CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance fluxapyroxad (BAS 700 F)[1]

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This conclusion, published on 4 May 2012, replaces the earlier version published on 27 January 2012[3]

SUMMARY

Fluxapyroxad, with the development code BAS 700 F, is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC[4] the United Kingdom received an application from BASF SE for inclusion in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision of 5 November 2010 (2010/672/EU)[5].

Following the agreement between the European Commission and the European Food Safety Authority (EFSA) for the EFSA to organise a peer review of those new active substances for which the decision on the completeness of the dossier had been published after June 2002, the designated rapporteur Member State the United Kingdom (RMS) provided its initial evaluation of the dossier on fluxapyroxad (BAS 700 F) in the Draft Assessment Report (DAR), which was received by the EFSA on 11 January 2011.

The peer review was initiated on 27 January 2011 by dispatching the DAR for consultation of the Member States and the applicant BASF SE. Following consideration of the comments received on the DAR, it was concluded that the EFSA should conduct a focused peer review in the areas of mammalian toxicology and environmental fate and behaviour, and deliver its conclusions on fluxapyroxad (BAS 700 F).

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fluxapyroxad (BAS 700 F) as a fungicide on wheat, durum wheat, triticale, barley, rye and oat, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No data gaps were identified in the section on identity, physical and chemical properties and analytical methods.

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[1] On request from the European Commission, Question No EFSA-Q-2011-00395, approved on 16 December 2011.

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[3] The list of endpoints at Appendix A (page 63) has been amended to correct the DT_{50} soil value for the metabolite M700F002. The corrected value has not affected the overall conclusion.

[4] OJ No L 230, 19.8.1991, p. 1. Directive as last amended by L 20, 22.1.2005, p.19 and by L309, 24.11.2009, p.1

[5] OJ No L 290, 06.11.2010, p. 0051 - 0052

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No data gaps or critical areas of concern were identified in the mammalian toxicology section.

A data gap was identified in the residues section for two additional residue trials on wheat covering respectively northern and southern Europe in order to derive a maximum residue limit (MRL) in wheat with extrapolation to rye and triticale.

The fate and behaviour of fluxapyroxad (BAS 700 F) in the environment was investigated with a complete set of studies, however a data gap was identified for the final report of the study on the accumulation in soil.

The risk for non-target organisms was assessed as low for the representative uses. Pending on the outcome of the data gap in the environmental fate and behaviour section, in particular, if the plateau concentration in soil observed in the field study will be greater than the estimated peak plateau predicted environmental concentrations (PECs), the risk assessment for non-target soil-organisms may need to be reconsidered. No critical areas of concern were identified.

KEY WORDS

Fluxapyroxad, BAS 700 F, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

In accordance with Article 6(2) of Council Directive 91/414/EEC[6] the United Kingdom received an application from BASF SE for inclusion of the active substance fluxapyroxad, with the development code BAS 700 F, in Annex I to Directive 91/414/EEC. Complying with Article 6 of Directive 91/414/EEC, the completeness of the dossier was evaluated and confirmed by Commission Decision 5 November 2010 (2010/672/EU)[7].

Following the agreement between the European Commission and the EFSA for the EFSA to organise a peer review of those new active substances for which the completeness of the dossier had been officially confirmed after June 2002, the RMS the United Kingdom provided its initial evaluation of the dossier on fluxapyroxad (BAS 700 F) in the DAR, which was received by the EFSA on 11 January 2011 (The United Kingdom, 2011a).

The peer review was initiated on 27 January 2011 by dispatching the DAR to the Member States and the applicant BASF SE for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The scope of the peer review and the need for additional information to be submitted by the applicant in accordance with Article 8(3) of Commission Regulation (EU) No 188/2011[8], was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 13 May 2011. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and environmental fate and behaviour, and that further information should be requested from the applicant in the areas of physical, chemical properties, mammalian toxicology, residues, and environmental fate and behaviour.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November – December 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide on wheat, durum wheat, triticale, barley, rye and oat, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer

[6] OJ No L 230, 19.8.1991, p. 1. Directive as last amended by L 20, 22.1.2005, p.19 and by L309, 24.11.2009, p.1
[7] OJ No L 290, 06.11.2010, p. 0051 - 0052
[8] OJ No L 53, 26.02.2011, p. 51

review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011b) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (13 May 2011),
- the Evaluation Table (9 December 2011),
- the reports of the scientific consultation with Member State experts,
- the comments received on the assessment of the additional information,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2011 containing all individually submitted addenda (The United Kingdom, 2011b)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fluxapyroxad, with the development code BAS 700 F, is the ISO common name for 3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide (IUPAC).

The representative formulated product for the evaluation was 'BAS 700 00F', an emulsifiable concentrate (EC), containing 62.5 g/L fluxapyroxad (BAS 700 F).

The representative uses evaluated comprise foliar spray applications as a fungicide for the control of various fungal pathogens on wheat, durum wheat, triticale, barley, rye and oat. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of the active substance is 950 g/kg. No FAO specification exists.

The technical specification is based on pilot plant production. Toluene was considered as a relevant impurity with a maximum limit of 1 g/kg (see also section 2). The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of fluxapyroxad (BAS 700 F) or the representative formulation. The main data regarding the identity of fluxapyroxad (BAS 700 F) and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of fluxapyroxad (BAS 700 F) in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

Appropriate analytical methods are available for the post-registration monitoring of fluxapyroxad (BAS 700 F) in food and feed of plant origin with a LOQ of 0.01 mg/kg (dry, high water, high fat and high acid commodities). Residues of fluxapyroxad (BAS 700 F) in food and feed of animal origin can be monitored with a LOQ of 0.01 mg/kg, and with a LOQ of 0.001 mg/kg in milk, skimmed milk, cream and eggs. Residues of fluxapyroxad (BAS 700 F) (as well as its metabolites M700F001 and M700F002) in soil can be analysed by HPLC-MS/MS and UPLC-MS/MS with a LOQ of 0.001 mg/kg. Residues of fluxapyroxad (BAS 700 F) (as well as its metabolites M700F001, M700F002 and M700F007) in drinking water and surface water can be monitored by HPLC-MS/MS with a LOQ of 0.03 µg/L. Fluxapyroxad (BAS 700 F) residues in air can be determined by HPLC-MS/MS or UPLC-MS/MS with a LOQ of 0.06 µg/m^3. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004b) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009).

Fluxapyroxad (BAS 700 F) was discussed at the Pesticides Peer Review Experts' Meeting 88 in September 2011.

The batches used in the toxicological studies support the technical specification as presented for the pilot plant manufacture. The relevance of the impurities has been addressed for this pilot specification, indicating that changes in the levels of impurities after storage are not significant and would not alter the toxicological profile of the substance. This indication together with the stability data over a period of 2 years gave reassurance that no toxicological concern is expected to arise from (slightly) increased levels of impurities. Toluene is considered as a relevant impurity, however there is no concern for this impurity at the level found in the pilot batches. Genotoxicity testing has been provided on some impurities and an artificial batch of fluxapyroxad (BAS 700 F) showing no concern regarding their genotoxic potential.

Low acute toxicity has been observed when fluxapyroxad (BAS 700 F) was administered by the oral, dermal or inhalation routes. Fluxapyroxad (BAS 700 F) did not produce skin or eye irritation, or potential for skin sensitisation.

The main target organs in rats were the liver and the thyroid upon short-term and long-term exposure; mice were less sensitive to the administration of fluxapyroxad (BAS 700 F) than rats, and in dogs the liver and the spleen presented iron staining. The most sensitive short-term NOAEL was found in the 90-day study in rats at 6 mg/kg bw/day, while the relevant long-term NOAEL was 2.1 mg/kg bw/day from the 2-year rat study. Mechanism studies were provided on enzyme induction, hepatocyte proliferation and thyroid hormone levels effects. Fluxapyroxad (BAS 700 F) produced liver tumours in males at 11 mg/kg bw/day and in females at 82 mg/kg bw/day, and accordingly, classification as carcinogenic category 3, R40 "limited evidence of a carcinogenic effect" was proposed according to Council Directive 67/548/EEC[9]. No genotoxic potential is attributed to the substance.

No reproductive or developmental effect was observed in rats; while minor transient developmental changes (post-implantation loss plus paw hyperflexation) were observed in rabbits in the presence of maternal toxicity. The maternal and developmental NOAEL in rabbits were 25 mg/kg bw/day; the same NOAEL of 25 mg/kg bw/day was obtained for the rat maternal toxicity based on decreased body weight gain in the first days of dosing. No evidence for a neurotoxic potential was found in a 90-day neurotoxicity study in rats.

Toxicological studies were provided on three metabolites. The groundwater metabolite **M700F001,** found at levels exceeding the limit of 0.1 µg/L but below 0.75 µg/L according to environmental fate and behaviour models (see section 4), was considered to be non-relevant from the toxicological point of view according to the guidance document on the assessment of groundwater metabolites (European Commission, 2003), as the studies provided sufficient evidence that this metabolite does not share the mode of action leading to carcinogenicity as observed with the parent fluxapyroxad (BAS 700 F). Metabolite M700F001 presented low oral acute and short-term toxicity, no adverse effects were observed up to 1000 mg/kg bw/day (limit dose) in a 90-day dietary study in rats; no adverse effect (regarding maternal and developmental toxicity) was observed in a developmental toxicity study in rabbits up to the highest dose tested of 250 mg/kg bw/day, but M700F001 produced high maternal toxicity at 500 mg/kg bw/day in a developmental range-finding study. No genotoxic potential is attributed to the metabolite. M700F001 was found to be clearly less toxic than the parent compound. If reference values are needed for this metabolite, no acute reference dose (ARfD) is allocated and the Acceptable Daily Intake (ADI) is 0.25 mg/kg bw/day, based on the NOAEL of 250 mg/kg bw/day from the developmental toxicity study in rabbits with an assessment factor (AF) of 1000 applied, to account for the limited database available (no long-term, multigeneration or rat developmental toxicity study available).

The groundwater and plant metabolite **M700F002,** found in groundwater above 0.75 µg/L according to environmental fate and behaviour models (see section 4), is non-relevant from the toxicological point of view according to the guidance document on the assessment of groundwater metabolites (European Commission, 2003), as the studies provided sufficient evidence that this metabolite does

[9] OJ 196, 16.08.1967, p. 001-0098

not share the mode of action leading to carcinogenicity as observed with the parent fluxapyroxad (BAS 700 F). Metabolite M700F002 presented low oral acute and short-term toxicity, no adverse effects were observed up to 1000 mg/kg bw/day (limit dose) in a 90-day dietary study in rats; in a developmental toxicity study in rabbits no adverse effect was observed on the development of the foetuses up to 1000 mg/kg bw/day (limit dose), while the maternal NOAEL was 300 mg/kg bw/day based on reduction of maternal body weight gain and decreased food intake. No genotoxic potential is attributed to metabolite M700F002. M700F002 can be considered to be less toxic than the parent compound. If reference values are needed for this metabolite, no ARfD is allocated and the ADI is 0.3 mg/kg bw/day, based on the NOAEL of 300 mg/kg bw/day from the developmental toxicity study in rabbits with an AF of 1000 applied to account for the limited database available (no long-term, multigeneration or rat developmental toxicity study available).

Toxicological studies were presented for the plant metabolite **M700F048**; it was shown that it is a precursor of metabolite **M700F008** when administered orally to rats; therefore the outcome of the studies presented for M700F048 could be applied to both metabolites. Metabolite M700F048 presented low acute oral toxicity; in a 28-day dietary study in rats a NOAEL of 200 mg/kg bw/day was identified based on reduced body weight gain and liver toxicity observed at 1000 mg/kg bw/day. It was shown to be a potential clastogen *in vitro*, but two *in vivo* tests (micronucleus and Unscheduled DNA Synthesis (UDS) assay) were negative. In a developmental toxicity study in rabbits both the maternal and developmental NOAELs were 30 mg/kg bw/day based on reduced maternal body weight gain, decreased food intake, and increased incidence of late resorptions and abortions at 100 mg/kg bw/day. It was concluded that the liver effects were observed at higher doses for the metabolite than for the parent fluxapyroxad (BAS 700 F) but the developmental toxicity was comparable between these compounds, therefore, if reference values are needed, the reference values of fluxapyroxad (BAS 700 F) are applicable to these two metabolites as they can be considered to be of similar toxicity as the parent compound.

The ADI for fluxapyroxad (BAS 700 F) is 0.02 mg/kg bw/day, based on the NOAEL of 2.1 mg/kg bw/day from the 2-year rat study and applying the standard AF of 100. The Acceptable Operator Exposure Level (AOEL) is 0.04 mg/kg bw/day, based on the NOAEL of 6 mg/kg bw/day from the 90-day rat study with an AF of 100 applied and a correction for low oral absorption of 68 %. The ARfD is 0.25 mg/kg bw, based on the NOAEL of 25 mg/kg bw/day for developmental effects in rabbits and decreased maternal body weight gain in rats with an AF of 100 applied.

The estimated operator exposure level is below the AOEL without considering the use of personal protective equipment (PPE) according to the German model, or when PPE (gloves during mixing, loading and application) are worn according to the UK POEM. The estimated bystander and worker exposures are below the AOEL.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev. 2 (European Commission, 1999), and the JMPR recommendations on livestock dietary burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004 and 2007).

The metabolism of fluxapyroxad (BAS 700 F) was investigated in tomatoes (fruit crops), soyabean (pulses and oilseed crops) and in wheat (cereals) under greenhouse conditions after foliar spray applications using the ^{14}C labelling on the aniline and the pyrazole moieties, respectively. Fluxapyroxad (BAS 700 F) was identified as the major component of the radioactive residues in the tomato and cereal plant parts investigated, accounting for 54 % TRR up to more than 90 % TRR and residue concentrations of 0.03 mg/kg in wheat grains and up to 0.16 mg/kg in tomato fruits. The metabolism was more extensive in soyabean seeds where fluxapyroxad (BAS 700 F) accounted for only 7 % TRR up to 21 % TRR, and the major metabolites were identified as M700F002 (33.5 %

TRR, pyrazole labelling) and M700F048 (20 % TRR, aniline labelling). Minor metabolites were identified at very low levels, accounting for less than 2 % of the TRR. Based on these studies, the main routes of biotransformation of fluxapyroxad (BAS 700 F) in plants were proposed to consist of N-demethylation of the pyrazole moiety, and hydroxylation of the biphenyl moiety with further glycosidation of the molecule. A minor pathway consisted of the loss of a fluorine atom at the biphenyl ring. No cleavage of the molecule was foreseen and the presence in soyabean seeds of the metabolite M700F002 resulting from the cleavage of the carboxamide bond was assumed to result from its uptake from the soil, where M700F002 was identified as a major soil metabolite. This statement is supported by the fact that the corresponding biphenyl counterpart metabolites were not detected in the primary crops when the labelling on the aniline moiety was used, and also by the higher total radioactive residues measured in soyabean seeds in the ^{14}C-pyrazole study compared to the ^{14}C-aniline study (0.26 mg/kg *vs.* 0.12 mg/kg).

Fluxapyroxad (BAS 700 F) was considered as a valid marker of the total residues in plants, and the residue definition for monitoring was limited to the parent compound only. For risk assessment, the inclusion of the metabolites M700F002 and M700F048 was considered during the peer review. Since metabolite M700F002 was concluded by the Pesticides Peer Review Experts' Meeting 88 to be less toxic than the parent compound (see section 2), EFSA proposes not to include this metabolite in the residue definition for risk assessment. Metabolite M700F048 was shown to be of similar toxicity as the parent compound, and as it was recovered at comparable levels in soyabean seeds, it was initially suggested to include this metabolite in the residue definition. However, in the framework of a MRL application (EFSA, 2011a), metabolite M700F048 was shown not to be present in supervised residue trials conducted in the USA and Canada in support of an import tolerance request on soyabean crop. Therefore, having regard to the results of the North American residue trials, EFSA is of the opinion not to include metabolite M700F048 and to limit the residue definition for risk assessment to fluxapyroxad (BAS 700 F) only for all categories of crops.

Only 6 residue trials were submitted on wheat covering respectively northern and southern Europe, and were found to be acceptable. A data gap was identified to provide two additional residue trials on wheat covering respectively northern and southern Europe in order to derive a MRL on wheat with extrapolation to rye and triticale. The residue database on barley was complete to derive a MRL of 0.6 mg/kg with extrapolation to oat. Fluxapyroxad (BAS 700 F) was also shown to remain stable under standard hydrolytic conditions representative of pasteurisation, baking, boiling, brewing and sterilisation. Residue trials on wheat and barley were provided to address the magnitude of the residues in processed commodities (bran, flour, germ, bread and beer). A concentration of fluxapyroxad (BAS 700 F) residues was observed in cereal bran and germ only, with average processing factors of 3 and 1.4, respectively.

In a confined rotational crop study, the soil was treated once at a dose rate of 250 g a.s./ha (1N) with ^{14}C-fluxapyroxad labelled either on the pyrazole or the aniline moiety. Spinach, radish and spring wheat were planted at plant back intervals of 30, 149 and 365 days. A similar residue pattern as in the primary crops was observed in the edible parts of the rotated crops. The available rotational field trials carried out on wheat, carrot root, cauliflower, broccoli and lettuce at a dose rate of 250 g a.s./ha were considered acceptable and showed that no significant residue levels of metabolites M700F002, M700F008 and M700F048 were recovered in the edible parts of the rotated crops at all plant back intervals (< 0.01 - 0.02 mg/kg). In contrast, significant levels of fluxapyroxad (BAS 700 F) residues were quantified in carrot roots (0.08 mg/kg) and in immature lettuce and cauliflower leaves (0.03 and 0.06 mg/kg, respectively). Therefore EFSA proposes a default MRL of 0.1 mg/kg respectively for the root and tuber vegetables crop group (including sugar beet and potatoes), and for the crop group "*leaves and sprouts of brassica spp*".

Frozen storage stability studies showed acceptable stability of the residues of the parent compound (737 days) as well as its metabolites M700F002 (824 days) and M700F048 (733 days) in all commodities, and covered the storage period of the residue samples in the field residue trials. The

desmethyl metabolite M700F008 was shown to be stable for up to 725 days in wheat grain (high starch content) and straw, but only for 133 days in high water and high oil content matrices.

Metabolism studies on lactating goats and laying hens were provided showing that besides the parent compound, the desmethyl metabolite M700F008 was found to be a significant compound of the total residues in all the ruminant and poultry matrices (17 % to 83 % TRR). Further minor metabolites were detected at a trace level (< 0.01 mg/kg) and resulted from the hydroxylation of the biphenyl moiety with a further step of conjugation reactions with glucuronic acid, amino acids or sulfate. An additional metabolism study on poultry using the ^{14}C-labelled M700F002 was provided and evaluated in Addendum 2 to the DAR (The United Kingdom, 2011b). Unchanged M700F002 was the major component of the total residues identified in all matrices (30 % to 90 % TRR). The agreed residue definition for monitoring in animal matrices is the parent compound only, whereas for risk assessment it is proposed to include both the parent compound and the desmethyl metabolite M700F008 expressed as parent equivalent. Feeding studies were also provided analysing fluxapyroxad (BAS 700 F), and metabolites M700F008 and M700F002 in ruminant and poultry matrices. MRLs were proposed at the LOQ for all the matrices except for ruminant fat (0.02 mg/kg) and eggs (0.01 mg/kg).

No chronic or acute intake concerns were identified for consumers. Using the EFSA PRIMo model, the TMDI is 15.5 % of the ADI (UK toddler) and the highest IESTI accounted for 4.9 % of the ARfD (potatoes, UK infant). It is also noted that the metabolite M700F002 is estimated to leach to groundwater at significant levels. The 0.75 µg/L trigger was exceeded in the majority of the pertinent FOCUS scenarios with a maximum concentration of 5.03 µg/L estimated for winter cereals in the FOCUS Jokioinen scenario (see section 4). Therefore an additional exposure of the consumers can be expected when groundwater is used as drinking water, although this route of exposure did not contribute significantly to the overall consumer exposure assessment (<1 % of the ADI allocated to metabolite M700F002).

4. Environmental fate and behaviour

The route and rate of degradation of fluxapyroxad (BAS 700 F) was investigated in four soils with pyrazole labelled fluxapyroxad (BAS 700 F), and in one soil with aniline and one with trifluorophenyl labelled fluxapyroxad (BAS 700 F). Fluxapyroxad (BAS 700 F) exhibits medium to very high persistence in these studies. No metabolites were identified above a concentration of 5 % AR in the aniline and trifluorophenyl labelled studies. Two metabolites, **M700F001** and **M700F002**, were observed in the pyrazole labelled study above 10 % AR. The levels of metabolite M700F002 were still increasing at the end of the study (120 d). Unextracted residues at the end of the studies (120 d) amounted to 54.7 % AR in the aniline labelled test, 29.9 % AR in the trifluorophenyl labelled test and up to 25.9 % AR in the pyrazole labelled ones. Mineralization (as CO_2) was 12.7 % AR in the aniline labelled experiment, 6 % in the trifluorophenyl labelled test and from negligible up to 7.3 % AR in the pyrazole labelled ones (end of studies, 120 d).

The rate of degradation of the metabolites M700F001 and M700F002 was also investigated in separate studies. Metabolite M700F001 may be considered to exhibit low persistence in soil, while metabolite M700F002 may be considered to exhibit high persistence in soil under aerobic conditions in laboratory experiments.

The cleavage of the carboxamide bond leading to the metabolites identified would be expected to concomitantly produce metabolite **M700F003** (from the aniline moiety side of the molecule). However, in the experiment performed with the substance labelled at the aniline moiety the metabolite M700F003 was not detected. The applicant considered that the metabolite M700F003 rapidly forms bound residues. An aerobic soil degradation study was submitted as supportive information for metabolite M700F003. In this study the majority of the radioactivity remained unextracted (78.3 % AR) at the study termination (30 d). During the peer review further information has been provided on the adequacy of the extraction methods employed in the soil studies to show that this potential

metabolite was appropriately extracted and quantified, and on its impact on the soil risk assessment. This information has been summarized and evaluated by the RMS in an addendum of September 2011 (The United Kingdom, 2011b). No further information on the eventual formation and fate of this metabolite is deemed necessary to finalise the EU risk assessment.

The applicant submitted a study to investigate the degradation of fluxapyroxad (BAS 700 F) in soil under anaerobic conditions with the substance labelled only in the aniline and pyrazole rings. A further study with triflurophenyl-U-^{14}C labelled fluxapyroxad (BAS 700 F) would be needed to complete the data requirements for the route and rate of degradation under anaerobic conditions. However, no further data have been requested at EU level since anaerobic conditions are considered to be unlikely to occur for the representative uses evaluated.

Photolysis in soil was investigated in an experiment under simulated summer sunlight at 49°N (Xenon lamp, filtered for $\lambda < 290$ nm) for 15 days of continuous irradiation. Photolysis slightly enhances the degradation of fluxapyroxad (BAS 700 F) in soil, producing minor metabolites not found in the dark control. However, these metabolites appeared at levels < 5 % AR and are not considered to require further assessment.

The dissipation of fluxapyroxad (BAS 700 F) under field conditions was investigated in six locations in Europe. In these trials the samples have also been analysed for the soil metabolites M700F001, M700F002 and the potential metabolite M700F003. The very high persistence of fluxapyroxad (BAS 700 F) observed in the laboratory studies was confirmed by these trials. Additionally, four field trials (Denmark, Germany, Italy and Southern France), where metabolite M700F002 was applied as parent, were performed. A soil accumulation study is currently ongoing, which, at the time of the peer review, had not yet reached a plateau. A data gap was identified for the final study when available. Accumulated PEC soil were calculated by the RMS for fluxapyroxad (BAS 700 F) and its metabolites M700F001 and M700F002 based on worst-case field half-life for fluxapyroxad (BAS 700 F). Plateau is expected to be reached after 13 years.

The mobility of fluxapyroxad (BAS 700 F) and its metabolites M700F001 and M700F002 was assessed by batch adsorption/desorption studies in eight soils. According to the results of these studies, fluxapyroxad (BAS 700 F) may be considered low to medium mobile in soil, while metabolites M700F001 and M700F002 high to very high mobile.

Fluxapyroxad (BAS 700 F) was estimated to be stable to hydrolysis in buffer aqueous solutions (25°C, pH 4, 5, 7 and 9; from measurements performed at 50°C). Fluxapyroxad (BAS 700 F) was stable to aqueous photolysis. The water sediment metabolite **M700F007** under irradiated conditions is also stable to hydrolysis (25°C, pH 4, 5, 7 and 9) and aqueous photolysis. Fluxapyroxad (BAS 700 F) is not readily biodegradable according to the available study (OECD 301B). The degradation of fluxapyroxad (BAS 700 F) was investigated under dark and irradiated water/sediment systems. In dark systems the primary dissipation from the water phase occurs by partition to the sediment phase. Only minor degradation occurred in the whole water/sediment system experiments under dark conditions. No metabolites > 5 % AR were observed. A default DT_{50} whole system = 1000 d has been assumed for the environmental risk assessment. Enhanced degradation was observed in the irradiated systems, resulting in the formation of two metabolites M700F001 (10.9 % AR at day 43) and M700F007 (7.5 % AR at day 57, increasing at the end of the study). The fact that fluxapyroxad (BAS 700 F) has shown to be practically stable in the aqueous photolysis study suggests that the acetone used as a vehicle to apply the product or other substances in the system may have acted as photosensitisers inducing indirect photolysis of fluxapyroxad (BAS 700 F). Also the fact that the temperature was higher in the irradiated systems may have contributed to the apparent enhanced degradation. Since the degradation was only marginally increased with respect to the dark experiments, the results of the irradiated systems have not been considered further in the environmental risk assessment.

The applicant proposed to refine the PEC_{SW} calculations by deviating from the default wash-off coefficient of 0.5 cm^{-1}, using the solubility correlation formula proposed in FOCUS SW guidance

(FOCUS 2001). Member State experts discussed the applicability of this formula to the case of fluxapyroxad (BAS 700 F). The experts noted that due to the low solubility of fluxapyroxad (BAS 700 F) the application of the formula to this substance was done outside of the range of solubility for which it had been validated. Additionally, it was also noted that the formulation (or a number of their components) may remain in the surface of the leaves for the time needed to have a rainfall event. In the particular case of the representative formulation (an emulsifiable concentrate) a number of components may significantly modify the effective solubility and wash-off potential of fluxapyroxad (BAS 700 F). Therefore, the experts concluded that for this low solubility compound and its formulation some experimental data would be needed on the wash-off from leaves allowing to move away from the default value for wash-off. Therefore calculations assuming this refinement were disregarded with respect to the EU risk assessment.

The potential for groundwater contamination was assessed by calculation of the 20 years 80th percentile concentration at 1 m depth for fluxapyroxad (BAS 700 F) and its metabolites M700F001 and M700F002 with the FOCUS GW I scheme (FOCUS, 2000; EFSA, 2004; EFSA, 2007)[10]. Leaching resulting from the representative uses in cereals (winter and spring) was simulated with FOCUS models PEARL 3.3.3, MACRO 4.4.2 (Châteaudun), and PELMO 3.3.2 for the available scenarios following the representative GAP. Appropriate combinations of input parameters were selected to cover the realistic worst case of the parent compound or the metabolites respectively. According to these calculations fluxapyroxad (BAS 700 F) does not exceed the limit of 0.1 µg/L for any of the scenarios simulated, metabolite M700F001 exceeds the limit of 0.1 µg/L in less than half of the scenarios simulated, while metabolite M700F002 exceeds 0.75 µg/L in the majority of the scenarios with a maximum of 5.03 µg/L for winter cereals in Jokioinen scenario (PELMO simulation).

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b and 2002c), SETAC (2001) and EFSA (2009).

The risk for **birds** via dietary exposure was assessed as low at tier 1 for the representative uses on cereals, based on the SANCO guidance (European Commission, 2002c). The risk assessment for **mammals** was carried out in accordance with the EFSA guidance (EFSA, 2009). The acute risk for mammals was assessed as low at the screening assessment for the representative uses on cereals. The reproductive risk for mammals was assessed as low at the tier 1 risk assessment, based on generic focal species. Since the log P_{ow} for fluxapyroxad (BAS 700 F) is 3.1, a risk assessment from secondary poisoning to birds and mammals was carried out. The risk for birds and mammals from secondary poisoning was assessed as low based on the use of the SANCO guidance (European Commission, 2002c).

Based on the toxicity data available fluxapyroxad (BAS 700 F) should be considered as very toxic to **aquatic organisms**. A similar toxicity was observed for the active substance and the representative formulation 'BAS 700 00F'. The risk from fluxapyroxad (BAS 700 F) for sediment-dwelling organisms (*Chironomus riparius)* and aquatic plants (*Lemna gibba*) was assessed as low at $FOCUS_{sw}$ step 1, as well as the chronic risk to aquatic invertebrates. The acute and chronic risk for aquatic invertebrates and algae, respectively, was assessed as low for the representative uses on cereals at $FOCUS_{sw}$ step 2. A low acute and chronic risk for fish was observed in seven out of nine relevant scenarios (D3, D4, D5, D6, R1, R3 and R4) at $FOCUS_{sw}$ step 3. A low acute and chronic risk for fish was observed for the scenarios D1 and D2 based on the use of PEC_{sw} step 3 with refined interception values according to $FOCUS_{sw}$ recommendations. Overall, it can be concluded that the risk from fluxapyroxad (BAS 700 F) to aquatic organisms was assessed as low. A BCF-value of 36 obtained for

[10] A Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7 was used in these simulations and for the normalization of the degradation input parameters used in the modelling.

whole fish indicates no potential for bioaccumulation. The risk from the metabolites (M700F001, M700F002 and M700F007) for aquatic organisms was assessed as low for the representative uses.

The oral and contact hazard quotients (HQs) for **bees** were below the Annex VI trigger, indicating a low risk to bees for the representative uses on cereals. Since mortality and behavioural abnormalities (such as apathy, moving coordination problems) were seen in the acute contact toxicity test with the formulation on bees, a higher tier test (tunnel study) was submitted. The results showed that the formulation did not cause effects on mortality, larvae or pupae, or foraging activity of honeybees. There was an initial decrease in colony strength compared to the control, however the effect was considered minor and not sustained. The test item groups recovered to come in line with the colony growth rate of the controls. The risk to honeybee brood development from the exposure of the formulation 'BAS 700 00 F' was assessed as low.

Whilst the off-field risk for the two standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri* was assessed as low, the in-field risk was assessed as low only for *A. rhopalosiphi* for the representative uses on cereals. The in-field risk for *T. pyri* was addressed based on aged-residue studies on *T. pyri.*

The active substance and its soil metabolite M700F002 are considered persistent in soil, while the soil metabolite M700F001 showed low persistence (see sections 4 and 6). The TERs values were calculated on the basis of the peak plateau $PEC_{soil,}$ and initial PEC_{soil} for the active substance, metabolite M700F002 and metabolite M700F001. The acute and chronic risk from fluxapyroxad (BAS 700 F) and the soil metabolites M700F001 and M700F002 to earthworms and soil non-target macro-organisms was assessed as low for the representative uses on cereals. An earthworm field study and a litter bag study were submitted. No statistically significant effects from the exposure of the active substance to non-target soil-organisms were observed in these studies, confirming the outcome of the first-tier risk assessment. It is noted that there is a soil accumulation field study ongoing in the area of environmental fate and behaviour (see data gap in section 4). Pending on the outcome of this issue, in particular, if the plateau concentration in soil observed in the field study will be greater than the estimated peak plateau PECs, the risk assessment for **non-target soil-organisms** may need to be reconsidered.

The risk for **non-target terrestrial plants** and the organisms involved in **biological methods of sewage treatment plants** was assessed as low for the representative uses.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Fluxapyroxad (BAS 700 F)	Medium to very high ($DT_{50\ 20\ °C}$ = 89.3 d – 696 d)	The acute and chronic risk from the exposure of fluxapyroxad (BAS 700 F) to soil-organisms was assessed as low. Pending on the data gap in section 4, the risk assessment for non-target soil-organisms may need to be reconsidered.
M700F001	Low ($DT_{50\ 20\ °C}$ = 2.3 d– 10 d)	The acute and chronic risk from the exposure of metabolite M700F001 to soil-organisms was assessed as low. Pending on the data gap in section 4, the risk assessment for non-target soil-organisms may need to be reconsidered.
M700F002	High ($DT_{50\ 20\ °C}$ = 131 d -197d)	The acute and chronic risk from the exposure of metabolite M700F002 to soil-organisms so was assessed as low. Pending on the data gap in section 4, the risk assessment for non-target soil-organisms may need to be reconsidered.

6.2. 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 activity
Fluxapyroxad (BAS 700 F)	low to medium mobile (K_{Foc} = 320 – 1101 mL/g)	FOCUS: No	Yes	Yes	Very toxic to aquatic organisms, end point driving the aquatic risk assessment: acute fish LC_{50} = 0.29 mg a.s./L (regulatory concentration including a safety factor of 100 = 0.0029 mg a.s./L). The risk assessment for the aquatic environment was assessed as low.
M700F001	high to very high (K_{Foc} = 0 – 65.8 mL/g)	FOCUS: Yes, 0.1 µg/L exceeded for a number of scenarios and uses	No	No Rat oral LD_{50} > 2000 mg/kg bw Not genotoxic 90-day rat NOAEL 1000 mg/kg bw/day Rabbit developmental and maternal NOAELs 250 mg/kg bw/day ADI: 0.25 mg/kg bw/day No ARfD allocated	Harmful to aquatic organisms, end point driving the aquatic risk assessment: algae E_yC_{50} = 26.42 mg /L (regulatory concentration including a safety factor of 10 = 2.642 mg/L). A low risk to the aquatic environment was indicated in the surface water risk assessment.

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 activity
M700F002	high to very high (K_{Foc} = 1 – 99.9 mL/g)	FOCUS: Yes, 0.75 µg/L exceeded for the majority of scenarios and uses. Max. 5.03 µg/L for winter cereals in Jokioinen.	No	No Rat oral LD_{50} > 2000 mg/kg bw Not genotoxic 90-day rat NOAEL 1000 mg/kg bw/day Rabbit maternal NOAEL 300 mg/kg bw/day Rabbit developmental NOAEL 1000 mg/kg bw/day ADI: 0.3 mg/kg bw/day No ARfD allocated	Harmful to aquatic organisms, end point driving the aquatic risk assessment: algae E_yC_{50} = 22.44 mg /L (regulatory concentration including a safety factor of 10 = 2.244 mg/L). A low risk to the aquatic environment was indicated in the surface water risk assessment.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Fluxapyroxad (BAS 700 F)	Very toxic to aquatic organisms, end point driving the aquatic risk assessment: acute fish LC_{50} = 0.29 mg a.s./L (regulatory concentration including a safety factor of 100 = 0.0029 mg a.s./L). The risk to the aquatic environment was assessed as low in the surface water risk assessment.
M700F001 (soil metabolite)	Harmful to aquatic organisms, end point driving the aquatic risk assessment: algae E_yC_{50} = 26.42 mg /L (regulatory concentration including a safety factor of 10 = 2.642 mg/L). A low risk to the aquatic environment was indicated in the surface water risk assessment.
M700F002 (soil metabolite)	Harmful to aquatic organisms, end point driving the aquatic risk assessment: algae E_yC_{50} = 22.44 mg /L (regulatory concentration including a safety factor of 10 = 2.244 mg/L). A low risk to the aquatic environment was indicated in the surface water risk assessment.
M700F007 (aqueous metabolite in water / sediment systems under irradiated conditions).	The LC_{50} > 100 mg /L, classification is not required, end point driving the aquatic risk assessment: acute fish or *Daphnia Magna* E_yC_{50} = 100 mg /L (regulatory concentration including a safety factor of 100 = 1.00 mg/L). A low risk to the aquatic environment was indicated in the surface water risk assessment.

6.4. Air

Compound (name and/or code)	Toxicology
Fluxapyroxad (BAS 700 F)	Rat LC_{50} inhalation > 5.31 mg/L air (4h., nose only); no classification proposed.

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

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- 2 additional residue trials are required on wheat covering respectively northern and southern Europe in order to derive a MRL on wheat with extrapolation to rye and triticale (relevant for the representative uses on wheat, rye and triticale evaluated; no submission date proposed by the applicant; see section 3)

- Final report of the accumulation in soil field study once the plateau is reached should be submitted as soon as it becomes available (see section 4.2.8 in Level 4 of Vol. 1 of the DAR). If the plateau concentration in soil observed in the field study will be greater than the estimated peak plateau PECs, the risk assessment for non-target soil-organisms may need to be reconsidered (relevant for all representative uses evaluated; submission date proposed by the applicant: as soon as available; see sections 4 and 5)

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

- None

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

None.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

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

None.

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

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

Representative use		Foliar spray applications as a fungicide for the control of various fungal pathogens on wheat, durum wheat, triticale, barley, rye and oat (application rate of 2 x 0.125 kg a.s./ha)
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated within sections 9.1 and 9.2. Where there is no superscript number, see sections 2 to 6 for further information.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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APPENDICES

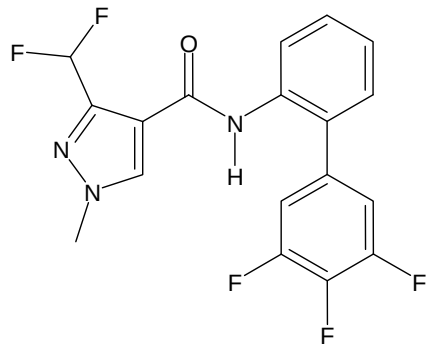
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Fluxapyroxad (BAS 700 F)
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	United Kingdom
Co-rapporteur Member State	France

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide
Chemical name (CA) ‡	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide
CIPAC No ‡	828
CAS No ‡	907204-31-3
EC No (EINECS or ELINCS) ‡	not assigned
FAO Specification (including year of publication) ‡	not assigned
Minimum purity of the active substance as manufactured ‡	950 g/kg (pilot plant)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	toluene max. 1 g/kg
Molecular formula ‡	$C_{18}H_{12}F_5N_3O$
Molecular mass ‡	381.31 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	156.8 °C (99.3 % pure)
Boiling point (state purity) ‡	decomposes before boiling
Temperature of decomposition (state purity)	~ 230 °C (99.3 % pure)
Appearance (state purity) ‡	Fine crystalline powder (99.3 % pure)
	Fine powder (99.4 % technical)
Vapour pressure (state temperature, state purity) ‡	2.7×10^{-9} Pa at 20 °C (99.3 % pure) 8.1×10^{-9} Pa at 25 °C (99.3 % pure)
Henry's law constant ‡	3.028×10^{-7} Pa m^3 mol^{-1} [Based on vapour pressure of 2.7×10^{-9} Pa at 20 C and water solubility of 3.4 mg/L]
Solubility in water (state temperature, state purity and pH) ‡	3.78 mg /L at 20 °C (pH 4.01) 3.88 mg /L at 20 °C (pH 5.84) 3.44 mg /L at 20 °C (pH 7.00) 3.84 mg /L at 20 °C (pH 9.00) (99.3 % pure)
	No significant pH dependency of the water solubility was found.
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (99.2 % pure) acetone > 250 acetonitrile 167.6 ± 0.2 dichloromethane 146.1 ± 0.3 ethylacetate 123.3 ± 0.2 methanol 53.4 ± 0.0 toluene 20.0 ± 0.0 octanol 4.69 ± 0.01 heptane 0.106 ± 0.001
Surface tension ‡ (state concentration and temperature, state purity)	73.3 mN/m at 20 °C, 3.1 mg/L (90 % of the saturation solubility in pure water) (99.3 % technical)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.08 at 20 °C in water log $P_{O/W}$ = 3.09 at 20 °C (pH 4) log $P_{O/W}$ = 3.13 at 20 °C (pH 7) log $P_{O/W}$ = 3.09 at 20 °C (pH 9) (99.3 % pure)
	no pH dependency expected at pH< 12.58
Dissociation constant (state purity) ‡	$pK_{a\ (HL/H+L)}$ = 12.58 ± 0.70 (calculated) $pK_{a\ (H2L/H+HL)}$ = -2.78 ± 0.50 (calculated) $pK_{a\ (H3L/H+H2L)}$ = -5.52 ± 0.50 (calculated) pK_a was estimated using modelling software version 6.00 from ACD/Labs

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	99.7 % pure Neutral solution in methanol (pH = 6.5): absorption maxima λ_{max} 203 nm; ε 31582 L.mol^{-1}.cm^{-1} secondary maxima λ 229 nm; ε 23928 L.mol^{-1}.cm^{-1} Neutral solution methanol water (1:9) (pH = 5.9) absorption maxima λ_{max} 193 nm; ε 44100 L.mol^{-1}.cm^{-1} secondary maxima λ 230 nm; ε 24010 L.mol^{-1}.cm^{-1} Acid solution methanol : HCl 1 mol/L : water (10:5:85)(pH = 1.4) absorption maxima λ_{max} 199 nm; ε 35913 L.mol^{-1}.cm^{-1} secondary maxima λ 230 nm; ε 24137 L.mol^{-1}.cm^{-1} Basic solution methanol : NaOH 1 mol/L : water (10:5:85) (pH = 12.2) absorption maxima λ_{max} 229 nm; ε 23473 L.mol^{-1}.cm^{-1} secondary maxima λ 215 nm; ε 23227 L.mol^{-1}.cm^{-1}
Flammability ‡ (state purity)	not highly flammable (99.4 % technical)
Explosive properties ‡ (state purity)	not explosive (99.4 % technical)
Oxidising properties ‡ (state purity)	not oxidising (99.4 % technical)

Summary of representative uses evaluated for fluxapyroxad (BAS 700 F)

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment				PHI (days)	Remarks:
(a)			(b)	(c)	Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (days)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max	Product (kg,L/ha) min max	(l)	(m)
W. Wheat S. Wheat Durum W. Barley S. Barley Triticale Rye Oat	EU	'BAS 700 00F'	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. trticirepentis* *P. teres* *R.secalis* *R. collo-cygni*	EC	0.0625	Foliar spray	25-69	2	21 days	0.0417-0.125	100-300	0.125	2.0	35	-

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) emulsifiable concentrate (EC),
(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) kg/L
(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) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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 (230 nm)
Plant protection product (analytical technique)	HPLC-UV (230 nm)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Fluxapyroxad (BAS 700 F)
Food of animal origin		Fluxapyroxad (BAS 700 F)
Soil		Fluxapyroxad (BAS 700 F)
Water	surface	Fluxapyroxad (BAS 700 F)
	drinking/ground	Fluxapyroxad (BAS 700 F)
Air		Fluxapyroxad (BAS 700 F)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS - LOQ 0.01 mg/kg (fluxapyroxad) UPLC-MS/MS - LOQ 0.01 mg/kg (fluxapyroxad) (dry, high water, high fat and high acid commodities)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS - LOQ 0.01 mg/kg (0.001 mg/kg milk, skimmed milk, cream and egg) (fluxapyroxad)
Soil (analytical technique and LOQ)	HPLC-MS/MS - LOQ 0.001 mg/kg (fluxapyroxad) UPLC-MS/MS - LOQ 0.001 mg/kg (fluxapyroxad)
Water (analytical technique and LOQ)	HPLC-MS/MS - LOQ 0.03 µg/L (fluxapyroxad) (drinking and surface water)
Air (analytical technique and LOQ)	HPLC-MS/MS - LOQ 0.06 µg/m^3 (fluxapyroxad) UPLC-MS/MS - LOQ 0.06 µg/m^3 (fluxapyroxad)
Body fluids and tissues (analytical technique and LOQ)	No methods of analysis were submitted or required, as fluxapyroxad (BAS 700 F) is not classified as toxic or very toxic.

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

	RMS/peer review proposal
Active substance	-

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	At least 68 % of administered dose absorbed within 72 h based on urine (11.5 %) and bile (51 %) excretion, cage wash and carcass residues.
Distribution ‡	Widespread distribution, with highest concentrations in gastrointestinal tract, liver, adrenals and adipose tissues at early sampling times.
Potential for accumulation ‡	Low
Rate and extent of excretion ‡	Rapid, excretion almost complete 2-3 days after dosing. 85-91 % excreted via faeces (51-55 % via bile) and 3.4-9.3 % via urine by 7 days.
Metabolism in animals ‡	Extensive. Major metabolites formed by hydroxylation at the biphenyl ring, N-demethylation at the pyrazole ring, loss of a fluorine atom at the biphenyl ring, and conjugation with glucuronic acid or with glutathione derivatives. Trace amounts of products from cleavage between the pyrazole and aniline rings.
Toxicologically relevant compounds ‡ (animals and plants)	Fluxapyroxad (BAS 700 F)
Toxicologically relevant compounds ‡ (environment)	Fluxapyroxad (BAS 700 F)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.31 mg/L air (4h, nose only, to dust)	
Skin irritation ‡	Not irritating	
Eye irritation ‡	Not irritating	
Skin sensitisation ‡	Not sensitising (M&K test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: Liver (increased weight, hepatocellular centrilobular hypertrophy, enzyme induction), thyroid (follicular cell hypertrophy/hyperplasia, thyroid hormone changes), blood (accelerated clotting), increased calcium, globulin and cholesterol levels Mouse: Clinical chemistry changes (decreased triglyceride, cholesterol) Dog: Clinical chemistry changes in spleen (iron staining of connective tissue) and liver (iron staining of hepatocytes, fibrosis)

Relevant oral NOAEL ‡	28-day rat: 9 mg/kg bw/day 90-day rat: 6 mg/kg bw/day 90-day mouse: 21 mg/kg bw/day 1-year dog: 8 mg/kg bw/day	
Relevant dermal NOAEL ‡	28-day rat: 300 mg/kg bw/day	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Not genotoxic (negative in Ames test, *in vitro* chromosome aberration, *in vitro* mammalian gene cell mutation, *in vivo* micronucleus and *in vivo* UDS assays).	

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

Target/critical effect ‡	Rat: Liver (increased weight, hepatocellular hypertrophy, hepatocellular tumours, fatty change, spongiosis), thyroid (follicular hypertrophy/hyperplasia), bone (iron deposition, hyperstosis of skull bones, tooth whitening), blood (accelerated clotting, reduced MCV, MCH). Mouse: Liver (increased weight and macrovesicular fatty changes), tooth whitening.	
Relevant NOAEL ‡	2.1 mg/kg bw/day; 2-year, rat 21 mg/kg bw/day; 18-month, mouse	
Carcinogenicity ‡	Carcinogenic (liver tumours in rats) Increased incidence of thyroid follicular cell tumours at high dose of limited relevance to humans	**R40** **H351**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parent: increased liver weight, hepatocellular hypertrophy, reduced body weight gain Offspring: reduced body weight gain Reproduction: No effect observed up to the highest dose tested	
Relevant parental NOAEL ‡	LOAEL 10 mg/kg bw/day	
Relevant reproductive NOAEL ‡	300 mg/kg bw/day	
Relevant offspring NOAEL ‡	10 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal: reduced body weight gain, clinical chemistry changes Developmental: no effect up to the limit dose Rabbit: Maternal: reduced body weight gain Developmental: post-implantation loss plus increased incidence of paw hyperflexation, a minor transient change	
Relevant maternal NOAEL ‡	Rat: 25 mg/kg bw/day Rabbit: 25 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rat: 1000 mg/kg bw/day Rabbit: 25 mg/kg/day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Transient minor behavioural changes observed, NOAEL 125 mg/kg bw	
Repeated neurotoxicity ‡	90-day study: No evidence of neurotoxicity up to 302 mg/kg bw/day NOAEL 11.5 mg/kg bw/day based on increased thyroid weight and liver hypertrophy	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	A **liver enzyme induction study** showed that fluxapyroxad (BAS 700 F) induced liver hypertrophy is associated with increased activity of phase I enzymes, PROD and BROD (both of the CYP2B1 family), and increased activities of the phase II enzymes MUF-GT, HOBI-GT and T4-UDP-GT. This response is indicative of a phenobarbital-type enzyme induction by fluxapyroxad (BAS 700 F). A weak enzyme induction response occurred at the lowest oral dose level investigated (dietary level of 50 ppm, intake of ~3 mg/kg bw/day). A **thyroid hormone study** showed that fluxapyroxad (BAS 700 F) causes increased TSH levels and decreased T_4 levels at a relatively high exposure level (dietary level of 1500 ppm, intake of ~105 mg/kg bw/day). A thyroid function test demonstrated that fluxapyroxad (BAS 700 F) induced thyroid hypertrophy is not related to a defect in the organification of iodine. A quantitative analysis of fluxapyroxad (BAS 700 F) induced **hepatocyte proliferation** demonstrated that this response occurs in mainly the centrilobular region of the liver and is more pronounced in females. Proliferation occurred from dietary concentration of 1500 ppm (intake ~60-80 mg/kg bw/day) in males and from 50 ppm in females (intake ~15 mg/kg bw/day, the lowest dose level investigated).

Studies performed on metabolites or impurities ‡	**Metabolite M700F001** Rat oral LD_{50} > 2000 mg/kg bw Not genotoxic (negative in Ames, *in vitro* chromosome aberration, *in vitro* mammalian gene cell mutation, *in vivo* micronucleus tests). NOAEL in 90-day dietary rat study 1000 mg/kg bw/day (highest dose level tested). NOAEL in rabbit developmental toxicity study for maternal and developmental toxicity 250 mg/kg bw/day (highest dose level tested; severe maternal toxicity at ≥500 mg/kg/day in range-finding studies). No ARfD allocated. ADI 0.25 mg/kg bw/day based on the developmental toxicity study, AF 1000. **Metabolite M700F002** Rat oral LD_{50} > 2000 mg/kg bw Not genotoxic (negative in Ames, *in vitro* chromosome aberration, *in vitro* mammalian gene cell mutation, *in vivo* micronucleus tests). NOAEL in 90-day dietary rat study 1000 mg/kg bw/day (highest dose level tested). NOAELs in rabbit developmental toxicity study: 300 mg/kg bw/day for maternal (based on reduction of body weight gain and food consumption) and 1000 mg/kg bw/day developmental toxicity (the highest dose tested). No ARfD allocated. ADI 0.3 mg/kg bw/day based on the developmental toxicity study, AF 1000. **Metabolite M700F048** Rat oral LD_{50} > 2000 mg/kg bw Not genotoxic (negative in Ames, *in vitro* mammalian gene cell mutation, *in vivo* micronucleus, *in vivo* UDS assays, positive in *in vitro* chromosome aberration test). NOAEL in 28-day dietary rat study 200 mg/kg bw/day. LOAEL 1000 mg/kg bw/day, based on observation of liver hypertrophy and reduced body weight gain. NOAELs in rabbit developmental toxicity study: 30 mg/kg bw/day for maternal and developmental toxicity based on reduced body weight gain and food intake and increased incidence of abortions at 100 mg/kg bw/day. In this study there was no evidence of a specific adverse effect on development.

Medical data ‡ (Annex IIA, point 5.9)

No adverse health effects suspected to be related to fluxapyroxad (BAS 700 F) exposure have been observed.

Summary (Annex IIA, point 5.10)

	Value	Study	Assessment factor
ADI ‡	0.02 mg/kg bw/day	Rat, 2-year study	100
AOEL ‡	0.04 mg/kg bw/day	Rat, 90-day study	147* (100 + 68 %*)
ARfD ‡	0.25 mg/kg bw	Rabbit (developmental effects), and rat, (maternal effects) developmental toxicity studies	100

* correction for low oral absorption (68 %)

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation ('BAS 700 00F', 62.5 g fluxapyroxad (BAS 700 F)/L EC)	Concentrate: 8 % Dilution (0.37 g/l): 16 %

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Exposure estimates using tractor-mounted equipment, application rate 0.125 kg a.s./ha: German model — % of AOEL Without PPE — 48 % UK POEM — % of AOEL Without PPE — 450 % With PPE (gloves at mixing/loading) — 350 % With PPE (gloves at mixing/loading & application) — 68 %
Workers	Exposure estimates for workers entering cereal crops to perform tasks such as crop inspection indicate that the levels of exposure to fluxapyroxad (BAS 700 F) will be 50 % of the systemic AOEL without PPE, assuming 2 applications and no dissipation of dislodgeable foliar residues between treatments.
Bystanders	Exposure estimates for bystanders exposed to fluxapyroxad (BAS 700 F) through spray drift, vapour and fallout: % of AOEL Exposure to spray drift: < 2 % Exposure to vapour: 10 % (adult), 21 % (child) Exposure to fallout: < 1 %

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

	RMS/peer review proposal
Fluxapyroxad (BAS 700 F)	***Under Council Directive 67/548/EEC:*** **R40** Carcinogenicity category 3 "limited evidence of a carcinogenic effect" ***Under Regulation (EC) 1272/2008:*** **H351** Carcinogenicity category 2 "suspected of causing cancer"

Residues

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

Plant groups covered	Cereals (wheat), fruit (tomato), pulses and oilseeds (soyabean).
Rotational crops	Confined metabolism studies on leafy crops (spinach), root crops (radish) and cereals (wheat).
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Parent compound stable under hydrolytic conditions representative of pasteurisation, baking, brewing and boiling and sterilisation.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes.
Plant residue definition for monitoring	Fluxapyroxad (BAS 700F) - All crop categories.
Plant residue definition for risk assessment	Fluxapyroxad (BAS 700F) - All crop categories.
Conversion factor (monitoring to risk assessment)	N/A

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

Animals covered	Goats, hens
Time needed to reach a plateau concentration in milk and eggs	Milk: 5-7 days (feeding study) Rapid depletion of the total radioactivity 1 day post dosing. Eggs: 10-12 days (metabolism study)
Animal residue definition for monitoring	Fluxapyroxad (BAS 700F)
Animal residue definition for risk assessment	Fluxapyroxad (BAS 700F) and metabolite M700F008 expressed as parent equivalent.
Conversion factor (monitoring to risk assessment)	N/A. A feeding study analysing fluxapyroxad (BAS 700F), and metabolites M700F008 and M700F002 in poultry and ruminant matrices is available.
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes Log P_{ow} at pH 7 = 3.13 Feeding studies indicate the highest residue level in ruminant fat (0.024 mg/kg).

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

Rotational crops field trials on cereals (wheat), root crops (carrots), flowering brassica (cauliflower, broccoli) and leafy crops (lettuce) were conducted at a dose rate of 250 g a.s/ha (1N).

-Fluxapyroxad (BAS 700F):

Up to 0.08 mg/kg in carrot root (plant back interval: 31 d),

Up to 0.06 mg/kg in immature cauliflower leaves (PBI: 31 d),

Up to 0.03 mg/kg in immature lettuce (PBI: 31 d).

-M700F048:

Very low residue situation : <0.01-0.02 mg/kg in immature cauliflower leaves at all PBIs.

-M700F008, M700F002:

Residue levels below the LOQ (0.01 mg/kg) in all crops at all PBIs.

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

Frozen storage stability (-20°C):
Fluxapyroxad (BAS 700F): 737 days in all matrices
Metabolite M700F002: 824 days in all matrices
Metabolite M700F048: 733 days in high starch, high acid, high oil and high water content matrices and in wheat straw.
Metabolite M700F008: 725 days in high starch matrices and in wheat straw, and up to 133 days in high oil and high water content matrices.

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)	Dairy: 1.627 mg/kg DM Beef: 3.76 mg/kg DM	0.22 mg/kg DM	N/A
Potential for accumulation (yes/no):	Yes	No	N/A
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes (liver, kidney, only)	No	N/A
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Overdosing factor	1.6 N (Beef) 3.7 N (Dairy)	1.4 N	

Muscle	<0.01 mg/kg[(1)]	<0.01 mg/kg[(1)]	N/A
Liver	0.015 mg/kg[(1)]	<0.01 mg/kg[(1)]	N/A
Kidney	<0.01 mg/kg[(1)]	N/A	N/A
Fat	0.024 mg/kg[(1)]	<0.01 mg/kg[(1)]	N/A
Milk	0.0025 mg/kg[(2)]	N/A	N/A
Eggs	N/A	0.0111 mg/kg[(2)]	N/A

[(1)]: The highest residue levels were considered in tissues.
[(2)]: The average of the residue levels in whole milk and eggs recovered over the course of the feeding study (28 days).

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 (d)	HR (c)	STMR (b)
Wheat	N EU	Grain: 0.01; 0.02; 0.03; 0.04; 0.04; 0.06 mg/kg Straw: 0.44; 1.0; 1.02; 1.80; 2.78; 6.05 mg/kg	2 additional residue trials on wheat are required. Extrapolation to triticale and rye.	0.1 (Provisional)	0.06 (Provisional)	0.03 (Provisional)
	S EU	Grain: 0.01; 0.01; 0.01; 0.02; 0.03; 0.05 mg/kg Straw: 0.46; 0.55; 0.64; 1.0; 1.19; 2.58 mg/kg	2 additional residue trials on wheat are required. Extrapolation to triticale and rye.	0.1 (Provisional)	0.05 (Provisional)	0.02 (Provisional)
Triticale	N EU	Grain: <0.01; 0.03 mg/kg Straw: 0.32; 1.55 mg/kg				
	S EU	Grain: 0.02; 0.02 mg/kg Straw:				

		0.49; 0.55 mg/kg				
Barley	N EU	Grain: 0.02; 0.05; 0.08; 0.13; 0.17; 0.18; 0.19; 0.23 mg/kg Straw: 0.11; 0.12; 0.44; 0.47; 0.64; 0.74; 1.79; 2.37 mg/kg	Extrapolation to oat.	0.5	0.23	0.15
	S EU	Grain: 0.08; 0.09; 0.10; 0.10; 0.15; 0.23; 0.24; 0.41 mg/kg Straw: 0.11; 0.36; 0.45; 0.80; 0.96; 1.03; 1.29; 1.24 mg/kg	Extrapolation to oat.	0.6	0.41	0.13

(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
(d) Based upon a UK MRLs application the proposed MRLs for wheat and barley are proposed at 0.4 mg/kg and 2.0 mg/kg respectively.

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)(3)

ADI	**0.02 mg/kg bw/day**
TMDI (% ADI) according to EFSA PRIMo Model rev.2A°	15.5% ADI (UK toddler)
Factors included in TMDI	-STMR values for cereal grains, -Default MRL of 0.1 mg/kg on root and tuber vegetables (including sugar beet and potatoes) and on leaves and sprouts of brassica *spp*., -MRLs on animal matrices, -Processing factor of 3 set for cereal bran.
ARfD	**0.25 mg/kg bw**
IESTI (% ARfD) according to EFSA PRIMo Model rev.2A	4.9% ARfD (potatoes, UK infant)
Factors included in IESTI and NESTI	-STMR values for cereal grains. -HR of 0.08 mg/kg on root and tuber vegetables (including sugar beet and potatoes), -HR of 0.06 mg/kg on leaves and sprouts of brassica *spp*., -MRLs for animal commodities, -Processing factor of 3 set for cereal bran.

(3): The consumer dietary intake will be recalculated according to the outcome of the 2 additional residue trials requested on wheat.

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	
Wheat → bran	4 trials (2 replicates each)	3.1	-	-
Flour		0.24	-	-
Bread white		0.17	-	-
Whole meal		1.04	-	-
Bread whole meal		0.71	-	-
Germ		1.4	-	-

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

Commodity	Proposed EU MRLs (mg/kg)
Wheat/Triticale/Rye	0.1 (provisional)
Barley/Oats	0.6
Root and tuber vegetables (including potatoes and sugar beet)	0.1
Leaves and sprouts of brassica *spp*.	0.1
Whole milk	0.001*
Eggs	0.01
Muscle, liver, kidney, poultry fat	0.01*
Ruminant fat	0.02

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

Environmental fate and behaviour

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

Mineralization after 100 days ‡	12.7 % after 120 d, [aniline-^{14}C]-label (n[11]= 1) 0.2 - 7.3 % after 120 d, [pyrazole-4-^{14}C]-label (n= 4) 6 % after 120 d, [trifluorophenyl-U-^{14}C]-label (n= 1)
Non-extractable residues after 100 days ‡	54.7 % after 120 d, [aniline-^{14}C]-label (n= 1) 10.2 – 25.9 % after 120 d, [pyrazole-4-^{14}C]-label (n= 4) 29.9 % after 120 d, [trifluorophenyl-U-^{14}C]-label (n= 1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	**M700F001** – 13.9 % at 30 d (n= 4) **M700F002** – 38.9 % at 120 d (n= 4) [pyrazole-4-^{14}C] label None > 5 % AR for [aniline-^{14}C]- and [trifluorophenyl-U-^{14}C]- label

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

Anaerobic degradation ‡

Mineralization after 100 days	2.3 % after 120 d, [aniline-U-^{14}C]-label (n= 1) 0.6 % after 120 d, [pyrazole-4-^{14}C]-label (n= 1)
Non-extractable residues after 100 days	*30.3-32.1* % after 120 d, [aniline-U-^{14}C]-label (n= 1) *13.4-13.9* % after 120 d, [pyrazole-4-^{14}C]-label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	**M007F001** – 19.6-*19.9* % at 120 d (n= 1) **M007F002** – 3.5-3.9 % at 120 d (n= 1) [pyrazole-4-^{14}C]-label None > 5 % AR for [aniline-^{14}C]-label

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None > 5 % AR

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

Laboratory studies ‡

Parent – Fluxapyroxad (BAS 700 F)	Aerobic conditions					
Soil type (USDA)	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation

[11] n corresponds to the number of soils.

Bruch West - Sandy loam – aniline label	**7.1**	**20 °C / 40 %**	**71.9/ 455**	**55.4**	**1.0**	**FOMC**
Bruch West - Sandy loam – aniline label	7.1	20 °C / 40 %	76.5/ 254	59.0	2.2	SFO
Bruch West - Sandy loam – pyrazole label	**7.1**	**20 °C / 40 %**	**68.8/ 229**	**53.0**	**2.0**	**SFO – box model**
Bruch West - Sandy loam – trifluorophenyl label	**7.1**	**20 °C / 40 %**	**144/ 478**	**111**	**1.4**	**SFO**
Bruch West - Sandy loam Geomean			**89.3**	**68.8**		
Arahal – silty clay loam - pyrazole label	**7.6**	**20 °C / 40 %**	**357/ >1000**	**203**	**2.3**	**DFOP**
Arahal – silty clay loam - pyrazole label	7.6	20 °C / 40 %	244/ 809	139	6.9	SFO
Kleve Keeken – loam – pyrazole label	**6.7**	**20 °C / 40 %**	**689/ >1000**	**424**	**2.2**	**SFO**
Nierswalde – silt loam – pyrazole label	**6.4**	**20 °C / 40 %**	**599/ >1000**	**396**	**1.1**	**DFOP**
Nierswalde – silt loam – pyrazole label	6.4	20 °C / 40 %	409/ >1000	271	2.7	SFO
Nierswalde – silt loam – pyrazole label	**6.4**	**10 °C / 40 %**	**810/ >1000**	**207**	**1.8**	**SFO**
Nierswalde – silt loam – pyrazole label Geomean			**696**	**286.3**		
**Geometric mean DT_{50} (calculated for modelling)			281	183		

Bold font = best fit kinetics for triggering purposes. Standard font is an alternative fit for that soil used for modelling purposes.

**Geometric mean DT_{50} values were calculated for use in modelling. Therefore, where both best fit and modelling fit kinetics are reported, the geometric mean is calculated from the kinetic fit for modelling. Where more than one test value is available for an individual soil, a geometric mean was taken of those values for use in the overall geometric mean calculation. The calculated geomean value for Bruch West soil used in the overall geometric mean calculation for use in modelling was 70.3 d.

M700F001	Aerobic conditions						
Soil type (USDA)	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
†Bruch West - Sandy loam – pyrazole label	**7.1**	**20 °C / 40 %**	**10/ 33.1**	**0.99**	**7.7**	**25.1**	**SFO – box model**
***Li10 – Loamy sand – pyrazole label**	**6.3**	**20 °C / 40 %**	**9.3/ 30.7**	**-**	**8.9**	**2.9**	**SFO – box model**
***LUFA 2.2 – Sand – pyrazole label**	**5.9**	**20 °C / 40 %**	**6.5/ 21.5**	**-**	**5.2**	**1.1**	**SFO – box model**
***Wisconsin – Loamy sand – pyrazole label**	**5.9**	**20 °C / 40 %**	**2.3/ 9.2**	**-**	**2.1**	**3.1**	**FOMC – box model**
*Wisconsin – Loamy sand – pyrazole label	5.9	20 °C / 40 %	2.5/ 8.2	-	2.3	4.8	SFO – box model
Geometric mean DT_{50} (calculated for modelling)			6.2		5.4		

*M700F001 applied

† Parent applied study

Bold font indicates best fit kinetics for triggering purposes

M700F002	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	†f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation
***Li10 – Loamy sand – pyrazole label**	**6.3**	**20 °C / 40 %**	**168/ 557**	**0.90**	**161**	**2.2**	**SFO – box model**
***LUFA 2.2 – Sand – pyrazole label**	**5.9**	**20 °C / 40 %**	**148/ 490**	**0.79**	**117**	**2.1**	**SFO – box model**
***Wisconsin – Loamy sand – pyrazole label**	**5.9**	**20 °C / 40 %**	**131/435**	**0.77**	**118**	**3.4**	**SFO – box model**
‡Li10 – Loamy sand – pyrazole label	**6.3**	**20 °C / 40 %**	**152/ 567 – overall;** **0.968 DT50 fast;** **178 DT50 slow**	**-**	**123 overall;** **0.786 fast;** **145 slow**	**0.4**	**DFOP**
‡LUFA 2.2 – Sand – pyrazole label	**5.9**	**20 °C / 40 %**	**147/ >1000**	**-**	**147**	**1.9**	**FOMC**

‡LUFA 2.2 – Sand – pyrazole label	5.9	20 °C / 40 %	120/ 567 overall; 4.86 DT50 fast; 193 DT50 slow	-	120 overall; 4.86 fast; 193 slow	2.1	DFOP
‡Wisconsin – Loamy sand – pyrazole label	**5.9**	**20 °C / 40 %**	**76.6/ >1000**	**-**	**70.4**	**2.2**	**FOMC**
‡Wisconsin – Loamy sand – pyrazole label	5.9	20 °C / 40 %	83.1/ 454 – overall; 5.06 DT50 fast; 161 DT50 slow		76.3 overall; 4.65 fast; 148 slow	2.5	DFOP
‡Bruch West – Sandy loam – pyrazole label	**7.4**	**20 °C / 40 %**	**197/ >1000**	**-**	**134**	**2.0**	**FOMC**
‡Bruch West – Sandy loam – pyrazole label	7.4	20 °C / 40 %	158/ 636 – overall; 9.94 DT50 fast; 204 DT50 slow	-	108 overall; 6.78 fast; 139 slow	2.2	DFOP
Geometric mean DT_{50}** (calculated for modelling)			164 slow	0.82	143 slow		

*M700F001 applied
‡M700F002 applied
†Formation fraction from M700F001
**Geometric mean DT_{50} values were calculated for use in modelling. Therefore, where both best fit and modelling fit kinetics are reported, the geometric mean is calculated from the kinetic fit for modelling. Where more than one test value is available for an individual soil, a geometric mean was taken of those values for use in the overall geometric mean calculation. Calculated geomean values for individual soils were 153 d for Li10; 150 d for LUFA 2.2; and 132 d for Wisconsin. Bold font indicates best fit kinetics for triggering purposes.

Field studies ‡

Fluxapyroxad (BAS 700 F) – triggering endpoints	Aerobic conditions							
Soil type (USDA).	Location (country or USA state).	pH ($CaCl_2$)	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Loam – bare soil	Wilson, UK	6.9	0-30	370	>1000	6.8	-	FOMC
Loamy sand – bare soil	Garz, Germany (East)	5.0	0-30	140	>1000	8.5	-	FOMC

Silt Loam – bare soil	Goch-Nierswalde, Germany (West)	6.1	0-30	132	>1000	6.4	-	FOMC
Silt Loam – bare soil	Meistratzheim, France	7.4	0-20	284	>1000	7.0	-	FOMC
Silt Loam – bare soil	Poggio Renatico, Italy	7.6	0-10	38.9	854	6.7	-	DFOP
Silty Clay Loam – bare soil	Alberic, Spain	7.7	0-50	124†	882†	8.4†	-	FOMC
Geometric mean/median				-	-	-	-	-
M700F002 – triggering endpoints	Aerobic conditions							
Soil type (USDA)	Location	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Loamy sand – bare soil	Middelfart, Denmark	5.8	0 - 40	39.2	188	12.0	-	FOMC
Silt Loam – bare soil	Goch-Nierswalde, Germany	6.4	0 - 40	38.0	155	5.7	-	FOMC
Silt Loam – bare soil	Poggio Renatico, Italy	7.7	0 - 70	37.4	186	7.0	-	FOMC
Loam – bare soil	Meauzac. Southern France	5.5	0 - 60	25.5	84.8	6.9	-	SFO
Geometric mean/median				-	-	-	-	-

† Modelling performed by the RMS excluding the initial concentration (see text at Section B.8.1.3.1.1 for full discussion)

Fluxapyroxad (BAS 700 F) – Modelling endpoints	Aerobic conditions							
Soil type (USDA).	Location (country or USA state).	pH ($CaCl_2$)	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Loam – bare soil	Wilson, UK	6.9	0-30	-	-	7.1	26.8 fast; 187 slow	HS
Loamy sand – bare soil	Garz, Germany (East)	5.0	0-30	-	-	7.1	83.9	SFO
Silt Loam – bare soil	Goch-Nierswalde, Germany (West)	6.1	0-30	-	-	4.6	28.5 fast; 193 slow	HS
Silt Loam – bare soil	Meistratzheim, France	7.4	0-20	-	-	7.7	132	SFO

Silt Loam – bare soil	Poggio Renatico, Italy	7.6	0-10	-	-	8.3	40.1 fast; 224 slow	HS
Silty Clay Loam – bare soil	Alberic, Spain	7.7	0-50	-	-	8.0†	131†	SFO
Geometric mean/median				-	-	-	59.5 fast; 151 slow	-
M700F002 – Modelling endpoints	Aerobic conditions							
Soil type	Location	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Loamy sand – bare soil	Middelfart, Denmark	5.8	0 - 40	-	-	13.2	17.9	SFO
Silt Loam – bare soil	Goch-Nierswalde, Germany	6.4	0 - 40	-	-	10.3	23.1	SFO
Silt Loam – bare soil	Poggio Renatico, Italy	7.7	0 - 70	-	-	11.9	44.1	SFO
Loam – bare soil	Meauzac. Southern France	5.5	0 - 60	-	-	9.1	24.6	SFO
Geometric mean/median				-	-	-	25.9	-

† Modelling performed by the RMS excluding the initial concentration (see text at Section B.8.1.3.1.1; The United Kingdom, 2011a)

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Studies ongoing. No analysis performed at the time of the assessment.

Laboratory studies ‡

Fluxapyroxad (BAS 700 F)	Anaerobic conditions					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (χ^2)	Method of calculation

BruchWest – Sandy loam – Aniline label	7.4	20 °C/ 40 % MWHC up to 30 d – flooded thereafter	81.5/ 271 (aerobic phase, 0-30 d*); 301/ >1000 (anaerobic phase, 30 d – 120 d*)	-	1.3	HS*
BruchWest – Sandy loam – Pyrazole label	7.4	20 °C/ 40 % MWHC up to 30 d – flooded thereafter	76.2/ 253 (aerobic phase, 0 – 30 d*); 224/ 743 (anaerobic phase, 30 d – 120 d*)	-	1.6	HS*
Geometric mean		-	78.8 d DT_{50} (aerobic phase, 0 – 30 d*); 260 d DT_{50} (anaerobic phase, 30 d – 120 d*)	-	-	-

* HS modelling performed – Break point fixed to 30 d when the soils were flooded, with the first phase assumed as aerobic degradation and the second phase as anaerobic degradation

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Fluxapyroxad (BAS 700 F) ‡							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
LUFA 2.1, Sand	0.52	5.2			4.3	818	0.945
Obihiro, Sandy Loam*	2.74	5.6			15.2*	556*	0.897*
Li 10, Loamy Sand	0.88	5.9			6.8	777	0.916
New Jersey, Silt Loam	0.90	6.3			8.6	955	0.921
Nierswalde, Silt Loam	1.63	6.5			17.9	1101	0.942
LUFA 2.3,Sandy Loam	1.09	6.9			5.7	527	0.875
La Gironda, Silty Clay Loam	3.84	7.5			12.3	320	0.902
California, Sandy Loam	0.41	7.6			2.5	603	0.900
Arithmetic mean/median					8.3	728	0.914
pH dependence, Yes or No			No				

*Volcanic ash - excluded from mean calculation

M007F001 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
LUFA 2.1, Sand	0.52	5.2			0.02	4.2	0.715
Obihiro, Sandy Loam*	2.74	5.6			1.8	65.8	0.981
Li 10, Loamy Sand	0.88	5.9			0.03	3.6	1.047
New Jersey, Silt Loam	0.90	6.3			0.03	3.4	0.914
Nierswalde, Silt Loam	1.63	6.5			0.11	6.7	1.002
LUFA 2.3,Sandy Loam	1.09	6.9			0	0	0.9**
La Gironda, Silty Clay Loam	3.84	7.5			0	0	0.9**
California, Sandy Loam	0.41	7.6			0	0	0.9**
Arithmetic mean/median					0.03	2.6	0.911
pH dependence (yes or no)							

*Volcanic ash - excluded from mean calculation; **Focus default

M007F002 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
LUFA 2.1, Sand	0.52	5.2			0.07	13.1	0.969
Obihiro, Sandy Loam*	2.74	5.6			2.74	99.9	0.963
Li 10, Loamy Sand	0.88	5.9			0.04	4.8	0.842
New Jersey, Silt Loam	0.90	6.3			0.13	14.1	1.165

Nierswalde, Silt Loam	1.63	6.5			0.15	9	0.937
LUFA 2.3,Sandy Loam	1.09	6.9			0.06	5.6	1.078
La Gironda, Silty Clay Loam	3.84	7.5			0.04	1	0.99
California, Sandy Loam	0.41	7.6			0.02	5.6	0.764
Arithmetic mean/median					0.07	7.6	0.964
pH dependence (yes or no)							

*Volcanic ash - excluded from mean calculation

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

Column leaching ‡	No data submitted – none required.
Aged residues leaching ‡	No data submitted – none required.
Lysimeter/ field leaching studies ‡	No data submitted – none required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent – Fluxapyroxad (BAS 700 F) Method of calculation	*DT_{50} (d): 370 days (field, worst-case, best-fit, non-normalised) *DT_{90} > 1000 d (alpha = 0.2059; beta = 13.1342) *Kinetics: FOMC Field or Lab: representative worst-case from field studies.
Application data	Crop: wheat Depth of soil layer: 5cm Soil bulk density: 1.5 g/cm^3 % plant interception: first application 50 % second application 70% (FOCUS Groundwater guidance) Number of applications: 2 Interval (d): 21 Application rate(s): 2 x 125 g a.s./ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.083		0.119	
Short term 24h	0.082	0.082	0.117	0.118
2d	0.081	0.082	0.116	0.117

	4d	0.079	0.081	0.114	0.116
Long term	7d	0.076	0.079	0.112	0.115
	28d	0.066	0.072	0.100	0.108
	50d	0.060	0.068	0.093	0.103
	100d	0.053	0.062	0.084	0.095

*Plateau concentration	Peak concentration 0.188 mg/kg after 13 yr Steady state concentration 0.070 mg/kg after 13 yr (20 cm mixing depth) Data gap for final report of the accumulation in soil field study once the plateau is reached.

* For the calculation of $PEC_{soil,accu}$ a DFOP kinetic fit was used

Metabolite I –M700F001 Method of calculation	Molecular weight relative to the parent: 0.462 (176.1/381.13) DT_{50} (d): 10 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies.
Application data	Application rate assumed: 13.98 g a.s./ha (assuming M700F001 is formed at a maximum of 12.1 % of the applied dose, no degradation between applications) Crop interception: 50 % for 1st application; 70 % for the second.

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0075		x	
Short term	24h	0.0070	0.0075	x	x
	2d	0.0065	0.0072	x	x
	4d	0.0056	0.0070	x	x
Long term	7d	0.0046	0.0059	x	x
	28d	0.0011	0.0033	x	x
	50d	0.0002	0.0021	x	x
	100d	0.0000	0.0011	x	x

Plateau concentration	Peak concentration 0.0105 mg/kg (following 13 years accumulation of parent and correction for molecular mass and maximum occurrence). Data gap for final report of the accumulation in soil field study once the plateau is reached.

Metabolite II – M700F002 Method of calculation	Molecular weight relative to the parent: 0.425 (162.0/381.13)

	DT_{50} (d): 39.2 days; DT_{90}: 188 days Kinetics: FOMC (alpha 2.4056; beta 117.5) Field or Lab: worst-case field
Application data	Application rate assumed: 74.91 g a.s./ha (assumed M700F002 is formed at a maximum of 70.5 % of the applied dose, no degradation between applications) crop interception: 50 % for 1st application; 70 % for second.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.040		x	
Short term 1d	0.039	0.040	x	x
2d	0.038	0.039	x	x
4d	0.037	0.038	x	x
Long term 7d	0.035	0.037	x	x
28d	0.024	0.031	x	x
50d	0.017	0.026	x	x
100d	0.009	0.019	x	x

Plateau concentration	Peak concentration 0.056 mg/kg (following 13 years accumulation of parent and correction for molecular mass and maximum occurrence). Data gap for final report of the accumulation in soil field study once the plateau is reached.

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	**Fluxapyroxad (BAS 700 F)** pH 4,5,7, 9: stable at 50 °C No metabolites detected. **M700F007** pH 4,5,7, 9: stable at 25 °C No metabolites detected.
Photolytic degradation of active substance and metabolites above 10 % ‡	**Fluxapyroxad (BAS 700 F)** DT_{50} : stable continuous irradiation for 15 days with a xenon arc lamp of light intensity 30 W/m^2 (λ<290 nm removed; simulating 48°N) **M700F007** DT_{50} : stable continuous irradiation for 15 days with a xenon arc lamp of light intensity 30 W/m^2 (λ<290 nm removed; simulating 48°N)
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not calculated
Readily biodegradable ‡ (yes/no)	Not readily biodegradable.

Degradation in water / sediment

Fluxapyroxad (BAS 700 F) – dark system	Maximum observed in water immediately after application at day 0; Maximum observed in sediment 73.9 – 77.0 % AR at study termination (day 100)									
Water / sediment system	pH water phase	pH sed ($CaCl_2$)	t. °C	DT_{50}-DT_{90} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}- DT_{90} sed	St. (χ^2)	Method of calculation
Berghauser Altrhein Speyer, Germany	7.3	7.4	20	> 1000	0.8	3.4/ 87.7	1.4	NC	NC	HS – whole system; FOMC - water
Ranschgraben Schifferstadt, Germany	7.2	5.4	20	694/ >1000	0.8	5.1/ 264	2.5	NC	NC	SFO – whole system; FOMC - water
Geometric mean/median			-	-		-		-		-

NC = Not calculated due to insufficient decline phase

Metabolites – dark experiment	No metabolites observed above 5 % AR.

Mineralization and non-extractable residues					
Water / sediment system - Dark	pH water phase	pH sed ($CaCl_2$)	Mineralization x % after 100 d. (end of the study).	Non-extracted residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after 100 d (end of the study)
Berghauser Altrhein Speyer, Germany	7.3	7.4	0.5 - 1.1 % AR	9.1 - 11.2 % AR after 62 – 100 d	9.1 - 11.1 % AR
Ranschgraben Schifferstadt, Germany	7.2	5.4	0.2 – 0.7 % AR	6.8 – 8.8 % AR after 100 d	6.8 – 8.8 % AR

Fluxapyroxad (BAS 700 F) – irradiated system (13 hr light/ 11 hr dark)	Maximum observed in water immediately after application at day 0; Maximum observed in sediment 62.3 – 67.9 % AR (day 43)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (χ^2)	DT_{50}-DT_{90} water	St. (χ^2)	DT_{50}-DT_{90} sed	St. (χ^2)	Method of calculation
Berghauser Altrhein Speyer, Germany	7.3	7.4	22 – 26 light; 18 – 20 dark	145/ 482	1.1	3.4/ 55.9	3.9	NC	NC	SFO – whole system; DFOP - water
Ranschgraben Schifferstadt, Germany	7.2	5.4	22 – 26 light; 18 – 20 dark	116/ 387	0.9	7.0/ 55.6	3.5	NC	NC	SFO – whole system; DFOP - water
Geometric mean/median			-	-		-		-		-

NC = Not calculated due to insufficient decline phase

M700F001 - irradiated experiment	Max. in water 3.2 and 10.9 % AR after 43 d (Berghäuser Altrhein and Ranschgraben system; pyrazole label). Not observed in sediment.
M700F007 - irradiated experiment	Max. in water 7.5 % AR after 57 d (study termination) and 3.3 % AR after 43d in Berghäuser Altrhein and Ranschgraben systems, respectively. (Both with pyrazole label). Not observed in sediment.

Mineralization and non-extractable residues					
Water / sediment system - Irradiated	pH water phase	pH sed ($CaCl_2$)	Mineralization x % after 57 d. (end of the study).	Non-extracted residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after 57 d (end of the study)
Berghauser Altrhein Speyer, Germany	7.3	7.4	0.2 – 2.5 % AR	12.5 – 19.7 % AR after 57 d	12.5 – 19.7 % AR
Ranschgraben Schifferstadt, Germany	7.2	5.4	0.3 – 2.8 % AR	12.0 – 21.1 % AR after 57 d	12.0 – 21.1 % AR

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

Parent – Fluxapyroxad (BAS 700 F) Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Vers. 1.1 Molecular weight (g/mol): 381.3 Water solubility (mg/L): 3.8 at 20 °C K_{OC} (L/kg): 728 (arithmetic mean; n=7) DT_{50} soil (d): *151* days (Geometric mean of normalised field studies based on slow phase HS DT_{50} where appropriate.) DT_{50} water/sediment system (d): 1000 (default worst-case assumption based on FOCUS Kinetics guidance (FOCUS, 2006)) DT_{50} water (d): 1000 (default worst-case assumption based on FOCUS Kinetics guidance (FOCUS, 2006)) DT_{50} sediment (d): 1000 (default worst-case assumption based on FOCUS Kinetics guidance (FOCUS, 2006)) Crop interception (%): average crop cover (50 %)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH version 1.1, FOCUS-PRZM version 1.1.1, FOCUS-MACRO version 4.4.2, FOCUS-TOXSWA version 2.2.1. Vapour pressure: 10^{-10} Pa (20°C) Kom/Koc: 422/728 1/n: 0.914 (Freundlich exponent general or for soil, susp. solids or sediment respectively)
Application rate	Crop: winter cereals; spring cereals Crop interception: 1st application 50 %, 2nd application 70 % Number of applications: *2* Interval (d): *21* Application rate(s): 2 x 125 g a.s./ha Application window: <u>Step 1 and Step 2</u> Winter cereals – North Europe – March-May South Europe – Oct-Feb Spring cereals – North Europe – June-Sept South Europe – March-May <u>Step 3</u> See Table B.8.107 (The United Kingdom, 2011a)

FOCUS STEP 1 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	44.59		307.85	
	24 h	43.42	44.00	316.12	311.99
	2 d	43.39	43.71	315.90	314.00
	4 d	43.33	43.53	315.47	314.84
	7 d	43.24	43.43	314.81	314.97
	14 d	43.03	43.28	313.29	314.51
	21 d	42.83	43.17	311.77	313.85
	28 d	42.62	43.05	310.26	313.14
	42 d	42.21	42.84	307.27	311.68

FOCUS STEP 2 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.18		36.24	
	24 h	4.98	5.08	36.22	36.23
	2 d	4.97	5.03	36.19	36.22
	4 d	4.97	5.00	36.14	36.19
	7 d	4.96	4.98	36.07	36.15
	14 d	4.93	4.96	35.89	36.07
	21 d	4.91	4.95	35.72	35.98
	28 d	4.89	4.94	35.54	35.89
	42 d	4.84	4.91	35.20	35.72
Southern EU	0 h	9.14		65.06	
	24 h	8.94	9.04	65.01	65.03
	2 d	8.93	8.99	64.97	65.01
	4 d	8.92	8.96	64.88	64.97
	7 d	8.90	8.94	64.74	64.90
	14 d	8.86	8.91	64.43	64.74
	21 d	8.81	8.88	64.12	64.59
	28 d	8.77	8.86	63.81	64.43
	42 d	8.69	8.82	63.19	64.12

FOCUS STEP 3 Winter cereals, single application Scenario	Water body	$PEC_{SW\ max}$ (µg/L)	
		Tier A	Tier C
D1	ditch	2.285	1.970
D1	stream	1.534	1.342
D2	ditch	1.744	1.338
D2	stream	1.089	0.915
D3	ditch	0.789	0.789
D4	pond	0.294	0.223
D4	stream	0.648	0.647
D5	pond	0.142	0.108
D5	stream	0.637	0.633
D6	ditch	0.844	0.834
R1	pond	0.078	
R1	stream	0.840	
R3	stream	0.852	
R4	stream	1.339	

FOCUS STEP 3 Winter cereals, twofold applications Scenario	Water body	$PEC_{SW\ max}$ (µg/L)	
		Tier A	Tier C
D1	ditch	3.846	2.786
D1	stream	2.406	1.811
D2	ditch	3.694	2.668
D2	stream	2.306	1.665
D3	ditch	0.691	0.691
D4	pond	0.622	0.421
D4	stream	0.939	0.653
D5	pond	0.299	0.222
D5	stream	0.572	0.566
D6	ditch	0.965	0.879
R1	pond	0.170	
R1	stream	1.192	
R3	stream	1.042	

FOCUS STEP 3 Winter cereals, twofold applications Scenario	Water body	$PEC_{SW\ max}$ (µg/L)	
		Tier A	Tier C
R4	stream	1.997	

FOCUS STEP 3 Spring cereals, single application Scenario	Water body	$PEC_{SW\ max}$ (µg/L)	
		Tier A	Tier C
D1	ditch	1.579	1.443
D1	stream	0.964	0.797
D3	ditch	0.791	0.792
D4	pond	0.269	0.189
D4	stream	0.658	0.658
D5	pond	0.090	0.107
D5	stream	0.694	0.695
R4	stream	1.216	

FOCUS STEP 3 Spring cereals, twofold application Scenario	Water body	$PEC_{SW\ max}$ (µg/L)	
		Tier A	Tier C
D1	ditch	2.523	2.530
D1	stream	1.589	1.589
D3	ditch	0.693	0.693
D4	pond	0.461	0.399
D4	stream	0.671	0.603
D5	pond	0.202	0.241
D5	stream	0.639	0.639
R4	stream	2.078	

FOCUS STEP	Water	$PEC_{SED\ max}$ (µg/kg)

3 Winter cereals single application Scenario	body	Tier A	Tier C
D1	ditch	17.579	14.185
D1	stream	9.801	7.912
D2	ditch	11.226	8.637
D2	stream	6.481	4.981
D3	ditch	0.326	0.327
D4	pond	2.449	1.897
D4	stream	0.882	0.672
D5	pond	1.606	1.254
D5	stream	0.310	0.236
D6	ditch	0.767	0.670
R1	pond	0.654	
R1	stream	0.350	
R3	stream	0.311	
R4	stream	0.757	

FOCUS STEP 3 Winter cereals twofold application Scenario	Water	$PEC_{SED\ max}$ (µg/kg)	
	body	Tier A	Tier C
D1	ditch	33.619	24.690
D1	stream	18.635	13.688
D2	ditch	22.742	16.243
D2	stream	13.099	9.324
D3	ditch	0.383	0.384
D4	pond	4.961	3.461
D4	stream	1.805	1.235
D5	pond	3.280	2.504
D5	stream	0.642	0.479
D6	ditch	1.475	1.381
R1	pond	1.311	
R1	stream	0.696	
R3	stream	0.645	

FOCUS STEP 3 Winter cereals twofold application Scenario	Water body	$PEC_{SED\ max}$ (µg/kg)	
		Tier A	Tier C
R4	stream	2.435	

FOCUS STEP 3 Spring cereals single application Scenario	Water body	$PEC_{SED\ max}$ (µg/kg)	
		Tier A	Tier C
D1	ditch	16.902	14.673
D1	stream	9.149	7.927
D3	ditch	0.399	0.400
D4	pond	2.307	1.660
D4	stream	0.763	0.533
D5	pond	1.115	1.306
D5	stream	0.200	0.240
R4	stream	1.169	

FOCUS STEP 3 Spring cereals twofold application Scenario	Water body	$PEC_{SED\ max}$ (µg/kg)	
		Tier A	Tier C
D1	ditch	26.754	27.739
D1	stream	14.392	15.001
D3	ditch	0.497	0.497
D4	pond	3.850	3.343
D4	stream	1.286	1.104
D5	pond	2.407	2.815
D5	stream	0.448	0.534
R4	stream	1.844	

Metabolite - M700F001	Molecular weight (g/mol): 176.1
Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): 39990 Soil or water metabolite: Soil and water Koc (L/kg): 2.6 (arithmetic mean of 7 soils) DT_{50} soil (d): 5.4 days (Geometric mean of normalized laboratory studies) DT_{50} water/sediment system (d): 1000 (Conservative assumptions according to FOCUS (2006)) DT_{50} water (d): 1000 (Conservative assumptions according to FOCUS (2006)) DT_{50} sediment (d): 1000 (Conservative assumptions according to FOCUS (2006)) Crop interception (%): average crop cover (50 %) Maximum occurrence observed (% molar basis with respect to the parent) Water/ sediment: 10.9 (only detected in the water phase) Soil: 12.1 (Maximum from laboratory aerobic soil degradation studies.)
Application rate	Crop: winter cereals; spring cereals Number of applications: 2 Interval (d): 21 Application rate(s): 2 x 125 g a.s./ha Application window: Step 1 and Step 2 Winter cereals – North Europe – March-May South Europe – Oct-Feb Spring cereals – North Europe – June-Sept South Europe – March-May
Main routes of entry	Drainflow/ run-off

FOCUS STEP 1 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	4.76		0.12	
	24h	4.75	4.75	0.12	0.12
	2d	4.75	4.75	0.12	0.12
	4d	4.74	4.75	0.12	0.12
	7d	4.73	4.74	0.12	0.12
	14d	4.71	4.73	0.12	0.12
	21d	4.69	4.72	0.12	0.12
	28d	4.66	4.71	0.12	0.12
	42d	4.62	4.69	0.12	0.12

FOCUS STEP 2 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.25		0.01	
	24 h	0.25	0.25	0.01	0.01
	2 d	0.25	0.25	0.01	0.01
	4 d	0.25	0.25	0.01	0.01
	7 d	0.25	0.25	0.01	0.01
	14 d	0.25	0.25	0.01	0.01
	21 d	0.25	0.25	0.01	0.01
	28 d	0.24	0.25	0.01	0.01
	42 d	0.24	0.25	0.01	0.01
Southern EU	0 h	0.40		0.01	
	24 h	0.40	0.40	0.01	0.01
	2 d	0.40	0.40	0.01	0.01
	4 d	0.40	0.40	0.01	0.01
	7 d	0.40	0.40	0.01	0.01
	14 d	0.39	0.40	0.01	0.01
	21 d	0.39	0.39	0.01	0.01
	28 d	0.39	0.39	0.01	0.01
	42 d	0.39	0.39	0.01	0.01

Metabolite - M700F002	Molecular weight (g/mol): 162
Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): 31580 Soil or water metabolite: Soil Koc (L/kg): 7.6 (arithmetic mean of 7 soils) DT_{50} soil (d): 25.9 days (Geometric mean of normalized field studies) DT_{50} water/sediment system (d): 1000 (Conservative assumptions according to FOCUS (2006)) DT_{50} water (d): 1000 (Conservative assumptions according to FOCUS (2006)) DT_{50} sediment (d): 1000 (Conservative assumptions according to FOCUS (2006)) Crop interception (%): average crop cover (50 %) Maximum occurrence observed (% molar basis with respect to the parent) Water/ sediment: not observed. Default value of 0.01 % used in calculations Soil: 70.5 % (Max formation, plus remaining parent and M700F001 in soil as still increasing at study termination.)
Application rate	Crop: winter cereals; spring cereals Number of applications: 2 Interval (d): 21 Application rate(s): 2 x 125 g a.s./ha Application window: Step 1 and Step 2 Winter cereals – North Europe – March-May South Europe – Oct-Feb Spring cereals – North Europe – June-Sept South Europe – March-May
Main routes of entry	Drainflow/ run-off

FOCUS STEP 1 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	24.71		1.88	
	24h	24.69	24.70	1.88	1.88
	2d	24.68	24.69	1.88	1.88
	4d	24.64	24.68	1.87	1.88
	7d	24.59	24.65	1.87	1.87
	14d	24.47	24.59	1.86	1.87
	21d	24.35	24.53	1.85	1.86
	28d	24.24	24.47	1.84	1.86
	42d	24.00	24.35	1.82	1.85

FOCUS STEP 2 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.74		0.13	
	24 h	1.74	1.74	0.13	0.13
	2 d	1.74	1.74	0.13	0.13
	4 d	1.74	1.74	0.13	0.13
	7 d	1.73	1.74	0.13	0.13
	14 d	1.73	1.73	0.13	0.13
	21 d	1.72	1.73	0.13	0.13
	28 d	1.71	1.73	0.13	0.13
	42 d	1.69	1.72	0.13	0.13
Southern EU	0 h	3.49		0.26	
	24 h	3.48	3.48	0.26	0.26
	2 d	3.48	3.48	0.26	0.26
	4 d	3.48	3.48	0.26	0.26
	7 d	3.47	3.48	0.26	0.26
	14 d	3.45	3.47	0.26	0.26
	21 d	3.44	3.46	0.26	0.26
	28 d	3.42	3.45	0.26	0.26
	42 d	3.39	3.44	0.26	0.26

Metabolite - M700F007	Molecular weight (g/mol): 175.1
Parameters used in FOCUSsw step 1 and 2	Water solubility (mg/L): 39990 (Assumed value taken from M700F001 due to similarity of structures) (water solubility determined experimentally post-modelling was 1770 mg/L although it was not considered to influence the outcome of the SW modelling.) Soil or water metabolite: Water Koc (L/kg): 1 (default worst case value for PECsw calculation; substance not found in sediment) DT_{50} soil (d): 1 days (default value, substance not found in soil) DT_{50} water/sediment system (d): 1000 (Conservative assumptions according to FOCUS (2006)) DT_{50} water (d): 1000 (Conservative assumptions according to FOCUS (2006)) DT_{50} sediment (d): 1000 (Conservative assumptions according to FOCUS (2006)) Crop interception (%): average crop cover (50 %) Maximum occurrence observed (% molar basis with respect to the parent) Water/ sediment: 17.7 % (Max. formation, plus remaining parent in water phase as concentration still increasing at study termination.) Soil: Not observed in soil studies. Default value of 0.01 % used in calculations.
Application rate	Crop: winter cereals; spring cereals Number of applications: 2 Interval (d): 21 Application rate(s): 2 x 125 g a.s./ha Application window: <u>Step 1 and Step 2</u> Winter cereals – North Europe – March-May South Europe – Oct-Feb Spring cereals – North Europe – June-Sept South Europe – March-May
Main routes of entry	Spray drift and subsequent formation in surface water body

FOCUS STEP 1 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.19		0.00	
	24h	0.19	0.19	0.00	0.00
	2d	0.19	0.19	0.00	0.00
	4d	0.19	0.19	0.00	0.00
	7d	0.19	0.19	0.00	0.00
	14d	0.19	0.19	0.00	0.00
	21d	0.19	0.19	0.00	0.00
	28d	0.19	0.19	0.00	0.00
	42d	0.19	0.19	0.00	0.00

FOCUS STEP 2 Winter & Spring Cereals Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.16		0.00	
	24 h	0.16	0.16	0.00	0.00
	2 d	0.16	0.16	0.00	0.00
	4 d	0.16	0.16	0.00	0.00
	7 d	0.16	0.16	0.00	0.00
	14 d	0.16	0.16	0.00	0.00
	21 d	0.16	0.16	0.00	0.00
	28 d	0.16	0.16	0.00	0.00
	42 d	0.16	0.16	0.00	0.00
Southern EU	0 h	0.16		0.00	
	24 h	0.16	0.16	0.00	0.00
	2 d	0.16	0.16	0.00	0.00
	4 d	0.16	0.16	0.00	0.00
	7 d	0.16	0.16	0.00	0.00
	14 d	0.16	0.16	0.00	0.00
	21 d	0.16	0.16	0.00	0.00
	28 d	0.16	0.16	0.00	0.00
	42 d	0.16	0.16	0.00	0.00

Accumulation PEC in sediment

Fluxapyroxad (BAS 700 F)

Accumulation PEC in sediment ($PEC_{sed,plateau}$) for fluxapyroxad (BAS 700 F) were calculated with equation based on the plateau concentration after multi-year use and the maximum PEC in sediment of the tiered approach at Step 3. For each tier at Step 3, concentrations only for the scenario showing the highest global maximum PEC in sediment were derived.

Calculation of $PEC_{sed,plateau}$

$$PEC_{sed,\ plateau} = \frac{PEC_{sed,\ max}}{1 - e^{-k \cdot t}} \cdot e^{-k \cdot t}$$

$PEC_{sed,plateau}$ Plateau concentration at steady state [µg/kg] [µg/kg]
$PEC_{sed,max}$ Highest global maximum concentration at Step 3, [µg/kg]
k Degradation rate in sediment ($ln(2)/DT_{50}$)
t Time interval between growing seasons (365 days), [d]

PECsed,accumulation values of fluxapyroxad (BAS 700 F) after multi-year use of the substance on winter and spring cereals

Crop	Worst-case scenario, water body	Tier	$PEC_{sed,plateau}$	$PEC_{sed,max}$	$PEC_{sed,accu,overall}$ (= $PEC_{sed,plateau}$ + $PEC_{sed,max}$)
			[µg/kg]	[µg/kg]	[µg/kg]
Winter cereals	D1, ditch	A	116.781	33.619	150.400
		B	105.783	30.453	136.236
		C	85.764	24.690	110.454
		D	56.798	16.351	73.149
Spring cereals	D1, ditch	A	92.934	26.754	119.688
		B	63.113	18.169	81.282
		C	96.356	27.739	124.095
		D	67.882	19.542	87.424

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO v3.3.2, FOCUS PEARL v3.3.3, FOCUS MACRO v4.4.2 Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop: winter cereals Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Porto Crop: spring cereals Geometric mean of normalized field studies HS slow phase DT_{50} 151 d HS fast phase DT_{50} 59.5 (selected to provide more precautionary assessment for metabolites) (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{OC}: parent, Fluxapyroxad (BAS 700 F): arithmetic mean 728, $^1/_n$= 0.914. Koc Metabolites: M700F001: arithmetic mean 2.6, $^1/_n$= 0.911 M700F002: arithmetic mean 7.6, $^1/_n$= 0.964
Application rate	Application rate: 125 g a.s./ha. No. of applications: 2 Interception: 1st application 50 %, 2nd application 70 % Application interval: 21 days Time of application (month or season): Winter cereals:

	1st Application	**2nd Application**
Châteaudun	1st March (60)*	22nd March (81)*
Hamburg	1st March	22nd March
Jokioinen	1st April	22nd April
Kremsmünster	1st March	22nd March
Okehampton	1st March	22nd March
Piacenza	1st March	22nd March
Porto	15th February	8th March
Sevilla	15th February	8th March
Thiva	15th February	8th March

Spring cereals

	1st Application	2nd Application
Châteaudun	9th April (99)*	30th April (120)*
Hamburg	1st May	22nd May
Jokioinen	17th June	8th July
Kremsmünster	1st May	22nd May
Okehampton	1st May	22nd May
Porto	9th April	30th April

*Julian day for MACRO simulations

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) Parent Slow phase DT50 151 days

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
PEARL /Winter Cereals	Châteaudun	< 0.001	0.029	1.451
	Hamburg	0.003	0.215	3.081
	Jokioinen	< 0.001	0.315	3.369
	Kremsmünster	0.002	0.056	1.895
	Okehampton	0.005	0.135	2.017
	Piacenza	0.011	0.082	0.374
	Porto	< 0.001	0.022	0.635
	Sevilla	< 0.001	0.020	0.677
	Thiva	< 0.001	0.032	1.048

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
PEARL /Spring Cereals	Châteaudun	< 0.001	0.031	1.468
	Hamburg	0.0028	0.243	3.406
	Jokioinen	< 0.001	0.376	3.647
	Kremsmünster	0.0012	0.060	1.972
	Okehampton	0.0035	0.133	2.081
	Porto	< 0.001	0.030	0.764

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
PELMO /Winter Cereals	Châteaudun	< 0.001	0.023	0.955
	Hamburg	< 0.001	0.29	2.621
	Jokioinen	< 0.001	0.507	3.594
	Kremsmünster	< 0.001	0.05	1.606
	Okehampton	0.001	0.152	1.938
	Piacenza	0.002	0.151	1.504
	Porto	< 0.001	0.052	0.691
	Sevilla	< 0.001	0.017	0.241
	Thiva	< 0.001	0.018	0.574

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
PELMO /Spring Cereals	Châteaudun	< 0.001	0.011	0.722
	Hamburg	< 0.001	0.280	2.777
	Jokioinen	< 0.001	0.406	3.701
	Kremsmünster	< 0.001	0.030	1.533
	Okehampton	< 0.001	0.099	1.925
	Porto	< 0.001	0.022	0.731

MACRO	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
Winter Cereals	Châteaudun	0.001	0.048	1.342
Spring Cereals	Châteaudun	0.002	0.055	1.280

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) Parent Fast phase DT50 59.5 days

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
PEARL /Winter Cereals	Châteaudun	< 0.001	0.019	1.374
	Hamburg	< 0.001	0.162	3.252
	Jokioinen	< 0.001	0.297	4.629
	Kremsmünster	< 0.001	0.046	2.025
	Okehampton	< 0.001	0.097	2.173
	Piacenza	< 0.001	0.040	1.162
	Porto	< 0.001	0.014	0.50
	Sevilla	< 0.001	0.012	0.449
	Thiva	< 0.001	0.017	0.825

	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
PEARL /Spring Cereals	Châteaudun	< 0.001	0.021	1.447
	Hamburg	< 0.001	0.211	4.025
	Jokioinen	< 0.001	0.439	4.857
	Kremsmünster	< 0.001	0.056	2.255
	Okehampton	< 0.001	0.115	2.250
	Porto	< 0.001	0.018	0.573
PELMO /Winter Cereals	Châteaudun	< 0.001	0.014	1.059
	Hamburg	< 0.001	0.182	3.158
	Jokioinen	< 0.001	0.381	5.031
	Kremsmünster	< 0.001	0.031	2.106
	Okehampton	< 0.001	0.108	2.251
	Piacenza	< 0.001	0.057	1.185

	Porto	< 0.001	0.022	0.529
	Sevilla	< 0.001	0.006	0.167
	Thiva	< 0.001	0.007	0.366

PELMO /Spring Cereals	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
	Châteaudun	< 0.001	0.007	0.767
	Hamburg	< 0.001	0.180	3.592
	Jokioinen	< 0.001	0.425	4.637
	Kremsmünster	< 0.001	0.022	2.090
	Okehampton	< 0.001	0.027	0.869
	Porto	< 0.001	0.012	0.594

MACRO	Scenario	Parent (µg/L)	Metabolite (µg/L)	
			M700F001	M700F002
Winter Cereals	Châteaudun	< 0.001	0.024	1.11
Spring Cereals	Châteaudun	< 0.001	0.030	1.10

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT_{50} of 0.69 days derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5 x 10^6 radicals cm^{-3}
Volatilisation ‡	Not studied - no data requested
	Not studied - no data requested
Metabolites	None

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, water solubility and dimensionless Henry's Law Constant.

$PEC_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	**Soil:** Fluxapyroxad (BAS 700 F) and the metabolites M700F001 and M700F002
	Surface water: Fluxapyroxad (BAS 700 F) and the metabolites M700F001, M700F002 and M700F007
	Sediment: Fluxapyroxad (BAS 700 F)
	Ground water: Fluxapyroxad (BAS 700 F) and the metabolites M700F001 and M700F002
	Air: Fluxapyroxad (BAS 700 F)

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

Soil (indicate location and type of study)	No data submitted – none required.
Surface water (indicate location and type of study)	No data submitted – none required.
Ground water (indicate location and type of study)	No data submitted – none required.
Air (indicate location and type of study)	No data submitted – none required.

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53

Ecotoxicology

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 ‡				
Colinus virginianus	a.s.	Acute LD_{50}	>2000	n/a
Anas platyrhynchos	a.s.	Acute LD_{50}	>**2000**	n/a
Colinus virginianus	a.s.	Short-term LC_{50}	> **912.00**	>5000
Anas platyrhynchos	a.s.	Short-term LC_{50}	>1716	> 5000
Colinus virginianus	a.s.	Long-term NOEC	74.6	1000
Anas platyrhynchos	a.s.	Long-term NOEC	**33.6**	300
Mammals ‡				
Rat	Fluxapyroxad (BAS 700 F)	Acute LD_{50}	>**2000**	NA
Rat	'BAS 700 00F'	Acute LD_{50}	>**2000**	NA
Rat	M700F001	Acute LD_{50}	>**2000**	NA
Rat	M700F002	Acute LD_{50}	>**2000**	NA
Rat	M700F007	Acute LD_{50}	> **500**	NA
Rat	Fluxapyroxad (BAS 700 F)	Two generation study NOAEL	**10**	Dietary dose adjusted weekly
Rabbit	Fluxapyroxad (BAS 700 F)	Teratology study NOAEL	25	NA
Rabbit	M700F001	Teratology Study NOAEL	250	NA
Rabbit	M700F002	Teratology study NOAEL	300	NA
Additional higher tier studies ‡				
-				

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

Crop and application rate: Two applications to cereals at 0.125 kg a.s./ha at growth stages BBCH 25 to 69, with 21 day spray interval.

Indicator species/Category	Time scale	ETE/DDD	TER	Annex VI Trigger
Tier 1 (Birds)				
Large herbivorous bird	Acute	9.02	222	10

Indicator species/Category	Time scale	ETE/DDD	TER	Annex VI Trigger
Insectivorous bird		6.76	296	10
Large herbivorous bird	Short-term	5.16	177	10
Insectivorous bird		3.77	242	10
Large herbivorous bird	Long-term	2.73	12.3	5
Insectivorous bird		3.77	8.9	5
Higher tier refinement (Birds)				
	Acute			10
	Short-term			10
	Long-term			5
Avian risk assessment for consumption of contaminated water (spray-contaminated water droplet)*				
Large herbivorous bird	Acute	3.42	585	10
Insectivorous bird		22.49	89	10
Avian risk assessment for consumption of contaminated water (spray-contaminated surface water)*				
Large herbivorous bird	Acute	0.0018	1 111 111	10
Insectivorous bird		0.012	166 667	10
Large herbivorous bird	Short-term	0.0018	506 667	10
Insectivorous bird		0.012	76 000	10
Large herbivorous bird	Long-term	0.0018	18 667	5
Insectivorous bird		0.012	2800	5
Secondary poisoning				
Vermivore	Long-term	0.1904	177	5
Piscivore	Long-term	0.366	100	5
Acute and reproductive screening assessment (Mammals)[1]				
Small herbivorous mammal	Acute	17.8	112	10
Small herbivorous mammal	Reproductive	4.48	**2.23**	5
Tier I reproductive risk assessment (mammals)				
Cereals BBCH >20 Common shrew (*Sorex araneus*)	Reproductive	0.15	66.2	5
Cereals BBCH >40 Common vole (*Microtus arvalis*)	Reproductive	1.73	5.8	5
Cereals BBCH >10-29 Wood mouse (*Apodemus sylvaticus*)	Reproductive	0.62	16.1	5
Cereals BBCH>30-39 Wood mouse (*Apodemus sylvaticus*)	Reproductive	0.31	32.3	5
Cereals BBCH>40 Wood mouse (*Apodemus sylvaticus*)	Reproductive	0.18	54.7	5
Mammalian risk assessment for consumption of contaminated water (spray-contaminated water droplet)*				
Small herbivorous mammal	Acute	0.06	>33333	10

Indicator species/Category	Time scale	ETE/DDD	TER	Annex VI Trigger
Small insectivorous mammal		0.03	>66667	10
Mammalian risk assessment for consumption of contaminated water (spray-contaminated surface water)*				
Small herbivorous mammal	Acute	0.0064	312 500	10
Small insectivorous mammal		0.007	285 714	10
Mammalian risk assessment for consumption of contaminated water (metabolite M700F700)				
Small herbivorous mammal	Acute	12.0	42	10
Small insectivorous mammal		13.33	38	10
Secondary poisoning				
Vermivore	Reproductive	0.24	42	5
Piscivore		0.21	48	5

[1] Risk assessment conducted using the EFSA guidance on birds and mammals (EFSA, 2009). Unless stated otherwise, all values relate to the active substance.

*** Not necessary for the use on cereals**

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 (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	a.s.	96 hr (static)	Mortality, LC_{50}	0.546 nm
Lepomis macrochiris	a.s.	96 hr (static)	Mortality, LC_{50}	1.15 mm
Pimephales promelas	a.s.	96 hr (static)	Mortality, LC_{50}	0.466 mm
Cyprinus carpio	a.s.	96 hr (semi-static)	Mortality, LC_{50}	**0.29** mm
Cyprinodon variegatus	a.s.	96 hr (static)	Mortality, LC_{50}	1.3 mm
Pimephales promelas	a.s.	33d ELS (flow-through)	Growth NOEC	**0.0359** mm
Oncorhynchus mykiss	M700F001	96 hr (static)	Mortality, LC_{50}	>**100** nm
Oncorhynchus mykiss	M700F002	96 hr (static)	Mortality, LC_{50}	>**100** nm
Oncorhynchus mykiss	M700F007	96 hr (static)	Mortality, LC_{50}	>**100** nm
Oncorhynchus mykiss	'BAS 700 00F'	96 hr (static)	Mortality, LC_{50}	7.1 (0.44) nm
Aquatic invertebrates				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	6.78 mm
Americamysis bahia	a.s.	96 h (static)	Mortality, EC_{50}	3.6 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Crassostrea virginica	a.s.	96 h (flow-through)	Mortality, EC_{50}	**1.1** mm
Daphnia magna	a.s.	21 d (static)	Reproduction, NOEC	**0.5** nm
Daphnia magna	M700F001	48 h (static)	Mortality, EC_{50}	>**100** nm
Daphnia magna	M700F002	48 h (static)	Mortality, EC_{50}	>**100** nm
Daphnia magna	M700F007	48 h (static)	Mortality, EC_{50}	>**100** nm
Daphnia magna	'BAS 700 00F'	48 h (static)	Mortality, EC_{50}	**19.8** (1.24) nm
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC	[1]**75.9** mm initial
Algae				
Pseudokirchnella subcapitata	a.s.	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	0.7 nm **0.4** nm
Anabaena flos-aquae	a.s.	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	2.61 mm 1.38 mm
Navicula pelliculosa	a.s.	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	>3.42 mm 2.31 mm
Pseudokirchnella subcapitata	M700F001	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	36.31 nm **26.42** nm
Pseudokirchnella subcapitata	M700F002	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	26.52 nm **22.44** nm
Pseudokirchnella subcapitata	M700F007	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	>100 nm >**100** nm
Pseudokirchnella subcapitata	'BAS 700 00F'	72 h (static)	Growth rate: E_rC_{50} Yield: E_yC_{50}	42.4 (2.65) nm 5.4 (**0.34**) nm
Higher plant				
Lemna gibba	a.s.	7-day (static)	Biomass E_rC_{50} Frond E_yC_{50}	>3.43 mm **2.19** mm
Microcosm or mesocosm tests				
Indicate if not required				

[1] nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations, concentrations in brackets are presented as units of a.s.

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

FOCUS Step1

A risk assessment for the formulation has been removed as the toxicity of the active substance and the formulation are in the same order of magnitude.

Crop and application rate: Two applications to cereals at 0.125 kg a.s./ha at growth stages BBCH 25 to 69, with 21 day spray interval.

TERs for aquatic organisms at FOCUS Step 1

Test substance	Organism	Toxicity end point (mg/L)	Time scale	**$PEC_{sw,max}$ [µg L^{-1}]**	TER	Annex VI Trigger[1]
a.s.	*Cyprinus carpio*	0.29	Acute	44.586	**6.5**	100
a.s.	*Pimephales promelas*	0.0359	Chronic	44.586	**0.805**	10
a.s.	*Crassostrea virginica*	1.1	Acute	44.586	**24.7**	100
a.s.	*Daphnia magna*	0.5	Chronic	44.586	11	10
a.s.	*Pseudokirchnella subcapitata*	0.4	Chronic	44.586	**9.0**	10
a.s.	*Lemna gibba*	2.19	Chronic	44.586	49	10
a.s.	*Chironomus riparius*	75.9	Chronic	307.8[2]	246	10
M700F001	*Oncorhynchus mykiss*	>100	Acute	4.76	>21008	100
M700F001	*Daphnia magna*	>100	Acute	4.76	>21008	100
M700F001	*Pseudokirchnella subcapitata*	26.42	Chronic	4.76	5550	10
M700F002	*Oncorhynchus mykiss*	>100	Acute	24.71	>4047	100
M700F002	*Daphnia magna*	>100	Acute	24.71	>4047	100
M700F002	*Pseudokirchnella subcapitata*	22.44	Chronic	24.71	908	10
M700F007	*Oncorhynchus mykiss*	>100	Acute	0.19	>526316	100
M700F007	*Daphnia magna*	>100	Acute	0.19	>526316	100
M700F007	*Pseudokirchnella subcapitata*	>100	Chronic	0.19	>526316	10

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

[2] PECsed were used.

FOCUS Step 2

FOCUS Step 2 calculations were conducted for each compound. The calculations were based on the two applications of 0.125 g a.s./ha to cereals, with an average crop cover of 50 %. Crop application at step 2 included applications made in the winter and spring.

TERs for aquatic organisms at FOCUS Step 2

Test substance	N/S	Organism	Toxicity end point (mg/L)	Time scale	$PEC_{sw,max}$ [µg L^{-1}]	TER	Annex VI Trigger
a.s.	N	*Cyprinus carpio*	0.29	Acute	5.182	**56.0**	100
a.s.	S	*Cyprinus carpio*	0.29	Acute	9.143	**31.7**	100
a.s.	N	*Crassostrea virginica*	1.1	Acute	5.182	212	100
a.s.	S	*Crassostrea virginica*	1.1	Acute	9.143	120	100
a.s.	N	*Pseudokirchnella subcapitata*	0.4	Chronic	5.182	77.2	10
a.s.	S	*Pseudokirchnella subcapitata*	0.4	Chronic	9.143	43.7	10
a.s.	N	*Pimephales promelas*	0.0359	Chronic	5.182	**6.9**	10
a.s.	S	*Pimephales promelas*	0.0359	Chronic	9.143	**3.9**	10

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

Surface water modelling of fluxapyroxad (BAS 700 F) was conducted using the FOCUS surface water models and scenarios. The Step 3 simulations were conducted for all relevant FOCUS surface water scenarios using the MACRO or PRZM models to simulate potential surface water exposure and TOXSWA to simulate the fate and behaviour of the compound in the water body.

TERs for aquatic organisms at FOCUS Step 3 (tier A) application to winter cereals

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC_{sw} Global max [µg L^{-1}]	TER	Annex VI trigger
a.s.	D1	ditch	*Cyprinus carpio*	Acute	0.29	3.846	**75.4**	100
a.s.		stream	*Cyprinus carpio*	Acute	0.29	2.406	120.5	100
a.s.	D2	ditch	*Cyprinus carpio*	Acute	0.29	3.694	**78.5**	100
a.s.		stream	*Cyprinus carpio*	Acute	0.29	2.306	125.6	100
a.s.	D3	ditch	*Cyprinus carpio*	Acute	0.29	0.691	419.7	100
a.s.	D4	pond	*Cyprinus carpio*	Acute	0.29	0.622	466.2	100
a.s.		stream	*Cyprinus carpio*	Acute	0.29	0.939	308.8	100
a.s.	D5	pond	*Cyprinus carpio*	Acute	0.29	0.299	969.9	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC_{sw} Global max [µg L^{-1}]	TER	Annex VI trigger
a.s.		stream	*Cyprinus carpio*	Acute	0.29	0.572	507	100
a.s.	D6	ditch	*Cyprinus carpio*	Acute	0.29	0.965	300.5	100
a.s.	R1	pond	*Cyprinus carpio*	Acute	0.29	0.17	1705.9	100
a.s.		stream	*Cyprinus carpio*	Acute	0.29	1.192	243.3	100
a.s.	R3	stream	*Cyprinus carpio*	Acute	0.29	1.042	278.3	100
a.s.	R4	stream	*Cyprinus carpio*	Acute	0.29	1.997	145	100
a.s.	D1	ditch	*Pimephales promelas*	Chronic	0.0359	3.846	**9.3**	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	2.406	14.9	10
a.s.	D2	ditch	*Pimephales promelas*	Chronic	0.0359	3.694	**9.7**	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	2.306	15.6	10
a.s.	D3	ditch	*Pimephales promelas*	Chronic	0.0359	0.691	52.0	10
a.s.	D4	pond	*Pimephales promelas*	Chronic	0.0359	0.622	57.7	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	0.939	38.2	10
a.s.	D5	pond	*Pimephales promelas*	Chronic	0.0359	0.299	120.1	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	0.572	62.8	10
a.s.	D6	ditch	*Pimephales promelas*	Chronic	0.0359	0.965	37.2	10
a.s.	R1	pond	*Pimephales promelas*	Chronic	0.0359	0.17	211.2	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	1.192	30.1	10
a.s.	R3	stream	*Pimephales promelas*	Chronic	0.0359	1.042	34.5	10
a.s.	R4	stream	*Pimephales promelas*	Chronic	0.0359	1.997	18.0	10

TERs for aquatic organisms at FOCUS Step 3 (tier A) application to spring cereals

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point [mg/L]	PEC_{sw} Global max [µg L^{-1}]	TER	Annex VI trigger
a.s.	D1	ditch	*Cyprinus carpio*	Acute	0.29	2.523	114.9	100
a.s.		stream	*Cyprinus*	Acute	0.29	1.589	182.5	100

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point [mg/L]	PEC_{sw} Global max [µg L^{-1}]	TER	Annex VI trigger
			carpio					
a.s.	D3	ditch	*Cyprinus carpio*	Acute	0.29	0.693	418.5	100
a.s.	D4	pond	*Cyprinus carpio*	Acute	0.29	0.461	629.1	100
a.s.		stream	*Cyprinus carpio*	Acute	0.29	0.671	432.2	100
a.s.	D5	pond	*Cyprinus carpio*	Acute	0.29	0.202	1435.6	100
a.s.		Stream	*Cyprinus carpio*	Acute	0.29	0.639	453.8	100
a.s.	R4	Stream	*Cyprinus carpio*	Acute	0.29	2.078	139.6	100
a.s.	D1	ditch	*Pimephales promelas*	Chronic	0.0359	2.523	14.2	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	1.589	22.6	10
a.s.	D3	ditch	*Pimephales promelas*	Chronic	0.0359	0.693	51.8	10
a.s.	D4	pond	*Pimephales promelas*	Chronic	0.0359	0.461	77.9	10
a.s.		stream	*Pimephales promelas*	Chronic	0.0359	0.671	53.5	10
a.s.	D5	pond	*Pimephales promelas*	Chronic	0.0359	0.202	177.7	10
a.s.		Stream	*Pimephales promelas*	Chronic	0.0359	0.639	56.2	10
a.s.	R4	Stream	*Pimephales promelas*	Chronic	0.0359	2.078	17.3	10

TERs for aquatic organisms at FOCUS Step 3 application to winter cereals using the refined PECsw from tier C[1].

Test substance	**Scenario**	**Water body type**	**Test organism**	**Time scale**	**Toxicity end point (mg/L)**	**PEC_{sw} Global max [µg L^{-1}]**	**TER**	**Annex VI trigger**
a.s.	D1	ditch	*Cyprinus carpio*	Acute	0.29	2.786	104	100
a.s.	D2	ditch	*Cyprinus carpio*	Acute	0.29	2.668	109	100
a.s.	D1	ditch	*Pimephales promelas*	Chronic	0.0359	2.786	12.9	10
a.s.	D2	ditch	*Pimephales promelas*	Chronic	0.0359	2.668	13.5	10

[1] Simulations with refined interception values in MACRO according to FOCUS recommendations

Bioconcentration				
	Fluxapyroxad (BAS 700 F)	M700F001	M700F002	M700F007
$logP_{OW}$	3.11	<0.39	<0.39	<0.3
Bioconcentration factor (BCF)[1]	36/37	NA	NA	NA
Annex VI Trigger for the bioconcentration factor	1000	5	5	5
Clearance time (days) (CT_{50})	0.73	NA	NA	NA
(CT_{90})	0.84	NA	NA	NA
Level and nature of residues (%) in organisms after the 14 day depuration phase	0.011% radioactivity remaining after 16 days	NA	NA	NA

[1] only required if log $P_{O/W}$ >3.
NA: not applicable

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

Test substance	Acute oral toxicity (LD_{50})	Acute contact toxicity (LD_{50})
a.s. ‡	> 110.9 (µg a.s./bee)	> 100 (µg a.s./bee)
'BAS 700 00 F'	> 2721 (µg product/bee)	448 (µg product/bee)
Field or semi-field tests	No effect on foraging activity, mean brood termination rate or the brood compensation index compared with the control at 2.0 L product/ha.	

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

Crop and application rate: Two applications to cereals at 0.125 kg a.s./ha at growth stages BBCH 25 to 69, with 21 day spray interval.

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 1.25	50
a.s.	Oral	< 1.13	50
'BAS 700 00 F'	Contact	4.64	50
'BAS 700 00 F'	Oral	< 0.764	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	LR_{50} (L product/ha)
Typhlodromus pyri ‡	'BAS 700 00 F'	Mortality	0.128
Aphidius rhopalosiphi ‡	'BAS 700 00 F'	Mortality	4.70

Crop and application rate: Two applications to cereals at 0.125 kg a.s./ha at growth stages BBCH 25 to 69, with 21 day spray interval.

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field (at 1 m)	Trigger
'BAS 700 00 F'	*Typhlodromus pyri*	0.128	**26.6**	0.632	2
'BAS 700 00 F'	*Aphidius rhopalosiphi*	4.70	0.723	0.0172	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (L product/ ha)	End point (L product/ha)	% effect on fecundity	Trigger value
A. rhopalosiphi	Adult	'BAS 700 00 F'	6.0	$LR_{50} > 6.0$	29.4 % reduction at 6.0 L	50 %
T. pyri	Protonymph	'BAS 700 00 F'	2.0	$LR_{50} = 1.62$	53.9 % reduction at 2.0 L	50 %
T. pyri[1]	Protonymph	'BAS 700 00 F'	4.0	$LR_{50} > 4.0^{+}$	No effects at 4.0 L	50 %
C. carnea	Larval	'BAS 700 00 F'	6.0	$LR_{50} > 6.0$	No effects at 6.0 L	50 %

[+] Initial residues
[1] this study should be used in the risk assessment.

Field or semi-field tests
Not required.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
	a.s. ‡	Acute	$LC_{50} > 1000$ mg a.s./kg d.w.soil
	'BAS 700 00 F'	Acute	$LC_{50} = 17.22$ mg a.s./kg dry soil
	'BAS 700 00 F'	Chronic	NOEC (56 d) = 21.3 mg a.s./kg dry soil
	M700F001	Acute	$LC_{50} > 1000$ mg M700F001/kg dry soil
	M700F001	Chronic	NOEC (56 d) = 5.33 mg M700F001/ kg dry soil
	M700F002	Acute	$LC_{50} > 1000$ mg M700F002/kg dry soil

Test organism	Test substance	Time scale	End point
	M700F002	Chronic	NOEC (56 d) = 2.56 mg M700F002/ kg dry soil
Other soil macro-organisms			
Soil mite			
	'BAS 700 00 F'	Chronic	NOEC = 500 mg 'BAS 700 00 F'/kg dry soil NOEC = 29.64 mg a.s./kg dry soil*
Collembola			
	M700F002	Chronic	NOEC = 1000 mg M700F002/kg dry soil
	'BAS 700 00 F'	Chronic	NOEC (28 d) = 50.0 mg 'BAS 700 00 F'/kg dry soil NOEC = 2.99 mg a.s./kg dry soil+
Organic matter breakdown			
	'BAS 701 00 F'*	Field study	Effects below 10 % after 12 months exposure to total application rate of 5 L product/ha. Effects between 10-25 % after 12 months exposure to total application rates of 8 and 10 L product/ha.
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡	28 d	< 25 % effect at 0.40 and 2.01 mg a.s./kg dry soil after 28 d
	M700F001	28 d	< 25 % effect at 0.037 and 0.37 mg metabolite/kg dry soil after 28 d
	M700F002	28 d	< 25 % effect at 0.1, 0.7 and 1.0 mg metabolite/kg dry soil after 28 d
	'BAS 700 00 F'	28 d	< 25 % effect at 5.54 and 27.71 mg formulation/kg dry soil after 28 d
Carbon mineralisation	a.s. ‡	28 d	< 25 % effect at 0.40 and 2.01 mg a.s./kg dry soil after 28 d
	M700F001	28 d	< 25 % effect at 0.037 and 0.37 mg metabolite/kg dry soil after 28 d
	M700F002	28 d	< 25 % effect at 0.1, 0.7 and 1.0 mg metabolite/kg dry soil after 28 d
	'BAS 700 00 F'	28 d	< 25 % effect at 5.54 and 27.71 mg formulation/kg dry soil after 28 d
Field study	'BAS 701 00 F'*	Field test	No statistically significant effects

Test organism	Test substance	Time scale	End point
			on earthworm abundance or biomass up to a total application rate of 10 L product/ha compared to the control.

* 'BAS 701 00 F' is a formulation containing 62.5 g/L (nominal) BAS 700 F and 62.5 g/L (nominal) epoxiconazole.
+ Endpoint calculated by RMS.

Toxicity/exposure ratios for soil organisms

Crop and application rate: Two applications to cereals at 0.125 kg a.s./ha at growth stages BBCH 25 to 69, with 21 day spray interval.

Test organism	Test substance	Time scale	Soil PEC*	TER	Trigger
Earthworms					
	a.s. ‡	Acute	0.1882 mg a.s./kg	> 5313	10
	'BAS 700 00 F'	Acute	0.1882 mg a.s./kg	91.50	10
	'BAS 700 00 F'	Chronic	0.1882 mg a.s./kg	113.2	5
	M700F001	Acute	0.0075[1] mg M700F001/kg dry soil	(>142857)	10
	M700F001	Chronic	0.0075[1] mg M700F001/kg dry soil.	706	5
	M700F002	Acute	0.056[2] mg M700F002/kg dry soil	> 17857	10
	M700F002	Chronic	0.056[2] mg M700F002/kg dry soil	45.71	5
Other soil macro-organisms					
Soil mite	'BAS 700 00 F'	Chronic	0.1882 mg a.s./kg dry soil	157.49	5
Collembola	M700F002	Chronic	0.056 mg M700F002/kg dry soil	17857	5
	'BAS 700 00 F'	Chronic	0.1882 mg a.s./kg dry soil	15.89	5

* Plateau PEC plus one season's application.
[1] Initial PECs were used.
[2] following 13 years of parent and correction for molecular mass and maximum occurrence.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (L formulation/ha) vegetative vigour	ER_{50} (L formulation/ha) emergence	Exposure* (g/ha)	TER	Trigger
NA+	'BAS 700 00 F'	> 2.0	-	0.0554	> 36.1	5
NA+	'BAS 700 00 F'	-	> 2.0	0.0554	> 36.1	5

* Based on Ganzelmeier drift data

+ Endpoints were the same for all species tested.

NA: not applicable

Additional studies (e.g. semi-field or field studies)

-

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge	3 hour EC_{50} > 1000 mg a.s./L
Pseudomonas sp	-

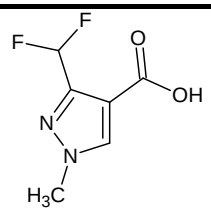
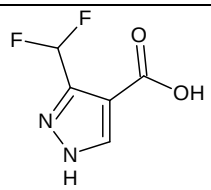
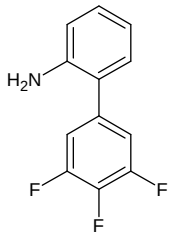
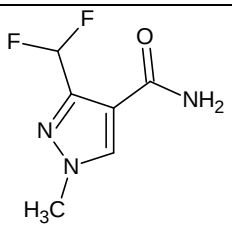
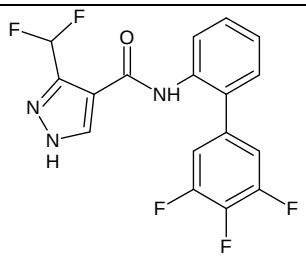
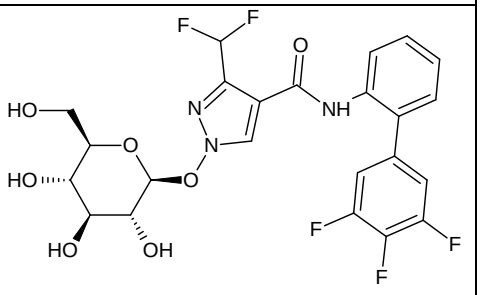
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Fluxapyroxad (BAS 700 F).
water	Fluxapyroxad (BAS 700 F).
sediment	Fluxapyroxad (BAS 700 F).
groundwater	Fluxapyroxad (BAS 700 F)

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance	RMS/peer review proposal
	R50; R53 (Regulation 1272/2008: H410; H411)
	RMS/peer review proposal
Preparation	R51; R53 (Regulation 1272/2008: H411)

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
M700F001	3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxylic acid	
M700F002	3-(difluoromethyl)-1*H*-pyrazole-4-carboxylic acid	
M700F003	3',4',5'-trifluorobiphenyl-2-amine	
M700F007	3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide	
M700F008	3-(difluoromethyl)-*N*-(3',4',5'-trifluorobiphenyl-2-yl)-1*H*-pyrazole-4-carboxamide	
M700F048	3-(difluoromethyl)-1-(b-D-glucopyranosyloxy)-*N*-(3',4',5'-trifluorobiphenyl-2-yl)-1*H*-pyrazole-4-carboxamide	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC	emulsifiable concentrate
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use

FOMC	first-order multi-compartment model
g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HQ	hazard quotient
HS	hockey stick kinetics
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake

ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UK POEM	United Kingdom Predictive Operator Exposure Model
UPLC-MS/MS	ultra performance liquid chromatography with tandem mass spectrometry
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation

wk	week
yr	year