FINAL REPORT OF A MISSION
CARRIED OUT IN INDIA
FROM 05 TO 11 OCTOBER 2007

TO GATHER INFORMATION ON THE SOURCE OF CONTAMINATION OF GUAR GUM WITH PENTACHLOROPHENOL AND DIOXINS AND TO ASSESS THE CONTROL MEASURES PUT IN PLACE BY THE INDIAN AUTHORITIES TO AVOID A REOCCURRENCE OF THIS CONTAMINATION

Please note that in response to the competent authority's comments to the draft report a factual error in this report has been corrected.
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<tr>
<td>AOAC</td>
<td>Association of Official Analytical Chemists</td>
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<td>APEDA</td>
<td>Agricultural and Processed Food Products Export Development Authority</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<td>CODEX</td>
<td>Codex Alimentarius</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EPA</td>
<td>Environmental Protection Agency</td>
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<td>EU</td>
<td>European Union</td>
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<td>FAPAS</td>
<td>Food Analysis Performance Assessment Scheme</td>
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<td>FTE</td>
<td>Full Time Equivalent</td>
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<td>FVO</td>
<td>Food and Veterinary Office</td>
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<td>GAP</td>
<td>Good Agricultural Practice</td>
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<td>GC/ECD</td>
<td>Gas Chromatography/ Electron Capture Detector</td>
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<td>GGMA</td>
<td>Guar Gum Manufacturers Association</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Point</td>
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<td>HRMS</td>
<td>High Resolution Mass Spectrometry</td>
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<td>HRGC</td>
<td>High Resolution Gas Chromatography</td>
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<tr>
<td>LC-MS/MS</td>
<td>Liquid Chromatography- tandem mass spectrometry</td>
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<td>LOD</td>
<td>Limit of Detection</td>
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<td>MCI</td>
<td>Ministry of Commerce and Industry</td>
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<td>MRL</td>
<td>Maximum Residue Limit</td>
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<td>MS</td>
<td>Member States</td>
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<td>PCP</td>
<td>Pentachlorophenol</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>SHEFEXIL</td>
<td>Shellac and Forest Produce Export Promotion Council</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>SPCP</td>
<td>Sodium Pentachlorophenate</td>
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<tr>
<td>TCDD</td>
<td>Tetrachlorodibenzo-p-dioxin</td>
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<td>WHO-TEQ</td>
<td>World Health Organization Toxic Equivalents</td>
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EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office in India, from 05 to 11 to October 2007. The mission was carried out as an urgent mission in response to the finding of elevated levels of dioxins and pentachlorophenol (PCP) in guar gum exported from India to Europe.

The objective was to gather information on the possible source of the contamination of some lots of guar gum with PCP and dioxins exported to Europe, and to assess the control measures put in place by the Indian authorities to avoid the re-occurrence of this contamination.

The mission team noted that Sodium Pentachlorophenate ((SPCP) the salt of PCP) is produced and readily available in India. It has been used extensively in the production of industrial grade guar gum, and was still marketed for this purpose at the time of the mission, although its use was denied by the competent authority and visited producers. It is concluded that the contaminant was likely to be either due to the chemical being added intentionally or accidentally to industrial grade gum, and this either being sold as food grade, or to gross cross-contamination from industrial to food grade gums.

The Indian authorities have conducted an investigation that concluded there was no generalised contamination, but that some low levels of both PCP and dioxins were found. The investigation by the Indian Authorities did not focus on identifying a source of contamination linked to contaminated products exported to Europe. Thus the competent authority had not identified a source of contamination in the affected lots.

A significant amount of action had been undertaken privately in the companies visited, including sampling and analysis.

The primary processing and storage of guar beans observed was in conditions that were not hygienic (in contravention of Article 4 (1) and Annex 1 of Regulation (EC) No 852/2004).

There is no requirement in India for the registration of premises who export to Europe with an appropriate Competent Authority (Article 6 (2) of Regulation (EC) No 852/2004, no requirement for HACCP in exporting premises (Article 5 of the same Regulation) and no system of official control to ensure that processors establishments meet the requirements of Article 4 (2) of the same Regulation.

In the visited laboratory for official analysis, analytical procedures for dioxin demonstrated inadequate procedural quality control regarding the consideration of background levels. Analysis for PCP in the accredited laboratory visited was, however, adequate.

The overall conclusion reached is that there is to date insufficient evidence of the cause of the contamination incident, and the official Indian investigation has been inadequate to provide any conclusions. With the availability of SPCP and its use in the guar gum industry, and with a largely self regulating industry there are inadequate controls in place to ensure that this contamination does not occur again.

The report provides a number of recommendations to the Indian Authorities to address the noted deficiencies.
1. **INTRODUCTION**

The mission took place in India from 05 to 11 October 2007. The mission team comprised 2 inspectors from the Food and Veterinary Office (FVO) and one Member State national expert.

The mission was undertaken in response to an emergency health situation, and in agreement with the Indian authorities.

The mission team was accompanied during the whole mission by representatives from the central competent authority (CCA) the Ministry of Commerce and Industry (MCI).

An opening meeting was held on the 5th October at the premises of the Ministry of Commerce and Industry, representatives of the Shellac and Forest Produce Export Promotion Council (SHEFEXIL) and the Guar Gum Manufacturers Association (GGMA) were also present. During this meeting, the objectives of and itinerary for the mission were finalised and confirmed by the mission team.

2. **OBJECTIVES OF THE MISSION**

The objectives of the mission were:

- To gather information on the possible source of contamination of Guar Gum with pentachlorophenol and dioxins.

- To assess control measures put in place by the Indian authorities to avoid a reoccurrence of this problem.

In pursuit of these objectives, the visits were carried out in accordance with the itinerary agreed between the MCI, and the FVO of the European Commission and were as follows:

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<thead>
<tr>
<th>COMPETENT AUTHORITY VISITS</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Competent authority</td>
<td></td>
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<tr>
<td>Central</td>
<td>2 MCI, SHEFEXIL</td>
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<td></td>
<td>1 Ministry of Agriculture, Plant Protection Quarantine</td>
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<td></td>
<td>1 Guar Gum Manufacturers association</td>
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<tr>
<th>LABORATORY VISITS</th>
<th>Comments</th>
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<tr>
<td></td>
<td>2 Private accredited laboratories in Hyderabad and Delhi</td>
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<tr>
<th>FOOD PROCESSING ESTABLISHMENTS</th>
<th>Comments</th>
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<tr>
<td>Harvesting Areas</td>
<td>1 Guar bean field near Jodhpur</td>
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<tr>
<td>Primary Processing Establishment</td>
<td>1 1 Producer of Guar Split in Rajasthan</td>
</tr>
<tr>
<td>Processing Establishments</td>
<td>5 5 Producers of Guar Gum, 4 in Rajasthan, 1 in Uttaranchal</td>
</tr>
<tr>
<td>Warehouse</td>
<td>2 1 Private warehouse, 1 Traders Commodity exchange</td>
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<th>OTHER SITES</th>
<th>Comments</th>
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<tr>
<td>Chemical Company</td>
<td>1 Manufacturer of Sodium Pentachlorophenate (SPCP)</td>
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3. **BASIS AND LEGAL FRAMEWORK FOR THE MISSION**

The mission was carried out in agreement with the competent authority (MCI) under the general provisions of Community legislation, and in particular
• Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

4. OTHER RELEVANT LEGISLATION

Other legislation referred to in this report is listed in the annex.

5. BACKGROUND

5.1. Background to present mission

Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council, requires that information on foodstuffs and feedingstuffs found to have public health implications is disseminated as notifications through the Rapid Alert System for Food and Feed (RASFF) to all MS and to the exporting country.

The RASFF received on the 24th July 2007 a notification from the competent authorities of Switzerland concerning the finding of a contamination of guar gum from India with dioxins and PCP. One Swiss company had imported a number of batches from India that were subsequently found to be contaminated and these were incorporated into food ingredient products disseminated to at least 9 Member States (MS). Two MS also received products directly from the implicated Indian company. This information was disseminated through the rapid alert system in an alert of the 25th July, as were 127 additional messages regarding the tracing and withdrawal of affected food products.

Subsequent analysis indicated that the dioxin profile found indicates that the source of dioxins is PCP, and not another environmental or industrial source.

As the source of the PCP contamination and the contamination pathway was not clear and as there are no guarantees that further contaminated products might be exported a decision was made to conduct an urgent mission to India.

5.2. Food product information related to public health issues

Guar Beans (Cyamopsis tetragonoloba) are grown predominately in Rajasthan (70% of Indian production) where the growth is with no irrigation. Smaller volumes are grown in other Indian States such as Gujurat and Haryana, and in Pakistan and China where irrigation may be used. 80% of world production is in India. The crop is an annual legume growing in semi-arid conditions and thus the yield is very much rain dependant. It can grow to 6-9 feet, but in the arid regions the height and crop is significantly reduced. Field size is usually 1 hectare or less and the crop is grown alongside or with, other crops such as millet, sorghum and lentils. In Rajasthan harvesting of the single annual crop takes place in October and November. The crop is used for human consumption and for animal feed, as well as for guar gum production. The whole process, including harvesting, is manual.

Guar gum is commonly imported to Europe as a powder. It is manufactured from the endosperm ('split') of the Guar bean. India exports approximately 187,000 tonnes of guar (including guar splits, guar gum powder and its derivates (for both food and non-food use)) annually. Some 40% of the export is of the un-milled endosperm (splits) which is primarily for further processing for industrial applications. Of the remaining 60% (i.e. ...
guar gum powders), approximately 60% is food grade and 40% industrial grade. Food grade production is focussed in the Rajasthan state, industrial grade in Gujarat state.

The manufacturing process necessitates the removal of partially dried beans from the pod (done by manual threshing at the farmers' fields) and their mechanical splitting to remove the husk and germ to produce the endosperm ('splits'). The process observed in visited establishments is described in sections 6.2.1 and 6.3.2.

The food grade guar gum powder is an authorised food additive in Europe (E412), used as a thickener, emulsifier, stabilizer or gelling agent. It is used extensively in the production of ice cream and yoghurts, in bakery products, dressings, sauces, beverages and a range of other processed food products.

Industrial grade guar gum powder is also marketed, which is widely used in the printing, mining, textile and explosive industries. This may be straight guar gum powder or may be chemically processed, including the addition of biocides such as Sodium Pentachlorophenol (SPCP).

Pentachlorophenol (PCP) is an artificially manufactured chemical, part of the chlorophenol group that are used as fungicides and insecticides, commonly in wood treatments. PCP is known to be highly toxic to humans, with developmental and reproductive effects, and is classed as a category 3 carcinogen. Commercially produced PCP contains impurities, such as a range of dioxins and furans. The salts and esters (commonly SPCP) are also used in the same way as they are better water soluble, but with similar health concerns. SPCP readily breaks down to form PCP, particularly in an acidic environment.

Within EU pesticides legislation (Regulation (EC) No 396/2005 of the European Parliament and of the Council) there is currently no established Maximum Residue Level (MRL) for PCP, and thus it should be absent in food products or ingredients. A proposal for an MRL of 0.01 mg/kg (the Limit of Detection (LOD)) is foreseen and this is used as an indication of levels being found above the background. SPCP is produced by at least three companies in India and is marketed for a range of industrial application such as paint, textiles, wood treatment, industrial water systems, industrial guar gum production, adhesives and in pharmaceuticals.

For dioxins there is no limit in guar gum established by Commission Regulation (EC) No 1881/2006, as the contamination has previously not been known or suspected. A limit of 0.75 pg/g WHO-TEQ is established for vegetable oil and this is suggested to the MS as a limit to indicate levels above background.

**6. MAIN OBSERVATIONS**

**6.1. Relevant national legislation**

The Prevention of Food Adulteration Act and Rules, 1954 as amended (PFA) describe the legal use of guar gum as an additive in food, and prescribe the maximum doses allowed in specific foodstuffs.

The Insecticides Act 1968 is administered by the plant protection sector of the Ministry of Agriculture and lists PCP under Annex A as banned for pesticide manufacture, import
and use. The mission team was informed by the Ministry of Agriculture that this includes the use of the chemical as a fungicide in the treatment of wood.

India is a signatory to the Rotterdam Convention and under the Prior Informed Consent (PIC) procedure India is listed as having banned PCP and its salts and esters as a pesticide since 1991. In accordance with the Rotterdam Convention any other use or production should have a clear national legal basis, to avoid misuse.

The legal status of PCP/SPCP as regards industrial usage in India is not clear. The mission team was informed that this was the responsibility of the Ministry of Environment or Ministry of Chemicals and Fertilisers. A meeting with the former was requested but not possible. The mission team requested that this be clarified but at the stage of drafting the report no response had been received.

6.2. Competent Authorities

6.2.1. Ministry of Commerce and Industry (Department of Commerce)

The MCI is divided into two main departments, the Department of Industrial Policy and Promotion and the Department of Commerce. The latter is responsible within the scope of this mission and is charged with promoting foreign trade, co-ordination of commercial activities, policy and providing financial incentives.

This department is divided into Divisions that have either territorial export responsibilities (for example the Division of European Exports), or Commodity based responsibilities (for example the Chemical Exports Division which is responsible for the scope of this mission).

Within the Chemical Exports Division there are six Commodity Exports Councils, one of which is SHEFEXIL.

6.2.2. Shellac and Forest Produce Export Promotion Council (SHEFEXIL)

SHEFEXIL is an export promotion body sponsored by the Ministry of Commerce and Industry. Its primary role is in the promotion of exports of the commodities for which it responsible, which include shellac (an excretion from an insect which is used in coatings for foods or pharmaceuticals), guar gum and a range of minor forest products such as seeds and gums. It began covering guar gum in 2004 when its commodity list expanded from just shellac, the responsibility previously being with the Agricultural and Processed Food Products Export Development Authority (APEDA). This was due to the fact that guar gum and lac/shellac besides being classified under the same chapter 13 of Indian Trade Classification (harmonised system), have also the same or similar mechanism in the sense that these are cultivated or grown by the economically weaker section/below poverty line/marginal farmers.

SHEFEXIL is headed by a Chairperson, nominated by Industry, and an Executive Director recruited from the open market. It has 10 staff. It is funded by contributions from industry, but administers government funding in the form of government grants to promote industrial exports. SHEFEXIL has funded the investigation analysis into the PCP and dioxin contamination incident but will apply to the Ministry of Economy and Finance to meet these costs.
It describes a three fold mission; to strengthen plans and initiatives for product exports of minor forest products, to maximize export potential through collective action and to assist members in meeting responsibilities under foreign trade policy.

In the area of guar gum it has produced a project proposal which aims to increase the production and exports of guar gum by 50% by 2011. This proposal is aimed at the traditional guar bean producing areas of Rajasthan, Haryana and Gujurat. It states a proposed strategy to set up a pilot guar farm in Haryana, to train cultivators in more modern methods of production, to increase the hectarage of guar production, and to create a Guar Resource Centre in Rajasthan to aid all stages of guar production and processing.

SHEFEXIL has no stated role in the inspection of guar facilities, or in the enforcement of any legislative or international standards in premises. It does though recommend the use of internationally recognised certification standards and has provided lists of consultants for HACCP certification to industry.

6.2.3. Other organisations

6.2.3.1. Guar Gum Manufacturers Association (GGMA)

GGMA is a private trade association for the support and promotion of the Guar Gum industry. Membership is voluntary but is commonplace.

6.2.3.2. State Agricultural Universities

There are three national state agricultural universities, co-ordinated under the Industrial Council of Agricultural Research. They have three activity areas; research, extension work and professional training. The University in Hisar, in Harayana state has some involvement in the scope of this mission in that it has done work on the growing of guar beans, including pesticide use and possible uptake from the soil.

A research director from the University is contracted to act as a national expert in the context of the investigation into the possible incidence of PCP/ dioxin in guar bean production.

6.3. Process Controls in Guar Gum production

6.3.1. Guar Bean Cultivation

In India, approximately 70% of the guar bean cultivation takes place in the State of Rajasthan. The remainder is grown in Gujurat and Haryana states.

The mission team visited a typical farm of approximately 1 hectare. The crop is grown in semi-arid conditions annually and is not irrigated in Rajasthan, although it may be in other growing states of Haryana and Gujurat. The use of pesticides in this crop is rare and is unheard of in the area of Rajasthan visited, for economic and climatic condition reasons. The soil is sandy.

Harvesting is manual and the product is sun dried and then manually threshed to separate out the beans from stalks, pods and leaves.
The guar beans are then stored at the farms until economic conditions make sale beneficial. The goods are sold at a commodity exchange. They are unloaded in bulk and auctioned to buyers. They are then bagged and stored until sold to the processing companies. Storage may be many months to ensure year round supply. The storage conditions in the visited warehouse were basic, with problems of birds gaining access and of insect damage to stored goods. Storage is in 100 Kg jute bags. Some bags had evidently (from labelling) been previously used for storage of non-food items. (Article 10 of Regulation (EC) No 852/2004 which refers to Article 4 of the same Regulation).

Larger manufacturers may have their own long term storage facilities for the storage of either the beans or the splits. The mission team visited one such storage facility which was well structured.

Guar beans are purchased from the open market which makes traceability from finished product to producers impossible.

One processor had invested in the production of a GAP guide which was disseminated to farmers in the region. It includes advice on the use of pesticides, harvesting and the storage of goods.

6.3.2. Guar Gum processors visited

The mission team visited one guar split manufacturer and five guar gum processing facilities in the Indian States of Uttaranchal and Rajasthan. Of these, two produced both industrial grade and food grade powders and the others only produced food grade powders.

The manufacture of guar 'splits' (the endosperm) is done by primary processing. This involves firstly the use of physical separators to remove unwanted stalks, stones and other physical contaminants. The beans are then ground to allow further separation of the smaller germ, which is used for cattle feed. The remaining product is exposed to heat (about 100°C) in a rotating 5 tonne metal drum. A final separator then removes husks and powder/dust. There are no chemicals used and the heat source in the visited premises is burning of wood but with no direct exposure of the guar gum powder to combustion gases. The process is an industrial one, with a structure not commensurate with food product production, high temperatures and dust and pest presence, particularly birds inside the factory. (Contrary to Article 10 of Regulation (EC) No 852/2004 which refers to Article 4 of the same Regulation). At this stage the husk and germ usually go for animal feed. Splits may be stored long term before processing, and are usually sold on the open market to the guar processing facilities.

For the manufacture of guar gum powder the splits are screened to remove physical contaminants using vibrating gravity tables, blown air and cyclones. The splits are then hydrated with an equal volume of warmed water (75-85 °C) in a rotating vat for 45-60 minutes. The pre-soaked splits are then flaked using physical sheering forces from rotating metal drums and then ground mechanically. The ground product may be dried during grinding or at a separate heating/drying stage, before being screened again for separation of impurities. The quality of the finished products and the exhibited qualities are dictated by the size of the particles, and this is controlled by sifting through decreasing mesh sizes. The finished product is then blended in 2-4 tonne blenders which provides for an even product. The finished product is then packaged, usually in 25 Kg bags of three layer paper and an internal plastic layer. All processors visited had records to demonstrate this was food grade packaging material.
Registration with SHEFEXIL is not mandatory for guar gum production or export, but 72 producers are registered, including all those visited. There is no mandatory requirement for HACCP in guar gum manufacture, but 3 of the 5 had a system in place, usually certified by a private certification body.

All commercial producers have to be registered for commercial production either by the State where it is situated (for small premises) or by the Ministry of Industry for larger processors.

The food grade guar gum powder is usually marketed with a 1-2 year shelf life.

All of the processors visited were fully aware of the issue of PCP/ dioxin contamination in guar gum powder exported to Europe. They had been made aware rapidly via the importers in Europe and through the GGMA. No formal communication had been received from the competent authority.

Further processing or addition of other ingredients may take place dependant on specific use. This may include physical/ thermal or chemical depolymerisation for both industrial and food grade products. In the premises visited hydrogen peroxide was used for such depolymerisation. It may also involve the addition of preserving chemicals, for industrial grade goods. There is no standard chemical used and the chemical used is often at the request of the client, who may even provide the preserving chemical for addition. All visited premises were aware that chemical preservation agents should not be used in the production of food grade products. For industrial grades, the premises visited claimed to use sodium propionate, para-chloro-meta cresol, bromo-nitropropandiol, 5-chlorine-2-methyl-2H-isothiazole-3-on, or in some cases no chemicals.

The processors visited stated that SPCP had not been used since 2002/3. One processor dealing with industrial grade products had a fully separate building for industrial grade product processing, packing and distribution. One, the company implicated with contaminated lots, produced industrial grade products on the same production line and in the same production environment.

The mission team visited a chemical manufacturer who stated it was selling about 200-250 tonnes of SPCP to the guar gum industry annually, for industrial applications, and there are at least two other companies known to be producing the chemical in India. It marketed the product as a branded biocide, but it was aware that another company sold the product as SPCP. The recommended industrial application level made by the chemical manufacturers for guar gum powder is 1-3 %. Promotional literature states that the product is for use ‘in the preservation of wood’.

None of the premises visited are subject to official control activities in the context of food safety. There are no inspections of the facilities and no official samples have been taken prior to the survey for PCP recently launched. No communication had been received officially regarding the incident.

The companies visited had taken positive steps to ensure the safety of their products. Samples had been taken of raw and finished ingredients for private analysis for dioxin and PCP in both Indian or European private accredited laboratories, and many of the importing companies in Europe had also done so. The larger premises had their own laboratories for the analysis of physical and microbiological parameters.
Some low levels of PCP had been found in splits in one company, slightly exceeding the level proposed by the EU. There was no known cause of this, but the European importer had rejected some goods on this basis.

The company implicated in the contaminated lots exported to Europe had conducted analysis of some reference samples in an Indian laboratory for dioxins and PCP. No dioxins or PCP was found but the nature of the sampling and analytical procedures in use (see section 6.5.2) render these results invalid.

Export is carried out through either ports such as Mumbai, or more commonly through inland 'dry ports' such as the one in Jodhpur. A usual container is 20 tonnes, with a lot size of between 5-20 tonnes. Containers may be loaded at the processing company or at the port, depending on client request. As there are no specific requirements for export of this commodity there is no involvement of customs within the scope of this mission.

6.4. Possible Source of Contamination

SHEFEXIL and the MCI have commissioned a study into possible sources of contamination of the guar gum industry.

The original RASFF message was the 25<sup>th</sup> July and the message was passed to the Indian Embassy and from them to APEDA, an export agency of the MCI. The alert was re-attributed to the MCI on the 5<sup>th</sup> August, and initial enquiries to find a private laboratory for analysis was made on the 7<sup>th</sup> August.

The Ministry indicated that it initiated a response to this alert by visiting the main growing areas in Rajasthan where meetings were held with the relevant stakeholders. On the 17<sup>th</sup> of August a further meeting was held with the stakeholders, including the MCI, SHEFEXIL, the private laboratory capable of dioxin analysis and the GGMA. It was stated that the purpose of this meeting was to agree the terms of the investigation.

The private laboratory received and accepted the contract to undertake the study on the 29<sup>th</sup> August and surveys of the three growing regions commenced on this day. The objective of this study was stated as being the determination of the source of the PCP and dioxin contamination in guar gum manufacturing in India. This would be achieved through interaction with the companies during a preliminary study (31 August to 3 September) in the 3 principal manufacturing regions, focussing on standard food grade production, and then in a second phase (18 and 19<sup>th</sup> September) with the company implicated in having exported contaminated batches, focussing on modified guar products. The private company stated that it was not in the terms of the contract to link samples taken in the companies visited with those which had been identified in Europe with high levels of contamination.

To date 68 samples have been analysed which include 7 seed, 31 splits, 24 natural powder, 3 modified guar gum powder, 2 water and 1 soil sample. The final report was sent to the mission team shortly after the mission.

The report does not contain any detailed description of manufacturing processes in individual premises. The three samples from the premises implicated in contaminated lots were only taken on the 18<sup>th</sup> September. One was from current production, two from held reference samples. However these were not taken as official samples and were received unlabelled and without details of lot number or date of production.
The findings of the Indian investigation did not identify high levels of either PCP or dioxins. However, some elevated levels above background were found in splits and powder, particularly for dioxins, but this could not be related to PCP as a source, and low levels of PCP and dioxin were also identified in the raw ingredient. These levels were however low compared to those found in contaminated lots (the highest PCP level being 0.051 mg/kg in a seed) and did not result in any significant levels in the finished guar gum powder. The highest levels of dioxin found were 1.591 pg WHO-TEQ/g, found in guar gum powder and 4.095 pg WHO-TEQ/g in guar splits. The types of dioxin found were not however identified as a PCP profile and are likely due to another source.

These low levels, identified by analysis conducted as part of the survey and by some private analysis, suggest there may be another source of contamination. Neither the Indian survey nor the mission team are able to conclude on the source of these low levels, but the possibilities include: use of PCP in treatment of wooden pallets which subsequently contaminate the product, treatment of jute bags with PCP, combustion processes, including wood, during the heating of the seeds to create splits and low level contamination from use of SPCP in the past.

The very high levels found in specific lots exported to Europe were in some cases 1000 times above legal limits. This extent of contamination cannot be explained by the pathways above. The use of SPCP in food grade gum powder, cross contamination from industrial to food grade products, or the selling of industrial grade products for food use are the only likely sources identified.

6.5. Laboratory services

There is limited capability for the analysis of dioxins in India. To date there is only one laboratory which is accredited by the National Accreditation Board for Calibration and Testing Laboratories (NABL) for the analysis of dioxins in all food commodities. This private laboratory, based in Hyderabad, was mandated by SHEFEXIL to undertake the study on traceability of dioxins and PCP in guar products grown and manufactured in three regions with different climatic conditions.

A second private laboratory, based in New Delhi, was mandated by the implicated manufacturer to perform analyses of guar products as well as cleaning aids for dioxins and PCP. Both laboratories were visited by the mission team.

6.5.1. Visit to private laboratory in Hyderabad

This private laboratory, established in 1984, comprises 4 divisions with a total of 650 employees. Analyses of food and agricultural commodities are performed in the analytical division in a new building completed in 2006. Residue laboratories are designed according to CODEX guidelines and are separated for trace and ultra trace analyses. The modern laboratories are very well equipped with up-to-date instrumentation and trained personnel. More than 20 mass spectrometers are available, including one HRGC/HRMS mandatory for dioxin analysis. The scope of accreditation for dioxins covers all kind of food commodities but is based on the analysis of spiked water samples. Nine persons are involved in the dioxin analysis. The analytical method, which covers all 17 toxic dioxin and furan congeners, follows the EPA standard 1613 using HRGC/HRMS at 10,000 resolution. The laboratory has no detailed SOP for the determination of dioxins in guar products, working directly from the published method, and validation data for dioxins in guar products or other food commodities of plant origin.
are lacking. Coding and traceability of samples, handling of standards and documentation of sample tables, order of injections and quantitative calculation are well performed. The limits of determination achieved for the analyses of guar products are satisfactory although some procedural deficiencies regarding the treating of laboratory blanks that might influence the dioxin levels at low concentrations around the maximum limit suggested by the European Commission (in a letter to MS disseminated through the RASFF and discussed at the Standing Committee of the Food Chain and Animal Health, were noticed.

The analysis of PCP is performed following acidification of the samples using solvent extraction and analytical determination by LC-MS/MS. SOP and validation data for other matrices than guar are available. The method is accredited within the scope of pesticide determination. Spiked samples as part of quality control measures are analysed simultaneously with each batch of samples. Performance is adequate and traceability of analyses is well documented, in line with International standards (ISO 17025).

6.5.2. Visit to private laboratory in New Delhi

The laboratory is a private, independent and self sustainable institute. It is specialised inter alia in method development and validation. It has a total of 340 employees of which 55 are involved in residue method development. The laboratory performed 14 analyses for dioxins and/or PCP for the implicated guar gum producer between the beginning of August and the middle of September. The laboratory is not accredited for dioxin analysis. The method applied only covers 2,3,7,8-TCDD and on request also 2,3,7,8-TCDF performed with combined gas chromatography/low resolution mass spectrometry. The limit of determination for 2,3,7,8-TCDD is given as 0.4 ng/kg. Thus, the laboratory does not meet the requirements for dioxin analysis neither with respect to accreditation nor to mandatory instrumentaion and sensitivity. Based on the negative results reported for the analysed guar products no conclusion can be drawn with respect to dioxin contamination of the samples because 2,3,7,8-TCDD only contributes to a negligible part of the dioxin profile caused by PCP.

The PCP analysis is performed using gas chromatography with electron capture detection (GC/ECD) after derivatisation. The extraction does not include an acidification of the samples prior to Soxhlet extraction with dichloromethane. No internal standards are used. The recovery of the method is given as 80-90%. Accreditation was received for the analysis of PCP in leather in 1995. The method was adapted to the determination of PCP in guar products in 2007. The samples were not acidified during the extraction process.

7. Conclusions

7.1. Relevant national legislation

(1) Indian legislation establishes guar gum as an authorised food product and bans the manufacture, use and sale of PCP as an insecticide.

(2) The status of PCP/SPCP use in industrial applications, or as a wood preservative, is not clear.
7.2. Competent Authorities

(3) The CCA is defined regarding promotion of foreign trade, but not for the inspection and official controls of exported products regarding food safety issues.

7.3. Process Controls in Guar Gum Production

(4) There is no evidence of the use of PCP/SPCP as a pesticide in production of guar beans.

(5) The beans are usually sold through a local commodity exchange, conditions in the one visited by the mission team were not meeting the hygiene requirements of Article 4(1) of Regulation (EC) No 852/2004 in the context of Article 10 of the same Regulation.

(6) There is no requirement for the official control of processors to ensure that standards at least equivalent to those required by Article 4 (2) of Regulation (EC) No 852/2004 are in place.

(7) There is no requirement for procedures based on the HACCP principles to be in place in exporting guar gum powder or split manufacturers, and two of the five premises visited did not have such a system in place. This is not in line with the requirements of Art 5 of Regulation (EC) No 852/2004 (in the context of Art 10 of the same Regulation).

(8) The standard production of food grade guar gum uses a fairly standard physical process and is not likely to result in high level contamination with PCP or dioxins.

(9) There is no standard process for the production of depolymerised guar gum (which may be physical/thermal or chemical), or for the production of industrial grade guar gums that use a range of chemical preservatives including SPCP.

(10) Where production takes place of both industrial and food grade guar gums there is a possibility of either selling of industrial grade products as food grade, or of gross cross-contamination, particularly where products are produced on the same line.

(11) In the processors visited significant efforts had been made to follow international standards, and significant amounts of private analysis had been undertaken using private accredited laboratories in India and Europe.

(12) There is no requirement of registration with an appropriate competent authority for export to Europe, although most exporters are registered with SHEFEXIL. This is not in line with the requirements of Art 6 of Regulation (EC) No 852/2004 (in the context of Art 10 of the same Regulation)

7.4. Possible Sources of Contamination

(13) SPCP is readily available in India and according to the chemical manufacturer is still used in the guar gum industry, marketed either as a branded biocide or as SPCP.
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(14) The official investigation carried out by the Indian authorities has not identified the source of contamination. Investigation in the implicated factory was delayed.

(15) The presence of high level contamination with PCP/dioxin is not seen as likely in standard production of food grade guar gum powder in a dedicated factory.

(16) Low levels of contamination could be from a number of contamination sources.

(17) The only identified possible source of high levels of contamination is the industrial use of high levels of SPCP in guar gum manufacture and the subsequent use of industrial grade gum for food use, or for cross-contamination due to lack of separation of the two processes.

7.5. Laboratory services

(18) There is only one private laboratory accredited to ISO 17025 for analysis of dioxins and PCP in India.

(19) In the visited laboratory there is no SOP or internal validation for the guar gum dioxin analysis method, which brings into doubt the validity of the accreditation process, made on the basis of the analysis of a spiked water sample.

(20) The accredited laboratory was well staffed and equipped, with good environmental conditions, but demonstrated inadequate procedural quality control regarding the consideration of background levels due to cross contamination in the analytical procedure for dioxins.

(21) Analytical performance for PCP in the accredited laboratory visited was adequate.

(22) A second private laboratory was visited used by industry in its own investigation of the incident. The methods performed for dioxin and PCP analysis were considered inadequate for the purpose and not able to produce dependable results.

7.6. Overall Conclusion

(23) There is to date insufficient evidence of the cause of the contamination incident, and the Indian investigation has been inadequate to provide any conclusions. With availability of SPCP and its use in the guar gum industry, and with a largely self regulating industry there are inadequate controls in place to ensure that this contamination does not occur again.

8. Closing Meeting

A closing meeting was held on 11 October 2007 at the premises of the MCI. Representatives from SHEFEXIL, the Guar Gum Manufacturers Association and the EC Delegation in India were present. At this meeting, the main observations and initial conclusions were presented by the mission team. The MCI questioned the use of the term unhygienic relating to the production conditions of primary processing and storage, and disagreed with the findings that the Indian investigation was delayed and inadequate. They also stated that minutes of meetings held regarding
the contamination incident were internal documents and would not be released to the mission team.

9. **RECOMMENDATIONS**

To the Competent Authorities of India

(1) Carry out a detailed investigation into the specific contamination incident to identify the source of PCP/dioxin contamination of lots exported to Europe, report to the Commission the outcome of this investigation and put in place specific measures to ensure it does not reoccur at this premises.

(2) Ensure that conditions of the storage and primary processing of guar beans is conducted in conditions at least equivalent to the requirements of Article 4 (1) and Annex 1 of Regulation (EC) No 852/2004.

(3) Ensure that conditions in the processing of guar gum powder are conducted in conditions at least equivalent to the requirements of Article 4 (2) and Annex II of Regulation (EC) No 852/2004.

(4) Ensure that food business operators exporting guar gum or guar splits to the EU implement procedures based on HACCP principles at least equivalent to Article 5 of Regulation (EC) No 852/2004.

(5) Ensure that companies are registered with an appropriate competent authority to ensure they comply with standards described in Recommendations 2)-3), by using provisions equivalent to the requirements laid down in Article 6 of Regulation (EC) No 852/2004.

(6) Ensure that the use of PCP/SPCP and similar chemicals in an industrial situation or as a fungicide has a national legal basis.

(7) Provide detail of the levels of SPCP/PCP production in India and a statistical breakdown of the uses of these products.

(8) If operating with a sound legal basis as per Recommendation 7) ensure that the industrial use of SPCP/PCP poses no risk of cross contamination to the food grade gum, or possible sale of an industrial product for food use (Article 11 of Regulation (EC) No 178/2002). Provide details for each exporting company of how this is ensured.

An action plan in response to these recommendations should be produced by the Competent Authority **within 10 days of receipt of the report**, which should provide detailed information of the actions that will be taken and propose deadlines by which these actions will be completed.

10. **COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS.**

The competent authority’s response to the recommendations can be found at:  
### 11. ANNEX: REFERENCES TO COMMUNITY ACTS QUOTED IN THE REPORT

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<thead>
<tr>
<th>European Legislation</th>
<th>Official Journal</th>
<th>Title</th>
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