TECHNICAL REPORT

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Outcome of the Public Consultation on the draft scientific report of EFSA on the "repair action" of the FOCUS surface water scenarios

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Abstract

EFSA performed a public consultation of the draft scientific report of EFSA on the "repair action" of the FOCUS surface water scenarios from 24 September to 5 November 2018. EFSA was asked the European Commission to prepare a public consultation on the draft scientific report. The EFSA scientific report provides an update of the current FOCUS surface water report currently used for surface water exposure assessments of substances to aquatic organisms when performing risk assessments according to Regulation (EC) No 1107/2009 of the European Parliament and the Council. This report presents statistics on the comments received and answers to them. These comments were considered when finalising the EFSA scientific report.

Key words: pesticides, PECs, modelling, environmental exposure

Requestor: European Commission

Question number: EFSA-Q-2017-00072

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Summary

EFSA performed a public consultation of the EFSA draft scientific report on the "repair action" of the FOCUS surface water scenarios from 24 September to 5 November 2018. EFSA was asked by the European Commission to prepare a public consultation on the draft scientific report. The EFSA scientific report provides an update of the FOCUS surface water scenarios currently used for surface water exposure assessments of substances to aquatic organisms when performing risk assessments according to Regulation (EC) No 1107/2009 of the European Parliament and the Council. This report presents statistics on the comments received and answers to them. These comments were considered when finalising the EFSA scientific report.

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1. Introduction

In the context of the development of the EFSA draft scientific report on the "repair action" of the FOCUS surface water scenarios a public consultation was organised for a 6 week open consultation period on the EFSA website from 24 September to 5 November 2018. EFSA was asked by the European Commission to prepare a public consultation on the draft scientific report. The EFSA Pesticide Steering Network, risk assessors, risk managers, stakeholder and the scientific community were additionally informed via emails about the open public consultation. This technical stakeholder report presents statistics on the comments received and answers to them. These comments were considered when finalising the EFSA scientific report.

The EFSA scientific report provides an update of the FOCUS surface water scenarios currently used for surface water exposure assessments of substances to aquatic organisms when performing risk assessments according to Regulation (EC) No 1107/2009 of the European Parliament and the Council[3].

1.1. Terms of Reference as provided by the requestor

EFSA was asked by the European Commission (DG SANTE) to draft a "Scientific Report of EFSA on the "repair action" of the FOCUS surface water scenarios. EFSA was requested to organise public consultations on the draft Scientific Report, to ensure the full involvement of Member States and other stakeholders.

2. Screening and Evaluation of the comments received

All the comments received were scrutinised and subsequently tabulated with reference to the author(s) and the section of the draft scientific report each comment referred too. Duplicate comments received from the same contributor appear only once in the table and where there was more than one comment from the same contributor but for different sections of the scientific report, the comments were separated and added to the relevant section. The references to chapters and appendices in the comments and the answers to the comments refer to the draft scientific report of September 2018 and not to the final document. The final number of comment boxes were 193. Comments submitted formally on behalf of an organisation appear with the name of the organisation. A statistical summary of the comments received is provided in Tables 1 and 2. In Table 3 the comments to the draft scientific report are provided together with the responses by the EFSA FOCUS surface water repair WG.

Table 1: Comments received on the draft Scientific Report per section

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[3] EC (European Commission), 2009. Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309/1, 24.11.2009, pp. 1–50.

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Total number of comments	**193**

Table 2: Comments received on the draft EFSA Scientific Report by organisation

Organisation	**Country**	**Total**
Agence Nationale de Sécurité Sanitaire de l'Alimentation de l'Environnement et du Travail (ANSES)	FR	16
Umweltbundesamt (German Environment Agency) (UBA)	DE	16
College voor de Toelating van Gewasbeschermingsmiddelen en Biociden (Ctgb)	NL	6
The Danish Environmental Protection Agency (Miljøstyrelsen)	DK	12
European Crop Protection Association (ECPA)	BE	24
Enviresearch Ltd	UK	14
GAB Consulting GmbH	DE	3
HSE (Chemical Regulation Division)	UK	10
Institute of Environmental Protection (NRI)	PL	36
Pesticide Registration Division, Department of Agriculture, Food and the Marine	IR	2
Redebel Regulatory Affairs SCRL	UK	4
Rifcon GmbH	DE	4
Scientific Consulting Company GmbH (SCC)	DE	8
TSG Consulting	UK	4
Swedish Chemicals Agency (KEMI)	SW	21
The Norwegian Food Safety Authority (Mattilsynet)	NO	6
WSC Scientific GmbH	DE	7
Total Number of comments		**193**

Table 3: Comments received on the draft EFSA Scientific Report

Num-ber	Organization	Country	Chapter	Comments and EFSA WG responses
1	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	General comments	Anses wishes to thank the experts involved in this draft document. The contribution for improving risk assessment at EU and zonal level is appreciated. EFSA: Thank you
2	UBA (Umweltbundesamt, German Environment Agency)	DE	General comments	The "repaired" version of the FOCUS SW Tool could not be tested. Are there any plans for further comments when the tool is available? EFSA: No further public consultation is foreseen under this mandate. The tools will be submitted into FOCUS version control before they are released for regulatory use. The final EFSA scientific report and link to the FOCUS website will be shared with SCoPAFF for note taking.
3	The Danish Environmental Protection Agency	DK	General comments	Denmark welcomes an update of the FOCUS surface water scenarios and modeling approach. An 20-yrs assessment will increase the reliability of the model significantly. We acknowledge that the mandate for the "repair action" was fixed, but we will like to point out, that there is still room for improvements to the FOCUSsw model. Issues like e.g. the lack of macrophytes, lack of infiltration and constant water depth that should be considered in future update of the FOCUSsw model. EFSA: EFSA consulted the Pesticide Steering Network and the issues above were not put forward by MSs. The mandate from the EU commission did not request the additional aspects to be considered. We agree that there is a need for further revision of the FOCUS surface water scenarios as proposed by the PPR Panel.
4	ECPA	BE	General comments	General comment Extension of the timeframe of the EFSA mandate: The EFSA WG lists a number of important issues that could not be addressed in the limited timeframe of the current mandate. This leaves the Repair activity with only the absolute minimum results required by the mandate, and misses the opportunity to make FOCUS SW fit for the future with a limited number of relatively minor additional changes. One example is the inclusion of a crop model to link crop development and agronomy to weather conditions (see comment 6). Therefore, we ask EFSA to assess the option to extend the timeframe of the mandate, or to directly establish one or more follow-up WGs that deal with those main open issues that can be resolved relatively quickly. EFSA: EFSA consulted the Pesticide Steering Network and the issues above were not put forward by MSs. The mandate from the EU commission did not request the additional aspects to be considered. We agree that there

				is a need for further revision of the FOCUS surface water scenarios as proposed by the PPR Panel. General comment Second round of commenting when adapted model versions are available: Since neither updated input data files according to the proposed changes, nor model versions (PRZM, MACRO, TOXSWA, SWASH) adapted to the proposed 20 year assessment period were available for the current commenting round, the proposals of the EFSA WG could not be systematically tested for their practicability and their consequences for risk assessment. We note that also the EFSA WG could only do very limited testing of its own proposals. The results of later, more extensive testing may show inconsistencies or unintended consequences of the proposed changes and lead to the conclusion to revise or refine some of them. We therefore ask the EFSA WG to establish a second opportunity for commenting once the adapted models are available. EFSA: A second round of commenting is not foreseen under the current mandate. However the updated modelling tools will be submitted into the FOCUS version control before they are released for regulatory use. General comment Keep at least a simplified PAT in FOCUS SW to avoid unrealistic application situations: It is understood that the existing Pesticide Application Timer (PAT) for FOCUS SW with quite complex rules is not suitable for multi-year evaluations, and is also not necessary anymore to ensure worst-case application conditions (as this is covered by the variability of weather conditions across the 20 years). Nevertheless, at least a very simple PAT is still needed in order to prevent agronomically unrealistic use situations (e.g. applications under very wet conditions, or directly preceeding rainfall). Farmers will consider weather conditions and weather forecast on the day of application, and will avoid applications that reduce the efficacy of the product e.g. due to foliar wash-off. Such a simple PAT is readily available and was even already implemented in the German surface water exposure assessment tool GERDA. The GERDA PAT only considers the rainfall on the day of application and on the preceeding day to shift the application date by one or a few days. To ensure that the GAP is fully respected with regard to the minimum application interval, additionally relaxation rules could be defined. It should be considered, however, that it is highly unrealistic to assume that the worst case GAP is fully respected for 20 years in a row, considering variable weather conditions and variable pest pressure, not even allowing for a shift of application by a few days under clearly defined circumstances. So far, we could only run limited test calculations, the results of which were presented at the European Modelling Workshop in October (presentation available at pfmodels.org, or upon request). There are clear indications that for specific combinations of crop, compound and scenario the complete removal of the PAT results in very high exposure peaks which the simple GERDA PAT can filter out.

				For a more detailed discussion of the above points and responses to specific proposal and arguments by the EFSA WG, please also refer to comments under section 3.2 EFSA: The mandate requires the WG to consider approaches for use of a PAT. After further extensive testing (new Appendix I) a simplified PAT (extension period of ± 3 days) has been retained.
5	The Norwegian Food Safety Authority (Mattilsynet)	NO	General comments	We think that you have done a good job with the repair of the FOCUS SW scenarios and overall agree with your suggestions. EFSA: Thank you. We have a comment to the following summary text: "The FOCUS surface water Repair WG recommends ignoring the 'single application approach' in case of multiple applications and to allow for simulations with multiple applications only in line with the GAP. As mentioned above it is proposed to always apply the 90th percentile spray drift value independent of the number of applications in a year, thus excluding different drift loadings with respect to single vs. multiple applications." The first sentence is not entirely clear. Do you mean "multiple applications only in line with the GAP" or "multiple applications only, in line with the GAP"? EFSA: In view of the modified percentile approach finally implemented in the models (setting only the last application to the 90th percentile), the summary has been adopted accordingly.
6	Pesticide Registration Division, Department of Agriculture, Food and the Marine, Ireland	IR	General comments	We highly appreciate your initiative and efforts in trying to repair the current version of the FOCUS surface models. EFSA: Thanks.
7	TSG consulting	UK	General comments	Regarding sediment PECs in general it should be acknowledged within the repair action document that there are some significant limitations highlighted in the existing guidance/literature regarding TOXSWA with regards to the sediment compartment: The sediment layer is assumed to be identical to the sediment of Step1 and 2"… "Step 1 and 2 scenarios are simple 'unrealistic worst-cases'" FOCUS SW guidance (2014, p98 & p210) "The main limitations of the TOXSWA model are: …Sedimentation and re-suspension are not considered" FOCUS SW guidance (2014, p217) "…chronic exposure is tested for a maximum of 28 days. Initially, this was also the period TOXSWA has been developed for" TOXSWA Manual (2006, p21)

				"Increases in sediment thickness and deposition of suspended solids …have not been incorporated in TOXSWA…TOXSWA may be applied for periods of up to 200 d. One should, however be aware of the limitations of the suspended solids behaviour" TOXSWA 3.3.1 Help file Clearly the expansion of simulation periods to 26 year durations (or perhaps longer) would mean these limitations and assumptions are more relevant than previously with regards to PECsed calculation and should be given consideration within the document. Perhaps this could be addressed by acknowledging the above limitations and stating that the percentile pec for sediment can therefore be considered more worse case than PECsw? EFSA: The WG introduced a new chapter concerning PECs in sediment. The conservativeness of the PEC in sediment was not addressed by the original SANCO FOCUS surface water WG. Several factors play a role, some promoting best case, some worst case. However, the organic matter content in the sediment of stream and ditch scenarios cannot be considered worst case as peer reviewed papers show that organic matter can be higher.
8	ECPA	BE	Abstract	The sediment layer is assumed to be identical to the sediment of Step1 and 2"… "Step 1 and 2 scenarios are simple 'unrealistic worst-cases'" EFSA: The WG introduceed a new chapter concerning PECs in sediment. The conservativeness of the PEC in sediment was not addressed by the original SANCO FOCUS surface water WG. Several factors play a role, some promoting best case, some worst case. However, the organic matter content in the sediment of stream and ditch scenarios cannot be considered worst case as peer reviewed papers show that organic matter can be higher.
9	SCC Gmbh	DE	Summary	"The main limitations of the TOXSWA model are: …Sedimentation and re-suspension are not considered" EFSA: The WG introduced a new chapter concerning PECs in sediment. The conservativeness of the PEC in sediment was not addressed by the original SANCO FOCUS surface water WG. Several factors play a role, some promoting best case, some worst case. However, the organic matter content in the sediment of stream and ditch scenarios cannot be considered worst case as peer reviewed papers show that organic matter can be higher.
10	ECPA	BE	Summary	"…chronic exposure is tested for a maximum of 28 days. Initially, this was also the period TOXSWA has been developed for" EFSA: The WG introduced a new chapter concerning PECs in sediment. The conservativeness of the PEC in sediment was not addressed by the original SANCO FOCUS surface water WG. Several factors play a role, some promoting best case, some worst case. However, the organic matter content in the sediment of stream and ditch scenarios cannot be considered worst case as peer reviewed papers show that organic matter can be higher.

11	UBA (Umweltbundesamt, German Environment Agency)	DE	1. Introduction	"Increases in sediment thickness and deposition of suspended solids …have not been incorporated in TOXSWA…TOXSWA may be applied for periods of up to 200 d. One should, however be aware of the limitations of the suspended solids behaviour" EFSA: The WG introduced a new chapter concerning PECs in sediment. The conservativeness of the PEC in sediment was not addressed by the original SANCO FOCUS surface water WG. Several factors play a role, some promoting best case, some worst case. However, the organic matter content in the sediment of stream and ditch scenarios cannot be considered worst case as peer reviewed papers show that organic matter can be higher.
12	Swedish Chemicals Agency	SW	2. Model framework	Clearly the expansion of simulation periods to 26 year durations (or perhaps longer) would mean these limitations and assumptions are more relevant than previously with regards to PECsed calculation and should be given consideration within the document. Perhaps this could be addressed by acknowledging the above limitations and stating that the percentile pec for sediment can therefore be considered more worse case than PECsw? EFSA: The WG introduced a new chapter concerning PECs in sediment. The conservativeness of the PEC in sediment was not addressed by the original SANCO FOCUS surface water WG. Several factors play a role, some promoting best case, some worst case. However, the organic matter content in the sediment of stream and ditch scenarios cannot be considered worst case as peer reviewed papers show that organic matter can be higher.
13	UBA (Umweltbundesamt, German Environment Agency)	DE	2. Model framework	Line 274 page 9: comment to "realistic" in the sentences "The scenarios cover a realistic range of surface …" The development of the scenarios was performed more than 20 years ago. The whole EU is not covered and the proof how realistic these scenarios are is limited and was not focused on the PECsw resulting with the model for the combination of an active substance/product/use. The wording should set into this context. EFSA: Line 274 was rephrased to explain that during the development of the FOCUS scenarios the EU had 15 MSs and that the intention was to cover a realistic range of surface at that time.
14	Institute of Environmental Protection - National Research Institute	PL	2. Model framework	No comments to this part of the document (after thorough examination). EFSA: Noted.
15	Institute of Environmental Protection - National Research Institute	PL	3. Addressing the Terms of References from the European	No comments to this part of the document (after thorough examination). EFSA: Noted.

			Commission	
16	Institute of Environmental Protection - National Research Institute	PL	3.1 Introduction of a 20-yrs assessment period into all FOCUS surface water scenarios	The comments are provided individually to each subsection. EFSA: Noted.
17	The Norwegian Food Safety Authority (Mattilsynet)	NO	3.1 Introduction of a 20-yrs assessment period into all FOCUS surface water scenarios	In our opinion, it would be very good to introduce a 20-year assessment period for the surface water scenarios, same as the groundwater scenarios. EFSA: Noted.
18	Rifcon GmbH	DE	3.1 Introduction of a 20-yrs assessment period into all FOCUS surface water scenarios	In regard to the practical aspect of this approach, this will not only consume more time but also require significantly higher computing capacities and larger volumes for storing and managing the data output. For instance, a current Step 4 assessment for one crop considering all mitigation measures suggested by the Landscape and Mitigation guideline requires a storage volume up to 10 GB. Consequently, a new assessment considering a 20 year simulation with a similar output structure would require up to 200 GB. Therefore, we suggest implementing a simplified standard output with smaller file sizes covering only the essential outputs. EFSA: The WG has considered that processing times of revised weather scenario definitions are not excessive and results are still easily produced and reproduced as part of regulatory assessments.
19	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	3.1.1 Weather data	Lines 317-399, page 10-12. It is appreciated that the changes made to the weather datasets are well explained and transparently reported. The proposals seem reasonable. It is noticeable that, MARS25 database is considered the best data currently available. It is questioned whether MARS50 data should have been replaced and updated by MARS25 data for all scenarios instead of using MARS25 to complete missing data only. In addition, the relevance of keeping old climatic data (time period from 1975) is questionable. Considering the limited time frame available for the present mandate, it is understandable that the FOCUS surface water Repair WG did not wish to change all the climatic data. Thus, we suggest that this issue should be pointed out for further improvements.

				EFSA: The EFSA WG on FOCUS repair was targeted to replace the 1-year assessment period in TOXSWA with a 20-year assessment period. It was not in the remit of this working group to reassess the vulnerability or validity of the FOCUS surface water scenarios with respect to weather, soil or crop conditions considered by FOCUS (2001). Nevertheless, the scientific report has been amended with a recommendation for further improvements of weather data including replacement of old MARS50 data with new MARS25 data and considering actual time periods, thus accounting for possible changes of weather events with respect to climate change.
20	Swedish Chemicals Agency	SW	3.1.1 Weather data	330-331, p. 10: Please clarify whether local and MARS50-weather data (in 2001) were compared for all 10 FOCUS scenarios and (significant) differences in the precipitation data only observed for D1-Lanna and D4-Skousbo, or were only these two scenarios analysed with respect to precipitation data? Maybe worth to be more clear in the text regarding this aspect. 376, 381-382, p 11: Why was no correction performed for the MARS25 data, if it had previously been identified that there is a consistent and severe underestimation of the MARS50-data compared to local precipitation measurements? Of course, the correction factor should not be the same for the 25km-resolution data compared to the 50km-resolution data; a new correction factor should be estimated. Did you test, if a correction is needed (and concluded it wasn't) or did you simply assume that MARS25 is the best available and no correction necessary? If it was tested and no need for corrections identified, please add this to the text to avoid further questions. If it was not tested, the approach taken is inconsistent and might have consequences for the PECsw-calculations. As precipitation is highly variable in space, even precipitation data at a 25km-resolution might underestimate local precipitation. It is suggested to compare the MARS25-data to the local weather data for Lanna, in an equivalent way as done for FOCUS (2001). In case the local precipitation data are not available any longer, or do not cover the entire period that is needed, you may use the comparison between MARS25 and MARS50 to estimate the correction factor for MARS25. Example (Local = local precipitation data): Local/MARS50 = 1.43 Local/MARS25 = Local/MARS50 * MARS50/MAR25 EFSA: Please refer to comment above.
21	UBA (Umweltbundesamt, German Environment Agency)	DE	3.1.1 Weather data	Line 335-339 page 10: Regarding the used weather data it is to be noted critically that the time period from 1975-1994 is not up to date. More current time periods are available now and should be considered by the WG. The conclusion by the WG that the FOCUS (2001) data are still appropriate cannot be followed as no comparison is provided to current data. A comparison to current weather data is important against the background of increasing tendency of heavy rainfall events, which is a sensitive parameter for the occurrence of runoff events. The approach to compare the weather of field studies as laid down in the OECD Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies (Series on Testing and Assessment No. 232, Series on Pesticides No. 82, ENV/JM/MONO(2016)) using the ENASGIPS model -Europe-North America Soil

				Geographic Information for Pesticide Studies (http://www.enasgips3.org/home.html)- might be applied for such an estimation. EFSA: Please refer to comment above.
22	The Danish Environmental Protection Agency	DK	3.1.1 Weather data	The weather data currently used in FOCUS surface water modelling is still considered appropriate for use. Denmark would like to question this assumption. The following points should be considered with regard to the weather data used: - The weather data from the MARS50 database covers the time period primarily from 1975 to 1994. Hence the weather data is outdated, in regard to climate change and (possibly) with regard to technological development of measuring methodology and equipment. These factors may cause substantial changes in the weather data. It is generally recognized that climate change will, or has already, introduced greater variability in weather patterns, which may have substantial effects on run-off and the transport of water and solutes to subsurface drains. - Is the MARS weather data used in the different scenarios interpolated, or is it measured data from the nearest weather stations? Are the statistical properties of the interpolated weather similar to measured data? - The MARS50 data is daily averages, which may be sufficient to simulate water and solute transport to groundwater, but is likely insufficient in representing realistic rainfall events initiating preferential flow and runoff. The ideal (with respect for model run times, and available weather data) temporal resolution is hourly, and it should be possible to locate useable hourly measured weather data relatively close to the location of the "scenario-fields". EFSA: Please note that hourly weather data are neither available nor is PRZM capable to use hourly weather data. Another possibility is to use statistically generated weather data (by use of weather generators). - It is mentioned in section 3.1.1 that a correction of the precipitations data was necessary in 2001, and additional corrections have been made by the "repair team". The corrections were conducted by use of simple factors, which are multiplicative? And when correction has already been necessary, then why not "start from scratch", and re-think the general approach of weather data? In general the MARS50 data appears slightly untrustworthy (the "repair group" mentions several changes which cannot be explained), as the weather data (especially precipitation) has a significant effect on the predicted fate of pesticides.

				- It is stated that the MARS50 has been replaced/supplemented by MARS25, but it is unclear if the "repair team" has replaced the current weather files with the higher resolution weather data? EFSA: Please also refer to comment above.
23	Institute of Environmental Protection - National Research Institute	PL	3.1.1 Weather data	There are two problems here: 1) It was proposed to maintain the weather data sets currently implemented into the scenarios, with some modifications for D1 and D6 scenarios. However, in light of the observed climate change and related to it changes of the weather patterns maybe it would be a good idea to consider updating the weather patterns for each scenario, taking into account the data or more recent periods for each location, if available? That would probably better reflect current climatic situation at each site rendering the modelling more reliable. 2) The approach to Lanna and Thiva in comparison to other scenarios does not seem very consistent. If for those two scenarios weather files are updated, why not do the same for other scenarios and for the same time periods? The whole assessment would probably gain therefore more consistency. EFSA: Please refer to comment above.
24	ECPA	BE	3.1.1 Weather data	Line 330/331: Has the correction of the MARS50 data in the original FOCUS SW report been checked for its validity before it was decided to keep it? Is there any evidence (e.g. climate station precipitation data against MARS50 precipitation data) that substantiates the vague statement in the original FOCUS SW report ("appeared to be too low")? If it was decided to change all FOCUS SW weather data to MARS25, the upscaling of precipitation data in some of the scenarios would be perhaps unnecessary. Line 357-359: Is it possible to provide the different precipitation data sets (i.e. MARS vs. Swedish climate station) in a figure in the Appendix of the report? Line 375: Since the EFSA WG considers the new MARS25 to be the best data currently available (see Line 375), shouldn't the whole weather dataset be changed to MARS25? Also considering other small deficiencies of the MARS50, such as the one mentioned in Line 390. If it is decided to switch to the MARS25 data, how do the MARS25 vs MARS50 data compare for each of the scenario locations? Line 383: Large rainfall on the day before and after could create an unrealistically large rainfall event on the averaged day (29 February); has this been checked? EFSA: Only one day (i.e. the 29.02.1996 in D1) is affected by this procedure. There are no extreme weather events on this day. Line 390-393: The EFSA WG proposes to retain the second precipitation dataset "for pragmatic reasons". Could those reasons be explained?

				EFSA: In the data file there is no indication which dataset is the correct one, thus the more conservative one was retained. The increase in precipitation is marginal.
25	The Norwegian Food Safety Authority (Mattilsynet)	NO	3.1.1 Weather data	It was unclear to us whether the precipitation data for D1 Lanna should only be scaled by a factor of 1.077, or if the original scaling of 1.432 should be kept, with an additional scaling of 1.077 for the whole period. EFSA: FOCUS (2001) already applied the factor of 1.432 to the entire dataset of D1. In fact, non-scaled data (without this correction) are not available anymore to the WG. The factor of 1.077 was additionally applied by FOCUS (2001) for the 16-months assessment period in MACRO, thus the same is now done for the entire 20-year assessment period.
26	HSE (Chemical Regulation Division)	UK	3.1.1 Weather data	Line 360 (p.11) "the two years of…" we think this should read "the second year of …" EFSA: Noted. The typo will be adequately corrected.
27	Enviresearch Ltd	UK	3.1.1 Weather data	Has it been checked that extending the 1-year weather data to 20 years still covers the same geospatial distribution of climate? Or, to put it another way, have the 20-year data been selected on the basis of a defined protection goal? EFSA: Please refer to comment above.
28	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	3.1.2 Warming-up period	Lines 403-406, page 12. It is concluded that the warming-up period for runoff scenarios is not relevant with respect to the water layer since pesticide mass does not accumulate in streams due to their short residence times. However pond water bodies are also relevant for run-off scenarios and have significantly longer residence time. It is suggested to add a statement regarding ponds. EFSA: The text was changed to focus on the importance of the pesticide entries into the sediment, instead of on the hydraulic residence times. Lines 411-412, page 12: March to September is reported to be the « main application period ». Further justification for this statement might be provided. This application period excludes for example autumn applications whereas it is a significant application period (e.g. autumn application on winter cereals). EFSA: The analysis in Appendix A was based upon the 3 application seasons used for the runoff scenarios (March-May, June-Sept and Oct-Feb) In order to remove the winter season with no applications, the season Oct-Feb was not considered. However we agree that considering March to October included might have been a more representative period. Lines 420-423, page 12. It is understood that, as for run-off scenarios, it is assumed that the warming-up period is not relevant with respect to the water layer for drainage scenarios. This point should be further justified for pond and ditch water bodies. In addition, at first sight it does not seem to be fully consistent with FOCUS (2001) which reported in section 5.5.3 : « In preliminary model runs with MACRO, it was noted that, especially for persistent compounds, the travel time of the pesticide to the drains was significantly longer than sixteen months, such that concentrations in drain outflow were still increasing at the end of the simulation. It was

				therefore decided to employ a six-year warm-up period, in the same way as in the FOCUS groundwater scenarios (FOCUS, 2000) ». EFSA: We do still have a 6-year warming-up period for the D scenarios. We employed a simple procedure to determine these 6 warming-up years as we do not consider it to be so critical exactly which years are used and in which order. Line 417, Table 3, page 12. The way the 6 warming-up years for R scenarios were ordered is not clear and does not seem to follow the same logic as for D scenarios (alternating years with higher and lower precipitation totals than the 20 years median). Please clarify how the 6 years were ordered for R scenarios. EFSA: Clarification has been given in lines 1173-1178 in Appendix A. Note that the WG took care not to repeat the error made in the past by FOCUS (2001), i.e. selecting "50th percentile representative" years that appeared to have periods of months without any runoff event. Therefore, the number of runoff/erosion events as well as their distribution in time was considered (and thus not precipitation) while selecting the 6 warming-up years. Lines 409-434, pages 12-13. The selection criteria for the 6 years warming-up period are different for D scenarios (based on precipitation totals nearest to the median) and R scenarios (selected years with number of run-off events equal or greater to the 20 years average number of events). We assumed this has a relevant justification with respect to the model operating. However, a small explanation would be welcome, and could be included in this section or in appendix A. EFSA: Yes, the selection of the 6 warming-up years for runoff is more critical because of erosion inputs, and so an event-based approach was used. There are no erosion inputs with the drain flow so a simpler approach to select and order the years was used (see above) Lines 427-428, page 12. Given the selection criteria for warming-up years for D scenarios, it would be useful to include in Appendix tables presenting the mean annual rainfall for each year of the 20 years assessment period for D scenarios, and the corresponding median value. EFSA: Yes, agreed. Annual precipitation for each year of the 20-year assessment period (+ 6-year warming-up period) for the D- and R-scenarios was added in an appendix.
29	The Danish Environmental Protection Agency	DK	3.1.2 Warming-up period	The main purpose of the 6 year warm-up period is to reach a "plateau concentration" in the sediment, and in the soil layer above the drains. Has the repair group considered whether it is necessary with an initial warm-up period prior to pesticide application, in order to assure realistic soil moisture content? EFSA: From long experience with soil water balance modelling, we know that a 1-year warming-up period is sufficient for hydrological processes (and even less than one year is sufficient for soil temperatures, which are also relevant, as they control degradation)

30	Institute of Environmental Protection - National Research Institute	PL	3.1.2 Warming-up period	Justification for the introduction of the warming-up period for R scenarios does not look very convincing (itn is even a bit confusing) taking into account the phenomena occurring in the fast-flowing water bodies - streams. In those water bodies sedimentation is, comparing to static (ponds) and slow-flowing (ditches) water bodies low, and hence is lower related to it accumulation of the compounds of concern in sediment phase. This may be clearly seen when the results of PECsed for ditch and stream or pond and stream in pedo-climatic scenarios having those two types of water bodies defined are compared. EFSA: The approach has been rephrased in this section and is explained into more detail in lines 1173 and further Maybe therefore it would be a good idea to re-consider the whole justification to make it more scientifically sound? EFSA: See above, explanation has been improved.
31	ECPA	BE	3.1.2 Warming-up period	Line 409-410: The procedure for the selection of years for the warm-up period seems complex and somewhat arbitrary. Why were not real time series of weather data (e.g. from MARS25) used for the corresponding warm-up years instead of using ""six relatively average years""? Alternatively, the approach for the drainage scenarios to select precipitation years closest to the median value, and alternating them in the warm-up sequence, is a simple but reasonable procedure that could also be applied to the run-off scenarios. EFSA: The WG took care not to repeat the error made in the past by FOCUS (2001), i.e. selecting "50th percentile representative" years that appeared to have periods of months without any runoff event. Therefore, the number of runoff/erosion events as well as their distribution in time was considered (and thus not precipitation) while selecting the 6 warming-up years (see lines 1173-1178 in Appendix A). Line 414-416: What is the rationale and justification for selecting six years with runoff events equal or greater than the average? To what extent were runoff events ""greater than the average"" actually selected, andw what is the effect of selecting these? EFSA: See explanation above. The rationale for selecting a number of runoff/erosion events equal or greater than the average number is that in regulatory risk assessment it is common use to be rather on the conservative side, i.e. protective side of the assessment than on the non-protective side.
32	Enviresearch Ltd	UK	3.1.2 Warming-up period	In the header row of Tables 4 and 5 it would be interesting to see the 'target' precipitation for each of the scenarios. In Table 6, it would be interesting to see the data for the first 6 years, the final 20 years and the full 26 years. EFSA: Yes, agreed. Annual precipitation for each year of the 20-year assessment period (+ 6-year warming-up period) for the D- and R-scenarios has been added in an Appendix.

33	Swedish Chemicals Agency	SW	3.1.3 Irrigation	447-452, page 13: We appreciate the harmonisation with approaches for groundwater and soil exposure assessment. EFSA: Thank you
34	The Danish Environmental Protection Agency	DK	3.1.3 Irrigation	Denmark supports that MACRO and PRZM regulate irrigation internally. Are pesticide application still conducted independently of irrigation? EFSA: Yes. In MACRO pesticides are always technically applied as "irrigation", but only with a very small amount of water (typically 0.1 mm). However, this is not to be confused with irrigation for water supply. Hence, in both MACRO and PRZM irrigation events and pesticide application events are and will be separate. How is run-off initiated, since it is possible to simply "de-activate" run-off? If the model is prevented from initiating run-off, where does the water then go? Infiltration? And thereby changes the pathways of potentially sprayed pesticides? EFSA: In PRZM surface runoff is calculated with the SCS Curve Number procedure. "Deactivating runoff" for irrigation events simply means that the irrigation volume is not subject to the Curve Number equation, but directly added as infiltration to the soil. The infiltrated irrigation water can cause leaching of eventual pesticide residues, of course.
35	Institute of Environmental Protection - National Research Institute	PL	3.1.3 Irrigation	Introducing only options 5-7 is a strongly limiting factor. What about the irrigation at early growth stages, with minimal crop canopy? Such situations occur as well. In such cases of course option 7 may be used, but that introduces a substantial subjectivity (the modeller gets significant freedom with regard to the selection of the input values for this parameter). Maybe therefore it would be a good idea to introduce the options 3 and 4 as well providing clear recommendations as to when and how they are applicable? EFSA: The usability of options 5-7 (or 3-4, for that matter) is not limited by the growth stage: One either applies above the canopy (3, 5) or below (options 4, 6, 7), no matter what the current degree of ground cover is. The main difference between options 3-4 and options 5-7 is that the former are subject to surface runoff, while the latter are not. Sprinkling irrigation causing surface runoff would be agronomically inefficient; hence, options 5-7 can be considered more realistic than options 3-4.
36	ECPA	BE	3.1.3 Irrigation	Line 444: We support the decision that irrigation should not generate run-off, as this would be agronomically unrealistic. EFSA: Thank you. Since the irrigation volumes are not added to the weather file as rainfall anymore, but are simulated with the new PRZM irrigation options 5-7, irrigation will not cause surface runoff any more. Line 450: Can the consequences of using the internal irrigation routines in PRZM be explained in more detail? What are the consequences, how do the results differ from the external calculation approach? EFSA: If irrigation is scheduled internally instead of externally with ISAREG, this will remove inconsistencies caused by different water balances between ISAREG and MACRO/PRZM. On basis of the proposed irrigation

				parameter settings in PRZM there is a good agreement in annual irrigation amounts in the current and in the new approach. Tables on annual average irrigation amounts (current vs. new approach) have been added in Appendix D. Line 453: We appreciate the decision to improve the irrigation schemes in the FOCUS SW scenarios and the irrigation sub-models in PRZM. We would encourage to make the new PRZM version available for wider testing before it is implemented in the regulatory process. EFSA: The models have been tested internally in the WG. The updated models will be submitted into FOCUS version control before released for regulatory use. Line 487: It is not clear whether this recommendation by the EFSA WG is intended for implementation in this repair activity - please clarify. We note that this recommendation is not repeated in Appendix J. EFSA: The FOCUS surface water Repair WG recommends reviewing the values of PFAC used in the runoff scenarios (e.g. by checking against the Kc factors against those recommended by FAO) and adapting them if necessary. Reviewing the PFAC values is not part of the mandate of this WG Added to the recommendations of the EFSA report. Line 491-492: We agree that irrigation events between cropping seasons are not realistic. EFSA: Noted.
37	HSE (Chemical Regulation Division)	UK	3.1.3 Irrigation	It is noted that the model is building in soil water deficit to the assumptions. Is there possibility that this could also be used to address soil moisture excess to limit periods when application won't take place i.e. due to trafficability issues on the land, especially for heavy clay soils such as those represented by scenarios D1 and D2. EFSA: For PRZM this won't be possible, because PRZM does not simulate waterlogging. For MACRO, it is already possible to output water content and matric potential for every soil layer. From these outputs and the soil physical characteristics of the D scenarios it should be possible to derive periods of non-trafficability. However, the proposed rules for irrigation scheduling in MACRO (Appendix D.4.2) cannot be adapted for this purpose. A simplified PAT is proposed by the WG in the updated scientific report.
38	Enviresearch Ltd	UK	3.1.3 Irrigation	Line 452 – it is recommended to adapt Macro to calculate irrigation analogous to PRZM. What is proposed as an interim solution? EFSA: The adaptation of MACRO has been completed.
39	Anses (French Agency for Food, Environmental and	FR	3.1.4 Crop interception	Lines 501-518, pages 14-15. It is agreed that using the crop interception values defined in EFSA 2014 in MACRO and PRZM will bring more consistency between both models and with exposure models for soil and groundwater. It would also be helpful to have the possibility to easily modify via the FOCUS interface the default values

	Occupational Health & Safety)			reported in Table 7 in case of need, e.g. for products applied on non-established grass (crop interception = 40%) or for herbicide application on vines (crop interception = 0%). It is also suggested that this parameter is included in the input/output reports of the models for transparency. EFSA: In the revised SWASH shell, default crop interception values are provided depending on the BBCH stage. However, these default values can be modified by the user if justified. Final BBCH stages and crop interception assumed in the calculations are echoed in the SWASH output files.
40	Swedish Chemicals Agency	SW	3.1.4 Crop interception	501-508, page 14-15: We appreciate the harmonisation of crop interception with approaches for modelling for other compartments. 507, page 15, and page 27: The reference EFSA (2014) is missing in the reference list. Table 7 page 15: Error in column heading: "90-89" should be "90-99". EFSA: There are indeed errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list.
41	UBA (Umweltbundesamt, German Environment Agency)	DE	3.1.4 Crop interception	Line 496 ff. page 14: We appreciate to use the same interception values in MACRO and PRZM and to not calculate them internally (and different) by MACRO and PRZM and to align the interception values used in different exposure models (e.g. FOCUS groundwater and soil exposure) with those used in MACRO and PRZM. EFSA: Noted
42	The Danish Environmental Protection Agency	DK	3.1.4 Crop interception	Denmark supports that it is the same interception values in the two models. It is questioned if all values in Table 7 are correct. E.g. 'BBCH 90-89' should be corrected to 'BBCH 90-99' and cereals at bbch 90-99 should be 0.8 rather than 0.9. EFSA: There are indeed errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list.
43	Redebel Regulatory Affairs SCRL	UK	3.1.4 Crop interception	The crop interceptions are linked to the FOCUS crops. However, in some time, the difficulty is to find the corresponding representative crop to crops presented in the GAP tables (for example, with the crop miscanthus). A table like the one presented in the birds and mammals guidance (EFSA Journal 2009; 7(12):1438, Table 5) would be interesting to refer to all possible existing crops. Furthermore, there are no FOCUS crops specific for ornamental crops. It would be interesting to add an additional FOCUS crops like ornamentals, or specify appropriate surrogate crops for this use. EFSA: The proposal was discussed in the WG. Finally, the WG concluded that definition of further crops in the repaired FOCUSsw scenarios or further guidance on corresponding representative crops is outside the remit of this WG.

44	Institute of Environmental Protection - National Research Institute	PL	3.1.4 Crop interception	The proposed approach seems to harmonise in this area the Step 3/Step 4 SW exposure assessment with that for the ther compartments - GW and soil. However, it looks that there is still no internal harmonisation of the CI values in the SW model exposure assessment - the CI values at Step 2 and Step3/Step4, except for olives, still seem to be different. Maybe therefore it would be a good idea to take additional steps to have such harmonisation? That would probably render the whole SW model exposure assessment internally more coherent EFSA: Crop interception in the revised FOCUSsw scenarios at STEP 3 is now in alignment with FOCUS GW and the new guidance on PECs in soil. Crop interception at FOCUSsw STEP 2 is indeed different. However, in view of the simplicity of FOCUSsw STEP 2, the WG does not see the need to implement more complex crop interceptions already at FOCUSsw STEP 2. Notice that the WG recommend revising FOCUSsw STEP 2 in any case, as STEP 2 does not always cover the new STEP 3. This may implement reconsideration of crop interception at FOCUSsw STEP 2 as well.
45	ECPA	BE	3.1.4 Crop interception	Line 501-504: The harmonization of crop interception values between exposure models used in the different areas is appreciated in principle. However, it is not clear how this will actually be implemented in FOCUS SW models and what the impact would be. Specifically, it would be beneficial to know which variables are affected by this change in MACRO and PRZM. Other processes make use of the current internal phenological models in MACRO and PRZM (also in the calculation of washoff), so this change might go beyond calculating the intercepted substance amount. EFSA: The proposed change only affects pesticide interception by the crop canopy in MACRO and PRZM. Crop development in the models is not affected. The process of foliar wash-off is still handled internally in the models. Consequently, the change of pesticide interception fractions will affect predicted foliar wash-off fluxes only via the intercepted pesticide mass, and will not have any indirect effects. Lines 501 - 504: The proposal to adopt a framework for interception similar to that used for PECgw modelling could be seen as a step backwards from a programming and scientific perspective. It is unclear how this framework will be implemented (i.e. will the user input an application date and specify an interception fraction from a published table of values?). Some more clarity around this issue would be appreciated. EFSA: As outlined more in detail in chapter 3.5.3 ("Revised application timing in SWASH") the new SWASH shell automatically selects the default crop interception from the EFSA crop interception table (Table 7) on basis of the BBCH code selected. This default crop interception may then be overwritten by the user if justified. Lines 501 - 504: It is unclear how the intercepted fraction will be handled and in particular if it will be available for simulation of degradation and washoff as a refinement. Given the large influence of the degradation on the crop surface and subsequently wash-off and rainfastness of some fast-degrading compounds (which can cause unrealistic delayed peak concentrations modelled in surface water), consideration should be given to the possibility of retaining the option to refine the default washoff value with robust experimental data. EFSA: Degradation on the crop canopy and washoff are still internally handled by MACRO and PRZM on basis of the default crop DegT50 and the default wash-off factor (there is no change to this procedure). Both

				parameters may be changed by the user if justified. However, is it not in the remit of this working group to give guidance on how to refine these parameters (e.g. on basis of experimental data). Lines 501 - 504: The fixed application timing framework proposed by the EFSA WG would not take into consideration seasonality issues that affect e.g. ""early spring"" vs ""late spring"" shifts in timing that are particularly relevant for the heavy clay soils of scenarios D1 and D2. The inability to refine this in the suggested framework could be a significant liability in Northern Europe as the upper percentile reported PECsw profiles in spring applications in D1 will probably be focussed on agronomically inappropriate representations of timing (""late spring season"") EFSA: SWASH delivers a default application timing on basis of the BBCH period. This is done either on basis of the first BBCH stage (forward calculation) or the last BBCH stage (backward calculation). The user may then change/adapt the default application timing provided by SWASH if justified. Line 509: Table 7 states that the interception values are "in alignment with EFSA, 2014". However, there are several values in the table that differ from EFSA 2014, e.g. for cereals (BBCH30-39: 0.8 instead of 0.2, BBCH 90-99: 0.8 instead of 0.9), hops, olives, bulb veg. and leafy veg. Are these differences deliberate or typos? If deliberate, can it be explained in the report why the changes have been made? EFSA: There are indeed errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list.
46	The Norwegian Food Safety Authority (Mattilsynet)	NO	3.1.4 Crop interception	We have compared table 7 to table 1.5 on page 28 of EFSA Journal 2014;12(5)3662, and there are a couple of typing errors in table 7. For the BBCH stages 90-99 (senescence/ripening), it says 90-89 in table 7. As well, for cereals at BBCH 90-99, suggested crop interception is 0.9, while in EFSA (2014) this is 0.8. We also cannot find the reference in the table header of table 7 (EFSA, 2014) in the reference list for chapter 3. EFSA: There are indeed typing errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list. We have had problems with applicants suggesting "fixed" crop interception when calculating PECsw because the model internally calculates crop interception values that are significantly lower than what is assumed in the EU groundwater guidance for the same BBCH stage. This might be due to wrong choice of application window in relation to the growth curves in the SW scenarios. Whatever the cause, we welcome the approach taken by the FOCUS SW repair WG, where MACRO/PRZM are not allowed to calculate the interception internally. This makes it possible to ensure that the same crop interception is used in MACRO and PRZM as in all other exposure models and would make the calculations more transparent. EFSA: Noted.
47	HSE (Chemical Regulation Division)	UK	3.1.4 Crop interception	The UK welcomes the standardisation of crop interception based upon BBCH code and the advantages in having this value pre-defined outside the models, as we have experienced differences in the values generated within MACRO and PRZM as compared to standard recommended tables in pervious evaluation work. Our question is

				are the interception input values able to be amended at all in the event of non-standard uses, for example with banded applications, or use on pome fruit around the base of trees? Also, where the crop is not parameterised within FOCUS SW is there any proposal to have examples or details of potential surrogate crops that can be modelled in these cases? EFSA: Default crop interception values selected by SWASH on basis of the BBCH period may be changed by the user if justified or required (e.g. non-standard uses). The new SWASH also allows for downward spraying in tall crops (e.g. due to herbicide use). Definition of surrogate crops is outside the remit of this working group. Table 7 appears to have some errors in the crop interception values detailed: • for cereals interception at BBCH 30-39, this is at 0.2 and we believe this should be at 0.8 • for cereals at BBCH 90+ a value of 0.9 is detailed we believe this should be 0.8. • For olives at BBCH 0 a value of 0.7 is detailed we believe this should be 0. EFSA: There are indeed typing errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list.
48	Enviresearch Ltd	UK	3.1.4 Crop interception	There appear to be some transcription errors in the Table 7: the interception does not always match EFSA (2014) (e.g. cereals BBCH 30-39). EFSA (2014) does not appear to be in the reference list. EFSA: There are indeed typing errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list.
49	GAB Consulting GmbH	DE	3.1.4 Crop interception	Rows 497 - 508, pages 14/15 "Use of default FOCUS GW interception values instead of internal calculation by PRZM and MACRO" Comment: Since the crop interception calculated by PRZM and MACRO is not part of the output reports, more transparency would be preferred in order to be able to compare the current (calculated) interception values with the default FOCUS GW interception values. Hence, it would be helpful if the FOCUS surface water Repair WG could present data (e.g. example calculations) to assess the impact of switching to default GW interception values for Step 3. EFSA: Predefined crop interception values are considered to increase transparency and robustness of PECsw calculations and are in full alignment with approaches used in other exposure assessments. The WG does not see the need to demonstrate the overall impact on the PECsw assessment solely resulting from switching from internally calculated crop interception to predefined crop interception. Row 509 (Table 7), page 15 "Proposed crop interception at FOCUS Step 3"

				Comment: There is a mistake in the crop interception table for the crop "cereals, spring and winter". According to EFSA (2014), the interception at BBCH 30-39 is 0.8 (instead of 0.2) and also 0.8 at 90-99 (instead of 0.9). EFSA: There are indeed typing errors in the crop interception table (Table 7). These errors have been corrected and the reference EFSA (2014) was added in the reference list.
50	Swedish Chemicals Agency	SW	3.1.5 Reassessment of the drift percentile approach	561-565, page 16: We suggest that the effect of the proposed pragmatic solution on the PECsed needs to be assessed. This is because we should perhaps not exclude that PECsed may be critical for the risk assessment and the pond scenarios are likely to present higher PECsed than ditches and streams. Apart from this uncertainty, the pragmatic solution seems to make sense since concentrations in ditches and streams do not accumulate. As indicated in Appendix I the assumption of no accumulation in the compartment water is not true for the pond scenarios but this could be acceptable because the PECsw for ponds are lower than the PECsw for the corresponding ditches/streams. The simplification (no longer a need for modelling single application for GAP with multiple applications) is a valuable feature of the proposal. EFSA: Dependent on the scenario and the type of end-point the suggested approach might be indeed too conservative. Therefore, the methodology has been changed without losing the advantage of having only one run instead of two (single and multiple). Only for the last application the 90th percentile is considered whereas for the previous applications within a season the existing percentages will remain.
51	UBA (Umweltbundesamt, German Environment Agency)	DE	3.1.5 Reassessment of the drift percentile approach	Line 533 page 15: Please add the explanation that μ means expectation and σ means standard derivation. EFSA: More information was added in the final report.
52	The Danish Environmental Protection Agency	DK	3.1.5 Reassessment of the drift percentile approach	Support the new approach EFSA: Noted.
53	WSC Scientific GmbH	DE	3.1.5 Reassessment of the drift percentile approach	Page 16, lines 554-560: As the residence time in pond scenarios is longer than in the other two water bodies, an accumulation is possible and the final PECmax resulting from 90th percentile spray drift entry for every application is too high. In the appendix it was demonstrated that this is the case for PECmax in surface water but negligible as the concentration in pond is always below the maximum concentration in stream or ditch. Nevertheless, for substances with higher adsorption values, partitioning into sediment can be expected and increase the PECsed (accumulation). The effects of the 90th percentile drift values have not been demonstrated for PECsed. EFSA: see comment above.

54	Institute of Environmental Protection - National Research Institute	PL	3.1.5 Reassessment of the drift percentile approach	The proposed approach looks very sound and, finally, renders the calculations at Step 3 coherent (there is no need to perform separate calculations in case spray drift is not a single driver of exposure pattern). However, it becomes inconsistent with the assessment at lower tiers, at which the problem of percentile of the drift for different applications in multiple application pattern seems to remain unchanged. Maybe therefore it would be good, in order to grant more internal consistency, to reassess that issue at lower tiers as well? EFSA: The WG recommends revising FOCUSsw STEP 2 accordingly.
55	ECPA	BE	3.1.5 Reassessment of the drift percentile approach	Line 529: FOCUS (2001) indeed recommended "that a 90th percentile cumulative drift probability is used for all drift applications made in a single cropping season." It should be noted that this framework of assessment is also supported in the proceesdings of the ""Workshop on Risk Assessment and Risk Mitigation Measures (WORRM)"" (Rautmann, D., Streloke, M., Winkler, R. (1999): New basic drift values in the authorization procedure for plant protection products). The proceedings state that "this group recommended for multiple uses the use of percentiles depending on the number of applications in order to avoid the multiplication of worst case situations." Thus, the use of an overall 90th percentile is in fact supported by the drift research community, the risk mitigation specialists attending the WORRM workshop and the original researchers whose work the drift profiles are based upon. The proposal to withdraw this framework in FOCUS SW repair represents a major change from that consensus recommendation. EFSA: Dependent on the scenario the suggested approach might be indeed too conservative. The methodology has therefore been changed without losing the advantage of having only one run instead of two (single and multiple). The updated approach (only the last application is set to the 90th drift percentile) is closer to the original FOCUS ideas. Line 539-553: It is noted that "the assumption of a cumulative drift probability of 90th percentile to determine PECmax is not justified" and "Taking (...) the example of a series of six applications, the correct procedure would be to calculate the distribution of the maximum of six dawings from a normal distribution and taking the 90th percentile of this distribution of the maximum of six drawings". Whilst the statistical reasoning behind these statements may be sound it is noted that no attempt appears to have been made to present alternatives that avoid the implications of unrealistic compounded worst-case representations of drift by defining all applications on the basis of a 90th percentile that would currently only be associated with a single application. On the basis of what is presented it is not possible to determine the scale or context of discrepancy that would arise from an alternative handling in the manner discussed. It is recommended that further background information is presented in order to better assess whether the proposed revision is warranted. EFSA: see above. Line 539-553: We further recommend that when considering the statistical discrepancy that arises from the point raised above there should be consideration of further probabilistic context surrounding drift potential. For example, the current status quo framework of drift representation assumes that in each application the wind direction is always from the point of application to the surface water body. For multiple applications this is unlikely to be a reliable assumptions which has just been implemented for expediency and pragmatism

				recognising that this is a landscape-specific consideration. Nonetheless, it is noteworthy that the framework of drift representation is already somewhat conservative and adjustments that further increase conservatism should only be taken with full recognition of this. Consideration of this point is embedded in the assessment conducted by Van de Zande et al (2012) in PRI 419 cited in the consultation document - it is appropriate to present more complete context in this manner. EFSA: see above. Line 539-543 and 554-560: The ECPA WG suggests that drift loadings ""do not accumulate in the simulated watercourse"". This is a simplification based on the situation of the water compartment of flowing water bodies. The implications of dilution/advection as ""resulting peak concentration have already flowed out before the next spray drift deposition event"" ignore the consequences for the associated static sediment compartment. Where drift is the primary route of entry the exposures associated with sediment may be derived in large part from partitioning of drift loadings and a more conservative handling will unrealistically exaggerate the potential for accumulation there. It is noted that sediment handling is already somewhat conservative due to the simplified process representation in TOXSWA (simulation without sediment burial, resuspension and potential for advective dilution) and, in some cases, is compounded by representation of degradation with defaults tied to kinetic interpretation of water-sediment studies. This would suggest that further investigations of the impact in sediment are warranted. The FOCUS SW repair group have then noted the exceptions of the pond simulations where it is acknowledged that ""spray drift depositions do accummulate and using cumulative drift deposition is justified"". It is suggested that this statement should be widened to include all water bodies taking into consideration potential for accumulation in sediment. In addition, in slowly flowing ditches accumulation from drift entries may even occur in the water phase. EFSA: see above.
56	HSE (Chemical Regulation Division)	UK	3.1.5 Reassessment of the drift percentile approach	The UK acknowledges that adopting a 90th percentile drift deposition for each individual application in case of multiple applications, except for the pond scenario, is a pragmatic approach with respect to annual peak concentrations PECmax resulting from spray drift deposition. This proposal is based upon an indicated hydraulic residence times for the D1, D4, D5, R1-R4 streams of <1d (line 545) and therefore the argumentation seems clear. Should further discussion and thought be given to the scenarios for the D2 ditch/stream, D3 or D6 ditches, which can have longer average residence times, as also detailed in the Appendix F of the FOCUS SW guidance (2001). Also, as the approach is now to include 20 years of applications it is considered that within this time scale there may be climatic variability to include very dry years which would result in drift dominated outcomes such that the maximum 90th percentile deposition of multiple applications would be too conservative i.e. as detailed in line 552 and 553 of the repair action document. Will there be any further guidance provided on approaches to be taken in refining these situations

				EFSA: Dependent on the scenario the suggested approach might be indeed too conservative. The methodology has therefore been changed without losing the advantage of having only one run instead of two (single and multiple). The updated approach (setting only the last application to the 90th percentile) is closer to the original FOCUS ideas.
57	Enviresearch Ltd	UK	3.1.5 Reassessment of the drift percentile approach	The conclusion of this section depends on the single endpoint of the maximum SW PEC. A full risk assessment is much more nuanced than this and depends on the patterns of exposure and also the sediment concentration. The suggested approach over-estimates the exposure, especially of sediment. The Rautmann drift curves are based on a large number of drift trials. In principle, the distribution for multiple (e.g. six) applications should be the same as the full distribution (these six applications are basically equivalent to six trials). Of course, this is not possible because the whole distribution cannot be accurately represented with a small number of samples. For a single application, it had been decided in the past to use the 90th percentile. For multiple applications, it is very unlikely that drift will correspond to the 90th percentile every time an application is made. This would result in a deviation from the underlying distribution of drift data. It would be nice if the group could talk to Dirk Rautmann about his view on this, if this has not yet been done. The drift data compiled by SETAC DRAW should be considered. If this is not possible within the timeframe of this group, please add a recommendation for further work. As an interim solution, drift percentiles could be selected in an approximate way from the whole distribution. So for 8 applications you might have 3 with low drift %, 3 with medium and 2 with high. EFSA: The drift approach has been reconsidered by the WG setting only the final application in series of applications to the 90th drift percentile. This drift approached is indeed rather simple. However, the WG did not have a mandate for new developments with regard to drift. Therefore, the consideration of improved spray drift models have to be addressed by future working groups.
58	GAB Consulting GmbH	DE	3.1.5 Reassessment of the drift percentile approach	Rows 579 - 581, page 16 "A 90th percentile drift deposition for each individual application in case of multiple applications" Comment: For PECsed, assuming a 90th percentile drift (in case of multiple applications) is considered as extreme worst case since the decision to regard spray drift deposition as separate events due to the low hydraulic residence times of FOCUS stream and ditch is not appropriate for the sediment compartment. Substances could accumulate in the sediment, especially under high adsorption of the a.s. and hence, the 90th drift percentile - representing a single application - would overestimate sediment exposure. Further example calculations to investigate the effect of the new procedure on PECsed are strongly recommended. This is especially true for FOCUS pond, for which it is already stated in the report that "the 90th percentile deposition is indeed too conservative".

				EFSA: Dependent on the scenario the suggested approach might be indeed too conservative. The methodology has therefore been changed without losing the advantage of having only one run instead of two (single and multiple). The updated approach (setting only the last application to the 90th percentile) is closer to the original FOCUS ideas.
59	Rifcon GmbH	DE	3.1.5 Reassessment of the drift percentile approach	Consistently using the 90th percentile, even for multiple applications, could prove to be too conservative and lead to the overestimation of PECsed results. It may be advisable to implement –at least at Step4 level- refinement options to take into account a more realistic approach. Exposure patterns and effect modelling are becoming increasingly important in the current ecotoxicological risk assessment. Consistently using the 90th percentile will lead to overly conservative exposure patterns, especially when drift entries occur together with drainage or runoff events. Which can be the case for multiple applications. EFSA: Dependent on the scenario the suggested approach might be indeed too conservative. The methodology has therefore been changed without losing the advantage of having only one run instead of two (single and multiple). The updated approach (setting only the last application to the 90th percentile) is closer to the original FOCUS ideas.
60	TSG consulting	UK	3.1.5 Reassessment of the drift percentile approach	Lines 539 – 543 Whilst drift events may well be considered independent in the water column during periods of normal or fast flow in some FOCUS water bodies, this is not the case for considerable time periods in: D1 Ditch, D2 Ditch, D6 Ditch, D4 Pond, D5 Pond, R1 Pond or D2 Stream (June, July). Whilst this has been acknowledged to some extent in the draft document, this means that approximately half of the scenarios display hydraulic residence times where drift event are not independent for significant periods of time in the water column. In addition no consideration is given in the draft to the sediment loading from spray drift events which are much more likely to accumulate between spray events given the longer dissipation times from the sediment compartment vs the water compartment. EFSA: Dependent on the scenario the suggested approach might be indeed too conservative. The methodology has therefore been changed without losing the advantage of having only one run instead of two (single and multiple). The updated approach (setting only the last application to the 90th percentile) is closer to the original FOCUS ideas.
61	Swedish Chemicals Agency	SW	3.2 Review of pesticide application timing	601-604, page 17: We appreciate the simplification and the harmonisation with approach for FOCUS GW. EFSA: Thank you.
62	UBA (Umweltbundesamt, German	DE	3.2 Review of pesticide	Line 608-609 page 17: Would it be possible to explain how the FOCUS surface water Repair WG came to the conclusion that the impact is low also with a link to chapter 3.5.3. Appendix H comprises only examples for R1 scenario.

	Environment Agency)		application timing	EFSA: Following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made. A reference in this chapter to Appendix H would also be appreciated. EFSA: Not applicable anymore.
63	The Danish Environmental Protection Agency	DK	3.2 Review of pesticide application timing	Denmark agrees with the new approach suggested by the repair group. However, we suggest using three different actual dates to cover the application interval instead of just one date. The dates should represent the beginning, the middle and the end of the application interval as specified in the GAP. EFSA: In the revised SWASH shell there is the option to select applications starting from the first BBCH stage ('forward calculation', covering BBCH) or ending at the last BBCH ('backward calculation', covering late BBCH). There is no option for a 'mid BBCH' calculation. However, the user may manually adjust the default application dates selected by SWASH if justified.
64	WSC Scientific GmbH	DE	3.2 Review of pesticide application timing	Page 17, lines 601-607: The influence of the pesticide application timer and hence the actual date of application was considered negligible for the 20 years simulation period. To our experience the influence of application timing can have severe effects on soil load and hence on surface water concentrations. An evaluation of groundwater concentrations in 2015 (see Wang et al. 2015. Development of a Pesticide Application Timer (PAT) for the FOCUS groundwater models. Poster at SETAC 2015) revealed that the difference in PECgw between worst-case (rainfall on day of application) and realistic case (use of PAT rules) was up to 20 fold for substances with small DT50 in soil. EFSA: Following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made.
65	SCC Gmbh	DE	3.2 Review of pesticide application timing	Line 599ff, page 17: The PAT procedure reflects the good agricultural practice that plant protection products are generally not applied at times were significant rainfall is likely. In practice, farmers have much advice at hand (e.g. pest development and application timing forecast by agricultural services via internet) and are interested in avoiding application of plant protection products at bad weather periods that would result in reduced efficacy and economic benefit. The selection of the actual application dates over the simulation period based on PAT thus realistically reflects changing weather conditions from year to year. On the other hand, the PAT ensures a sufficient level of conservatism by assuring that 10mm of rainfall are falling within 10 days after the application. The suggested approach to use one application date over the 20-year simulation period is expected to result in the selection of extreme weather conditions, either with unrealistic high or unrealistic low rainfall. In order to be consistent among the FOCUS models, it should rather be considered to introduce a PAT functionality also for PECgroundwater and future PECsoil calculations.

				EFSA: See also the comment above. Forecast is never perfect and unfortunate events could always occur. Nevertheless, following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made.
66	Institute of Environmental Protection - National Research Institute	PL	3.2 Review of pesticide application timing	The abandonement of PAT is probably not a very good idea. PAT granted some level of the objectivity of the results for similarily defined application windows. In contrast the introduction of the proposed system, in order to render its high level of objectivity, comparability and repeatability, would require to provide in the guidelines much more specific and detailed crop calendars for each crop, with the application timings defined at least for each range of BBCH stages for each CI values are defined. EFSA: Following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made. Maybe such amendments should be considered, and not only in SW Guidelines, but also those providing the recommedations on how to perform the modelling exposure assessment in GW and, possibly, soil compartments? That done, maybe the whole model exposure assessment would become more coherent, consistent and objective? EFSA: This is a good idea but unfortunately outside the mandate of this working group.
67	ECPA	BE	3.2 Review of pesticide application timing	Line 561-578: The EFSA WG points out that the recommendation is made as a ""pragmatic solution"" and present further arguments based upon assessments undertaken by Van der Zande et al. (2012). Their assessment has a number of merits when considering variable exposure potential including factors acknowledged by the authors such as wind speed and wind direction. It is noted that the framework of assessment considered by Van de Zande et al. also focussed upon flowing water systems and, thus, does not directly address the problems acknowledged by the EFSA WG regarding accumulation potential in ponds. It is recommended that for sake of transparency and to more thoroughly investigate the implications in terms of accumulation potential and conservatism an assessment similar to that of Van de Zande should be repeated within the FOCUS SW framework. This can be carried out based upon the distribution of drift values underpinning the current FOCUS SW scheme, taking into consideration the variation in the hydraulic residence times of the FOCUS SW bodies and the associated partitioning behaviour. EFSA: This comment refers to section 3.1.5. Dependent on the scenario the suggested approach might be indeed too conservative. The methodology has therefore been changed without losing the advantage of having only one run instead of two (single and multiple). The updated approach is closer to the original FOCUS ideas. It is particularly noted that van de Zande et al. also factored in wind direction in their assessments and this would result in a broader distribution of PEC values that underpins some of the argumentation made by the authors and translated across to context to support the current FOCUS SW reapair proposals - without a parallel

				ability to represent the impact of wind direction in the FOCUS SW framework this would significantly alter the ability to directly apply the conclusions reached in PRI 419 to address the problem highlighted with static/semi-static systems." EFSA: see the comment above. General: The corresponding adjustment of the FOCUS Drift Calculator in the SWASH tool that would be necessary is not discussed. EFSA: The FOCUS Drift Calculator in the SWASH tool calculates the deposition on the three types of FOCUS water bodies as a function of the drift percentile of the event. These calculations remain valid; thus the FOCUS Drift Calculator does not need an update. Lines 583 to 612: The proposed deletion of the Pesticide Application Timer (PAT) would allow applications to take place shortly before or during a rainfall event which is not a realistic reflection of good agricultural practice. Even though applications shortly before or during a rainfall event ""may sometimes happen"", it should not be the intention of a FOCUS SW exposure assessment to model accidental or unintended application patterns. EFSA: Following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made. It is therefore recommended to retain at least a simplified PAT (see also Comment 4) in order to maintain consistency with normal agricultural practice. To ensure that the GAP is fully respected with regard to the minimum application interval, additionally relaxation rules could be defined. It should be considered, however, that it is highly unrealistic to assume that the worst case GAP is fully respected for 20 years in a row, considering of variable weather conditions and variable disease pressure, not even allowing for a shift of application by a few days under clearly defined circumstances. EFSA: Respecting the GAP is a major point in the whole risk assessment. The models should therefore simulate all requested applications also when the simulation period covers 20 years. As stated above a simplified PAT is maintained in the updated scenarios. Line 598: A PAT is deemed important and necessary also in a multi-year assessment framework. In contrast to groundwater, the surface water exposure by drainage and runoff is highly event-driven and the choice of application date can have a larger impact on PEC concentrations, which underlines the need for a PAT to avoid unrealistic application dates. Furthermore, the conclusions of the EFSA WG regarding the ""minor"" impact of removing PAT are based on very limited testing (as presented in Appendix H) and naturally restricted to the current state of the assessment framework and the FOCUS SW models. The impact needs to be tested in view of all other proposed modifications, e.g. the revision of the interception values. As was already seen in the limited testing that we could do so far, there are combinations of crop, scenario, substance and application

				timing where the impact is significant, and an unrealistic application date may result in artificially inflated PEC values (see also Comment 4). EFSA: More results based on an extensive modelling exercise are presented in the new Appendix I. As stated above a simplified PAT is maintained in the updated scenarios. Line 606-609: Removing the PAT will in many situation result in an unnecessarily high sensitivity of the PEC values on the selected application date. This is an avoidable shortcoming for a multi-year approach. EFSA: We agree as further analysis showed that this is indeed the case. Therefore we have now included a simplified PAT.
68	The Norwegian Food Safety Authority (Mattilsynet)	NO	3.2 Review of pesticide application timing	We welcome a different and less subjective way of handling application dates. The strategic selection of application windows by the applicant in order to get the highest possible crop interception and lowest possible PEC is often a source of conflict in the risk assessment of PPPs. EFSA: Thank you. However, it is very important to us that the new way of handling crop interception and selection of application dates does not give huge differences in results between the new and old versions of SWASH, for reasons of continuity and consistent assessment of dossiers over time. EFSA: The idea of the repair action was to improve the current risk assessment. To guarantee that the level of protection does not change is not possible as this is outside the remit of the WG. It will be the decision of the risk managers to select a suitable percentile which is used for the risk assessment.
69	HSE (Chemical Regulation Division)	UK	3.2 Review of pesticide application timing	The UK CA acknowledges the reasoning behind the removal of the PAT tool and the move to set application dates at the same calendar days in a year, based upon the improved approach to include 20 years of data. However, The UK CA would like to draw attention to the poster presented at the 2018 SETAC conference in Rome (13 – 17 May, 2018) which summarised analysis conducted by the UK CA and Cambridge Environmental Assessments regarding the effect of comparing the current FOCUS PAT and the UK PAT (which is very similar to the PAT tested in Appendix H) on the UK specific 30 year MACRO simulations. The poster is available to download here https://www.researchgate.net/publication/326415846_Selecting_application_dates_for_UK_higher_tier_drainflow_modelling_comparing_the_FOCUS_and_CRD_pesticide_application_timing_rules. Analysis showed that generally larger annual maximum PECsw values were obtained using the FOCUS PAT than the UK PAT, due to the worst-case nature of the FOCUS PAT designed for 1 year simulations. Further analysis of the application dates selected by MACRO using the UK PAT showed that in the majority of years, the application date corresponded to the target application date. On the occasions when a different application date was selected, the date generally differed by only 1-2 days from the target date - due to a significant rainfall event occurring on the target date. Therefore, the UK CA would support the use of a PAT tool, like that assessed in Appendix H, in determining appropriate application dates in the revised FOCUS surface water calculations as any

				change in application date from the target date is likely to be minor. EFSA: Following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made.
70	Enviresearch Ltd	UK	3.2 Review of pesticide application timing	The suggested approach is not mechanistic. The goal of FOCUS modelling is to use the most mechanistic models possible, but to use the same date every year does not deliver that. We should have rules that correspond to realistic farmer behaviour, i.e. 'covering all eventualities' that might happen in practice. The suggested scheme means that your final risk assessment could be based on an unrealistic year. This might not matter if you just use the maximum PEC in water but could have a big impact on any refined analysis (e.g. patterns of exposure). EFSA: Reality demonstrates that there is never a guarantee that unfortunate events can't happen. Nevertheless, following public consultation the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made. Even if there was a limited effect of PAT on the frequency distribution of the annual maximum PECS in water, we do not know at this stage whether a single percentile from this frequency distribution will be the final endpoint selected by risk managers. At the higher tiers of the risk assessment, time series of exposure concentrations will have to be considered. The proposal is to select the application date based on growth stage. If a PAT is no longer used, then it should be ensured that the start day of each growth stage falls onto a day without rainfall or irrigation in all 20 years to reflect good agricultural practice. EFSA: See comment above.
71	Rifcon GmbH	DE	3.2 Review of pesticide application timing	In accordance with good agricultural practice, no farmer is expected to apply pesticides when (heavy) rainfall events are taking place. The AppDate tool can easily be modified to produce an acceptable application date for each scenario and BBCH stage where no (significant) rainfall events take place. For instance, if a rainfall of ≥ 20mm will occur, use the next day as application day. We agree that the magnitude of effect will of course depend on the selected output criteria e.g. maximum PEC or a specific percentile. EFSA: Following public consultation, the WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Details on the revised PAT are given in the fully revised chapter and reference to Appendix I is made.
72	Anses (French Agency for Food, Environmental and	FR	3.3 Substance parameters depending	Line 631, page 17. Typo : « has to be kept » (missing « be ») EFSA: Typo addressed in an update of the scientific report. Lines 655-659, page 18. Depending on the available dataset, it is sometimes not possible to determine an

	Occupational Health & Safety)		on soil properties (e.g. pH or clay)	equation to link degradation or adsorption to pH (for example when the dataset leads to 2 independent groups of values). In this case, an alternative method according to current practice could be to use in modelling the minimum and maximum values from the available dataset or the geomean for each group identified. EFSA: The WG agrees that such a split-approach is commonly used in the risk assessment. The scientific report was amended accordingly to also account for such a "split-approach". Lines 664-666, page 18. It is mentioned that "If only one of the two runs results in an acceptable risk, application of risk mitigations measures may be necessary". More details on how to deal with such issue may be provided by the FOCUS surface water Repair WG. EFSA: Such a proposal is considered outside the remit of the EFSA WG. Considering the two "extreme" pH values at which the runs are proposed to be done (i.e.5.1 and 8, representing the 10th and 90th spatial percentile of pH values for arable soils), it might be difficult to set any mitigation measures if only one of the two runs results in an acceptable risk (or if one run need higher mitigation measures). Indeed, it will not be possible to set a clear and convenient pH limit above/below which risk assessment becomes acceptable. That means that either the unacceptable risk conclusions (or the largest mitigation measures) eventually applies to all situations, or additional run(s) with intermediate pH value(s) are required to set a pH limit suitable at field. EFSA: It is up to applicant/user to also apply intermediate pH values in order to identify a pH limit above/below to help determine if the risk assessment becomes acceptable.
73	Swedish Chemicals Agency	SW	3.3 Substance parameters depending on soil properties (e.g. pH or clay)	644, page 18: Reference is made to "EFSA, 2013a". This should probably read "EFSA, 2013". In any case, the recommendations on pH dependency from EFSA Journal 2013;11(2):3114 were taken on-board and further developed in section 2.3 of the "Generic Guidance for Tier 1 FOCUS Ground Water Assessment", ver 2.2., May 2014. Therefore, we suggest that reference to FOCUS (2014) would be more relevant than reference to EFSA (2013). 644-660, page 18: Preferably, the same adsorption parameters should be used to calculate PECgw, PECsw, and PECsoil. We realise that in the case of pH dependency the approach for PECsoil may need to be different due to another modelling approach (EFSA, 2017). However, we see no obvious reason to introduce a different approach for PECsw/sed as compared to PECgw, in case of pH dependency. In particular, we see no reason to request additional work and apply different approaches just because different data sets were used to describe pH of European agricultural soils. We would therefore suggest that the approach described in section 2.3 of FOCUS (2014) should be followed also for FOCUS SW, instead of the approaches described from the end of line 644 to the sentence ending on line 660.

				(Summary of the different approaches recommended: - Current guidance for PECgw (section 2.3 of FOCUS Generic guidance for Tier 1, 2014) recommends that best and worst case conditions should be represented in separate calculations of PECgw. This is currently done in a pragmatic way by using the mean adsorption parameters below and above pH 7, respectively, as input to modelling. FOCUS (2014) add some specific guidance for S shaped relationships (weak acids), and for these the parameters associated with pH of 5.0 and 7.5 should be used. FOCUS (2014) also add some guidance for U or ∩ shaped relationships. No statistical tests are recommended. - In FOCUS SW Repair Action (2018) pH values for arable soils are said to range from 4.1 to 8.8 and it is recommended to perform individual calculations for pH 5.1 and 8.0, representing 10th and 90th percentile. Furthermore, the sigmoid equation (for weak acids) or any other equation should be applied. The correlation should be proven by statistical tests. - PECsoil, EFSA (2017) on PECsoil states that pH values in normal agricultural soils range between 4 and 8.) EFSA (as a reply to all comments above): The FOCUS surface water Repair WG is aware that there is a slight mismatch regarding *p*H limits in the generic guidance on substance input parameter selection (EC, 2014) and given here. Notice that soil pH limits stated in EC (2014) are uncertain as the matrix for pH measurement is not specified further. Preferably, the same substance properties are used in all exposure assessments. In view of the extensive analysis of spatial data made to address this mandate, the FOCUS surface water Repair WG recommends adapting the generic guidance on substance input parameter selection (EC, 2014) accordingly. This may include the recommendation for a dedicated soil *p*H split point in case of the split approach as stated above. Notice that the new guidance on PEC soil does not recommend to perform runs at contrasting pH values. Recommendation on how to handle pH-dependent sorption of weak acids can be found in Boesten et al., 2012 (Alterra report 2264), which was considered for PEC gw and EFSA higher tier soil scenarios. Notice that in the revised scientific report the pH split approach was additionally included to allow for more flexibility (in this case the exact limits for the lower and upper pH values are indeed meaningless). Line 664-668, p 18: We propose to delete statements that suggest risk mitigation options, as this is not considered relevant in the frame of this Scientific Report. Risk mitigation measures are decided upon by individual MS during the national authorisation process; partly reflecting political issues. EFSA: We just mentioned that risk mitigation may be applied, without given advice on how to do so. This is of course up to the risk managers. Nevertheless, in our experience risk managers will highly welcome options from which they can choose.

74	UBA (Umweltbundesamt, German Environment Agency)	DE	3.3 Substance parameters depending on soil properties (e.g. pH or clay)	Line 614-668 page 17: DE generally agrees with the recommendations given by the FOCUS surface water Repair WG in case of substance properties depending on the soil pH. Regarding adequate statistical tests to judge whether a pH-dependent degradation and/or sorption exists, we recommend to use the Kendall test where more than 6 data pairs are available. From 3 to 6 data pairs the Pearson test should be applied. Proposed numbers of data pairs are based on an expert judgement following considerations in Bonett, Douglas & A. Wright, Thomas. (2000). Sample size requirements for estimating Pearson, Kendall and Spearman correlations. Psychometrika. 65. 23-28. EFSA: The chapter was updated accordingly. Line 614-675 page 17: Irrespective of the general approach how pH-dependency of Koc and DT50 should be defined on the basis of several data points, the recommendation of the FOCUS surface water Repair WG to perform two runs in case substance properties are depending on the soil pH should be re-considered. It was not discussed whether the DT50 or Koc are sensitive parameters for the resulting PECsw calculated with FOCUS SW. In the GERDA project (Bach et al. 2016: Bewertung des Eintrags von Pflanzenschutzmitteln in Oberflächengewässer: Weiterentwicklung der Konzepte zur Modellierung der Einträge über die Expositionspfade Runoff, Erosion und Drainage unter Berücksichtigung der Harmonisierungsanforderungen im zukünftigen europäischen Zulassungsverfahren. Umweltbundesamt UFOPLAN FKZ 371163427) sensitivity analysis was performed for FOCUS Surface Water. Application rate was obviously the most sensitive parameter on the PECsw followed by the definition of the scenario (as combination of soil including organic content, weather and water bodies, crop management, definition of upstream catchment, …). Koc was among the sensitive parameters. DT50soil showed only little or no sensitivity on the PECsw. However, FOCUS surface water scenarios were selected according to the worst case character of various features (mean rainfall and temperature, soil texture and organic matter, slope). A link to the resulting PECsw as an interaction of scenario and substances properties is missing. [Bach et al. 2016: Pesticide exposure assessment for surface waters in the EU. Part 1: Some comments on the current procedure. Pest Manag Sci, 4281]. Therefore, it is not clear why these two values, pH and Koc, should now be dealt with differently to other input parameters. Have PECsw calculations and risk assessment already been performed to conclude on influence of the proposal on the PECsw and on the risk assessment? EFSA: No further test calculations have been performed to investigate the impact of using different substance properties related to soil properties. The WG agrees that minor differences in soil DegT50 or Koc may hardly have an impact on the exposure assessment. However, considering more significant differences in soil DegT50 or Koc at two contrasting pH values (e.g. by a factor of 2 or more) it is difficult to imagine that these differences will not have a significant impact on the PEC sw, particularly if the exposure assessment is driven by drainage or runoff.
75	SCC Gmbh	DE	3.3 Substance parameters depending	Lines 614ff, page 17, lines 650-652, page 18: In view of the aim of the work group that processing times should not become excessive, modeling of two complete sets of all scenarios with alkaline and acidic substance parameters should be avoided. The current approach to perform calculations only for sets of scenarios representing either acidic or alkaline properties in

			on soil properties (e.g. pH or clay)	case of pH dependency is considered sufficiently conservative as respective scenarios are available. According to the Generic guidance for FOCUS surface water Scenarios (Version 1.4, EFSA 2015, Table 4.9.1-1) the soil pH for 4/10 Scenarios are in the range of 4.5 to 6.9 and 6/10 in the range between 7.0 and 8.4. EFSA: As already indicated in the scientific report, it should be kept in mind that the soil pH, stated for each individual scenario, has no meaning with respect to the vulnerability of this scenario. Notice that each of these scenarios is considered to cover large areas in the EU.
76	Redebel Regulatory Affairs SCRL	UK	3.3 Substance parameters depending on soil properties (e.g. pH or clay)	As in the pesticide dossiers, substance parameters based on average values are increasingly replaced by substance parameters depending on certain soil properties, it would be useful to be able to run the model with the parameters considering several pH values in a single simulation. EFSA: Allowing specification of different substance properties for one substance (e.g. if depending on soil properties) would be a major change in the SPIN database. This is not foreseen in the remit of this working group.
77	Institute of Environmental Protection - National Research Institute	PL	3.3 Substance parameters depending on soil properties (e.g. pH or clay)	The approach to the pH dependence of substance-specific parameters, in particular Kfoc (broadly discussed in this section) may cause some problems when applied in practice. The problem is that at present adsorption for any compound is determined in soil and the data from that examination are used to parametrise the modelling tool in each compartment - not only soil, but water and sediment as well. And while the soils may be acidic/neutral, the receiving water body, both water and sediment, may have higher, more alkaline pH. As a result, it may be assumed that in case pH dependence of the adsorption for the given compound is stated the number of the necessary runs may increase from two to four in order to take into consideration not only the situation: acidic/neutral soil - acidic/neutral receiving water body and alkaline soil - alkaline receiving water body, but also acidic/neutral soil- alkaline water body and alkaline soil - acidic/neutral water body. The situation may become even more complicated in case further differentaition is made in the receiving water body between the pH of water phase and that of the sediment phase. Additionally, the available experimental results indicate that adsorption parameters forn the given compound in soil and freshwater sediment may differ significatnly. All that taken into account, could any sound solution of that problem be proposed. EFSA: In order to keep the overall complexity of the exposure assessment low, sorption parameters used in the modelling should be the same in all environmental compartments (soil, water and sediment, assuming that they all have the same pH). In case of the clay-content dependence situation is even more complex. That dependency may be relevant in case of soil and, possibly sediment, but becomes completely irrelevant for the water phase. In addition, already modelling for a single-compartment situation - calculation of PECgw, in case of stating such dependency is complicated and requires significant effort from modeller. How to perform it for a triple-compartment system,

				which is a case of the SW model exposure assessment? Probably a more detailed gguidelines on how to do that should be provided. EFSA: As already noted in the scientific report, substance properties related to soil clay content should be set to values which best represent the given clay content for a scenario.
78	ECPA	BE	3.3 Substance parameters depending on soil properties (e.g. pH or clay)	Line 616-621: It should be mentioned here that potential pH dependence of sorption in soil is in fact mechanistically well understood and guidance to evaluate such dependency is available (see Comment 38). On the other hand, a systematic dependency of aerobic soil degradation on soil properties can rarely be concluded from the experimental data. Line 621-623: Some guidance to evaluate potential pH dependency on sorption can be taken from Alterra report 2264 (Boesten et al., 2012) which is already acknowledged by the PPR panel (EFSA PPR Scientific Opinion on GW2 Lower Tier, 2013). Further guidance can be found in the scienific literature. Line 626-628: Can this statement be substantiated with data, e.g. an increasing fraction of EFSA conclusions that indicate pH dependency for soil degradation? EFSA: In view of WG members, a considerable time is spent in expert meetings to agree on soil depending substance properties. Line 645: There are different databases of soil pH values in Europe. Were other databases also considered to derive the specific lower and upper boundary pH values? What is the quality of the soil pH map of Hiederer (2012) compared to those other available soil databases? EFSA: Other dataset have been accounted for as well (JRC, LUCAS). Data on soil pH (measured in water) with respect to the 10^{th}, 50^{th} and 90^{th} spatial percentile soil pH are broadly in line with the EFSA spatial dataset. Line 655 to 660: In case of pH-dependent substance properties, the report proposes to determine the respective parameters at pH5.1 and pH8, based on mathematical functions/regressions. For practical reasons, it will often not be possible to derive sound regression functions for a pH-dependency on the basis of a data package, e.g. due to practical limitations of soils available for actual study conduct. It should be mentioned in the report that applying a linear equation to describe pH dependency is problematic in case extrapolation is done beyond the experimental pH range (this problem does not occur with a sigmoid curve). EFSA: The WG gives further advice on different kinds of relationship, including the "split-approach" as well as the need to define upper and lower limits in order to omit extensive extrapolation. In other areas of exposure assessment, no specific pH values are given, but it is recommended to chose two contrasting data sets, e.g. one for acidic soils and another one for alkaline soils (the guidance on FOCUS GW mentions ""realistic best case "" and ""realistic worst case"" sorption data). These data sets are often mean

				values from a subset of soils representing acidic and alkaline conditions, respectively. In the surface water assessment, also for reasons of consistency, a similar approach should be considered. EFSA: The "split-approach" was taken on board for the scientific report. In case of equations used to describe the relationship, predefined "realistic worst case" low/high pH should be used as already indicated in the scientific report. Line 664-665: This differs from the evaluation approach for leaching as described in the EFSA PPR Scientific Opinion on GW2 Lower Tier (2013): ""two contrasting simulations to demonstrate whether at least one gives results below the threshold level"" (i.e. passing with one of the alternative data sets constitutes a safe use). For surface water assessments the EFSA WG seems to request passing (with mitigation, if necessary) for both alternative data sets. If that is indeed intended, what is the reason and justification to differ from the leacing approach? EFSA: There is no restriction in the scientific report that both runs have to pass. As stated, there is always the possibility to apply risk mitigation options to one of the runs if necessary. Otherwise there should be a clear message to risk managers that only soils with certain properties result in save use conditions. Lines 666 to 668: The EFSA WG proposes that risk mitigation could be applied at an EU or MS state level using soil property datasets such as pH maps, but does not give recommendations with regard to the need for guidance on concrete mitigation approaches, including the selection of approriate and credible datasets. In reality, it may be very difficult to get acceptance for such approaches by regulators, e.g. because of a lack of standardisation and alignment of soil property maps and databases. EFSA: Guidance on risk mitigation options is out of the scope of this working group. In principal, risk mitigation is handled on national level as it has to follow national requirements.
79	Enviresearch Ltd	UK	3.3 Substance parameters depending on soil properties (e.g. pH or clay)	3.3 Lines 642-660 This means that the properties at pH 5.1 and 8.0 are calculated. There is usually only a small number of measurements available, and the pH range is often narrower than 5.1 to 8.0. What are the uncertainties arising from an extrapolation outside the pH range of the measured data? EFSA: Extrapolation outside of experimentally available data should of course be avoided. This indicates the need for upper and lower limits to be set by the applicant/user. This will be reconsidered in an update of the scientific report. It might be better to calculate the distribution of pH values for annual arable crops and permanent crops separately, and calculate the 10th and 90th percentile for each distribution. The pH values to be used in the assessment would then depend on the crop type.

				EFSA: In order to avoid different substance input parameter for different exposure assessment it is recommended to keep the modelling approach as simple as possible. The general FOCUS philosophy was to place the vulnerability in the scenarios and select median or average substance properties. Selection of a property at the 10th and 90th percentile is not consistent with this approach. EFSA: As already highlighted in "Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of lower tiers" (EFSA, 2013) soil pH was not accounted for when defining the vulnerability of the groundwater scenarios, the same is true for the surface water scenarios. Therefore, substance parameter selected on basis of the scenario pH may results in insufficiently/overly conservative PEC values. In line with EFSA (2013) it is therefore recommended to make two calculations at two contrasting pH values. Please specify if the arithmetic mean 1/n value should be used in combination with the calculated KF or KFOC values at pH 5.1 and 8.0. EFSA: The recommended approach specified in the scientific report should include the 1/n value as well. The report has been updated accordingly.
80	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	3.4 Review of the foliar wash-off in MACRO and PRZM	Lines 701-706, page 19. The harmonization of wash-off coefficient (0.1 mm-1) with soil and groundwater exposure assessments is welcome. EFSA: Noted.
81	Swedish Chemicals Agency	SW	3.4 Review of the foliar wash-off in MACRO and PRZM	705-706, p 19: The sentence suggests that wash-off has already been implemented in FOCUS GW. Suggest amendment of sentence just to clarify that this has not yet been done. EFSA: The wash-off has been included into new versions of PELMO and PEARL submitted into FOCUS version control.
82	The Danish Environmental Protection Agency	DK	3.4 Review of the foliar wash-off in MACRO and PRZM	Denmark supports the harmonisation. EFSA: Noted.
83	WSC Scientific GmbH	DE	3.4 Review of the	Page 19, lines 701-703: FOCUS surface water Repair WG proposes to use the to replace the wash-off coefficient 0.05 mm-1 currently used in FOCUS surface water (2001) with the coefficient 0.1 mm-1 as proposed by the

			foliar wash-off in MACRO and PRZM	PPR Panel. The use of the higher wash-off coefficient of 0.1/mm does not necessarily result in a higher PECsw concentration. Scenario, substance data and application date also have influence on the wash-off amount. Especially high rainfall events can wash-off most of the amount shortly after application. If these substances have a shorter DT50 in soil than on crop, the final PECsw will be lower. This effect was demonstrated at SETAC 2018 (Kind et al. 2018. Determine how runoff and drainage is triggered in FOCUS surface water models using a PEC automation tool. Poster at SETAC 2018). EFSA: Noted.
84	Institute of Environmental Protection - National Research Institute	PL	3.4 Review of the foliar wash-off in MACRO and PRZM	No comments to this part of the document (after thorough examination). EFSA: Noted.
85	ECPA	BE	3.4 Review of the foliar wash-off in MACRO and PRZM	Line 701-706: The impact of the proposed change of the default wash-off coefficient from 0.05 mm-1 to 0.1 mm-1 on surface water concentrations has not been investigated by the EFSA WG. But we suggest in any case to stay with the current default value, for the following reasons: The orginial discussion and decision to change the foliar wash-off default coefficient from 0.05 mm-1 to 0.1 mm-1 took place during the preparation of PPR opinion 1442 (outline proposal soil exposure, 2010). The main reason for this was a lack of experimental evidence to underpin the old value of 0.05 mm-1. Since then a high number of wash-off studies has been conducted to determine wash-off factors suitable as input for FOCUS modelling. Results have been presented at several conferences. The available experimental data from industry and from scientific literature do not support to increase the current default wash-off factor. The result from all these studies strongly underpins that the existing default value of 0.05 mm-1 ensures sufficient protection level in line with stated EFSA objectives. The proposed revision to a default of 1.0 cm-1 would represent an extreme worst case. The experimental data can be made availble upon request. EFSA: The reconsideration or any refinement of the default wash-off factor recommended in EFSA-PPR (2010) is outside the scope of this working group.
86	HSE (Chemical Regulation Division)	UK	3.4 Review of the foliar wash-off in MACRO and PRZM	Line 679: Based upon the testing of varying half-lives of the active substance on the crop canopy, does the FOCUS SW repair action group consider that the current 10 d default value should still be used? Whilst possibly outside the scope of this work it may be useful to add a comment here regarding the agreed default value for use and the possibility of refining this value in light of data presented by applicants. Can the WG provide any advice as to what studies would be acceptable to support refinement of the foliar half-life value? EFSA: The reconsideration or any refinement of the default DT50 on crop (10 days) is outside the scope of this working group.
87	CTGB NL	NL	3.4 Review of the foliar	3.4 Review of the foliar wash-off in MACRO and PRZM Ctgb agrees with the proposal to adjust the wash-off factors in PRZM and MACRO to a conservative default of w = 0.1 mm-1 in line with the scientific opinion on PEC soil scenarios (EFSA 2012). Ctgb however does not

			wash-off in MACRO and PRZM	understand why in future the MACRO approach is followed instead of the PRZM approach for applications on days with rainfall below 18 mm. Can this be substantiated scientifically? EFSA: The WG identified some coding errors in PRZM that we have fixed, but otherwise the two approaches are very similar in principle. However, PRZM has a daily time step, while MACRO runs at sub-hourly time steps, which causes differences on rainy days. We modified PRZM to harmonize the two models as far as possible.
88	The Danish Environmental Protection Agency	DK	3.5 Processing times and user friendliness of the revised FOCUS surface water scenarios	Having short run times for model simulations are preferable, but comparing the resources spent on laboratory and field studies, it seems less important if a simulation takes a few minutes or a few hours. It is more important to get reliable results than having a short run time, e.g. using weather data based on hourly averages (see 3.1.1) instead of daily averages is preferred even if this will increase the run time. EFSA: Noted.
89	Institute of Environmental Protection - National Research Institute	PL	3.5 Processing times and user friendliness of the revised FOCUS surface water scenarios	The comments are provided individually to each subsection. EFSA: Noted.
90	Institute of Environmental Protection - National Research Institute	PL	3.5.1 Processing time	Maybe this is of minor importance, but since probably the new SWASH tool was broadly tested, maybe it would be a good idea to provide in the document more detailed estimates of the time needed to perform calculations? If those available, they could help users of the new version of SWASH in planning their work. EFSA: Noted, has been included in updated version of report.
91	ECPA	BE	3.5.1 Processing time	Line 710: In support of reducing the run-times and the number of model runs, the EFSA WG may re-consider the need to run two sets of assessments with exchanged water and sediment degradation rates (as required by FOCUS SW Generic Guidance, v1.4, p. 213). Experience shows that the influence of the exchange of parameters is relatively small and has usually no impact on the conclusions of the risk assessment. Therefore, a single set of DT50water and DT50sediment, derived according to the FOCUS kinetics guidance, is deemed sufficient. EFSA: Giving guidance on input parameter estimations is outside the remit of the WG. Line 719: The ECPA tool SWAN is cited as a tool for applying different risk mitigation options. This citation

				should be accompanied by a detailed reference, and a more detailed explanation in what context SWAN may be used (i.e. as a tool to faciliate implementation of multiple mitigiation options) EFSA: The text in the main report has been extended. Line 720: We strongly agree that the automation of MACRO, PRZM and TOXWSA has to be improved. EFSA: Noted.
92	Enviresearch Ltd	UK	3.5.1 Processing time	A specification for compliant third-party solutions would be helpful to allow other people to overcome some of the constraints currently inherent in SWASH. EFSA: This proposal is considered outside the remit of the WG.
93	GAB Consulting GmbH	DE	3.5.1 Processing time	Rows 710 - 719, row 3155, pages 19 and 129 "No changes for PRZM, MACRO SW similar to MACRO GW (Chateaudun), TOXSWA improved (running on several cores), MACRO to be improved" Comment: Given the fact that the simulation time and usability has a crucial effect on the overall effort/costs, it is much appreciated that the FOCUS surface water Repair WG is taking the processing time into their considerations - especially the improvement of TOXSWA running time and the planned, likewise improvement of MACRO. A thorough follow-up related to shortening of model runtimes and facilitating user interfaces is strongly recommended. EFSA: Noted.
94	Institute of Environmental Protection - National Research Institute	PL	3.5.2 Single vs. multiple application if the GAP indicates multiple applications	No comments to this part of the document (after thorough examination). EFSA: Noted.
95	ECPA	BE	3.5.2 Single vs. multiple application if the GAP indicates multiple	Lines 752 - 760: We understand that the ""AppDate"" functionality may be hard-coded into SWASH. How will it be guaranteed that likely code changes in the standalone AppDate will be transferred into SWASH? Alternatively the standalone AppDate.exe could be employed directly from SWASH without the need for recoding. This would prevent the additional synchronizing effort. The same would be applicable in case a simple PAT would be retained. " EFSA: The output (results) of AppDate are used as input for SWASH. That means that AppDate does not become part of SWASH.

			applications	
96	CTGB NL	NL	3.5.2 Single vs. multiple application if the GAP indicates multiple applications	3.5.2 Single vs. multiple application if the GAP indicates multiple applications We welcome the use of 90th percentile drift percentages for individual spray drift deposition events, instead of assuming a cumulative drift probability of 90th percentile, and agree that single application runs are deemed unnecessary when this approach is implemented. EFSA: Notice that the drift percentile approach has been reconsidered (see above). However, there is still no need any more to perform an additional single application run.
97	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	3.5.3 Revised application timing in SWASH	Line 765, page 20. The applications will always be made at the first calendar date which is specified for a given BBCH stage. We agree with this proposal. However it is suggested to add that several simulations may be needed to cover the whole application period when a long application period is intended. EFSA: In the new SWASH shell, intended application dates may either be allocated to the start of the BBCH period ('forward calculation') or to the end ('backward calculation'). The user may always adapt the application dates provided by SWASH if justified.
98	Swedish Chemicals Agency	SW	3.5.3 Revised application timing in SWASH	752-754, page 20: We agree to the alternative procedure proposed which we believe may decrease variability, increase confidence and simplify the assessments. EFSA: Noted.
99	The Danish Environmental Protection Agency	DK	3.5.3 Revised application timing in SWASH	As mentioned in 3.2 Denmark suggests using three different actual dates to cover the application interval in the GAP instead of just one date. EFSA: In the new SWASH shell, intended application dates may either be allocated to the start of the BBCH period ('forward calculation') or to the end ('backward calculation'). The user may always adapt the application dates provided by SWASH if justified.
100	SCC Gmbh	DE	3.5.3 Revised application timing in SWASH	Line 745ff, page 20: The PAT procedure reflects the good agricultural practice that plant protection products are generally not applied at times were significant rainfall is likely. In practice, farmers have much advice at hand (e.g. pest development and application timing forecast by agricultural services via internet) and are interested in avoiding application of plant protection products at bad weather periods that would result in reduced efficacy and economic benefit. The selection of the actual application dates over the simulation period based on PAT thus realistically reflects changing weather conditions from year to year. On the other hand, the PAT ensures a sufficient level of conservatism by assuring that 10mm of rainfall are falling within 10 days after the application. The suggested approach to use one application date over the 20-year simulation period is expected to result in the selection of extreme weather conditions, either with unrealistic high or unrealistic low rainfall. In order to be

				consistent among the FOCUS models, it should rather be considered to introduce a PAT functionality also for PECgroundwater and future PECsoil calculations. EFSA: Forecast is never perfect and unfortunate events could always occur. The WG has reconsidered the PAT approach on basis of an extensive modelling exercise with the conclusion to maintain a simplified PAT with a shorter application window (please refer to chapter 3.2).
101	Institute of Environmental Protection - National Research Institute	PL	3.5.3 Revised application timing in SWASH	Not challenging the whole approach, which after much broader testing may turn out to be a better option than currently used, maybe it would be a good idea to provide in the relevant Guidelines, more detailed crop calendars for each pedo-climatic scenarios? At present only selected key phases are defined, and their definition is not fully coherent when the data for D and R scenarios are compared (e.g. some phases defined for D scenarios are not defined for R scenarios). EFSA: The communication between AppDate and SWASH is organised via tables which provide information about the recommended application date for every BBCH code dependent on the crop and the location. The user are able to see the AppDate results via the SWASH shell.
102	ECPA	BE	3.5.3 Revised application timing in SWASH	Lines 752 - 760: The use of ""AppDate"" is mentioned here. If the application dates are constrained through standardisation in this way (either by using a mirror of AppDate built into the models or by the sole use of AppDate to define acceptable application dates for each BBCH stage), there is likely to be disagreement between member states over how representative the modelling is with regard to national agronomic and geoclimatic conditions. In some member states, for example, the trafficability of typical crop sites may be at odds with the typical application timings suggested by this form of fixed timing framework. EFSA: The results of AppDate are already considering the crops dependent on the FOCUS location. If member states disagree with the recommendations of AppDate they may also disagree with the complete crop development at the FOCUS R and D locations, so a fundamental disagreement. In any case, if the user justifies he may always select individual application dates. In this context, please consider again Comment 6 about the general need for and benefits of including a refined crop model that links application dates to weather conditions. EFSA: Within the mandate of the repair action it wasn't possible to include such complex crop models. The primary idea was to use AppDate to increase reproducibility between different users. Line 759: In some cases, in particular for speciality crops, linear interpolation between BBCH scale may not be a good representation of the crop development. Also, sometimes, surrogate crops have to be chosen for a particular use. Therefore, it should still be possible to replace AppDate by user-defined application timing. EFSA: There is agreement that linear interpolation is not always representing the real crop development well. However, linear interpolation is the simplest methodology to recommend application dates with maximum transparency.

				Line 766 - 769: For multiple applications, the proposal is to select the first date and then apply at the specific intervals, subesquently. This is reasonable. However, in relation to section 3.1 4 of the report, the interception of the crop at the subsequent growth stages will not be determined by a crop growth model, but will be fixed according to the specified initial BBCH range. This does not allow for crop growth and development into subsequent BBCH ranges. In this context, please consider again Comment 6 about the general need for and benefits of including a refined crop model that links application dates to weather conditions. EFSA: Linking crop development to actual weather conditions would be a major step to more realistic modelling. However, at the current stage none of the FOCUS models is able to consider this information. The development of such a model is unfortunately far beyond the current mandate.
103	HSE (Chemical Regulation Division)	UK	3.5.3 Revised application timing in SWASH	It is noted that within the proposed application timings "applications are always made at the first calendar date which is specified for a given BBCH stage" and it is noted that there is flexibility allowed for winter crops with long application periods (line 770). It may be useful to confirm here the approach for extended GAP periods, whereby it is required that the GAP should be modelled at early and late stages for crops with an extended period of application, this is to ensure the worst case PEC values are determined within the allowed application window. Advice on whether this should be done at the beginning, end or middle of the period maybe useful. EFSA: In the new SWASH shell, intended application dates may either be allocated to the start of the BBCH period ('forward calculation') or to the end ('backward calculation'). The user may always adapt the application dates provided by SWASH if justified. Line 768: It is noted that application intervals can be specified by the user, in cases when there is an interval range specified by the GAP it may be useful to have guidance that the minimum application interval should be used. EFSA: In our experience, there is a common understanding that the shortest interval should be used in the exposure assessment. Therefore, we do not see the need to amend the text accordingly. It is noted that the application dates will be detailed in a set of individual tables. Will there be an option of a reality check that the date chosen is agronomically feasible e.g. model may tell you that application date at D2 is 1st December which would not always be a feasible option considering limitations on trafficability of land in wet years. It is our experience that that first request applicants will do to refine assessments is to consider application dates that are selected by the models. This may be something that is discussed further when the proposed application dates are detailed. EFSA: The models have limitations and will surely not perform a complex reality check on agronomic feasibility. However, it is possible that the user overwrites the intended application dates selected by SWASH if justified. Notice that the actual application dates in each year are finally selected by the simplified PAT. Dates selected by the PAT cannot be modified by the user.
104	Enviresearch Ltd	UK	3.5.3 Revised	AppDate is very useful as a guide to typical dates for the various growth stages. But if we always make the target date the first date in the growth-stage range that is available, that won't be realistic. Farmers will usually

			application timing in SWASH	apply on the basis of actual or predicted pest pressure. Autumn and spring applied products will have differing levels of conservatism. AppDate (in its current form) will not be suitable for every year in the data set as it is based on a specific weather year for each scenario. The scenarios are not single locations, but they are intended to represent a range of locations in the EU. Therefore, there will be a wide range of typical dates for each growth stage within a single scenario. EFSA: The idea of implanting results of AppDate is to increase transparency and reproducibility. It does not necessarily also increase realism. The new SWASH tool provides intended application dates on basis of the BBCH period, which can be overwritten by the user. Finally, the simplified PAT selects application dates which are specific for each year. We need a bit more flexibility here to allow applicants to use realistic timings. For example, it should be possible to select dates that are more in line with the actual conditions in individual MS for the risk assessment underpinning product registration in that country. EFSA: The principal problem here is that the FOCUS parametrisation does not consider any pest pressure or crop development based on actual weather conditions. In so far, it is not helpful considering actual weather conditions for the recommended date but don't consider any link between crop development and actual weather conditions in the FOCUS model. Anyway, the software allows flexibility here. Nevertheless, the idea of using AppDate is to have in many situations accepted default intended applications dates. It is not realistic to apply on a day with rainfall or irrigation EFSA: The WG reconsidered the PAT approach in an extensive modelling exercise (Appendix I) with the conclusion to maintain a simplified PAT with a shorter application window. Therefore, application on days with high rainfall will hardly occur. Line 770 – 773 Placing the dormancy period between growth stages BBCH 20 and 21 for winter crops in AppDate needs to be supported by agronomic data. Implications for winter application timings and label restrictions need to be explored. EFSA: A fix date for the dormancy period in winter crops is indeed a very drastic simplification. Background is the current FOCUS parametrisation of the crop, which does not change over the period of 20 years. Furthermore, the group decided to have the dormancy period between BBCH 20 and 21 for pragmatic reason. That definition should guarantee application at low BBCH stages at the end of the year (BBCH 10 to 20) as well as the simulation of similar growth stages (BBCH 21 to 30) in early spring. This may be important in various member states for some GAPs. Not all crops are included in the list of FOCUS crops and one of the FOCUS crops is then used as a surrogate in the simulations. The user must have the flexibility to change the application timing and interception from those for the FOCUS crop to those relevant to the crop in the GAP.

				EFSA: The user gets that flexibility. However, still the FOCUS parametrisation of the original crop in the model is the same.
105	Pesticide Registration Division, Department of Agriculture, Food and the Marine, Ireland	IR	3.5.3 Revised application timing in SWASH	Line 761 Several Member States currently use the FOCUS surface models for national assessments. In the proposed new version of SWASH the application dates will be based on the BBCH growth stage and the FOCUS crop parameterisation in each scenario. However, as noted in AppDate the recommended dates may differ from real applications in the field due to actual conditions in different European regions. In our opinion it would be useful to add guidance for Applicants/Member States on how to deal with this issue. EFSA: The SWASH tool allows flexibility regarding application timing. The idea is that the user enters a different BBCH stage or date. If these individual settings are selected there may be additional fields to justify the decision. Line 765 In the case of multiple applications, the application window often spans several BBCH growth stages (e.g. BBCH 20-39). In current groundwater modelling, applicants generally model applications towards the end of the BBCH window as these applications have generally higher amounts of crop interception etc., leading to more favourable groundwater/soil PECs. Member States want to assess the realistic worst case scenario and to minimise the amount of modelling required where possible. In our opinion it would be useful (if possible) to include guidance for Applicants and Members States on how to model the realistic worse-case scenario for surface water when the intended use spans several growth stages (BBCH 20-39) EFSA: This is a valid point. The idea is it to let the software not only recommend the earliest but also the latest possible application date according to the GAP. Furthermore, the user will always be able to change the recommended application and pick an individual date to cover the whole window.
106	CTGB NL	NL	3.5.3 Revised application timing in SWASH	3.5.3 Revised application timing in SWASH Ctgb agrees with the intention of adjustment of SWASH regarding the application timing (absolute date based on BBCH code in GAP). Appendix G provides an example of date selection for one crop-scenario combination. It would mean quite some work to look up all dates for a multiple crop/scenario dossier, but if this is all automated within the swash shell and the user should only provide start BBCH then this is fine. Will the used date be reflected in the output report? EFSA: Yes, it's the intention to provide this information in the output report. However in the case of a large application window it was (in the current version) recommended to always perform an early and a late simulation. Now only the first calender date of the GAP is indicated as starting date. Would this be sufficient, also in cases where the application window extends over more than e.g., 3 months? Has it been tested whether the use of a 20-year period would be sufficient to level out seasonal differences ? It

				could be worthwhile to investigate the effect of starting at the end of the application window/BBCH-scale with the last application and then back-calculate the dates for earlier applications. EFSA: In the new SWASH shell, intended application dates may either be allocated to the start of the BBCH period ('forward calculation') or to the end ('backward calculation'). The user may always adapt the application dates provided by SWASH if justified.
107	UBA (Umweltbundesamt, German Environment Agency)	DE	3.5.4 Handling of different spray drift curves for vines and pome/stone fruits	Line 811 to 815 page 21: Is an upper limit foreseen for using pome/stone fruits late, BBCH 93. So that BBCH 71 till 93 refers to pome/stone fruits late? EFSA: The FOCUS surface water Repair WG adapted the SWASH software using the more conservative drift data for 'pome/stone fruits, early' from BBCH 09 to 69 and the less conservative drift data 'pome/stone fruits, late' from BBCH 71 to 95, switching back to 'pome/stone fruits, early' at BBCH 97 and onwards.
108	SCC Gmbh	DE	3.5.4 Handling of different spray drift curves for vines and pome/stone fruits	Lines 779ff, page 20: The UK approach used for spray drift values could be used for vines as well as it is pragmatic and realistic as well as in line with the recommendation for pome/stone fruit. The current UK proposal states that: "Early spray drift values for grapevines are used up to and including BBCH 15. Late spray drift values for grapevines should apply at BBCH 16 and onwards." Alternatively, additional experimental data for the different crop stages to identify the cut-off point between early and late should be generated. EFSA: In case of vines, the "early application" drift curve was skipped completely. The difference of drift values for "early vines" and "late vines" is not caused by different growth stage of vines but by the activation and de-activation of the air assistance in the experimental drift trials. De-activation of the air assistance is not agricultural standard practice for applications in vines. Applications in early vine may be also done with partial air assistance, for which experimental drift values do not exist.
109	Redebel Regulatory Affairs SCRL	UK	3.5.4 Handling of different spray drift curves for vines and pome/stone fruits	Concerning the spray drift, only the foliar application is considered in the simulations with crops such as vines, pome/stone fruits, etc. The application method of "ground application" could be envisaged for these crops (in addition to "air blast" as method) in order to consider the herbicide application at the bottom of trees. This should allow to avoid to manually encode the spray drift from ground application in FOCUS TOXSWA. EFSA: Downward spraying in tall crops is addressed in the new SWASH shell.
110	Institute of Environmental Protection - National Research Institute	PL	3.5.4 Handling of different spray drift curves for vines and	No comments to this part of the document (after thorough examination). EFSA: Noted.

			pome/stone fruits	
111	ECPA	BE	3.5.4 Handling of different spray drift curves for vines and pome/stone fruits	Line 783: To our understanding, the report of Ganzelmeier et al. (1995) describes the difference between ""vine early"" and ""vine late"" by the fact that the air assistance was switched off in the ""vine early"" trials. The present report seems to infer that the use of a ""tunnel sprayer"" is the distinguishing factor between early and late curves. Since this point may become important in future re-dicsussions of the FOCUS SW guidance, it should be clarified and revised, if necessary. EFSA: Agreed, the section in the text has been revised accordingly. The PPR Panel has recommended to update the spray drift curves for all crops based on data that has become available after Ganzelmeier et al. (1995). Line 802 & 804: It is not clear who ""the UK"" is, please clarify. EFSA: "UK" means United Kingdom. This was clarified in an update.
112	CTGB NL	NL	3.5.4 Handling of different spray drift curves for vines and pome/stone fruits	3.5.4 Handling of different spray drift curves for vines and pome/stone fruits Regarding the drift figures for early vs. late application in pome/stone fruit, we want to mention that drift values for early application are around twice as high as the drift values for late application, which is an artificial and rather rigorous cut-off between 2 neighboring BBCH intervals. This may lead to a (too) conservative exposure for early applications close to BBCH69. We however agree with the provided argumentation. As a sharp distinction is to be made (as there are only two experimental drift curves for fruit, dormant and full-leaf), that this is the best BBCH scale to do so (since flowering may indeed be on the dormant tree, i.e. without leaves), in line with the Dutch drift values in pome fruit as described in Holterman et al 2016. It is not completely clear why specifically the UK point of view is mentioned, we suspect this is because of the substance review of trifloxystrobin (UK=RMS). Maybe UK can be replaced with WG, since this seems to be the adopted opinion of the working group? NB In future, modelled drift-BBCH relations could be used to more realistically model the exposure due to spray drift for fruit culture (see also Holterman 2016). Within the limited scope of the current revision we agree with the proposal. EFSA: Noted. The reference to "UK" was reconsidered.
113	Institute of Environmental Protection - National Research Institute	PL	3.6 Use and presentation of the results of the revised FOCUS surface	The comments are provided individually to each subsection. EFSA: Noted.

			water scenarios	
114	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	3.6.1 Reconsideration of the temporal percentile approach	Lines 820-823, page 21. Please note that the choice of the temporal percentile should be carefully considered bearing in mind that the risk assessment is not only based on maximum PECsw values but can be based also on time weighted average PECsw values. Refined approaches based on the whole exposure profiles (after EPAT analysis) can also be used for the risk assessment for aquatic organisms based on EFSA guidance for aquatic organisms (EFSA Journal 2013;11(7):3290). It will be important to clarify how to deal with these approaches. EFSA: The choice of the final temporal percentile for the final PEC in surface water and sediment is a risk management decision. On basis of example calculation, the impact of choosing different temporal percentiles is demonstrated (from the approx. 50th to the approx. 90th percentile). It is not in the remit of the working group to give advice on how obtained exposure pattern should be interpreted or evaluated further.
115	Swedish Chemicals Agency	SW	3.6.1 Reconsideration of the temporal percentile approach	820-823, page 21: We agree to the proposed further approach and notes that further checking and example runs (as stated in Appendix H, lines 2868-2870) will be important for risk managers. EFSA: Noted.
116	UBA (Umweltbundesamt, German Environment Agency)	DE	3.6.1 Reconsideration of the temporal percentile approach	Line 820-823 page 21 (also line 156-159 and line 1034-1037): As the spatial percentile of the FOCUS standard scenarios with regard to specific member states is unknown, it might be difficult or even impossible to derive adequate temporal percentiles which represent an overall realistic worst-case. EFSA: The WG agrees that the actual spatial percentile of the FOCUS scenarios is unknown. The choice of the final temporal percentile for the final PEC in surface water and sediment is indeed a risk management decision. On basis of example calculation, the impact of choosing different temporal percentiles is demonstrated (from the approx. 50th to the approx. 90th percentile).
117	SCC Gmbh	DE	3.6.1 Reconsideration of the temporal percentile approach	Line 820ff, page 21: It should be noted that the protection level provided for by current modeling results is accepted and considered as sufficiently conservative based on long-term experience. It is most likely that choosing a fixed calendar date for application and performing calculations for a 20-year period, will result in a wide range of PECsw values. With regard to the selection of the adequate temporal percentile after implementation of the 20-year simulation period, it should therefore be ensured that the current protection level is maintained. EFSA: The choice of the final temporal percentile for the final PEC in surface water and sediment is a risk management decision. On basis of example calculation, the impact of choosing different temporal percentiles is demonstrated (from the approx. 50th to the approx. 90th percentile). Please notice that the WG concluded to maintain a simplified PAT.
118	Institute of Environmental Protection -	PL	3.6.1 Reconsideration of the	The whole paragraph is not fully clear. Maybe, for an average reader, it would be good to specify the meaning of some terms used in it, e.g. to explain whatv is the meaning of the term "adequate temporal percentile for exposure assessment"?

	National Research Institute		temporal percentile approach	EFSA: The entire chapter has been reconsidered on basis of example calculations.
119	ECPA	BE	3.6.1 Reconsideration of the temporal percentile approach	Line 820-823: In the current scheme, the Step 3 PECmax, for each scenario, represents a 90th percentile worst case. These defined maxima are then 'mitigated' at Step 4 (drift & runoff) to yield refined PECmax for the risk assessment. How does the EFSA WG envisage this working in regard to the 20 year simulation and associated temporal percentile(s)? EFSA: No changes with respect to Step 4 calculations are regarded necessary (of course, the same temporal percentile has to be used at FOCUS sw STEP 3 and 4).
120	HSE (Chemical Regulation Division)	UK	3.6.1 Reconsideration of the temporal percentile approach	It is noted that the FOCUS surface water Repair WG, will produce details of an adequate temporal percentile for exposure assessment to be presented. It is very likely that higher exposure values will be obtained based upon a 20 years climatic data set compared to the current model output. In the event that the standard Step 3 output concentrations are higher, we can imagine Applicants wanting to use data from the full 20 year simulations to refine the exposure assessments at Step 4. Therefore, will the models provide exposure data for the full 20 year simulation period that Applicants and Regulators can easily access? In addition will any consideration be given to using knowledge of vulnerability and the spatial distribution of individual scenarios across either the whole EU or within the 3 EU regulatory zones as a tool to weight the output. The UK has extensive experience of weighting the output from multi-year (30 years) MACRO drainflow simulations based on vulnerability of the scenarios and spatial distribution in the UK landscape to provide further insight into the associated risk. These methods (see HSE website http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook/fate/macro.htm) have built on original work by Brown et al, Exposure to sulfosulfuron in agricultural drainage ditches: field monitoring and scenario-based modelling (2004) abstract at https://www.ncbi.nlm.nih.gov/pubmed/15307668) and may provide a useful starting point for developing approaches to using comparable data generated by the new FOCUSsw models. EFSA: There is of course the option of performing Step 4 calculations as usual. On request, full (hourly) data for the 20-year assessment period can be obtained from the TOXSWA output files. It is not in the remit of this working group to re-consider the vulnerability or spatial distribution of the surface water scenarios amongst the whole EU or individual member states. On a separate note it is assumed as part of this proposal to detail adequate temporal percentiles for exposure assessment that the graphical outputs will also then be reviewed, some accompanying guidance on the interpretation of this output would be welcome. EFSA: Graphical outputs can be produced if requested. It is not in the remit of the working group to give advice on how obtained exposure pattern should be interpreted or evaluated.
121	Enviresearch Ltd	UK	3.6.1 Reconsideration of the temporal	This paragraph seems to suggest that we can fix all the shortcomings by calibrating the percentile output to choose from the distribution of outputs. This has some merit, but we should aim to make the calibration phase as small as possible, by getting the rest of the system as right as possible.

			percentile approach	Is the 'adequate temporal percentile' of the 20 annual maxima the right approach for such a complex system as surface water, bearing in mind the patterns of exposure are often more important than the levels. Will the decision of the Risk Managers be challengeable when more experience is gained with the system? EFSA: The choice of the final temporal percentile for the final PEC in surface water and sediment is a risk management decision. On basis of example calculation, the impact of choosing different temporal percentiles is demonstrated (from the approx. 50th to the approx. 90th percentile). It is not in the remit of the working group to give advice on how obtained exposure pattern should be interpreted or evaluated.
122	Rifcon GmbH	DE	3.6.1 Reconsideration of the temporal percentile approach	Exposure patterns and effect modelling are becoming increasingly important. For instance, TKTD is mentioned in the EFSA aquatic guideline as higher tier tool and the recently published EFSA opinion on TKTD classified the GUTS tool as ready to use. Since effect modelling often deals with probabilistic approaches, simulations are repeated very often e.g. for the estimation of confidence intervals. Consequently, longer simulation periods, caused by 20 year exposure patterns, will significantly impact work efficiency. Therefore, we appreciated the suggested temporal percentile approach and we recommend involving effect modelers in the decision process. EFSA: Noted. Notice, that it is not in the remit of the working group to give advice on how these exposure pattern should be interpreted or evaluated.
123	CTGB NL	NL	3.6.1 Reconsideration of the temporal percentile approach	3.6.1 Reconsideration of the temporal percentile approach & 3.6.3 Analysis of peak pattern in water and sediment We note that 3.6 still needs to be further determined. This section deals specifically with the impact that the revision may have on the overall vulnerability, protection goal and tiered methodology. We would like to emphasize that when a certain temporal percentile is chosen on the basis of the peak concentration, this does not necessarily mean that the exposure pattern will also be the same temporal percentile. This should be clearly stated in the final version. A good rationale is that often the peak concentration drives the risk assessment but as stated with new ecotoxicological modelling tools the pattern may become more important. EFSA: The choice of the final temporal percentile for the final PEC in surface water and sediment is a risk management decision. On basis of example calculation, the impact of choosing different temporal percentiles is demonstrated (from the approx. 50th to the approx. 90th percentile). Notice, that it is not in the remit of the working group to give advice on how exposure pattern should be interpreted or evaluated with respect to possible percentile approaches. Please note that temporal percentiles are hardly used within ecotoxicological risk assessments since 2015 or so, as issues were raised whether use of temporal percentiles gives the protection of aquatic organisms demanded. We therefore consider focusing on the temporal percentile approach, including additional refinement approaches while working on the strengthening of the EU FOCUS SW scenarios to be untimely, and urge to put this issue on hold until further guidance has been developed and implemented clarifying what kind of input can be requested as model output.

				EFSA: It is not in the remit of the working group to give advice on how exposure pattern should be interpreted or evaluated with respect to possible percentile approaches.
124	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	3.6.2 Consistency of the tiered approach	Lines 831-833, page 21. We agree that the FOCUS tiered approach should keep its consistency following introduction of the 20-yr assessment period. However, this would require to be checked in a quite exhaustive manner before planning a STEP 1-2 revision. We assume that this, and the revision of the STEP 1-2 tool (if required) are not compatible with the time frame available for the present mandate of the FOCUS surface water Repair WG. EFSA: On basis of extensive model calculations (Appendix I), the WG concluded that revision of FOCUS sw STEP 1 & 2 is necessary. The entire chapter was updated accordingly. Revision of FOCUS STEP 1 & 2 is neither in the remit nor in the timeframe of this WG. We would suggest that, in first instance, Step 1-2 results could be included in the examples comparing the old (single year) and the revised surface water scenarios (20 years) that the WG plans to present, to show whether the tiered approach is consistent in these cases. EFSA: On basis of extensive model calculations (Appendix I), it is evident that FOCUS sw STEP 2 does not sufficiently cover the new FOCUS STEP 3.
125	UBA (Umweltbundesamt, German Environment Agency)	DE	3.6.2 Consistency of the tiered approach	Line 826-833 page 21: We agree to revise the run-off/drainage percentages applied at FOCUS surface water Step 2 as the current approach (FOCUS, 2001) does not always take care to keep the tiered approach consistent. For substances with extremely high Koc-values (e.g. >100000 L/kg) the PECsw,max-value from Step 3 calculations could be higher than the PECsw,max-value form Step 2 calculations due to the different consideration of the behavior of substances with high Koc values in FOCUS Step 1 & 2 and FOCUS Step 3 models. EFSA: Agreed.
126	Redebel Regulatory Affairs SCRL	UK	3.6.2 Consistency of the tiered approach	Indeed, having a consistent tiered approach in the FOCUS surface water exposure assessment (Step 1 to 4) is important. However sometimes, scenarios D1 and D2 in FOCUS Step 3 are more critical than the values obtained in the FOCUS Step 2. Furthermore, in Step 4, there are no modifications of values from Step 3 while the risk mitigation measures are implemented. It would be interesting to obtain reduced PECsw values when mitigation measures are used in scenarios D1 and D2. EFSA: The WG is aware that already in the current system STEP 2 might give less conservative PECs compared to STEP 3 depending on substance properties and application timing. As demonstrated in this chapter this is also true for the new 20-year assessment approach. There are no changes to STEP 4. So, applying risk mitigation measures, STEP 4 will always give less conservative PECs compared to STEP 3, independent of the scenario. Another point should be in FOCUS step 2, when the PECsw values are obtained with the drift only simulation and separately with the run-off only simulation, their addition is not the same as the PECsw values calculated considering all routes of contamination.

				EFSA: The mandate focuses on the repair of Step 3 of the FOCUS SW scenarios (SWASH). Revision of FOCUS sw STEP 1 & 2 is outside of the remit of this WG. Finally, about the risk mitigation measures used after the FOCUS Step 2, it could be useful to have a correspondence table between several risk mitigation measures. For example, 20m buffer zone is equivalent to drift reduction nozzles of 90% for run-off. EFSA: It is questionable whether such a correspondence table between mitigation measures will be developed for Step 2 since that is not part of mandate (repair of Step 3)
127	Institute of Environmental Protection - National Research Institute	PL	3.6.2 Consistency of the tiered approach	The proposed in the document harmonisation seems to be only a half-measure, covering the issue of the migration by drainage and run-off. but what about the harmonisation of the drift percentile and CI values? EFSA: Revision of FOCUS sw STEP 1 & 2 is outside of the remit of this WG.
128	ECPA	BE	3.6.2 Consistency of the tiered approach	Line 831: It should be considered that the need for a revision of FOCUS SW Step 1 and 2 will depend on the conservativeness of the evaluation criteria at Step 3 (which are not yet defined). For example, preliminary calculations presented at SETAC Europe 2018 indicate that no change of FOCSU Step 2 may be necessary, if the 80th percentile annual maximum PECsw from the 20-year calculations is selected (data can be made available upon request). EFSA: We agree on that. However, on basis of extensive testing, the WG concluded that revision of FOCUS sw STEP 1 & 2 is necessary. STEP 2 should also take care of the new drift percentile approach.
129	Swedish Chemicals Agency	SW	3.6.3 Analysis of peak pattern in water and sediment	836-846, page 21-22: Note that refinement of the aquatic risk assessment by using detailed analysis of time-variable exposure derived from the FOCUS modelling as described in the EFSA AGD is not accepted within the Northern Zone. This is mainly because refined exposure tests with single or few species (chapter 9.2 of the EFSA AGD) cannot be considered to cover all sensitive life stages or all species in the field, since the effect of e.g. a pulsed exposure is highly species specific and dependent on sensitive life stages and/or different life strategies. EFSA: Thank you for sharing this information. Anyway, for any potential update of SWASH in the future to enable analyses of exposure peaks, it would seem necessary to analyse the peak pattern over the entire 20 year period and not only for the year during which the maximum PEC (or, the x percentile regulatory PEC) occurred. For instance, it may be the case that the duration of the peak may be longer (but at a slightly lower level) at another year. EFSA: Agreement. It is up to the user to decide on how to interpret peak exposure pattern. Further recommendations are outside of the remit of this WG.
130	UBA (Umweltbundes	DE	3.6.3 Analysis of	Line 836 till 846 page 21: Our experience during the German GERDA project was that any analysis of the peak pattern would be difficult based on 20 yearly pattern. So far, no solution is found. When used in some

	amt, German Environment Agency)		peak pattern in water and sediment	refinement approaches for aquatic risk assessment, exposure profiles obtained after FOCUS repair will be linked in principle to less uncertainties than in the current FOCUS regarding the selection of worst case exposure profile among the various scenarios since 20 yearly patterns are available versus 1 year previously. This analysis (20 year profiles versus one year profile) will considerably increase the time for analysis, although this issue can be facilitated by using TKTD models EFSA: Agreement. In addition, it should be noted that this type of refinements using TKTD modelling is up-to-now restricted to cases where survival of individuals is of concern (i.e. not applicable to sublethal effects on populations). Indeed in EFSA 2018 (Scientific Opinion on TKTD modelling for aquatic risk assessment), it has been concluded that only GUTS models are considered as fit for purpose at this stage. EFSA: Agreement. In general, it would be appreciated that exposure pattern can be easily readout of TOXSWA in a user friendly way. EFSA: Agreement. However, in view of the limited time for this mandate, no such tools as e.g. EPAT have been implemented in the models (outside of the mandate).
131	The Danish Environmental Protection Agency	DK	3.6.3 Analysis of peak pattern in water and sediment	Tools to analyze peak/exposure pattern are welcome, but there is a need for EFSA agreed models (e.g. TK/TD modeling) to match such exposure profiles EFSA: Agreement. Nevertheless, in this scientific report no detailed advice on that will be given (outside the mandate).
132	Institute of Environmental Protection - National Research Institute	PL	3.6.3 Analysis of peak pattern in water and sediment	No comments to this part of the document (after thorough examination). EFSA: Noted.
133	The Norwegian Food Safety Authority (Mattilsynet)	NO	3.6.3 Analysis of peak pattern in water and sediment	Note that refinement of the aquatic risk assessment by using detailed analysis of time-variable exposure derived from the FOCUS modelling as described in the EFSA AGD is not accepted within the Northern Zone. This is mainly because refined exposure tests with single or few species (chapter 9.2 of the EFSA AGD) cannot be considered to cover all sensitive life stages or all species in the field, since the effect of e.g. a pulsed exposure is highly species specific and dependent on sensitive life stages and/or different life strategies. EFSA: Thank you for sharing this information.

134	HSE (Chemical Regulation Division)	UK	3.6.3 Analysis of peak pattern in water and sediment	The UK agrees with EFSA in that analysis of peak patterns are essential in refinement of assessments. Therefore, subject to the outcome of the testing of the proposed 20 years climate data with the additional scenarios and the impact this has on predicted exposure levels, the use of a tool to extract data from TOXSWA would be considered to be a useful addition to this repair. EFSA: In principle, we agree. Nevertheless, in the scientific report no detailed advice on that will be given (outside of the mandate)
135	Swedish Chemicals Agency	SW	3.7 Dealing with rotational crops in the aquatic exposure assessment	896-905, page 23: To keep consistency with the current approach, and as a pragmatic solution we agree to the second option (keep upstream catchment, and carry out modelling in the same way regardless of applications every year, every 2nd year, or every 3rd year). However, as recognised on lines 896-899, this option may be far too conservative for the pond scenarios. In contrast to the FOCUS SW Repair WG (lines 904-905) we suggest that the modelling strategy for pond scenarios would need to be adapted to avoid this. First, we should not exclude that PECsed may be critical for the risk assessment and the pond scenarios are likely to present higher PECsed than ditches and streams. Secondly, the models should not produce results that are inconsistent and which should not be used for any purpose. Would it be an option to implement in the TOXSWA that PECsw and PECsed for the pond scenarios are simply divided by a factor 2 or 3 in case of application every 2nd or 3rd year, respectively? EFSA: Yes, such a factor would be easy to implement and we agree that a consistent approach for all water bodies would be desirable, but changing the definition of the pond scenarios lies outside the current mandate of the WG.
136	UBA (Umweltbundesamt, German Environment Agency)	DE	3.7 Dealing with rotational crops in the aquatic exposure assessment	Line 848-905 page 22: The second option should be considered as proposed by FOCUS SW repair WG. In addition to the remarks on the catchment the calculated PECsw represents just a PEC somewhere in Europe, it might occur at any year. Considering of crop rotation is not appropriate. EFSA: Noted.
137	The Danish Environmental Protection Agency	DK	3.7 Dealing with rotational crops in the aquatic exposure assessment	Both of the suggestions should be implemented. As we understand the model, both the upstream water and the adjacent field should reflect rotational crop, if that is used. I.e. both options are valid and should be implemented. EFSA: The proposed approach results in a simple dilution factor applied to the treated field that is simulated. The FOCUS approach may overestimate losses for very persistent compounds if soil accumulation occurs in the simulated field at annual time-scales.
138	WSC Scientific GmbH	DE	3.7 Dealing with	Page 22, lines 877-880: EFSA considers exposure peaks caused by spray drift entries only not to be affected by crop rotations as they do not accumulate during the year. But what about the sediment concentrations? The

			rotational crops in the aquatic exposure assessment	potential of substances with higher adsorption values to accumulate in sediment following spray drift entry and partitioning to sediment is not considered here. EFSA: The assumptions underlying the approach mean that the different time-scales of inputs from spray drift, runoff and drainage will influence the extent of dilution. Spray drift inputs occur over much shorter time scales than runoff or drainage and this is why dilution is not considered.
139	Institute of Environmental Protection - National Research Institute	PL	3.7 Dealing with rotational crops in the aquatic exposure assessment	No comments to this part of the document (after thorough examination). EFSA: Noted.
140	ECPA	BE	3.7 Dealing with rotational crops in the aquatic exposure assessment	Line 886 to 905: The EFSA WG acknowledges that representing crop rotation in the pond scenarios with the current approach is ""far too conservative"", but then disregards this as concetrations are ""usually much lower"". This is not appropriate and leads to an unrealistic assessment of exposure, often represented as a chronic exposure profile in the aquatic risk assessment. EFSA: The WG considers that changing the definition of the pond scenarios lies outside the current mandate of the WG.
141	Enviresearch Ltd	UK	3.7 Dealing with rotational crops in the aquatic exposure assessment	For ponds and ditches, the proposed approach seems fine. However, for the streams, the intention of the original SW scenario was to assume upstream applications all on the same day. This was adequate for a single-year to represent a long time-series, but would be unrealistically conservative to happen every year. Therefore, we prefer some way of smoothing out the upstream contributions over some time. EFSA: The dilution factor of (nearly) 5 implies that 20 % of the upstream catchment is treated on the same day, which may be quite conservative, although perhaps not unrealistic for a small catchment. Crop rotations i.e. application every second or third year also reduce the accumulation of residues in the soil over the warm-up period and the 20-year simulation and can thereby reduce drainage or runoff losses. EFSA: Yes, if accumulation in soil occurs at annual time-scales (i.e. very persistent compounds), then the proposed approach may overestimate losses. However, there are considerable practical difficulties in implementing any alternative. In principle, the only strictly correct way to handle crop rotations and temporal patterns of pesticide inputs is to model at the landscape scale, but that is unrealistic at the present time.

142	CTGB NL	NL	3.7 Dealing with rotational crops in the aquatic exposure assessment	3.7 Dealing with rotational crops in the aquatic exposure assessment Ctgb does not really have a preference for either one of the options described regarding the incorporation of application to rotational crops within the FOCUS SW risk assessment, but wonders whether it is possible to perform an indicative impact assessment to evaluate the differences between the two methodologies. EFSA: This would be ideal of course, but the WG does not have the resources to carry out such a large analysis, primarily because it would require significant programming effort.
143	TSG consulting	UK	3.7 Dealing with rotational crops in the aquatic exposure assessment	Lines 860 – 905 The upstream catchment is an intrinsic component of the stream scenario. Its primary purpose being to provide "a realistic description of the dynamics in flow and water depth" (FOCUS SW guidance section 4.4.3). According to the scenario definition the upstream catchment is assumed to be present regardless of what percentage of its area is treated. The percentage treatment rate of the upstream scenarios was set to make these scenarios "as realistic as possible, but maintain consistency between scenarios" (FOCUS SW guidance section 4.4.3). It should be acknowledged in the draft that the PECsw values for stream scenarios are driven not by the adjacent field but by the upstream catchment. This is highlighted in the existing guidance in the FOCUS scenario assumptions section of the guidance (section 8.7.4, FOCUS SW 2014) under the heading "Percentage treatment of the upstream catchment": "The FOCUS stream has an upstream catchment of 100 ha, of which 20% is assumed to be treated. So, water fluxes of 100 ha and pesticide fluxes from 20 ha enter the FOCUS stream of 100 m via its upstream end and they mix with the lateral fluxes from the 1 ha neighbouring field. As the size of the catchment is 100 times larger than the size of the neighbouring field, the fluxes coming out of the catchment dominate those from the neighbouring field. If 50% of the upstream catchment would be treated pesticide fluxes from 50 ha would enter the FOCUS stream. This implies that in this case the PECmax in the FOCUS stream would maximally be a factor 50% / 20% = 2.5 times higher." FOCUS SW guidance (2014, p233) Thus it is clear that the upstream portion of the stream scenario is intrinsic to the scenario definition and provides no dilution (a dilution factor of 5 for the stream is stated in the draft), but rather the upstream catchment accounts for the greater proportion of the concentration reported by TOXSWA. The effect of upstream catchment treatment can easily be demonstrated by setting the treatment ratio to 0.0 in a TOXSWA input file and the resulting PECsw value will be approximately x21 times smaller than when the treatment ratio is at the default 0.2 value. Therefore the proposal to substitute a "space for time" substitution with regards to crop rotation is at odds with the scenario definition. Furthermore the calculated spatial "dilution" factors of 33% for ditches and 20% for streams [sic - see above] do not match the ones implied by a "temporal" approach (1 yr in 2 - 50% or 1 yr in 3 - 33%). Additionally, according to a crop rotation of 1 in 2 years at, for example, D1 we would expect to see the same "temporal" factor applied to both the ditch and the stream water bodies associated with this scenario. However, the current

				proposal outlined in the draft as being preferred by the working group would effectively apply different factors (based on space, not time) despite the agricultural practice being identical. Finally the "space for time" approach does not account for eroded soil input in the R scenarios which only comes from the adjacent field and not from the upstream catchment. Thus the proposed "space for time substitution" is not valid for all chemical mass input routes. Whilst it would increase run times, running the simulations for 46 or 66 years is the only way to simulate crop rotation whilst maintain fidelity to the scenario definitions as laid out in guidance. EFSA: The proposal to keep the original approach for the FOCUS streams, ditches and ponds is a pragmatic one. We agree that it is only approximate. However, there are considerable practical difficulties in implementing any alternative. In principle, the only strictly correct way to handle crop rotations and temporal patterns of pesticide inputs is to model at the landscape scale, but that is unrealistic at the present time. Lines 882 - 885 The current (and likely future) approach of loading all drift events from the upstream catchment into the water body at one time is at odds with the concept that spray events are independent i.e. separate spray events across the entire catchment are "accumulating" simultaneously in the 100m assessment section of the stream. So it would appear that maintaining the differing drift percentiles for multiple applications would at the very least be required for stream scenarios where the events are not independent. EFSA: The WG opted for maintaining different drift percentiles for multiple applications, but now with one application always representing a 90th drift percentile. In addition, for stream scenarios the logic of FOCUS (2001) was maintained, i.e. the spray drift deposition on the 100 m stretch is multiplied by a factor of 1.2 accounting for a 20 % additional spray drift deposition from the upstream catchment, passing through the simulated stretch of stream at the same time as the 100 % deposition from the 1-ha field.
144	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	4 Comparison of old and revised FOCUS surface water scenarios	Lines 908-913, page 23. As outlined in this chapter, it will be important to provide an evaluation of the impact of the new procedure on the risk assessment. +E200 EFSA: The entire chapter has been updated giving more details on how the new multi-year approach performs in comparison to the current singe-year approach. Example calculations are presented in the new Appendix K. Line 910, page 23. Typo: "prevent" is written instead of "present". EFSA: Not relevant anymore. The entire chapter has been updated.
145	Swedish Chemicals Agency	SW	4 Comparison of old and revised	910, p 23: There is a typo; 'prevent' should read 'present'. EFSA: Not relevant anymore. The entire chapter has been updated.

			FOCUS surface water scenarios	
146	UBA (Umweltbundesamt, German Environment Agency)	DE	4 Comparison of old and revised FOCUS surface water scenarios	Line 910 page 23: Spelling error, it should read „intends to present this comparison". EFSA: Not relevant anymore. The entire chapter has been updated.
147	SCC Gmbh	DE	4 Comparison of old and revised FOCUS surface water scenarios	Line 910, page 23: There seems to be a typo; it should read "provide" instead of „prevent". EFSA: Not relevant anymore. The entire chapter has been updated.
148	Institute of Environmental Protection - National Research Institute	PL	4 Comparison of old and revised FOCUS surface water scenarios	Please reconsider the decision concerning not providing such comparison, at least indicative, in this document. When presented it may help by providing users with a broader view of the upgraded tool and, possibly, cutting short the would be discussions on the reliability/credibility of the results obtained using the updated SWASH. EFSA: The entire chapter has been updated giving more details on how the new multi-year approach performs in comparison to the current singe-year approach. Example calculations are presented in the new Appendix K.
149	ECPA	BE	4 Comparison of old and revised FOCUS surface water scenarios	Lines 907 to 913: The EFSA WG acknowledges that it was not possible to provide examples comparing the current and new procedures in time for the public consultation. Given the extensive changes proposed to the modelling framework it is not considered possible to comprehensively comment on the implication of these changes without these comparisons being made available. An impact assessment, benchmarking of those values against the values currently used in risk assessment should help to make a realistic recommendation of the percentile to be used to the risk manager. A further consultation once these comparisons become available is recommended. EFSA: The entire chapter has been updated giving more details on how the new multi-year approach performs in comparison to the current singe-year approach. Example calculations are presented in the new Appendix K. The mandate from the European Commission asked only for one consultation. A further consultation is therefore not foreseen.

				Line 908: There is probably a typing error: ""prevent"" should be ""present"""" EFSA: Not relevant anymore.
150	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	5 Conclusions	Line 998, page 25. Typo : the word "adopting" was used instead of "adapting". EFSA: Noted. Typo was corrected.
151	Swedish Chemicals Agency	SW	5 Conclusions	983-993, page 25: This paragraph starts by saying that the recommendations for FOCUS GW should be applied. But the pH values to consider (5.1 to 8.0) later mentioned deviates from those recommended for FOCUS GW. Which would (in the case of pH dependency) result in use of different adsorption parameters as input for groundwater and surface water modelling, respectively. We do not agree to that and suggest that the current recommendation for FOCUS GW should be adopted also for surface water (see our related comment on this to section 3.3.). EFSA: Please refer to the related comment in Section 3.3. 1028-1033, page 26: While we agree to the suggested approach for ditches and streams we suggest that adaptations are necessary for the pond scenarios (see our related comment on this to section 3.7). EFSA: Please refer to the related comment in Section 3.7.
152	SCC Gmbh	DE	5 Conclusions	Lines 920ff, page 24; lines 970ff, page 25; lines 1011ff, page 25: The PAT procedure reflects the good agricultural practice that plant protection products are generally not applied at times were significant rainfall is likely. In practice, farmers have much advice at hand (e.g. pest development and application timing forecast by agricultural services via internet) and are interested in avoiding application of plant protection products at bad weather periods that would result in reduced efficacy and economic benefit. The selection of the actual application dates over the simulation period based on PAT thus realistically reflects changing weather conditions from year to year. On the other hand, the PAT ensures a sufficient level of conservatism by assuring that 10mm of rainfall are falling within 10 days after the application. The suggested approach to use one application date over the 20-year simulation period is expected to result in the selection of extreme weather conditions, either with unrealistic high or unrealistic low rainfall. In order to be consistent among the FOCUS models, it should rather be considered to introduce a PAT functionality also for PECgroundwater and future PECsoil calculations.

				EFSA: The WG has reconsidered the PAT approach on basis of an extensive modelling exercise with the conclusion to maintain a simplified PAT with a shorter application window (please refer to chapter 3.2). Lines 983ff, page 25: In view of the aim of the work group that processing times should not become excessive, modeling of two complete sets of all scenarios with alkaline and acidic substance parameters should be avoided. The current approach to perform calculations only for sets of scenarios representing either acidic or alkaline properties in case of pH dependency is considered sufficiently conservative as respective scenarios are available. According to the Generic guidance for FOCUS surface water Scenarios (Version 1.4, EFSA 2015, Table 4.9.1-1) the soil pH for 4/10 Scenarios are in the range of 4.5 to 6.9 and 6/10 in the range between 7.0 and 8.4. EFSA: As already indicated in the scientific report, it should be kept in mind that the soil pH, stated for each individual scenario, has no meaning with respect to the vulnerability of this scenario. Notice that each of these scenarios is considered to cover large areas in the EU. Lines 1022ff, page 26: The UK approach used for spray drift values could be used for vines as well as it is pragmatic and realistic as well as in line with the recommendation for pome/stone fruit. The current UK proposal states that: "Early spray drift values for grapevines are used up to and including BBCH 15. Late spray drift values for grapevines should apply at BBCH 16 and onwards." Alternatively, additional experimental data for the different crop stages to identify the cut-off point between early and late should be generated. EFSA: In case of vines, the WG agreed to completely skip the "early application" drift curve. The difference of drift values for "early vines" and "late vines" is not caused by different growth stage of vines but by the activation and de-activation of the air assistance in the experimental drift trials. De-activation of the air assistance is not agricultural standard practice for applications in vines. Applications in early vine may be also done with partial air assistance, for which experimental drift values do not exist.
153	Institute of Environmental Protection - National Research Institute	PL	5 Conclusions	The comments to this section may repeat those already given for each point of concern, therefore no comments provided to that part. EFSA: Noted
154	Anses (French Agency for Food, Environmental and Occupational	FR	6 Recommendations	Lines 1042-1045, page 26. Please clarify if the "minor" improvements listed in Appendix J will be considered in the frame of the FOCUS surface water repair action mandate. We would suggest to consider also the following, if possible in the allocated time frame. With the current versions of FOCUS models, herbicide applications in orchards or vineyards and in-row or between-row applications cannot be easily simulated using the FOCUS interfaces but require modifying the input files. It

	Health & Safety)			would be appreciated if the interfaces could be modified, allowing for orchards/vineyards to select a low drift value and the possibility to exclude crop interception and for in-row applications the possibility to adapt the application dose considered for runoff/drainage entries. EFSA: Downward spraying in tall permanent crops (orchards, vines) is addressed in the new SWASH tool. Notice, that the application rate as well as the crop interception may always be changed in SWASH by the user if justified. The application timing is kept flexible.
155	Institute of Environmental Protection - National Research Institute	PL	6 Recommendations	No comments to this part of the document (after thorough examination). EFSA: Noted.
156	Swedish Chemicals Agency	SW	References	page 27: EFSA (2014) should be added to the reference list. (see comment to section 3.3) page 27: FOCUS (2014) Generic guidance document on Tier 1 Groundwater assessment should be added to the reference list. (see comment to section 3.3) EFSA: Noted. EFSA scientific report updated.
157	Institute of Environmental Protection - National Research Institute	PL	References	No comments to this part of the document. EFSA: Noted.
158	UBA (Umweltbundesamt, German Environment Agency)	DE	Glossary and abbreviations	Line 1131 page 29: Spelling error, it should read TOXSWA. EFSA: Noted. Guidance will be updated.
159	Institute of Environmental Protection - National Research Institute	PL	Glossary and abbreviations	No comments to this part of the document. EFSA: Noted.
160	Anses (French Agency for Food, Environmental and	FR	Appendix A	Line 1140, page 30. Please note that D2 ditch scenario has, contrarily as mentioned in the sentence, a long hydrological residence time. EFSA: Text has been adjusted, the appendix only considers runoff and there are no ditches receiving runoff.

	Occupational Health & Safety)			Line 1151-1156, page 30. Please clarify why the data excluding snow were considered rather than the other data set including water coming from snowmelt. Please indicate which dataset is used by the model. EFSA: The precipitation data from the zts file, representing rainfall only (i.e. not including snowfall as precipitation) were used for the analysis because they reflect better the potential for surface runoff generation. While snowmelt can contribute to surface runoff in PRZM, snowfall does not. Note that in PRZM snowfall only occurs on days with daily mean air temperature (Tmean) < 0 °C, while rainfall and snowmelt only occur on days with Tmean > 0 °C. Hence, on a day with snowfall there will be no surface runoff in PRZM. Lines 1217 to 1221, page 33. We do not question the relevance of a warm up period, nor the FOCUS surface water repair WG proposition to define it as a 6 year period, in line with what is done in FOCUS (2001) for D scenarios and in FOCUS GW. However, the conclusions that "the results indicate that six years warm up period is sufficient" should be nuanced. Indeed, it is not obvious from the graphs that a plateau concentration in the sediment layer is reached within the warm up period in every case. Even so, we think the restricted number of tested situations (1 substance, 1 application dose, 2 scenarios and water bodies) would not allow reaching a definitive conclusion on this point, which is probably highly dependent on the substance properties and GAP. EFSA: The test compound was defined in such a way ($DegT_{50sed}$ of 1000 d) that it has a relatively strong tendency to build up in the sediment. The results of the four simulations presented in Figures 1 to 4 show that concentrations may build up for approximately 2 to 4 years and that this process is slower for the 5 cm layer than for the 1 cm layer. As expected, the 1 cm sediment layer has a faster response to concentration peaks in the water layer above than the 5 cm layer. Based upon these results the WG decided to adopt a 6 years warming up period for all repaired FOCUS scenarios, equivalent to what was done in the D scenarios of FOCUS (2001). Lines 1207, page 33. Typo : "her" is written instead of "its". EFSA: Typo was corrected.
161	Swedish Chemicals Agency	SW	Appendix A	1222-1233, p 34-37: We appreciate these visual presentations. However, it would be good to improve the printing quality of the graphs as header and axis descriptions can hardly be seen. EFSA: Noted. However the quality can not be improved as it depends on the resolution and the quality for the graphs provided.
162	Institute of Environmental Protection - National Research Institute	PL	Appendix A	No comments to this part of the document (after thorough examination). EFSA: Noted.

163	Swedish Chemicals Agency	SW	Appendix B	1234-1284, p. 38-55: We appreciate that the entire drainage and rainfall time series are visually presented for all FOCUS-Drainage scenarios in this Scientific Report. This improves the transparency and might help evaluating PECsw calculations. EFSA: Thank you.
164	Institute of Environmental Protection - National Research Institute	PL	Appendix B	No comments to this part of the document (after thorough examination). EFSA: Noted.
165	ECPA	BE	Appendix B	Line 1245: To which extent is the exceptional rainfall event on the 9th of July, 1989 (144.2 mm) driving the results for the D1 scenario? What is the annuality of this event, and is it realistic to include it in the framework of FOCUS SW? EFSA: Depending on the compound properties and GAP the event of 9th July 1989 may result in the annual maximum PECsw for 1989 and even in the highest PECsw of all 20 simulated years. However, the use of a temporal percentile not representing the highest annual PECmax,sw of all annual PECmax,sw, this result will not lead to the peak annual PECmax,sw used in the tiered risk assessment. Line 1285: Please specify which crop was selected for the simulation of runoff events. EFSA: The crop elected for the simulation of the runoff events has been specified in the final report.
166	Swedish Chemicals Agency	SW	Appendix C	1285-1315, p. 56-66: We appreciate the visual presentation of rainfall and runoff events for all FOCUS-runoff scenarios. EFSA: Thank you.
167	Institute of Environmental Protection - National Research Institute	PL	Appendix C	No comments to this part of the document (after thorough examination). EFSA: Noted.
168	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	Appendix D	Pages 67-99. A lot of information and formula are presented in this appendix. A glossary of the acronyms used (e.g. PFAC, SMCRIT, XMPOR, etc) and an explanation of the processes they represent would be welcome to really get the approaches. EFSA: We agree that section is very technical. The information has been provided for transparency reasons and to provide more detail.

				Pages 67-99. Especially for Appendix D, the general quality of the graphs is low and prevents their assessment. This could be improved in the report. EFSA: The resolution of the graphs depends on their origin. If possible, the resolution and quality of the graphs will be improved. Table 16, page 89. Please clarify why table 16 is presented while it is clearly written that option 6 is "strictly suitable only for tall crops such as pome/stone fruits" (lines 2300-2301) and why the analysis was not performed with option 5 instead. EFSA: The information was provided for transparency reasons and an overview of options and to provide examples.
169	Swedish Chemicals Agency	SW	Appendix D	1316-2644, p. 67-99: We appreciate the transparency and that detailed information including the source codes are presented in the Appendix. However, we would appreciate if the graphs could be improved visually. EFSA: Yes, we noted that too. Apparently, there was a problem during pdf creation.
170	WSC Scientific GmbH	DE	Appendix D	Page 67, lines 1343-1344: A new PRZM version was tested here. It would be nice to test this new version, too. EFSA: When the PRZM version is updated it will be submitted into the FOCUS version control for further testing before released for regulatory use.
171	Institute of Environmental Protection - National Research Institute	PL	Appendix D	No comments to this part of the document (after thorough examination). EFSA: Noted.
172	ECPA	BE	Appendix D	Line 1346: The reference to ""Chapter 2"" should probably be replaced by a reference to Section D.2. EFSA: Yes, correct. We'll fix that. Line 1393: It seems that definition of the soil moisture content and of the soil moisture content at field capacity have been mixed up. EFSA: Noted. Yes, sorry. We'll fix that.
173	Institute of Environmental Protection - National Research Institute	PL	Appendix E	No comments to this part of the document (after thorough examination). EFSA: Noted.

174	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	Appendix F	Lines 2811-2814, page 105. The modifications of PRZM routine to calculate wash-off is welcome. EFSA: Thank you.
175	Institute of Environmental Protection - National Research Institute	PL	Appendix F	No comments to this part of the document (after thorough examination). EFSA: Noted.
176	Anses (French Agency for Food, Environmental and Occupational Health & Safety)	FR	Appendix G	Table 18, page 106. AppDate is considered as a very valuable tool for risk assessment. Please note that in Appdate (v3.0) one issue was identified linked to the introduction of senescence dates at BBCH 90 (BBCH 90 is usually associated to harvest). Our suggestion would be to exclude the senescence dates that were implemented in the v3.0. We suggest that an amended Appdate version only should be used. EFSA: We agree to the suggestion. The senescence date has been removed and AppDate was changed accordingly.
177	UBA (Umweltbundesamt, German Environment Agency)	DE	Appendix G	Line 2816 page 106: correct name UBA = German Environment Agency EFSA: The report was updated accordingly. Line 2895ff page 110: Unfortunately only the preliminary modelling runs for the FOCUS surface water scenario R1 with different options for the PAT (including no PAT) are presented in Appendix H. It would be interesting to see the effect of different PATs also for other FOCUS surface water scenarios and different crops/application times. EFSA: Following public consultation, different options for a simplified PAT have been thoroughly investigated in all scenarios applying different dummy substances (new Appendix I). On basis of these calculations the WG decided to maintain a simplified PAT. Preliminary calculations provided in appendix H have been deleted therefore.
178	Institute of Environmental Protection - National Research Institute	PL	Appendix G	No comments to this part of the document (after thorough examination). EFSA: Noted.

179	ECPA	BE	Appendix G	Line 2816-2850: The exact meaning of the term ""spring point"" should be explained. Spring points have not been defined for the original SW scenarios (FOCUS, 2001). AppDate employes the spring point for winter crops to describe the end of hibernation (winter dormancy) to derive application dates. This is not consistent with the spring point dates considered in FOCUS GW. Crop/scenario specific spring points in FOCUS GW are much later, mainly in April/May, which clearly does not represent the end of hibernation. Alignment between GW and SW is needed here, in particular because AppDate relies heavily on the spring point dates for winter crops. EFSA: Though the spring point is not explicitly mentioned in the FOCUS SW report it was nevertheless used by MACRO (parameter ZDATEMIN = date of intermediate crop development). As it was not the intention of the repair action to re-define the crop parametrisation the spring points were not moved to earlier times. Nevertheless the report has been improved by giving additional information. Line 2822: Note that the current version of AppDate is 3.01 (15th May 2018) which may or may not include relevant changes over version 3.0 mentioned here. EFSA: Agreement. Line 2851: While no BBCH codes may be needed for established grassland, BBCH codes and interception data are needed for newly sown lawns and pastures. EFSA: The problem here is that the FOCUS parametrisation for grass is based on fully developed grassland. Therefore, no recommendations are given. The default crop interception of 90 % for established grassland may be adapted by the user.
180	WSC Scientific GmbH	DE	Appendix H	Page 110, lines 2914-2916: From the results presented here for substance G, the timing of application seems to have a great influence on the final PECmax in surface water (range of 0 - 140 µg/L). EFSA: The range of 0-140 µg/L occurs for all 7 PAT versions (see descriptions of Fig 24 and 26), so this means that the range does not depend on the timing of the application, but is primarily due to the fact that these are results for 20 different years. Page 124, lines 3044-3049: It was concluded that for the R1-Weiherbach stream simulations with one application in autumn and compound G and I (mobile and non-mobile persistent) the annual maximum concentrations in both water and sediment are not very sensitive to the timing of application. This conclusion was drawn after testing different PAT rules and just one example without PAT (application on the same day every year). Therefore it would be necessary to test more than 1 example without PAT to come to this conclusion. Furthermore, testing more scenarios than just one would help to verify the results. What are the results of the other substances, e.g. with lower DT50? Research with FOCUS GW models has shown that for substances with low DT50 values the timing of application / rain can have a significant effect. The final PECgw can vary up to 20 fold (see Wang et al. 2015. Development of a Pesticide Application Timer (PAT) for the FOCUS groundwater models. Poster at SETAC 2015).

				EFSA: Following public consultation, different options for a simplified PAT have been thoroughly investigated in all scenarios applying different dummy substances (new Appendix I). On basis of these calculations the WG decided to maintain a simplified PAT. Preliminary calculations provided in appendix H have been deleted therefore.
181	Institute of Environmental Protection - National Research Institute	PL	Appendix H	No comments to this part of the document (after thorough examination). EFSA: Noted.
182	ECPA	BE	Appendix H	Line 2864: In general this anlaysis is very interesting, and exactly what is needed. However, given the complexity of the issue (adequately discussed in the main text), much more extensive testing is required before robust conclusions can be drawn. In addition, scenario R1 might be seen as a relative ""best-case""; more ""reactive"" R scenarios could produce more significant differences for the different application timing options. It might also be interesting to investigate compounds with shorter DT50 values. EFSA: Following public consultation, different options for a simplified PAT have been thoroughly investigated in all scenarios applying different dummy substances (new Appendix I). On basis of these calculations the WG decided to maintain a simplified PAT. Preliminary calculations provided in appendix H have been deleted therefore.
183	HSE (Chemical Regulation Division)	UK	Appendix H	As detailed in our comment on section 3.2, the UK CA would welcome further testing of the impact of the removal of the PAT and with a revised simplified PAT on other scenarios. EFSA: Following public consultation, different options for a simplified PAT have been thoroughly investigated in all scenarios applying different dummy substances (new Appendix I). On basis of these calculations the WG decided to maintain a simplified PAT. Preliminary calculations provided in appendix H have been deleted therefore.
184	Enviresearch Ltd	UK	Appendix H	For the compound G, the spread of concentrations is very wide. This makes it hard to pick a 'correct' percentile. More certainty can be obtained if a percentile is taken near the middle of the distribution rather than the tail. Compound I does not suffer from this problem in water, although it does have this problem in the sediment. EFSA: Noted. The WG is aware of the fact that extreme percentiles are less robust than percentiles near the middle of the distribution. Notice that the issue of the temporal percentile selection was thoroughly recovered in Appendix I.
185	Swedish Chemicals Agency	SW	Appendix I	All Figures, p 126-128: It is appreciated that the comparisons are presented in graphs. However, it would be good to improve the printing quality of the graphs as header and axis descriptions can hardly be seen. EFSA: Agreement. Improvement of visibility of figures and graphs will be done if possible.
186	WSC Scientific GmbH	DE	Appendix I	Page 128, lines 3128-3130: The 90th percentile spray drift values for single application should be used also for multiple applications although higher concentrations (up to 40%) were simulated for persistent substances in pond scenarios. This increase was only calculated regarding the PECmax in surface water. Especially for pond

				scenarios, where the residence time is longer than in the other scenarios, a comparison of the PECsed would be interesting. An accumulation in sediment following runoff entry was considered by adding a warm-up period for the runoff and drainage entries. Isn't it also possible that the concentration in sediment can accumulate following entry by spray drift and partitioning into sediment? EFSA: Dependent on the scenario and the type of end-point the originally suggested approach might be indeed too conservative. Therefore, the methodology has been changed without losing the advantage of having only one run instead of two (single and multiple). Only for the last application the 90th percentile is considered whereas for the previous applications within a season the traditional percentages will remain. The entire appendix will be revised accordingly.
187	Institute of Environmental Protection - National Research Institute	PL	Appendix I	No comments to this part of the document (after thorough examination). EFSA: Noted.
188	ECPA	BE	Appendix I	Line 3051-3135: It is noted that whilst the ratios of new procedure vs current procedure PECsw remain close to 1.00 for ditches and streams, a marked increase in conservatism is apparent for the pond systems with PECsw ratios of up to 1.38 - 1.41 for all compounds tested. It is noteworthy that the impact assessment should not only consider simple peaks but also the impact on patterns of exposure (duration and frequency of exceedances) as these increasingly feature in ecotoxicological contextualisation of risk. Whilst the increased depth of pond systems versus ditches and streams means that they are typically less problematic in risk assessments, the distinctive nature of the exposure patterns in these systems also needs to be taken into consideration. The increased potential for exposure in these systems for the acknowledged pragmatic handling of drift is likely to lead to unanticipated difficulties with accumulation that should be considered with greater context presented. Unfortunately, unlike the other scenarios, no graphs are presented for ponds to allow for consideration of impact, with only a general statement that ""...these concentrations are always significantly below the respective stream scenarios"". In the context of pattern based risk assessments where duration and frequency of exceedance are critical the pond scenarios can present challenges on their own and should be characterised more completely. Line 3051-3135: The assessments presented here focus entirely upon water phase exposure and do so with the confounding influence of other routes of entry such as run-off and drainage. It is suggested that an assessment is presented for ""drift-only"" and includes a presentation of the ratios that emerge for the PECsed values and associated comparative patterns of exposure to more clearly investigate the impact in an essentially static compartment. EFSA: Dependent on the scenario and the type of end-point the originally suggested approach might be indeed too conservative. Therefore, the methodology has been changed without losing the advantage of having only

				one run instead of two (single and multiple). Only for the last application the 90th percentile is considered whereas for the previous applications within a season the traditional percentages will remain. The entire appendix will be revised accordingly.
189	Enviresearch Ltd	UK	Appendix I	It is not acceptable to have a 40% uplift on the pond concentrations solely for the sake of simplicity. Such a decision should be based on scientific realism. Lines 3098 to 3110. If a farmer decides to apply only once per season, then the background concentrations are in reality lower at the time of this application. This is accurately reflected in the simulation with the current system. If the farmer applies six times, then the background concentrations can be higher. Adding drift to the background concentration from six applications using the 90th percentile drift value for all of the six applications is inconsistent with the underlying probability distribution of drift. It is possible that, by chance, one of the six applications corresponds to the 90th percentile drift whereas the other five applications have different drift values. But this would not happen in all 20 years. EFSA: Dependent on the scenario and the type of end-point the originally suggested approach might be indeed too conservative. Therefore, the methodology has been changed without losing the advantage of having only one run instead of two (single and multiple). Only for the last application the 90th percentile is considered whereas for the previous applications within a season the traditional percentages will remain. The entire appendix will be revised accordingly.
190	Swedish Chemicals Agency	SW	Appendix J	3146-3157, p. 129: We appreciate these improvements, in particular to add crops to scenarios. We suggest that the WG consider to also add the following improvement which would facilitate the evaluations: Generation of one model file that contains all relevant input parameters for PECsw/PECsed-calculation and the results, e.g. adding parameters only relevant for MACRO or PRZM (e.g. DT50 in soil, wash-off factor, etc) to the TOXSWA-summary file. EFSA: Thank you and noted. In the new sum output file of TOXSWA some additional input parameters, not relevant for TOXSWA have been echoed, e.g. crop, crop interception at all application dates.
191	Institute of Environmental Protection - National Research Institute	PL	Appendix J	Please consider the revision of the second part of the recommendation 7, i.e. that stating "[...] and express the PECsed in mg/kg dry sediment mass instead of mg/L sediment volume." ant present the modelling tool provided PECsed values in mg/kg, not in mg/L, therefore that recommendation looks a it strange. EFSA: The WG does not understand what is suggested to be changed.
192	Enviresearch Ltd	UK	Appendix J	It would be sensible to have a protocol for third-party applications to show that they are compliant with SWASH requirements. This may help to ease the problem with run-times. EFSA: This request is considered outside the remit of the WG.
193	TSG consulting	UK	Appendix J	Line 3142 – 3145 There would need to be consideration of the effect of daily temperature implementation in TOXSWA on the currently used method to estimate aquatic metabolite formation in the upstream section of the stream scenarios. This upstream correction factor for aquatic metabolites is currently based on annual average scenario

				temperatures rather than a daily timestep. Given the now longer length of weather data proposed this methodology for upstream correction factor calculation will need revision anyway as the currently utilised scenario average temperature will be changing purely on the basis that there is now a much longer period of weather data EFSA: The WG has written additional text on the way the upstream correction factor has been calculated. Note that each FOCUS stream scenario has its own correction factor, that is fixed over the entire simulation period, depending on (over the 20 years evaluation period): (i) the most conservative hydraulic residence time in the upstream catchment and (ii) the formation time for maximum metabolite formation. The formation time is a function of the transformation rates of the parent and the metabolite which on their turn depend on the average temperature in the water of the upstream catchment. We expect that the average temperature will not change much by substitution of monthly by daily temperatures. Average temperatures did not change much: the largest difference found between the average temperature for the 12/16 months period and the 20 years was 1.4 ºC for the D5 scenario. The hydraulic residence times used did not change except for D2 where 107 d instead of the former 90 d was used. (Note that 107 d represents the last-but-one most conservative residence time; the most conservative one was discarded, being considered too extreme (186 d).)

References

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EC (European Commission), 2009. Regulation (EC) No1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309/1, 24.11.2009, p. 1-50.

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