CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 7

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DISCUSSION PAPER ON THE APPLICABILITY OF CODEX MAXIMUM RESIDUE LIMITS FOR CITRUS FRUITS TO KUMQUATS

(Prepared by Japan)

The Committee is invited to consider the recommendations put forward in paragraph 15 to determine how to proceed with the inclusion of kumquats in the MRL for citrus fruits including the recommendation to JMPR.

PURPOSE

1. Based on the decision made at the 45th Session of the Committee, Japan requested Codex members to provide consumption data/information on kumquats and performed further analysis to determine whether or not MRLs for citrus fruits should apply to kumquats.

2. In this paper the findings from analysis of the latest available data and recommendations from Japan are presented.

BACKGROUND

3. The Committee considered at its 45th Session whether the existing MRLs for citrus fruits group, the revision of which had been adopted at the 35th Session of the Commission, should be applied to kumquats as they were eaten with the peel (edible portion = whole fruit) as opposed to other citrus fruits, which were eaten without the peel (edible portion = flesh), on the basis of *Discussion Paper on the Review of the Commodity Groups in the Database for Maximum Residue Limits for Pesticides to Determine the Need for Revision of Relevant Group MRLs (revised fruit commodity groups of the Classification of Food and Animal Feed)*.

4. The Committee agreed that MRLs for citrus fruits should also apply to kumquats for compounds for which dietary risk assessment for citrus fruits was conducted based on residues for whole fruit or for compounds for which no ARfD was established, while the remaining group MRLs for citrus fruits listed in Annex of Appendix IX should not be applied to kumquats (REP13/PR, para 110). The revised MRLs were subsequently adopted at the 36th Session of the Commission (REP13/CAC, para 32).

5. The Committee also agreed that the delegation of Japan would request Members to provide relevant consumption data on kumquat to perform further analysis to determine the appropriateness to include kumquats or to carry out additional dietary exposure assessment and would present its findings in a discussion paper for consideration by the next session of the Committee (REP13/PR, para 111).

6. Exposure assessment for kumquats should be conducted on the basis of residues in the whole fruit because the whole fruits including the peels are eaten, as opposed to other citrus fruits, which are eaten after peeling. Kumquats are smaller in size and unit weight (as shown in the following figure) and therefore have higher surface/weight ratio than other citrus fruits such as oranges.

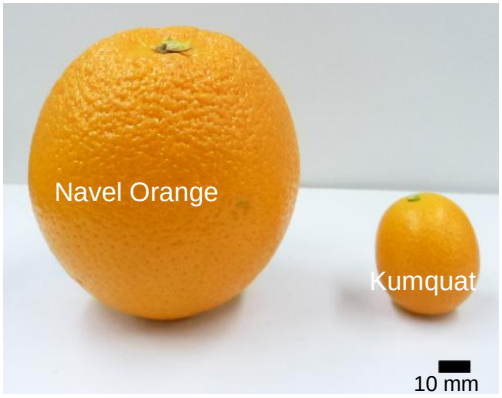

Figure. Kumquat (medium-large size) in comparison with typical navel orange

DATA AVAILABILITY

7. In response to the call for data by Japan in July 2013 on kumquat consumption, relevant information was provided by four members, namely, European Union, Italy, Thailand and the United States of America. All of the respondents indicated that there were no or only few events of kumquat consumption identified in their food consumption database, therefore it was not possible to calculate a 97.5 percentile consumption of kumquats for use of acute exposure assessment in these populations.

8. Consumption data on kumquats for use in acute exposure assessment were available only in Japan, which were obtained from a Research project by the Ministry of Health, Labour and Welfare on the short-term intake assessment for pesticide residues (2010-2012). In this project, food consumption survey was conducted for the general population at or above 1 year old throughout Japan, in a total of 25 cities/towns/villages in the fiscal years of 2005 through 2007. The survey covered all four seasons. In each season, three independent days including two weekdays and one of weekend days/holidays were chosen, though not all subjects could participate in the investigation in all four seasons. Total number of subjects was 4,510 (male 2,459; female 2,051). Total number of participating person･days was 40,394.

ANALYSIS OF DATA AND CONSIDERATIONS

9. From the above Japanese survey, data were obtained on large portion consumption (97.5th percentile of eaters) and the mean body weight for the general population (over 1 year old) consuming kumquats (raw). Data on unit weight for kumquats were separately obtained through commercially available database and measurement of the products on the market, in order to determine which case (case 1, 2a, 2b or 3) should be used in the calculation of International Estimate of Short Term Intake (IESTI). As the number of consumer days for children over 1 year old up to 6 year old consuming kumquats was only 5, it was not appropriate to derive 97.5 percentile consumption data for this commodity. Therefore the relevant data are summarised only for the general population (over 1 year old) consuming kumquats (raw) as follows:

- Number of consumer days: 135 person･days
- Highest large portion reported (97.5th percentile of eaters): 120 g food/person/day
- Mean body weight of eaters: 50.2 kg bw
- Unit weight of the whole commodity: less than 25 g (there are variations in size depending on variety)

Note: 97.5 percentile consumption data for kumquats for all the participants in the survey are 0 g food/person/day.

10. Assuming that the above consumption data represent the global worst-case scenario, IESTI was calculated for kumquats in accordance with the procedures described in Chapter 7 of FAO Manual on the submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (second edition, 2009)[1]. Since the unit weight of kumquat is less than 25 g, it is appropriate to use Case 1, where *the residue in a composite sample (raw or processed) reflects the residue level in a meal-sized portion of the commodity (unit weight, U, is below 25 g)*. As kumquats are eaten with the peel (edible portion = whole fruit), for each compound, the highest residue (HR) in composite sample of the whole commodity of citrus fruits, which was derived from supervised trials contained in the respective JMPR Evaluation, was used.

11. Following the above procedure, IESTI was calculated for kumquats for 19 compounds for which the indication of “excluding kumquats” was inserted in the MRL for citrus fruits (REP13/PR, Annex of Appendix IX) as well as for 3 compounds for which the 2013 JMPR recommended maximum residue levels for “citrus fruits” or “lemons and limes.” Calculated IESTIs were then compared with the ARfDs of respective compounds as shown in Tables 1 and 2.

Table 1. Percentage of the ARfD found in the short-term dietary risk assessments of kumquats for the general population (over 1 year old) for 19 compounds (Annex of Appendix IX of REP13/PR)

Codex code	Pesticide	CXL for Citrus fruits (mg/kg)	HR[a] (whole fruit) (mg/kg)	ARfD (mg/kg bw)	IESTI for kumquats /ARfD (%)
8	Carbaryl	15	10	0.2	12
17	Chlorpyrifos	1	1.2	0.1	3
27	Dimethoate	5 [b]	4.4	0.02	53
49	Malathion	7	4.7	2	1
65	Thiabendazole	7 Po	5.2	0.3[c]	4
90	Chlorpyrifos-methyl	2	0.89	0.1	2
94	Methomyl	1	0.89	0.02	11
101	Pirimicarb	3	2.5	0.1	6

[1] http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/FAO_manual2nded_Oct07.pdf

Codex code	Pesticide	CXL for Citrus fruits (mg/kg)	HR[a] (whole fruit) (mg/kg)	ARfD (mg/kg bw)	IESTI for kumquats /ARfD (%)
103	Phosmet	3	1.8	0.2	2
118	Cypermethrins	0.3	0.16	0.04	1
142	Prochloraz	10 Po	6.8	0.1	16
146	Lambda-cyhalothrin	0.2	0.16	0.02	2
173	Buprofezin	1	0.46	0.5	0
193	Fenpyroximate	0.5	0.28	0.02	3
196	Tebufenozide	2	0.95	0.9	0
206	Imidacloprid	1	0.88	0.4	1
210	Pyraclostrobin	2	1.3	0.05	6
238	Clothianidin	0.07 (T) [d]	0.05	0.6	0
245	Thiamethoxam	0.5	0.26	1	0

a: Highest value of the individual trial results according to the residue definition for estimation of dietary intake for plant commodities

b: According to 2003 JMPR Report and Evaluation, IESTI was not calculated for dimethoate for citrus fruits because it seems that STMR: 0.27 mg/kg, instead of HR: 1.4 mg/kg was mistakenly entered into the corresponding colum of IESTI spreadsheet.

c: for women of child-bearing age

d: The source of the residue is Thiamethoxam

Table 2. Percentage of the ARfD found in the short-term dietary risk assessments of kumquats for the general population (over 1 year old) for 3 compounds for which the 2013 JMPR recommended maximum residue levels for citrus fruits or lemons and limes

Codex code	Pesticide	Maximum Residue Level (mg/kg)	HR[a] (whole fruit) (mg/kg)	ARfD (mg/kg bw)	IESTI for kumquats /ARfD (%)
Citrus fruits					
31	Diquat	15	0	0.8	0
224	Difenoconazole	1	0.49	0.3	0
Lemons and Limes					
197	Fenbuconazole	1	0.42	0.2	1

a: Highest value of the individual trial results according to the residue definition for estimation of dietary intake for plant commodities

12. For general population (over 1 year old), the IESTI calculation for kumquats represented 0-16% of the ARfD for 18 compounds (except for dimethoate which represented 53% of the ARfD) listed in Table 1 and 0-1% of the ARfD for 3 compounds listed in Table 2. For children up to 6 year old, it was not appropriate to conduct IESTI calculations for kumquats due to lack of relevant consumption data. However, as the flesh of kumquat is bitter and tart, it is unlikely that children consume as much kumquats as adults.

13. It may seem that the safety margin for kumquat is exceptionally small in case of dimethoate. Nonetheless, the situation occurs not only for kumquats but also for citrus fruits in general. It seems that Codex MRL for citrus fruits for dimethoate was adopted at the 29th Session of the Commission in 2006 without considering IESTI for citrus fruits for this compound, since there is no corresponding IESTI calculation in JMPR Evaluation in 2003 and thereafter. We noted that, using HR of 1.4 mg/kg in pulp and the current consumption data, IESTI for dimethoate for Mandarins, Oranges, Shaddock or Pomelos would exceed the ARfD (max: 230% for general population).

14. Based on the above considerations, it can be concluded that the short-term intake of residues of each of these 22 compounds listed in Tables 1 and 2 resulting from uses that have been considered by the JMPR to estimate group maximum residue levels for citrus fruits is unlikely to present a public health concern and therefore group MRLs for “citrus fruits” or “lemons and limes” should also apply to kumquats.

RECOMMENDATIONS

15. Based on the outcome of analysis, the delegation of Japan recommends that the Committee should decide the following:

i. Group MRLs for citrus fruits or those for lemons and limes apply to kumquats for the following pesticides:

8 Carbaryl;

17 Chlorpyrifos;

27 Dimethoate;

49 Malathion;

65 Thiabendazole;

90 Chlorpyrifos-mehyl;

94 Methomyl;

101 Pirimicarb;

103 Phosmet;

118 Cypermethrins;

142 Prochloraz;

146 Lamda-cyhalothrin;

173 Buprofezin;

193 Fenpyroximate;

196 Tebufenozide;

206 Imidacloprid;

210 Pyraclostrobin;

238 Clothianidin; and

245 Thiamethoxam.

ii. The indication *“excluding kumquats”* be removed from the Codex MRL database for MRLs for citrus fruits for the above-listed pesticides.

iii. The Committee consider the advancement of draft MRLs for citrus fruits or that for lemons and limes with the understanding that these MRLs also apply to kumquats:

31 Diquat (citrus fruits);

197 Fenbuconazole (lemons and limes); and

224 Difenoconazole (citrus fruits).

iv. The Committee request the JMPR to calculate IESTI also for kumquats using the following factors when estimating maximum residue levels for “citrus fruits” or “lemons and limes”:

- the above-mentioned large portion data on kumquats; and
- HR of citrus fruits in whole fruits