Codex Committee on Pesticide Residues  
(38th Session)  
Fortaleza, Brazil (3-8 April 2006)  

European Community comments on the  
Draft and proposed draft CXLs in steps 3-7  

(Agenda item 7,  
Overview; CL 2006/2-PR; CX/PR 06/38/5)  

European Community Competence  
European Community Vote  

General comments  

Fixing endpoints for separate consumer groups  
The European Community (EC) is in favour of continuation of the risk management policy to fix ADIs and ARfDs for the general population and not for subgroups. This policy is also used in other areas.  

Use of data from human volunteers  
The EC objects to the lowering of the interspecies uncertainty factor when setting an ARfD, if solely based upon studies on human volunteers.  

Specific comments  

007 Captan  
The EC opposes the setting of the MRL for grapes because of acute dietary exposure problems (152% of the JMPR ARfD, vf 5, LPS 300g). When using the provisional EC ARfD (0.1 mg/kg bw/d) the MRLs proposed for apples, pears, cherry, peach, plum, strawberry, and melon are also unsafe. The final evaluation in the EC is, however, still pending. Based on the present risk assessment the EC cannot accept the advancement of these MRLs.  
The EC approach on this point is to fix the ADI/ARfD for the whole population based on the critical hazard for a specific group and do the risk assessment using this critical endpoint for all groups.  

008 Carbaryl  
An acute intake assessment should be carried out before the EC accepts advancement of the MRLs.  
Because of acute intake problems the EC opposes the MRLs for grapes (364 % of JMPR ARfD vf 5) and cherries (157% of JMPR ARfD vf 5). The chronic intake (Spanish children) shows that the JMPR ADI is exceeded by 105%.  
The EC request that the value proposed to be reconsidered on the basis of the trials data which seem to indicate that lower MRLs would be appropriate for: Citrus fruit, cherries and grapes. The database is very poor and based on outliers.  
Carbaryl is presently being evaluated in the EC. Based upon the draft EU ARfD also intake problems for children are expected for peach, plum, apricot.  

027 Dimethoate  
For many of the proposed MRLs, the EC has set lower MRLs or set MRLs at the LOQ because of intake concerns. This is largely due to the contribution of omethoate residues. EC opposes advancement for citrus (border line V=7), lettuce, pepper, barley, tomato (border line V=7) and leafy brassicae due to intake concerns.  
Although JMPR have agreed to include omethoate in risk assessments for uses of dimethoate, this is not made clear from consideration of the proposed CXLs, without referring back to JMPR documentation. Hence, the potential risk to consumers from the proposed CXLs could be underestimated.  
The proposed MRL for chilli peppers is high. Although no measured consumption data are available, less than 1g of
dried chilli would be required to exceed the ARfD, even without consideration of omethoate residues. Using the assumptions in JMPR report 2005, IEDI is 130% of ADI, therefore the EC opposes the advancement of this MRL.

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<th>041 Folpet</th>
<th>The EC opposes the setting of the MRLs at the high levels proposed for apple (168% for children), grapes (207%) and lettuce (191%). The final evaluation of folpet in the EU is pending. Whereas the ADI is the same, the EC provisional ARfD is two times lower (0.1 mg/kg bw/day) than the JMPR one (0.2 mg/kg bw/day). Based on the present risk assessment the EC cannot accept the advancement of these MRLs.</th>
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<th>049 Malathion</th>
<th>The EC wishes to express concern on the proposed MRLs for malathion. Presently in the EC discussion on malathion has not been finalised yet and the toxicological relevance of the some metabolites of malation, especially of desmethyl malathion is not fully clarified. Presently the provisional EC ARfD is 0.3. For this reason, the EC opposes the advancement of the MRLs for grapes (106% of the ARfD for children up to 6 years old $L_P = 0.388$ kg, $U$ of the edible portion = 0.438 kg, $V_f$=5, $ARfD= 0.3$ mg/kg bw) beyond step 6. The EC opposes to advance the proposed MRLs for commodities which can also be used as animal feed beyond step 6 until animal feeding studies on ruminant animals and analytical methods for animal products are available.</th>
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<th>051 Methidathion</th>
<th>The EC acute risk assessment using the Codex MRL’s and a variability factor of 5, gives an exceedance of the ARfD (0.01 mg/kg bw) on grapefruit (2092,8%-toddler), lemons (275,8%-infant), limes (287,6%-toddler), mandarins(2092,8%-toddler), oranges (1546,6-toddler), apples (1361,1%-infant), pears (559,2%-toddler), wine grapes (237,2%-adult) and table grapes (619,3-toddler). EC proposes the withdrawal of those CXL MRL’s.</th>
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<th>059 Parathion-methyl</th>
<th>The EC opposes to advance the proposed MRLs for commodities which also can be used as animal feed beyond step 6 until animal transfer studies are available.</th>
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<th>072 Carbendazim (incl. benomyl and thiophanate-methyl)</th>
<th>In 2005 the JMPR established for carbendazim an ARfD of 0.5 mg/kg bw for the general population, including children and an ARfD of 0.1 mg/kg bw for women of child bearing age. In the EC only one ARfD is set for the general population based upon the most critical NOAEL (see general comments). In the EC, for carbendazim both an ADI and ARfD of 0.02 mg/kg bw have been set. Using the German model for children aged from 2 to below 5 years the ARfD is exceeded for MRLs for oranges, cherries, grapes, mango, and lettuce (step 6). The ARfD is also exceeded for apples, pears, apricots, peaches and nectarines and pineapples. In the EC separate residue definitions are fixed for carbendazim and benomyl on the one hand and thiophanate-methyl on the other. The EC opposes to advance the MRLs for oranges, cherries, grapes, mango, and lettuce head. The EC requires revoking the CXLs for apples, pears, apricots, peaches and nectarines and pineapples.</th>
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<th>074 Disulfoton</th>
<th>The EC opposes the advancement for broccoli, cabbages (head), cauliflower, lettuce head and leaf until the intake problem is clarified or new critical GAPs have been evaluated by JMPR.</th>
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<th>085 Fenamiphos</th>
<th>The EC opposes the advancement beyond Step 6 for peppers (0.5), tomato (0.5) and watermelon (0.05), until the intake problem is clarified or new critical GAPs have been evaluated by JMPR</th>
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<th>090 Chlorpyrifos-methyl</th>
<th>The EC oppose to advance for cereals MRLs and 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.</th>
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<th>094 Methomyl</th>
<th>The EC opposes advancement beyond step 6 for apple (119 % of ARfD for adults (unit weight 90 g, large portion 500 g) and 387 % of ARfD for children (large portion 375 g), $V_f$=5), brassica (cauliflower, broccoli, head cabbage) (214 % for adults (large portion 183 g), 433 % for children (large portion 98 g)), grapes (1231%), leafy vegetables, lettuce (Lettuce: 500 % of ARfD for adults (large portion 80 g), 1350 % of ARfD for children (large portion 57 g), $V_f$=3.) and spinach (Spinach: 139 % of ARfD for adults (large portion 80 g) and 375 % of ARfD for children (large portion 57 g)) because of an acute intake concern. The EC opposes advancement beyond step 6 for apple and pears because acute intake concern.</th>
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For dried chilli peppers, the EC requires a long-term intake calculation based on all uses to finalize the risk assessment before the MRL proposed can be advanced.

095 Acephate
All uses have been withdrawn in the EC.

We oppose advancement of pome fruits (123 %, children) MRLs due to an intake concern. Existing MRLs based on European uses only, must be withdrawn. Moreover, methamidophos is a metabolite of acephate and the use of acephate resulted into MRL proposals for both methamidophos and acephate. The methamidophos MRLs that are associated with the proposed acephate MRLs give an exceedance of the EC ARfD (see comment methamidophos). Consequently, the EC also opposes the advancement of the proposed acephate MRLs on beans, flowerhead brassicas, mandarins, nectarine, peach and peppers.

096 Carbofuran
The risk assessment for carbofuran in mandarins and oranges has been revised at EC level using a metabolism study performed on citrus. This study indicates that carbofuran+3-OH-carbofuran levels in citrus pulp are below 0.001 mg/kg. At this residue level, the EC ARfD of 0.001 mg/kg bw/d is not anymore exceeded. Advancement of the MRLs on oranges and mandarins is therefore now acceptable.

For the other proposed MRLs however there is still an exceedance of the EC ARfD, even when using a variability factor of 3 (700% for cantaloupe, 510% for cucumber, 330% for potatoes, 900% for squash and 150% for sweet corn). EC therefore opposes to any advancement of the MRLs on cantaloupe, cucumber, potato, squash and sweet corn.

100 Methamidophos
The EC ARfD is more than three times lower (0.003 mg/kg bw/day) than JMPR ARfD (0.01 mg/kg bw/day)

The EC opposes the advancement beyond step 6 for tomatoes (99 % of ARfD for adults; unit weight 75 g, large portion 174 g, 189 % of ARfD for children, large portion 141 g). V=5 and peppers (71 % of ARfD for adults, large portion 64 g and 130 % of ARfD for Children large portion 57 g. V=5)

The EC also opposes advancement of the MRLs for head cabbages (158 % of ARfD for adults (large portion 183 g and 174 % of ARfD for children (large portion 98 g) V=3), beans (170%), pome fruit (96 % of ARfD for adults (unit weight 90 g, large portion 500 g), 168 % of ARfD for children (large portion 375 g), V=5), stone fruit (: 125 % for adults (unit weight 130 g, large portion 250 g), 236 % for children (large portion 188 g, V=5), cauliflower (140 % of ARfD for adults (large portion 183 g and 154 % of ARfD for children (large portion 98 g) V=5) and mandarins(46 % of ARfD for adults (large portion 179 g, unit weight 50g), 110 % of ARfD for children (large portion 143 g), V=5) because the EC ARfD is exceeded.

103 Phosmet
The ARfD proposed by the JMPR was increased from 0.02 to 0.2 mg/kg.day in 2003, but the new ARfD is not accepted by the EC because of the lack of scientific validity of the human volunteer studies. They did not provide a complete scientific picture as brain ChE was not measured. If the human study was used in the derivation of the ARfD, an additional safety factor would be required to account for this. It was noted that the critical effect of phosmet was ChE inhibition, and that in the mouse 2 year study brain ChE was the more sensitive endpoint. The EC therefore fixed the ARfD at 0.045 mg/kg bw, based on the NOAEL of 4.5 mg/kg bw in the rat acute neurotoxicity study. NESTI exceeds the ARfD for the following foods: Apple (175%), peach (172,8%) and pear (201,8% Spanish diet,adults), Apricot (119,9%), apple (317,8%), peach and nectarines, (306,1%), peach preserved (138,4%) and pear (336,0% Spanish diet (children)).

110 Imazalil
The EC requests that the existing CXLs be reviewed urgently in view of the ARfD.

112 Phorate
The EC opposes the advancement of the MRL for potato because of an acute intake concerns (Potato: 114 % of ARfD for adults (unit weight 75 g, large portion 631 g), 194 % of ARfD in children (large portion 473 g) V=5).

117 Aldicarb
The EC will withdraw all uses (potatoes, carrots, oranges) in 2007.

The EC opposes the advancement beyond Step 6, until the intake problem is clarified or new critical GAPs have been evaluated by JMPR

126 Oxamyl
The EC requests not to advance the MRL beyond step 6 because the Acute intake concern (EC ARfD = 0.001). Even with JMPR ARfD (0.009) there are exceedences for children (even using 3 as variability factor) for: Citrus (269 %), cucumber (191 %), melon (207 %) and peppers (233 %).
These MRLs and CXL should be listed for withdrawal or deletion and EC to support the CCPR chairman’s intention in this (CCPR 2004 point 61).

For dried chilli peppers, the EC does not support the advancement because of short-term intake concern.

135 Deltamethrin
Leafy vegetables (2 mg/kg, step 6 - CXL 0.5 mg/kg).
The ARID recommended by JMPR 2000 (0.05 mg/kg bw) differs from that established by EC 2003 (0.01 mg/kg bw).
The EC opposes an MRL of 2 mg/kg for leafy vegetables based on intake concern for the individual leafy vegetables Chinese cabbage (250 % of the ARID) and lettuce (180 % of the ARID), taken into account the EC-ARID.
The EC ARID is exceeded even with the variability factor used by JMPR for Chinese cabbage and lettuce.

145 Carbosulfan
The EC has no longer objections to the advancement of the proposed MRLs on oranges and mandarins. However, carbofuran is a metabolite of carbosulfan and the use of carbosulfan on potatoes therefore resulted into MRL proposals for both carbofuran and carbosulfan. The MRL for carbosulfan itself doesn't give rise to unacceptable consumer exposure, but the associated carbofuran MRL gives an exceedance of the EC ARID (see comment carbofuran). Consequently, the EC also opposes to the advancement of the proposed carbosulfan MRL on potatoes.

148 Propamocarb
The EC disagree with the proposed ADI (0.4 mg/kg bw/d) and ARfD (2 mg/kg bw/d) values

Acceptable Daily Intake (ADI)
As always, the ADI is derived from the lowest, relevant long-term NOAEL or NOEL in the most sensitive species. The rat has been identified as the most sensitive species, the critical endpoint being vacuolar change in the epithelial cells of the choroids plexus of the brain. The NOEL (female) in this study was 375 ppm (29 mg/kg bw/day).
Using the usual SF of 100, the proposed ADI = 29 / 100 = 0.29 mg/kg bw/day propamocarb hydrochloride.

Acute Reference Dose (ARfD)
The NOAEL of 100 mg/kg bw/day in the 28-day rat gavage study, where the critical effect is again one of vacuolation of the choroid plexus and of the lacrimal glands is used in the derivation of this value. The usual SF of 100 is used.
The proposed ARfD = 100/100 = 1 mg/kg bw/day

155 Benalaxyl
For the establishment of the ADI, JMPR took in consideration the NOAEL from 1 year study in dog (6,5 mg/kg bw/day) and f =100. In EU, for the same parameter, the NOAEL of the 2 years study in rats (4,4 mg/kg/bw/day) was considered and f = 100.
Concerning the ARID, EU considered a general NOAEL of 12,5 mg/kg bw/day in the developmental study in rat and concluded that in absence of any effects of concern, there was no need to establish an ARID.

166 Oxymeton-methyl
EC requests not to advance the MRLs beyond step 6 because the ADI is exceeded for toddlers.
ARID was also exceeded for toddlers for apples, pears, cabbages head, grapes, oranges.
The LOQ for cattle fat, eggs, meat of cattle, pig and sheep were not acceptable for the compound with an ADI of 0.0003 mg/kg because the consumers were not protected against misusing.

193 Fenpyroximate
The EC opposes the advancement the MRLs for grapes (200 %) and apples (220%) because intake of residues exceeds the ARID.
The EC is informed that a new study is ongoing. MRL proposals for apples and grapes should be on step 6 awaiting the results of a new evaluation by JMPR for acute toxicity.

194 Haloxyfop
EC requests not to advance the MRLs beyond step 3 or 6 awaiting the 2006 JMPR to establish an ARfD and doing a risk assessment.
All uses in the EC will be withdrawn in 2007.
201 Chlorpropham
The EC opposes the advancement of the MRL for potatoes because of intake concerns (215%, for toddlers V=3 (based on data)). In this case the MRLs for cattle milk, cattle meat and cattle and edible offal, can also be deleted. In the EC a different processing factor for cooking is applied
EC has an MRL on potatoes of 10 mg/kg.

214 Dimethanamid-P
The 2005 JMPR established an ADI of 0.07 mg/kg bw and an ARfD of 0.05 mg/kg bw.
The JMPR evaluation of dimethenamid-P has resulted in recommendations for MRLs at the limit of quantification with STMRs and HRs of 0 for raw and processed commodities. The JMPR concluded that the long-term and short term intake of residues of dimethenamid-P from uses that have been considered by the JMPR do not present a public health concern.
The EC has established in 2004 an ADI of 0.02 mg/kg bw and an ARfD of 0.5 mg/kg bw. The EC evaluation for residues has resulted in recommendations for MRLs at the limit of quantification (0.01* mg/kg for all crops except oil seed 0.02* mg/kg, tea 0.02* mg/kg and hops 0.02* mg/kg).
The EC has no concern to advance the proposed MRLs.

215 Fenhexamid - No EC comments

216 Indoxacarb
The EC request not to advance the MRLs beyond Step 6, because of intake concern.
The EC has established a lower ADI of 0.006 mg/kg bw/day based on a 2 year rat study. The JMPR has established an ADI of 0.01 mg/kg bw/day based on a 1 year dietary study in dogs. The use of the EC-ADI of 0.006 mg/kg bw/day lead to exceedance of the ADI of 131% for adults and 186% for toddlers according to the UK diet. Lettuce and milk contribute for the main part.
The Acute RfD is higher in the EC (0.125 mg/kg bw/day) than the JMPR Acute RfD (0.1 mg/kg bw/day). Both are based on the same study. For leafy lettuce the EU Acute RfD is exceeded of 120% (v=5) for children of 4-6 years old, according to the UK diet

217 Novaluron
The EC Rapporteur evaluation of novaluron identified the possibility of accumulation of residues in animal tissues beyond the maximum sampling interval in the cow feeding study. Therefore, it is not possible to estimate MRLs for animal products from the available study. Furthermore, the MRL for milk proposed by JMPR report 2005 leads to an exceedance of the ADI using the UK model (infants 195%).
The EC opposes advancement of the proposed MRLs for commodities which also can be used as animal feed until JMPR have considered the possibility of accumulation in animal tissues and milk.

218 Sulfuryl fluoride - No EC comments

MRLs for dried peppers at Step 6
The EC accepts the levels for dried chilli pepper, except for dimethoate, dicofo, oxamyl and mevinphos as for these there acute and chronic intake concern