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DIETARY EXPOSURE IN RELATION TO MRL SETTING: DISCUSSION PAPER ON THE ADOPTION OF PROBABILISTIC METHODOLOGY FOR THE PURPOSE OF THE CODEX MRLS SETTING

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Australia, Canada, Denmark, France, Germany, Sweden, US, The Netherlands, WHO, EU, International Banana Association, CropLife International

Introduction

1. Exposure to acutely toxic compounds has received increasing attention since the early nineties of the last century. It was soon realized that this requires a different evaluation of both the toxicology of and of the exposure to these compounds. For this reason the acute reference dose (ARfD) has been introduced in 1993 by the JMPR as the toxicological parameter for assessing an acute exposure. In the following years this concept has been further refined, lastly by the 2002 JMPR.

2. The issue of how to assess the intake has also evolved considerably since the earliest international acknowledgement that a specific approach is needed (FAO/WHO consultation, May 1995, York). The 1997 Geneva FAO/WHO Consultation on food consumption and exposure assessment of chemicals developed methods for the acute exposure assessment and recommended the use of the point estimate approach to assess a short term intake level (IESTI or NESTI). At the same time the meeting recognized the usefulness of a probabilistic approach for assessing short-term exposures, but concluded that application of probabilistic techniques at the international level would only be possible after the development of these techniques and the necessary databases to use them (especially adequate food consumption data bases, containing short term consumption data). The concept of the point estimate was since then further refined by the JMPR, lastly in 2002. The methodology used can be viewed at the website of the JMPR.

3. The concept of the point estimate is based on the idea that exposure to high level residues and high level consumption is unlikely to occur for various foodstuffs at the same short time period, so the exposure estimation can be performed by calculations based on exposure to separate foodstuffs. In order to estimate the highest possible exposure in relation to the evaluation of an MRL based on GAP, national contributions about high consumption levels of foodstuffs are used. These are then combined with a possibly occurring high residue level. These levels are derived from field trials under GAP conditions. In the international exposure assessment performed by the JMPR, the highest national consumption level (selected as the 97.5th percentile of the distribution) for a foodstuff is combined with the highest residue found in the supervised field trials. Because it had become clear that residues in individual items of a commodity can have higher residues than those found in a composite sample, as normally analysed, the variability factor was introduced

in the calculation to take account of this aspect. It will be clear that the accumulation of these various high levels leads to a sort of assumed maximum exposure level. The likelihood of occurrence of such a maximum exposure level has however until now not been taken into consideration.

4. The results of point estimate calculations by the JMPR exceeded the ARfD for a number of pesticide-commodity combinations and caused problems for the CCPR in deciding about the acceptability of existing or proposed Codex MRLs. When probabilistic exposure assessment methodology was introduced in some countries for decision-making about the acceptability of MRLs, often results were obtained which are rather different (usually much lower) in relation to the point estimate results of the JMPR, resulting in different national decisions on these items. It was suggested that probabilistic methods for exposure assessment are useful for obtaining a more complete picture of the dietary intake of residues. This implies that the Codex methodology may be unnecessarily restrictive and that the international guidance given by this point estimate method may be questioned. The 33rd CCPR therefore requested further information about this probabilistic methodology and about the possibility to use it for Codex purposes.

5. The 34th CCPR (2002) discussed the probabilistic approach to acute dietary exposure analysis and its applicability at the international level (ALINORM 03/24, para 33-39). This matter was extensively elaborated in CX/PR 02/3-Add.1. It was concluded that the probabilistic methodology can lead to a better general assessment of the exposure than deterministic point estimates and deserves to be promoted both nationally and internationally. It was acknowledged however that the necessary data to apply Monte Carlo methods on an international basis are not yet available and that procedural decisions regarding the application of probabilistic methodology for international purposes need to be taken. Therefore point estimates remain to be used in an international context as the primary applicable methodology for international acute exposure assessment and the basis for international risk management decisions. The Committee agreed that there was a need to improve the current methodology used for point estimates. The Committee requested the preparation of a paper containing proposals on the improvement of the current methodology and proposals on risk management options for MRLs of acutely toxic compounds, for consideration by the next session of the Committee.

6. The 35th CCPR discussed a paper (CX/PR 03/3) on proposals for improved methodology for point estimates of acute intake of pesticide residues. This paper suggested some possibilities of improvement of point estimates. It was also suggested that the differences between results of point estimates and probabilistic assessments are related to the probability aspects of the reported results. The conclusion in the paper was that probabilistic assessments could increase insight in the acute intake of pesticide residues. The Committee decided among other things (ALINORM 03/24A, paras 20-31) to install a Working Group to prepare a paper considering the adoption of probabilistic methodology for international acute intake estimations. This should include working examples of probabilistic calculations for some compounds for which compound-commodity combinations exceed the ARfD in international point estimates. These probabilistic calculations should use the same parameters (field trial data, consumption data, influence of processing and variability) as those, which were the basis of the JMPR, point estimates. The Working Group should also discuss and propose parameters to be used in probabilistic calculations at the international level.

7. The 35th CCPR was informed that a FAO/WHO Consultation on intake assessment including considerations related to probabilistic modelling and improving deterministic approaches was planned, as part of its project to up-date the principles and methods for the safety assessment of chemicals in food. This Consultation has not yet taken place. The Committee was also informed that an IUPAC project on acute dietary assessment was close to completion; this would summarize the state of the art for assessment methods and would include proposals for improving the currently employed deterministic approach. The final IUPAC report was not yet published at the time of writing this paper, but a finalised version has been used as far as possible and where appropriate in the preparation of this paper.

8. The Working Group, consisting of representatives from the Netherlands, Australia, Canada, Denmark, France, Germany, Sweden, the EU, the USA, WHO, Crop Life International and the International Banana Association, established a working programme aimed at presenting a broad overview of the possibilities of probabilistic methodology for acute intake assessments. In order to facilitate a general understanding of the methodology, and to ensure that calculations are made in a comparable manner, the Netherlands opened a website to enable probabilistic calculations (http://www2.rikilt.dlo.nl/mcra/mcra.html) as already made public in a Room Document at the 2003 CCPR. Countries can upload their national consumption and field trial data, or monitoring data, using this same software to achieve comparable results. Also, training was provided to ensure proper use of the calculation programmes. The results of the various national calculations

made with this method are enclosed in the annexed report. The discussion paper, which is provided here, is to a large extent based on these results and on comments on the first draft of the Working Group members about the best way to proceed with the outcome of probabilistic assessments in the CCPR.

Review of the results of the probabilistic exposure calculations and of the parameters used

9. The results of the probabilistic exposure calculations are extensively mentioned in the annexed report. For the calculations presented, reliable national consumption databases were included, and as agreed within JMPR and in the CCPR, only the residue data of acceptable field trials performed under the highest internationally notified GAP conditions of pesticide use have been used. This implies that the calculated exposure results are usually much higher than the average national situation, which can be better assessed by using monitoring results of foods, as they are available on the market. The effects of further industrial or household processing of foods are usually not included. Bearing in mind that the results presented are most likely a gross overestimation of actual intake patterns, they can be considered a suitable basis for discussions on their possible use in risk management.

10. The assessment results are presented in the report as national point estimates based on the agreed principle for point estimate calculation. For comparison purposes, the JMPR point estimate result is given, and the results of probabilistic assessments (in this case Monte Carlo Risk Assessments, MCRAs) at various percentiles, both for the total population and for the whole group of children, and also for the consumers only group of the total population and of the children, respectively. The substance-commodity calculation results that are presented relate to the items requested by the 35th CCPR to be investigated by probabilistic assessment.

11. Regarding the calculation results based on Dutch food consumption data, and on initial calculations with data from some other countries, the following general observations are made. The results show that for the **total population** and for all children, the rise in levels of the probabilistic results is often steep between the 99.9 and the 99.99th percentile, especially for foods that are eaten only by a small percentage of the population. Only for some often eaten foods, the 99.99th percentile of the MCRA approach comes near to the result of a point estimate calculation or may exceed it (as for the second banana calculation for aldicarb). This total population approach gives a good view of the very low probability of exceeding of the ARfD, even when calculated under these overestimated conditions. The **consumers' only** approach gives higher calculated exposures than the total population approach, as expected. This is related to the percentage of the eaters within the total population. For this type of calculation, the results of the 99.9th percentile of the probabilistic risk assessment can reach levels more or less corresponding with the result of the point estimate.

12. Calculations for the exposure resulting from a combination of the mentioned treated commodities (mentioned as "foods together") show that the results on a total population level are often somewhat higher than the highest contributing commodity yields alone, whereas for the consumers only these combination calculations give lower results than the highest contributing commodity alone. This last effect is caused by the "dilution of the result" because more consumers are considered in a calculation of combined exposures than the number of eaters of each specific commodity only. Obviously a calculation of the exposure resulting from all foods that could contain this residue makes only sense when it is done on a total population basis.

13. Further calculations are desirable to assess the effects of including the whole range of residues in which a specific pesticide could occur. The examples show that high exposures resulting from multiple high commodity exposures occur seldom, usually the contribution from one commodity dominates the outcome. This is, however, not a general rule. Sometimes there are significant contributions from more then one food item in the upper part of the exposure distribution, e.g. when the residue has been measured in commonly eaten foods like wheat and potatoes. The probabilistic methodology is the only reliable way to assess complex simultaneous exposure situations with various residue contributions at the same time. In an earlier discussion in the 2002 CCPR (CX/PR 02/4, ALINORM 03/24 para 40-45), about the methodology for cumulative risk assessment, it was already concluded that the probabilistic approach is the only method to assess exposures resulting from a combination of various substances with the same toxic effect. Further exploration and guidance of this concept is recommended.

14. In the annexed report, probabilistic calculations are reported for both the 99.9th and the 99.99th percentile. This is done for comparison purposes, to show the progression in the calculated results. It has to

be mentioned however that the use of the 99.99th percentile is generally not considered suitable because especially the high consumption part of the food consumption databases inevitably contains less reliable figures. Therefore the results of the calculations in the highest percentiles are less reliable and the 99.9th percentile is preferred as a cut-off level for reporting. Higher levels need to be scientifically discussed regarding their validity. This is especially relevant for consumers' only calculations when the number of consumers in the database is low.

15. Refinements might be needed for the calculations performed with the Dutch Food Consumption data. For example calculations were mostly performed with the variability factor used by the 2001 and the 2002 JMPR, whereas this factor was changed by the 2003 JMPR. Revised point estimate calculations were presented by this JMPR. Therefore, the calculations that are shown in the report should be seen only as examples of the relationship between calculations that are performed with the same residue data but with different calculation methods and different consumption databases. The tables 4A and 4B in the report show the difference by applying the old and the new variability factor for aldicarb and carbaryl, which the CCPR has asked to be evaluated by the Working Group. Table 1 shows the relevant calculations (but with the old variability factor) for the Dutch situation. Other relevant calculations with Dutch data mentioned in the report are those for disulfoton, fenamiphos and methomyl (table 5A and 5B). The calculations from some other countries on carbaryl are mentioned in table 6 of the report. Probably, improved calculations can be made at the occasion of the 2004 JMPR.

Discussion of the use of probabilistic exposure assessment results in risk management

16. Risk management decisions on acute intake assessment require clear decision criteria, based on adequate scientific evaluations. It is evident that a probabilistic assessment can provide better insight in the exposure pattern based on a specific residue distribution. The whole residue pattern of the acceptable field trials is used and can therefore result in a more complete risk assessment, while still using the same sources of data as the present point estimate approach. The variability can be introduced as a distribution of the residues on individual units, instead of using only a maximum value. Various situations can be easily calculated; including combined exposure to all treated commodities. This will be useful for gaining insight in the exposure as a whole and for specific cases, which need further consideration. For the CCPR, it is important, however, to agree on a simple scheme for making decisions on specific substance-commodity combinations. The probabilistic risk assessment is from a scientific point of view superior to the point estimate calculation, but requires sophisticated software for the calculations and experienced operators. It could be used either as a second tier to the more simple and easily calculated point estimates, or directly as a first assessment, when the calculation can be performed quickly enough. In order to maintain comparability with point estimates, it is important that calculations are done with the same consumption and residue data as used for the point estimate, to obtain a clear and scientifically acceptable outcome. Because the probabilistic calculations give a range of results and depend on the parameters used, care must be taken to define the parameters needed for sound decision making. Therefore appropriate cut-off points have to be designated for the probabilistic exposure assessment approach that are suitable as a basis for risk management decisions.

17. In order to reach a simple but adequate approach for risk management decisions based on probabilistic exposure assessment results, different options must be discussed. The probabilistic approach is recommended to be used in a tiered approach as suggested for the EU and used in the US. For all examples given in the annexed report a tiered approach was assumed. Within a tiered approach various ways to include probabilistic risk assessment exist. One of the main choices is whether decisions should be based on a total population basis or on a consumers' only basis. From a statistical and general risk management point of view, it is more realistic to use the total population exposure as a basis for decisions. The results that were obtained in this project show that when simulating intake of residues of seldom eaten foods, in the total population approach, the 99.99th percentile of exposure is much lower than the point estimate. The MCRA-results at this percentile level are still rather variable in relation to the outcome of a point estimate for the same commodity. This can be explained by the small number of eaters of specific foods in a database of consumption days. It can be questioned of course if events that occur so seldom should be fully included in risk management decisions. On the other hand, when it is considered essential to exclude high intakes, even when the risk of occurrence is low, an alternative strategy can be considered (see point 17). The use of the total population model for risk management therefore requires a scientific evaluation of the acceptability of risks involved. Risk assessment can, in specific cases, be combined with the results of calculations for consumers only. In the US the accepted approach is to use the 99.9th percentile for the total population, and to additionally address consumers only for commodities eaten infrequently. In the EU this matter is still

under debate; in a recent proposal also the 99.9th percentile is proposed for consideration as sufficient for use as a cut-off point in the evaluation. For consistency and general risk management reasons it seems better to maintain this and to use the 99.9th percentile of (specific groups out of the) total population MCRA-results (based on field trials) as a primary basis for decision-making in the CCPR. This however should then be combined with a strategy for the exclusion or conditional acceptance of risks from potentially occurring higher exposures.

18. An alternative approach which would be more in line with the point estimate approach, is to base decisions on the probabilistic calculation results for consumers only. The consumers' only approach would sufficiently include the public health protection for eaters of foods that are only seldom eaten in the population as a whole. Because the database is smaller here, calculations with a higher percentage than the 99.9th are statistically too uncertain to be included, and this figure could be lower for foods that occur in only a small number of the reported daily consumptions. Some food commodities might even be consumed by only one or two consumers, as seen in particular in the relative small group of children. Depending on the number of field trial data it can be argued, from a statistical point of view, to use the 90th or 95th percentile. In those cases it would be preferable to use consumption data of that particular food commodity from other reliable food consumption databases, available to the JMPR. Please note that in probabilistic exposure assessment these uncertainties are visualised, while in the current point estimates the same uncertainties also exist but remain invisible and consequently unsolved.

19. Disadvantages of the consumers only approach are the following; the exposure of residues via more than one food item cannot be accounted for in a reliable way, residues in commonly eaten food commodities are more likely found to be acceptable than residues in rarely eaten food (floating percentiles depending on the number of consumers), it doesn't fit in a harmonised risk assessment approach where risk from different chemicals have to be equivalent, and it is not consistent with the tiered approach in the USA and the tiered approach currently proposed in the EU. It would be difficult to propose a consistent food safety approach based only on a consumers only approach, because the probability of occurrence of the ARfD-exceedings on which decisions would be based, varies enormously. It would therefore be more valuable to compare results of point estimates and/or consumer only approaches with results of probabilistic calculations on a total population basis. In that way conclusions can be drawn on the statistical possibility of finding high exposures and links can be made to general risk management views on dealing with events with a very low possibility of occurrence.

20. From comments received on a first draft of the annexed report and a first draft of the discussion paper it became clear that the working group is divided in supporters of a total population approach and supporters of a consumers' only approach. The project team has presented advantages and disadvantages of both approaches (see point 16, 17 and 18). As a compromise it is recommended to perform probabilistic exposure assessment on a total population basis in all cases and, in addition, for consumers only for rarely eaten food commodities. This concept, however, needs further discussion and scientific scrutiny, but a provisional proposal is mentioned in the recommendations of the annexed report.

21. In those cases where both the total population concept and the consumers' only concept are used, the risk management decisions should be consistent e.g. one should not be stricter for rarely eaten food commodities than for commonly eaten food commodities. In this perspective risk is defined as the frequency of occurrence in relation to severity of the effect. This might imply that a lower percentile of exposure is considered as the cut-off point for a rarely eaten food item than for (a combination of) commonly eaten food(s). The risk of missing very high potential exposures in the probabilistic approach (which, however, to some extent also happens in the deterministic point estimate approach) and possibly not adequately protecting groups of consumers within the population, is obviously a crucial aspect of the choice about the method which shall be used for decision making. This should be balanced against the current knowledge of the magnitude of overestimating the risk (point 23 and 24). Case by case evaluations of the validity and extent and of the risk aspects of potential higher exposures might be possible and could probably be performed by the JMPR. A quality check of the potential extreme levels will be necessary anyhow, to exclude unrealistic calculated exposures. In general, it is advisable to ask the opinion of experts on the issue of risks related to seldom occurring potential exposures higher than the ARfD for pesticides, in relation to comparable risk assessment and risk management issues.

22. Vulnerable groups, such as children, and, for some chemicals, women of childbearing age, should be addressed separately in the risk assessment process. Higher intakes are calculated for children, because their consumption/body weight ratio is higher. For some commodities, the number of consumers below age 7 in

the databases is (very) small, resulting in exposure levels based on few numbers (see also point 17). In those cases, the higher percentiles of exposure for children should not be considered statistically sound. Separate analysis for vulnerable groups, however, will give more insight in their risk, especially because they might be more susceptible to the effects.

23. The approach for all foods together can in principle be considered as a valuable possibility of probabilistic calculations, which should be incorporated in the risk assessment of acutely toxic chemicals. However, there are still some questions to be solved regarding the methodology in the case of acute exposure assessment. The single commodity calculations for the acute intake are often derived from the consumption databases of different countries. This means that calculations of the intake of residues from all foods together can be performed on a national basis, but at the moment there is no clear guidance about how this could be performed on an international basis. Another aspect of the use of this all foods approach in risk management is that it could lead to non-acceptance of pesticide-commodity combinations, which would be acceptable when evaluated individually. Further consideration of this issue and the presentation of more examples of calculations are therefore desirable before decisions can be made on the use of the all foods together approach in Codex.

24. In the United States exposures are calculated with the probabilistic risk assessment in a tiered approach using the total population approach. Some factors, which mitigate the calculated risk, are also applied. The main factors which differ from the present JMPR-approach to acute risk assessment is that when field trial data are used, variability ("decompositing") of the residues in individual product units is not taken into account, because it is considered (on the basis of monitoring results and research on variability in practice) that the field trial data are already a considerable overestimate of actually occurring residues in foods moving in trade. Further reports on this issue are expected later this year. Another factor is the use of monitoring and/or % use data, which usually contributes to further reduced exposure calculation results. Also, in further tiers of the US approach, the 95th percentile is used for decision-making. On the other hand, the calculations are based on exposure from all foods together. As mentioned in paragraph 17, the use of an all foods together approach will be difficult on the present international basis and needs further study. Also the use of % crop treated can obviously only be done in a responsible way at a national level, but will be difficult to apply in international approaches. Also the use of monitoring data probably must continue to be confined to national exposure calculations. Variability of the residue is a proven aspect of residue distributions. This means that in principle the international approach should be based on field trial data and information or default factors about variability. The inherent large overestimation of the actual risks involved in the present JMPR assessment should however be taken into account in the decision making procedures of Codex.

25. In an EU funded project a validation study has been performed comparing the calculated intake (both point estimates and probabilistic exposure assessment) with the measured intake in duplicate diets. For the calculated intake, monitoring results were used instead of field trial data. The study performed in Spain and The Netherlands both indicated that for six often found pesticides, the probabilistic exposure assessment was overestimating the real exposure by a factor of 10 to 100. The point estimate was overestimating the real exposure to an even larger extend. It is not known whether these results are applicable for all other pesticides or all age groups.

26. The use of national consumption databases for acute exposure assessments in the future may require some further consideration. At the moment, the WHO uses food consumption data from 7 countries for the derivation of large portion sizes and unit weights for use in the calculation of the point estimates. It is expected that the number of available food consumption databases will increase in the future and that they will be updated regularly. Increase in data will result in revision of risk management decisions. Because the highest national food consumption figure is always chosen for the decisive assessment, there might be an upward trend in the calculated exposure results. Another issue is that some national food consumption databases are skewed in so far that they may be only directed to adults, or they may contain an overrepresentation of vulnerable groups, such as children. These matters can be addressed by use of weighing factors. This means that international consumption data, both for the point estimate approach and the probabilistic calculations, should be used wisely. The fact that international decision making in the present system is based on the highest nationally calculated exposure implies that many other countries could accept the residue situation, which is evaluated. This could place an increasing burden on the Codex decisions. The development of more stable regional or even global dietary intake models might be useful to

tackle this problem. However, eating patterns will keep on changing over time. All these matters will need further consideration and the development of a policy to address the way to handle them.

Conclusions and recommendations

27. It is concluded that probabilistic risk assessments by or for CCPR are possible both for chronic and for acute risk assessment, for countries which have an appropriate food consumption database. When these databases would be accessible to the JMPR, we would have the same situation as now for the point estimates, and the JMPR could perform the acute exposure calculations. Countries might also make the result of their calculations available on request. The probabilistic assessment can be based on the same parameters, which are now used for point estimates of acute exposure to pesticide residues to yield comparable results. Further refinement can be considered when relevant. Probabilistic risk assessment has the advantage of giving better insight in risk distributions and opens the possibility to incorporate more complex issues, such as the risk associated with exposure to residues from more than one food item or even all sources and also cumulative exposure to compounds with the same toxic activity. Probabilistic software has now been made available and results can be used in an international context as a tiered system after a first screening with point estimates. It is recommended that action is taken to further enable international probabilistic exposure calculations and that JMPR uses this method in its intake calculations.

28. Probabilistic assessment is a versatile system, which can accommodate various requirements for risk management decisions. A decision is needed on the type of calculations and the cut-off points on which decisions will be based. Essentially a choice has to be made between two approaches for acute dietary risk assessment: assessment primarily based on a total population approach, or on a consumers only approach. The total population approach is more consistent with general risk management policy approaches. It may however need to be complemented with a policy to protect the consumers in the population against appreciable high intakes, even if they occur with an extremely low level of probability. The preferable choice would therefore be (as a provisional policy, subject to further experience and guidance) to request primarily the presentation of probabilistic acute risk assessment results at the 99.9^{th} percentile level for both the whole population and for children based on a total population concept. In order to maintain sufficient protection of consumers of less often eaten foods, the presentation of calculations for consumer only is proposed, for all consumers and for children. This is recommended only for rarely eaten food items. Further discussion is necessary on decision making in this combined approach and about the most suitable cut-off point for the consumers only calculations. As a provisional proposal, it is suggested to develop a formula, which provides for consistency with the total population approach. To avoid discrepancy between acceptability of MRLs for commonly eaten food commodities opposed to MRLs for rarely eaten food commodities. Stricter decisions for rarely eaten foods should be avoided. Considering statistical validity, some lowering of the cut-off level for less commonly consumed foods might be allowed assuming sufficient protection of consumers (see also point 17, 23 and 24).

29. Decisions should be taken on the food consumption database to use for calculations. This might be the one including the highest food intakes from which also the point estimate would be derived. The decisions should in principle be based on the calculations that give the highest result.

30. Allowing potentially higher intakes, which occur at a very low probability level, can be mitigated by developing a specific strategy for these cases. This should at least include a quality check on the available data on a case-by-case basis and consideration of the actual extent of risks involved. Further specific guidance should be developed on this issue. The advice of experts is required on the question of very seldom occurring potential exposures higher than the ARfD, in relation to comparable risk assessment and risk management issues. It should be kept in mind that actual potential intake levels will be much lower, because the use of field trial data in risk assessment calculations can be regarded as considerably overestimating residue exposures. This is also confirmed by duplicate diet studies aiming at measuring the real intake. A correction factor for a general agreed overestimation of risk is not incorporated in the current risk assessment approach.

31. Based on the before mentioned proposals for approaches, it has to be stressed that the calculations which can be found in the annexed report, are not as such suitable for completely showing which conclusions could be drawn on the cases which were requested by the CCPR to be investigated by the working group. Refining might still be necessary. The working group demonstrated the potential of probabilistic exposure assessment in several examples. It was also demonstrated that probabilistic models can be used at the international level in connection with several food consumption databases. It was, however, impossible

within given timeframe to organise all data in the most appropriate formats and to elaborate on an affective electronic platform. All calculations reported in this document or in the report should be regarded as examples. Final calculations and reviewing the quality of the data and documents provided are the responsibilities of the JMPR.

32. The Working Group considered the availability of food consumption databases at the international level. There are many food consumption data collected at the national level and there is considerable willingness to provide information from these food consumption databases to the CCPR.
The Working Group demonstrated that food consumption databases can be made technically compatible with the probabilistic software, and once made compatible, these different food consumption databases can relatively easily be used in a probabilistic exposure assessment. It is, however, recognised that creating a perfect platform of databases and probabilistic software, still requires a significant project.
The Working Group considered access to consumption data gathered and stored at the national level as a significant problem. In order to avoid complicated access issues, the best way to proceed is to store food consumption data at national websites, to regulate access at the national level and to enable data subtraction via queries on the Internet. This concept will be worked out in European funded integrated project SAFE foods.

33. It is recognised that different food consumption databases are not compatible on all levels. Food consumption databases are not compatible with the Monte Carlo software on all levels either. Some of these compatibility issues are easily solved others are more complex. It was recognised that even an incompatible food consumption database is already a considerable improvement. Increased complexity when using more than one food consumption database needs further consideration. Before concluding on acceptability of pesticide use, based on probabilistic calculations, decisions should be made by the CCPR on the appropriate methodology and advice should be given by the JMPR.

34. A working group is recommended to assist the JMPR/CCPR to solve technical and compatibility issues regarding food categorisation and regarding the translation of food as eaten into raw agricultural commodities relevant for MRL setting in a pragmatic way. It might be useful to discuss the possibilities of developing an international food consumption model for exposure calculations for decision making, because the constant changing of parameters which would be required when existing national food consumption data bases are used is problematic in relation to consistent decision making on these matters.