Brussels, 17 March 2003

European Community Position
for the 35\textsuperscript{th} Session of the Codex Committee on Pesticide Residues
Rotterdam, 31 March-5 April 2003


Report 2001:

2.1 Methodology acute intake. The EC strongly encourages the discussion and development of methodology for both acute intake estimation and on the setting of an Acute Reference Dose. However, the EC has some reservations on the details under discussion. The EC considers it an urgent matter to reach agreement on internationally agreed guidelines and is willing to contribute to their establishment.

The EC supports the proposal made by the JMPR that the WHO establish a working group to consider all points related to setting an ARfD and considers that the OECD Test Guidelines Programme be involved in this activity.

2.2 Worksharing. The EC supports the conclusions of the workshop.

2.3 Numerical expression. The EC welcomes the more flexible approach.

2.5 Estimation of maximum residue levels and supervised trials median residue values for commodities of animal origin. The EC is pleased with the excellent recommendation.

2.6 Statistical Methods. The EC supports the use of statistical methods and agrees with the conclusions.

Report 2002:

2.2 Further guidance on derivation of the acute RfD

The guidance given is welcomed. Nevertheless it seems to be necessary to summarize the guidance given in various JMPR Reports in one single document to be adopted by the Codex Alimentarius Commission now.

On page 5, last paragraph, the last sentence on the refinement of the acute RfD by a single dose toxicity study is very important and should be highlighted. There is an urgent need to reach agreement on a harmonized OECD test guideline for such a specific study, which particularly considers animal welfare reasons and available data from full toxicological database.

According to page 7, “Different acute RfDs for different population groups” it is proposed by JMPR to set different acute RfDs for different population groups, which should be based on available consumption data (i.e. adults and toddlers). The EC feels that RfDs should be based on toxicological, rather than on consumption data. Moreover, the EU position is not to set different RfDs for different population groups. An acute reference dose should be protective of the whole population. Acute dietary risk assessments should take account of exposures as well as the underlying toxicological database.
2.3 **Reconsideration of acute RfDs**

The conclusion of the Meeting that for some pesticides reconsideration of previous JMPR assessments of acute toxicity could not be fully considered without undertaking full evaluations of the toxicological data on those particular compounds is accepted. This issue supports the urgent need of a consistent and harmonized guidance on the derivation of the acute RfD.

2.4 **Developmental neurotoxicity studies**

The EC supports the statement of the JMPR.

2.5 **Draft report of the OECD/FAO zoning steering group**

The EC welcomes the activities of OECD and FAO to address the question of the global acceptability of comparable residue trials and is looking forward to considering the final report once it has been adopted by the OECD Working Group on Pesticides. It is important that this activity and the project “minimum data requirements for Maximum Residue Limits” get a follow up in the CODEX framework (see comment under 2.8).

2.7 **Guidance for submission of pesticide residue monitoring data on spices**

See comments agenda Item 12

2.8 **Statistical methods for estimation of MRLs (see item 2.5)**

The EC does not agree that statistical methods necessarily lead to overestimation. A consistent and systematic approach should be used. Overestimation might apply where there are small data sets. It is important that statistical methods be applied only where sufficiently large data sets exist. It is important that minimum data requirements are defined by CODEX. A follow up should be given to the EU/OECD project “minimum data requirements for Maximum Residue Limits” presented at the CCPR 33.

2.9 **Variability of residues in natural units of crops**

The EC welcomes the activity by ECPA and FAO/IAEA to conduct supervised residue trials for single unit residue data on grapes and head lettuce and agrees with JMPR’s recommendation to decrease the default variability factor for head lettuce (and by extrapolation for head cabbage) to 3. The EC recalls that in any case, decisions on the use of a variability factor for a specific pesticide/commodity combination should be taken on a case by case basis.

The EC notes the recommendation to retain the current default variability factor of 7 for table grapes until additional results are available. The EC uses a value of 5 due to the higher unit weight value used in the Community and considers this to be more appropriate. The EC looks forward to using the results of the ongoing field trials to create a new single unit default residue value for grapes by FAO/IAEA.

2.10 **Intake calculation for meat and fat**

At the 34th CCPR the EC expressed the opinion that the procedure of the 2001 JMPR ignores the contribution of fat soluble pesticide residues from fat to meat. The 2002 JMPR changed the procedure to calculate the dietary intake for meat. For mammalian animals, 20% of the meat consumption portion was considered to contain residue at the level of fat and 80% of the meat.
consumption was considered to contain residue at the level of meat with trimmable fat removed (corresponding values for poultry 10% and 90%). The EC is pleased with that 20:80 procedure moves towards the EC position (where values of 10 and 90%) are used but prefers that in the absence of a specific justification for 20/80, values of 10 and 90% are used by JMPR.

**Agenda Item 7: Draft and proposed draft maximum residue limits in foods and feeds at steps 7 an 4. CL 2003/1– PR, CL 2001/14 – PR.**

General remarks: As, in the EC, statistical methods are used for setting MRLs, then data underlying Codex MRLs, could lead to EU MRLs set at different values than the actual Codex MRLs. In general, the EC is reluctant to accept MRLs that are based on a GAP where no PHI has been specified or where post harvest data are mixed with preharvest data. The EC would welcome if guidance would be developed for submission of data to JMPR. Because the raw data are not available yet it is not possible for the EC to base its comments on them. Comments are therefore preliminary.

The EC recalls that in 2001, the CAC decided not to fix any normative standard while scientific evaluations had not yet been completed. This decision is relevant to many of the EC comments on individual MRLs that follow.

**Captan (007)**

As Captan is classified as a skin sensitiser in the Community and because the toxicological evaluation is very old, and in the absence of a full evaluation of the acute toxicity, the EC opposes the setting of the MRLs at the high levels proposed for blueberries, cherries, grapes, dried grapes, strawberries and plums. Moreover, for cherries and nectarines the database is poor.

The toxicology of the metabolite THPI should be investigated and if necessary the residue definition for risk assessment should include THPI as this is the main source of intake by the consumer.

**Grapes (25 mg/kg):**

For wine grapes, the 0-days PHI could affect the fermentation process and is therefore not a good GAP. In 1994 a PHI of 21 days was proposed and the MRL was then 20. Also the exposure of children drinking grape juice is not acceptable. The EC cannot accept the proposal.

Dried grapes (50 mg/kg). This is an unrealistically high MRL based on an accumulation of worst cases.

**Tomatoes (5 mg/kg):**

The EC notes that only a limited number of trials data are available - particularly from those carried out under glass. The trials data show that 3 mg/kg is sufficient.

**Carbaryl (008)**

For this substance the database is very poor and based on outliers. An acute intake assessment should be carried out before the EC accepts advancement of the MRLs. In addition, the EC requests that the values proposed to be reconsidered on the basis of the trials data which seem to indicate that lower MRLs would be
appropriate for Citrus fruit: (15 mg/kg), Plum: (10 mg/kg), Cherries: (20 mg/kg), Grapes: (40 mg/kg), Olives: (30 mg/kg) and Rice: (50 mg/kg).

**Chlormequat (015)**
Based on the available data, the EC considers 2 mg/kg more appropriate for wheat, triticale and rye and 20 mg/kg for dry straw and dry fodder of cereals.
Processed products from rye: (bran, flour and wholemeal): one study is not sufficient as a basis for the MRLs.
For wheat: (bran, flour and wholemeal) the MRLs are not acceptable because based on 2 studies that differ widely. The processing factors are not comparable and therefore not to be used for deriving MRLs. Not acceptable.

**Chlorpyrifos (017)**
For Broccoli 2 mg/kg is acceptable

**2,4 D (020)**
The EC has an ADI of 0.05 mg/kg bw (from a 2001 evaluation) that is different from Codex (0.01 JMPR 1996). The EC has a different residue definition (Sum of 2,4 D and its esters expressed as 2,4 D). For citrus the GAP in which the MRL proposal is made is not clear and should be clarified.

**DDT (021)**
For eggs the EC has a lower MRL of 0.05 ppm based on monitoring data.

**Diazinon (022)**
Due to the new situation it seems that the proposal should be maintained at the step 6
An MRL of 0.7 mg/kg was proposed instead of 2 mg/kg for meat of cattle, pigs and sheep; For kidney and liver of cattle, goats, pigs & sheep, the MRL value disappeared, where 0.05 mg/kg would be appropriate.

**Dimethoate (027)**
The plant metabolism needs clarification. There are also concerns related to omethoate that appears when longer PHIs are applied. Omethoate should be included in the residue definition. This metabolite is 7 times more toxic than the parent compound. The EC opposes advancement of MRLs until the residue definition is agreed. An ARfD and better residue definition need to be agreed by JMPR. In addition, there is an exceedence of 2 regional diets in the calculations of the 1998 JMPR. The EU has reduced most of its MRLs because of acute and chronic intake problems. The ARfD applied by the EU for dimethoate is 0.03 mg/kg bw. There is also concern over animal feed uses, as the residue definition for animal products has not been confirmed.
An MRL of 0.3 for wheat is supported in the EU.

**Diphenyl amine (030)**
The proposed MRL for Cattle, milk (0.0004* mg/kg) is not acceptable because the analytical methods for the determination of diphenylamine in whole milk has only been validated to a level of 0.01 mg/kg. This level is the effective LOQ for this compound in whole milk.
Spain will provide a copy of the GAP for diphenylamine use on pears (10 mg/kg is the EC MRL) and the supporting residue database to the next JMPR to allow the MRL for diphenylamine in pears to be re-assessed.

**Folpet (041)**
The EC requires the setting of an ARfD and an estimation of the acute risk for all relevant consumer groups for this substance before MRLs can be advanced for apple (10 mg/kg), grapes (10 mg/kg) and head lettuce (50 mg/kg). It is unclear how this is calculated as the database is very poor and unacceptable for the EC. For melons (3 mg/kg), the EC accepts the MRL-proposal as the residue will be predominantly on the peel.
For strawberry (5 mg/kg) the EC considers an MRL to be too high and not supported by the trials data. The highest residue in the trials was 2.2 mg/kg.
For tomato the same comment applies.

**Lindane (048)**
The EC cannot comment on the JMPR ADI and ARfD as the detailed toxicological evaluation and certain studies (study on immunotoxicity) are not available. The EC has different toxicological endpoints. The EC has withdrawn all plant protection uses of lindane.

**Malathion (049)**
The EC does not accept advancing the MRLs for all feeding stuffs commodities before farm animal feeding studies are presented and evaluated. The establishment of an ARfD is also necessary.

**Parathion-methyl (059)**
The EC opposes MRLs for commodities that can be used as animal feeds before adequate animal feeding studies are presented. EC (and USA) has withdrawn all the uses of the substance and as a result most of the MRLs will be withdrawn. All proposals based on withdrawn USA and EC GAPs should be deleted.

**Phosalone (060)**
The EC has not finalised its evaluation of Phosalone. The toxicological endpoints have not been fixed. If the evaluation confirms the ARfD of JMPR (0.3 mg/kg bw/d), the Codex-MRLs are acceptable with respect to the acute risk.

**Piperonyl butoxide (62)**
The database is rather limited for many crops and all the trials reported are conducted with 0-day PHI. In the EC this product is not considered as a pesticide but as a synergist, used with pyrethrins or pyrethroid products.
JMPR proposals for processed product as molasses, mustard green, radish leaves should be deleted because they are not relevant for international trade. For maize oil crude treated after harvest, some explanations should be provided.
**Citrus (5 mg/kg)**
The data support a lower MRL for large fruits; for small fruits more data points are required.
**Leafy vegetables (50 mg/kg)**
The data are insufficient to set 50 mg/kg – it is not acceptable
For spinach, legume vegetables, beans, pulses, carrot and radish, information is missing.

**Potatoes (0.5 mg/kg)**

3 trials without detectable residues makes 0.1* acceptable.

**Cereals (30 mg/kg)**

Data from Australia demonstrate that in 31 trials (1981-1982), 30 are below 10 mg/kg and only one at 30. Applied 8 mg/kg in the storage it should be difficult to find 30.

In 1998 at the registered uses of 8 mg/kg, 27 trials show residues below 10 mg/kg.

GAP in USA used 26 mg/kg of piperonyl butoxide against 10 in Australia and 8 in Europe. Not clear why different GAPs for stored products are necessary.

**Products of animal origin**

For cattle fat 3 mg/kg is more appropriate.

For liver of cattle and poultry based on the feeding studies 0.5 mg/kg is appropriate.

**Pyrethrins (063)**

The database available for the periodic review is very limited.

Metabolism: Only pyrethrin 1, labelled in the cyclopropane moiety of the acid, was used in all metabolism studies in plants and animals. No information about the fate of the alcohol moiety is available because linkage of the other side of the ester linkage, e.g. in the cyclopentene moiety was not used in any metabolism study.

**Dried fruit (0.2 mg/kg):** Only data for prunes, treated in a warehouse were available.

The extrapolation of these data to all dried fruit is not acceptable.

**Pulses (0.1 mg/kg):** Two trials each were made for dried peas and dried beans treated by foliar application. All residues were less than 0.04 mg/kg (LOD). It is therefore not clear how the proposed draft MRL of 0.1 mg/kg was derived. The proposal is not acceptable.

**Cereals:** The EC objects to withdrawal of postharvest treatments on cereals because post Harvest treatments are used in the EU.

**Thiabendazole (065)**

This product is no longer allowed for foliar treatment in EU, only post-harvest treatments are authorised, due to problems of high persistence in soil.

Melon: 1 mg/kg is based on residues trials from Spain and according to the Spanish GAP but as it is not longer registered in Spain the MRL should be withdrawn.

Strawberry: 5 mg/kg is based on residues trials from Spain and according to the Spanish GAP but as it is not longer registered in Spain the MRL should be withdrawn.

EC is waiting for more data coming from USA.

EC disagrees with proposed MRL for mushroom because insufficient data (3 trials) and await new data from US for evaluation.

**Carbendazim (072) /Benomyl (069)/Thiophanate-methyl (077)**

Benomyl is not longer supported by the main notifier in the EC and USA. Because the proposed carbendazim MRLs are based mostly on USA and European residue trials with benomyl, carbendazim or thiophanate-methyl, the MRLs must be reconsidered on the basis of carbendazim and thiophanate-methyl GAP and residue data only.

The re-evaluation of carbendazim and thiophanate-methyl is further pending in the EC. The following comments are therefore preliminary pending finalising the evaluations.

**Berries and other small fruits 1 mg/kg (Step 6)**
The proposed withdrawal of this MRL is acceptable. But the EC wants to point out again that new residue data for use in blackberries and raspberries became available. Evaluation by JMPR 2003 has to be waited for.

Lettuce, head (Step 6)
The EC informed the Committee in the 33rd and 34th Session, that new residue data became available. The evaluation by the JMPR 2003 has to be awaited.

Cucumber (Step 8)
MRL proposal of 0.05* mg/kg is acceptable. New indoor trials with carbendazim became available to the EC showing that an MRL of 1 mg/kg is necessary.

Garden pea, Shelled (Step 8)
The proposed MRL of 0.02 mg/kg is not acceptable. The number of trials is insufficient. Furthermore garden peas are also traded with shells so that data for peas with pods are necessary. The proposal setting an MRL lower than the practical limit of determination of 0.05 mg/kg will imply practical problems in enforcement.

Oranges, Sweet, Sour (Step 8)
The reported 6 trials with one application from USA and Brazil seems to be insufficient to cover the wide range of agricultural and climatic conditions. Furthermore results on citrus fruits without stating the distribution of the residues between pulp and peel are not acceptable. Therefore the MRL proposal of 1 mg/kg cannot be accepted.

Rye
Extrapolation from wheat to rye is supported by the EC.

Disulfoton (074)
The EC welcomes the dietary risk assessment for disulfoton and supports the withdrawal of the MRLs for broccoli, cabbages (head), cauliflower, lettuce head and leaf, poultry meat, rice and sorghum where the IESTI exceeds the ARfD.

Fenamiphos (085)
The 2002 JMPR established an ARfD of 0.003 mg/kg bw. Calculations with the new ARfD of 0.003 showed that for peppers and tomatoes (both at 0.5 mg/kg), the ARfD is, both for the general population and for children, grossly exceeded; also for watermelon (at 0.05 mg/kg) the intake for children is 258% of the ARfD. Therefore, the EC oppose advancement of the proposed MRLs for peppers, tomatoes and watermelon. The other proposed MRLs in step 6 and 6(a) (at 0.05 mg/kg or lower) can in principle be advanced to step 8. However, because its toxicity, the EC would prefer lower levels (0.02 mg/kg). For the existing CXL for carrot, the ARfD is also exceeded for children and therefore the EC requests revocation of this CXL. In view of the high acute toxicity of the compound it is necessary to lower the LOQ to protect the consumer.

Dinocap (087)
For EC it is not acceptable to have different ARfDs for different groups in the general population. The ARfD for the general population is therefore regarded as 0.008 mg/kg bw. The MRL for wine grapes is acceptable. No residues are expected in the wine.
If the combined database for table and wine grapes is used for the risk assessment, the ARfD is exceeded. The EU evaluation of Dinocap is not finalised yet. New residue trials (application regime according to the intended uses, i.e. 8 x 0.21 kg a.i./ha, PHI = 21 days) are being evaluated. Residue levels range from <0.05 mg/kg to 0.1 mg/kg, resulting in rather low residues compared to these evaluated by JMPR.

**Chlorpyrifos-methyl (090)**
The proposed level for cereals need to be in line with the results from feeding studies that led to very low MRLs for milk and other products of animal origin.

**Carbofuran (096)**
Only the MRL for sweet corn can be advanced. For other commodities at step 6 (cantaloupe, cucumber, mandarins, oranges sweet and sour, summer squash) short-term intakes have still to be carried out. The MRLs for rice (husked), rice straw and fodder, as well as for cotton are not acceptable because results of trials in different countries and with different GAPs have been mixed to derive these MRLs.

**Methamidophos (100)**
New ARfD of 0.01 is set by JMPR and the existing ADI of 0.004 is confirmed (JMPR 2002). The EC requires the estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced beyond step 6. The periodic reevaluation by JMPR 2003 (residues) has to be awaited.

Peach (1 mg/kg, step 6), Pome fruits (0.5 mg/kg, step 6), Tomato (1 mg/kg, step 6)
In view of the potential acute dietary risk the European Community cannot accept the proposed MRLs.
EC proposes not to advance the MRLs beyond step 6.

**Phosmet (103)**
For all MRLs except tree nuts the ARfD exceeded. The advancement of MRLs is not acceptable.
For pome fruit and stone fruit the GAPs differ too much to mix the trials
Blue berries data justify an MRL of 10 mg/kg only.

**Propargite (113)**
The EC oppose the advancement of MRLs for grapes, because information of transfer of hydroxy metabolites to wine is insufficient and the intake for children drinking grape juice is unacceptable and for citrus group extrapolation to the whole group is insufficiently documented and incomparable GAPs are mixed.
The proposal for tomato (1 in stead of 2 mg/kg) peach (2 in stead of 4 mg/kg) and nectarine plums (other stone fruit 3 in stead of 4 mg/kg) apple (2 in stead of 3 mg/kg) should be modified because lower values are sufficient and the request was from Europe.

**Aldicarb (117)**
The EC opposes advancement of the MRLs for bananas and potatoes before a definitive Acute intake assessment is done.
**Oxamyl (126)**
The raw data are not available yet; postponement of discussions until 2004 JMPR is appropriate.

**Diflubenzuron (130)**
The EC evaluation is not yet started. There are no EC-harmonised MRLs.
The ADI of 0.02 mg/kg bw was established by JMPR 1985 and was confirmed 1994 and 2001. In 2001 JMPR concluded that the overall toxicological profile of diflubenzuron indicates that establishment of an acute reference dose is unnecessary. The evaluation of diflubenzuron is not included in the JMPR Evaluation 2001 that is available on internet.
The information in the JMPR report 2001 is not detailed enough to allow any definitive comments. The proposed MRL of 5 mg/kg for pome fruit is not acceptable. The residue data has been combined from widely differing GAPs. Residue data from 40 apple and 7 pear trials have been combined, 30 of the 47 trials were considered as not valid. MRL-calculation according to EC-model: 2 mg/kg would be sufficient (present MRL for apples and pears is 1 mg/kg).

**Deltamethrin (135)**
The ADI of 0.01 mg/kg bw was established by JMPR 1982 and was confirmed 2000. The ARfD was established at 0.05 mg/kg bw in 2000. The evaluation of deltamethrin is not included in the JMPR Evaluation 2000 that is available on Internet. The ARfD differs from that established by EC (0.01 mg/kg bw). The JMPR evaluation is based upon an acute neurotoxicity study. In the toxicological evaluation (91/414-review) this study was judged in the EC as not acceptable due to lack of neuropathology.
Leafy vegetables (2 mg/kg, step 3 - CXL is 0.5 mg/kg). Residue data from trials on kale, lettuce and spinach were available. The JMPR Meeting decided to pool the data to support a leafy vegetable MRL that is not acceptable. For chinese cabbage, children are estimated to be exposed at 115% of the ARfD and for spinach at 130% of the ARfD. Therefore, the EC cannot accept the proposed MRL for the group Leafy vegetables, pending final JMPR evaluation.

**Carbosulfan (145)**
It remains necessary to examine if an ARfD needs to be established for carbosulfan. Also, as residues of carbosulfan and carbofuran on oranges and mandarins results from the use of carbosulfan, the MRL for the 2 compounds have to remain in the same step.

**Oxydemeton-methyl (166)**
The EC have re-evaluated the MRLs in light of the acute risk (ArfD 0,002 mg/kg/day). The LOQ was changed to 0.02 mg/kg. MRLs for all commodities should
not be advanced before an acute intake assessment for all relevant consumer groups for this substance is done by JMPR. The LOQ should be lowered.

**Clethodim (187)**
The 2002 CCPR postponed the advancement of all draft MRLs because the available methods of analysis could not make a distinction between clethodim and sethoxidim. One method was submitted very recently but not yet used. When the method were more experienced by using it, the draft MRLs at Step 6 could be advanced.

**Fenpyroximate (193)**
The EC requires the setting of an ARfD and estimation of the acute risk for all relevant consumer groups for this substance, before MRLs can be advanced.

**Haloxyfop (194)**
The EC request not to advance the MRLs beyond step 3 because the ADI is exceeded, until new toxicological data about the new product (isomers) is available. The manufacture should indicate if he is willing to submit the data. EC requests the establishment of an ARfD.

**Tebufenoizide (196)**
The 2001 JMPR indicated short-term intake concerns on apples, pears, grapes, head cabbages and leafy vegetables. EC proposes to revoke the CXL on pome fruits and not to advance the MRLs for grapes, head cabbages and leafy vegetables beyond step 6.

**Chlorpropham (201)**
The acute intake for raw potato as well as for unpeeled and cooked potato exceeds, both for the general population and for children, grossly the ARfD. Only for peeled and cooked potato the ARfD is not exceeded. As potatoes are sometimes consumed with the peel, and processing studies on microwave and oven-baked potatoes are lacking, as well as information on the fate of the residue after hydrolysis under cooking conditions, we oppose advancement of the draft MRL.

- **Cattle milk 0.0005***
- **Cattle, edible offal 0.01***

We consider the proposed MRL as impracticably low.
We propose a value not lower than the achievable LOQ.

**Fipronil (202)**
EU has concerns with the residue definition (sum of fipronil and fipronil sulphone expressed as fipronil).
EU has some reservation for the MRL proposal on sugar beet and potatoes.

**Spinosad (203)**
The proposed MRLs (all in Step 3) do not exceed the ADI (30%) and the establishment of an ARfD is not necessary.
The EC welcomes the idea of proposing MRLs for crop groupings where this is necessary to cover authorised uses. However, setting MRLs for crop groupings can only be done when there is prior clear agreement on guidelines, criteria, extrapolation, etc. in general and in the specific case of spinosad, we request a reconsideration of the
current proposal for spinosad (brassica vegetables, citrus fruits, fruiting vegetables (cucurbits), leafy vegetables, legume vegetables and stone fruits) to ensure that there are existing and comparable GAPs.

For all proposed MRLs, the databases contained sufficient field trials; in those cases where there was not a sufficient number of trials available, no MRLs should be proposed.

We are aware of the Codex procedure to recommend a MRL always above the highest result of the individual field trials, while the approach of the EU is a more statistical one based on the critical GAP, often leading to lower MRLs.

As a consequence, in the view of the EU the MRLs for the following crop (groups) are too high, based on the data: apple (0.1); brassica vegetables (2); leafy vegetables: (10); legume vegetables (0.3); maize fodder (5); sorghum (1); stone fruits (0.2) and tomato (0.3).

In addition, the proposed MRLs for both citrus fruits and peppers should be lowered from 0.3 mg/kg; not only on statistical grounds, but also on the basis of the trial data. Not acceptable.

The proposed MRL for celery is on statistical grounds too low, and should better read 3 mg/kg. Not acceptable.

We welcome proposed MRLs for animal products also to accommodate external animal treatments, which resulted for cattle and sheep products in higher residues than from feed intake.

**Esfenvalerate (204)**

A) (Proposed) draft MRLs/EMRLs and withdrawals

Residue definition: EC does not agree with definition proposed by the JMPR because there are analytical methods that separate the SS+RR and SR+RS isomers in two peaks. The residue to be taken into account in the case of the use of esfenvalerate is only the amount of the SS+RR isomers. So we propose a residue definition that considers the two peaks separated.

In routine monitoring 0.01 mg/kg is very difficult to determine being a fat-soluble compound. The Group established 0.05 for oil seed and 0.02 for cereals and other products of plant origin.

B) Toxicology - ARfD:

EU: 0.05 mg/kg bw/day - Based on the NOAEL of 5 mg/kg bw/day from the existing studies at the moment of the EU evaluation on a safety factor of 100.

JMPR: 0.02 mg/kg bw/day - Based on a NOAEL of 2 mg/kg bw/day of a different study from those used in the EU evaluation. EC would like to see the study

**Imidacloprid (206)**

The compound was reviewed by the 2002 JMPR. Based on the report, we agree with the conclusions by JMPR in regard with the dietary risk assessment.

The International Estimated Daily Intakes (IEDI) of imidacloprid, based on the STMRs estimated for 47 commodities, for the five GEMS/Food regional diets were in the range of 0 to 2 % of the ADI. The long-term intake of residues of imidacloprid resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

The International Estimated Short term Intake (IESTI) of imidacloprid was calculated for 49 food commodities (and their processing fractions) for which MRLs, STMR values and/or HR values were established and for which data on consumption were available. The IESTI represented 0 – 4 % of the acute RfD for the general population.
and 0 – 15 % of the acute RfD for children. The short-term intake of residues of imidacloprid, resulting from its uses that have been considered by the JMPR, is unlikely to present a public health concern.

**Agenda Item 9: Matters related to methods of analysis for Pesticide Residues**

(a) **Guidelines GLP (CL 2001/14-PR)**

The EU has accepted a quality control procedure on the analysis of pesticide residues as a recommendation to EU Member States for monitoring and enforcement purposes (SANCO/3103/00, available on http://europa.eu.int/comm/food/fs/ph_ps/pest/qualcontrol_en.pd). The EU also has a guideline for validation of analytical methods for post-registration monitoring (SANCO/825/00). In the EU a paper is under development taking into account quality control, validation, "performance verification" and uncertainty, but being less prescriptive and more flexible. A draft will be available before the CCPR-meeting to be circulated and presented at the ad hoc working group on methods of analysis. It will be discussed thoroughly at a EU-QC-workshop to be held in 2003. To keep the discussion open it would be useful to keep the current Codex text at step 3 and advance an elaborated well balanced text at step 5 at CCPR-2003.

**Agenda Item 10: Establishing a CODEX Priority Lists of pesticides**

**Additions to the priority list (CL 2002/16)**

Last year lambda-cyhalothrin was included in the priority list for residue evaluation (as replacement for cyhalothrin) by JMPR 2008. However, lambda-cyhalothrin is not scheduled for a toxicological evaluation by JMPR. JECFA evaluated cyhalothrin in February 2002. JECFA recommends a temporary ADI of 0.002 mg/kg bw. Results of appropriate studies to establish a no-observed-effect level (NOEL) for neurobehavioral effects in laboratory animals are required for evaluation in 2004 by JECFA. EU would be in favour of JECFA harmonising the ADI of cyhalothrin for veterinary products with that of lambda-cyhalothrin established for plant protection products in the Community (0.005 mg/kg bw). We propose that lambda-cyhalothrin (used as plant protection product) should be scheduled for toxicological evaluation by JMPR or JECFA.

**New toxicological data for persistent pesticides (CL 2002/16)**

No new toxicological data is available, but new monitoring data are available from:

- BE: in milk, eggs, meat (bovine, calves, porc, sheep, horses), poultry (chicken, turkey), rabbit, ostriches, aquaculture: routine monitoring of HCB, HCH (alpha, beta, gamma), heptachlorepoxide, dieldrin, DDT (pp' DDE, pp' DDD, op'DDT, pp'DDT).
- Austria 1997-2002: DDT, Aldrin dieldrin chlordane endrin heptachlor, heptachlorepoxid on rabbit fish deer horse poultry sheep cattle pig
- IR: DDT sheep 97-2002

**Agenda Item 11**
Discussion Paper on Pilot Project for the examination of National MRLs as Interim Codex MRLs for safer replacement Pesticides (CX/PR 03/14)
The EC welcomes this important discussion paper with many well elaborated options. The Member States of the EU are still internally discussing the contents. The EC is looking forward to a fruitful and lively discussion during CCPR. There would, in any case, be a need for the secretariat to clarify the legal status of such MRLs in WTO.

**Agenda Item 12**  
**Consideration of Elaboration of MRLs for Spices (CX/PR 02/12)**  
EC welcomes this well elaborated and interesting paper which for the first time gives an overview on the various pesticide residues that can be found on spices. The EC agrees that an effort should be done to set MRLs for spices. However the EC is opposed to set MRLs on monitoring data only. For each pesticide commodity combination the GAP should be clearly defined. The EC favours extrapolation over the use of monitoring data.

In the EC MRLs are set for the most important spice commodity, chilli peppers. The MRLs are set for the fresh commodity, but apply, taking into account the appropriate transfer factor also to the traded dry commodity. There are different opinions concerning classifications e.g. anise, caraway would in the EC be classified as herbs, sesame as oil seed.

**Agenda Item 13**  
**Discussion Paper on the need for revision of the CODEX classification of foods and Animal feeds. (CX/PR 03/16)**  
The EC is in favour of the limited review and reserves its position on the substantial update. It is important that this takes place but it is doubtful whether the resources for that can be found.

It would be preferable if international agreement would be reached about the crop groupings so that extrapolation would be supported.

**Agenda Item 14 Other Business and future work**  
The EC agrees with all recommendations. The EC agrees that there is a need for the reinforcement of the secretariat and archives of JMPR.

**Removal of An Extraneous Burden from the Workload of the JMPR (CX/PR 03/18)**
The EC agrees with the proposal made in document CX/PR 03/18 that the CCPR should consider advising the JMPR to restrict its review of environmental fate to those areas specifically related to the estimation of dietary exposure and the estimation of MRLs.