



Notification Number: 2002/300/UK

The Kava-Kava in Food (England) Regulations 2002.

Date received : 24/07/2002

End of Standstill : 25/10/2002

Message

Message 001

Communication from the Commission - SG(2002) D/51496

Directive 98/34/EC

Notifikation - Notifizierung - Γνωστοποίηση - Notification - Notificación - Notifica - Kennisgeving -
Notificação - Ilmoitus - Anmälan : 2002/300/UK.

Fristerne indledes ikke - Kein Fristbeginn - Καμμία έναρξη προθεσμίας - Does not open the delays - No abre el
plazo - N'ouvre pas de délais - Non fa decorrere la mora - Geen termijnbegin - Nao inicia o prazo - Määräaika ei
ala tästä - Inleder ingen frist.

(MSG: 200201496.EN)

1. Structured Information Line

MSG 001 IND 2002 0300 UK EN 25-10-2002 24-07-2002 UK NOTIF 25-10-2002

2. Member State

United Kingdom.

3. Department Responsible

Department of Trade and Industry: Standards and Technical Regulations Directorate

3. Originating Department

Food Standards Agency.

4. Notification Number

2002/300/UK COOA

5. Title

The Kava-Kava in Food (England) Regulations 2002.

6. Products Concerned



Any food consisting of or containing Kava-kava.

7. Notification Under Another Act

Not applicable.

8. Main Content

These Regulations 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 *Piper methysticum*) (regulation 3). Any such food may be treated as being unfit for human consumption and be liable to be seized and destroyed (regulation 5(3)).

9. Brief Statement of Grounds

The proposed Regulations are considered a necessary measure to protect consumers against the risk of liver toxicity from consuming foods containing or consisting of Kava-kava.

Kava-kava is a herbal ingredient derived from the plant *Piper methysticum*. In recent months evidence has emerged that, in rare cases, use of products containing Kava-kava may be associated with liver toxicity. The UK's Committee on Safety of Medicines (CSM) has reviewed a total of 68 case reports (from Germany, Switzerland, France, United States, Canada and UK) 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. Most of the effects have been at the less serious end but in six cases the patients suffered irreversible liver failure and received liver transplants. Three patients died, including one whom had received a transplant. There have been three reported cases in the UK, one of which has yet to be medically confirmed. None of these cases has been fatal but one of the confirmed cases was jaundiced and was hospitalised for seven weeks. The outcome is currently unknown.

The CSM considered the latest evidence on 10 July and advised that there was sufficient evidence that Kava-kava was associated with rare cases of liver toxicity that may be serious in nature. The CSM considered a number of regulatory options and recommended that medicines containing the herbal ingredient Kava-kava should be removed from the UK market on safety grounds. The UK Medicines Control Agency is consulting which would prohibit the use of Kava-kava in unlicensed medicinal products.

The majority of Kava-kava products currently on the market in the UK are medicines however there may also be some food products. Currently there are no specific controls on the inclusion of Kava-kava in foods. New information gathered since December 2001 has reinforced previous concerns and now supports the need to prohibit sale of Kava-kava in food (please see the risk assessment below).

10. Reference Documents - Basic Texts

i. 1) Draft Regulations 2) Partial RIA.

ii.

iii Risk assessment:

There is a paucity of toxicological data on Kava-kava or its component lactones and the available data are inadequate to identify a no observed adverse effect level.



The UK's CSM has considerable experience in assessing evidence from case reports of adverse reactions. Whilst acknowledging the uncertainties in its analysis the CSM concluded that Kava-kava is associated with liver toxicity. This toxicity is relatively rare but there are neither any data permitting identification of the mechanism of toxicity nor any data on any patient or product characteristics that might increase the risk. It is not possible to conclude that the liver toxicity is dose dependent nor can we exclude an immune-mediated toxicity for which dose would not be relevant.

There is evidence to suggest that hepatotoxicity can occur in users of the traditional Kava-kava preparations as well as in users of other Kava-kava products.

There are no data to compare the effects of extraction in hot liquid on the composition of the Kava-kava preparations. Thus we are not able to determine if tea bags (one food product of which we are aware) containing Kava-kava result in exposures comparable to traditional or solvent-extracted Kava-kava preparations.

In absence of a clear understanding of the hepatotoxicity, including its mechanism and relevant patient and exposure characteristics, it is not possible to exclude hepatotoxicity arising from food uses of Kava-kava. The information provided since December 2001 provides further evidence that consumption of Kava-kava may cause liver toxicity.

We have no statistics on the level of consumption of Kava-kava food products by the population of this country and therefore the level of risk to health cannot be determined. The risk assessment does not allow us to predict whether certain consumers may be more at risk than others. However, given the concerns over potentially serious liver toxicity associated with Kava-kava consumption we consider it prudent to prohibit sale of Kava-kava foods.

11. Invocation of the Emergency Procedure

No.

12. Grounds for the Emergency

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13. Confidentiality

No.

14. Fiscal measures

No.

David O'Sullivan
General Secretary
European Commission



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