Irradiated Herbal Supplements and Herbal Substances Survey 2005

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SUMMARY

The FSAI has recently carried out a follow up survey targeting herbal supplements that had previously been shown to be either “irradiated” or have an “irradiated component”. Of eight products previously identified as “irradiated” in 2002/2003, four were again found to be “irradiated”, three had an “irradiated component” and one was negative. Of 11 products identified as having an “irradiated component” in 2002/2003, one was found to be “irradiated” and the remainder were identified as having an “irradiated component”. These results show that despite the considerable efforts of the FSAI and the Irish health food industry in tackling this problem with suppliers, the illegal sale of unlabelled irradiated herbal supplements persists in Ireland. The FSAI has decided to focus on products that have been identified as “irradiated” and requested the health food and pharmacy industry representatives to withdraw the implicated batches. Due to possible uncertainty about results categorised as “irradiated component”, this withdrawal only applies to herbal supplements falling within the “irradiated” category. The FSAI has been, and continues to work closely with the UK Food Standards Agency which is dealing with a similar problem within their jurisdiction.

It is the sole responsibility of food business operators to ensure that foods are accurately labelled and that only authorised foods are on the Irish market. In the interests of consumers, the FSAI plans to continue testing herbal supplements for evidence of irradiation. Food business operators may face prosecution where products previously shown to be “irradiated” and unlabelled continue to be marketed illegally.

BACKGROUND

Food irradiation is a process in which food is exposed to defined levels of ionising radiation for a limited time period. The radiation, which can be emitted by electronic or radioactive sources, is used to reduce the levels of harmful or spoilage microorganisms in food or kill insects and pests that a food may harbour. Irradiation is also used to delay certain natural processes that may affect the quality of a food such as the ripening, sprouting or germination of various fruit and vegetables, (http://www.fsai.ie/industry/irradiated_food_info.pdf). While irradiation may not be suitable for all foods, the process is generally considered to be safe when carried out under controlled conditions in suitable facilities.

The European Commission reports annually on inspections of food irradiation facilities and checks of the food supply for appropriate labelling carried out by Member States. Eight Member States submitted data for the period 2000 to 2001 and in the subsequent Commission report (published in 2002, *http://europa.eu.int/comm/food/fs/sfp/fi_index_en.html*) only 97 of the 6,748 samples tested (1.4%) were found to be in breach of the food irradiation legislation in that they were inaccurately labelled. In that report the UK Food Standards

Agency highlighted the fact that 42% of the herbal supplements tested in the UK were found to have been irradiated but not appropriately labelled. Based on this information the Commission requested that Member States target this sector to determine whether a similar problem existed within their jurisdictions.

EU LEGISLATION GOVERNING FOOD IRRADIATION

Under EU legislation, food or food ingredients may be irradiated only if the following criteria are met; (a) there is a reasonable technological need, (b) it does not present a health hazard, (c) it is of benefit to consumers and (d) it is not used as a substitute for hygiene or health practices or for good manufacturing or agricultural practice.

Two EC Directives govern the irradiation of foods and their marketing within the EU: the Framework Directive (1999/2/EC) and the Implementing Directive (1999/3/EC). These were transposed into Irish law by Statutory Instrument number 297 of 2000.

The Framework Directive covers general and technical aspects for carrying out the irradiation process, conditions for authorising food irradiation, exemptions, and labelling requirements of irradiated foods. Facilities that irradiate food destined for the EU market must be recognised by the European Commission and must comply with conditions set out in the Framework Directive.

The Implementing Directive provides a list of foods and food ingredients that are authorised within the EU for treatment with ionising radiation. Currently, only dried aromatic herbs, spices and vegetable seasonings are listed, with a maximum overall average absorbed dose of 10 kGy permitted. Until the EU list is finalised, Member States may continue to irradiate those foods on the list of national authorisations and they may also maintain any existing national restrictions or bans on irradiated foods. Some national authorisations include garlic, but herbal supplements or food supplements as specific categories are not included.

Survey of Herbal Supplements in the EU

As a result of the Commission's request for information in 2002, four Member States including Ireland, the United Kingdom, Germany and the Netherlands found evidence that a combined average of 30% of the herbal supplements tested were irradiated but not appropriately labelled within their jurisdictions. Three out of 17 samples tested in Germany (18%), 31 out of 124 (25%) in the Netherlands, six out of 25 (24%) in the UK and 10 out of 24 (42%) in Ireland (http://www.fsai.ie/industry/irradiated_food_report.pdf) had been irradiated or contained an irradiated component.

In 2003, the FSAI tested a further 26 herbal supplements and herbal substances to find that 13 samples (50%) were irradiated or contained irradiated ingredients,

(Irradiated Herbal Supplements and Herbal Substances Survey 2003). Also in 2003, other Member States (Denmark - 15 out of 106, Germany - 8 out of 86 and the UK - 29 out of 64) identified herbal supplements that were "irradiated" or contained an "irradiated component".

In 2005, the FSAI tested new batches of herbal supplements that had previously been found to be irradiated or contain irradiated ingredients. As a form of negative control, one product chosen had tested negative for irradiation in a previous survey.

SAMPLING AND ANALYSIS

A total of 20 herbal supplements (or substances) were purchased "off the shelf" in central Dublin in January and February of 2005. Of the 23 samples that were identified as having been irradiated in previous surveys (http://www.fsai.ie/surveillance/index.asp), five were unavailable (discontinued or out of stock), and MedicHerb Devil's Claw was purchased in place of Rivo Devil's Claw (the packaging was very similar suggesting a link between the two brand names). Two extra herbal supplements were included in the survey. Aloe Vera superstrength tablets (Aloe Pura) was found to have been irradiated when tested by the Public Analyst Laboratory, Cork in February 2003. Korean Ginseng (Red Kooga) was selected as the negative control since a separate batch of the same product was tested previously and found to have been not irradiated.

Many of the herbal supplements were in capsule form, but only the contents were tested, and not the capsules. Two of the samples tested are referred to as "herbal substances" as they were not presented for sale in dose form.

The European Committee for Standardisation (CEN) has approved a number of analytical methods for the analysis of irradiated food products (http://europa.eu.int/comm/food/fs/sfp/fi07_en.html). In this survey a luminescence detection method was used to test samples for evidence of irradiation. The method relies on the fact that most foods contain some level of mineral debris (typically silicates or bioinorganic materials) that trap energy when exposed to ionising radiation. When irradiated mineral debris is exposed to additional energy in the form of heat or infrared light, the trapped energy is released as light that can be measured by sensitive light detection instruments.

Thermoluminescence (TL) analysis (EN 1788:2001) of food involves the extraction of mineral grains from a food sample and heating the extracted mineral grains to release any trapped energy which can then be quantified. As a calibration procedure, the extracted mineral grains are then irradiated, heated and the released energy quantified.

RESULTS

Thermoluminescence (TL) results show that 18 of the 20 samples tested were found to have been “irradiated” or to contain an “irradiated component” (Table 1). None of the samples tested were labelled to indicate that they had been irradiated.

Table 1: Herbal supplements and substances tested by Thermoluminescence (TL)

Product name	Brand	Best Before date	Batch code	TL result 2005	TL result 2002/2003
Dong Quai	Boots	00/03/2007	F001104	irradiated	irradiated
Kyolic garlic 1000	Quest	28/02/2007	410084	irradiated	irradiated
Siberian Ginseng	FSC	31/03/2005	A03351	irradiated	irradiated
Aloe Vera superstrength tablets	Aloe Pura	31/07/2007	2044	irradiated	Irradiated
Saw Palmetto Extract	Nature's Aid Herbal range	30/06/2006	882012	irradiated	irradiated component
Aloe Vera (*Aloe barbadensis*)	Solgar	31/08/2007	77021	irradiated component	irradiated
Devil's Claw	Solgar	28/02/2007	72447	irradiated component	irradiated
Raspberry leaves	Good'n'Natural Select Herbals	28/02/2007	60667-17	irradiated component	irradiated
Devil's Claw	MedicHerb (same packaging as Rivo)	00/08/2007	0001/04	irradiated component	irradiated component (Rivo)
Dong Quai Root	Viridian	12/05/2006	341205	irradiated component	irradiated component
Effervescent Echinacea extract (citrus flavoured)	Healthcrafts, Chefaro UK Ltd	00/08/2006	L 42536	irradiated minor component	irradiated component
Ginger root (*Zingiber officinale*)	Solgar	28/02/2007	79950	irradiated component	irradiated component
Korean Ginseng	Down To Earth packed herbs	31/05/2005	-	irradiated component	irradiated component
Saw Palmetto	Good'n'Natural Select Herbals	31/08/2007	219425-03	irradiated component	irradiated component
Siberian Ginseng	Down To Earth packed herbs	31/01/2007	30115	irradiated component	irradiated component
Silymarin Milk Thistle	Good'n'Natural Select Herbals	31/08/2007	6500818	irradiated component	irradiated component
Turmeric	Cynara	31/07/2007	L23534	irradiated component	irradiated component
Unique Garlic	Holland & Barrett	30/06/2008	63701-05	irradiated component	irradiated component
Black Cohosh	Sona Herbal Remedies	31/11/2007	BN16608	negative	irradiated
Korean Ginseng	Red Kooga	30/09/2006	94250	negative	negative

The only samples that tested negative were Korean Ginseng (Red Kooga), the negative control sample and Black Cohosh (Sona Herbal Remedies), a batch of which had previously been identified as “irradiated”.

The term “irradiated” indicates that the entire sample may have been irradiated, while the term “irradiated component”, is used where it is calculated that only some of the ingredients, (eg. the herb, or talc) have been irradiated individually prior to mixing with other non-irradiated ingredients. It is also worth noting that the TL method cannot identify irradiated ingredients that do not contain extractable minerals and they may therefore go undetected.

CONCLUSIONS

Under EU law any food that has legally been treated with ionising radiation may be on the market only if it is appropriately labelled. None of the products that were found to be “irradiated” in this survey were labelled accordingly and thus were on the Irish market illegally. The presence of an unlabelled irradiated food on the market raises a number of questions such as; whether it was irradiated because it was subjected to poor production or processing practices, whether it was contaminated with bacteria or pests, or whether it received the recommended radiation dose in an authorised facility. Food irradiation is designed to augment good manufacturing and hygiene practices, not replace them. Therefore, proper labelling, as required by law, is not only essential for consumer choice but also critical for consumer confidence in the food itself.

Irradiation positive results are presented as “irradiated” or “irradiated component”. While there is little doubt that samples categorised as “irradiated” have been treated with ionising radiation, those categorised as “irradiated component” are frequently challenged. For this reason the FSAI has decided, in the current survey, to focus on herbal supplements identified as “irradiated”. The FSAI continues to liaise with the UK Food Standards Agency where the issue was first identified and continues to be encountered.

The results of this survey have not identified any immediate food safety issues. However, the FSAI is disappointed that previous efforts by the industry to encourage suppliers to deal with this problem at source have largely failed. This failure means that consumers continue to be exposed to illegal food supplements more than 12 months after the problem was initially highlighted, a situation that will not be tolerated. The FSAI have directed food business operators to remove the five batches of “irradiated” herbal supplements from sale in Ireland and notified the European Commission and other Member States. The FSAI is satisfied that it has highlighted the problem of illegal herbal supplements that are irradiated, but unlabelled, on the Irish market. In the best interests of the Irish consumer, the FSAI may consider the prosecution of food business operators where products previously shown to be “irradiated” and unlabelled continue to be marketed illegally.

FURTHER INFORMATION

Further information on this survey can be obtained from:

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