse) / spray lance with stationary tank	Mich, 1996 (study)*	25	1

PPE = personal protective equipment

*PPE: gloves, standard protective garment and sturdy footwear during mixing/loading (M/L).

**PPE: gloves, standard protective garment and sturdy footwear during M/L and application (A)

°PPE: gloves during M/L °°PPE: gloves during M/L and A

* greenhouse study providing data for A, combined with data from the German model for M/L

Gaucho FS 600

According to the RMS, the coating of sugar beet seed is a technological process with special equipment and trained operators with full protective clothing, resulting in a much lower exposure

than observed within the Seed Tropex[8] data. However, some experts were of the opinion that the worst case of low automation should be considered and further refinements should be discussed at MS level.

Crop / Application method	Model	Exposure with PPE* (% AOEL)
Sugar beet seed / industrial processing	Seed Tropex	552

*PPE (personal protective equipment): coveralls for bagging tasks; coveralls and gloves for other tasks (calibration, mixing/loading and cleaning).

In summary, the operator exposure is below the AOEL for Confidor without the use of personal protective equipment; whereas for Gaucho, the exposure is above the AOEL with the use of personal protective equipment (coveralls and gloves).

EFSA notes: The use of the default dermal absorption value of 100% (in line with the guidance document) is a very conservative worst case approach. As mentioned in the addendum 6 of February 2008 new experimental data from exposure studies during use of imidacloprid on sugar beet seeds have been submitted to the RMS but not accepted due to Commission Regulation 1095/2007.

Worker exposure

Confidor SL 200 : The exposure of workers during re-entry in treated crops (Krebs, B. et al., 1996) is expected to be 12.6% of the AOEL for high crops (apples) and 6.0% of the AOEL for low crops (tomatoes).

EFSA notes: The recalculations with the agreed AOEL (0.08 instead of 0.2 as proposed in addendum 2) were only provided in the list of end points but not in the addendum 6 provided after the expert meeting.

Gaucho FS 600 : Using surrogate values from Seed Tropex model to estimate the exposure during loading and sowing of treated seeds, by workers wearing adequate work clothing and gloves when direct hand contact with treated seed is necessary, results in an exposure of 129% of the AOEL.

EFSA notes: The Seed Tropex data, related to loading and sowing of treated cereal seed, were considered as conservative by the RMS since the sugar beet seeds have an additional protective coating which limits the generation of dust during handling.

Bystander exposure

For Confidor SL 200, the estimated exposure of bystanders (according to Ganzelmeier, 1995) is not expected to exceed 6% of the AOEL. For Gaucho FS 600, the incidental exposure of bystanders during seed treatment was assumed to be negligible.

EFSA notes: The recalculations with the agreed AOEL (0.08 instead of 0.2 as proposed in addendum 2) were not performed in the addendum provided after the expert meeting, but based on the

[8] SEED TROPEX calculations (Report TMF 4896, 1996 revised by PSD), based on Chester, G., Wiseman, M., Pontal, P-G., Worker Exposure During Seed Treatment and Sowing of Treated Seed in the UK and France: An Overview. Zeneca Agrochemicals, Fernhurst, Haslemere.

preliminary estimations in the addendum 2 (September 2007), the estimated exposure of bystanders to Confidor SL 200 are not expected to exceed 6% of the AOEL.

3. Residues

Imidacloprid was discussed at the PRAPeR experts meeting for residues (PRAPER 35) in October 2007.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of imidacloprid has been investigated in several crops, according to several modes of application. Pyridinyl-^{14}C-methylene labelled active substance was used.

Metabolism studies after spray applications were conducted in tomatoes, apples, potatoes and tobacco. Studies in apples and tomatoes are relevant for the supported representative uses on these crops.

Within 14 days after spray application the metabolic pattern in aerial parts of the plants is dominated by the parent compound which represents 70 to 90% of the extractable residues. Most of the residues can be washed with methanol from the surface of fruits and leaves.

From the structure of the identified metabolites three main routes of metabolic degradation were established:

- Hydroxylation of the imidazolidine ring and subsequent loss of H_2O;
- Reduction and/or loss of the nitro group, leading in particular to a minor nitrosimine metabolite (M07[9]) for which some toxicological testing was performed;
- Oxidative cleavage of the methylene bridge to form 6-chloropicolyl alcohol and further oxidation to 6-chloropyridine-3-carboxylic acid.

This cleavage is also supposed to result in production of nitroimino-imidazoline. Nevertheless the metabolic fate of this part of the imidacloprid structure and in particular its potential reduction to -nitrosimine compounds has not been investigated by appropriate labelling. In rats, nitroimino-imidazoline as well as its dehydro- derivative were found as major urine metabolites, showing that in animals cleavage of the intact imidazolidine moiety is a main metabolic process.

The expert meeting on residues estimated that the amount of cleaved metabolites was low in comparison to uncleaved metabolites, showing that this route of metabolism is minor in plants. In addition the possible further degradation of the imidazoline moiety to nitrosimine is not expected to be a preferred pathway. It was nevertheless concluded that the applicant should submit a robust scientific assessment/statement on possible formation of nitrosimines or other degradates of toxicological concern from the cleaved nitroimino-imidazoline moiety in plants. The notifier provided comments on this issues as reported in the evaluation table. These comments were however not peer reviewed.

Metabolism studies after soil granular application were conducted on eggplants, potatoes and rice, and after seed treatment on rice, corn and cotton. These studies showed active uptake and

[9] M07: 2-imidazolidinone, 1-[(6-chloro-3-pyridinyl)methyl]-,oxohydrazone

translocation of the radioactivity to aerial plant parts. Qualitatively the metabolic routes of degradation suggested by these studies are the same as after foliar treatment. But in contrast with foliar application the residue pattern found after seed and soil treatments reflects a more extensive degradation. Some metabolites were found in concentrations of the same order of magnitude as the parent compound (metabolites M01, M06[10], M09[11] and M14[12]).

The residue definition for monitoring proposed by the RMS is the sum of the parent compound and its metabolites M01 and M06. Although this proposal might be acceptable, the expert meeting could not endorse it as the setting of MRLs according to this residue definition is not possible on the basis of available residue data. Individual analyses of metabolites M01 and M06 were not performed in supervised residue trials and the use of available results from the common moiety method of analysis could overestimate the needed MRL level. It was decided by the expert meeting to leave open the setting of a residue definition for monitoring and related MRLs.

No data gap was proposed for supervised residue trials according to definition proposed by the RMS as sufficient data are available for alternative residue definitions without performing further studies. It is the view of EFSA that the definition for monitoring could be restricted to the parent compound. Another feasible option with the available data base is to adopt for enforcement the same residue definition as proposed for risk assessment (see below). This second option would however not allow multi-residue methods to be used.

Rodent metabolism involves all the degradative processes observed in plant although the oxidative cleavage of the methylene bridge is the major one. Most of the plant metabolites were also observed in rats. In particular, the nitrosimine metabolite (M07) was identified under chronic exposure to high doses of imidacloprid. This metabolite showed negative results in a battery of standard mutagenicity tests. Acute and short term oral toxicity studies in rodents suggest that its toxicity is similar to that of parent compound. Other representative metabolites (M06 and M09) were also found of comparable acute toxicity. Therefore it is considered that the plant metabolic pattern is covered by the toxicological studies on the active substance itself, and that the produced metabolites have the same toxicological profile as the parent compound.

As metabolites produced after soil application or seed treatment can contribute significantly to the global toxicological burden, the proposed residue definition for risk assessment is the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl (which can be oxidised to 6-chloropyridine-3-carboxylic acid) moiety, expressed as imidacloprid.

As no agreement was reached on a residue definition for monitoring, no proposal related to conversion factors can be made.

A sufficient number of supervised residue trials are available to support the representative uses in apples, tomatoes and sugar beets. These trials included analysis of imidacloprid individually as well as of the total amount of residues after oxidation to 6-chloropyridine-3-carboxylic acid). Metabolites M01 and M06 were not analysed individually. Results obtained from the common moiety method can

[10] M06: 1[(6-Chloro-3-pyridinyl)methyl]N-nitro-1H-imidazol-2-amine
[11] M09: 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine
[12] M14: 6-chloropyridine-3-carboxylic acid

be used for risk assessment. All figures reported here below refer to total residues, meaning the sum of imidacloprid and its metabolites which can be oxidised to 6-chloropyridine-3-carboxylic acid.
A total of 20 trials (12 for Northern Europe and 8 for Southern Europe) were conducted in apples. The highest residues (HR) were 0.08 and 0.23 mg/kg in Northern and Southern Europe respectively. In tomatoes 20 trials were submitted. In glasshouse (12 trials) the HR amounted to 0.29 mg/kg, while in tomatoes grown in field condition in Southern Europe HR did not exceeded 0.11 mg/kg. For seed treated sugar beets 15 trials were conducted in Northern Europe and 5 in Southern Europe. Residues in roots were in all cases below the limit of quantification of the analysis method (0.05 mg/kg), while they occasionally exceeded the LOQ up to 0.14 mg/kg in leaves. These studies show that under practical conditions and in open air the contribution of the parent compound to the total residues is only about 50 %.
These results can be considered as reliable as storage stability studies demonstrated that residues of the parent compound, when analysed individually, as well as mixtures of imidacloprid and its main metabolites, when analysed as total residues, are stable under deep-freeze conditions for at least 2 years.
Standard studies in buffer solution simulating main processing practices indicated that the chemical nature of imidacloprid is not affected during pasteurisation, boiling, sterilisation. Processing studies with apples showed that residues are transferred to apple juice, apple sauce and apple dry pomace. Respective transfer factors of 0.8, 0.9 and 5 were calculated on the basis of total residues. Processing factors related to commodities produced from tomatoes show consistency with the dry matter content of the processed product: 1.4 for tomato juice, 2 for ketchup and puree and 6 for tomato paste.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A confined rotational crops study has been submitted with red beets, Swiss chard and wheat sown 30, 120 and 271 days as rotational crops after application of imidacloprid. The rate of application was 450 g/ha, representing 150% of the total dose proposed in glasshouse tomatoes.
The nature of metabolites in rotational crops was essentially the same as in primary crops and major constituents of the residue pattern were the same as in primary crops after seed or soil treatment. The residue definitions proposed for primary crops are therefore equally valid for rotational crops.
The lowest total radioactive residues (TRR) were found in wheat grains and red beet roots ranging from 0.03 to 0.07 mg/kg. TRR in aerial plant parts were higher, ranging from 0.09 to 0.24 mg/kg in red beet leaves and Swiss chard. They amounted up to 1.0 and 2.38 mg/kg in wheat forage and straw respectively. This suggests possible contamination of rotational crops mainly for post application intervals up to 120 days.
Therefore a field study was conducted with an application rate of 0.14 kg imidacloprid/ha on bare soil. Barley was used as primary crop and was either destroyed and incorporated into soil simulating crop failure or grown until normal harvest, simulating normal rotation practice. Lettuce and turnip were sown as succeeding crops 30 days or 112 days after treatment, reflecting the respective scenarios. At maturity, residues of imidacloprid were below the LOQ of 0.01 mg/kg in both crops and total residues were detected in turnip leaves and leaves of immature lettuce at levels below the LOQ of 0.05 mg/kg.

It was therefore concluded that under field conditions no significant residues in following crops are to be expected.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Considering the supported representative uses, livestock may be exposed to imidacloprid residues through consumption apple pomace, fodder beet and sugar beet pulp.

The critical potential exposure of livestock to total imidacloprid residues present in feed items is rather low (about 0.5 mg/kg dry matter in feed, corresponding to 0.02 mg/kg bw/d) for ruminants and not significant for pigs and poultry.

Metabolism studies in lactating goats and laying hens were submitted. The exposure rate of lactating goats was 3 orders of magnitude above the predicted exposure level. Overall, imidacloprid is rapidly excreted and no sign of accumulation is present in livestock.

The identified metabolites suggest that livestock metabolism proceeds through several pathways, including hydroxylation of the imidazolidine ring, step-wise reduction and loss of the nitro group, opening and progressive degradation of the imidazolidine ring and cleavage of the methylene ring. It can be considered that goat and rat metabolisms are similar. The metabolic pattern in livestock is covered by the toxicological studies performed with the active substance.

In lactating goats, the parent compound dominates the metabolic pattern in milk, fat and muscles. Glucuronide conjugates of hydroxy- metabolites (M01 and M02[13]), olefine metabolite (M06) and a glycine-conjugate of 6-chloropyridine-3-carboxylic acid were major constituent of the residue in kidneys. In liver only a desnitro- metabolite (M09) was identified above 10 % of the TRR.

The proposed residue definition for risk assessment is the same as for plant products.

For monitoring the RMS proposal was as for plant products the sum of the parent compound and its metabolites M01 and M06. This definition does not cover adequately the residue pattern in liver. Nevertheless, on the basis of livestock exposure resulting from the representative uses assessed in this peer review, no residue above 0.01 mg/kg is expected in any animal commodities whatever the type of analysis performed (analysis of individual compounds or analysis of total residues). This was demonstrated by a feeding study performed in dairy goats, with the lowest dose being 1 order of magnitude above the expected critical exposure. Under these conditions, total imidacloprid residues were below the LOQ (0.02 mg/kg) in milk, muscle and fat. In liver and kidneys, total residues ranged from 0.02 to 0.05 mg/kg. This shows that under practical conditions of exposure residues are low and below usual limits of quantification of method of analysis.

Therefore the RMS proposal is acceptable. It must however be kept in mind that any additional use of imidacloprid leading to a significantly animal exposure would necessitate to reconsider this definition. In case of possible transfer of residues in animal matrices at analytically measurable levels, the only option at this stage would be to adopt the same residue definition as for risk assessment. Any other definition would require new feeding studies in order to set respective MRLs in animal commodities.

[13] M02: 1[(6-Chloro-3-pyridinyl)methyl]-4,5-dihydro-2-(nitroamino)-1H-imidazol-4-ol

3.3. CONSUMER RISK ASSESSMENT

Acute and chronic consumer exposure assessments have been conducted following current WHO methodologies and no risk for the consumer is expected resulting from the use of imidacloprid according to the representative uses. These assessments were conducted on the basis of total residues determined in supervised residue trials and feeding studies.

Chronic exposure.

Theoretical maximum daily intakes (TMDI) were calculated using the typical European diet for adult consumers and the German diet for the 4-6 year old girl. Residue levels in apples, tomatoes and animal products were considered to be at the level of the respective MRLs that could be derived from the available data for total residues (0.5 mg total imidacloprid residues/kg for apples and tomatoes). In addition the RMS included in the calculation a contribution from a range of commodities for which applications for import tolerances in EU are foreseen (citrus fruits, tree nuts, table and wine grapes, bananas and mangoes). Based on this, the calculated TMDI were 7 and 10 % of the ADI for the European adult consumer and the German 4-6 year old girl, respectively. Considering this low level of ADI exhaustion, intake calculation considering only the representative uses covered by the peer review were not performed.

Acute exposure.

Considering the toxicological end point used for setting the ARfD, all categories of consumer need to be considered in the acute dietary risk assessment. National Estimates of Short Term Intakes (NESTI) were carried out by the RMS on the basis of UK national consumption data for adults and toddlers. Residues in apples and tomatoes were considered to be at the level of the respective HRs found for total residues. This constitutes a severe underestimation (2 fold factor) of the exposure that would result from consumption of these commodities at the corresponding MRL level that would be set. Variability factor of 7 were used. Based on this, calculated NESTIs for toddlers were less than 20 % of the ARfD for apples and tomatoes. Therefore it is predictable that even at MRL level, treated commodities do not represent an acute health concern.

3.4. PROPOSED MRLS.

No agreement on the residue definition for monitoring of plant commodities was reached during the peer review process. Therefore no MRLs can be proposed.

For all animal products, MRLs can be set at 0.1* mg/kg (sum of imidacloprid, metabolites M01 and M06), based on the results of the available feeding study in lactating cows.

4. Environmental fate and behaviour

Imidacloprid was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 32 in October 2007.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Soil experiments (4 different soils) were carried out under aerobic conditions in the laboratory (20°C 40% maximum water holding capacity (MWHC) in the dark. The formation of residues not extracted by acetonitrile followed by dichloromethamne and reflux with acetonitrile were a sink for the applied pyridinyl-^{14}C-methylene radiolabel (17-27% of the applied radiolabel (AR) after 91-100 days). Mineralisation to carbon dioxide of this radiolabel accounted for 3.3-16.6 % AR after 91-100 days. No extracted metabolite accounted for >5%AR (max 3.4%AR) at any sampling time in any soil, 9 metabolites were identified.

In an anaerobic sediment water study, where the silt loam sediment was considered to represent topsoil (organic carbon (oc) 3.1%, pH 6.9), the metabolites identified were the same as those identified in the aerobic studies with no metabolite in non Soxhlet sediment extracts accounting for more than 2.2%AR (at day 120). When Soxhlet extraction (6 hours) with acidified methanol was utilised a desnitro metabolite M09[14] was a major (>10%AR) metabolite accounting for a maximum of 51.5% AR after 249 days of incubation. This metabolite already accounted for 15.3%AR after 30 days of anaerobic conditions. The member state experts discussed whether this metabolite needed to be considered in the soil exposure assessment. The experts considered that for the applied of uses on apples and sugar beet and any other uses that might be requested at the member state level where anaerobic conditions might be expected, because imidacloprid would persist and be present in soil over the winter period when saturated soil conditions may be encountered, consideration of the potential for the formation of M09 was justified. This was contrary to the argument of the RMS in addendum 4 dated September 2007. The experts agreed that for the applied for intended uses on tomatoes anaerobic soil conditions would not be expected. They also agreed that even for the uses being assessed on apples and sugar beet, there will be significant areas of the EU where these two crops are grown where anaerobic conditions will not be encountered. The experts considered that experimental data on degradation of the desnitro metabolite M09 under aerobic conditions and adsorption measurements would be necessary to support pertinent uses in territories where anaerobic conditions cannot be excluded. In drafting the conclusion EFSA considers that this request for aerobic degradation data is justified, but considers that experimental data on soil mobility is probably not necessary as M09 required harsh (Soxhlet) extraction, which provides a good indication that M09 will exhibit low mobility in soil. In conclusion, in Member States where anaerobic soil conditions cannot be excluded, there is a need to address the rate of degradation if M09 in soil when aerobic conditions return in the spring. Depending on the results of any experiments provided, a risk assessment for soil dwelling organisms from exposure by M09 may be required. The experts proposed that the EU level assessment could be concluded without these data. In a laboratory soil photolysis study, no photodegradation product accounted for >6.3%AR.

[14] M09: 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The rate of degradation of imidacloprid was estimated from the results of the studies described in 4.1.1 above. DT_{50} were: 106- 193 days (single first order non linear regression, 20°C 40% MWHC, 4 different soils). After normalisation to FOCUS reference conditions[15] (20°C and -10kPa soil moisture content using a Q10 of 2.2 and Walker equation coefficient of 0.7) this range of single first order DT_{50} was 99-129 days (geometric mean from the laboratory database that is appropriate for use in FOCUS modelling 118 days).

Field soil dissipation studies (bare soil, spray to the surface) were provided from 5 sites in Germany and 4 sites in southern Europe (2 in Italy, 1 each in France and Spain) where applications were made in April and May in Germany and April to August in southern Europe. Using the residue levels of parent imidacloprid determined over the top 10 cm (residues in the deeper soil layers sampled usually to 30cm, in some experiments to 50cm, were below the LOQ (0.006mg/kg), clarification provided by the RMS in the reporting table), single first order DT_{50} were 104-228 days in Germany and 40-288 days in Southern Europe. These DT_{50} were normalised to FOCUS reference conditions (20°C and -10kPa soil moisture content using a Q10 of 2.2 and Walker equation coefficient of 0.7) using the time step normalisation procedure as specified by FOCUS kinetics recommendations. Following normalisation the range of single first order DT_{50} becomes 27 to 180 days (median that is appropriate for use in FOCUS modelling 78 days, note that a median can also be calculated that takes account of the field accumulation study results, see below). At two of the German trial sites where the dissipation was also simultaneously investigated when application was as a seed treatment (sugar beet seed) the rate of degradation was faster than application was as a bare soil surface spray (see addendum 6 of February 2008 where this is presented and discussed, the data are also contained in the DAR). As the not normalised DT_{90} associated with these DT_{50} are 132-957 days, an assessment of accumulation is required.

Field accumulation studies were carried out at 3 trial sites in Germany and 2 in the UK. In Germany a ground spray application was made in orchards to bare soil below the trees and to short grass between the tree rows. When grass was cut the clippings were left as a mulch on the ground and not removed. Soil cores were taken from both the bare soil and grass/mulch covered areas. The soil segments from both sampling areas were combined and homogenised before analysis to get an average residue for bare soil and grassed areas at each sampling time. Applications were made every year for 6 years. In the UK winter barley seed was treated and the treated seed was drilled. When the barley was harvested all the straw (not just the stubble) was chopped and incorporated into the soil by ploughing over a depth of 15 to 19 cm. Again applications were made every year for 6 years.

The results of the field accumulation studies were discussed by the member state experts. At the trial sites in Germany it was agreed that it was clear that soil residues levels had plateaud after about 3

[15] Using section 2.4.2 of the generic guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

years of applications. The pattern of decline measured could be roughly represented at all 3 trial sites by a single first order DT_{50} of 182 days (as reported in the DAR, note average temperatures over the 6 year study durations, estimated by EFSA when drafting the conclusion from information available in the original study reports were 9.6, 10 and 10.4°C). After normalisation to 20°C using a Q10 of 2.2 (no soil moisture normalisation) the values for these 3 trials are ca. 80, 83 and 86 days (EFSA normalisation calculation). At the two UK study sites accumulation occurred over the full 6 year duration of the studies and the experts considered a plateau was not reached. The experts asked the RMS to estimate single first order DT_{50} from these two UK sites and estimates are included in the addendum 6 dated 8 February 2008 provided after the expert meeting (not peer reviewed). These values are 1333[16] days (Bury St. Edmunds site, average temperature 9.5°C, estimated by EFSA from information in the original study report) and 1268[17] days (Wellesbourne site, average temperature also 9.5°C, EFSA estimate). After normalisation to 20°C using a Q10 of 2.2 (no soil moisture normalisation) these values are 586 and 554 days (EFSA normalisation calculation).

EFSA experts consider that the methodology used for the DT_{50} calculations was valid and that these single first order DT_{50} represent conservative estimates that reflect the experimental conditions at these UK trial sites over the duration of the studies. In addendum 6 it is stated that PEARL simulations of the UK field accumulation experiment trial sites were carried out that used the two longest normalised to FOCUS reference condition field DT_{50} from the available guideline field dissipation studies (98.2 and 179.8 days). This modelling is not peer reviewed and is only briefly described in the addendum, so the applicability of the approach used cannot be verified. It is therefore impossible to see if the conclusion that the RMS draws from these simulations is appropriate or not. Therefore EFSA is unable to agree with the conclusion of the RMS that the behaviour observed in the UK field accumulation studies is in principle sufficiently represented by the range of DT_{50} values derived from the 9 guideline soil field dissipation studies available in the dossier, due to the lack of available information on these simulations. Even if more details on the simulations were available, EFSA notes that the soil mixing depth and bulk density utilised in the simulations is not directly comparable with these parameters as measured / used to report the results of the field accumulation studies. These differences between the simulations and the trial sites are an example of a possible alternative valid explanation of why the measured concentrations were lower than the simulated values. It is not clear that difference in degradation rate occurring at the trial sites and assumed in the simulations was why the measured concentrations were lower than the simulated values, as proposed of the RMS. Therefore the issue of the accumulation potential of imidacloprid in soil and the expected realistic range of field DT_{50} to assume in exposure assessment remains open. As agreed by the Member State experts a data gap is identified for the applicant to appropriately calculate the DT_{50} from the field accumulation study trial sites and estimate normalised (FOCUS reference condition) values for each of these sites following FOCUS kinetics guidance (including a soil moisture normalisation), so the degradation pattern from these sites (both German and UK sites) can be more accurately incorporated into future exposure assessments, should imidacloprid be

[16] DT50=LN (2) / ((-LN fdeg)/365) where fdeg =0.827 (geomean of 0.803 and 0.852) see addendum 6 pp. 14-18
[17] DT50=LN (2) / ((-LN fdeg)/365) where fdeg =0.819 (geomean of 0.859 and 0.781) see addendum 6 pp. 14-18

included in annex 1. As EFSA does not accept that the available PEARL simulations for the UK and German accumulation trial sites can be relied on for regulatory purposes (because currently they are reported in insufficient detail) EFSA considers that the accumulation factors reported in addendum 6 cannot be accepted either, as some of the argumentation for the acceptability of the approach used was based on these simulations. This is also the case for the PEC soil presented in addendum 6.

EFSA proposes that a soil accumulation factor of 1.713 (calculated assuming the longest single first order field dissipation trial DT_{50} of 288 days) might be appropriate for all the uses in situations where significant amounts of treated plant material are not incorporated into soil after the crop is harvested each year. However the realistic worst case accumulation factor is 5.275 (calculated using the longest single first order field accumulation trial DT_{50} of 1333 days) which would also be applicable for all uses, but might be overly conservative for uses where large amounts of treated plant material with high cellulose / lignin content (i.e. straw) are not incorporated into the soil. This was the one major difference in the experimental design of the UK field accumulation studies with barley. This might be an explanation why very long DT_{50} of 1333 and 1268 days were estimated at these 2 experimental sites and a plateau in soil residues had not occurred after 6 years of experimentation?

EFSA therefore calculated soil PEC for the applied for intended uses that are included in appendix 1 of this conclusion using single first order DT_{50} of 288 days (the longest completely peer review agreed DT_{50} from field dissipation studies, that is from the Bagnolo di Nogarole Rocca site in Italy, that is a location representative of where sugar beet, apples and tomatoes may be cultivated). For completeness soil PEC for the applied for intended uses are also set out below using the single first order DT_{50} of 1333 days from the UK field accumulation site at Bury St Edmunds. The Member state experts requested that the soil PEC calculations using the DT_{50} from the UK field accumulation site at Bury St Edmunds (1333 days) be provided (hence their inclusion here).

PEC (soil) (Annex IIIA, point 9.1.3)

(Calculated by EFSA, requested by the meeting of experts, not peer reviewed)

Parent Method of calculation	DT_{50} (d): 1333 days Kinetics: SFO Field or Lab: representative worst case from field accumulation studies. Soil bulk density: 1.5 kg/L (default)
Application data	Crop: Apples; depth of soil layer 5cm % plant interception: 1st appl. 50 %, 2nd appl. 70 % Number of applications: 2 Interval (d): 28 d Application rate(s): 1st appl. 70 g as/ha, 2nd appl. 105 g as/ha

	$PEC_{(s)}$ (mg/kg)	Multiple application Actual
	Initial	0.088
	Plateau concentration (accumulated maximum)	0.463 mg/kg after > 6 years

Application data	Crop: Tomatoes; depth of soil layer 5cm (20cm management depth for residual plateau estimation) % plant interception: 1st appl. 50 %, 2nd appl. 70 % Number of applications: 2 Interval (d): 14 d Application rate(s): 100 g as/ha

	$PEC_{(s)}$ (mg/kg)	Multiple application Actual
	Initial	0.106
	Plateau concentration (accumulated maximum)	0.219 mg/kg after > 6 years

Application data	Crop: Sugar beet; depth of soil layer 5cm (20cm management depth for residual plateau estimation) % plant interception: none Number of applications: 1 Application rate(s): 117 g as/ha

	$PEC_{(s)}$ (mg/kg)	Single application Actual
	Initial	0.156
	Plateau concentration (accumulated maximum)	0.322 mg/kg after > 6 years

EFSA considers that the soil PEC values calculated with a single first order DT_{50} of 288 days (in appendix 1) in addition to the calculations presented above may be useful information to complete a

soil dwelling risk assessment that will be of use to risk managers when considering imidacloprid. If the incorporation of large quantities of barley straw is the correct explanation for the very long DT_{50} at the 2 UK accumulation trial sites, then this practice is not representative of the applied for intended uses that have been assessed. In line with the agreement in the meeting of experts a data gap is identified for the applicant to provide an assessment of the potential effect of plant uptake and plant matter incorporation on calculated soil dissipation rate and if possible degradation rate. This assessment should include particular consideration of the field accumulation studies.

For member states that wished to use a median normalised 20°C field single first order DT_{50} from all the available data in FOCUS scenario modelling, the best estimate currently available is a value of 81.5 days[18].

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The adsorption / desorption of imidacloprid was investigated in 12 soils in satisfactory batch adsorption experiments. Calculated adsorption K_foc values varied from 109 to 411 mL/g, (mean 225 mL/g) (1/n 0.74 – 0.89, mean 0.8). There was no evidence of a correlation of adsorption with pH.

BBA guideline lysimeter studies (some of extended durations, necessary because of the potential persistence of imidacloprid) were provided by the applicant. Three different studies were provided covering a range of good agricultural practices that encompass the applied for intended uses being considered in this EU assessment for annex 1 listing. All three studies were carried out in Germany. In the first study with a duration of 2 years an application of 500g/ha was made in just the first year as a potato seed treatment. This study therefore had about 2.5 times more substance applied than pertinent for the applied for intended uses assessed in the DAR (assuming no accumulation, note accumulation factors of 1.7-5.3 have been estimated, see section 4.1.2). In a second study with a duration of 5 years, an application rate of 117 g/ha was made in the first and 126 g/ha made in the fourth year as sugar beet seed treatments, (intermediate crops were cereals and phacelia where no imidacloprid applications were made). This represents the requested application rate for a sugar beet crop and is roughly equivalent to the annual rate requested for apples and tomatoes when potential crop interception is accounted for. In the third study with a duration of 2.5 years, applications were made as a sugar beet seed treatment at 117 g/ha, followed by a winter wheat application at 140g/ha. Again these application rates are roughly equivalent to the annual rate requested for apples and tomatoes when potential crop interception is accounted for. In the experiments the test substance used was radiolabelled in the pyridinyl-^{14}C-methylene position with the exception of the sugar beet

[18] Median of: 27, 45.5, 58.5, 65.7, 77.9, 78.5, 80*, 83*, 86*, 87.9, 93.9, 179.8, 554* and 586* days, (note values with an * are not normalised for soil moisture and are the values from the field accumulation studies). The equivalent median value that was estimated in the expert meeting included in the report of that meeting was slightly longer at 88 days, this value estimated in the meeting did not include the DT50 from the 3 German accumulation studies.

only experiment where the imidazolodine-4,5-^{14}C position was utilised. Annual average total radioactivity in lysimeter leachate were in the range 0.033-0.09µg imidacloprid equivalents /L. Imidacloprid or any metabolite for which analytical standards were available (4-10 different compounds depending on the study) were never present above their validated limits of quantification of 0.01µg/L in individual leachate samples. These lysimeter study results support the FOCUS groundwater modelling results (see section 4.2.2) that indicate a low leaching potential for parent imidacloprid, though it should be noted that the lysimeter studies alone would not be sufficient to conclude this low leaching potential as the durations of 2 of the studies are not really long enough. They also provide some reassurance that minor soil metabolites of imidacloprid, would not be expected to be present in vulnerable shallow groundwater as a consequence of the applied for intended uses.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Imidacloprid was essentially stable under sterile hydrolysis conditions at 25°C at pH 5, 7 and 9.

It has been demonstrated both through evidence from laboratory and outdoor studies that aqueous photolysis of imidacloprid will contribute to it breakdown in the aquatic environment with laboratory derived single first order DT_{50} being 0.2 to <5 days (latitude 50°N), and outdoor experiments (May application in Germany or June and July application in Texas, USA) giving single first order DT_{50} in the range of 1.4 to 10 days. The major photolysis breakdown products identified were M09 (max 17.2 % AR) , M23[19] (max 12.6 % AR), M12[20] (max 18.4 % AR) and M14[21] (max 16.4 % AR).

In water-sediment studies (3 systems studied at 22°C in the laboratory in the dark) imidacloprid degraded with whole system single first order DT_{50} values of 30 to 150 days (see addendum 4 to the DAR where the kinetic assessment (indicated as P-I) is presented for the 2 systems with a sufficiently long study duration to estimate reliable kinetics). No major (>10 % AR) metabolites were formed. The terminal metabolite, CO_2, accounted for only 1.3-2.5 %AR of the pyridinyl-^{14}C-methylene radiolabel by 92 days (study end). Residues not extracted from sediment by methanol:water were a significant sink representing 66 %AR at study end in the system with 4.09%oc in the sediment. This value was much lower at 15.4%AR in the system with only 0.89% oc in the sediment, that of course had the longer DT_{50} of 150 days. The experts agreed that for imidacloprid a mean single first order DT_{50} of 90 days (derived from whole system values) was acceptable for use as FOCUSsw scenario calculation input. They agreed at FOCUSsw steps 3 and above, it was appropriate to use the average 90 day value for the water phase in simulations and a conservative default value of 1000 days for the sediment in the EU level assessment. The experts from the member states discussed the fate and behaviour of imidacloprid as had been measured in mesocosm experiments carried out in Germany where photolysis would also have contributed to the degradation of imidacloprid. They considered

[19] M23: 1-[(6-chloropyridin-3-yl)methyl]-1,3-dihydro-2*H*-imidazol-2-imine
[20] M12: 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-one
[21] M14: 6-chloropyridine-3-carboxylic acid or 6-chloronicotinic acid

that taking into account all the other available data on how imidacloprid behaves in aquatic systems that the behaviour in this German mesocosm study (as was evaluated in the fate and behaviour section of the DAR) was not anomalous. Therefore the experts agreed that it would be appropriate for the measured concentrations in the mesocosm to be used to derive effects concentrations for this mesocosm and use them in the risk assessment. The experts also agreed that based on the information available, the results of the mesocosm can not be used to overrule a standard exposure assessment done for surface water in an EU level assessment. The experts did however consider that with clarification of some information and some standardisation, that it might be possible / appropriate to use the exposure pattern from this mesocosm in national assessments for individual product authorisations in some member states, depending on the GAP being requested and the light intensity / climate in the member state. It should be noted that that the applicants kinetic assessment of the mesocosm study summarised on pages 8 and 9 in addendum 4 was not asked for by the EU peer review, was not discussed by the experts and the endpoints (single first order: water DT_{50}, sediment DT_{50} and whole system DT_{50}) identified were not endpoints agreed by the EU level peer review.

The experts at the meeting discussed the FOCUSsw simulations presented in addendum 5 of the DAR and those in the DAR. They concluded that they would not accept the calculations in the DAR. They also identified some problems with some of the simulations reported in Addendum 5. As discussed in this conclusion the substance properties that should have been used in simulations are: imidacloprid single first order soil DT_{50} 82 days (best available median normalised for soil temperature value from all field dissipation and accumulation studies), K_{foc} 225 mL/g, 1/n=0.8, single first order water DT_{50} 90 days, sediment DT_{50} 1000 days (default). These were the substance parameters used in the modelling summarised in addendum 5 with the exception of the soil DT_{50} where a very comparable but marginally more favourable value of 76.8 days was used. The experts agreed that new simulations would not be necessary because of just the small difference in soil DT_{50}. However some other deficiencies were identified and the RMS was asked to make available new simulations and report these in an addendum after the expert meeting. The RMS did not complete this task. The deficiencies identified were:
Information on the application window defined for simulations (of particularly important for the seed treatment use but also for the other uses) was not reported in addendum 5 and clarification was necessary. A clarification of this issue, provided by EFSA is now included in appendix 1 of this conclusion (the list of endpoints). EFSA considers the application windows defined for the simulations reflect the applied for intended uses and are in line with FOCUS guidance. This was the only concern related to the sugar beet seed treatment simulations. Now this is resolved the simulations results reported in addendum 5 for the sugar beet seed treatment can be relied on. The experts could not accept the foliar half life used in simulations for tomatoes (a value from a single experiment that could not be considered to represent situations across all southern Europe, that was derived with different kinetics to that assumed by PRZM and MACRO). They agreed the default value of 10 days should be used in simulations, as there was an absence of an available assessment of a larger database of experiments on foliar degradation rates. Therefore the simulation results in addendum 5 for tomatoes should not be relied on. The results of simulations where a single

application was made in addition to 2 applications should have been provided in accordance with FOCUS guidance, as spray drift was an important route of exposure. New FOCUS surface water simulations were therefore necessary. As imidacloprid is hazardous to aquatic organisms, to support the decision making task of risk managers EFSA carried out some new simulations for the use in tomato (both single and 2 applications, with the default foliar half life of 10 days) and use in apples with a single application. In these new simulations a single first order soil DT_{50} of 82 days was used as input, the other inputs used were as indicated above. These simulations for apples confirmed that with one exception, when single applications were defined (early application timing that gave the highest areic mass deposition input via spray drift), maximum concentrations were always lower than when 2 applications had been defined. Therefore the results in addendum 5 for apples are considered reliable, but it is noted that the numerical value for sediment concentration from the R4 stream scenario is higher from the single application simulation. The effect of spray drift and runoff mitigation was also investigated in the new simulations completed by EFSA for tomato (Step 4 calculations, assuming 90% runoff reduction and 95% spray drift reduction, these being the maxima considered reliable and recommended for use in annex 1 assessments in the FOCUS landscape and mitigation report[22]). As the input parameters were those agreed by the meeting of experts the output from these simulations can be considered agreed values and are included in appendix 1. Appendix 1 includes risk mitigation of drift up to 95% and runoff up to 90% for the use on apples where these could be extracted from the information already described in addendum 5. The estimated 95% spray drift mitigation values tabulated in appendix 1 for the apple use (stream and ditch water bodies) are the values reported for the combination of a 20m no spray zone and 50% drift mitigation technology as reported in addendum 5.

Risk managers may wish to note that whilst runoff mitigation is included in the Step 4 calculations available, the EFSA PPR panel opinion on the FOCUS landscape and mitigation report[23] indicated that for substances with Kfoc < 2000 (i.e. imidacloprid), the general applicability and effectiveness of runoff mitigation measures had been less clearly demonstrated in the available scientific literature reviewed by the FOCUS report authors. The peer review confirmed that it would be appropriate to use PEC in surface water for imidacloprid as conservative exposure values for the aquatic metabolites: M09, M23, M12 and M14.

[22] FOCUS (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. 169pp.

[23] Opinion of the Scientific Panel on Plant protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EFSA Journal (2006) 437, 1-30. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770123.htm

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

The applied for representative use of sugar beet seed treatment (incorporation depth 3cm), apples and tomatoes (surface application) were simulated (see the DAR) using FOCUS PELMO 3.3.2 using the following input parameters: imidacloprid single first order DT_{50} 118 days (geomean normalised laboratory value, more conservative than a median field value which is currently estimated at ca. 82 days , K_{foc} 225 mL/g, 1/n=0.8. Levels of soil metabolites in laboratory studies were always below the trigger for a groundwater modelling exposure assessment (i.e. < 5 % AR, see section 4.1.1). In the available lysimeter studies no identified metabolites were present in individual leachate samples at > 0.01µg/L and annual average total radioactive residues in leachate samples were always < 0.1µg imidaclorpid equivalents /L (see section 4.1.3).

Parent imidacloprid was calculated to be present in leachate leaving the top 1m soil layer at 80th percentile annual average concentrations of <0.001µg/L. The available data provide no indications that soil metabolites of imidacloprid containing the pyridinyl-methylene or imidazolodine-4,5 moieties would be expected to leach to groundwater as a consequence of the applied for intended uses.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of imidacloprid ($4x10^{-10}$ Pa at 20°C) means that imidacloprid would be classified under the national scheme of The Netherlands as very slightly volatile, indicating losses due to volatilisation would not be expected. Based on the results of a field experiment (Monheim Germany) where an imidacloprid formulation was applied as a spray to apple seedlings in pots, all the applied radioactivity was recovered from the plants and soil within 24 hours, confirming negligible volatilisation losses of imidacloprid are to be expected. Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at 0.85 hours (assuming an atmospheric hydroxyl radical concentration of $1x10^6$ radicals cm^{-3}), indicating the small proportion of applied imidacloprid that might form aerosols at the time of application and reach the atmosphere would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Imidacloprid was discussed at the PRAPeR Expert's Meeting on ecotoxicology (PRAPeR 33) in October 2007.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The representative uses are spray application in apples (northern Europe and southern Europe) and tomatoes (southern Europe) indoors and outdoors and seed treatment of sugar beet. The risk

assessment for birds and mammals was conducted for uptake of contaminated food items for the outdoor uses only. No exposure of birds and mammals was assumed for the glasshouse use.
Standard scenarios:
Spray application in apples: insectivorous bird, small herbivorous mammal
Spray application in tomatoes: insectivorous bird, medium herbivorous bird, medium herbivorous mammal
Seed treatment: granivorous bird, granivorous mammal, since the compound is systemic and taken up by the seedlings, the risk from uptake of treated seedlings by a medium sized herbivorous bird species was assessed in addition.

The acute, short-term and long-term endpoints used in the risk assessment for birds were discussed in the meeting of experts. An acute toxicity study with partridges was available with a lower endpoint than that used in the risk assessment. However the study report was too brief to allow a conclusion on the reliability of the study. Therefore it was decided to use the lowest endpoint from the studies which were conducted under GLP and which were reported in full detail (LD_{50} = 31 mg/kg bw).
Strong food avoidance was observed in the short-term (dietary) studies. Several studies were available and the RMS proposed using the highest NOEC which is below the LOEC from all available dietary studies. This approach was accepted by the meeting. The RMS presented a table with the short-term endpoints in addendum 6 (not peer-reviewed). The NOEC of 29.4 mg a.s./kg bw/d (based on mortality) is proposed to be used in the short-term risk assessment.

The experts discussed whether the effects on hatchling body weight and eggshell thickness observed in the reproduction study should be considered in deriving the endpoint for the long-term risk assessment. The effects on eggshell thickness did not follow a clear dose-response relationship and there were no effects on the number of eggs cracked. It was noted that the eggs are not bred in the test system as they re bred in the field and hence the cracking rate of eggs may be different in the natural environment. The effects on body weight were statistically significant. But the magnitude of effect was low (3-4% difference). The experts considered that this low magnitude of effect may not be of relevance. The experts agreed that the endpoint of 126 ppm (NOAEL of 9.3 mg/kg bw/d) should be used in the risk assessment as suggested by the RMS.

The first tier risk assessment for birds from uptake of treated seeds (sugar beet seed pellets) resulted in TER values of 0.003, 0.003 and 0.008 for the acute, short-term and long-term risk to seed eating birds.
Field trials were conducted to measure the number of unburied sugar beet seed pellets, the degradation of imidacloprid from the seed pellets and also residue trials in plants were conducted.
Acceptance of sugar beet seed pellets were tested with canary birds (*Serinus canaries*), zebrafinches (*Taeniopygia guttata*) and with Japanese quail (*Coturnix coturnix japonica*). Canary birds and zebrafinches did not consume sugar beet seed pellets. The seed pellets were not treated with imidacloprid but were coloured blue. It was concluded by the RMS that sugar beet seed pellets are not taken up by small granivorous birds. No mortality was observed when quails were offered treated

sugar beet seed pellets 12 g and standard feed 4 g after a starvation period of 16 hours. Only one treatment related death was observed in the second study where birds were offered treated sugar beet seed pellets (75% of their daily food consumption rate) and untreated food (25% of their daily food consumption rate). Sublethal effects like apathy and behavioural impairments were observed in the tests. Therefore it was concluded by the RMS that birds do not ingest treated sugar beet seeds. Only if they are starved prior to the test and if the treated seeds are available at high amounts some individuals may take up a lethal dose.

The RMS concludes that the risk to birds from uptake of treated sugar beet seed pellets is low due to the low availability and low attractiveness as a food item.

The risk from uptake of seed pellets as grit was assessed as low. The risk assessment is based on the data of de Leeuw et. al. (1995)[24]. The percentage size overlap between grit and sugar beet seed pellets was 0% for small birds, 5.6% for large granivorous birds, 1.6% for large non-granivorous birds and 0.1% for ducks and geese. The number of ingested particles with a size which overlaps with the size of sugar beet seed pellets was estimated as 5.1, 2 and 2.8 for large granivorous birds (625 g), large non-granivorous birds (288 g) and large herbivorous birds (2338 g).

Based on the assumption that all the particles in the relevant size are sugar beet seed pellets, the resulting TERs are below the relevant Annex VI triggers of 10 and 5 for large granivorous birds and large non-granivorous birds. The TER values for large herbivorous birds exceed the TER triggers of 10 and 5 indicating a low risk. This risk assessment covers the exposure from seed pellets where birds may take up the full amount of grit as sugar beet seed pellets. However the availability in the field is much lower since the sugar beet seed pellets are drilled and only few seed pellets remain on the soil surface.

The number of particles in the size class of sugar beet seed pellets was 71 per m^2 in dutch soils. For the risk assessment it was assumed that 0.17 % of drilled seed pellets remain on the surface (average proportion from different test sites according to de Leeuw 1995). This corresponds to one seed pellet per 45 m^2 resulting in a very low probability that a seed pellet is taken up as grit. The probability of ingestion of a sugar beet seed pellet in the relevant size class as a grit particle (on soil types comparable to the investigated dutch soils) is about 0.00156, 0.000626 and 0.000939 for large granivorous, large non-granivorous and large herbivorous birds.

The TER values were calculated for the uptake of one seed pellet per day. This is considered as a conservative assumption taking into account the low probability that a seed pellet is taken up as grit. The acute TER values were calculated as 21.6, 9.9 and 80.6 and the short-term dietary TER values were calculated as 19.7, 9.1 and 73.6 for large granivorous birds, large non-granivorous birds and large herbivorous birds, indicating a low acute and short-term risk to birds from uptake of one granule

[24] De Leeuw J., Goree M., de Snoo G.R., Tamis W.L.M., van der Poll R.J., Luttik R. (1995): Risks of granules and treated seeds to birds on arable fields. CML report 118,

per day as grit. The long-term TER values were calculated as 6.4, 2.9 and 24.1. The long-term TER for uptake of one sugar beet seed pellet per day was below the trigger of 5 for large non-granivorous birds. For an assumed uptake of one seed pellet every second day the TER is 5.8. Given the low probability that a sugar beet seed pellet is taken up as grit and that seed pellets are only available for a few days the long-term risk to birds from uptake as grit is considered to be low.

The attractiveness of spillages of the sugar beet seed pellets for birds and mammals was investigated in a field monitoring study. About 30% of the seed pellets were removed or cracked (45 and 86 out of 400) while almost all of the wheat seeds (used to demonstrate that birds/mammals feed in the vicinity of the sugar beet seed pellets) had disappeared within the observation period of 7 days. It was concluded by the RMS that spillages of sugar beet seed pellets are not attractive as a food source. The experts agreed to the conclusion of the RMS.

It was discussed in the expert meeting whether the average number of seed pellets (0.17%) (from all field tests) or the highest observed number of seed pellets (0.6%) on the soil surface should be used in the risk assessment. The experts agreed that for the acute and short-term risk assessment the highest number observed in the field trials should be used. An open point was identified for the RMS to recalculate the acute and short-term TERs based on 0.6% seed pellets on the soil surface. This calculation was provided in the not peer-reviewed addendum 6.

The experts concluded that the available risk assessment for the uptake of sugar beet seed pellets is acceptable and that the risk to birds from the use as seed treatment is low provided that the soil incorporation efficiency is high (not more than 0.17% of seed pellets remain on the surface) and spillages are removed from the soil surface.

The first tier risk assessment for the uptake of residues in seedlings resulted in TER values of 2, 1.9 and 1.2 indicating a potential high acute, short-term and long term risk for herbivorous birds. The refined risk assessment was discussed in the expert meeting. Wood pigeon (*Columba palumbus*) was accepted as a focal species. As a refinement step it was proposed that wood pigeons feed in bouts and one filling of the crop with sugar beet seedlings would constitute 20% of the daily food intake. This was used as a crop-filling factor of 0.2 in the exposure calculation. However it was noted by the experts that the birds may feed several times in one day on the same field and considerations of metabolic processes was missing. An open point was identified by the experts for the RMS to include information on the toxicokinetics to support the risk refinement (e.g. as suggested in the opinion of the PPR panel on pirimicarb[25]). The RMS proposed using the crop-limiting factor of 0.2 also for the short-term and long-term risk assessment. This was not accepted and it was proposed that real PD data would be a more appropriate refinement step for the short-term and long-term risk assessment. The suggested PT value of 0.1 was rejected by the experts because it was not sufficiently justified by

[25] Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the evaluation of pirimicarb. The EFSA Journal (2005) 240, 1-21 (http://www.efsa.europa.eu/EFSA/Scientific_Opinion/ppr_op_ej240_pirimicarb_en1,1.pdf)

data. The experts concluded that a high risk to birds from uptake of sugarbeet seedlings cannot be excluded for the representative use. The RMS noted in addendum 6 (not peer-reviewed) that the available studies on the metabolic processes cannot be used to support the suggested use of the crop limiting factor of 0.2. As an alternative it was suggested by the RMS to assume a PT of 0.5 (i.e. a bird obtains half of its daily food requirements from the treated area). However no investigations on wood pigeons feeding on seedlings in sugarbeet fields were provided to substantiate the assumption. Therefore this refinement step is not agreed by EFSA.

The risk of plant metabolites: NTN33893-5-hydroxy (M01), NTN33893-olefine (M06) and NTN33893-desnitro (M09) were found in different plant matrices in amounts of >5% of total radioactive residue. M01 and M06 were also determined to be present in sugar beet seedlings. (No mortality or other adverse effects were observed in a study with bobwhite quail where the birds were exposed for 4 hours to sugar beet seedlings). M06 (LD_{50} = 1100 mg/kg) is less toxic to rats compared to imidacloprid (LD_{50} 379 mg/kg bw). No toxicity data are available for the metabolite M01. But M01 and M06 appear in the hen metabolism. Therefore the risk from metabolite M01 and M06 to birds is considered to be covered by the risk assessment for imidacloprid. However the metabolite M09 is more toxic to rats than imidacloprid (LD_{50} = 280 mg/kg bw) and the metabolite does not appear in the hen metabolism. The RMS presented in addendum 5 further explanations on the metabolic patterns in plants. Metabolite M09 appears to exceed the concentration of imidacloprid after 14-35 days in eggplant leaves and 65 to 124 days in rice and straw. Although these observations cannot be directly extrapolated to sugar beet leaves it gives some indication that the concentration of M09 in sugarbeet seedlings is likely to be significantly lower in relation to the concentration of imidacloprid. In addition the maximum peak concentrations of M09 in plants were about two orders of magnitude lower than the concentrations of imidacloprid. The experts agreed to the line of argumentation and considered the risk from metabolite M09 to herbivorous birds and mammals as covered by the risk assessment for imidacloprid.

No risk assessment was conducted by the RMS for herbivorous birds in tomatoes. It was assumed that the risk to herbivorous birds is low due to the low attractiveness of tomato plants as a food source. The first tier TER values for insectivorous birds in tomato and apple orchards were calculated as 5.4 and 5.7 for the acute risk, 9.5 and 8.9 for the short-term risk and 3.1 and 2.9 for the long-term risk.
The applicant suggested a PT of 0.61 for blue tit (*Parus caeruleus*) in orchards and 0.1 for yellow wagtail (*Motacilla flava*) in tomato. The risk assessment was further refined by assuming that the food of blue tit consists of 70% small insects and 30% large insects and that yellow wagtails consumes 50% large and 50% small insects. The PT refinement was not accepted for the acute risk assessment. The PT of 0.1 for *Motacilla flava* is not supported by data. The study which was used to support the PT refinement was based on observations of occurrence of bird and mammal species in tomato fields in Italy. However no individuals were followed by radio tracking. The experts agreed that the study may be useful to identify focal species for the use in tomatoes in Italy but it is not appropriate to derive a quantitative refinement of the PT value. The PT refinement in the acute risk assessment for blue tit was also not accepted by the experts. As an alternative to the PD refinement

measured residues in insects were used to calculate the ETE values. The study on residues on insects in orchards was discussed in the meeting. It was noticed that first sampling was done 7 hours after spraying. It is likely that the insects which were killed within this first 7 hours after treatment were excluded from the study (they would carry high residues). It was further noticed that the highest residue levels were not measured at the first day of sampling in some of the replicates. The experts considered the study as not suitable for refinement of insect residues because of these uncertainties.

The recalculated TERs for blue tits in orchards were 7 (acute), 12.3 (short-term) and 6.4 (long-term). The TERs for yellow wagtail presented in addendum 6 (not peer-reviewed) are based on uptake of 89% large and 11% small insects. However the refinement agreed in the meeting was 50% large and 50% small insects. Also with the PD of 50% large and 50% small insects the resulting TERs are above the trigger values (10.6 acute, 19.6 short-term, and 6.2 long-term). The TER values indicate a low risk to insectivorous birds for the use in tomato but the acute TER for blue tits is below the trigger of 10 and further risk refinement is required for the use in orchards.

Mammals:

The first tier risk assessment for the uptake of treated sugar beet seed pellets resulted in acute and long-term TER values of 0.02 and 0.003 indicating a potential high risk. To refine the risk assessment the RMS proposed an avoidance factor of 0.16 based on a study with house mice (showing a repellent effect of treated sugar beet seed pellets). The RMS suggested using the LD_{50} from dietary studies instead of acute exposure and PD and PT values of 0.3 and 0.2. Furthermore it was assumed that cracking and dehusking of seeds would reduce exposure to 15% of the original loading (this figure is derived from a study with sunflower and rape seeds. The quantification of the avoidance factor as 0.16 was not agreed in the meeting. The refined PT values were not sufficiently supported by data and therefore rejected. It was noted that the PD refinement was based on observations not only on freshly sown sugar beet fields but also on oilseed rape fields. However the experts agreed to the PD of 0.3 since the food composition in both crop types was similar (about 70% insects). The dehusking factor (15%) was questioned since it was derived from studies with sunflower and rape seeds. Although the handling of seeds (dehusking) will reduce the exposure it is uncertain to which extend. The experts concluded that a high risk to granivorous mammals cannot be excluded from the available data and a data gap was identified for a new refined risk assessment.

The risk to medium herbivorous mammals from uptake of residues in sugar beet seedlings was assessed as low since the acute and short-term TERs of 23 (acute) and 5.8 (long-term) were above the Annex VI triggers of 10 and 5. The risk from metabolites in sugar beet plants was assessed as low. The metabolites M01, M06 and M09 were identified in corn at levels of > 5% of total radioactive residue after seed dressing. M01 and M06 were also determined to be present in sugar beet seedlings. M06 (LD50 = 1100 mg/kg) is less toxic to rats compared to imidacloprid (LD50 379 mg/kg bw). M09 is about 1.4 times more acutely toxic to rats than imidacloprid (LD50 = 280 mg M09/kg bw).

However the metabolite appears in the rat metabolism and is considered to be covered by the risk assessment for imidacloprid.

The risk assessment for the use in tomatoes was conducted for a small mammal instead of a medium sized herbivorous mammal on the basis of field observations where it was shown that the only mammal species with a slight preference for this habitat was the wood mouse (*Apodemus sylvaticus*). Since a small herbivorous mammal is worst case compared to a medium sized herbivorous mammal the change is considered acceptable.

The first tier risk assessment for the use in apple orchards and tomatoes resulted in acute and long-term TER values of 8.8 and 7.4 for the acute risk and 3.4 and 3.3 for the long-term risk indicating a potential high risk to mammals.

A PD value of 0.5 was suggested to refine the risk to herbivorous mammals in tomatoes. This refinement is based on the assumption that tomato foliage is not attractive as a food source for mammals. A quantitative refinement of the PD is not substantiated by data. But the experts agreed that tomato foliage is not an attractive food source and the risk to herbivorous mammals in tomatoes was considered to be low. To refine the risk to herbivorous mammals in apple orchards the risk was calculated with measured residue values in grass and the multiple application factor (MAF) of 1.2 was set to 1 based on the DT_{50} of 2.6 days observed in residue trials. It is noted that also without the refinement of the MAF the acute TER of 17 is above the trigger of 10 (taking into account 50% interception at BBCH 10). The experts in the meeting agreed that the risk to herbivorous mammals in orchards is low.

The risk from plant metabolites was assessed as low. The available data on the acute toxicity to rats show that the metabolites M01, M07 and M12 are of lower toxicity to rats than imidacloprid. However the metabolite M09 which is considered the most abundant metabolite is about a factor of 1.4 more toxic than imidacloprid (LD_{50} = 280 mg M09/kg bw) and 500 mg imidacloprid/kg bw). M09 appears in the rat metabolism and therefore the risk could be covered by the risk assessment for the parent. The highest peak residue concentration of M09 was observed in residue trials with rice (52.9% of applied radioactivity at the time of sampling). Since M09 is not more than two times more toxic as imidacloprid the risk to mammals from metabolite M09 is likely to be covered by the risk assessment for imidacloprid.

The risk from bioaccumulation is considered to be low since the logPow of Imidacloprid is 0.57 and also the log Pow of the plant metabolites M09 and M06 (also M16 and M12) were determined to be <1.

A risk assessment for the uptake of contaminated drinking water was presented in addendum 5. It was noted by EFSA after the expert meeting that the calculated values presented in addendum 5 are not correct. The acute TERs based on exposure to a 5 fold dilution of the sprayed solution would lead to

acute TERs above the trigger of 10 for birds and mammals for the use in tomatoes and for mammals in orchards. Only the acute TERs for birds in orchards would be below the trigger of 10. In the expert meeting it was agreed that the risk from uptake of drinking water is low for the representative uses evaluated.

Overall it is concluded that the risk to birds is low for the uptake of pelleted seeds but a potential high acute risk cannot be excluded for granivorous mammals. The consumption of sugar beet seedlings poses a potential high acute risk to herbivorous birds. The risk to herbivorous mammals was assessed as low for the representative uses in tomato and orchards. The risk to insectivorous birds is considered as low for the use in tomatoes but a potential high acute risk to insectivorous birds cannot be excluded for the representative use in orchards.

5.2. RISK TO AQUATIC ORGANISMS

The lowest endpoints from the tested organisms were observed for *Chironomus riparius*. The spray formulation Confidor SL 200 was tested with *Chironomus riparius*. The toxicity of formulated imidacloprid was similar to technical imidacloprid. Testing with the granular formulation Gaucho FS 600 Uncoloured was considered as not necessary since aquatic organisms are expected to be exposed to the active substance but not to the formulation.
The TER values based on maximum PECsw of the worst case FOCUSsw scenario R3 were well above the Annex VI triggers for fish, daphnids and algae. The acute and chronic TER for *Chironomus riparius* were 6.39 and 0.28, respectively.

A microcosm study was conducted in Texas and another one in Germany. The dissipation of imidacloprid was much faster under the subtropic climatic conditions with higher temperatures and solar irradiation in Texas (DT_{50} in water = 1.4 d). In the study conducted in Germany the DT_{50} in the water phase of the test systems was in the range of 5.8 to 13 days. The first study was not used in the risk assessment because of the very high pH values of >10 during several weeks, short exposure periods because of very rapid dissipation from the water phase due to the subtropic climatic conditions and a general concern on the representativeness for environmental conditions in central and northern Europe. A high diversity of invertebrate species was observed in the microcosm study conducted in Germany. Chironomidae and Baetidae were the most sensitive insect families determining the NOEC for macrozoobenthos as 0.6 µg imidacloprid/L (nominal concentration). 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. Ephemeroptera are very sensitive due to their long larval development. It was not possible to draw a clear conclusion on recovery of sensitive mayfly species since they were present in too low abundances to allow a reliable statistical evaluation. The experts agreed that the endpoints from the mesocosm should be based on nominal concentrations and that the endpoint of 0.6 µg imidacloprid/L should be used in the risk assessment. No agreement was reached on the safety factor. It was proposed that MSs use a safety factor of 1-3 in combination with the NOEC of 0.6 µg imidacloprid/L. When the safety factor is

chosen it should be considered that the endpoint is a NOEC but also that uncertainties remain with regard to the representativeness to different environmental conditions and the presence of other (more sensitive) insect taxa.

The PECsw values were recalculated by EFSA (see section on fate and behaviour). The TER values based on the endpoint of 0.6 µg imidacloprid/L and FOCUS step3 PECsw were in the range of 0.09 and 1 indicating a high risk to aquatic insects for the uses in tomatoes and apples. The TER was above 3 for all scenarios for the use in sugar beet.
With no-spray buffer zones of 20 m a TER of ≥1 is achieved in the full FOCUS step4 drainage scenarios (D3, D4, D5) and in the run-off scenarios R1, R2, R3 (without additional run-off mitigation) and R4 (including 50% run-off mitigation) for the use in orchards. A TER of ≥3 was reached in none of the full FOCUS step4 scenarios.
The drainage scenario (D6) resulted in a TER of 0.96 without spray drift reduction and in a TER of 1.3 with 95% spray drift reduction for the use in tomato. Without run-off mitigation no full run-off scenario (R2, R3, R4) resulted in a TER ≥1 including spray drift reduction of 95% (equivalent to a no-spray buffer zone of 30 – 40 m). However none of the scenarios except R3 resulted in TERs ≥3.
Overall it is concluded that a high risk for aquatic organisms is indicated for the representative uses in orchards and tomatoes requiring substantial risk mitigation measures to reduce spray drift and run-off.

The metabolites M01, M07, were about 1 order of magnitude acutely less toxic and the metabolites M09, M12, M16[26] and M23 were more than 2 orders of magnitude less chronically toxic to *Chironomus riparius* than imidacloprid. The TER values based PECsw values from FOCUSsw scenario R3 (which resulted in highest PECsw values for imidacloprid) were above the trigger of 100 except for metabolite M07 where a TER of 46 was observed. It is concluded that the risk from metabolites is low for all representative uses and that the risk from metabolite M07 is covered by the risk mitigation required for imidacloprid. No toxicity data were made available for the photolysis metabolite M14. The risk from this metabolite to aquatic organisms needs to be addressed.

The logPow for imidacloprid and the metabolites M09, M12, M16 and M23 are below 3. No log P_{ow} values were given for the metabolites M01 and M07. However it is unlikely that these metabolites are much less hydrophilic than imidacloprid. Therefore the risk of bioaccumulation from imidaclorprid and its metabolites which are predicted to reach surface water is considered as low.

5.3. RISK TO BEES

A large number of studies with bees including tunnel tests, field and semi-field tests were submitted by the applicant. Imidacloprid is acutely very toxic to bees. The observed LD_{50} values ranged from 3.7 to >70.3 ng/bee for the acute oral toxicity and from 42.2 to 129 ng/bee for the acute contact toxicity. The acute toxicity of the main plant metabolites was also investigated. The metabolites olefine-imidacloprid and hydroxyl-imidacloprid are very toxic to honey-bees.

[26] M16: Imidacloprid-AMCP, NTN33893-AMCP

In addition to the standard acute toxicity tests also chronic tests and studies to investigate sublethal effects (bee behaviour) were conducted. The NOEC values for the dietary exposure were determined as 46 ppb (acute oral toxicity), 50 ppb sublethal effects (learning behaviour), 24 ppb chronic lethal effects and 20 ppb behavioural impacts including bee hive development. It was questioned during the peer-review whether effects on bee-brood are sufficiently addressed. No effects on bee-brood were observed in a number of field tests. The experts agreed that the available studies provide sufficient information to conclude on the representative uses evaluated.

The HQ values for oral and contact exposure were far in excess of the HQ trigger value of 50 indicating a high risk to bees from the use as a spray application in orchards and tomatoes.

Imidacloprid has a distinct systemic mode of action. Therefore the uptake in plants from soil/seed treatment applications was investigated in different crops (maize, cotton, egg-plant, potato and rice). The plants absorbed up to 20% (maize) of the amount of imidacloprid applied as seed dressing. Imidacloprid is preferentially translocated to leaves and shoots and to a much lower extend to the reproductive organs. The concentrations of imidacloprid and its main plant metabolites were investigated in the nectar and pollen of sunflower where the seeds were treated with 0.7 mg radiolabelled imidacloprid/seed. Only imidacloprid was found in the study but no plant metabolites (limit of detection was 0.1 ppb). Imidacloprid concentrations measured in pollen and nectar of different crops from different locations in Europe suggest that it is likely that residue levels in nectar of pollen will not exceed 5 ppb for the seed dressing uses currently registered in Europe. It was noted by the experts that extrapolation of measured residues to other crops is uncertain and should be interpreted with caution. No major soil metabolites were detected in the soil degradation studies. Bees would therefore only be exposed to imidacloprid residues in succeeding crops.

In order to assess the risk from application as a seed treatment the RMS calculated TER values on the basis of NOEC values from the available studies for the acute oral toxicity, sublethal effects (learning behaviour), chronic lethal effects and chronic behavioural impacts including bee hive development as 46, 50, 24 and 20 ppb. These NOECs were compared to residue levels in nectar and/or pollen of <5 ppb resulting in TER values of >9.2, >10, >4.8 and >4 indicating a low risk to bees from the representative use as a seed treatment. These findings were confirmed by the field tests where no adverse effects were observed where bees were exposed to flowering sunflowers, rape and maize treated as seeds with imidacloprid. Furthermore sugar beet is harvested before flowering hence no risk to bees is anticipated from the use as a seed treatment in sugar beet.

In the expert meeting it was discussed whether adverse long-term effects to bees are sufficiently covered by the risk assessment since the duration of most of the studies was 4-6 weeks. Two studies with a longer duration were available and one study also investigated winter bees. No sublethal effects were observed in the studies below a concentration of 5 ppb. The experts considered the

information on long-term effects as sufficient to conclude on the risk from the representative uses evaluated.

The risk from exposure to honeydew excreted from aphids was considered as low. The acute oral LD_{50} for aphids is several orders of magnitude lower than for bees. Therefore it was suggested that it is highly unlikely that aphids would survive exposure to imidacloprid at concentrations in sap which could lead to the excretion of honeydew which is toxic to bees. Therefore it was assumed that appreciable amounts of honeydew will only be present at residue concentrations which are not hazardous for bees. The line of argumentation was agreed by the experts but it was not clear how the toxicity value for aphids was derived and the experts suggested a data gap for the applicant to clarify this point.

Overall it is concluded that the spray applications of imidacloprid pose a high risk to bees. Risk mitigation is required for the use in orchards. The risk to bees is considered to be low if the product is not applied during flowering and if flowering weeds are removed/mown before the product is applied. However it should be noted that bees potentially foraging in the off-crop area would still be exposed via spray drift and hence not be protected by the suggested risk mitigation measure.

Flowering tomato plants are visited by honey-bees and other pollinators. The risk mitigation suggested for orchards is not an option for the use in tomato since the tomato plants flower almost continuously. The RMS informed in a comment that it may be possible to apply risk mitigation measures in tomato e.g. restrict the application to the time before tomatoes start flowering. It was further noted that bumblebees are used in glasshouses to pollinate tomatoes. An appropriate waiting period should be kept before bumblebees are released after treatment. However no data are available for bumblebees to determine the waiting period.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The first tier risk assessment (according to ESCORT II) resulted in HQ values for *Aphidius rhopalosiphi* far in excess of the trigger of 2 indicating a high in-field and off-field risk for the spray applications in orchards and tomatoes. The HQ values for *Typhlodromus pyri* were above the trigger of 2 for the in-field area. The HQ values for the off-field area were below or equal to the trigger of 2 for the use in tomato at a no-spray buffer zone of 3 metres and in orchards at a no-spray buffer zone of 10 m. In addition to the standard indicator species also tests with *Coccinella septempunctata*, *Chrysoperla carnea*, *Aleochara bilineata*, *Poecilus cupreus*, *Pardosa sp*., were conducted. *A. rhopalosiphi, T. pyri and P. cupreus* were tested also in extended laboratory studies. Field and semi-field tests were conducted with *A. rhopalosiphi*, *Trichogramma dendrolimi*, *Poecilus cupreus*. The effects of applications of Confidor SC200 mite fauna was investigated in apple orchards.

Aphidius rhopalosiphi was the most sensitive tested arthropod species. The RMS assumed that if the risk is sufficiently addressed for *A. rhopalosiphi* then the risk to other arthropod species would also be covered with this assessment. No significant effects on mortality or reproduction were observed

after 14 d (apple-orchards) and 21 d (tomatoes) of aging of residues after the second application. Therefore it was concluded that recolonisation of apple-orchards and tomato fields would be possible. However the off-field HQ values suggest severe impacts on arthropod populations in the off-field area from where the in-field area could be rapidly recolonised. The applicability of a wind tunnel experiment with *A. rhopalosiphi* to address the risk in the off-field area was discussed. The RMS considered it not necessary to use a vegetation distribution factor (vdf) in combination with the endpoint from this study since it was conducted on whole plants. The experts agreed that the study can be used in the refined risk assessment. The experts discussed whether the risk to other insect species is covered by the risk assessment for *A. rhopalosiphi*. It was agreed that extrapolation to other insect species is difficult because of different sensitivity of different life stages and the potential to recolonise the in-field area. The available field studies with mites suggest that recolonisation takes place 4 weeks after the second application and hence the risk to mites is considered to be sufficiently addressed.

It was shown in an extended lab study and a semi-field study with the spray formulation Confidor SC200 that the risk to adult *Poecilus cupreus* is low if exposed to applications of 2x100 g imidacloprid/ha in tomato and 70 + 105 g imidacloprid/ha. Larvae of *P. cupreus* were much more sensitive than adult beetles. Extended lab studies with *P. cupreus* resulted in a LR_{50} of >0.1 mg a.s./kg and <0.4 mg a.s./kg. A combined probit analysis of the two studies of Neumann 1999a and 1999b gave a LR_{50} of 0.136 mg a.s./kg. This value is above the worst case PECsoil for tomatoes of 0.119 mg a.s./kg. Additional studies have been performed to demonstrate the potential for recolonisation/recovery. After ageing of 247 days the residues up to a maximum concentration of 5 mg a.s./kg dry soil effects on mortality of *P. cupreus* larvae were low (max. 11.1%). Ageing of 247 days is not considered as a timeframe that suggests recovery of a population within an ecologically relevant time.

The effects of seed treatment uses on larvae of *P. cupreus* was investigated in a number studies. Effects of >50% were observed in studies with application rates higher than suggested in the GAP for sugar beet. Less than 50% effect was observed in a semi-field study with *P. cupreus*. Concerns were raised in relation to the soil concentrations tested in the semi-field test. The experts considered the overall concentration tested as too low. The experts agreed that the study may be useful as supplementary information but it is not sufficient to conclude on a low risk to soil dwelling arthropods.

The applicant proposed using the spray drift values for vegetables less than 50 cm high. The risk to non-target arthropods in the off-field area was calculated for both, tomatoes higher than 50 cm as well as for tomatoes smaller than 50 cm. The experts agreed that at national level the approach which is most suitable for their agronomic practice should be chosen.

Overall it is concluded that the application of imidacloprid will cause severe impacts on non-target arthropods in the in-field and off-field area. However in semi-field and field studies it was

demonstrated that recolonisation of the in-field area is possible. A high risk to soil dwelling arthropods cannot be excluded for the seed treatment use. The available data suggest that ageing of residues of 273 days is required in order not to be hazardous to larvae of *P. cupreus*. The available semi-field test with *Poecilus cupreus* was conducted at too low concentrations of imidacloprid in soil to allow a conclusion on the risk from the representative use in sugar-beet.

5.5. RISK TO EARTHWORMS

The TER values for the acute risk to earthworms were above the trigger of 10 for all representative uses. Therefore the acute risk to earthworms was considered to be low. Long-term studies were conducted with technical imidacloprid and the formulations Confidor SL 200 and Gaucho FS 600 Red. It was observed that imidacloprid formulated as Confidor SL 200 was slightly less toxic to earthworms compared to technical imidacloprid. The TER_{lt} for technical imidacloprid were below the trigger of 5 for all representative uses.

Field studies were submitted for a seed treatment formulation (Zelmone 350) in barley and for a spray formulation (Confidor WG 70) in apple orchards. No significant adverse effects on abundance of earthworms were observed in the 6 year study periods in the barley fields (6 x 200 ml product/100 kg seed) and in the apple orchard at application rates of: 0.105 kg imidacloprid/ha. The real exposure situation in the field studies is unclear since no relation to the amount of applied active substance per ha is given for the seed treatment, the concentration of imidacloprid in soil is not given and it is not clear if the product was applied only once per season in the orchard instead of twice as recommended in the GAP table. The RMS confirmed in addendum 5 that the concentration of imidacloprid was not measured in the field studies but suggested that earthworms were sufficiently exposed to imidacloprid by assuming that the studies were conducted at the same sites as the soil accumulation studies

The experts agreed that exposure is likely to have taken place. The field studies may be applicable to address the long-term risk to earthworms. However it was not clear whether the application pattern in the field studies was the same as suggested in the GAP and whether the accumulated maximum PECsoil is covered. An open point was set in the meeting for the RMS to check whether the exposure in the field studies were in accordance to the GAP. The RMS included an assessment of the exposure in addendum 6. The RMS confirmed that the application patterns were different from the representative uses but suggest that the application rates of 133 g a.s./ha (seed treatment) and 150 g a.s./ha (spray application) would cover the representative uses. However the estimated PECsoil in the field studies (0.1773 mg a.s./kg and 0.2 mg a.s./kg) are below the accumulated maximum PECs calculated by EFSA. Therefore uncertainty remains with regard to the long-term risk to earthworms. The risk assessment can be finalised when the assessment of the accumulation in soil is finalised.

The study conducted with Confidor SC200 on grassland was considered as not valid by the RMS since no information was given on the earthworm abundance prior to the test. Cold and dry weather conditions may have influenced exposure of earthworms and the measurement of abundance. The experts agreed to the assessment of the RMS and suggested not to use the study in the risk assessment.

EFSA calculated Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6) **based on not peer reviewed EFSA calculated PEC in section 4.1.2**

Application rate (kg as/ha)	Crop	Time-scale	$PEC_{soil, ini}$ (mg/kg)	TER	Annex VI Trigger
Imidacloprid					
0.07 + 0.1	apple	acute	plateau: 0.463	23	10
2 x 0.1	tomato	acute	plateau: 0.219	49	10
0.117 (nominal)	sugar beet	acute	plateau: 0.322	33	10
0.07 + 0.1	apple	sublethal	plateau: 0.463	0.38 *	5
2 x 0.1	tomato	sublethal	plateau: 0.219	0.81 *	5
0.117 (nominal)	sugar beet	sublethal	plateau: 0.322	0.55 *	5
* In 6-year field study: no effect, however the plateau was not reached					

Overall it is concluded that the acute risk to earthworms is low but uncertainty remains with regard to the long-term risk.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

Litterbag studies with the spray formulation Imidacloprid SL 200 and the seed treatment formulation Gaucho FS 600 were made available. Soil litter degradation was not affected at a concentration of 179 µg imidacloprid/kg (upper 5 cm soil layer) (the measured concentration was 45.8 µg imidacloprid/kg plus 1 application of Imidacloprid SL 200 (100 g a.s./ha). At the day of application the concentration in soil was measured as 135.25 µg imidacloprid/kg. No significant effects were observed in the study with Gaucho FS 600 where treated barley seeds were sown at a rate of 131 g a.s./ha on top of measured soil background concentrations of 22.2 to 45.3 µg a.s./kg (total concentrations of 197 – 220 µg a.s./kg. The accumulated maximum PECsoil values calculated by EFSA (see point 4.1.2 in the section on fate and behaviour) are about 2-3 times higher than the concentrations measured in the litterbag study. Therefore it cannot be concluded that the risk to organic matter breakdown is addressed.

No adverse effects were observed in a test with technical imidacloprid and the predatory mite *Hypoaspis aculeifer* at the highest tested application rate of 120 g a.s./ha. (the concentration in the tested soil is not stated in the study summary but was recalculated as 2.67 mg a.s./kg soil).

The NOEC observed for technical imidacloprid and *Folsomia candida* was 1.25 mg a.s./kg soil The endpoint observed for the formulations were lower compared to technical imidacloprid (Confidor SL 200 = 0.32 mg a.s./kg soil, Gaucho FS 600 in soil = 0.2 mg a.s./kg, Gaucho FS 600 on seeds = 7.1 units/ha with 90 g a.s./unit, which is about 656 g a.s./ha). The TERs for the formulations are below the trigger of 5 except for the seed treatment use.

The metabolites M06 and M07 were tested with *Folsomia candida*. The metabolites are less toxic compared to imidacloprid. The metabolites are formed in amounts of less than 3% and no risk assessment is triggered.

Overall it is concluded that a potential high risk to soil dwelling arthropods cannot be excluded for the representative uses of imidacloprid in orchards and tomatoes.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects ±25% on soil respiration and nitrification were observed in tests with technical imidacloprid and the spray formulation Confidor SL 200 up to the highest tested application rate of 2 kg a.s./ha and 2.25 kg a.s./ha, respectively. Since no effects were observed at an application rate of about 10 times the recommend rate in the GAP table the risk to soil micro-organisms is considered to be low. No studies were conducted with the seed treatment. However the GAP for the seed treatment use suggests an application rate of 0.117 kg a.s./ha. The application rate where no effects of ±25% were observed is about 17times higher. Therefore it was concluded by the RMS that the margin of safety is sufficient to conclude that the risk to soil micro-organisms is low from the representative use as a sugar beet seed treatment.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

No phytotoxic effects of >50% were observed up to the highest tested concentration of 1 kg a.s./ha in studies with technical imidacloprid in five dicotyledon and six monocotyledon plant species.
In a study according to OECD 208 the lowest NOEC for phytotoxic effects (visual effects) was determined as 10 mg a.s./kg soil and the EC_{50} values for growth and emergence rates were ≥100 mg /kg soil. Since the effects are <50 % at an application rate 10 times the suggested GAP the risk to non-target plants is considered to be low.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Inhibition of respiration of 27.9 % was observed at the highest tested concentration of 10 g imidacloprid/L. The EC_{50} is therefore > 10 g imidacloprid/L. It is not expected that imidacloprid reaches biological sewage treatment plants at higher concentrations. Therefore the risk to biological methods of sewage treatment is expected to be low from the representative uses.

6. Residue definitions

Soil

Definitions for risk assessment: imidacloprid (M09[27] under anaerobic conditions)
Definitions for monitoring: imidacloprid

Water

Ground water

Definitions for exposure assessment: imidacloprid
Definitions for monitoring: imidacloprid

[27] M09: 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine

Surface water

Definitions for risk assessment: water: imidacloprid, M09, M23[28], M12[29] and M14[30]
Sediment: imidacloprid

Definitions for monitoring: at least imidacloprid, however a data gap needs to be filled before it can be concluded if M14 would need to be monitored.

Air

Definitions for risk assessment: imidacloprid
Definitions for monitoring: imidacloprid

Food of plant origin

Definitions for risk assessment: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl (which can be oxidised to the 6-chloropyridine-3-carboxylic acid (M14) moiety), expressed as imidacloprid
Definitions for monitoring: not agreed

Food of animal origin

Definitions for risk assessment: sum of imidacloprid and its metabolites containing the 6-chloropyridinyl (which can be oxidised to 6-chloropyridine-3-carboxylic acid (M14) moiety), expressed as imidacloprid
Definitions for monitoring: sum of imidacloprid, metabolites M01[31] and M06[32], expressed as imidacloprid

[28] M23: 1-[(6-chloropyridin-3-yl)methyl]-1,3-dihydro-2*H*-imidazol-2-imine
[29] M12: 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-one
[30] M14: 6-chloropyridine-3-carboxylic acid or 6-chloronicotinic acid
[31] M01: 1-[(6-Chloro-3-pyridinyl)methyl]-4,5-dihydro-2-(nitroamino)-1H-imidazol-5-ol
[32] M06: 1-[(6-Chloro-3-pyridinyl)methyl]N-nitro-1H-imidazol-2-amine

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Imidacloprid	Single first order field DT_{50} in the range 40 to 1333 days Exhibits moderate to very high persistence.	Low acute risk to earthworms but a high long-term risk to earthworms and soil dwelling arthropods (collembola) cannot be excluded
M09 (anaerobic conditions)	No data available, data gap identified for degradation rate information under aerobic conditions	No data available.

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
imidacloprid	Kfoc 109 to 411 mL/g high to medium mobility	No	Yes	Yes	Yes

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
imidacloprid	Very toxic to aquatic organisms and a high risk is indicated in particular for aquatic insects.
M09	Lower toxicity and lower risk to aquatic insects compared to imidacloprid
M23	Lower toxicity and lower risk to aquatic insects compared to imidacloprid
M12	Lower toxicity and lower risk to aquatic insects compared to imidacloprid
M14	No data available. The risk to aquatic organisms needs to be addressed.

Air

Compound (name and/or code)	Toxicology
imidacloprid	Not acutely toxic by inhalation (LC_{50} >5.3 mg/L) In rats, 28-d NOAEC 0.03 mg/L

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Method of analysis for the active substance in the SL formulation (relevant for all uses except sugar beet, data gap identified by meeting of experts October 2007, date of submission unknown, refer to chapter 1).
- Method of analysis for body fluids (relevant for all uses), data gap identified by rapporteur February 2008, date of submission unknown, refer to chapter 1).
- Experimental data from field exposure studies with imidacloprid on sugar beet seeds (relevant for the use on sugar beet seeds, availability of the new data indicated by the notifier in the addendum 6 to Volume 3 (February 2008), submission of this new study not accepted by the RMS due to Regulation 1095/2007, refer to point 2.12).
- robust scientific assessment/statement on possible formation of nitrosimines or other degradates of toxicological concern from the cleaved nitroimino-imidazoline moiety in plants (relevant for all representative uses evaluated; data gap identified by the expert meeting on residues, the notifier has submitted comments on this issue in the evaluation table but these comments were not peer reviewed; refer to point 3.1.1)
- Data on the rate of aerobic degradation of the major anaerobic soil metabolite M09 in 3 soils is required (relevant for all pertinent uses in territories where periods of anaerobic conditions cannot be excluded, relevant for the representative uses on apples and sugar beet in some (but not all) EU territories; submission date unknown, refer to point 4.1.1).
- Applicant to appropriately calculate the DT_{50} from the available field accumulation study trial sites and estimate normalised (FOCUS reference condition) values for each of these sites following FOCUS kinetics guidance (including a soil moisture normalisation). (relevant for all representative uses evaluated; submission date unknown: refer to point 4.1.2).
- Applicant to provide an assessment of the potential effect of plant uptake and plant matter incorporation on the calculated soil dissipation rate and if possible degradation rate. This assessment should include particular consideration of the field accumulation studies (relevant for all representative uses evaluated; submission date unknown: refer to point 4.1.2).
- The risk to granivorous mammals needs refinement (relevant for the use as a seed treatment; data gap identified at the experts´ meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.1
- The risk to herbivorous birds from uptake of sugarbeet seedlings needs refinement (relevant for the use as a seed treatment; data gap identified at the experts´ meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.1)
- The acute risk to insectivorous birds in orchards needs further refinement (relevant for the use in orchards; data gap identified at the experts´ meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.1)
- The risk to aquatic organisms from the photolysis metabolite M14 needs to be addressed. (relevant for all uses; data gap identified by EFSA after the experts´ meeting on ecotoxicology

(PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.2.)

- It needs to be clarified how the toxicity endpoint for aphids was derived (relevant for all representative uses; data gap identified at the experts´ meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.3)
- The risk to soil dwelling arthropods needs to be addressed further. (relevant for all uses; data gap identified by EFSA after the experts´ meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to points 5.4 and 5.6).
- The long-term risk to earthworms needs to be addressed further. (relevant for the uses in tomato and orchards; data gap identified by EFSA after the experts´ meeting on ecotoxicology (PRAPeR 33) in October 2007; no submission date proposed by the applicant; refer to point 5.5)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as an insecticide seed treatment for sugar beet and as a foliar spray for apples and tomatoes. Full details of the GAP are in the attached list of end points.

The representative formulated products for the evaluation were "Confidor", a soluble concentrate formulation (SL) and “Gaucho” a flowable concentrate for seed treatment (FS).

Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues. However it should be noted that the residue definition in plants and surface water for monitoring purposes has not been finalised. In addition to this as the peer review process found that the active substance should be classified as toxic a data gap for a method of analysis for body fluids was identified.

Sufficient data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. A method of analysis is available for the active substance in the FS formulation but not in the SL.

Within the toxicological assessment, imidacloprid is almost completely absorbed by oral administration, does not bioaccumulate and is excreted mainly by the urine. Showing a high acute oral toxicity in mice but a low toxicity after dermal or inhalative exposure, imidacloprid was not irritant to the skin or the eye and had no skin sensitisation potential. The proposed classification for the acute toxicity was T, R25 Toxic if swallowed. In short term studies with rats and mice, the most sensitive parameter was the decreased body weight development. In the dog studies, indications of an effect on the central nervous system were observed (clinical signs). No evidence of genotoxic or carcinogenic effects was observed with imidacloprid. Likewise it did not affect the reproductive parameters in rats, or the embryofoetal development in rats and rabbits. In neurotoxicity studies, effects occurred in the functional observational battery, without histopathological findings in the

nervous tissues. Several studies were performed with metabolites of imidacloprid, mainly on the nitrosimine (M07) which was negative in mutagenicity testing and didn't show a higher acute or subchronic toxicity in rats, compared with imidacloprid. Based on the available toxicological results, the impurity 1, observed in higher level in the technical specification than in the toxicological batches, was considered as non relevant.

The acceptable daily intake (ADI) was 0.06 mg/kg bw/day based on the chronic rat study, the acceptable operator exposure level (AOEL) was 0.08 mg/kg bw/day based on the 90-day dog study supported by the subchronic rat neurotoxicity study, and the acute reference dose (ARfD) was 0.08 mg/kg bw/day based on the 90-day dog study. All reference values were derived with a safety factor of 100.

The agreed dermal absorption values for Confidor SL 200 were 0.3% for the concentrate and 8% for the dilution, whereas the default value of 100% was adopted for Gaucho FS 600 in the absence of experimental data. The estimated operator exposure is below the AOEL for Confidor SL 200 without the use of personal protective equipment whereas it is above the AOEL for Gaucho FS 600 even with the use of coverall and gloves.

The plant metabolism of imidacloprid has been clearly elucidated after foliar, seed and soil treatments. Considering all information available, the residue definition for risk assessment is proposed to include the active substance and all metabolites containing the 6-chloropyridinyl moiety. A residue definition for monitoring was not agreed during the peer review process. EFSA is however of the opinion that 2 options are possible (either parent compound or the same residue definition as for risk assessment).

A sufficient number of field supervised residue trials is available in support of all representative uses. These data allow assessing acute and chronic consumer exposure. They also provide appropriate information for setting MRLs in accordance with the 2 options proposed for the residue definition. No significant transfer of soil residues to rotational crops is expected under practical conditions.

No change in the nature of residues is expected under processing.

Livestock may be exposed to residues of imidacloprid and its metabolites, but the metabolism and feeding studies demonstrate that the transfer of residues to animal commodities is limited and below the limit of quantification of analytical methods.

No risk for the consumer has been identified under acute or chronic exposure to residues resulting from the representative uses of imidacloprid. This conclusion needs however to be consolidated by further information confirming that the metabolism of the compound in plants does not lead to compounds of particular toxicological concern.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level with the exception that, there are data gaps identified, that need to be filled before the soil exposure assessment can be finalised (assessment of potential for accumulation in soil is not finalised). For the applied for intended uses, the potential for groundwater exposure by imidacloprid or its soil residues above the parametric drinking water

limit of 0.1 µg/L, is low. In territories where significant periods of anaerobic soil conditions occur, further data on the anaerobic soil metabolite M09 are required.

The first-tier TERs for birds for the uptake of sugar beet seed pellets as a food item and as grit were significantly below the Annex VI trigger values. The suggested refinements based on the low attractivity as food items and the low availability of sugar beet seed pellets (provided a high drilling efficiency leaving only 0.17% of the seed pellets on the soil surface and spillages are removed from the soil surface) was accepted and the risk to birds was considered as low. However the suggested refinements of the risk assessment for granivorous mammals were not sufficiently supported by data and therefore rejected by the experts. A data gap was identified for the applicant to refine the risk to granivorous mammals. The risk to medium herbivorous mammals from uptake of residues in sugar beet seedlings was assessed as low but the risk assessment for birds for the uptake of residues in sugar beet seedlings needed refinement. Wood pigeon (*Columba palumbus*) was accepted as a focal species. As a refinement step it was proposed that wood pigeons feed in bouts and one filling of the crop with sugar beet seedlings would constitute 20% of the daily food intake. This was used as a crop-filling factor of 0.2 in the exposure calculation. However it was noted by the experts that the birds may feed several times in one day on the same field and considerations of metabolic processes was missing. An open point was identified by the experts for the RMS to include information on the toxicokinetics to support the risk refinement. The RMS noted in addendum 6 (not peer-reviewed) that the available studies on the metabolic processes cannot be used to support the suggested use of the crop limiting factor of 0.2.The RMS proposed using the crop-limiting factor of 0.2 also for the short-term and long-term risk assessment. This was not accepted and it was proposed that real PD data would be a more appropriate refinement step for the short-term and long-term risk assessment. The suggested PT value of 0.1 was rejected by the experts because it was not sufficiently justified by data. The experts concluded that a high risk to birds from uptake of sugarbeet seedlings cannot be excluded for the representative use.

The first-tier TER values were below the triggers for insectivorous birds for the uses in tomatoes and orchards. The applicant suggested a PT of 0.61 for blue tit (*Parus caeruleus*) in orchards and 0.1 for yellow wagtail (*Motacilla flava*) in tomato. An insect residue study was submitted and discussed in the expert meeting. The results of the study were considered as not reliable by the experts. The PD refinements (relative proportion of small and large insects) were accepted by the experts. The suggested PT value for yellow wagtail was not supported by data and hence rejected by the experts as well as the PT to refine the acute risk of blue tit. The TERs based on accepted refinements indicate a low risk to insectivorous birds for the use in tomato but the acute TER for blue tits is below the trigger of 10 requiring further risk refinements for the use in orchards.

The first-tier acute and long-term TERs for herbivorous mammals were below the Annex VI trigger values of 10 and 5. The risk to herbivorous mammals from spray application in tomatoes was considered as low since tomatoes are not attractive as a food source. The risk assessment for herbivorous mammals in orchards resulted in TERs above the trigger taking interception factors into account and also residue decline to refine the long-term risk assessment.

The risk to herbivorous birds and mammals from uptake of plant metabolites is considered as covered by the risk assessment for imidacloprid.
The lowest endpoints from the tested aquatic organisms were observed for *Chironomus riparius*. The spray formulation Confidor SL 200 was tested with *Chironomus riparius*. The toxicity of formulated imidacloprid was similar to technical imidacloprid. Testing with the granular formulation Gaucho FS 600 Uncoloured was considered as not necessary since aquatic organisms are expected to be exposed to the active substance but not to the formulation. The TER values based on maximum PECsw of the worst case FOCUSsw scenario R3 were well above the Annex VI triggers for fish, daphnids and algae. The acute and chronic TER for *Chironomus riparius* were below the Annex VI trigger of 10. The experts agreed that the endpoints from the mesocosm of 0.6 µg imidacloprid/L should be used in the risk assessment. No agreement was reached on the safety factor which should be applied. It was proposed that MSs use a safety factor of 1-3 in combination with the NOEC of 0.6 µg imidacloprid/L. The TER values based on the endpoint of 0.6 µg imidacloprid/L and FOCUS step3 PECsw were in the range of 0.09 and 1 indicating a high risk to aquatic insects for the uses in tomatoes and apples. The TERs for the use as a seed treatment were >3 suggesting a low risk. With no-spray buffer zones of 20 m a TER of ≥1 is achieved in the full FOCUS step4 drainage scenarios (D3, D4, D5) and in the run-off scenarios R1, R2, R3 (without additional run-off mitigation) and R4 (including 50% run-off mitigation) for the use in orchards. A TER of ≥3 was reached in none of the full FOCUS step4 scenarios. The drainage scenario D6 resulted in a TER of ≥1 with spray drift reduction by 95% (equivalent to 35-40 m no-spray buffer zone) but no full run-off scenario resulted in a TER ≥1 for the use in tomatoes. If run-off is mitigated by 90% then the TERs were ≥1. However none of the scenarios except R3 resulted in TERs ≥3.

The metabolites M01, M07, were about 1 order of magnitude acutely less toxic and the metabolites M09, M12, M16 and M23 were more than 2 orders of magnitude less chronically toxic to *Chironomus riparius* than imidacloprid. The TER values based PECsw values from FOCUSsw scenario R3 (which resulted in highest PECsw values for imidacloprid) were above the trigger of 100 except for metabolite M07 where a TER of 46 was observed. It is concluded that the risk from metabolites is low for all representative uses and that the risk from metabolite M07 is covered by the risk mitigation required for imidacloprid. No toxicity data were made available for the photolysis metabolite M14. The risk from this metabolite to aquatic organisms needs to be addressed.
The risk of bioaccumulation from imidacloprid and its metabolites which are predicted to reach surface water is considered as low.
Imidacloprid is acutely very toxic to bees. In addition to the standard acute toxicity tests also chronic tests and studies to investigate sublethal effects (bee behaviour) were conducted. The HQ values for oral and contact exposure were far in excess of the HQ trigger value of 50 indicating a high risk to bees from the use as a spray application in orchards and tomatoes. Imidacloprid has a distinct systemic mode of action. Therefore the uptake in plants from soil/seed treatment applications was investigated in different crops. Imidacloprid is preferentially translocated to leaves and shoots and to a much lower extend to the reproductive organs. No major soil metabolites were detected in the soil degradation studies. Bees would therefore only be exposed to imidacloprid residues in succeeding

crops. The RMS presented a TER calculation based on NOEC values (acute and chronic lethal effects, behavioural impacts including bee hive development) and residue levels in nectar and/or pollen of <5 ppb resulting in TER values of >9.2, >10, >4.8 and >4 suggesting a low risk to bees from the representative use as a seed treatment. Furthermore sugar beet is harvested before flowering hence the risk to bees is expected to be low from the use as a seed treatment in sugar beet.

The risk from exposure to honeydew excreted from aphids was considered as low based on the argumentation that the acute oral LD_{50} for aphids is several orders of magnitude lower than for bees and hence it would be highly unlikely that aphids would survive exposure to imidacloprid at concentrations in sap which could lead to the excretion of honeydew which is toxic to bees. The line of argumentation was agreed by the experts but it was not clear how the toxicity value for aphids was derived and the experts suggested a data gap for the applicant to clarify this point.

Overall it is concluded that the spray applications of imidacloprid pose a high risk to bees. Risk mitigation is required for the use in orchards. The risk to bees is considered to be low if the product is not applied during flowering and if flowering weeds are removed/mown before the application. However it should be noted that bees potentially foraging in the off-crop area would still be exposed via spray drift and hence not be protected by the suggested risk mitigation measure. Flowering tomato plants are visited by honey-bees and other pollinators. The risk mitigation suggested for orchards is not an option for the use in tomatoes since the tomato plants flower almost continuously. The RMS commented that risk mitigation measures may be identified.

The risk mitigation suggested for orchards is not an option for the use in tomato.

The spray application of imidacloprid will cause severe impacts on non-target arthropods in the in-field and off-field area. However in semi-field and field studies it was demonstrated that recolonisation of the in-field area is possible. The available data suggest that ageing of residues of 273 days is required in order not to be hazardous to larvae of *Poecilus cupreus*. A high risk to soil dwelling arthropods cannot be excluded for the seed treatment use. The available semi-field test with *P. cupreus* was conducted at too low concentrations of imidacloprid to allow a conclusion on the risk from the representative use in sugar-beet.

The first tier risk assessment for earthworms resulted in TERs below the trigger. Field studies were submitted. However it was not clear whether the application pattern in the field studies were the same as suggested in the GAP and whether the plateau PECsoil is covered. An open point was set in the meeting for the RMS to check whether the exposure in the field studies were in accordance to the GAP. The RMS confirmed that the application patterns were different from the representative uses but suggest that the application rates of 133 g a.s./ha (seed treatment) and 150 g a.s./ha (spray application) would cover the representative uses. However the estimated PECsoil in the field studies (0.1773 mg a.s./kg and 0.2 mg a.s./kg) are below the accumulated maximum PECs. Therefore uncertainty remains with regard to the long-term risk to earthworms. This uncertainty needs to be addressed further. Organic matter breakdown was not affected in litterbag studies with the spray formulation Imidacloprid SL 200 and the seed treatment formulation Gaucho FS 600. However the maximum PECsoil values calculated are about 2-3 times higher than the concentrations in the litterbag studies. Therefore it cannot be concluded that the risk to organic matter breakdown is addressed.

No adverse effects were observed in a test with technical imidacloprid and the predatory mite *Hypoaspis aculeifer* at the highest tested application rate of 120 g a.s./ha. The NOEC observed for technical imidacloprid and *Folsomia candida* was 1.25 mg a.s./kg soil The endpoint observed for the formulations were lower compared to technical imidacloprid and the TERs for the formulations are below the trigger of 5 if the NOECs are compared to the accumulated maximum PECsoil concentrations indicating a potential high risk to soil dwelling arthropods. The risk from the metabolites M06 and M07 was assessed as low. The risk to non-target soil micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

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

- The risk assessment for granivorous birds is based on the assumption of a high drilling efficiency and that spillages are removed from the soil surface. Appropriate labelling should ensure these conditions.
- A safety factor of 1-3 was suggested by the experts to be applied to the endpoint from the mesocosm study. A no-spray buffer zone of at least 20 m is required to achieve a TER of ≥ 1 in the full FOCUS step 4 scenarios D3, D4, D5, R1 for the use in apples (the trigger of ≥ 1 was not exceeded in the run-off scenarios R2, R3, R4. The TER of ≥ 3 was not reached in a full FOCUS step4 scenario. The drainage scenario (D6) resulted in a TER of 0.96 without spray drift reduction and a TER of 1.3 was achieved with 95% spray drift reduction for the use in tomato. Without run-off mitigation no full run-off scenario (R2, R3, R4) resulted in a TER ≥1 including spray drift reduction of 95% (equivalent to a no-spray buffer zone of 30 – 40 m).
- The risk to bees needs mitigation. For the use in orchards it should be ensured through appropriate labelling that the product is not applied during flowering of the crop and that flowering weeds are removed.

Critical areas of concern

- The estimated operator and worker exposure using the SeedTropex model and with a default dermal absorption value of 100% is above the AOEL for Gaucho FS 600 with the use of coveralls and gloves.
- The risk to birds and mammals from the use in orchards and the use as a seed treatment in sugar beet needs further refinement.
- A high risk for aquatic organisms is indicated for the representative uses in orchards and tomatoes. Substantial risk mitigation measures are required to reduce spray drift and run-off to achieve TERs above the trigger of 1 in some of the FOCUS step4 scenarios. 95% spray drift mitigation (equivalent to a no-spray buffer zone of 30 - 40 m) combined with 90% run-off mitigation are not sufficient as risk mitigation measures if a TER trigger of 3 is applied.
- A high risk to bees is indicated for the spray applications of imidacloprid. Risk mitigation is suggested for the use in orchards.

- A high risk to soil (and soil surface) dwelling arthropods cannot be excluded for the representative uses evaluated.
- The risk assessment to soil dwelling organisms cannot be finalised because the assessment of soil accumulation is not finalised.

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

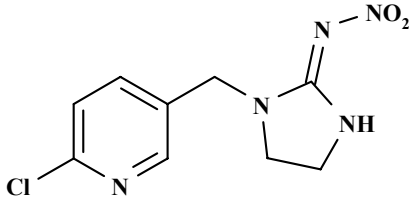
(Abbreviations used in this list are explained in appendix 2)

Appendix 1.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Imidacloprid
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*(E)*-1-(6-Chloro-3-pyridinylmethyl)-*N*-nitroimidazolidin-2-ylideneamine
Chemical name (CA) ‡	1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine
CIPAC No ‡	582
CAS No ‡	138261-41-3
EC No (EINECS or ELINCS) ‡	Not available
FAO Specification (including year of publication) ‡	970 g/kg [582/TC (May 2006), applicable to Bayer CropScience]
Minimum purity of the active substance as manufactured ‡	970 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula ‡	$C_9H_{10}ClN_5O_2$
Molecular mass ‡	255.7 g/mol
Structural formula ‡	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	144 °C (99.9 %)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	Decomposition starts at approx. 230 °C (99.5 %)
Appearance (state purity) ‡	Colourless crystals (99.8 %) or cream coloured powder (98.5 %)
Vapour pressure (state temperature, state purity) ‡	20 °C: 4 x 10^{-10} Pa 25 °C: 9 x 10^{-10} Pa extrapolated from measurement between 50 to 70 °C (99.9 %)
Henry's law constant ‡	1.7 * 10^{-10} Pa m3 mol-1 (20 °C)
Solubility in water (state temperature, state purity and pH) ‡	613 mg/L (demineralised water, pH 5.5, 20 °C), 607 mg/L (pH 4, 20 °C) 601 mg/L (pH 9, 20 °C) (99.9 % for all) independent of the pH in the range between 4 and 9.
Solubility in organic solvents ‡ (state temperature, state purity)	Solvent — Solubility (20 °C) *n*-Hexane — < 0.1 g/L Toluene — 0.69 g/L Dichloromethane — 67 g/L 2-Propanol — 2.3 g/L Acetone — 50 g/L Ethylacetate — 6.7 g/L Acetonitrile — 50 g/L Dimethylsulfoxide — > 200 g/L Dimethylformamide — > 200 g/L (97.2 % for all)
Surface tension ‡ (state concentration and temperature, state purity)	72.20 mN/m (458.91 mg/L) at 20 °C (99.9 %)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{o/w}$ = 0.57, demineralised water, 21 °C (99.8 %)
Dissociation constant (state purity) ‡	No pk_a in aqueous systems under the test conditions
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	λmax (nm) — ε (L.mol^{-1}.cm^{-1}) 212 — 13346 270 — 22054 ε at 290 nm >10.
Flammability ‡ (state purity)	Not highly flammable.
Explosive properties ‡ (state purity)	Not explosive (98.2 %)
Oxidising properties ‡ (state purity)	not oxidising (96.9 %)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of representative uses evaluated (Imidacloprid) *

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min - max (l)	water L/ha min - max	g as/ha min - max (l)		
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	1. 70 2. 105	14	[1]
Tomato	Southern Europe	Confidor	F	*aphids, white flies, leaf beetle*	SL	200	SPI	BIF	2	14	5	1000	100	3	[4]
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.	[2] [3] Seed rate 1.3 U/ha 1 U = 100,000 pelleted seeds

n.a. not applicable (fixed with time of seeding); BEZ/PIL = seed tretment; BIF = at infestation; * mCH/ha = Crown Height/ha

[1] For imidacloprid this is due to unacceptable risks to non-arthropods for broadcast application in the field. Also an unacceptable acute risk is shown for insectivorous birds.

[2] The risk to birds and mammals needs further refinement.

[3] Operator exposure using the SeedTropex model and the default dermal absorption value of 100% is above the AOEL even with the use of personal protective equipment.

[4] A high risk to bees is indicated, a high risk to soil dwelling non-target arthropods

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s). (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 suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (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 at 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 application 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

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.2. Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Open
Food of animal origin		Sum of imidacloprid and its metabolites imidacloprid-5-hydroxy (M1) and imidacloprid-olefine (M6), expressed as imidacloprid
Soil		Imidacloprid
Water	surface	Open
	drinking/ground	Imidacloprid
Air		Imidacloprid

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS 0.02 mg/kg (apple, cabbage head, citrus, cotton seed, potato, tomato, rape seed, wheat grain), 0.20 mg/kg (hop cones, dried) 0.01 mg/kg (sunflower, corn) 0.005 mg/kg (honey, rape, sunflower) LOQ for each analyte (i.e. imidacloprid, M01 and M06) separately. Open
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS 0.033 mg/kg (fat, meat, liver, kidney, eggs), 0.010 mg/kg (milk) LOQ for each analyte (i.e. imidacloprid, M01 and M06) separately.
Soil (analytical technique and LOQ)	LC-MS/MS 0.005 mg/kg HPLC/UV 0.007 mg/kg HPLC/UV 0.01 mg/kg
Water (analytical technique and LOQ)	HPLC/UV 0.03 µg/L (drinking and surface water) LC-MS/MS 0.10 µg/L (drinking water) LC-LC/UV 0.05 µg/L (drinking and surface water)
Air (analytical technique and LOQ)	HPLC-UV 5 µg/m³
Body fluids and tissues (analytical technique and LOQ)	No method for blood available. Data gap. For tissues see food of animal origin

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	none

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.3. Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid and extensive (> 92 %), based on urinary and biliary excretion and tissue residues.
Distribution ‡	Widely distributed, highest residues after 48 hr found in liver, kidney, lung and skin
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapid and virtually complete (73 – 75 % in urine within 48 hr, 20-25 % in faeces,); biliary excretion of up to 36 % suggesting significant enterohepatic circulation
Metabolism in animals ‡	Extensive with at least 16 metabolites occurring; Main pathways: oxidative cleavage with subsequent conjugation and hydroxylation of the imidazolidine ring
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound and imidacloprid nitrosimine (M07)
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	~ 500 mg/kg bw	
Mouse LD_{50} oral ‡	131 mg/kg bw	T; R25
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 0.069 mg/L (aerosol) > 5.33 mg/L (dust) (4-h nose-only exposure, maximum technically attainable concentration)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Not sensitising (M & K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Reduced body weight gain in rodents and dogs; liver (clinical chemistry and histopathological findings) in rats; CNS (trembling and tremors) in dogs	
Relevant oral NOAEL ‡	9.3 mg/kg bw/day (90-d, rat neurotoxicity study) 8 mg/kg bw/day (28 day and 90-day, dog)	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	41 mg/kg bw/day (1-yr dog) 86 mg/kg bw/day (107-day, mouse)	
Relevant dermal NOAEL ‡	1000 mg/kg bw/day (3-wk, rabbit)	
Relevant inhalation NOAEL ‡	0.03 mg/L (4-wk, rat, dust, 6 h/day, 5 d/wk)	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No evidence for genotoxicity	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Reduced body weight gain (rats, mice); thyroid (mineralisation in the follicular colloid) in rats; liver (blood chemistry, histopathology) in mice	
Relevant NOAEL ‡	5.7 mg/kg bw/day (2-yr, rat) 208 mg/kg bw/day (2-yr, mouse)	
Carcinogenicity ‡	No evidence for carcinogenicity	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Weight gain reduction in parents and pups.	
Relevant parental NOAEL ‡	20 mg/kg bw/day (2-gen, rat)	
Relevant reproductive NOAEL ‡	50 mg/kg bw/day (2-gen, rat)	
Relevant offspring NOAEL ‡	20 mg/kg bw/day (2-gen, rat)	

Developmental toxicity

Developmental target / critical effect ‡	Increased prenatal litter loss, reduced foetal weight, delayed ossification (rabbit) Skeletal anomalies (wavy ribs) (rat)	
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw/day Rabbit: 8 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 30 mg/kg bw/day Rabbit: 24 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Clinical signs and neurobehavorial effects ascribed to acute cholinergic toxicity; NOAEL 42 mg/kg bw	
Repeated neurotoxicity ‡	No evidence of neurotoxicity; subchronic	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	effects related to the general toxicity; NOAEL 9.3 mg/kg bw/day (90-day rat)	
Developmental neurotoxicity ‡	Decreased motor activity in pups; NOAEL 30 mg/kg bw/day	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Acute oral toxicity combination studies with cyfluthrin, methamidophos and flumethrin did not reveal evidence of synergistic or superadditive effects of imidacloprid and these compounds.
Studies performed on metabolites or impurities ‡	Metabolite M07 (nitrosimine) Negative in mutagenicity tests (in vivo/in vitro); Rat oral LD_{50} 1980 mg/kg bw; Mouse oral LD_{50} 200 mg/kg bw; 90-day rat study: NOAEL 13 mg/kg bw/day. Metabolites M12 (-urea), M06 (-olefine) and M09 (-desnitro): Ames test negative; Rat oral LD_{50} 1820 mg/kg bw (M12), 1100 mg/kg bw (M06) and 280 mg/kg bw (M09). Studies with the impurity 1: LD50 (rat and mouse, oral) > 2000 mg/kg bw; LD50 (rat and rabbit, dermal) > 2000 mg/kg bw; not irritant to skin and eye, not skin sensitiser; 90-d, rat, oral: NOAEL 316 mg/kg bw/day; no genotoxic potential; 2-gen, rat: no evidence of reproductive effects, parental NOAEL 300 mg/kg bw/day (based on bw ↓); dev. tox., rat and rabbit: NOAEL 316 mg/kg bw/day for maternal and developmental (foetal wt ↓, delayed ossification) toxicity, no evidence of teratogenicity. Impurity 3: Ames test negative

Medical data ‡ (Annex IIA, point 5.9)

No evidence of adverse effects, some formulations sensitising to humans

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.06 mg/kg bw/day	Rat, 2-yr	100
AOEL ‡	0.08 mg/kg bw/day	Dog, 28- & 90-day supported by subchronic rat neurotoxicity study	100
ARfD ‡	0.08 mg/kg bw	Dog, 90-day (acute effects) supported by the developmental study in the rabbit	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Representative formulation: Confidor SL 200	0.3 % (concentrate) and 8 % (diluted formulation), based on an *in vitro* study on human skin with Confidor OD 200
Representative formulation: Gaucho FS 600	No information available. Default value 100%.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Confidor SL 200: German model, without PPE: high crop 14 %, field crop 6 % of AOEL, UK POEM, without PPE: high crop 15 %, field crop 7 % of AOEL, Greenhouse, without PPE: 27 % of AOEL Gaucho FS 600: SeedTropex (with PPE, worst case for seed pelleting): seed treatment 552 % of AOEL,
Workers	Confidor SL 200: high crop 12.6 % of AOEL, field crop 6.0 % of AOEL Gaucho FS 600: SeedTropex, loading and sowing of treated seed: 129 % of AOEL
Bystanders	Confidor SL 200: max. 6 % of AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Substance classified (name)	T; R25 (Toxic if swallowed)

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.4. Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Foliar spray: apple, potato, tomato, tobacco Granular application: eggplant, potato, rice Seed treatment: rice, corn, cotton
Rotational crops	Chard, wheat, red beet
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Standard hydrolysis studies in buffer solutions available
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring	Residue definition was discussed at PRAPeR 35, but no agreement was reached.
Plant residue definition for risk assessment	Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid
Conversion factor (monitoring to risk assessment)	Not concluded as a residue definition for monitoring was not agreed.

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goat, laying hen
Time needed to reach a plateau concentration in milk and eggs	3 days (according to livestock feeding study)
Animal residue definition for monitoring	Sum of imidacloprid and its metabolites imidacloprid-5-hydroxy (M1) and imidacloprid-olefine (M6), expressed as imidacloprid
Animal residue definition for risk assessment	Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid
Conversion factor (monitoring to risk assessment)	None (not needed, residue levels very low in animal commodities)
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Residues in succeeding crops do not exceed 0.01 mg/kg

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Wheat grain, wheat forage, wheat straw, cotton seed, tomato, cauliflower, lettuce, orange whole fruit, orange dried pulp, orange juice, orange oil, sugar beet root, sugar beet leaf, barley grain, barley forage, barley straw, sunflower seed, hops green cone, hops dried cone > 24 months Milk, fat (bovine), kidney (bovine), egg, liver (poultry), muscle (poultry) > 12 months

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	0.53 mg/kg	No	-
Potential for accumulation (yes/no):	No	No	-
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	-
	Feeding studies (lactating cows, 5 mg/kg diet) Total imidacloprid residue levels in matrices : Mean (max) mg/kg		
Muscle	<0.02	not required	
Liver	0.05	not required	
Kidney	0.03	-	
Fat	<0.02	not required	
Milk	<0.02		
Eggs		not required	

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Apple	Northern	< 0.05 (7), 0.05, 0.06, 0.06, 0.08, 0.08 mg/kg	Total imidacloprid	0.2 mg/kg	0.08 mg/kg	0.05 mg/kg
	Mediterranean	< 0.05, 0.06, 0.07, 0.08, 0.08, 0.13, 0.17, 0.23 mg/kg	Total imidacloprid	0.5 mg/kg	0.23 mg/kg	0.08 mg/kg
Tomato	Glasshouse	0.06, 0.06, 0.07, 0.08, 0.09, 0.10, 0.10, 0.11, 0.14, 0.15, 0.19, 0.29 mg/kg	Total imidacloprid	0.5 mg/kg	0.29 mg/kg	0.1 mg/kg
	Mediterranean	< 0.05 (5), 0.05, 0.07, 0.11	Total imidacloprid	0.2 mg/kg	0.11 mg/kg	0.05 mg/kg
Sugar beet	Northern	<0.05(15) mg/kg	Total imidacloprid	0.05* mg/kg	0.05 mg/kg	0.05 mg/kg
	Mediterranean	< 0.05(5) mg/kg	Total imidacloprid	0.05* mg/kg	0.05 mg/kg	0.05 mg/kg
Bananas (Import tolerance)	Import	< 0.01(10), 0.01, 0.01, < 0.05 (4) mg/kg	Total imidacloprid	0.05* mg/kg	0.05 mg/kg	0.05 mg/kg
Grapes (Import tolerance)	Import	<0.05, 0.05, 0.06(3), 0.11(3), 0.12, 0.12, 0.16, 0.17, 0.19, 0.20, 0.21, 0.61 mg/kg	Total imidacloprid	1 mg/kg	0.61 mg/kg	0.115 mg/kg

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Mango (Import tolerance)		< 0.05 (3), 0.11, 0.15 mg/kg	Total imidacloprid	0.2 mg/kg	0.15 mg/kg	0.05 mg/kg
Pecan (Import tolerance)	Import	< 0.01(9), 0.011, < 0.05(6) mg/kg	Total imidacloprid, foliar spray application	0.05* mg/kg	0.05 mg/kg	0.01 mg/kg
	Import	< 0.05(7) mg/kg	Total imidacloprid, soil application	0.05* mg/kg	0.05 mg/kg	0.05 mg/kg
Citrus fruits (Import tolerance)	Import	0.14, 0.15, 0.17, 0.17, 0.18, 0.18, 0.21, 0.21, 0.26, 0.26, 0.28, 0.29, 0.30, 0.30, 0.31, 0.32, 0.34, 0.36, 0.36, 0.37, 0.38, 0.61, 0.62 mg/kg	Total imidacloprid	1 mg/kg	0.62 mg/kg	0.29 mg/kg
The data on bananas, grapes, mangoes, pecans and citrus fruits were not peer-reviewed as these uses are not part of the notified uses.						

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.06 mg/kg bw/d
TMDI (% ADI) according to WHO European diet	7 % (Including contribution of proposed import tolerances)
TMDI (% ADI) according to national (to be specified) diets	10 % German diet (Including contribution of proposed import tolerances)
IEDI (WHO European Diet) (% ADI)	1.4 % (Including contribution of proposed import tolerances)
NEDI (specify diet) (% ADI)	2.4 % German diet (Including contribution of proposed import tolerances)
Factors included in IEDI and NEDI	none
ARfD	0.08 mg/kg bw
IESTI (% ARfD)	See NESTI calculations
NESTI (% ARfD) according to national (to be specified) large portion consumption data	UK diet: Apples : 17% (toddlers) Tomatoes : 15% (toddlers)
Factors included in IESTI and NESTI	none

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Apple/washed	3	0.9		90
Apple/juiced	5	0.66		56
Apple/sauce	4	0.75		
Apple/dried	2	0.87		
Apple/pomace, wet	1	1.6		46
Apple/pomace, dry	3	5.2		60
Tomato/washed	1	2.1		
Tomato/preserve	1	0.91		
Tomato/juice	3	1.37		
Tomato/ketchup	2	1.8		
Tomato/puree	2	2.3		
Tomato/paste	3	5.73		
Tomato/pomace, wet	2	1.54		
Tomato/pomace, dry	2	4.3		

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Citrus fruit/pulp	3	0.31		
Citrus fruit/peel	3	2.78		
Citrus fruit/juice	4	0.28		<1
Citrus fruit/marmalade	2	0.625		
Citrus fruit/oil	1	0.26		<1
Citrus fruit/molasses	1	6.47		21
Citrus fruit/pulp, dried	1	7.47		49
Grape bunches/must	4	1.53		
Grape bunches/wine	4	1.17		
Grape bunches/washed berries	2	<0.5		
Grape bunches/juice	3	0.73		94
Grape bunches/retentate	2	<0.5		
Grape bunches/pomace, wet	5	2.23		1
Grape bunches/pomace, dry	1	4.3		9
Grape bunches/raisin	2	1.05		12
The data on citrus and grapes were not peer-reviewed as these uses are not part of the notified uses.				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Plant products	No proposal as no agreement was reached on the residue definition
Animal products	0.1* mg/kg

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.5. Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡	Investigated: pyridinyl-^{14}C-methylene labelled imidacloprid Loamy sand: 10 % after 100 days (study end) Silt loam 6.4 % after 100 days (study end) Sandy loam: 3.3 % after 100 days 7.4 % after 366 days (study end) Sandy loam: 2.7 % after 100 days 4.9 % after 366 days (study end) Sandy loam: 16.6 % after 91 days 20.3 % after 126 days (study end)
Non-extractable residues after 100 days ‡	Investigated: pyridinyl-^{14}C-methylene labelled imidacloprid Loamy sand: 21.6 % after 100 days (study end) Silt loam 21.5 % after 100 days (study end) Sandy loam: 16.6 % after 100 days 23.0 % after 366 days (study end) Sandy loam: 25.0 % after 100 days 39.5 % after 366 days (study end) Sandy loam: 26.9 % after 91 days 28.1 % after 126 days (study end)
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	Investigated: pyridinyl-^{14}C-methylene labelled imidacloprid In all studies (soils see above): 7 metabolites NTN33893-olefin (1.8 % TAR after 100 d), NTN33893-ring-open-nitroguanidine (max. 3.4 % TAR after 77 d) and NTN33893-desnitro (1.6 % TAR after 201 d).

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	no study conducted but an anaerobic water/sediment-study with a soil like sediment is available Investigated: pyridinyl-^{14}C-methylene imidacloprid DT_{50lab} (20 °C, anaerobic): 36 days total system DT_{90lab} (20 °C, anaerobic, calc. by RMS): 89 days total system, water 107 d /best fit, 1st order, Timme & Frehse) parent: water: 11.8 % TAR after 120 days, < 0.1 % after 358 days (study end) sediment: 16.8 % after 14 d, 1.4 % after 120 d, < 0.1 % after 358 days (study end) metabolite NTN33893-desnitro: water: 20 % TAR after 60 days, 14.3 % after 358 days (study end) sediment: 2.2 % after 120 days, 1.5 % after 358 days (study end). non-extracted: 16 % after 120 d, 22.6 % after 358 d.
Soil photolysis ‡	Investigated: pyridinyl-^{14}C-methylene labelled imidacloprid in sandy silt loam/sandy loam. Continuous irradiation 15 d, Xenon lamp, $3.24x10^{17}$ photon/sec.,

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	25 °C: DT_{50}:38.9 d, best fit according to Timme and Frehse, formal root function 2nd order; normalised to sun light, and natural conditions , 40°N: 171 days. Recoveries in % of total applied radioactivity: active substance: 58.5-103 % at all sampling dates; 61.5 % after 15 days (study end) metabolites: max. 6.3 % after 15 days (NTN33893-5-hydroxy), other metabolites < 5 %, 2 unknown 2.2 %; 1.3 % TAR

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	Lab. DT_{50} aerob: Imidacloprid, best fit and 1st order, and standardised to field capacity according to FOCUS
Laboratory studies (range or median, with n value, with r2 value) ‡	DT_{50lab} (20 °C, aerobic): measured at 40 % WHC Loamy sand: best fit 188 d (2nd order); 1st order 154 Silt loam: best fit 248 d (2nd order); 1st order 193 Sandy loam: best fit 341 d (sqrt 1st order); 1st order 186 Sandy loam: best fit 77 d (sqrt 1st order); 1st order 106 geometric mean: best fit 187 d; 1st order 156 d 1st order fit standardised to field capacity (according to FOCUS): Loamy sand 128.4 d Silt loam 129.3 d Sandy loam 117.0 d Sandy loam 98.9 d geometric mean DT_{50lab}: 117.7 d DT_{90lab} (20 °C, aerobic): not determined DT_{50lab} (10 °C, aerobic): calculated from 1st order 20 °C values using Q10 of 2.2 Loamy sand 339 d Silt loam 425 d Sandy loam 409 d Sandy loam 233 d geometric mean DT_{50lab}: 343 d DT_{50lab} (20 °C, anaerobic): not determined, reference to anaerobic water/sediment study (saturated zone)
Degradation in the saturated zone	No data available, not required

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Field studies (state location, range or median with n value) ‡

$DT_{50}f$

DT_{50f} (in days)
spray application to bare soil
(two values per site reflect two dosing levels, which do not constitute independent trials)

NE (Germany)	soil	best fit	1st order	r²
Kirchlauter	sandy loam	180	216	0.85
Kirchlauter	sandy loam	142	178	0.82
Swisttal Hohn	silt loam	140	185	0.88
Swisttal Hohn	silt loam	173	208	0.92
Burscheid-Höfchen	silt loam	79	131	0.61
Burscheid-Höfchen	silt loam	62	104	0.88
Worms	loam	196	228	0.74
Worms	loam	151	197	0.50
Laacher Hof	sandy loam	160	186	0.86
Laacher Hof	sandy loam	119	152	0.81
geom. mean (d)			174	

seed treatment application

Germany	soil	best fit	1st order
Swisttal Hohn	silt loam	102	89
Laacher Hof	sandy loam	125	94

spray application to bare soil

SE	soil	best fit	1st order
Italy	silty clay	183 d [2]	288
France	silty loam	63 d [1]	111
Italy	loamy sand	28 d [1]	40
Spain	silty clay loam	77 d [1]	116
geometric mean			110 d

[1] square root 1st order
[2] square root 1.5st order

normalised values according to FOCUS
(spray application to bare soil, trials in NE and SE)

location	DT_{50} (d)
Kirchlauter-Pettstadt	77.9
Swisttal-Hohn	93.9
Burscheid-Höfchen	45.5
Worms-Heppenheim	87.9
Laacher Hof	78.5
Bagnolo di Nogarole Rocca	179.8
St. Etienne du Gres	65.7
Ca Degli Oppi, Italy	27.0
Castellarnau	58.5
median	77.9
geometric mean	70.5

DT_{90f}

DT_{90f}:
spray application to bare soil
(two values per site reflect two dosing levels, which do not constitute independent trials)

NE (Germany)	soil	1st order
	sandy loam	717*)

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	sandy loam	591[*)]
	silt loam	614[*)]
	silt loam	690[*)]
	silt loam	435[*)]
	silt loam	345
	loam	757[*)]
	loam	654[*)]
	sandy loam	618[*)]
	sandy loam	504[*)]
geometric mean		578 d

SE	soil	1st order
Italy	silty clay	956[*)]
France	silty loam	368
Italy	loamy sand	133
Spain	silty clay loam	385
geometric mean		366 d

[*)] extrapolated value, longer than study duration

Soil accumulation and plateau concentration ‡

Study 1: Germany, apple orchards, 3 test sites, duration 6 years, silt loam (1)/ silty clay (2)/sandy loam (3), annual application rate nearly 105 g as/ha directly onto ground. Considering non-normalised field DT_{50} estimated at 182 days the calculated accumulation factor is 1.027

Study 2, Great Britain, seed dressing of winter barley. 2 study sites, sandy loam, duration 6 years, application rate 56/133 g product (Zelmone 350FS)/ha, soil was cultivated to a depth of 19cm
No agreed peer reviewed endpoint, plateau not reached at the end of the study, data gap identified.

Calculation: theoretical plateau (background concentration directly before annual application) according to SFO kinetics, considering worst case non-normalised field DT_{50} of 288 d
Calculated accumulation factor 1.713.

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Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡	Imidacloprid: K_{oc} 109 – 411, arithmetic mean 225 (n=10) soil — pH — K_{oc} — K_f — 1/n Sand — 5.1 — 411 — 0.956 — 0.783 (98.7 % sand, 0.3 % silt, 1.0 % clay, 0.23 % org .C.) Sandy soil, low humus — 5.6 — 157 — 1.17 — 0.77 (87.8 % sand, 8.7 % silt, 3.5 % clay, 0.75 % org. C.) Sandy loam — 5.2 — 256 — 3.59 — 0.744 (67 % sand, 27 % silt, 6 % clay, 1.4 % org. C.) Sandy loam — 5.7 — 153 — 1.83 — 0.888 (68.3% sand, 24.5 % silt, 7.2 % clay, 1.2 % org. C.) Sandy loam — 6.4 — 235 — 3.17 — 0.782 (72.4% sand, 22.6 % silt, 5.0 % clay, 1.35 % org. C.) Sandy loam — 6.4 — 109 — 1.52 — 0.783 (72.4% sand, 22.6 % silt, 5.0 % clay, 1.4 % org. C.) Sandy loam — 5.6 — 165 — 2.14 — 0.786 (71.6% sand, 21.5 % silt, 6.9 % clay, 1.3 % org. C.) Loamy sand — 4.5 — 292 — 1.02 — 0.878 (79.3 % sand, 15.5 % silt, 5.5 % clay, 0.35 % org.C.) Silt loam — 5.8 — 277 — 4.18 — 0.775 (29.3 % sand, 51.3 % silt, 19.5 % clay, 1.51 % org.C.) Silt soil — 5.3 — 132 — 2.38 — 0.827 (2 % sand, 89 % silt, 9 % clay, 1.8 % org.C.) Silty clay — 7.4 — 212 — 1.36 — 0.851 (15 % sand, 42.3 % silt, 42.7 % clay, 0.64 % org.C.) Loam — 6.5 — 296 — 3.45 — 0.755 (29.3 % sand, 47.2 % silt, 23.5 % clay, 1.16 % org.C.) arithmetic mean, n=12 — 225±87 — 0.80 median — 212
K_d ‡	-
pH dependence (yes / no) (if yes type of dependence) ‡	no

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Studies regarded as not valid, not relevant for the assessment. Lysimeter studies are of higher relevance.
Aged residues leaching ‡	Guideline: BBA IV 4-2, pyridinyl-^{14}C-methylene imidacloprid. 30 and 90 day ageing in the dark, 22 °C, 40 % WHC, Application rate 200 g as/ha. Height 14.5 cm. Soil: Monheim I, sandy loam soil (1.27 % C_{org}, pH 5.2, biomass 264 mg microbial carbon/kg soil at test start). and BBA 2.1 (slightly humous sand, 0.75 % Corg, pH 5.6, 146 - 264 mg microbial carbon/kg soil at test start Percolation 393 mL/48 h. 30 d ageing: < 3 % of applied radioactivity in eluate 90 d ageing: < 2 % of applied radioactivity in eluate Imidacloprid remained mainly in upper column segment: Monheim I, 90 d: 98.3 % of applied radioactivity BBA 2.1, 30 d: 71.4 % segment 1, 28.6 % segment 2 BBA 2.1, 90 d: 70.6 % segment 1, 20.7 % segment 2. Guideline EPA 163-1 Pyridinyl-^{14}C-methylene imidacloprid. 4 different soils 30 day ageing in the dark, 22 °C, 40 % WHC, Application rate 250 g as/ha. Height 30 cm. Soils: sandy loam #411 (75 % sand, 9 % clay, 0.93 % C_{org}, pH 6.2), fine sand #396 (98.7 % sand, 1 % clay, 0.12 % C_{org}, pH 5.1); silty clay loam Illinois #413 (22.7 % sand, 51 % silt, 26 % clay, pH 6.2, Corg 1.92); silty clay loam Kansas #414 (17 % sand, 41 % silt, 42 % clay, pH 5.6, Corg 1.22). Percolation 1200 mL/55 h. <u>Percent of applied radioactivity in leachates:</u> sand #396: 64 % sandy loam #411: 0.8 % silty clay loam #413: 0.4 % silty clay loam #414 dry packed: 9.3 % silty clay loam #414 moist packed: 3.6 % Mobility depends on the soil type. Imidacloprid remained mainly in upper column segments (0-15 cm) of soils containing loam. In soils with high sand content, distribution through column: <u>Percent of applied radioactivity in aged soil layer and per 5 cm segment:</u> sandy loam #411: 16.5/24.1/25.5/19.0/3.2 % silty clay loam #413: 22.6/43.9/18.4/2.7 % silty clay loam #414 dry packed: 21.6/14.4/17.2/12.6/ 8.5/6.9 % silty clay loam #414 moist packed: 18.7/34.6 segment 1+2) /19.0/11.9/4.8 % sand #396: 13.1 % aged layer, 10.6 % (10-15 cm)/ 11.9 % (20-25 cm)
Lysimeter/ field leaching studies ‡	3 lysimeter studies, Germany, soil: Laacherhof Monheim, sandy soil, lysimeter surface: 100 x 100 cm, depth 110 cm. ^{14}C-methylene imidacloprid. <u>1. study</u>: 2 lysimeters; application: 500 g as/ha on potato

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tubers already lying in their planting holes.
Cultural practice: potatoes/winter wheat/winter barley
Precipitation: 800 mm/year. Soil Monheim (72-78.3 % sand, 5.0-9.5 % clay. 0.18-1.35 % C_{org}, pH 6.9-7.1)
Leachate: distribution of radioactivity:

	as-equivalents (µg/L)	eluate (L)
1st year	0.036/0.047	95.5/95.5
1st+2nd year	0.069/0.081	175.2/213.7

Neither parent compound nor any relevant metabolite was detected (LOQ 0.01 µg/L).
In soil: after 2 years 54.6/57.5 % of applied radioactivity; 93 % of that in 0-20 cm soil layer. Extractable residues mainly as: 0.04 mg as/kg 0-20 cm layer; 0.0036 mg as/kg 20-30 cm layer. Below 30 cm as < LOD (0.5 µg/kg).

2. study: 2 lysimeters, study duration 5 years, 2 application as seed treatment: 117 g as/ha (1991); 126 g as/ha (1994). Cultural practice: sugar beet/ winter wheat/ winter barley/ intermediate crop Phacelia/ sugar beet/ winter wheat/ winter barley.
Precipitation: 800 mm/year. Soil Monheim (71.8-79.4 % sand, 11.0-16.5 % silt, 9.7-11.8 % clay. 0.19-1.41 % C_{org}, pH 6.9-7.1): 0-60 cm sandy loam, 60-115 cm loamy sand.
Leachate: distribution of radioactivity:

	as-equivalents (µg/L)	mean	eluate(L)	mean
1st year	0.012/0.020	0.02	94.4/102.6	98
2nd year	0.040/0.091	0.07	231.5/218.0	225
3rd year	0.045/0.104	0.07	281.7/320.2	301
4th year	0.070/0.108	0.09	378.6/334.7	357
5th year	0.062/0.114	0.09	114.4/89.3	102

Neither parent compound nor any relevant metabolite was detected throughout the 5 years (LOQ 0.01 µg/L).
In soil: after 5 years in 0-10, 10-20, 20-30 cm:
in lysimeter 1. 22.6/15.6/4.22 %TAR (0-30 cm 42.4 %)
in lysimeter 2. 21.7/14.0/4.26 %TAR (0-30 cm 39.96 %)
Extracted parent compound:

	in % TAR:	µg as/kg fresh weight soil
0-10 cm	7.685/6.408	13.2/11.0
10-20 cm	5.590/5.611	9.5/9.6
20-30 cm	1.698/1.921	2.7/3.1
30-40 cm	0.323/0.501	0.5/0.8
40-50 cm	0.034/0.162	0.1/0.3
50-60 cm	0.005/0.094	< LOQ/0.1
60-70 cm	< LOQ/0.019	< LOQ
< 70 cm	< LOQ	< LOQ

Residues in plants (total):	2.46 %/1.97 % TAR
Residues in leachates (total)	0.23 %/0.42 % TAR
Total recovery	47.01 %/46.22 % TAR
Loss (CO_2 etc.)	52.99 %/53.78 % TAR

3. study: 2 lysimeters, study duration 2.5 years, 2 application as seed treatment: 90 g as/unit= 117 g as/ha

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(1996); 140 g as/ha (1997). Cultural practice: sugar beet/ winter wheat/ winter barley.
Precipitation: 841 mm/year. Soil Monheim (71.8-79.4 % sand, 11.0-16.6 % silt, 9.7-11.8 % clay. 0.19-1.41 % C_{org}, pH 6.05-6.42): 0-60 cm sandy loam, 60-100 cm loamy sand. 100-115 cm loamy sand.
Distribution of total recovered radioact. (TRR):

	as-equivalents/ leachate (µg/L)	leachate (L)	CO_2 % TRR
1st year	0.018/0.026	133.3/146.7	43/31
2nd year	0.025/0.038	119.8/132.8	32/17
last 6 months	0.038/0.057	28.5/38.5	19/12
total		281.6/318.0	

Imidacloprid and metabolites not analysed, since equivalent-conc. < 0.1 µg/L.

In soil: predominant portion 86 %/89 % of total recovered radioactivity. (TRR) in 0-30 cm soil layer after 2.5 years:
TAR: 0-30 cm 47.6 %/ 45.53 %; 30-60 cm 6.75 %/ 4.6 %; < 60 cm 1.09 %/0.83 %
Besides as metabolites NTN33893-ring open nitro guanidine (Z1) and NTN33893-desnitro (Z2).

	Extractable residues µg/kg soil as equivalents	Z1	Z2
0-10 cm	15.2/13.3	3.3/2.8	1.6/1.2
10-20 cm	16.4/15.0	2.7/2.5	0.4/0.3
20-30 cm	4.7/4.3	0.3/0.3	<LOQ
30-40 cm	1.8/1.1	0.270.2	<LOQ
40-50 cm	0.9/0.4	0.1/0.1	<LOQ
50-60 cm	0.6/0.4	0.1/0.1	<LOQ
60-70 cm	0.2/< LOQ	0.1/<LOQ	<LOQ
< 70 cm	< LOQ/<LOQ	<LOQ	<LOQ
Residues in soil (total)		55.46 %/50.77 % TAR	
Residues in plants (sum all crop):		3.67 %/3.95 % TAR	
Residues in leachate (total)		0.02 %/0.04 % TAR	
Total recovery		59.16 %/54.77 % TAR	
Loss (CO_2 etc.)		38.48 %/43.26 % TAR	

PEC (soil) (Annex IIIA, point 9.1.3)

Sugar beet

Parent

Method of calculation

Seed treatment – single application
DT_{50} (d): 288 days
Kinetics: SFO
Field or Lab: representative worst case from field dissipation studies.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Application data	Crop: Sugar beet Depth of soil layer: 5 cm (20 cm management depth for plateau estimation) Soil bulk density: 1.5 kg/L (default) % plant interception: seed treatment, therefore no crop interception Number of applications: 1 Interval (d): -/- Application rate(s): 117 g as/ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.156		-/-	
Plateau concentration	0.184 mg/kg (theor. plateau)			

Tomatoes (SE)

Parent Method of calculation	DT_{50} (d): 288 days Kinetics: SFO Field or Lab: representative worst case from field dissipation studies.
Application data	Crop: tomatoes Depth of soil layer: 5 cm (20 cm management depth for plateau estimation) Soil bulk density: 1.5 kg/L (default) % plant interception: 1st appl. 50 %, 2nd appl. 70 % Number of applications: 2 Interval (d): 14 d Application rate(s): 100 g as/ha

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.104		-/-	
Plateau concentration	0.123 mg/kg (theor. plateau)			

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Apples

Parent	DT_{50} (d): 288 days Kinetics: SFO Field or Lab: representative worst case from field dissipation studies.
Application data	Crop: apples Depth of soil layer: 5 cm Soil bulk density: 1.5 kg/L (default) % plant interception: 1st appl. 50 %, 2nd appl. 70 % Number of applications: 2 Interval (d): 28 d Application rate(s): 1st appl. 70 g as/ha, 2nd appl. 105 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.086		-/-	
Plateau concentration	0.146 mg/kg (theor. plateau)			

For information, higher, not peer reviewed, not agreed PEC soil based on the field accumulation study in the UK, calculated by EFSA are included in section 4.1.2 of the conclusion.

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature) ‡	pH 5: stable at 25 °, DT_{50} > 1 year
	pH 7: stable at 25 °, DT_{50} > 1 year
	pH 9: slow hydrolysis at 25 °, DT_{50} approximately 1 year
Photolytic degradation of active substance and relevant metabolites ‡	(1) Photolysis artificial light: in sterile water up to 120 min, pH 7, natural sunlight mimic, cut off 290 nm (SUN-TEST apparatus). Conc. 6.31 and 5.18 mg as/L Tested: [pyridinyl-^{14}C-methylene]-imidacloprid Results: - Imidacloprid: absorption coefficient ε = 5714 L/Mole x cm at 295 nm and ε = 20 L/Mole x cm at 363 nm, quantum yield 0.0142 - Imidacloprid: 28.7 % TAR after 120 min. - DT_{50} 57 minutes under test conditions - Environmental DT_{50}, latitude 50° (GC-solar) spring 0.24 d summer 0.17 d - 10° longitude, 50° latitude (Frank & Klöpffer) April-summer 0.4 - 0.28 d November-December 3.1 - 6.73 d

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	(2a) Photolysis artificial light: in sterile buffer solution pH 7 up to 120 min, natural sunlight mimic, cut off 290 nm (SUN-TEST apparatus). Conc. 5.4 mg as/L Tested: [pyridinyl-^{14}C-methylene]-imidacloprid Results: - Imidacloprid: 28.7 % TAR after 2 h - Photo-transformation products after 2 h: NTN33893-desnitro (M09) 17.2 % TAR NTN33893- desnitro olefine (M23) 12.6 % NTN33893-urea (M12) 9.8 % others unknown 8.4 % volatile degradates none Photolysis natural sunlight: 4 and 7 h (greenhouse, Yuki, Japan). Conc. 10 mg as/L Tested: [pyridinyl-^{14}C-methylene]-imidacloprid Results: - Imidacloprid: 60 % was degraded after 4 hours (2b) Photolysis artificial light, study for identification of metabolites, 21 h natural sunlight mimic, cut off 290 nm (SUN-TEST apparatus). Conc. 100 mg as/L: Tested: [pyridinyl-^{14}C-methylene]-imidacloprid Results: - 46.2 % of TAR assigned to parent and degradates NTN33893- ring open guanidine 14.9 % in fraction NTN33893-desnitro 11.0 % in fraction NTN33893-urea minor amounts 6-chloro-nicotinic acid minor amounts (3) Degradation in natural water, water from pond in Norfolk County, Ontario CA Tested: [pyridinyl-^{14}C-methylene]-imidacloprid, nom. concentration 0.7 mg/L Results for non-sterile, light exposed conditions: 6-chloro-nicotinic acid (M14) 16.4 % (123 d), NTN33893-urea (M12) 18.4 % (91 d), NTN33893-desnitro (M09) 82.0 % (25 d), unknown degradate F 10.6 % (61 d)
Readily biodegradable (yes/no) ‡	Study not performed, thus considered 'not readily biodegradable'
Dissipation in water/sediment ‡	(1) Tested: [pyridinyl-^{14}C-methylene]-imidacloprid, application rate 2x335 g as/ha (=0.67 mg as/L 10 cm water body); 1 sediment type (Stillwell, Kansas, silty clay, 2.2 % sand, 50 % silt, 47.9 % clay, pH 7.62) Water: hardness 9 °DH=90 mg CaO equivalents. EPA Guideline §162-4 1982 (2) Tested: [pyridinyl-^{14}C-methylene]-imidacloprid, application rate 1x200 g as/ha (=0.2 mg as/L 10 cm water body); 2 sediment types, 2 replicates (IJzendoorn NL, loamy silt, 15.3 % sand, 69.7 % silt, 14.9 % clay, Corg 4.09, water pH 8.1-804; Lienden NL, loamy sand, 73.9 % sand, 16.8 % silt, 9.2 % clay, Corg 0.89,Water pH 8.1-8.9). EPA Guideline §162-4 1982

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Dissipation in water/sediment	- DT_{50} water ‡	Imidacloprid as: (1st order), Standard tests (- no data) Stillwell $DT_{50,water}$ > 30 d $DT_{90,water}$ - $DT_{50,system}$ 129 d $DT_{90,system}$ -
	- DT_{90} water ‡	
	- DT_{50} whole system ‡	
	- DT_{90} whole system ‡	
	- DT_{50} sediment ‡	ModelMaker 4.0 (Hardy & Patel, 2007), P-I IJzendoorn / Lienden $DisT_{50,water}$ as 14.2 d / 108.7 d r^2 0.986 / 0.854 min. χ^2 10.1 / 6.5 $DisT_{50\ sediment}$ as 35.7 d / no degradation r^2 0.996 / - min. χ^2 2.5 / - $DegT_{50\ total\ system}$ as 30 d / 149.7 d r^2 0.999 / 0.913 min. χ^2 1.9 / 3.6
	- DT_{90} sediment ‡	
	- DT_{50} water (only degradation) ‡	Model ecosystem with light (3) Tested: [pyridinyl-^{14}C-methylene]-imidacloprid, application rate 2x335 g as/ha (1x=0.67 mg as/L 10 cm water body); 1 sediment type (Stillwell, Kansas, silty clay, 2.2 % sand, 50 % silt, 47.9 % clay, pH 7.62). Water: hardness 9 °DH=90 mg CaO equivalents.). Irradiation with sunlight 21 d, natural cycle; Xenon light 95 h in 21 d test duration, 141 h in 30 d test duration Imidacloprid as: (1st order) Stillwell/Light Xenon light $DT_{50,water}$ < 5 d Mineralisation rate 5.8 % at day 21 d Natural sun light Mineralisation rate 9.8 % at day 21 d Outdoor pond system (4) Tested: Confidor SL200, 198 g as/L. Application rate 6 µg as/L. Mesocosm: latitude N 51°,Germany, Monheim. test duration 70 d. Sediment type Nespen Wiehltalsperre: silt loam, 23.4 % sand, 62.3 % silt, 14.2 % clay, Corg 4.1. Natural light $DT_{50,water}$ approximately 7 d Monheim (FRG) $DT_{50,total\ system}$ approximately 14 d (5) Tested: Imidacloprid. Concentrations 0, 2, 6, 20, 180 µg/L. Mesocosm: Denton, North Texas USA. Test duration 70 d. Sediment type: sandy loam, sandy clay loam, 62-78 % sand, 7-15 % silt, 8-24 % clay, Corg 0.6-1.4 %). Natural light $DT_{50,water}$ 1.4 d Texas (USA) $DT_{50,sediment}$ 14 d (6) Tested: Confidor SL200 (17.3 % as). 2 spray application, resulting in nominal concentrations of 0.6,

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	1.5, 3.8, 9.4, 23.5 µg as/L. Mesocosm: at Aachen, Germany. Test duration 70 d. Sediment type: Nespen Wiehltalsperre: silt loam, 24.3 % sand, 62.3 % silt, 12.4 % clay, Corg 3.4 %, pH 6.5). Natural light $DT_{50,water}$, after 2nd appl. 13 d Aachen (FRG) $DT_{50,total\ system}$ 30 d
Mineralisation	Water/sediment studies Study (1) after 30 d (study end) in % TAR: 0.7 % Study (2) after 92 d (study end) in % TAR: IJzendoorn 1.3/1.4 %; Lienden 1.4/2.5 %
Non-extractable residues	Water/sediment studies Study (1) after 30 d (study end) in % TAR: 8.2 % Study (2) after 92 d (study end) in % TAR: IJzendoorn 66.4/66.1 %; Lienden 17.4/13.4 %
Distribution in water / sediment systems (active substance) ‡	Maximum values in sediment: (as in % TAR) Study (1) after 7 d: 23.5 % Study (2) IJzendoorn (IJ) after 14 d: 31.9 % Study (2) Lienden (L) after 60 d : 13.6 %

Imidacloprid % total applied radioactivity (TAR) ([pyridinyl-^{14}C-methylene]-imidacloprid l)

days after applicat.	(1) **water**	(2)IJ/L	(1) **sediment**	(2)IJ/L
0	90.7	78.5/90.3	7.6	13.5/5.5
3	77.2		19.3	
7	69.4		23.5	
14	67.8	41.2/76.7	22.1	31.9/9.0
21	66.0		19.0	
30/29(2)	64.0	26.8/68.1	20.4	22.8/9.4
60		9.8/64.8		13.6/10.3
92		5.1/52.8		6.6/8.9

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Distribution in water / sediment systems (metabolites) ‡

Maximum values: NTN33893-desnitro (in % TAR)
Study (1) after 7 d: water 2.4 %
after 7, 21, 30 d sediment 0.4 %
Study (2) IJzendoorn (IJ) after 92 d: water 6.0 %
after 92 d: sediment 6.3 %
Study (2) Lienden (L) after 92 d: water 4.5 %
after 92 d: sediment 4.3 %

NTN33893-desnitro % total applied radioactivity (TAR)
(as [pyridinyl-^{14}C-methylene]-imidacloprid l)

days after applicat.	(1) **water**	(2)IJ/L	(1) **sediment**	(2)IJ/L
0	<0-1	< 0.1/<0.1	<0.1	< 0.1/<0.1
3	<0.1		0.1	
7	2.4		0.4	
14	0.9	0.8/0.7	0.3	1.1/1.2
21	1.4		0.4	
30/29(2)	1.4	2.3/1.9	0.4	3.0/1.7
60		4.4/1.7		5.6/2.4
92		6.0/4.5		6.3/4.3

other metabolites in lower concentrations, max 3.8 % in water, 0.7 in sediment for 6-chloro-nicotinic acid: NTN33893-PEDA; NTN33893-nitrosimine; NTN33893-urea; 6-chloro-nicotinic acid; 6-hydroxy-nicotinic acid

Studies with irradiation

Model ecosystem with light
(3): 6-chloro-nicotinic acid 9.6 % (sunlight, 21 d, water phase), no other metabolites > 5 %

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	FOCUS surface water Step 3 Input parameters: Degradation $DT_{50,\ water}$ from water/sediment study mean 90 d, $DT_{50,sediment}$ 1000 d. median of normalised field $DT_{50,soil}$ 82 d in all tomato simulations and single application simulations in apple or 76.8 days in 2 application apple simulations. Arithm mean Koc 225 L/kg. 1/n = 0.8. Vapour pressure 4 x 10^{-10} Pa 20 °C, molar enthalpy of vaporisation 95000 J/mol, water solubility 610 mg/L 20 °C, molar enthalpy of dissolution 27000 J/mol, diffusion coefficient in water 4.3 × 10^{-5} m²/d, diffusion coefficient in air 0.43 m²/d. Worst case scenario: sugar beet, apple R3 stream, tomatoes R4 stream
Application rate	annual rate: apples 70 + 105 g as/ha min. 40 day interval, PAT calculated application dates: D3 4 April/17May, D4 18 April/30May, D5 7 March/22 April, R1 21 March/30April, R2 5 March/14 April, R3 10 March/22 April, R4 2 March/23 April. tomatoes 2 x 100 g as/ha min. 14 day interval. PAT calculated application dates: D6 7 May, R2 22 April/7 May, R3 1 June/15 June, R4 5 May

PEC Apple

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Apple 70 + 105 g as/ha	D3	0 h	5.431		2.217	
	D4 pond	0 h	0.371		2.689	
	D4 stream	0 h	5.206		0.620	
	D5 pond	0 h	0.388		2.279	
	D5 stream	0 h	5.177		0.306	
	R1 pond	0 h	0.363		1.840	
	R1 stream	0 h	4.425		0.607	
		24 h	0.002	-	0.508	-
		2 d	0.001	-	0.428	-
		4 d	<0.001	-	0.340	-
		7 d	<0.001	-	0.275	-
		14 d	<0.001	-	0.208	-
		21 d	<0.001	-	0.176	-

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d	<0.001	-	0.172	-
		42 d	<0.001	-	0.168	-
	R2 stream	0 h	5.771		0.392	
	R3 stream	0 h	6.187		1.037	
		24 h	0.010	-	0.653	-
		2 d	0.004	-	0.491	-
		4 d	0.001	-	0.362	-
		7 d	<0.001	-	0.284	-
		14 d	<0.001	-	0.211	-
		21 d	<0.001	-	0.177	-
		28 d	<0.001	-	0.157	-
		42 d	0.012	-	0.267	-
	R4 stream	0 h	4.378		0.492*	

* value comes from a simulation with a single application as the 90th % spray drift for an early application of 70g/ha (assumptions used gives a higher PEC than the assumption of the overall 90th % value from 2 applications).

PEC Tomato

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Tomato 2 x 100 g as/ha	D6 ditch	0 h	0.628*		0.5	
	R2 stream	0 h	1.298		0.906	
	R3 stream	0 h	4.07		2.11	
	R4 stream	0 h	2.908*		1.276	

* This value comes from a simulation with a single application as the 90th % spray drift assumptions used gives a higher PEC than the assumption of the overall 90th % value from 2 applications.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC Sugar Beet

Parent

Method of calculation	FOCUS surface water Step 3, 6 different FOCUS locations with 10 scenarios. Input parameters: Degradation $DT_{50,\ water}$ from water/sediment study mean 90 d, $DT_{50,sediment}$ 1000 d. Median of normalised field $DT_{50,soil}$ 76.8 d. Arithm mean Koc 225 L/kg. 1/n = 0.8. Vapour pressure 4 x 10^{-10} Pa 20 °C, molar enthalpy of vaporisation 95000 J/mol, water solubility 610 mg/L 20 °C, molar enthalpy of dissolution 27000 J/mol, diffusion coefficient in water 4.3 × 10^{-5} m²/d, diffusion coefficient in air 0.43 m²/d.
Application rate	annual rate: sugar beet 117 g active substance /ha All pertinent scenarios simulated PAT calculated application dates: D3 10 April, D4 20 April, R1 26 April, R3 10 March

Due to soil incorporation (to a depth of 4 cm), maximum PEC_{sw} due to runoff 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.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS Step 4 (PECsw only)

PECsw Apple

Scenario	Water Body	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 % (µg/L)	Spray-Drift Reduction 90 % (µg/L)	[33]approximate spray drift reduction 95% (µg/L)
D3, Vredepeel	ditch	no buffer	5.431	0.543	
		5	4.267		
		10	2.620		
		15	1.179		
		20	0.598		0.3
D4, Skousbo	pond	no buffer	0.371	0.227	
		10	0.252		
	stream	no buffer	5.206	0.523	
		5	4.474		
		10	2.749		
		15	1.238		
		20	0.631		0.316
D5, La Jailliere	pond	no buffer	0.388	0.087	
		10	0.258		
	stream	no buffer	5.177	0.524	
		5	4.450		
		10	2.736		
		15	1.234		
		20	0.631		0.318

[33] Estimated by combining 20m buffer with 50 % spray drift reduction technology for the ditch and stream water bodies. This equates to a buffer distance of ca. 35m.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water Body	Runoff Reduction (%)	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 % (µg/L)	Spray-Drift Reduction 90 % (µg/L)	[34]Estimate spray drift reduction 95% (µg/L)
R1, Weiherbach	pond	0	no buffer	0.363	0.036	-
		0	10	0.226		
	stream	0	no buffer	4.425	0.442	
		0	5	3.803		
		0	10	2.334		
		50	10	2.334		
		75	10	2.334		
		90	10	2.334		
		0	15	1.050		
		50	15	1.050		
		75	15	1.050		
		90	15	1.050		
		0	20	0.534		0.382
		50	20	0.534		0.267
		75	20	0.534		0.267
		90	20	0.534		0.267
R2, Porto	stream	0	no buffer	5.771	0.577	
		0	5	4.959		
		0	10	3.044		
		50	10	3.044		
		75	10	3.044		
		90	10	3.044		
		0	15	1.369		
		50	15	1.369		
		75	15	1.369		
		90	15	1.369		
		0	20	0.696		0.555
		50	20	0.696		0.348

[34] Estimated by combining 20m buffer with 50 % spray drift reduction technology for the ditch and stream water bodies. This equates to a buffer distance of ca. 35m.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water Body	Runoff Reduction (%)	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 % (µg/L)	Spray-Drift Reduction 90 % (µg/L)	[34]Estimate spray drift reduction 95% (µg/L)
		75	20	0.696		0.348
		90	20	0.696		0.348
R3, Bologna	stream	0	no buffer	6.187	0.934	
		0	5	5.317		
		0	10	3.264		
		50	10	3.264		
		75	10	3.264		
		90	10	3.264		
		0	15	1.468		
		50	15	1.468		
		75	15	1.468		
		90	15	1.468		
		0	20	0.746		0.373
		50	20	0.746		0.373
		75	20	0.746		0.373
		90	20	0.746		0.373
R4, Roujan	stream	0	no buffer	4.378	0.981	
		0	5	3.762		
		0	10	2.310		
		50	10	2.310		
		75	10	2.310		
		90	10	2.310		
		0	15	1.039		
		50	15	1.039		
		75	15	1.039		
		90	15	1.039		
		0	20	0.981		0.981
		50	20	0.528		0.528
		75	20	0.528		0.275
		90	20	0.528		0.254

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PECsw Tomato

Scenario	Water Body	No Spray-Drift Reduction (µg/L)	Spray-Drift Reduction 95 % (equivalent to no spray buffer between 35 and 40m) (µg/L)
D6, Thiva	ditch	0.628	0.447

Scenario	Water Body	Runoff Reduction (%)	No Spray-Drift Reduction (µg/L)	Spray-Drift Reduction 95 % (equivalent to no spray buffer between 35 & 40m) (µg/L)
R2, Porto	stream	0	1.298	1.298
		90	0.607[&]	0.152[@]
R3, Bologna	stream	0	4.073	4.073
		90	0.820[&]	0.429[@]
R4, Roujan	stream	0	2.908	2.908
		90	0.768[&]	0.313[@]

[&] estimated by taking 1/10 Toxswa calculated concentration excluding a drift input + SWASH drift calculator nominal water concentration for FOCUS step 3 default distance
[@] estimated by taking 1/10 Toxswa calculated concentration excluding a drift input + SWASH drift calculator nominal water concentration for a 35m no spray buffer (0.0221µg/L)

Metabolite

Method of calculation	Peer review agreed to use the step 3 PECsw for the active substance as conservative worst case screening estimates for the major aqueous photolysis metabolites M09, M23, M12 and M14. Step 4 values could also be used.
Application rate	-
Main routes of entry	-

PEC (sediment)

Parent

Method of calculation	FOCUS surface water Step 3, input parameter see PECsw
Application rate	annual rate: sugar beet 117 g active substance /ha; apples 70 + 105 g as/ha, tomatoes 2x100 g as/ha.
	For PEC results see tabulations under PEC(surface water)

Metabolite

Method of calculation	not required, metabolite max. 6 % in water phase of water/sediment studies, 6.3 % in sediment

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS-PELMO 3.3.2 modelling. Soil DT_{50} standardised 20 °C, geometric mean from 4 laboratory studies 118 d; Koc 225 mL/g, 1/n = 0.8
Application rate	Annual rate: sugar beet seeds 117 g as/ha, incorporation depth 3 cm; apples 1st 70 g (BBCH 10), 50% crop interception and 2nd 105 g as/ha (BBCH69/71) 70% crop interception,; tomatoes 2 x 100 g as/ha 50% followed by 70% crop interception, 14 d interval Apples and tomatoes: spraying (Confidor SL200) sugar beets: seed treatment (Gaucho FS600)

$PEC_{(gw)}$

Maximum concentration	0.001 µg/L
Average annual concentration (Results quoted for modelling with FOCUS gw scenarios, according to FOCUS guidance)	Apples and sugar beets: < 0.001 µg/L for 8 scenarios, 1 scenario 0.001µg/L Tomatoes: 5 relevant scenarios < 0.001 µg/L

PEC(gw) - FOCUS modelling results

	Scenario annual application	Parent (µg/L) Apple, sugar beet	Parent (µg/L) Tomatoes	Metabolite (µg/L)	
				-	-
FOCUS-PELMO 3.3.2	Châteaudun	< 0.001	< 0.001		
	Hamburg	< 0.001	-		
	Jokioinen	< 0.001	-		
	Kremsmünster	< 0.001	-		
	Okehampton	< 0.001	-		
	Piacenza	0.001	< 0.001		
	Porto	< 0.001	< 0.001		
	Sevilla	< 0.001	< 0.001		
	Thiva	< 0.001	< 0.001		

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	Study not performed - not measurable, due to low vapour pressure.
Quantum yield of direct phototransformation	0.0142
Photochemical oxidative degradation in air ‡	DT_{50} ..0.85 hours. (calculation according to Atkinson 1987, 12 h daytime, 1.5 x 10^6 OH-radicals/cm³) 24 h time period, 5 x 10^5 OH-radicals/cm³ DT_{50}..2.54 h
Volatilisation ‡	(field experiment in container arrangement, 1 m², apple seedlings). Methylene-^{14}C labelled and formulated imidacloprid. from plant surfaces: ‡ No as evaporated from plant and soil surfaces within 24 h after application
	from soil: ‡ no evaporation within 24 h

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

PEC (air)

Method of calculation	not performed

$PEC_{(a)}$

Maximum concentration	not required

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Relevant for quantitation (> 5 % at 2 sequential measurements during the soil and water/sediment study) Soil : imidacloprid, (M09 anaerobic conditions) Water: imidacloprid, (M09, M23, M12, M14 photolysis) Sediment: imidacloprid Ground water: imidacloprid Air: imidacloprid

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	Germany, groundwater monitoring programme Data from 4 Federal States

	number				
	total	< LOQ	≤ 0.1	> 0.1-1.0	> 1.0 µg/L
2000	9	9	0	0	0
2001	23	22	1	0	0
2002	279	278	1	0	0
total	627	625	2	0	0

Air (indicate location and type of study)	not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R 53

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Appendix 1.6 Effects on non target species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Coturnix japonica.	as	Acute	LD_{50}: 31	
Colinus virginianus	Confidor SL200	Acute	LD_{50}: 2515 (prod.) LD_{50}: 503 (a.s.)	
Colinus virginianus (chicks)	as	Short-term	NOEL: 29.4	NOEC: 156
Colinus virginianus	as	Long-term	NOAEL: 9.3	NOEC: 126
Mammals ‡				
Mouse	as	Acute	LD_{50}: 131	
Rat	as	Long-term	NOAEL: 17	NOEAC: 250
Additional higher tier studies ‡				
-/-				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Apples

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	5.64	5.5	10
Small insectivore	Short-term	3.15	9.3	10
Small insectivore	Long-term	3.15	3.0	5
Higher tier refinement (Birds)				
Blue tit (*Parus caeruleus*) insectivorous diet: arthropod RUD for 30 % large/70 % small arthropods	Acute	4.44	7.0	10
Blue tit (*Parus caeruleus*) (see above)	Short-term	2.39	12.3	10
Blue tit (*Parus caeruleus*) (see above; PT 0.61)	Long-term	1.45	6.4	5
Tier 1 (Mammals)				
Small herbivore	Acute	14.91	8.8	10

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Small herbivore	Long-term	4.93	3.4	5
Higher tier refinement (Mammals)				
Common vole (*Microtus arvalis*) FOCUS interception 50%	Acute	7.6	17	10
Common vole (*Microtus arvalis*) (see above)	Long-term	0.43	39.3	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Tomatoes

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	5.37	5.8	10
Small insectivore	Short-term	3.00	9.8	10
Small insectivore	Long-term	3.00	3.1	5
Higher tier refinement (Birds)				
Yellow wagtail (*Motacilla flava*) insectivorous diet: arthropod RUD for 50 % large/50 % small arthropods	Acute	2.9	10.6	10
Yellow wagtail (*Motacilla flava*) (see above)	Short-term	1.5	19.6	10
Yellow wagtail (*Motacilla flava*) (see above)	Long-term	1.5	6.2	5
Tier 1 (Mammals)				
Wood mouse (*Apodemus sylvaticus*), replacing medium herbivorous mammal	Acute	12.69	10.3	10
Wood mouse (*Apodemus sylvaticus*), replacing medium herbivorous mammal	Long-term	3.61	4.7	5
Higher tier refinement (Mammals)				

see above for footnotes

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Sugar beet

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small granivore	Acute	10526	0.003	10
Medium herbivore (consumption of shoots)	Acute	15.3	2.0	10
Small granivore	Short-term	10526	0.003	10
Medium herbivore (consumption of shoots)	Short-term	15.3	1.9	10
Small granivore	Long-term	10526	0.0009	5
Medium herbivore (consumption of shoots)	Long-term	8.1	1.1	5
Higher tier refinement (Birds)				
Large granivore (bw 625 g) exposure as grit, calculation based on precision drilling with ≤ 0.6 % seeds available on surface	Acute	0.9 (1 pill per day as grit)	21.6 (TER > 10 with p > 0.994)	10
Large granivore (bw 625 g) (see above)	Short-term	0.9 (1 pill per day as grit)	20.4 (TER > 10 with p > 0.994)	10
Large granivore (bw 625 g) (see above)	Long-term	0.9 (1 pill per day as grit)	6.4 (TER > 5 with p > 0.994)	5
Large non-granivore (bw 288 g) (see above for large granivore)	Long-term	0.45 (1 pill per 2 days as grit)	5.8 (TER > 5 with p ~ 0.996)	5
Wood pigeon (*Columba palumbus*) (see above)	Long-term	0.78	11.9	5
Tier 1 (Mammals)				
Small granivore	Acute	6371	0.02	10
Medium herbivore	Acute	5.54	23.6	10
Small granivore	Long-term	6371	0.003	5
Medium herbivore	Long-term	2.94	5.8	5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Mammals)				
Currently open – data gap was set in PRAPeR 33	Acute			10
Currently open – data gap was set in PRAPeR 33	Long-term			5

see above for footnotes

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2) ‡

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L) *
Selenastrum capricornutum	imidacloprid	72 h	E_bC_{50} biomass E_rC_{50} growth rate NOEC biomass, NOEC growth rate	> 100 > 100 < 100 < 100
Scenedesmus subspicatus	imidacloprid	72 h	E_bC_{50} biomass E_rC_{50} growth rate NOEC biomass, NOEC growth rate	> 10 > 10 10 10
Daphnia magna	imidacloprid	48 h acute	EC_{50} immobilisation	85
Oncorhynchus mykiss	imidacloprid	96 h acute	LC_{50}	211
Cyprinodon variegatus	imidacloprid	96 h acute	LC_{50}	161
Chironomus riparius	imidacloprid	24 h acute	LC_{50}	0.0552
Daphnia magna	imidacloprid	21 d, static renewal	NOEC reproduction	1.8
Oncorhynchus mykiss	imidacloprid	91 d, flow-through	NOEC early life stage	9.02
Chironomus riparius	imidacloprid	28 d, static	EC_5 emergence EC_{10} emergence EC_{15} emergence EC_{50} emergence	0.00186 0.00209 0.00225 0.00311
Chironomus riparius	Confidor SL 200	28 d, static	NOEC emergence LC_{50} emergence	0.0027 0.0036
Chironomus riparius	imidacloprid-5-hydroxy (M01)	24 h acute	EC_{50} immobilisation LC_{50}	> 0.32 0.668
Chironomus riparius	imidacloprid-nitroso (M07)	24 h acute	LC_{50}	0.283
Chironomus riparius	imidacloprid-desnitro (M09)	28 d, static	EC_{15} emergence EC_{50} emergence	33.6** 46.0**
Chironomus riparius	imidacloprid-urea (M12)	28 d, static	EC_{15} emergence EC_{50} emergence	73.6** 249**
Chironomus riparius	imidacloprid-AMCP (M16)	28 d, static	EC_{15} emergence EC_{50} emergence	> 105** > 105**
Chironomus riparius	imidacloprid-desnitro-olefine (M23)	28 d, static	EC_{15} emergence EC_{50} emergence	12.4** 21.3**

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

* nominal concentrations, confirmed by chemical analyses
** reported for comparison with toxicity of parent compound, not used as critical value in the risk assessment

Microcosm or mesocosm tests
Outdoor microcosms with sediment, middle Europe: Aachen, Germany, under GLP conditions. Static systems with 2 applications of Confidor SL 200. Test conc: 0.6 -23.5 µg as/L (3.5 - 135.8 µg product/L). Time interval for application 21 d. NOEC considering chironomids and Batidae, most sensitive taxa, was 0.0006 mg/L. DT50 of imidacloprid in the water phase at all concentrations after both applications: 5.8-13 d.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
Imidacloprid						
0.07+0.105	apple	*Chironomus riparius*	acute	1.5	0.5	100
0.07+0.105	apple	*Chironomus riparius*	long-term	1.5	0.4	10
						100
2 x 0.1	tomato	Microcosm	long-term	ditch 1.0	0.15 - 0.95	1-3
0.07+0.105	apple	Microcosm	long-term	stream 1.5	0.1 - 1.5	1-3
1.3 U/ha coated seeds (90 g as/U)	sugar beet	Microcosm	long-term	pond 3.5	60	1-3
Metabolites						
M01	apple	*Chironomus riparius*	acute	1.5	108	100
M07	$PEC_{sw, ini}$ metabolite = $PEC_{sw, ini}$ as	*Chironomus riparius*	acute	1.5	46*	100
M14		*Chironomus riparius*	long-term	1.5	Data gap	10

*The risk from the metabolites is covered by the risk mitigation measures required for imidacloprid.

TER calculations based on FOCUS Step 4 PECsw based on mesocosm NOEC of 0.6 µg as/L

Apple

Scenario	Water Body	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 %	[35]approximate spray drift reduction 95%
D3, Vredepeel	ditch	no buffer	0.1	
		5	0.1	
		10	0.2	

[35] Estimated by combining 20m buffer with 50 % spray drift reduction technology for the ditch and stream water bodies. This equates to a buffer distance of ca. 35m.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

		15	0.5	
		20	1.0	2.0
D4, Skousbo	pond	no buffer	1.6	
		10	2.4	
	stream	no buffer	0.1	
		5	0.1	
		10	0.2	
		15	0.5	
		20	1.0	1.9
D5, La Jailliere	pond	no buffer	1.5	
		10	2.3	
	stream	no buffer	0.1	
		5	0.1	
		10	0.2	
		15	0.5	
		20	1.0	1.9

Scenario	Water Body	Runoff Reduction (%)	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 %	[36]Estimate spray drift reduction 95%
R1, Weiherbach	pond	0	no buffer	1.7	
		0	10	2.7	
	stream	0	no buffer	0.1	
		0	5	0.2	
		0	10	0.3	
		50	10	0.3	
		75	10	0.3	
		90	10	0.3	
		0	15	0.6	
		50	15	0.6	
		75	15	0.6	
		90	15	0.6	

[36] Estimated by combining 20m buffer with 50 % spray drift reduction technology for the ditch and stream water bodies. This equates to a buffer distance of ca. 35m.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water Body	Runoff Reduction (%)	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 %	[36]Estimate spray drift reduction 95%
		0	20	1.1	1.6
		50	20	1.1	2.2
		75	20	1.1	2.2
		90	20	1.1	2.2
R2, Porto	stream	0	no buffer	0.1	
		0	5	0.1	
		0	10	0.2	
		50	10	0.2	
		75	10	0.2	
		90	10	0.2	
		0	15	0.4	
		50	15	0.4	
		75	15	0.4	
		90	15	0.4	
		0	20	0.9	1.1
		50	20	0.9	1.7
		75	20	0.9	1.7
		90	20	0.9	1.7
R3, Bologna	stream	0	no buffer	0.1	
		0	5	0.1	
		0	10	0.2	
		50	10	0.2	
		75	10	0.2	
		90	10	0.2	
		0	15	0.4	
		50	15	0.4	
		75	15	0.4	
		90	15	0.4	
		0	20	0.8	1.6
		50	20	0.8	1.6
		75	20	0.8	1.6

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water Body	Runoff Reduction (%)	Buffer Zone to reduce spray drift (m)	Spray-Drift reduction technology 0 %	[36]Estimate spray drift reduction 95%
		90	20	0.8	1.6
R4, Roujan	stream	0	no buffer	0.1	
		0	5	0.2	
		0	10	0.3	
		50	10	0.3	
		75	10	0.3	
		90	10	0.3	
		0	15	0.6	
		50	15	0.6	
		75	15	0.6	
		90	15	0.6	
		0	20	0.6	0.6
		50	20	1.1	1.1
		75	20	1.1	2.2
		90	20	1.1	2.3

Tomato based on mesocosm NOEC of 0.6 µg as/L

Scenario	Water Body	No Spray-Drift Reduction	Spray-Drift Reduction 95 % (equivalent to no spray buffer between 35 and 40m)
D6, Thiva	ditch	0.96	1.3

Scenario	Water Body	Runoff Reduction (%)	No spray-Drift Reduction	Spray-Drift Reduction 95 % (equivalent to no spray buffer between 35 & 40m)
R2, Porto	stream	0	0.46	0.46
			-	-
			-	-
			-	-
			-	-
		90	0.99	3.9

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water Body	Runoff Reduction (%)	No spray-Drift Reduction	Spray-Drift Reduction 95 % (equivalent to no spray buffer between 35 & 40m)
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
R3, Bologna	stream	0	0.15	0.15
			-	-
			-	-
			-	-
			-	-
		90	0.73	1.40
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-
R4, Roujan	stream	0	0.21	0.21
			-	-
			-	-
			-	-
			-	-
		90	0.78	1.9
			-	-
			-	-

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water Body	Runoff Reduction (%)	No spray-Drift Reduction	Spray-Drift Reduction 95 % (equivalent to no spray buffer between 35 & 40m)
			-	-
			-	-
			-	-
			-	-
			-	-
			-	-

Bioconcentration

Bioconcentration factor (BCF)	not relevant, $logP_{ow}$ 0.57
Annex VI Trigger for the bioconcentration factor	100 (for bioaccumulation studies $logP_{ow}$ 3)
Clearance time (CT_{50}) (CT_{90})	not relevant
Level of residues (%) in organisms after the 14 day depuration phase	not relevant

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	LD_{50} = 0.0037 µg as/bee (active substance) LD_{50} = 0.0056 µg as/bee (formulation)
Acute contact toxicity	LD_{50} = 0.081 µg as/bee (active substance) LD_{50} = 0.042 µg as/bee (formulation)

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
Active substance:				
0.150	tomato	oral	40540	50
0.150	tomato	contact	1852	50
formulation:				
0.150	tomato	oral	26786	50
0.150	tomato	contact	3554	50

Field or semi-field tests
Because of the high toxicity of the active substance all spray applications have to be classified as hazardous for bees. Because of the distinct systemical mode of action in combination with the high toxicity a large number of practical tests have been performed regarding effects on bees by seed treatment. In total 14 cage tests and 11 field tests have been regarded for the evaluation. By all results the seed treatment with imidacloprid containing products has been proved as not hazardous for bees.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test substance	Dose (kg as/ha)	Endpoint	Effect	Trigger
Laboratory tests with inert substrate						
Typhlodromus pyri	proto-nymphs	Confidor SL 200		mortality	LR_{50} 4.23 g as/ha	30 %[1]
Aphidius rhopalosiphi	adults	Confidor SL 200		mortality	LR_{50} 0.022 g as/ha	30 %[1]
Extended laboratory tests with natural substrate						
Typhlodromus pyri	proto-nymphs	Confidor SL 200 on apple leaves		mortality	LR_{50} 19.13 g as/ha	50 %[2]
			0.011	reproduction	no effect (0 %)	
Aphidius rhopalosiphi	adults	Confidor SL 200 on apple leaves		mortality	LR_{50} 0.45 g as/ha	50 %[2]
			0.00032	reproduction	no reduction (-11 %)	
Coccinella septumpunctata	adults	Confidor SL 200 on apple leaves		mortality	LR_{50} 11.38 g as/ha	50 %[2]
			0.0047	reproduction	no reduction (-16 %)	
Chrysoperla carnea	Larvae	Confidor SL 200 on apple leaves		mortality	LR_{50} 10.51 g as/ha	50 %[2]
			0.025	reproduction	32 %	
Poecilus cupreus	adults	Confidor SL 200 on soil		mortality	LR_{50} 497 g as/ha	50 %[2]
			0.33	feeding rate	30 % inhibition	
Poecilus cupreus	larvae	imidacloprid (as)	mg/kg soil 0.04 0.4 4	mortality	0 % 100 % 100 %	50 %[2]
Poecilus cupreus	larvae	imidacloprid (as)	mg/kg soil 0.01 0.1	mortality	0 % 40.5 %	50 %[2]
Poecilus cupreus	larvae	imidacloprid (as)		mortality	LR_{50} 0.136 mg as/kg soil	50 %[2]
Poecilus cupreus	larvae	imidacloprid (as)	mg/kg soil 0.015 0.020 0.025 0.030 0.035	mortality	5 % 10 % 15 % 10 % 0 %	50 %[2]
Poecilus cupreus	larvae	Confidor WG 70	0.029 0.059 0.116	mortality	32 % 56 % 79 %	50 %[2]
Poecilus cupreus	adults	Gaucho FS 350 on wheat seeds		mortality	77.8 % at seeds coated with 200 mL/dt; drilled at 200 kg/ha	50 %[2]
Poecilus cupreus	adults	Gaucho WS70 sugar beet seeds		mortality	80.6 % at seeds coated with 90 g as/U; drilled at 25 U/ha	50 %[2]
Poecilus cupreus	adults	Gaucho WS70 sugar beet seeds		mortality	30 % at 14 seeds/m² 10 % at 40 seeds/m²	50 %[2]

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Stage	Test substance	Dose (kg as/ha)	Endpoint	Effect	Trigger
Aleochara bilineata	adults	Gaucho WS70, sugar beet seeds		reproduction	101 % offspring at seeds coated 90 g as/U; drilled at 10.5 U/ha	50 %[2]
Pardosa spp.	adults	Gaucho FS 600 on corn seeds	54.9 g as/U drilled at 3.4 U/ha	mortality	4.2 %	50 %[2]
				feeding rate	2.5 %	
Extended laboratory tests with natural substrate and aged residues						
Typhlodromus pyri	proto-nymphs	Confidor SL 200 on apple leaves	2 x 0.1, 14 d interval	mortality	7 days - 33 %	50 %[2]
				reproduction	21 days - 5 % reduced	
Aphidius rhopalosiphi	adults	Confidor SL 200 on apple leaves	2 x 0.1, 14 d interval	mortality	7 days - 0 %	50 %[2]
				reproduction	14 days - (-13 %)	
Aphidius rhopalosiphi	adults	Confidor SL 200 on tomato leaves	2 x 0.1, 14 d interval	mortality	0 days - 83 % 7 days - 54 % 14 days - 54 % 21 days – 3 %	50 %[2]
				reproduction	14 days - 54 % 21 days - (-28 %)	
Poecilus cupreus	larvae	Gaucho FS350 on soil	aged residue conc.	mortality	after 247 d ageing: 0.03 mg as/kg - 11 % 0.06 mg as/kg - (-5.6 %) 0.13 mg as/kg - 0 % 0.25 mg as/kg - 0 % 0.5 mg as/kg - 5.6 %	50 %[2]

[1] Trigger according to Annex VI 91/414/EEC
[2] Trigger at field rate according to Sanco/10329/2002 (apple 70+105 g as/ha; tomato 2 × 100 g as/ha)

Hazard quotients for other arthropod species: in-crop and off-crop scenario

Apple, 105 g as/ha (MAF = 1 due to fast dissipation in relation to application interval)
for off-field assessment: 70 g as/ha in connection with drift scenario 'orchards, early'

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Confidor SL 200	*Typhlodromus pyri*	4.2	25	4.9 (3 m) 3.3 (5 m) 2.0 (10 m)	2
Confidor SL 200	*Aphidius rhopalosiphi*	0.02	5250	1022 (3 m) 696 (5 m) 413 (10 m) 194 (15 m) 97 (20 m)	2

[1] indicate distance assumed to calculate the drift rate

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Tomato, 100 g as/ha (MAF = 1 due to fast dissipation in relation to application interval) drift scenario 'vegetables > 50 cm'

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Confidor SL 200	*Typhlodromus pyri*	4.2	24	2.0 (3 m)	2
Confidor SL 200	*Aphidius rhopalosiphi*	0.02	5000	401 (3 m) 181 (5 m) 62 (10 m) 33 (15 m) 21 (20 m)	2

[1] indicate distance assumed to calculate the drift rate

Tomato, 100 g as/ha (MAF = 1 due to fast dissipation in relation to application interval) drift scenario 'vegetables < 50 cm'

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Confidor SL 200	*Typhlodromus pyri*	4.2	24	0.7 (1 m)	2
Confidor SL 200	*Aphidius rhopalosiphi*	0.02	5000	139 (1 m) 29 (5 m) 15 (10 m) 10 (15 m) 8 (20 m)	2

[1] indicate distance assumed to calculate the drift rate

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Field or semi-field tests					
Species	Stage	Test substance	Dose (kg as/ha)	Endpoint	Effect
Semi-field studies					
Aphidius rhopalosiphi	adults	Confidor SL 200 on barley, Germany	0.0025 0.0045 0.008 0.014 0.025	reproduction	53 % 88 % 80 % 91 % 96 %
Aphidius rhopalosiphi	adults	Confidor SL 200 on barley, Spain	0.00046 0.0011 0.0024 0.0056 0.0112	reproduction	14.4 % (n.s.) 42.7 % 42.4 % 45.3 % 76.5 % ER_{50} 3.5 g as/ha
Aphidius rhopalosiphi	adults	Confidor SL 200 on barley, Spain	0.009	reproduction	day 0 - 69.9 % day 3 - 31.2 % day 7 - 20.6 %
			0.018		day 0 - 95.3 % day 3 - 30.6 % day 7 - (-9.6 %)
Aphidius rhopalosiphi	adults	Confidor SL 200, drift residues, wind tunnel	0.0028 0.0036 0.0058 0.0085 0.0288	reproduction	47.1 % 62.9 % 82.0 % 93.1 % 98.9 %; ER_{50} 2.9 g as/ha
Trichogramma dendrolimi	adult	Confidor WG 70, apple	0.015 % as in 1500 L/ha	parasitic efficiency	51.2 %
Poecilus cupreus	adult	Confidor SC 200, apple	2 x 0.75 L/ha. 7 d interval	mortality	not increased (-5.2 %)
Poecilus cupreus	larvae	Gaucho WS70	80 g as/U drilled at 1.1 U/ha	larvae development influence on indigenous arthropod species	no significant effect no influence
Field studies					
Mite fauna		Confidor SC 200, apple	0.244 + 0.227; 10 d interval	reduced abundance	day 7 - 36.6 % day 28 - no effects

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	LC_{50}: 10.7 mg as/kg soil dw Confidor SL 200: LC_{50}: 109 mg product /kg soil dw LC_{50}: 21.8 mg as/kg soil dw
Reproductive toxicity	NOEC ≥ 0.178 mg as/kg soil dw Confidor SL 200: NOEC ≥ 0.562 mg as/kg soil dw Gaucho WS 600 coated on seeds: NOEC ≥ 585 g as/ha (≥ 6.5 U/ha)
Field study	Confidor WG 70: natural earthworm population, duration 6 years NOEC for abundances 150 g as/ha as 1 application per year, including plateau formation. Zelmone 350FS: on barley seeds, annual sowing of winter barley, natural earthworm population, duration 6 years NOEC for abundances ≥ 200 mL product/100 kg seed, corresponding to 133 g as/ha nominal rate as 1 application per year, including plateau formation

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	$PEC_{soil, ini}$	TER	Annex VI Trigger
Imidacloprid					
0.07 + 0.1	apple	acute	0.086	124	10
2 x 0.1	tomato	acute	0.104	103	10
0.117 (nominal)	sugar beet	acute	0.156	69	10
0.07 + 0.1	apple	sublethal	0.086	2.1 *	5
2 x 0.1	tomato	sublethal	0.104	1,7 *	5
0.117 (nominal)	sugar beet	sublethal	0.156	1.1 *	5
0.07 + 0.1	apple	acute	plateau: 0.146	73	10
2 x 0.1	tomato	acute	plateau: 0.123	87	10
0.117 (nominal)	sugar beet	acute	plateau: 0.~~202~~184	58	10
0.07 + 0.1	apple	sublethal	plateau: 0.146	1.2 *	5
2 x 0.1	tomato	sublethal	plateau: 0.123	1.4 *	5
0.117 (nominal)	sugar beet	sublethal	plateau0.~~202~~184	1.0 *	5
					* see 6-year field study: no effect
Confidor SL 200					
0.07 + 0.1	apple	acute	0.086	253	10
2 x 0.1	tomato	acute	0.104	210	10
0.07 + 0.1	apple	sublethal	0.086	6.5	5
2 x 0.1	tomato	sublethal	0.104	5.4	5
Gaucho WS 70, coated on seeds (90 g as/Unit seeds)					
1.3 Units/ha	sugar beet	sublethal	1.3 Units/ha	5	5

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Lower, not peer reviewed TER soil based on the accumulation in the field accumulation study in the UK, calculated by EFSA are included in section 5.5 of the conclusion.

Effects on other soil macro-organisms (Annex IIIA, point 10.6.2)

Reproductive toxicity with collembolan species			*Folsomia candida* Imidacloprid NOEC 1.25 mg as/kg soil Confidor SL 200 NOEC 0.32 mg as/kg soil Gaucho FS 600 in soil NOEC 0.20 mg as/kg soil Gaucho FS 600 on seeds NOEC 7.1 U/ha 656 g as/ha Metabolite M06 NOEC 10 mg/kg soil Metabolite M07 NOEC 1.0 mg kg/soi *Hypoaspis aculeifer* Imidacloprid NOEC ≥ 2.67 mg as/kg soil		
Application rate (kg as/ha)	Crop	Time-scale	$PEC_{soil, ini}$	TER	Annex VI Trigger
Confidor SL 200					
0.07 + 0.1	apple	sublethal	plateau: 0.146	2.2 *	5
2 x 0.1	tomato	sublethal	plateau: 0.123	2.6 *	5
Imidacloprid					
0.117 (nominal)	sugar beet	sublethal	0.156	8.0	5
0.117 (nominal)	sugar beet	sublethal	plateau: 0.184	6.8	5
Field study: Decomposition of organic matter (litter bag test)					
Application rate (kg as/ha)	Test level (kg as/ha)		Effects		
2 x 0.1, tomato, 0.07 + 0.105 apple	background plateau conc. (45.8 µg as/kg soil measured) plus 1 application of 0.1 kg as/ha nominally corresponding to a total concentration of 179 µg as/kg in a 5 cm soil layer		Confidor SL 200, Germany, 182 days: no influence on organic matter breakdown after 1, 2, 3, and 6 months maximum initial measured concentration found after the second application was 0.135 mg as/kg		
1.3 U/ha (sugar beet seeds, 90 g as/U)	treated winter barley seeds (65.4 g as/100 kg seeds =131 g as/ha) on top of measured soil background conc: 22.2-45.3 µg as/kg nominally corresponding to total concentrations of 197-220 µg as/kg in a 5 cm soil layer		Gaucho FS 600, Germany, 196 days: no influence on organic matter breakdown after 28 d, 91 d, 196 d.		

The TERs are lower if based on the PECsoil values on the basis of the field accumulation study in the UK.

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity/exposure ratios for soil macro-organisms

Application rate (kg as/ha)	Crop	Time-scale	Organism	$PEC_{soil, ini}$ (mg as/kg soil)	TER	Trigger
Product Gaucho FS 600						
1.3 U/ha, 90 g as/U	sugar beet	reproduction 28 d	Collembola	0.0389 (in soil) 1.3 U/ha (seeds)	5.1 5.5	5

* field study and litter bag study: no effects

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralisation	Imidacloprid: 0.2 and 2.0 kg as/ha, 28 d		no effects
	Confidor SL 200: 0.225 and 2.25 kg as/ha, 28 d		no effects
Carbon mineralisation	Imidacloprid: 0.2 and 2.0 kg as/ha, 28 d		no effects
	Confidor SL 200: 0.225 and 2.25 kg as/ha, 28 d		no effects
Fungi		mg as/kg soil	Inhibition
	Phytophthora nicotianae	30	11.9 %
	Suillus granulatus	30	1.5 %
	Mucor circinelloides	30	0 %
	Paecilomyces marquandii	30	0 %
	Agaricus bisporus	≥ 0.32	NOEC
Field study	-		

Impact on water treatment procedures (Annex IIA, point 8.7)

Oxygen consumption by activated sludge	27.9 % inhibition of respiration at 10 000 mg as/L (highest test conc.) NOEC: 5600 mg as/L (18.4 % inhibition)

Effects on other non-target organisms (flora and fauna) (Annex IIA, point 8.6)

Flora species	Parameter	Test Substance	Effect plant weight	Effect visible damage	Trigger
Limit test, 14 days	mean plant weight and visible damage	imidacloprid	1000 g as/ha pre-emergence	1000 g as/ha post-emergence	50 %*
Avena fatua			no effect	no effect	
Echinochloa crus-galli			no effect	no effect	
Abutilon theoprasti			no effect	no effect	
Galium aparine			no effect	no effect	
Sinapis arvensis			no effect	< 50 % (also 500 g)	
Xanthium spec.			no effect	no effect	
Alopecurus myodonae			< 50 %	no effect	
Setaria viridis			< 50 %	no effect	
Amaranthus retroflexus			< 50 %	< 50 % (also 500 g)	
Zea mays			no effect	no effect	
Beta vulgaris			no effect	no effect	

‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

			mg as/kg soil			
OECD 208			NOEC	LOEC	EC_{50}	
Avena sativa	Emergence		> 100	≥ 100	> 100	$PEC_{s\ ini}$ 0.119 mg as /kg soil
Brassica rapa			> 100	≥ 100	> 100	
Lepidum sativum			> 100	≥ 100	> 100	
Avena sativa	growth		10	100	> 100	
Brassica rapa			> 100	≥ 100	> 100	
Lepidum sativum			10	100	> 100	

* Trigger at field rate according to Sanco/10329/2002

Fauna species	Parameter	Test substance	Effect
Steinernema carpocapsae	viability	imidacloprid 1.5 mg as/L	no effects at 1.5 mg as/L after exposure of 7 days
	parasitation efficacy		
	reproduction		

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N, R 50/53

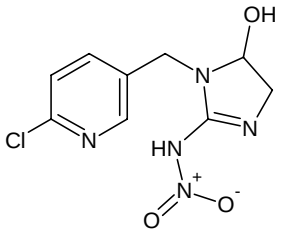
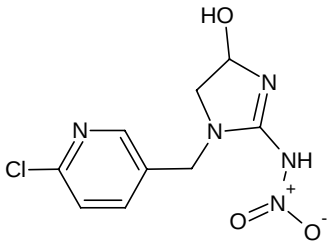
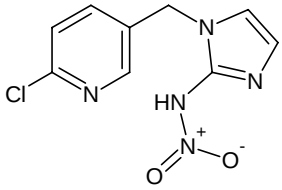
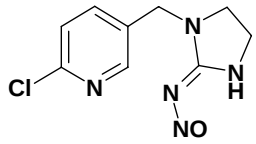
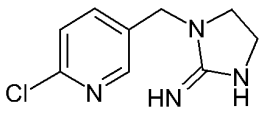
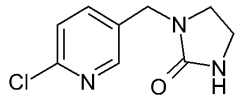
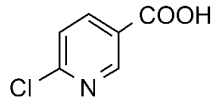
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

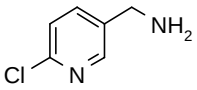
APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry

LC-MS-MS	liquid chromatography with tandem mass spectrometry
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 (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
M01	1-[(6-Chloro-3-pyridinyl)methyl]-4,5-dihydro-2-(nitroamino)-1H-imidazol-5-ol	
M02	1[(6-Chloro-3-pyridinyl)methyl]-4,5-dihydro-2-(nitroamino)-1H-imidazol-4-ol	
M06	1-[(6-Chloro-3-pyridinyl)methyl]N-nitro-1H-imidazol-2-amine	
M07 NTN33893-nitrosimine	1-[(6-chloro-3-pyridinyl)methyl]-, oxohydrazone	
M09 NTN33893-desnitro	1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine	
M12 NTN33893-urea	1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-one	
M14 6-chloronicotinic acid NTN33893-6-CNA	6-chloropyridine-3-carboxylic acid	

M16 NTN33893-AMCP	1-(6-chloropyridin-3-yl)methanamine	
M23 NTN33893-desnitro-olefine	1-[(6-chloropyridin-3-yl)methyl]-1,3-dihydro-2*H*-imidazol-2-imine