FINAL REPORT OF A MISSION CARRIED OUT IN CHINA FROM 24 FEBRUARY TO 02 MARCH 2009 IN ORDER TO EVALUATE FOOD IRRADIATION FACILITIES
Executive Summary

The Competent Authorities in China requested approval of four irradiation facilities under the provisions of Directive 1999/2/EC of the European Parliament and of the Council on foods and food ingredients treated with ionising radiation, which requires all Third Country facilities to be approved by the Commission for the purposes of exporting irradiated foodstuffs. A mission was undertaken to China to evaluate official control guarantees, and whether the facilities met the requirements of this Directive.

There are different authorities involved in the supervision of irradiation facilities in China, but there is no official supervision of food irradiation operations in the facilities visited, as required by Article 9(2)(a) of Directive 1999/2/EC.

All four companies visited have adequate technical and personnel capabilities to perform irradiation of food. They also have an adequate traceability system and general hygiene prerequisites in place. All facilities currently provide part of the information referred to in Article 9(1), second indent, of Directive 1999/2/EC.

The dosimetry system used in the companies is traceable to the Chinese national Standard as required by Directive 1999/2/EC and the Codex Alimentarius Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003).

None of the companies performed validation measurements which are required by point 2.1 and 2.2 of Annex III to Directive 1999/2/EC. As a consequence of lack of adequate validation measurements, routine dose measurements could not be carried out in accordance with point 2.3 of Annex III to this Directive.

In three of the four companies there is no system in place to guarantee that non-compliant food products may not be accepted for marketing, as the final decision is left to the customer (Article 9(1) first indent of Directive 1999/2/EC).

In some companies visited irradiated and non-irradiated products were kept separately (Art 7 of Directive 1999/2/EC and in particular in the Codex Alimentarius Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003)). Companies could not also guarantee that food has not been previously irradiated or chemically treated prior to delivery, as required by Article 5 (1) of and Annex I to Directive 1999/2/EC.

None of the facilities visited had implemented procedures based on the HACCP principles (Article 10 of Regulation (EC) No 852/2004).

In conclusion none of the companies visited meets all the requirements of Directive 1999/2/EC concerning the irradiation of foodstuffs. There is no sufficient official supervision of food irradiation operations in the facilities visited offered by the CA in China to guarantee that the requirements of Article 7 of Directive 1999/2/EC are fully met.

The report provides a number of recommendations to the Chinese authorities to address the noted deficiencies.
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<tr>
<td>ASTM</td>
<td>American Society for Testing and Materials</td>
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<td>CA</td>
<td>Competent Authority</td>
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<tr>
<td>Co-60</td>
<td>Isotope of cobalt</td>
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<td>Dmax</td>
<td>Maximum Dose</td>
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<td>Dmin</td>
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<td>EC</td>
<td>European Commission</td>
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<td>FAO</td>
<td>Food and Agricultural Organisation of the United Nations</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>HACCP</td>
<td>Hazard Analysis Critical Control Points</td>
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<td>IAEA</td>
<td>International Atomic Energy Agency</td>
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<td>ICGFI</td>
<td>International Consultative Group on Food Irradiation</td>
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<td>ISO</td>
<td>International Standards Organisation</td>
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<tr>
<td>kGy</td>
<td>Kilograys</td>
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<tr>
<td>MCi/kCi</td>
<td>Mega-Curie/ Kilo-Curie</td>
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<td>MeV</td>
<td>Mega-electron Volt</td>
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<td>NIM</td>
<td>National Institute of Metrology</td>
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<td>PBq</td>
<td>Peta-Becquerels</td>
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<td>QITCIP</td>
<td>Quality Inspection and Test Centre of Irradiated Products</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>TC</td>
<td>Third Country</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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1 INTRODUCTION

The mission took place in China from 24/02/09 to 02/03/09. The mission team comprised two inspectors from the Food and Veterinary Office (FVO), and one Member State expert. The mission was undertaken at the request of the Competent Authorities in China.

The inspection team was accompanied during the visits to the irradiation facilities by representatives from Quality Inspection and Test Centre of Irradiated Products (QITCIP) under the Ministry of Agriculture of the People's Republic of China.

An opening meeting was held on 24th February with QITCIP. At this meeting, the objectives of, and itinerary for the mission were confirmed by the inspection team, and additional information required for the satisfactory completion of the mission was requested.

2 OBJECTIVES OF THE MISSION

The objectives of the mission were:
– to assess whether the applicant irradiation facilities meet the requirements of Directive 1999/2/EC of the European Parliament, and;
– to assess the guarantees of official supervision of the irradiation facilities given by the CA in China.

In pursuance of the above objectives the following sites were visited:

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<tr>
<th>Visits</th>
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<td>Competent Authorities</td>
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<td>QITCIP</td>
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<td>Private Operators</td>
<td>4</td>
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<td></td>
<td>Irradiation facilities</td>
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3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation, and with the agreement of the CA in China. In particular:
- Article 9(1) of Directive 1999/2/EC concerning foods and food ingredients treated with ionising radiation
- Article 46 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal
welfare rules.

4 BACKGROUND

Third Country (TC) food irradiation facilities wishing to export foodstuffs treated with ionising radiation to the EU must be approved under Community legislation. In accordance with the procedure laid down in Article 12 of Directive 1999/2/EC, the Commission draws up a list of approved facilities for which official supervision guarantees that the requirements of Article 7 are complied with. For the purpose of assisting with the drawing up of this list, the Food and Veterinary Office of the Directorate General for Health and Consumers has to date carried out evaluations and inspections of irradiation facilities in TCs in accordance with Article 5 of Directive 93/99/EEC and more recently Article 46 of Regulation (EC) No.882/2004. More detailed information on Community legislation in this area and the current list of approved TC establishments can be found at the following web address:

http://ec.europa.eu/food/food/biosafety/irradiation/index_en.htm

Four facilities filed an application with the CA in China for the evaluation and inspection of their facilities with a view to being included on the list of approved facilities provided for under Article 9(2)(a) of Directive 1999/2/EC. The companies are identified in the report as companies 1, 2, 3 and 4 in order to protect the confidentiality of the companies. Two of them, 1 and 4, are described together as they are sister-companies and similar findings were made. Should the companies be placed on the List of irradiation facilities in TC approved by the Community they will be identified in that Commission Decision.

The companies evaluated are contract irradiators providing a service (irradiation treatment process) for owners of consignments, who dispatch untreated products and receive these back following irradiation processing.

5 MAIN FINDINGS

5.1 LEGISLATION

The basic legal requirements on food irradiation in China are established by Order of the Minister of Health of the People’s Republic of China No 47 on Measures on the Control of Hygiene of Irradiated Foods of 1996 and Standard GB/T 18524-2001 based on the Codex Alimentarius General Standard for Irradiated Foods (106-1983 am.1999). They include the main elements of the Codex Alimentarius General Standard, such as the calculation of minimum and maximum doses, requirements for process and product validation (dose mapping), packaging and labelling requirements of bulk products and rules prohibiting re-irradiation. According to these documents, the overall average absorbed dose for food should not exceed 10 kGy. Standard GB/T 18524-2001 has a specific chapter on HACCP principles and requirements.
The mission team was informed by the CA that the definition of food in China also included feedingstuffs, but Standard GB/T 18524 defines food as edible products, processed or unprocessed without any reference to feedingstuffs.

Despite the above framework requirements there are six mandatory national Standards on specific groups of products that can be irradiated in China. They cover specific hygiene requirements, overall average absorbed dose (e.g. 10 kGy for spices), wholesomeness of food, labelling of irradiated products and packaging requirements. There is also a specific mandatory Standard on the labelling of irradiated foodstuffs, which take account of the Codex Alimentarius General Standard for the labelling of pre-packaged foods (Codex STAN 1-1985 (rev 1-1991). These national Standards were prepared by the Ministry of Agriculture of the People’s Republic of China.

The mission team was informed by the QITCIP that the above-mentioned Order No 47 and the national Standards are compulsory for food irradiation facilities in China. However, most of the irradiation facilities visited were not aware of this obligation, and they understood them to be voluntary.

There are also non-compulsory specific standards for irradiation of food prepared by the industry organisation.

### 5.2 COMPETENT AUTHORITY CONTROLS

**Responsibilities**

The mission team requested a meeting with the Chinese CAs on food irradiation, but only the Quality Inspection and Test Centre of Irradiated Products (QITCIP) under the Ministry of Agriculture was met. The mission team was informed that QITCIP is the main CA in the context of this mission and it has many duties concerning the quality inspection and testing of irradiated products and facilities, including inspection and microbiological and sensorial analysis of irradiated products, identification of irradiated foods, calibration of radiation doses, and protection of dosimeters. However, during the mission the mission team noted that QITCIP has no legal powers in the official control of food irradiation facilities. It performs annual surveys in chosen facilities irradiating foodstuffs, which mainly focus on the sampling and testing of products for microbiology and irradiation. These surveys are carried out on a voluntary basis as part of the national survey of quality and safety of agri-food products.

Different CAs at local level, such as the Environmental Department and the Hygiene Department at the provincial authorities, carry out controls on personal hygiene and safety, environmental safety and equipment in irradiation facilities, but none of them is responsible for official control of the whole food irradiation process. Usually these local authorities perform controls annually.

The mission team obtained no evidence that any of CAs performs controls of implementation of the requirements of Article 7 of Directive 1999/2/EC and Annex III of the Directive.

**Approval process for facilities which irradiate foodstuffs**

Each irradiation facility must obtain approval from the Environmental Department (local level authorities) before starting operations. This includes environmental and personal
safety and training of staff.

The National Institute of Metrology (NIM) is responsible for the approval and calibration of dosimetry equipment in irradiation facilities in China. The NIM certifies that transfer dosimeters are correctly calibrated to the national dose standard as required by Directive 1999/2/EC and the Codex Alimentarius Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003).

Once these two approvals have been granted facilities may start to irradiate products. If a company decides to irradiate food, Order No 47 requires specific approval to be granted by the Hygiene Authorities at local level in respect of food hygiene and working conditions. It also requires each new food product category to be subjected to irradiation to be approved by the Health Authorities and to have a specific number. No other specific approval is required for that purpose.

One of the companies had specific approval for the irradiation of food as issued by the Municipal Bureau of the Quality and Technical Supervision in Shanghai. However, the mission team noted that none of the companies visited had been authorised by the Hygiene Authorities at local level for specific irradiated food categories as described above.

5.3 Irradiation Facilities

The mission team was informed by the QITCIP that there are 57 irradiation facilities in China that irradiate food (food includes animal feed in China – see point 5.1).

The four companies visited irradiate different products such as medical products, feedingstuffs and technical devices. Food products are only a small percentage of what they irradiate.

5.3.1 Companies 1 and 4 irradiation facilities

Irradiation facilities 1 and 4 are branches of one company, and are “sister facilities”. They have the same technological, quality and safety systems in place. The companies irradiate mainly medical products. Food accounts for:

- 3% of total production in company 1 (spices, seasonings, shrimp powder, tomato powder, seafood);
- 20% of total production in company 4 (spices and seasonings).

Both facilities are automatic plants designed to operate continuously and consist of a processing chamber containing a gamma radiation source, a storage pool, a mechanical system conveying the products around the source, warehouses for treated and untreated products and auxiliary technical installations (ventilation, water treatment, etc.).

The radioactive sources in both companies are cobalt-60. The maximum source panel capacity is 4MCi (148Pbq) in both companies and the source strength at the time of the mission was 2.99 MCi (111 PBq) in company 1 and 2.1 MCi (77.7 PBq) in company 4.

The same technological and administrative processes apply at both companies. Packed products are placed into tote boxes (44 positions around the source) and transported around the source by a mechanical conveyor.
Dosimetry and process control

In both companies the customer (owner of the product) is responsible for specifying the dose (usually minimum dose (Dmin), but can also be maximum dose (Dmax)) and for providing information concerning the size of packaging and weight of products. This information may also include microbiological test results. Should a product be non-compliant the customer decides on what action is to be taken. This may include the product being accepted for marketing even where it does not comply with the Dmax and Dmin or microbiological criteria.

There are general management systems in place based on ISO-9001, and ISO standards for medical devices. The mission team was informed that both companies also use ASTM standards, including 51204 and the Joint FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003) and also Directive 1999/2/EC. These requirements are included in the companies’ SOPs for food irradiation processing. However, in practice these requirements are not implemented in full; the final decision is left entirely to the customer.

The companies use the same dosimetry system, which is traceable to the Chinese National Standard. The companies obtained specific licences from the NIM. Amber and red perspex dosimeters are used as routine dosimeters. The transfer-standard dosimeters used are dichromate dosimeters.

To measure the absorbed dose, routine dosimeters are placed on the packaging of products to ensure that there is at least one dosimeter in the irradiation chamber at any one time. If the customer so requires they will be placed at Dmin and Dmax. However, these locations do not relate to Dmin nor to Dmax values as they are not based on validation measurements as required by point 2.3 of Annex III to Directive 1999/2/EC.

The mission team was informed by the companies that, when processing food, the facilities operate within a dose uniformity ratio (Dmax/Dmin) of less than 2.

Systems are in place in both companies to ensure that irradiated and non-irradiated products are identifiable. These include physical separation of products, and colour indicators to identify irradiated and non-irradiated products. Different warehouses are used for irradiated and non-irradiated products. However, in company 4 the mission team observed that irradiated and non-irradiated products were placed together in the non-irradiated area.

None of the companies require their customers to guarantee that food has not been previously chemically treated for the same purpose (Article 5 (1) of Directive 1999/2/EC). The companies were not aware of such requirement.

The facilities do not have any arrangements in place with customers to guarantee that delivered food has not been previously irradiated (Article 7 of Directive 1999/2/EC and the Codex Alimentarius General Standard for Irradiated Foodstuffs (Codex Stan 106-1983, Rev 1-2003)).

Companies staff with overall responsibility for quality control is technically qualified and have received training in good irradiation practice and radiation safety.

The parameters of the plant cycle are recorded manually and automatically.
Calibration and validation of the process

With food, no validation measurements (dose mapping) are performed on real products. The dose mapping obtained when re-qualifying the process following source augmentation is used instead (installation qualification dose mapping) to place dosimeters at the positions on the product. This procedure is not in compliance with points 2.1 and 2.2 of Annex III to Directive 1999/2/EC. However, dose mapping on real products is done for medical products.

Documentation and labelling

Batch numbers are assigned sequentially, which provides traceability of product through each company’s facility. The mission team saw evidence of the traceability system in place in both companies.

The mission team was informed that records are kept for at least five years.

The companies use the same standard certificate for each batch of irradiated products. The format of the certificate of irradiation includes the following information:

- nature and quantity of product irradiated (description, size of cartons, weight, units),
- batch/lot number,
- name of the company irradiating the products,
- specific number and customer's name ordering the irradiation treatment,
- date of irradiation,
- process code,
- that the product was irradiated by gamma rays,
- minimum specified dose (specified by the customer) and minimum inspection area dose,
- maximum specified dose (specified by the customer) and maximum inspection area dose.

Under Article 9(1), second indent, of Directive 1999/2/EC, a foodstuff treated with ionising radiation may not be imported from a TC unless it is accompanied by documents showing the name and address of the facility which carried out the irradiation treatment and providing the information referred to in Article 8 of the Directive. Currently, the following information concerning this article is not provided for foodstuffs treated with irradiation:

- packaging materials used during treatment;
- reference to the initial dose validation measurements.

Food hygiene

The facilities had in place Standard Operating Procedures (SOPs) for hygiene prerequisites, both in the facility and its environment. Both companies have control procedures on food safety in place but they are not based on HACCP principles. Companies informed the mission team that there is no legal requirement in China for HACCP implementation.
5.3.2 Company 2 irradiation facility

The company irradiates mainly technical devices, medical products and pet-food. Concerning food - garlic powder and dried seafood are irradiated. The mission team noted during the visit that frozen seafood intended for export to the other country was also irradiated by the company.

The irradiation facility is an electron beam facility. A mechanical system conveys the products in front of a horizontal LINAC (linear accelerator). There is a warehouse storage (including cold store).

The maximum beam energy is 10 MeV, with a power of 100 kW, scanning uniformity is within 10% and the beam scanning width is 700mm.

Packed products are placed into hanging carriers/racks (62) and transported in front of the beam by a mechanical conveyor.

Dosimetry and process control

With reference to the national Standards, the customer (owner of the product) and the company agree on appropriate doses used for irradiation (usually Dmin and Dmax). Microbiological testing of products is performed by internal and/or external laboratories. The mission team was informed that should a product be non-compliant the customer will be consulted, but the final decision on the use and marketing of this product is up to the irradiation company.

There is a general management system in place based on ISO-9001, and ISO standards for medical devices. There is no specific SOP for food products.

The facility uses a dosimetry system which is traceable to the Chinese National Standard. The company obtained specific licences from the NIM. The company uses thin film dosimeters as routine dosimeters and silver dichromate as transfer dosimeters.

To measure the absorbed dose, three routine dosimeters are placed on the packaging of products to ensure that they are on the one rack in the product cycle (for 62 carriers). However, these locations do not relate to Dmin nor to Dmax values as they are not based on validation measurements (as required by point 2.3 of Annex III to Directive 1999/2/EC). No account was taken of any change from one product to a different one ("end load") (i.e. different products immediately follow a run without a dummy product loaded in between).

The mission team was informed by the company that, when processing food, the facility operates within a dose uniformity ratio (Dmax/Dmin) of less than 2 (based on dummy products).

There are two separate storage areas for irradiated and non-irradiated food. However, the mission team noted that there was no specific barrier in the cold store between non-irradiated and irradiated food.

The company does not require their customers to guarantee that food has not been previously chemically treated for the same purpose (Article 5 (1) of Directive 1999/2/EC). The company was not aware of such a requirement.

The facility does not have any arrangements in place with customers to guarantee that
delivered food has not been previously irradiated (Article 7 of Directive 1999/2/EC and the Codex Alimentarius General Standard for Irradiated Foodstuffs (Codex Stan 106-1983, Rev 1-2003)).

Company staff with overall responsibility for quality control in the facility is generally technically qualified and have received training in good irradiation practice and radiation safety.

The plant cycle parameters are recorded mainly manually.

Calibration and validation of the process

With food, validation measurements (dose mapping) are performed on the dummy load not on real products (product qualification) and this is used to put dosimeters in position on the products. This procedure is not in compliance with points 2.1 and 2.2 of Annex III to Directive 1999/2/EC. However, the mission team was informed that this kind of product dose mapping is done for medical products.

Documentation and labelling

Batch numbers are assigned sequentially, which provides traceability of product through the company facility. The mission team saw evidence that a traceability system is in place in the facility.

The mission team was informed that records are kept for at least five years.

The company uses the same standard certificate for each batch of irradiated products. The format of the certificate of irradiation includes the following information:

- description of the product, quantity,
- the batch/lot number,
- name of the company irradiating products,
- name of the customer ordering the irradiation treatment,
- date of irradiation,
- minimum dose specified by the customer,
- maximum dose specified by the customer,
- that the product was irradiated by the electron beam,
- minimum absorbed dose.

Currently, the following information concerning Article 8 of Directive 1999/2/EC is not provided for foodstuffs treated with irradiation:

- packaging materials used during the treatment;
- reference to the initial dose validation measurements.

Food hygiene

The facility has hygiene prerequisites in place, but there are no procedures based on HACCP principles.

In addition, inadequate storage of frozen seafood was seen by the mission team (it was stored at a temperature of -10°C whereas the labelling required -18°C.) The mission team
was informed by the company that these storage conditions were agreed with the customer for a range of temperatures from -10°C to -18°C.

5.3.3 Company 3 irradiation facility

The company mainly irradiates medical products and pet-food. Foodstuffs irradiated are dried and frozen seafood, spices and seasonings.

The irradiation facility is an automatic plant designed to operate continuously and consists of a processing chamber containing a gamma radiation source, a storage pool, a mechanical system conveying the products around the source, warehouse for treated and untreated products, and auxiliary technical installations (ventilation, water treatment, etc.). Packed products are placed in hanging carriers (38 around the source) and transported around the source by a mechanical conveyor.

The radioactive source consists of cobalt-60. The maximum source panel capacity is 2 MCi (74 PBq) (licensed maximum) and the source strength at the time of the mission was 0.7 MCi (26 PBq).

Dosimetry and process control

With reference to the national Standards, the customer (owner of the food) and the company agree on appropriate doses (usually Dmin and Dmax). The information required also includes microbiological test results. The company performs microbiological tests on every incoming delivery. If the product does not comply with the microbiological criteria it is refused by the irradiation company. Should a product be non-compliant the customer decides what action is to be taken (this may include the product being accepted for marketing).

There is a general management system in place based on ISO-9001, and ISO standards for medical devices. There is no specific SOP for food products.

The facility uses a dosimetry system which is traceable to the Chinese National Standard. The company obtained specific licences from the NIM. The company uses silver dichromate for routine dosimetry and Fricke for transfer dosimetry.

To measure the absorbed dose, routine dosimeters are placed on the packaging of products. There is at least one dosimeter in the irradiation chamber at any one time. The company considers these locations to be Dmin and/or Dmax, but these locations do not relate to Dmin nor to Dmax values as they are not based on validation measurements (as required by point 2.3 of Annex III to Directive 1999/2/EC).

The mission team was informed by the company that, when processing food, the facility operates within a dose uniformity ratio (Dmax/Dmin) of less than 2.

All products are stored in the same warehouse in specific areas for irradiated and non-irradiated products, but they are separated by temporary barriers.

The company does not require their customers to guarantee that food has not been previously chemically treated for the same purpose (Article 5 (1) of Directive 1999/2/EC). The company was not aware of such a requirement.

The facility does not have any arrangements in place with customers to guarantee that delivered food has not been previously irradiated (Article 7 of Directive 1999/2/EC and
the Codex Alimentarius General Standard for Irradiated Foodstuffs (Codex Stan 106-1983, Rev 1-2003)).

Company staff with overall responsibility for quality control in the facility is generally technically qualified and have received training in good irradiation practice and radiation safety.

The plant cycle parameters are recorded manually and automatically.

Calibration and validation of the process

With food, validation measurements (dose mapping) are not performed on real products (product qualification) but mapping of a dummy load is used to put dosimeters in position on the products. This procedure is not in compliance with points 2.1 and 2.2 of Annex III to Directive 1999/2/EC. However, the mission team was informed that such product dose mapping is done for medical products.

The company routinely mixes different products on carriers to reduce Dmax/Dmin further, but no dose mapping of such configurations is performed. Examples of mixed loads were seen by the mission team, such as cables with other products.

Documentation and labelling

Batch numbers are assigned sequentially, which provides traceability of product through the company facility. The mission team saw evidence that a traceability system is in place in the facility.

The mission team was informed that records are kept for at least five years.

The company uses the same standard certificate for each batch of irradiated products. The format of the certificate of irradiation includes the following information:

- description of the product, quantity,
- batch/lot number,
- name of the company irradiating products,
- name of the customer ordering the irradiation treatment,
- date of irradiation,
- minimum inspection (absorbed) dose,
- maximum inspection (absorbed) dose,
- that the product was irradiated by gamma rays.

Currently, the following information concerning Article 8 of Directive 1999/2/EC is not provided for foodstuffs treated with irradiation:

- packaging materials used during the treatment;
- reference to the initial dose validation measurements.

Food hygiene

The facility has hygiene prerequisites in place, but there are no procedures based on HACCP principles.
6 CONCLUSIONS

Legislation
(1) There is a set of Chinese legislation and Standards in relation to the scope of this mission.

(2) The implementation of national legislation and Standards on food irradiation is not considered compulsory by the irradiation facilities.

Competent Authorities
(3) There is no official supervision of food irradiation operations offered by the CAs to guarantee that the requirements of Article 7 of Directive 1999/2/EC are fully met, as required by Article 9(2)(a) of Directive 1999/2/EC.

Irradiation facilities
(4) All four companies visited have adequate technical and personnel capabilities to perform irradiation of food.

(5) The dosimetry system used in the companies is traceable to the Chinese national Standard as required by Directive 1999/2/EC and the Codex Alimentarius Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003).

(6) There were no validation measurements undertaken by the companies (point 2.1 of Annex III to Directive 1999/2/EC).

(7) None of the companies took into account changes in product and its geometry (point 2.2 of Annex III to Directive 1999/2/EC).

(8) Routine dose measurements were not carried out in accordance with point 2.3 of Annex III to the Directive 1999/2/EC.

(9) There is an inadequate storage of irradiated and non-irradiated products in some of the companies visited (Article 7 of Directive 1999/2/EC and in particular the Codex Alimentarius Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003)).

(10) The companies did not have adequate procedures in place to guarantee that food prior to delivery to the facility has not been chemically treated for the same purpose as irradiation (Article 5(1) of Directive 1999/2/EC).

(11) In the companies visited there are no adequate procedures in place to guarantee that food consignments meet the requirements of Annex I to Directive 1999/2/EC prior to accepting them for irradiation treatment.

(12) In most of the companies, there is no system in place to guarantee that non-compliant food products may not be accepted for marketing, as the final decision is left to the customer (Article 9(1) first indent of Directive 1999/2/EC).

(13) All facilities currently provided part of the information referred to in Article 9(1), second indent, of Directive 1999/2/EC.

(14) All the companies visited have an adequate traceability system and general hygiene prerequisites in place.
(15) None of the facilities had implemented procedures based on the HACCP principles, as required under Article 10 of the Regulation (EC) No 852/2004 in connection with Article 5 of this Regulation.

**Overall conclusion**

None of the companies visited meets all the requirements of Directive 1999/2/EC concerning the irradiation of foodstuffs. There is no official supervision of food irradiation operations in the facilities visited offered by the CAs in China to guarantee that the requirements of Article 7 of Directive 1999/2/EC are fully met.

7 **CLOSING MEETING**

A closing meeting was held on the 2 March 2009 with QITCIP. At this meeting, the main findings and conclusions of the mission were presented by the inspection team.

8 **RECOMMENDATIONS**

Recommendations for the CAs in relation to the irradiation facilities that have applied for the European Community approval:

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<tr>
<td>1</td>
<td>The CAs should establish an adequate official supervision in relation to food irradiation, as required by Article 9(2)(a) of Directive 1999/2/EC.</td>
</tr>
<tr>
<td>2</td>
<td>The CAs should ensure that the validation measurements are performed by the irradiation facilities, as required by point 2.1 of Annex III to Directive 1999/2/EC.</td>
</tr>
<tr>
<td>3</td>
<td>The CAs should ensure that the validation measurements are repeated whenever the product, its geometry or irradiation conditions are changed by the irradiation facilities, as required by point 2.2 of Annex III to Directive 1999/2/EC.</td>
</tr>
<tr>
<td>4</td>
<td>The CAs should ensure that the routine dose measurements are carried out in accordance with point 2.3 of Annex III to Directive 1999/2/EC.</td>
</tr>
<tr>
<td>5</td>
<td>The CAs should ensure that there are adequate procedures in place in the irradiation facilities to guarantee that food prior to delivery to the facility has not been chemically treated for the same purpose as irradiation (Article 5(1) of Directive 1999/2/EC).</td>
</tr>
<tr>
<td>6</td>
<td>The CAs should ensure that there are adequate procedures in place in the irradiation facilities to guarantee that food consignments meet the requirements of Annex I to Directive 1999/2/EC prior to accepting them for irradiation treatment.</td>
</tr>
<tr>
<td>7</td>
<td>The CAs should ensure that in all irradiation facilities irradiated and non-irradiated products are kept separately as required in Article 7 of Directive 1999/2/EC and in particular in Codex Alimentarius Recommended International Code of Practice for Radiation Processing of Food (CAC/RCP 19-1979, Rev. 2-2003).</td>
</tr>
<tr>
<td>8</td>
<td>The CAs should ensure that there is a system in place in all irradiation facilities to</td>
</tr>
<tr>
<td>No.</td>
<td>Recommendation</td>
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<td></td>
<td>guarantee that only food products which comply with Article 9(1) first indent of Directive 1999/2/EC, may be intended for the European market.</td>
</tr>
<tr>
<td>9</td>
<td>The CAs should ensure that companies comply with all the provisions of Article 9(1), second indent, of Directive 1999/2/EC concerning information which is required to accompany consignments referred to in Article 8 of that Directive.</td>
</tr>
<tr>
<td>10</td>
<td>The CAs should ensure that irradiation facilities implement procedures based on the HACCP principles, as required under Article 10 of Regulation (EC) No 852/2004 in connection with Article 5 of this Regulation.</td>
</tr>
</tbody>
</table>

The competent authority's response to the recommendations can be found at:

# Annex 1 - List of Legislation Referenced in the Report

<table>
<thead>
<tr>
<th>Reference</th>
<th>OJ Ref.</th>
<th>Detail</th>
</tr>
</thead>
</table>