European Community comments on the
Criteria for the advancement of JMPR recommendations in the Codex Step Procedure

(Agenda item 6,
CX/PR 06/38/4)

Mixed Competence
Member States Vote

The Member States of the European Community (MSEC) would like to present the following comments on the Criteria for the advancement of JMPR recommendations in the Codex Step Procedure.

The MSEC welcome the document of the drafting group led by the US in which most of the issues are addressed.

There are several sections in the paper the MSEC can whole-heartedly agree with. It is important that objections in CCPR to JMPR recommended MRLs, ADIs and ARfDs should be scientifically based and substantiated by relevant information (or based on other legitimate factors relevant for health protection and food safety). Such comments could be provided in a standard format.

Procedure and format for comments
It is a good idea to make guidance about how to object and about the detail in which an objection should be substantiated. Also the introduction of a format could be helpful and is supported by the MSEC. Comments in such a format could be submitted at or preferably before the CCPR meeting (provided that the JMPR reports have been issued well before the 1 February deadline). In addition to that, the format should also have a section for matters of clarification, which could be addressed by the applicant country or the manufacturer. Many misunderstandings may be taken away if some issues concerning the GAP (e.g. when there is a 0-day PHI, mixing of trials from different GAPs, extrapolation or limited number of trials) were explained. If clarifications were made before or during CCPR some objections could be lifted already and we gain one year or when it is clear that lower MRLs are needed, these data can already be prepared.

On two major issues the MSEC disagree with the paper.

(1) Work by consensus
Codex MRLs are meant to be generally applicable worldwide. They are not meant to remediate a trade problem in one part of the world, while at the same time a CXL can be ignored in the rest of the world. It is correct that if a country cannot accept a Codex MRL, it is possible to have a reservation noted in the CCPR and CAC report. But it is undesirable when this happens for many MRLs because many commodities circulate on the world market, traders on the world market must be able to rely on the Codex international standards when buying raw materials on the world market. Moreover, in WTO codex MRLs are considered international safe standards and are

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referred to in the SPS committee. For these reasons the MSEC prefer to adopt Codex MRLs by consensus.

(2) The Role of JMPR and CCPR
JMPR gives scientific advice to CCPR and recommends MRLs. The MSEC agree that JMPR is an internationally respected body using the most up to date science, but this does not mean that CCPR should accept entirely all of its conclusions and recommendations. Different interpretation of the science or differences in the application of methodology to derive endpoints or MRLs may lead to different conclusions.

Lack of agreement on methodology
For the chronic risk there is an agreed procedure and methodology and thus the outcome of this is nearly always uncontroversial (apart from a few details). Acute risk assessment, however, is a relatively new discipline and the methodology is still subject to change, in function of new developments and new information becoming available. JMPR guidance is available for deriving the ARfD, but there is no international agreement on all aspects yet, for example, the way to make use of human studies, the setting of different ARfDs for subpopulations and the different safety factors applied.

Concerning the exposure, the availability of short term diets is limited (JMPR uses diets from some member countries) and the parameters in the IESTI model are still under discussion. The latter is illustrated by the recent discussion between the European Food Safety Authority (EFSA), JMPR and IUPAC on the variability factor.

Other risk assessment bodies
JMPR and national or regional risk assessment bodies are often simultaneously working on the evaluation of the same active substances. If these bodies arrive to different conclusions than JMPR, this should not be ignored and the MRLs, ADIs and ARfDs should be reconsidered and not automatically accepted.

Some of these issues could be resolved, but as long as these are not resolved, it is up to the CCPR to decide about the advancement in the step procedure.

We could reduce the number of objections or prevent that similar objections are made over and over again, by agreeing in CCPR about the terms of reference for doing the risk assessment by JMPR and the form in which recommendations are made. In particular, the minimum data requirements should be agreed and used for the acceptance of MRL requests, the criteria used for the evaluation of the studies should be agreed and the methodology for deriving the toxicological endpoints from the studies and deriving the MRL from the trials including possible extrapolations should be agreed. Much of this is already available in the framework of OECD and could be taken forward under the framework of FAO and WHO.

Another problem is the lack of synchronisation between the toxicological and residues evaluations. This could be solved by organising parallel evaluations.

Draft MRLs could in principle be forwarded to the next step even if not all the issues are clarified, but they should not be forwarded beyond step 6 until we finally agree about their safety.

Comment on Annex I to document CX/PR 06/38/4
The following phrase (in bold) should be added:
«The pre-eminence of protecting the health of consumers regarding MRLs is clear and recognized in all of the procedures and writings of the CAC, CCPR and JMPR, regarding MRLs, » as MRLs are the only common topics for the three bodies mentioned.