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Maximum Residue Limits for Malachite Green and Leucomalachite Green

2005

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Report Highlights:
Japan invited foreign embassies to comment on the establishment of maximum residue limits for malachite green and leucomalachite green in food. The proposed level to be established is "not detected" (ND) for both substances. The deadline for submitting these comments is December 22, 2005. This proposal will be open for comments again when it is submitted to the WTO.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

On December 8, 2005, the Ministry of Health, Labor, and Welfare (MHLW) invited foreign Embassies in Tokyo to comment on the establishment of "not detected" (ND) as the maximum residue limits for malachite green and leucomalachite green in food. Details on this proposed action by MHLW are shown below. Foreign governments have until December 22, 2005 to comment.

All interested parties are encouraged to send their comments, well before the deadline, for consideration to USDA's Foreign Agricultural Service. The office responsible for the comments is:

Food Safety and Technical Services
International Trade Policy Division
USDA Foreign Agricultural Service
Fax: 202-690-0677
Email: fstsd@fas.usda.gov

I. Background
Malachite Green (MG) is prohibited for use in aquaculture animals for human consumption in many countries including Japan, because of concern about its toxicity. However, MG is sometimes found in aquaculture products at import examination in Japan.
Leucomalachite Green (LMG), a major metabolite of MG, is reported to remain for a longer period in animals than MG. In fact, there were detections of LMG in fish and shellfish in foreign countries. In Japan, both compounds have not been evaluated for safety, and no residue standard is set for them. Therefore, the Ministry of Health, Labour and Welfare has decided to have the Food Safety Commission evaluate the safety of them and establish residue standards for them in food, based on the evaluation of the commission.

II. A Summary of Report from the Joint Committee on Agricultural Chemicals and Veterinary Drugs under the Pharmaceutical Affairs and Food Sanitation Council.

1. Substances
Malachite Green: 4-[(4-Dimethylaminophenyl)-phenylmethyl]-N,N-dimethylaniline
Leucomalachite Green: 4,4'-Benzylidenebis (N,N'-dimethylaniline)

2. Use: Antifungal agent for aquaculture animals
MG is a green synthetic dye and has antimicrobial activity. The compound, which used to be widely used as an antifungal agent in the aquaculture industry, is prohibited for use in aquaculture animals for human consumption in Japan and many other countries.
LMG, a major metabolite of MG, is produced by the reduction of MG in the living body. LMG has little antimicrobial activity. However, there is a report showing that it persisted for a longer period in the tissues of fish treated with MG, compared with MG. LMG could persist in the fish tissues if MG is used for fish.

3. Evaluation of Acceptable Daily Intake (ADI)
The Food Safety Commission has concluded, from the following evaluation, that it is not appropriate to establish ADIs for MG and LMG.
The results of the two-year feed studies with rodents, which were thought to be only appropriate data to evaluate carcinogenicity at present, suggested that LMG has carcinogenic potential in the liver of female mice and in the liver and thyroid gland of rats, and MG has slight carcinogenic potential to the liver and mammary glands of female rats. Also, from in vitro genotoxicity studies with the liver of rats and mice, it was determined that both compounds could be genotoxic. Based on evaluations of these study data, the compounds are likely to be carcinogenic, and the possibility of their genotoxicity cannot be

ruled out although the mechanism of carcinogenicity cannot be clarified and the carcinogenic risk to humans is not clear.

4. Regulatory situation in foreign countries
For MG and LMG, a toxicity evaluation has not been conducted by the FAO/WHO Joint Expert Committee on Food Additives, and no international standard has been established. MG is not approved as an aquaculture veterinary drug in many countries including the United States, Canada, and the European Union. The EU established the minimum required performance limit of 2 µg/kg as the sum of MG and LMG. Australia and New Zealand set the standard at "not detected level," along with a limit of detection of 2 µg/kg.

5. Draft maximum residue limits (MRL)
MRLs will be established as "not detected" (ND) for MG and LMG, based on the evaluation of the commission.