



Notification Number: 2005/32/UK

The Kava-Kava in Food Regulations (Northern Ireland) 2005

Date received : 02/02/2005

End of Standstill : 03/05/2005

Message

Message 001

Communication from the Commission - SG(2005) D/50225

Directive 98/34/EC

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificação - Hlásenie-Obvestilo - Ilmoitus - Anmälan : 2005/0032/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: 200500225.EN)

1. Structured Information Line

MSG 001 IND 2005 0032 UK EN 03-05-2005 01-02-2005 UK NOTIF 03-05-2005

2. Member State

United Kingdom

3. Department Responsible

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

3. Originating Department

Department of Health, Social Services and Public Safety.

4. Notification Number

2005/0032/UK - C50A

5. Title

The Kava-Kava in Food Regulations (Northern Ireland) 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 Northern Ireland 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 on a proposed Order under Section 62 of the Medicines Act 1968, 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

c) 2002/0300/UK, 2002/0307/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

At present separate RIA's are not carried out in Northern Ireland, findings from the English RIA are taken as representative.

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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