

WORLD TRADE ORGANIZATION

G/SPS/N/GBR/3
13 November 2002

(02-6254)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION OF EMERGENCY MEASURES

1.	Member to Agreement notifying: <u>UNITED KINGDOM</u> If applicable, name of local government involved: England
2.	Agency responsible: Food Standards Agency in England, Scotland, Wales, Northern Ireland
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): Any food consisting of or containing <i>Piper methysticum</i> (known also as Kava-kava of Combined Nomenclature heading 1211 90 98).
4.	Regions or countries likely to be affected, to the extent relevant or practicable: Kava-kava producing countries e.g. Fiji, Samoa, Tonga, Vanuatu.
5.	Title, language and number of pages of the notified document: The Kava-Kava in Food (England) Regulations 2002 (5 pages in English).
6.	Description of content: Under Section 16 of the Food Safety Act 1990, these proposed Regulations will prohibit the sale, possession for sale, offer, exposure or advertisement for sale, and the importation into England from outside the United Kingdom, of any food consisting of, or containing, Kava-Kava (being a plant or part of a plant, or an extract from such a plant, belonging to the species <i>Piper methysticum</i>). Similar Regulations will be made in Scotland, Wales and Northern Ireland.
7.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests
8.	Nature of the urgent problem(s) and reason for urgent action: Evidence has emerged that, in rare cases, consumption of products containing Kava-kava may be associated with liver damage. The UK's Committee on Safety of Medicines (CSM) has reviewed a total of 68 case reports of suspected liver toxicity associated with consumption of Kava-kava. The severity of the liver damage suffered varies and includes abnormal liver function, jaundice, hepatitis, liver failure and death. In six cases the patients suffered irreversible liver failure and received liver transplants. Three patients died, including one who had received a transplant. The CSM advised that there was sufficient evidence to conclude that Kava-kava is associated with rare cases of liver toxicity that may be serious in nature. The UK Medicines Control Agency is consulting on a proposed Order that would prohibit the use of Kava-kava in unlicensed medicinal products. There are also a number of food products containing Kava-kava on the market in the UK. Currently there are no specific controls on the inclusion of Kava-kava in foods. A number of the case reports reviewed by the CSM concerned patients who were consuming food

<p>products containing Kava-kava as well as medicinal products containing Kava-kava. The advice from CSM also requires action on food uses of Kava-kava because there is no clear understanding of the nature of the hepatotoxicity, including its mechanism. Consequently, the FSA is proposing to prohibit food uses of Kava-kava.</p> <p>The proposed Regulations are considered necessary to protect consumers against the risk that consumption of foods containing or consisting of Kava-kava may cause liver damage.</p>
<p>9. International standard, guideline or recommendation: <input type="checkbox"/> Codex Alimentarius Commission, <input type="checkbox"/> Office International des Epizooties, <input type="checkbox"/> International Plant Protection Convention, <input checked="" type="checkbox"/> None</p> <p>If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:</p>
<p>10. Relevant documents and language(s) in which these are available: The package of consultation documents (consultation letter, draft Regulations and draft Regulatory Impact Assessment) is available free of charge from the Food Standards Agency. The documents are available in English. If the Regulations become law, they will be published on the website of the Stationery Office www.hmsso.gov.uk.</p>
<p>11. Date of entry into force/period of application (as applicable): In England, consultation on the proposed Regulations ended on 27 September 2002. If, after consideration of comments received, the Food Standards Agency considers that it is necessary to bring in the proposed legislation in order to protect public health, the Food Standards Agency's recommendation to the Secretary of State will be that he make the Regulations as soon as possible. The date of entry into force is then likely to be 21 days after the Regulations are made.</p> <p>The United Kingdom's Medicines Control Agency has proposed that, for human health reasons, the use of Kava-kava in unlicensed medicines should also be prohibited. This intention was notified under the TBT Agreement on 21 August 2002. Mention is made here for transparency.</p>
<p>12. Agency or authority designated to handle comments: <input type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body:</p>
<p>13. Texts available from: <input type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> National enquiry point, or address, fax number and E-mail address (if available) of other body:</p>