



Notification Number: 2005/78/UK

The Kava-Kava in Food (Wales) Regulations 2005

Date received : 03/03/2005

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Message

Message 001

Communication from the Commission - SG(2005) D/50466

Directive 98/34/EC

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan : 2005/0078/UK.

No abre el plazo - Nezahtuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200500466.EN)

1. Structured Information Line

MSG 001 IND 2005 0078 UK EN 06-06-2005 03-03-2005 UK NOTIF 06-06-2005

2. Member State

United Kingdom

3. Department Responsible

Department of Trade and Industry: Standards and Technical Regulations Directorate.

3. Originating Department

Food Standards Agency Wales.

4. Notification Number

2005/0078/UK – C50A

5. Title

The Kava-Kava in Food (Wales) Regulations 2005



6. Products Concerned

Any food consisting of or containing Kava-kava.

7. Notification Under Another Act

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8. Main Content

These Regulations prohibit the sale, possession for sale, offer, exposure or advertisement for sale, and the importation into Wales 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). Certain exceptions apply in relation to imports from EEA States. 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*. Since 2001 there has been increasing evidence 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) first considered the safety of medicinal products containing Kava-kava in December 2001 following reports, mainly from Germany, of liver toxicity associated with its usage. They reviewed a series 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. The CSM considered the cumulative evidence on 10 July 2002 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. In 2002, the Food Standards Agency took the view that Kava-kava in food posed a rare but serious risk to public health. On the basis of the Agency's advice, the National Assembly for Wales prohibited the sale and importation of Kava-kava for use in foods, through The Kava-kava in Food (Wales) Regulations 2002 but the regulations were later revoked.

In June 2003 (the latest date for which data is yet available) the total number of worldwide reports of suspected hepatotoxicity associated with Kava- kava had risen to 82 including 4 cases in the UK. In 8 cases patients suffered irreversible liver failure and received liver transplants. Five patients died, including one whom had received a transplant. None of these cases involved UK patients.

10. Reference Documents - Basic Texts

b) 2005/0032/UK, 2002/0307/UK, 2002/0300/UK

f) 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

15. Impact assessment

The impact assessment is attached.

16. TBT and SPS aspects

TBT Aspect

No

The draft is not a technical regulation nor a conformity assessment procedure in the sense of Annex 1 of the TBT Agreement.

SPS Aspect



Yes

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