WORLD TRADE ORGANIZATION

G/SPS/N/JPN/103
16 June 2003

(03-3178)

Committee on Sanitary and Phytosanitary Measures Original: English

NOTIFICATION

1.	**Member to Agreement notifying:** JAPAN **If applicable, name of local government involved:**
2.	**Agency responsible:** Ministry of Health, Labour and Welfare
3.	**Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):** Pig muscle and pig liver
4.	**Regions or countries likely to be affected, to the extent relevant or practicable:** All countries
5.	**Title, language and number of pages of the notified document:** Revision of maximum residue limits for veterinary drugs in food of animal origin (available in English, two pages)
6.	**Description of content:** Revision of maximum residue limits for quinoxaline-2-carboxylic acid (QCA) in pig muscle and liver
7.	**Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection, [ ] protect humans from animal/plant pest or disease, [ ] protect territory from other damage from pests**
8.	**International standard, guideline or recommendation:** **[X] Codex Alimentarius Commission, [ ] Office International des Epizooties, [ ] International Plant Protection Convention, [ ] None** **If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:** Not detected as quinoxaline-2-carboxylic acid (QCA) in pig muscle and liver.
9.	**Relevant documents and language(s) in which these are available:** The basic law is the Food Sanitation Law. The amendments will appear in "KANPO" (Official Government Gazette) when adopted.
10.	**Proposed date of adoption:** As soon as possible after the final date for comments period.
11.	**Proposed date of entry into force:** As soon as possible after the final date for comments period.
12.	**Final date for comments:** 1 August 2003 **Agency or authority designated to handle comments: [ ] National notification authority, [X] National enquiry point, or address, fax number and E-mail address (if available) of other body:**

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13.	**Texts available from: [ ] National notification authority, [X] National enquiry point, or address, fax number and E-mail address (if available) of other body:**

Proposal for the Revision of the MRLs
for quinoxaline-2-carboxylic acid (QCA)

Japan is going to revise the Maximum Residue Limit (MRL) for quinoxaline-2-carboxylic acid (QCA). This proposal is based on the background given below.

Purpose

This proposal is to make the MRL of QCA (carbadox metabolites) in meat stricter.

Under Article 7 Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour and Welfare may establish specifications and standards for veterinary drugs in foods derived from animal origin. Foods for which standards or specifications have been established based on this article the law may be marketed only when they meet the established standards or specifications. Currently, standards are established for 26 veterinary drugs in foods.

The Joint Subcommittee on Animal Origin Foods and Toxicity under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has finished its discussion on the revision of the residue standards for carbadox, on which the Council was earlier consulted by the Minister. The joint subcommittee has concluded that it is appropriate to revise the standards as below.

Outline of revision

Veterinary drug	Species	Tissue	Residue standards	
			Draft MRL	Current MRL
Quinoxaline-2-carboxylic acid	Pig	Muscle	No detection	5 ppb
		Liver	No detection	30 ppb

Necessity of standards

In 1997 Japan determined that the ADI for carbadox could not be established because the chemical and its metabolites, desoxycarbadox and hydrazine, were genotoxic and carcinogenic. On this basis Japan adopted maximum residue limits (MRLs) for pig muscle and liver at 5ppb and 30ppb respectively that were the limits of quantification (LOQs) on quinoxaline-2-carboxylic acid (QCA) as indicator of carbadox in these tissues by HPLC-UV. These MRLs are same as Codex standards.

On March 24, 2003 the Ministry of Health, Labour and Welfare (MHLW) convened the Joint Subcommittee on Animal Origin Foods and Toxicity in the Food Sanitation Committee under the Pharmaceutical Affaires and Food Sanitation Council since new study data on carbadox residue, unpublished report by Phibro Animal Health in 2003, was made available.

The subcommittee has reviewed the residue data for short withdraw period, 15 days, produced by using the new analytical method, LC-MS/MS. It shows that desoxycarbadox is detected in pig liver at 0.96 to 7.0 ppb although detected levels of QCA, 16–21ppb, remain below the current MRL for pig liver, 30ppb. In addition the subcommittee has reaffirmed that the ADI of carbadox could not be established because the chemical and its metabolites, desoxycarbadox and hydrazine, are genotoxic and carcinogenic. On these results the subcommittee has concluded that the current MRLs for carbadox is unable to secure that carbadox and its metabolites does not residue in foods.

The subcommittee has also discussed the regulatory method of genotoxic and carcinogenic substances by consulting the US management method, that is, risk management option on 1 in 1 million of carcinogenicity. However the subcommittee has not reached consensus and concluded to remain the regulatory method as currently applied, that is, genotoxic and carcinogenic chemicals such as veterinary drugs and food additives which are intentionally used and not contaminants should be regulated by imposing non-detectable standards. MHLW recognizes that JECFA has similar consideration on method for risk management of genotoxic and carcinogenic substances.

MHLW will make efforts to develop a practical and high-sensitive method for carbadox and its metabolites since the current MRLs are established referring to the LOQs by HPLC-UV.

Since JECFA expressed at its sixtieth meeting that *"consumers should have every confidence that there is no evidence that any harmful effects have been caused by residues of either of these two compounds(Note; carbadox and flumequine) that may have been present in food resulting from approved uses in animals"* and the subcommittee considers that products may not immediately pose adverse health effects in light of residues levels of source pigs treated with the chemical under appropriate conditions including withdrawal period MHLW does not think that products from pigs treated with carbadox are necessary to be recalled. It should be stressed that MHLW proposes to revise MRLs of carbadox rather than to prohibit its use.