

## **IRRADIATED FOOD SUPPLEMENTS: ENFORCEMENT EXERCISE**

### **Joint Food Standards Agency / Local Authority Enforcement Work**

This is the report of an Enforcement Exercise carried out by Local Authorities and co-ordinated by the Food Standards Agency. It has not, therefore, followed the usual time-scales or procedures set out in the Agency's Guidelines for Technical Surveys.

### **Key Facts**

- In 2002 the Agency published a survey which brought the issue of irradiated food supplements to the attention of consumers, Local Authorities, industry, the European Commission and other stakeholders.
- In 2003, the Agency and several Local Authorities undertook a follow-up enforcement exercise. A total of 48 samples of food supplements were analysed; 11 were found to be wholly irradiated and a further 13 contained an irradiated component.
- This is not a food safety issue, but consumers have been misled and, with some exceptions, irradiated food supplements are not permitted in the UK.
- Investigative work by Local Authorities has served to remind companies of their obligations and to raise the profile of irradiated food supplements in order to protect consumer interests.
- Two companies were given Formal Cautions.
- The food supplements industry must take steps to ensure that illegal, irradiated ingredients are not included in their products.

### **Summary**

1. Irradiation can be used to kill bacteria that may be present in food. UK and international experts have concluded that irradiation is a safe food process and UK legislation has been in place for over 10 years to regulate its application to certain foods and for the correct labelling of these foods.
2. The Food Standards Agency, working closely with a number of UK Local Authorities, has co-ordinated an enforcement exercise, which focused on food supplements to see if illegally irradiated products remained on the UK market. This followed an earlier Food Standards Agency survey published in June 2002 [1]. This enforcement work confirms that irradiated food supplements were still on sale in the UK a year after the publication of the 2002 survey. Local Authority enforcement officers investigated the irradiated products further. Two UK companies accepted formal cautions.

3. There are no immediate food safety implications arising from this enforcement exercise. However, food supplements are not products that are allowed to be irradiated (although there are a few possible exceptions where an ingredient of a food supplement could also be regarded as a dried spice or condiment, in which case irradiation may be permitted subject to controls). It is not known why or where these food supplements were irradiated nor do we know what irradiation dose was administered. Under UK and EU law only licensed or approved irradiation facilities may treat specific food products, for a specific purpose and within defined irradiation dose limits. Food Labelling regulations also require all irradiated foods on sale in the UK to be labelled “irradiated” or “treated with ionising radiation”. Correct labelling allows consumers to make informed decisions about the food that they buy.

### **Background**

4. The Food Standards Agency published the results of a survey on 7 June 2002 [1] which found that a wide range of food supplements sold in the UK were irradiated in breach of food regulations. Food supplements in general do not fall within one of the seven food categories that may be irradiated and sold in the UK. There may be some exceptions where ingredients of supplements could legally be irradiated and sold (for example products that contain culinary herbs or spices e.g. garlic, ginger or turmeric), but the irradiation must be undertaken at an approved facility and indicated on the label. It was not clear where or how these food supplements were irradiated. None of the irradiated products were labelled as “*irradiated*” or “*treated with ionising radiation*”. Labelling is a legal requirement, which ensures that consumers are able to choose whether or not to buy irradiated products. The prior approval requirement for irradiation facilities ensures that the authorities are satisfied of the suitability of premises to handle foodstuffs, and that the irradiation procedure used is suitable for the food being processed.
5. The 2002 survey, the first in our knowledge to include food supplements, was undertaken to see if irradiated foods (herbs, spices, prawns, shrimps or food supplements) were on the UK market. This first survey was for market surveillance and not for enforcement purposes; food samples were not collected under the necessary procedures required for formal enforcement action. Of the 138 food supplements analysed, 58 were found to be irradiated (44 were wholly irradiated and 14 contained an irradiated component). On publishing the survey in 2002, the Agency stated that the food supplements industry would need either to seek authorisation for the irradiation of food supplements capable of being approved (no applications were forthcoming) or to take steps to ensure that all ingredients used in food supplements were not irradiated. The relevant trade bodies, companies and Local Authorities were notified of the survey findings with a view to the industry taking corrective action. The Agency made it clear that the industry must take action to remove affected products from sale and that a further joint Food Standards Agency / Local Authority survey would check that the industry had taken appropriate action.

6. The results of the 2002 UK survey were noted by the European Commission who then asked all Member States to check food supplements [2,3]. Other Member States have found similar levels of irradiated food supplements [4,5,6].
7. Local Authority enforcement officers followed up the issue of irradiated products with food supplement manufacturers, and took what action they could, consistent with their policies and the appropriate codes of practice. Though a range of options were available to enforcement officers following the 2002 survey, they worked with businesses initially, to advise and assist with compliance, in line with good practice. Their graduated approach to enforcement recognised that most businesses want to comply with the law and that enforcement will take into account the particular circumstances. Initial actions therefore included educating proprietors, providing advice and / or taking informal action. More formal actions (e.g. formal sampling followed by a written warning or initiating a prosecution if appropriate) were unlikely to be immediately necessary. As a result of the 2002 survey and subsequent work by Local Authorities, a number of food supplements were removed from the market over the summer of 2002 and others were reformulated. There was also a significant increase in the number of food supplements and ingredients analysed for irradiation treatment.
8. The Food Standards Agency has since co-ordinated further work with Local Authorities, by way of additional follow-up, to check whether irradiated food supplements were still on sale in the UK in the early summer of 2003. In contrast to the Agency's first survey, this work was carried out in such a way as to ensure that the results could be used as evidence in court, allowing Local Authorities to take formal enforcement action (including prosecutions), if they decided it was necessary.

## **Methodology**

### **(A) Sample Collection**

9. Local Authority Enforcement Officers from sixteen Authorities collected, on a formal basis, a range of food supplements sold through a variety of outlets. The object was to determine, through laboratory analyses, whether the products had been irradiated. Samples were submitted to Public Analysts at Glasgow Scientific Services under the formal arrangements for passing on samples.
10. The Food Standards Agency assigned specific products to each Authority to collect. The sampling strategy was generally focused towards those products that had tested positive for irradiation in the Agency's survey of 2002, but the pool of brands and products sampled in 2003 was not identical with those reported in 2002. In total, forty-eight food supplements were sampled and analysed.

### **(B) Analytical Procedure**

11. Food supplements were analysed using photostimulated luminescence (PSL) [7] and thermoluminescence (TL) [8] at the Scottish Universities Environmental Research Centre (SUERC). These methods for detecting irradiated food are approved by the European Committee for

Standardisation (Comité Européen de Normalisation or CEN) and are described further in the Agency's previous survey report [1].

12. The PSL and TL tests for detecting irradiated food make use of mineral grains that are present in small amounts in many foods. Mineral grains store energy when they are exposed to ionising radiation. When light is shone on irradiated mineral grains (as with PSL), or when heated (as with TL), stored energy is liberated giving rise to emission of light that can be measured using sensitive light-detecting instruments.

## **Results**

13. The results are shown in Table 1, which lists the brands sampled, batch numbers, sell by date, sampling authority and the outcome of the test. Eleven of the forty-eight samples were wholly irradiated and thirteen were found to contain an irradiated component. Therefore, in total twenty-four out of the forty-eight products were irradiated.
14. Publication of this report was deferred until it was clear that possible legal action and any subsequent (or potential) legal proceedings had reached a conclusion.

## **Action Taken by Local Authorities**

15. When deciding what course of action to take, Local Authorities follow their enforcement policies, the Crown Prosecution Service Code of Practice and the Enforcement Concordat. Local Authority Enforcement Officers visited companies whose products were irradiated and investigated the issue further. This would involve Local Authority enforcement officers assessing what systems are in place to prevent irradiated products reaching the market and their focus would be to work with companies to improve and address deficiencies and so help companies comply with the law. Such activities have served to remind companies of their obligations and have raised the profile of irradiated food supplements.
16. The range of actions taken by Local Authority enforcement officers balance the need to protect the public with the requirement to act in an equitable, practical and consistent manner. Enforcement officers found it necessary to take a more direct formal approach with two companies.
  - Belfast City Council invited Health Aid (Pharmadass Ltd) to accept a formal caution after finding an irradiated Super alfalfa product. Health Aid (Pharmadass Ltd) accepted the formal caution in January 2005. Three other Health Aid brand products sampled as part of this work were also irradiated but it was not considered necessary to proceed with further legal action given that the company had accepted a formal caution in relation to one product.
  - Superdrug plc accepted a formal caution in May 2005 following enforcement action by Bath and North East Somerset Council. This action resulted from the irradiated Greenline brand guarana product, which was

manufactured outside of the UK and imported into the UK by Superdrug plc.

### **Feedback from Brand Owners and Trade Associations**

17. Companies whose products were sampled were invited to comment on the results of the enforcement exercise. Five companies responded and their comments are provided at Annex A. The Food Standards Agency also invited the Health Food Manufacturers Association (HFMA), the Proprietary Association of Great Britain (PAGB) and the Committee for Responsible Nutrition (CRN) to comment on the enforcement exercise. Comments were received from the HFMA and are included in Annex A.

### **Conclusion**

18. This is not a food safety issue, but it is primarily one of unauthorised use of irradiation and mislabelling. Consumers are being misled.
19. No company in the food supplements industry has sought approval for the irradiation of food supplements. Irradiated food supplements were still being sold in the UK in 2003. The majority of these food products do not fall into one of the categories of foodstuffs that are allowed to be irradiated under UK regulations. None of the irradiated food supplements were correctly labelled.
20. Irradiated food supplements should not generally be imported into the UK nor sold in the UK even if labelled as “irradiated” or “treated with ionising radiation”. The possible exception to this would be where a food supplement is made from an irradiated spice or condiment which meets the food irradiation regulations and is correctly labelled (for example irradiated garlic, ginger or turmeric could be permitted ingredients if labelled correctly).
21. It is not appropriate to make a detailed comparison between the results presented here and the results of the 2002 survey. The 2002 survey involved a broad range of food supplements with more popular brands sampled to a proportionately greater extent than others. In contrast, this more recent enforcement exercise was intentionally focused towards brands that had first been identified as irradiated in 2002, regardless of market share.
22. Those who import, manufacture or retail food supplements should be well aware that, with few exceptions, irradiated food supplements are not allowed in the UK. The food supplements industry must take steps to ensure that irradiated ingredients are not included in their products.

## References

- [1] Survey for irradiated foods – herbs and spices, food supplements and prawns and shrimps. Food Survey Information Sheet Number 25/02, Food Standards Agency, June 2002.
- [2] Report from the Commission on Food Irradiation for the Period September 2000 to December 2001. OJ C 255, 23.10.2002, p. 2-12
- [3] Commission adopts first EU report on irradiated food, Brussels 11/10/02. <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/02/1462&format=HTML&aged=0&language=EN&guiLanguage=en>
- [4] Irradiated herbal supplements survey 2002, Food Safety Authority of Ireland. May 2002. [http://www.fsai.ie/industry/irradiated\\_food\\_report.pdf](http://www.fsai.ie/industry/irradiated_food_report.pdf)
- [5] Irradiated ingredients in herbal food supplements, Danish Veterinary and Food Administration, October 2003. <http://www.uk.foedevarestyrelsen.dk/Food/Food+inspection/irradiatedingredientsherbalfood.htm>
- [6] Irradiated herbal supplements survey 2005, Food Safety Authority of Ireland. May 2005 [http://www.fsai.ie/industry/Irradiated\\_Herbal\\_Supp.pdf](http://www.fsai.ie/industry/Irradiated_Herbal_Supp.pdf)
- [7] Comité Européen de Normalisation. EN13751:2002 Foodstuffs – Detection of irradiated food using photostimulated luminescence, 2002.
- [8] Comité Européen de Normalisation. EN1788:2001. Foodstuffs – Thermoluminescence detection of irradiated food from which silicate minerals can be isolated, 2001.

FOOD STANDARDS AGENCY  
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**Table 1. Results of the Food Supplements Enforcement Exercise.**

<b>Brand / Company</b>	<b>Product</b>	<b>Batch or Lot Number (Best Before)</b>	<b>Wholly irradiated</b>	<b>Irradiated component</b>	<b>Sampling Authority</b>
Blackmores	Alfalfa	69845 (Oct 2005)	Yes	No	Wandsworth
Boots	Garlic-conc. Tablets	02017367 (Mar 2005)	No	No	Greenwich
Boots	Garlic-conc. Tablets	02013224 (Jun 2004)	No	Yes	Greenwich
Boots	Korean Ginseng	100666 (Nov 2004)	No	No	Northumberland
Cynara	Turmeric	L39319 (Dec 2005)	No	No	Luton
FSC	Ginger root	A03125 (Oct 2004)	No	Yes	Brent
FSC	Saw Palmetto	A03094 (Apr 2005)	No	Yes	Denbighshire
GNC Herbal Plus	Saw Palmetto	A03084 (Apr 2005)	No	Yes	Belfast
Health Aid	Turmeric root extract	2602D (Feb 2006)	Yes	No	West Yorkshire
Health Aid	Super alfalfa	1903F (Mar 2006)	Yes	No	Belfast
Health Aid	Strong Siberian Ginseng	1504D (Apr 2006)	Yes	No	Tower Hamlets
Health Aid	Korean Ginseng	1103D (Mar 2006)	Yes	No	Tower Hamlets
Healthcrafts	Ginkgo Biloba	75723 (Nov 2004)	No	Minor <sup>a</sup>	Denbighshire
Higher Nature	Ginkgo, Formula	13954 (May 2006)	No	No	Wrexham
Holland & Barrett	Ginseng Manchurian	5491904 (Oct 2005)	No	No	Harrow
Holland & Barrett	Guarana	GU003.35 (Aug 2004)	No	Yes	Bath & N.E Somerset
Holland & Barrett	Green Tea Extract	-	No	No	Conwy
Holland & Barrett	Ginkgo Biloba	5708007 (Dec 2005)	No	No	Denbighshire
Holland & Barrett	Ginseng Korean	G1013-10 (Mar 2005)	No	No	Harrow
Holland & Barrett	Ginseng Siberian	SG 010.24 (Jun 2005)	No	Yes	Harrow
Holland & Barrett	Aloe Vera	5382301 (Oct 2004)	No	No	Torfaen
Holland & Barrett Good 'N' Natural	Ginger	GR005.35 (Aug 2004)	No	No	Brent

Table 1 continued,

<b>Company / Brand</b>	<b>Products</b>	<b>Batch or Lot Number (Best Before)</b>	<b>Wholly irradiated</b>	<b>Irradiated component</b>	<b>Sampling Authority</b>
Holland & Barrett Good 'N' Natural	Saw Palmetto	320266.01 (Oct 2005)	No	No	Glasgow
Holland & Barrett Good 'N' Natural	Ginkgo herbal tabs	GL00B-47 (Nov 2004)	No	No	Torfaen
Holland & Barrett Good 'N' Natural	Turmeric	32037901 (Sep 2005)	No	Minor <sup>a</sup>	West Yorkshire
Holland & Barrett Herb Tech	Ginkgo Biloba	5453006 (Aug 2005)	No	Minor <sup>a</sup>	Denbighshire
Holland & Barrett Naturally	Garlic - odourless	55094-04 (Nov 2005)	No	Yes	Luton
Kordel's	Saw Palmetto	754199 (Jun 2005) 744292 (May 2004)	No	Yes	Belfast
Kudos	Saw Palmetto	XF0046 003A (Sep 2006)	No	Yes	Belfast
Kudos	Ginseng Korean	KF 0028/002A (Apr 2006)	Yes	No	Glasgow
Kudos	Aloe Vera Capsules	KF 0003001B & KF 0003001B (Apr 2004)	Yes	No	Swansea
Lamberts	Saw Palmetto	81204 B (Mar 2005)	No	No	Belfast
Life Plan	Guarana	03/14/11 (Apr 2006) 03/20/21 (May 2006)	No	No	Bath & N.E Somerset
Life Plan	Garlic – Odour Controlled	02/49/38 (Dec 2005)	Yes	No	Luton
Life Plan	Ginseng Siberian	03/4/43 (Jan 2006)	No	No	Northumberland
Natural Brand	Ginkgo Biloba	A03168 (Jul 2004)	No	No	Wrexham
Nature's Aid	Ginseng Siberian	012311 (Jan 2005)	No	No	Northumberland
Nature's Aid	Ginkgo Biloba	543011 (Nov 2004)	No	No	Torfaen
Quest	Ginkgo Biloba	0303011 (Dec 2005)	No	No	Wrexham
Rio	Guarana	411403 (Mar 2006)	No	No	Bath & N.E Somerset
Solgar	Aloe Vera	55589 (Jan 2006)	Yes	No	Swansea
Solgar	Alfalfa	58889 (Jan 2006)	No	No	Wandsworth



Table 1 continued,

<b>Company / Brand</b>	<b>Products</b>	<b>Batch or Lot Number (Best Before)</b>	<b>Wholly irradiated</b>	<b>Irradiated component</b>	<b>Sampling Authority</b>
Solgar	Turmeric root extract	57052 (Feb 2005)	No	No	West Yorkshire
Superdrug	Ginseng Korean	83628 (Jan 2005)	No	Yes	Glasgow
Superdrug	Aloe Vera capsules	82171A (Dec 2004)	No	No	Swansea
Superdrug	Ginkgo Biloba Extract	82563 (Apr 2005)	No	No	Wrexham
Superdrug (Greenline brand)	Guarana	B04 130 0405 (Apr 05)	Yes	No	Bath & N E Somerset
Wellbeing	Garlic – Odourless	752273 (Jun 2005)	Yes	No	Luton

<sup>a</sup> Three products are reported as having a “minor” irradiated component because although an irradiated component was detected it was deemed to be less than 2 percent of the total product and the Public Analyst cautioned that at this low level formal action is inadvisable but the manufacturer may wish the information for quality control purposes.

**FOOD STANDARDS AGENCY**

## **Annex A.**

The Food Standards Agency wrote to companies whose products were sampled and invited them to comment on the results. Written responses from five companies were received and their comments are presented below.

### **Comments from Companies**

#### **Superdrug Plc**

**118 BEDDINGTON LANE, CROYDON, SURREY, CR0 4TB**

In November 2003, Bath and North East Somerset Trading Standards advised us that they had tested a sample of Greenline Guarana and the results suggested that the product had been irradiated. We immediately withdrew the product from sale pending further investigation with the supplier. Although further tests were non conclusive, we concluded that it would not be appropriate to put the product back on sale.

#### **Health Aid**

**Health Aid House, Marlborough Hill, Harrow, Middlesex, HA1 1UD**

We are in receipt of your letter dated 29<sup>th</sup> November and the results of the irradiated food supplement contained within.

We would like to stress that since the problem was brought to our attention towards the end of 2003, we have conducted extensive research and since then, we have implemented quality control procedures so that by the beginning of November 2004, it became part of our quality control procedures.

*[Note : Two certificates of analysis were enclosed with the Health Aid response, one giving a PSL classification of 'intermediate' and one giving a PSL classification of 'negative']*

#### **BHM Health Group**

**BHM Health Group Limited, Lancaster Road, Carnaby Industrial Estate,  
Bridlington, East Yorkshire YO15 3QY**

I am responding to the letter I have received in the post from you regarding FSC products and irradiation. The products which were sampled were not manufactured by us and not supplied by us. We purchased the FSC company in December 2004 and although we did have some stock of the products, we are certain that we never received those batches.

All raw materials received into stock are sent away for Photo stimulated Luminescence (PSL) and are not released for use until the results are obtained and are not irradiated. If we obtain an intermediate result we then send a sample for Thermo Luminescence testing.

#### Lifeplan

**Lifeplan Products Limited, Elizabethan Way, Lutterworth, Leicestershire, LE17 4ND**

Lifeplan takes quality extremely seriously and would never knowingly allow irradiated products on to the market.

After the 2002 survey, we implemented a testing procedure. We can confirm that since 2002 no irradiated products have been dispatched by Lifeplan. The Odour Controlled Garlic sampled in 2003 was actually from an old batch produced in 2002.

Every single batch of Odour Controlled Garlic is now tested and we can confirm it is not irradiated.

#### Kudos

**Parkway House, Sheen Lane, London, SW14 8LS**

In reply to your survey carried out on some of our products for evidence of irradiation we would like to express our surprise at your finding especially that we endeavour always to buy our herbs from reputable UK suppliers who provide certificates of purity every time we purchase any raw material. Therefore we will relay your reports to them and ask for explanation and continue to seek certificates of purity for all our future products.

Kindly note also that we no longer produce and have not produced the Aloe Vera capsules for a few years. But that's just for your records as it was part of your report.

### **Comments from Trade Associations**

The Food Standards Agency asked the Health Food Manufacturers Association (HFMA), the Proprietary Association of Great Britain (PAGB) and the Committee for Responsible Nutrition (CRN) if they would like to comment on the enforcement exercise. The PAGB and CRN did not forward comments for inclusion in this report. The HFMA provided the comments below.

#### Health Food Manufacturers Association

### **FSA SURVEY OF IRRADIATED FOOD SUPPLEMENTS HFMA Response: 16.01.06**

As the UK leading trade association for specialist food supplements and health products representing 140 member companies, the Health Food Manufacturers Association (HFMA):

- Thanks the FSA for the opportunity to respond to the Agency's Survey
- Reaffirms Member commitment to supplying high quality and safe products supported by accurate and helpful consumer information

- Confirms the FSA comment that ‘this is not a food safety issue’
- Recognises that the Survey relates to products sampled nearly 3 years ago and only one year after the publication of an initial FSA survey
- Notes that, since the targeted samples were of products previously found to be irradiated, the data indicates substantial improvement in a short period of time
- Emphasises the work that HFMA Members have been carrying out for several years to eradicate irradiation or contamination of natural materials that are often sourced from different continents
- Draws attention to worrying inconsistencies that Member companies have reported in test results for different samples from the same production batch
- Points out that the use of irradiated materials in medicines is among the obstacles to eradication
- Is concerned that there is a scarcity of laboratories equipped to carry out the most sensitive of tests for irradiation
- Thanks the FSA for its commitment to assist in educating suppliers on these issues

**Food Standards Agency**

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