Webinar on revision 4 of the Pesticide Residues Intake Model: Q&A Report

Methodology and Scientific Support Unit

N	CATEGORY	QUESTION	REPLY
1	General	During the beta testing it is clear that we will be able to test how the v4 works and review the format of the result outputs. It is however unclear how we will be able to test if the calculations are done correctly in line with risk assessment principles. Several calculation bugs in PRIMo v3.0, v3,1 and the 2017 livestock tool have been reported via ASK EFSA in the past. It is unclear how we could contribute similarly for v4.	Although PRIMo 4 has been subject to extensive validation and testing, risks for bugs and inconsistencies can indeed not be completely excluded. The draft Technical Report that will accompany the beta-tool, describes the methodology applied in PRIMo 4 and annexes to the report will provide details on the underlying data. This should allow stakeholders to verify the outcome of the calculations during the public consultation.
2	General	Apart from food and human impact, will the tool also calculate impact on animal feed, animals and products of food-producing animals (e.g. milk, meat, etc.)?	As for PRIMo 3, the new release of PRIMo is only intended for calculating human dietary exposure through food (incl. foods of animal origin). A dedicated livestock dietary burden calculator is available to estimate exposure of livestock through feed.
3	General	Would it be possible to organize a similar webinar for those who only use PRIMo for post-authorisation risk assessment?	A first general webinar was organised in view of the public consultation. When the final tool will be released, additional webinars may be organised depending on the feedback received from the different stakeholders during the public consultation.
4	Accessibility	Will access to the online tool be open or will it be given by request (with login and/or password)?	The tool is freely accessible through self-registration. The registration is only required in view of user management. The tool is, however, available to any interested stakeholder, without any restrictions.
5	Accessibility	If companies enter data and do analysis a database is being built of all assessments. What will EFSA do with all such data?	EFSA will not store any information uploaded by third parties. Users will be able to upload the input data and download the output data. After closure of the session, the data are deleted.

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6	Accessibility	Why will you need a login + password for the tool? Tool must be publicly accessible for everyone	See reply to question 4.
7	Accessibility	Good morning ... will server downtimes be published in advance?	This is currently not possible for technical reasons, but EFSA would indeed support such practice.
8	Accessibility	Can login to open.EFSA used in the login, or new account has to be created?	Yes. You can use the same credentials for accessing both platforms.
9	Accessibility	If the name of the active substance is mandatory, how is the data protected? Does EFSA have access to any of the generated inputs and results?	See reply to question 5.
10	Accessibility	Good morning, considering that you need to be logged in to use the model, will there be some form of 'history', saving models created previously? Or will it be necessary to create them anew every time?	No. This is currently not possible. For the time being you will need to download results locally, but they are made available in a format that can be easily uploaded when starting a new session.
11	Accessibility	Will all risk assessments performed in PRIMo 4 be visible to EFSA, or can the output be saved locally?	See reply to question 5.
12	Accessibility	Is collaborative work possible? (e.g. different persons from the same company or persons from different companies)	No. This is currently not possible.
13	Consumption data	Will dietary surveys from the UK also be included?	No. As the UK is no longer part of the EU we are not allowed to include the UK dietary surveys in this tool.

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14	Consumption data	As consumption data are updated over time, will it be possible to select the consumption data that were current at the time the assessment was conducted? This is currently possible by using older versions of PRIMo and is helpful to understand older assessments.	In the future, PRIMo will be managed through a versioning system. When major versions will be released (e.g. when new consumption surveys are integrated), the versions will be made available in parallel.
15	Consumption data	Will data about food consumption from Bosnia and Herzegovina be included?	The dietary survey for Bosnia and Herzegovina was submitted to EFSA recently, and the data have not yet been converted to raw primary commodities (RPCs). EFSA is currently working on a revision of the RPC model that will be applied to the latest surveys. Meanwhile, PRIMo 4 cannot take into consideration those data.
16	Consumption data	Is the list of recipes and list of yield factors available outside of the tool?	Yield factors applied in PRIMo 4 will be reported in Annex D to the Technical Report. Further information on the conversion of consumed foods to raw primary commodities (incl. recipes) can be retrieved from a dedicated report on the 'Raw primary commodity (RPC) model: strengthening EFSA's capacity to assess dietary exposure at different levels of the food chain, from raw primary commodities to foods as consumed'.
17	Consumption data	To cover all- EU countries, do you use their previous consumption data of PRIMo 3?	No. Whereas PRIMo 3 relied on summary statistics of consumption reported by Member States, PRIMo 4 relies on EFSA's Comprehensive Database, where consumed amounts were converted to corresponding amounts of raw primary commodity. Although some surveys might overlap, these consumption data are not the same. An overview of the dietary surveys considered in PRIMo will be reported in Annex A to the Technical Report.

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18	Consumption data	Why we use only 2 days for chronic exposure?	It is acknowledged that the use of dietary surveys with a limited number of survey days may lead to an overestimation of the higher percentiles. However, in accordance with EFSA's Guidance on the use of the EFSA Comprehensive Database in exposure assessment, a minimum of 2 survey days was considered for chronic exposure assessment. This criterion is applied transversally across domains of EFSA. When more than 2 days were recorded in a national survey, this is also considered acceptable.
19	Consumption data	Statistically how representative is a database population of 100,000 compared to an EU population of approximately EU population of 447 million? Is it correct to start trying to draw out high percentiles etc?	Dietary surveys are conducted at national level, and it is Member States' responsibility to ensure representative sampling within their dietary surveys. The available data do not represent the whole EU population because some countries (or age classes within a country) are not covered by the available data. However, considering the wide coverage of countries and age classes, the data are considered adequate for an EU-wide assessment. When data are not sufficient to derive a reliable percentile (e.g. P97.5), EFSA uses the principle of the highest reliable percentile, i.e. the highest percentile that can be reliably estimate with the available observations.
20	Consumption data	Which Unit weights are used?	Unit weights considered for the IESTI equation will be published in Annex C to the Technical Report.
21	Consumption data	For chronic assessment, 2 survey days per subject may be used. This might be less representative for actual long term chronic exposure. To which extent does overestimate the chronic exposure at the higher percentiles?	See reply to question 18.

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22	Consumption data	Is it possible to extract the amount of consumed food that was considered in the calculation?	It will not be possible to extract amounts of food consumed at individual level, but summary statistics of the RPC consumption database will be made available as an annex to the draft Technical Report that will accompany the tool for public consultation.
23	Consumption data	Where can I find the large portion, the body weight etc of the survey?	Large portions considered in PRIMo 4 are already normalised by body weight. Summary statistics on the acute consumption of the different foods is reported in Annex F to the technical report, Table F.3. See also reply to question 22.
24	Consumption data	Which criteria must nutrition studies fulfil in order to qualify for PRIMo?	PRIMo 4 relies on the dietary surveys included in the EFSA Comprehensive Database. When new dietary surveys are integrated into the database, they need to comply with EFSA's Guidance on the EU Menu Methodology.
25	Consumption data	Are data from the latest Italian national dietary survey - IV SCAI ADULT and IV SCAI CHILD implemented in the PRIMo 4? Thank you.	The latest Italian dietary surveys (IV SCAI ADULT and IV SCAI CHILD) were submitted to EFSA after March 2018 and have not yet been converted to raw primary commodities (RPCs). EFSA is currently working on a revision of the RPC model that will be applied to the latest Italian surveys. Meanwhile, PRIMo 4 relies on the previous Italian dietary survey INRAN SCAI 2005-06. See also reply to question 15.
26	Consumption data	We do understand the decision to exclude the UK. Regarding the import and export to the UK. Can this be reconsidered?	No. This results from the EU-UK Withdrawal Agreement and cannot be reconsidered by EFSA on its own initiative. Only dietary surveys for Northern Ireland might be integrated in future versions of PRIMo, if available and reported to EFSA. See also reply to question 13.

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27	Food classification	It was mentioned that fish data will be included in PRIMo 4 - will fish also be included in Reg 396/2005?	The update of Regulation 396/2005 does not fall under EFSA's remit. We only provide the option to calculate exposure to fish and fish products. How this is implemented in the regulatory process, is to be discussed and agreed with risk managers through comitology procedures, i.e. European Commission and Member States representatives.
28	Food classification	Is the list which allows the conversion between legislation Matrix code and RPCD FoodEx2 code available?	Yes. This mapping is available in the Excel template for data entry (also available as Annex B to the Technical Report).
29	Food classification	The 396 coding is sometimes difficult to evaluate the hierarchical structure. Would it not be easier to use 2 digits for each level?	The regulatory codes defined under Regulation (EC) No 396/2005 do not fall under EFSA's remit and can therefore not be revised within this framework.
30	Data entry	What about Variability factors?	You can insert specific variability factors during the data input process, under the RPC occurrence data.
31	Data entry	What is 'use pattern' here? What for?	The use pattern refers to the type of pesticide application, i.e. pre-harvest, post-harvest, etc. Although this still needs to be implemented in the final version of PRIMo 4, this field will be used to define the correct IESTI case in case of a post-harvest treatment.
32	Data entry	Are standard settings available for raw products? There are a lot of fields to be filled.	Only the RPC FoodEx2 Name, the STMR and the HR are mandatory fields. Other fields are only provided for information or refinement of the calculations.
33	Data entry	Can't the entry of STMR be optional? Often we enter the MRL and calculate STMR only if a refinement is necessary	In this case, we suggest entering the value of the MRL in the STMR field and indicate in the comment field that the MRL was used.

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34	Data entry	As a commercial laboratory we provide risk assessments per sample. Which 'default' information is recommended to be used? It is impossible to calculate for all sorts of consumers	In this case, we suggest inserting the measured concentration in both the STMR and HR fields. The tool will then calculate both chronic and acute exposure associated with that specific sample. If a sample is intended for the European market, we consider that exposure to any subpopulation is relevant, and the most critical subpopulation is usually considered for decision making. However, users can filter out countries and age classes of interest if deemed relevant.
35	Data entry	It seems it is not possible to enter directly PF. This would be a good option.	While the importance of processing factors is acknowledged, it is noted that residue concentrations in processed/peeled commodities may also be derived from measurements (instead of applying a processing factor). The estimated concentration in the processed/peeled commodity was therefore considered more adequate. When PRIMo will be connected to other data sources in the future, specific protocols for importing and transforming the data may be considered on the basis of the data available.
36	Data entry	Will there be a way to input data for whole crop groups? (e.g. citrus fruit) - or do you have to add inputs for each individual commodity?	Yes. When uploading the data using the Excel template, input data for a crop group will be propagated to the specific commodities.
37	Data entry	How to use PRIMo Rev. 4 for risk assessment in case of MRL non-compliances found in official food control?	In this case, we suggest inserting the measured concentration in both the STMR and HR fields. The tool will then calculate both chronic and acute exposure associated with that specific sample.

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38	Data entry	For transparency, usability and error-reduction, it would be highly desirable to be able to add PFs directly into unique fields (like PRIMo v3.1) instead of needing to add STMR-P / HR-P values directly. Could this improvement be made?	See reply to question 35.
39	Data entry	There is not a way to include the whole data manually in a list- as done in previous version? Manually means to include the info per each commodity in the way explained in the presentation?	When uploading the data using the Excel template, lists of data can be copied and pasted in the Excel file prior to upload. See also reply to question 36.
40	Data entry	When the consumer risk assessment by using the MRLs is more than ADI, can we always use the STMRs?	Yes. The use of STMRs is also possible.
41	Data entry	For the Excel data upload, we seem to be losing usability compared to PRIMo v3.1 (where different columns are used for e.g. residue data, PFs, CFs). In v4 we have a single column for the finalised residue data so we would have to update every cell if, for example, we wanted to adjust the value of a CF. Could an improvement to support different columns for different residue data types be made?	We encourage stakeholders to provide this type of comments during the public consultation. Based on the comments received, possible modifications to the tool will be considered.
42	Data entry	Can you enter a substance which does not have a ParamCode or ParamName assigned yet?	Yes. You can leave the ParamCode empty and add the name of the substance as free text.

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43	Data entry	Where to insert residues from rotational crops? Difference from primary uses and uptake from soil should be easily identifiable	The primary purpose of PRIMo is to assess dietary exposure to pesticide residues. It is not intended to assess the residue behaviour of the pesticides. Nevertheless, depending on the outcome of the public consultation, if there is a clear interest in identifying entries originating from crop rotation, the drop-down menu for the use pattern may be adjusted accordingly.
44	Data entry	Is it possible to enter experimentally derived variability factors?	See reply to question 30.
45	Interoperability	Is it possible to request the data for example webapi connection or equal, which we can automatically connect?	This is currently not yet feasible for security reasons. However, we have taken the first crucial step to develop the web-application and we will explore how interoperability with other tools and databases (incl. webapi) may be improved.
46	Interoperability	Will there be an API available in order to connect other systems to retrieve the evaluation?	See reply to question 45.
47	Interoperability	Will the model also use data retrieved from the FEIM and FAIM models?	The Food Enzymes Intake Model (FEIM) and the Food Additives Intake Model (FAIM) were developed for other regulatory domains with specific requirements. PRIMo 4 can therefore not use data generated by those models. However, the underlying dietary surveys are aligned between all models.
48	Interoperability	Are median processing factors from EU database automatically included in the calculation?	No. This is not yet possible but interoperability with other databases (incl. the EU Processing Factor Database) will be explored in the future. See also reply to question 35.

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49	Interoperability	Could HBGV be imported automatically from EU pesticides database?	A direct connection to the EU Pesticide Database is currently not possible because this database is not managed by EFSA and it does not use the same data catalogues. However, EFSA is working together with European Commission to facilitate interoperability in the future.
50	Interoperability	In the RPC Occurrence Data tab, if we know substance and RPC product, why is the MRL not auto-entered from a database?	See reply to question 49.
51	Interoperability	In PRIMo 3 the ARfD and ADI values were automatically suggested including the source. This will no longer be possible?	Although this is currently not possible in PRIMo 4, EFSA will explore possibilities to improve interoperability and retrieve this information from other databases. Meanwhile, it was decided not to include a 'fixed' list of HBGVs in the tool because it may be misleading for users when the list is not up-to-date. See also reply to question 49.
52	Interoperability	Is it possible that PRIMo 4 suggests HBGVs for residues (pre-set). Please be aware that many food businesses are using PRIMo in order to estimate risks of their products. Hence, can it be made user friendly (pre-set HBGV; fewer obliged fields; etc) for quicker assessment?	See replies to questions 49, 51.
53	Interoperability	Direct import of HBGV from a pesticide database may not always be appropriate (cyfluthrin is just such an example).	Indeed, it was decided not to include a 'fixed' list of HBGVs in the tool because it may be misleading for users when the list is not up-to-date. See also replies to questions 49, 51.

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54	Interoperability	Perhaps I missed it: can the Excel output of all MRLs from the EU pesticide database be imported to PRIMo 4?	This is currently not yet possible but an option to re-use the Excel output from the EU MRL database may be explored. Please make sure to provide this feedback during the public consultation if you believe this is an essential functionality.
55	Interoperability	Will it still be possible to copy/paste MRLs from the EU Pesticide database Excel file, as in PRIMo rev.3.1? This would avoid manually entering the current MRLs for each commodity.	See reply to question 54.
56	Interoperability	Will there be a link to the ARfD and ADI values in the pesticide web of the EU?	See replies to questions 49, 51.
57	Interoperability	Why are the MRLs of the EU Pesticide Database not integrated in PRIMo 4 RPC Occurrence tab, as they now need to be entered manually?	See reply to question 49.
58	Interoperability	Similar question, why are ADI and ARfD not auto-filled for the commodities?	See replies to questions 48, 49.
59	Interoperability	Why cannot be the PRIMo tool directly linked to the MRL values to perform the calculations clearly with the update value of MRL?	See reply to question 49.
60	Interoperability	Will Rev.4 contain Conversions Factors for those active substances for which the definitions of residues (for enforcement and risk assessment) are different?	This is currently not possible. However, EFSA will explore possibilities for improved interoperability with other databases (provided this information is available in a database). See also reply to question 49.

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61	Methodology	Which model is used to obtain chronic exposure distribution?	PRIMo 4 calculates chronic exposure of each individual subject surveyed, by multiplying the occurrence data (i.e. the concentration of the residue reported as Supervised Trial Median Residue, STMR) with the amount of food consumed by each individual, averaged over the surveyed days and divided by the individual's own body weight. By calculating the total chronic exposure for each individual subject, a distribution of chronic exposure estimates is obtained per population class, country and survey combination, allowing users to explore the variability of exposures within each population. Further information will be provided in the Technical Report.
62	Methodology	Noting that 'acute assessments will be normalised for individual consumption amounts and body weights', does this mean that PRIMo v4 will be able to identify the 97.5th percentile exposure individual from a survey, rather than combining mean body weights and 97.5th percentile Large Portions? If so, will that be used for IESTIs, and will PRIMo v4 be able to re-identify the 97.5th percentile exposure individual in case a measured Variability Factor is provided?	Indeed, rather than considering one standardised large portion combined with an average body weight, PRIMo 4 considers the consumptions and body weights at individual level. However, the IESTI equations are still applied, and it will be possible to insert a measured variability factor if available.
63	Methodology	How will Rev.4 handle left-censored data?	PRIMo 4 relies on the estimated concentrations in the different food items, i.e. STMR and HR estimates. How these estimates are obtained, incl. the handling of left-censored data, does not fall within the scope of PRIMo 4.

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64	Methodology	What about IESTI new?	The revision of the IESTI equation is not within the scope of PRIMo 4. If the IESTI equations are revised in the future, PRIMo will be updated accordingly.
65	Methodology	The way IESTI equation is used in PRIMo 4 seems rather different from PRIMo 3. Was it discussed at EU level?	The main differences compared to PRIMo 3 is that the large portion is now normalised for individual body weight and that acute exposure can now be calculated for a wider range of processed foods. These adjustments are scientifically justified but stakeholders will have the opportunity to comment during the public consultation.
66	Processed foods	Will processed commodities be taken into account for chronic consumption as well as acute?	Yes. Processed foods are considered for both.
67	Processed foods	Can the list of processing factors for different products be shared separately?	The PRIMo tool does not include processing factors, but it considers yield factors for the different processed foods. The yield factors applied in PRIMo will be shared in Annex D to the Technical Report.
68	Processed foods	What if PF is not defined, for RPCD assessment?	If a processing factor is not available and residue concentrations in the processed commodity cannot be estimated, PRIMo 4 applies a worst-case approach, assuming that all residues present in the raw primary commodity will migrate to the processed foods. This approach can then be refined when specific data are made available.
69	Processed foods	In the RPCD occurrence tab, why is 'beet molasses' not listed as a derived product of 'sugar beet root'?	This is because consumption of sugar beet molasses has not been captured by the available dietary surveys. This may be due to a low frequency of consumption or because the options for reporting at that time were not sufficiently detailed.

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70	Processed foods	How is drinking water incorporated in view of re-constituted juice concentrates, soft-drinks or beer?	PRIMo 4 does not consider composite foods to avoid double counting. Beverages were therefore disaggregated into drinking water and other ingredients.
71	Processed foods	Is there any intention to align the processed commodities in PRIMo with the requirements of OECD 508?	The processed commodities listed in OECD 508 do not provide the same level of detail as the processed commodities defined by FoodEx2. Therefore, it would not allow the same level of refinement for the assessments. However, a mapping of the information may be explored if considered relevant by stakeholders.
72	Reporting	With the move to web-based software we may lose the ability to clearly follow the way the equations work. This would make it difficult to check that the equations are working as intended with respect to established risk assessment principles. Will PRIMo v4 be able to export tables of data/equations/results in an Excel format for the user to be able to peer review results?	Detailed tables are included in the reports. Further information on the equations applied and on the underlying data are also reported in the accompanying Technical Report (incl. annexes). See also reply to question 1.
73	Reporting	Will the results be automatically included e.g. in EFSA connect account and saved? Or it will just have to be download and included in the dossier?	No. This is currently not possible. For the time being you will only be able to upload the input data files and download results for integration in your workflows/dossiers. See also reply to question 10.
74	Reporting	When you complete the assessment, does it get saved/can you save it or do you have to download the results?	See replies to questions 10, 73.

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75	Reporting	With PRIMo 3 it was possible to download the RAs conducted by EFSA during A.12 reviews as Excel from OPEN EFSA. Will this be possible with PRIMo 4?	The input and output data can be downloaded in an Excel format and can therefore be made available in the same way results obtained with PRIMo 3 were shared.
76	Reporting	Is a distinction of results by country/consumer group still possible?	Yes. Results are provided per country and age class.
77	Reporting	As far I can see only the 'Graphical output' cannot be exported ... why?	Graphical outputs can also be exported under the option 'Generate Report'.
78	Reporting	For refinements? A new report should be generated?	If it is the user's intention to report results for a baseline scenario and a refined scenario, two report can be generated. However, this is not mandatory and users can also generate a report only when all refinements have been implemented.
79	Reporting	Can the generated report be shared online?	Reports cannot be shared directly through the tool. Reports can be downloaded locally and subsequently shared through other channels as needed.
80	Reporting	Is it possible to select a population group or select a single country to do the calculations?	No. Calculations are carried out for all countries and age classes, but results can be filtered for the subpopulation of interest.
81	Reporting	Since we are adding ADI/ARfD values up-front, and users are likely to want to know if their risk assessments pass or not, would it not make sense to have results presented as %ADI / %ARfD by default? The availability of results on a per/kg BW basis is welcome but perhaps it would not be most common use case.	This may be considered based on the feedback received. Please make sure to provide the feedback during the public consultation.

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82	Reporting	How are the results of the assessment included in the submitted dossiers?	Results can be downloaded locally, and subsequently integrated in your workflows/dossiers. See also replies to questions 10, 73.
83	Implementation	Drinking water - can PRIMo be used for registration purposes and which data can be used? PECgw values? And what about relevant metabolites for which intake was calculated as a part of Registration Report, Part B10?	The use of PRIMo 4 for performing the risk assessment for groundwater needs to be discussed with risk managers. It should be highlighted that the consumption data for water implemented in PRIMo 4 are based on data submitted in food surveys. Hence, these data would allow a more robust exposure assessment than using default consumption data.
84	Implementation	Which percentile of the distribution will be used at regulatory level?	In PRIMo 4, exposure calculations will be provided that are performed according to the current methodologies (with some modifications due to the fact that the calculations will be performed for the individual consumers for which we have consumption data in the EFSA Comprehensive food consumption database). The results will be reported for the agreed percentiles (i.e. P97.5 for acute exposure; if the number of consumers was not sufficient, alternative percentiles will be reported). For the chronic exposure assessment, the mean exposure for the individual population subgroups will be reported. As the calculations are performed with the individual consumption data (instead of a point estimate for the large portion or the mean consumption of a population subgroup), more information on the distribution of the exposure will be available in PRIMo 4, which could be used for taking regulatory decisions. However, discussions at risk management level are still required to agree whether the additional results provided in PRIMo 4 should be used for regulatory decisions.

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85	Implementation	Which percentile of the distribution will be used at regulatory level?	See reply to question 84.
86	Implementation	Which percentile of the distribution will be used at regulatory level? What if the mean value below the reference dose and the highest percentile is exceeding the reference dose? The highest percentile still representing the whole population despite the mean value present?	See reply to question 84.
87	Implementation	Since the public consultation is going to start next week, what is the estimated timing of replacing V3 with V4?	The final decision on the implementation of PRIMo 4 to be used for regulatory decisions requires an agreement with risk managers. The decision on the implementation date will be taken together with risk managers. We are confident that PRIMo 4 will be used soon, because we think that the improvements of PRIMo 4, in particular the use of a more comprehensive food consumption database, will provide robust information for taking decisions on MRLs. However, the final decision is not in EFSA's hands.
88	Implementation	When a big difference among the highest and lowest ingestion is reported, as the case explained in the presentation, how it should be considered for the risk assessment? Only the mean value will be considered for the evaluation?	It is current practice that MRLs are set if it is demonstrated that they do not pose a risk for any subgroup of the European population. It is not expected that this general principle, that should ensure that MRLs are safe for all European consumers, will not be used in future.

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89	Implementation	Will EFSA be publishing clear acceptance criteria. As asked before what happens if some surveys fail - how many would lead to an overall failure. If this is not clear, then you may have one model but Member States will have the potential to make individual conclusions or have specific requirements etc.? Is EFSA instructing Member States to up-scale their dietary exposure experts as it seems likely review time will be massively increased based on the new model?	See reply to question 88.
90	Implementation	At the beginning of the presentation, it has been mentioned 'drinking water' as new commodity in PRIMo 4, which data should be used to calculate the dietary risk assessment for water? And what about metabolites that are taken in consideration in PECs calculation? Those will be introduced in residue definition for drinking water?	The decision on the most appropriate input values for the exposure assessment for water will be discussed further with risk managers and experts assessing the residues in drinking water. See also reply to question 83.
91	Implementation	Which output will be required to be included in submission dossiers? Currently it is just the results table.	The calculations performed by an applicant need to be reproduceable. Hence, the report derived in PRIMo 4 should be submitted with the application.
92	Implementation	Is this tool to be used from now on? How long can the rev 3.1 be used for PPP dossiers?	See reply to question 87.

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93	Implementation	Have comparisons of exposure using Primo 3.1 and PRIMo 4.1 been made with a given set of data?	We performed comparative assessments with PRIMo 3.1 and PRIMo 4. For some food commodities, the exposure calculated with PRIMo 4 will be higher, but there were also other cases, where the calculations with PRIMo 4 gave lower results. In case PRIMo 4 gives higher results, we may have the possibility to perform more refined calculations (e.g. including information on processing studies) which we did not have in PRIMo 3.1.
94	Implementation	Have you compared the results from using PRIMo v3.1 and V4?	See reply to question 93.
95	Implementation	What is the purpose for the chronic exposure assessment in presenting the HRP maximum? Surely the distribution is irrelevant in the context of regulatory decision making?	See reply to question 84.
96	Implementation	In the case where a substance was authorized with PRIMo rev.3.1 (so the risk was acceptable) but no longer passes with PRIMo rev.4 in the framework of a dRR, will it be possible to justify that it is the new method of calculation that leads to this result and therefore that the use of the dRR is still acceptable?	The same issue occurred when we switched from PRIMo rev. 2 to PRIMo rev.3 and rev. 3.1. The difference with the introduction of PRIMo 4 is the fact that we will be able to perform more refined risk assessment for processed products which may help to solve some of the problems identified. In general, a risk management decision will be taken if the intake concerns identified with the most recent version of PRIMo trigger a re-evaluation of the MRL.
97	Implementation	When the new PRIMo 4 will be mandatory?	See reply to question 87.
98	Implementation	When the use of new PRIMo 4 will be mandatory?	See reply to question 87.

N	CATEGORY	QUESTION	REPLY
99	Implementation	Do you have provisional / "aspirational" timeline for completion of consultation processes and implementation of PRIMo 4 for supporting regulatory submissions?	EFSA has explained the roadmap for finalising PRIMo 4 and the technical report. EFSA will support the follow-up actions at risk management level, but EFSA is not in a position to define the timelines for the actual implementation of PRIMo 4. See also reply to question 87.
100	Implementation	A lot of risk management decisions are still to be taken. Will these be clarified before implementation?	A clear implementation plan for the new PRIMo revision is essential. The dialogue with risk managers to decide on the use of PRIMo 4 is expected to take place in the framework of the PAFF committee meetings and the conclusions will be clearly communicated.