



**Irradiated Herbal Supplements  
and Herbal Substances  
Survey 2003**

**February 2004**

## BACKGROUND

Food irradiation is a process whereby a food is exposed to ionising radiation at a specific intensity and for a limited time period. The radiation can be produced by electronic or radioactive sources and is used to reduce the level 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 such as the ripening of fruits and vegetables and sprouting or germination in potatoes, onions and garlic ([http://www.fsai.ie/industry/irradiated\\_food\\_info.pdf](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 and in suitable facilities.

The European Commission produces an annual report on inspections of food irradiation facilities and checks of the food supply for appropriate labelling 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](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 ([www.foodstandards.gov.uk](http://www.foodstandards.gov.uk)) highlighted the fact that 42% of the herbal supplements tested in the UK were found to have been irradiated but not properly labelled. Products from 14 categories were tested including: alfafa, *Aloe vera*, cat's claw, devil's claw, garlic, ginger, *Gingko biloba*, ginseng, green tea, guarana, kava kava, saw palmetto, silymarin and turmeric. Irradiated samples were detected in each product category except for green tea. Forty four of the 138 samples tested had been wholly irradiated, while a further 14 samples were identified as containing irradiated components. Based on this information the Commission requested that all Member States focus on this sector within their own jurisdictions to determine whether a similar problem existed in other Member States.

## 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), ([http://europa.eu.int/comm/food/fs/sfp/fi\\_index\\_en.html](http://europa.eu.int/comm/food/fs/sfp/fi_index_en.html)). 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 Directives.

The Implementing Directive provides a list of foods and food ingredients that are authorised across the EU for treatment with ionising radiation. Currently, only dried aromatic herbs, spices and vegetable seasonings, with a permitted maximum overall average absorbed dose of 10 kGy, are listed. Until the list is completed, EU countries may continue to irradiate those foods on the EC list of national authorisations and they may also maintain any existing national restrictions or bans on irradiated foods.

### **Survey of Herbal Supplements in the EU**

As a result of the Commission request for information, in 2002 four Member States (Ireland, the United Kingdom, Germany and the Netherlands) tested herbal supplements within their jurisdictions for evidence of irradiation. Almost 30% (29.4%) of the total products tested by these four countries were found to have been irradiated or to contain irradiated components. Germany found 3 out of 17 samples (18%) were positive, the Netherlands reported 31 positive samples out of 124 tested (25%) and the UK reported 6 positives out of 25 samples (24%). In Ireland, an FSAI survey ([http://www.fsai.ie/industry/irradiated\\_food\\_report.pdf](http://www.fsai.ie/industry/irradiated_food_report.pdf)) identified 10 positives out of 24 herbal supplements tested (42%).

In 2003 Denmark reported the withdrawal of a number of herbal supplements from the Danish market as they were found to have been irradiated but not labelled appropriately. Also in 2003 the FSAI carried out further checks of herbal supplements and herbal substances on the market in Ireland, the results of which are reported here.

### **SAMPLING AND ANALYSIS**

Twenty-six herbal supplements and substances were purchased “off the shelf” in central Dublin in April 2003. Many of the herbal supplements were in capsule form, but only the contents and not the capsules were tested. Ten of the samples tested are referred to in this report 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](http://europa.eu.int/comm/food/fs/sfp/fi07_en.html)). In this survey a luminescence detection method was used to test samples for signs 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 in the form of light that can be measured by sensitive light detection instruments.

Thermoluminescence (TL) analysis (EN 1788:2001) is a sensitive and reliable method that involves the extraction of mineral grains from a food sample, heating them to release any trapped energy which is then measured. As a calibration procedure, the sample is then irradiated and the heating step repeated.

## **RESULTS**

Results of the thermoluminescence (TL) tests for herbal supplements (Table 1) and herbal substances (Table 2) show that 13 of the 26 samples (50%) tested were found to have been irradiated either wholly or in part. Eleven of the 16 herbal supplements (69%) tested had been irradiated with 5 being wholly irradiated and 8 having a component irradiated. Of the 10 herbal substances tested, only 2 had an irradiated component.

The herbal supplements examined in this survey were not the same as those in the previous survey ([http://www.fsai.ie/industry/irradiated\\_food\\_report.pdf](http://www.fsai.ie/industry/irradiated_food_report.pdf)) reported in 2003. In this survey, none of the samples that had been irradiated carried the required labelling.

**Table 1: Herbal Supplements tested by Thermoluminescence (TL)**

<b>Product name</b>	<b>Brand</b>	<b>Best Before date</b>	<b>Batch code</b>	<b>TL result</b>
Agnacast ( <i>Agnus castus</i> )	Gerard House	00/02/04	75690	irradiated
Aloe vera ( <i>Aloe barbadensis</i> )	Solgar	00/01/06	55589	irradiated
Feverfew ( <i>Tanacetum parthenium</i> )	Solgar	00/02/04	32658	irradiated
Kyolic garlic 1000	Quest	00/08/05	0212007	irradiated
Siberian ginseng	FSC	00/07/04	A02352	irradiated
Cranberry concentrate	FSC	00/04/04	A02344	irradiated component
Dong quai root	Viridian	23/10/05	342310	irradiated component
Effervescent echinacea extract (citrus flavoured)	Healthcrafts	00/09/04	L 22843	irradiated component
Ginger root ( <i>Zingiber officinale</i> )	Solgar	00/02/06	56350	irradiated component
Garlic - odour controlled	Lifeplan	00/12/05	02/50/20	irradiated component
Saw palmetto extract	Nature's Aid Herbal range	00/12/04	881431	irradiated component
Artichoke	Cynara	00/07/04	2014648	indeterminate
Guarana seed	Lifeplan	00/11/05	02/46/26	not irradiated
Cats claw tea-bags	Rio Amazon	00/04/05	CCTB50	not irradiated
Butcher's broom with rosemary oil	Solgar	00/07/04	43236	not irradiated
Valerian root ( <i>Valeriana officinalis</i> )	Solgar	00/01/06	56034	not irradiated

Three of the 5 “wholly” irradiated samples were in capsule format, but as the capsule shell was removed prior to testing it is unknown whether irradiation was carried out before or after the capsule filling stage. There may be some ingredients present in a sample that do not contain extractable minerals and for which TL testing is unsuitable. Thus, the term “wholly” irradiated for some samples may not be entirely correct. For samples that are classed as containing an “irradiated component”, one or more of the ingredients, (eg. the herb, or talc) may have been irradiated individually prior to mixing with other non-irradiated ingredients.

TL analysis of the Siberian ginseng and Korean ginseng herbal substances indicated that they only contained small amounts of irradiated material. Both of these herbal substances carried labels stating they were products of Korea which is not on the list of third countries with EU-authorized food irradiation facilities.

**Table 2: Herbal Substances tested by Thermoluminescence (TL)**

<b>Product name</b>	<b>Best Before date</b>	<b>TL Result</b>
Korean Ginseng	00/02/05	irradiated component
Siberian Ginseng	00/02/05	irradiated component
Black cohosh	n/a	not irradiated
Devils Claw	00/06/03	not irradiated
Don Quai	00/02/03	not irradiated
Ginseng -cut	00/10/02	not irradiated
Milk thistle herb	00/02/03	not irradiated
Raspberry leaf	00/08/03	not irradiated
Skullcap	00/02/04	not irradiated
Strawberry leaves	00/04/03	not irradiated

n/a not available

## **CONCLUSIONS**

While the results of this survey do not give rise to any immediate food safety issues, the FSAI is concerned that such a high percentage of one food type (herbal supplements) on the Irish market is inaccurately labelled and that in direct contravention of EU law, Irish consumers purchasing these products would be misled by the incorrect labelling.

The results of the sampling and analysis carried out in Ireland during 2002 and 2003 show that more than 50% of herbal supplements tested had at least some components that were irradiated, though none were labelled to indicate this fact. Food irradiation is generally regarded as a safe tool in the EU to enhance food safety and preserve the quality of certain foods, but only when used under controlled conditions and in authorised facilities. Because none of the irradiated products found to be on sale in Ireland were labelled to indicate they had been subjected to irradiation, it is difficult to ascertain whether these products received appropriate doses of radiation, in line with internationally accepted standards, or whether the process had been carried out in suitable facilities. It also raises the question as to why these substances required treatment initially as this process is not meant to replace good manufacturing and hygiene practices.

While certain constituents of some herbal supplements may be irradiated and marketed within the EU, they must carry a label to indicate this fact, whether sold

individually or as part of a herbal supplement. Additionally, since there is no EU provision for the irradiation of “Herbal Supplements” as a food category they may not be marketed within the EU if they have been wholly irradiated. For these reasons all of the products identified in this report as having been irradiated, either partially or in total, were on the market illegally.

## **FURTHER INFORMATION**

Further information on food irradiation can be accessed at:

[http://www.fsai.ie/industry/irradiated\\_food\\_info.pdf](http://www.fsai.ie/industry/irradiated_food_info.pdf)

Further information on this survey can be obtained from:

Food Safety Information Centre  
Food Safety Authority of Ireland  
Abbey Court, Lower Abbey St, Dublin 1

Tel: 1890 336677  
Email: [info@fsai.ie](mailto:info@fsai.ie)

Fax: (01) 817 1301  
Website: [www.fsai.ie](http://www.fsai.ie)