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FINAL REPORT OF A MISSION

CARRIED OUT IN

CHINA

FROM 14 TO 19 SEPTEMBER 2009

IN ORDER TO ASSESS THE OFFICIAL CONTROLS SYSTEMS IN PLACE FOR FOOD CONTACT MATERIALS FOR EXPORT TO THE EU TO PREVENT MIGRATION OF THEIR CONSTITUENTS INTO FOOD AND FOLLOW-UP RECOMMENDATIONS MADE IN REPORT SANCO 7572/2007.

*In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of an endnote.*

## *Executive Summary*

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in China from 14 to 19 September 2009.

The objective of this mission was to assess the official control systems in place for Food Contact Materials (FCM) to be exported to the European Union and to follow up the recommendations made in report SANCO 7572/2007.

The two authorities (The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China, (AQSIQ), and Customs) with responsibility within the scope of this mission have not changed since the previous mission. Communication within and between the two authorities was considered adequate.

The general and specific national legislation has been amended since the previous mission in that plastic and silicone FCM are now subject to compulsory checks prior to export outside China. In addition, the new legislative provisions on plastics are broadly in line with the EC requirements for plastic FCM, with some exceptions, such as migration of primary aromatic amines (PAAs).

In addition to ceramics, there is now an export official control system in place for plastics, silicones and some metal FCM. However, there is no equivalent export official control system for other FCM to the EU, in particular non-fillable metal kitchenware, which is mainly subject to RASFF notifications.

When FCM are exported to the EU via Hong Kong, products are only tested for compliance with Chinese national standards. This means that tests for compliance with some EU requirements, such as PAAs, are not carried out.

The laboratory method for testing migration from plastic FCM differs from that described in Directive 2002/72/EC with the consequence that tests by EU and Chinese laboratories could produce different results.

The AQSIQ did not conduct a full investigation into the companies notified through the RASFF.

The control system in place for FCM destined for export to the EU has improved since the previous mission, including the introduction of some EU requirements on FCM. However, deficiencies related to laboratory performance, incomplete investigation of companies notified through the RASFF and the potential risk of non-compliant FCM exported to the EU via Hong Kong mean that equivalence with EU requirements cannot be guaranteed.

The report makes a number of recommendations to the competent authorities of China to address the deficiencies noted.

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
AQSIQ	The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China
CA	Competent Authority
CCA	Central Competent Authority
CIQ	Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China
CNAS	China National Accreditation Service for Conformity Assessment
DEHA	Bis(2-ethylhexyl) adipate
EN	European Norm
EU	European Union
EUCTP	EU-China Trade Project
FCM	Food Contact Materials
FVO	Food and Veterinary Office
GC-MS	Gas Chromatography-Mass Spectrometry
GIQTC	Guangdong Inspection and Quarantine Technology Center
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
HS	Harmonised System
ISO	International Organisation for Standardization
LOD	Limit of Detection

MS	Member States
OML	Overall Migration Limit
PAAs	Primary Aromatic Amines
RASFF	Rapid Alert System for Food and Feed
SANCO	Health and Consumers Directorate-General
SML	Specific Migration Limit
SOP	Standard Operation Procedure

## 1 INTRODUCTION

The mission took place in China from 14 to 19 September 2009. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

The mission was undertaken as part of the FVO's planned mission programme.

The inspection team was accompanied during the whole mission by representatives from the central competent authority (CCA) the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ).

An opening meeting was held on 14 September 2009 at the Guangdong Entry-Exit Inspection and Quarantine Bureau (CIQ) with the CCA and the AQSIQ. Representatives of the Guangdong CIQ province, Customs, the Foreign Trade Administration Department and the EU Delegation in Beijing were also present. At this meeting, the objectives of and the itinerary for the mission were confirmed by the inspection team, and additional information necessary to complete the mission satisfactorily was requested.

## 2 OBJECTIVES OF THE MISSION

The objective of the mission was:

- To assess the official control systems in place for food contact materials (materials and articles intended to come into contact directly or indirectly with food) for export into the European Union to prevent the migration of their constituents into food, in particular primary aromatic amines and plasticisers from plastics, lead and cadmium from ceramic wares and formaldehyde from melamine kitchenware. The aim was to assess whether food contact materials (FCM) can be manufactured within specified European Union migration limits and in line with Regulation (EC) No 1935/2004;
- To follow up on the recommendations made in report SANCO 7572/2007.

To achieve these objectives, the following sites were visited in accordance with the itinerary agreed between the AQSIQ and the FVO of the European Commission:

<b>competent authority visits</b>			<b>Comments</b>
Competent authority	Central	1	AQSIQ at Guangdong CIQ premises
	Provincial	1	Guangdong CIQ
		1	Guangdong Customs
		1	Foreign Trade Administration Department
<b>laboratory visit</b>			<b>Comments</b>
Guangdong CIQ laboratory			1 FCM analyses

<b>visits to premises</b>		
Nylon FCM manufacturer	1	Guangdong province
Metal FCM manufacturer	1	Guangdong province
Melamine FCM manufacturers	2	Guangdong province

### **3 LEGAL BASIS FOR THE MISSION**

The mission was carried out in agreement with the CCA and under the general provisions of Community legislation, specifically:

- Regulation (EC) No 882/2004 of the European Parliament and of the Council, in particular Article 46.

All legal references relevant to this mission are listed in Annex 1. Legal acts quoted refer, where applicable, to the last amended version.

Other legislation relevant to this report is listed in the Annex.

### **4 BACKGROUND**

#### **4.1 BACKGROUND TO PRESENT MISSION**

Article 50 of Regulation (EC) No 178/2002 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. From 2007 to the time of the mission, there were a significant number of notifications (267) regarding FCM from China mainly relating to the migration of primary aromatic amines (PAAs) from nylon kitchen utensils (39), the migration of chrome and cadmium from stainless-steel kitchenware (58), the migration of lead and cadmium from ceramic articles (16), the migration of formaldehyde from melamine kitchenware (43), total migration (35), and the migration of phthalates (10). The breakdown by year of these notifications is as follows: 61 notifications in 2007, 111 notifications in 2008 and 85 notifications in 2009 up to September.

In view of this high number of RASFF notifications, the European Commission decided to undertake a mission to China and to follow up the recommendations made in report SANCO 7572/2007.

## 4.2 PUBLIC HEALTH INFORMATION

### **Primary aromatic amines**

Commission Directive 2002/72/EC lays down general specifications for plastics which states that primary aromatic amines (PAAs) should not migrate into food, or to a food simulant in detectable quantities. Some PAAs are considered potential human carcinogens. They can be formed from isocyanates used in glues, adhesives in laminates, and released from azo dyes or azo pigments used as colours. There may also be other sources.

### **Lead and cadmium from ceramic ware**

Council Directive 84/500/EEC lays down migration limits for lead and cadmium from ceramic ware into 4% acetic acid. Commission Directive 2005/31/EC amending the above-mentioned Council Directive requires a declaration of compliance for ceramic articles and appropriate documentation to demonstrate that they comply with the migration limits for lead and cadmium. The manufacturer or the importer into the Community shall make the documentation available to the national competent authorities (CA) on request. It shall contain the results of the analyses carried out, the test conditions and the name and address of the laboratory that performed the tests.

### **Formaldehyde**

Directive 2002/72/EC lays down a specific migration limit of 15 mg/kg for formaldehyde, a monomer used to manufacture melamine kitchenware.

### **DEHA**

DEHA is used as a plasticiser in polyvinyl chloride (PVC) cling films and other PVC applications. Directive 2002/72/EC lays down a specific migration limit of 18 mg/kg of food for DEHA. Certain cling films exceeded the migration limit for DEHA, especially into meat.

## 5 FINDINGS AND CONCLUSIONS

### 5.1 LEGAL REQUIREMENTS

- Article 3 of Regulation (EC) No 1935/2004 states that materials and articles, including active and intelligent materials, shall be manufactured in compliance with good manufacturing practice (GMP) so that, under normal foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health or bring about an unacceptable change in the composition of food or a deterioration in the organoleptic characteristics thereof.
- Article 16 of the above Regulation states that FCM with specific measures (e.g. plastics, ceramics) shall be accompanied by a written declaration stating that they comply with the applicable rules. Article 17 of same Regulation establishes traceability requirements in FCM.
- Article 2 of Directive 84/500/EEC lays down specific migration limits for lead and cadmium in ceramic.
- Article 2 of Directive 2002/72/EC lays down the overall migration limit of constituents from plastics to foodstuffs. In addition, a list of monomers, starting substances and additives authorised to use in plastics and specific migration limits for these constituents is provided in the Annexes to this Directive. Article 9 of the Directive requires that at the marketing

stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

- Regulation (EC) No 2023/2006, in particular Article 4, requires business operators to ensure that manufacturing operations are carried out within the general rules of GMP or detailed rules on GMP as set out in the Annex to this Regulation.
- Article 3 of Directive 82/711/EEC requires that compliance with the limits of migration of constituents of plastic materials and articles into foodstuffs shall be verified under the most extreme conditions of time and temperatures foreseeable in actual use, by using food simulants following the basic rules for testing as laid down in the Annex to the Directive.
- Annex of Directive 85/572/EEC lays down the list of food simulants to be used for testing the migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

## 5.2 COMPETENT AUTHORITIES

### Findings

No changes have been made since the previous mission regarding the structure and organisation of the AQSIQ (The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China). The Consumer Product Division of the Department for Supervision on Inspection at central level is still responsible for organising export controls in FCM manufacturing facilities which export outside China. The number of staff dealing, among other things, with FCM, both at central level (4) and provincial level (4000), has not changed since the previous mission. The 35 CIQs at provincial level are responsible for implementation.

The mission team visited the Guangdong CIQ office located in Guangzhou, which consists of 34 branches, under which there are 100 local CIQ offices. Within the Guangdong CIQ office, the Textile and Industrial Product Section of the Department for Supervision on Inspection and Survey is responsible for implementing official controls, including FCM for export, and for circulating instructions from AQSIQ to the branches and local offices. Three members of staff deal with FCM in the Textile and Industrial Product Section. Across the province, 300 members of staff deal with FCM, out of a total 7000 inspectors.

Communication in the context of this mission between the AQSIQ and the CIQ was carried out by means of fax or written documentation.

With regard to training on FCM, the above consumer product division is responsible for organising and providing training sessions. Since the previous mission, two training sessions were carried out in April 2008 in Guangdong province (Yangjiang) and Zhejiang province (Hangzhou) under the EC scheme 'Support to China's integration into the World Trading System' and funded by the EU-China Trade Project (EUCTP). These two training sessions targeted representatives of CIQ staff and the Chinese FCM industry. There were 378 participants, 140 of whom were from enforcement authorities. In the context of this event, an English website was set up including all training material, question and answers documents and EU legislation translated into Chinese. The website is accessible at <http://www.euchinafcm.org>. In addition, the EUCTP also supported an internship (the intern was an official at the Guangdong CIQ) in the Community Reference Laboratory of the European Commission DG Joint Research Centre.

The Guangdong CIQ also organised a number of training sessions on EC FCM legislation and GMP for the FCM industry (e.g. in December 2007 a GMP tailored course was put on for FCM companies and a half-day course was held in June 2009 for plastic FCM in Dongguan).

The mission team was informed that, in terms of supervision, the internal audit department of AQSIQ central level is responsible for supervising the work carried out by the CIQs. A final meeting is held with the CIQ concerned but no report is drawn up unless a severe infringement is found.

The role of the Customs General Administration in the context of FCM has not changed since the previous mission. The mission team was informed that Customs is responsible for the final release of FCM for export outside China, including Hong Kong.

## **Conclusions**

AQSIQ's structure, organisation and staffing level has not changed since the previous mission. The role of Customs in the context of this mission has not changed either.

A number of training sessions on FCM, including EC requirements and GMP, has been provided since the previous mission.

## **5.3 LEGISLATION**

### **Findings**

Some changes have been made regarding national general and specific FCM legislation since the previous mission. In addition to the Law of the People's Republic of China on Import and Export Commodity and its Regulation for implementation, there is the New Food Safety Law of the People's Republic of China, applicable since 1 June 2009. Controls on FCM fall under this Law. However, implementation is at an early stage as the Food Safety Committee and a surveillance system for food safety have not yet been established, as required by Articles 4 and 11 respectively.

With regard to specific legislation, the following changes have been made:

- The Catalogue of Enter-Exit Goods has been amended to address the recommendation made in the previous mission. Since 30 August 2007 (Joint Notice No 131 between Customs and AQSIQ), plastic FCM under HS codes 3924100000 and 3924900000 (e.g. nylon kitchen utensils, melamine kitchenware and other plastics) and silicone elastomers are included in this Catalogue, which requires compulsory inspection by the CIQ prior to export outside China. In addition, this Catalogue includes a limited number of metal FCM (kettles, pots and other fillable articles).
- Classification Administration Measure for Manufacturers of Export Commodities No 51/2003 was amended in June 2009. It extends the classification of export manufacturers to plastics and silicones. These manufacturers will be now classified into four categories, taking into account three levels of risk and five levels of controls. However, the mission team was informed that implementation of this provision will be finalised at the end of this year.
- The Chinese standard GB 9690-2009 lays down limits for formaldehyde and melamine. The migration level for formaldehyde is equivalent to the EC limit and the migration limit for melamine is lower than the EC limit. It entered into force on 1 September 2009.
- The Chinese standard GB 9685-2003, which lays down hygienic standards for uses of additives in food containers and packaging materials, has been replaced by GB 9685-2008. It entered into force on 1 June 2009. It is broadly in line with the EU requirements but the migration of PAA is not regulated because it is not considered as an additive.
- The Chinese standard GB 23296, which lays down test methods for overall migration and specific migration in plastics, consists of 26 subsections based on EN 1168 and EN 13130.

## Conclusions

The general and specific national legislation has been amended since the previous mission.

The Catalogue of Enter-Exit Goods now includes plastic FCM and silicones.

The new legislative provisions on plastics are broadly in line with EC requirements for plastic FCM, with some exceptions, such as the migration of PAAs.

### 5.4 COMPETENT AUTHORITY CONTROLS

## Findings

### Organisation of controls

The organisation of official controls on FCM for export has changed since the previous mission in that silicone and plastics, including those intended to come into contact with food, are now included in the products listed in the Catalogue of Enter-Exit Goods and are therefore subject to compulsory checks prior to export outside China. The official controls on FCM for export are drawn up by AQSIQ and implemented by the 35 CIQs, including their branches and local offices.

No changes have been made since the previous mission regarding the two types of controls on FCM (one for products listed in the catalogue and the other for non-listed products). The mission team was informed that the AQSIQ draws up a program for checking listed products every two or three years. CIQs have to report back to AQSIQ on implementation of this program. However, the mission did not see any documentation regarding this program. Companies producing and exporting FCM included in the catalogue are subject to at least an annual inspection. The classification of ceramic manufacturers is described in point 7.3.1 of report SANCO 7572/2007 and the mission team was informed that silicone and plastic manufacturers are categorised following the classification for ceramic manufacturers. This categorisation will change once the Classification Administration Measure for Manufacturers of Export Commodities 2003 as amended in 2009 is fully implemented.

Controls of products which are not listed in the above catalogue have not changed since the previous mission. These are based primarily on voluntary industry controls. They include metalware (e.g. utensils like sieves, ladles, and cutlery) mainly subject to RASFF notifications, paper, glass and wood. As mentioned in the previous report, the 'Administrative Measures for Random Inspection of Import and Export Commodities' provides for some measures regarding inspection and sampling, such as the annual random control plan. For 2009, the mission team was informed that the release of heavy metals in metalware was included.

The mission team was also informed that there was a special campaign on consumer product safety, which included FCM. The main purpose of this campaign was to raise producer awareness of safety issues.

In 2008, CIQs nationwide inspected 112 109 batches of export domestic ceramics, of which 353 (0.31 %) batches included non-compliant products. The main reason was the excessive migration of lead and cadmium. With regard to plastics, 86 708 batches of export plastic material and article used for food packaging were tested and 743 (0.85 %) of products were non-compliant. The main items exceeding the limit were evaporation residue, phthalates and formaldehyde. No PAAs were found.

### Enforcement

As mentioned in report SANCO 7572/2009, the AQSIQ has powers to ban the export of non-compliant products, including FCM, when these products do not comply with the standards either issued by the Chinese or the country of destination. The AQSIQ also has legal powers to suspend

the export activities of companies and to suspend or withdraw their export license and impose financial penalties. However, the mission team saw no evidence of the execution of these powers in any of the FCM manufacturers involved in the RASFF system.

#### On-site visits

The mission team visited four FCM manufacturing companies (one metalware company, one nylon kitchen articles manufacturer and two melamine kitchenware companies) in the Guangdong province (one of the companies visited had been the subject of a RASFF notification). During these visits, the inspection procedures and the history of inspections in companies were evaluated. The mission team asked to visit another melamine kitchenware company which was also the subject of a RASFF notification, but the mission team was informed that it had closed down at the beginning of the year.

All the FCM companies visited had been inspected by CIQ inspectors and information on EU requirements had been provided through training and guidelines (a hard copy of EU requirements was made available to companies by the CIQ) including some tailored training on GMP in one company. In addition, all the manufacturers visited were certified according to ISO 9001:2001.

Only one FCM producer visited had received information on EU FCM requirements from EU importers.

The metalware producer visited had received information from EU importers regarding the composition of metals but no requirements were specified to the manufacturer concerning the migration of metals. Although the manufacturing company visited performed some tests on the composition of raw materials, chromium and nickel were not tested in the finished products. The company did not provide any documentation regarding the safety of FCM (migration of metals) to EU importers.

The nylon kitchenware company visited was also visited during the previous mission. In addition to nylon kitchenware, the company produces silicone and cutlery. The visit to the company focused on the manufacturing of nylon kitchenware. The company received from one of its raw material suppliers (polyamide) a declaration of compliance, which contains additional information related to substances with specific migration limits (SML) (e.g. Hexamethyldiamine, SML 2.4 ppm). However, the finished product was only tested for the migration of PAAs, not for specific migration of the above substance or any other substance (e.g. caprolactam). The overall migration limit (OML) was not tested either. The plastic company stated that the finished products fully comply with EU requirements. The company has been classified as type III based on the history of the company and RASFF notifications.

In the two melamine kitchenware producers visited, documentation regarding raw materials including test reports for formaldehyde and melamine were available. The finished products were in-house tested for formaldehyde in both cases and for melamine and OML in one case. However, a private laboratory undertook the melamine test. One of these two companies provided test reports on finished products to EU importers. No additional tests (e.g. possible deterioration in the organoleptic characteristics) were carried out by the companies visited. The two companies visited were classified as type I and II respectively.

#### **Conclusions**

The official controls on ceramic manufacturers have not changed since the previous mission.

Similarly to ceramics, plastics, silicones and some metal FCM are now included in the mandatory pre-export controls by AQSIQ.

The official controls on non-catalogue FCM have not changed since the previous mission.

Special campaigns on consumer product safety are implemented nationwide to raise producers awareness of safety. The products covered include FCM.

The AQSIQ has adequate legal powers of enforcement regarding FCM which are defined under Chinese law, however, no evidence of the use of these powers was observed by the mission team.

The inspections evaluated by the mission team were well organised and covered raw materials, processing and traceability.

Some deficiencies were noted regarding information on the EU's FCM requirements provided by EU importers to FCM manufacturers.

Although the migration of PAAs was tested in one of the companies visited, the information provided in the declaration of compliance of raw materials with the specific migration limits of other substances was not taken into account. In addition, the company declared full compliance with EC requirements on the basis of very few migration tests.

Deficiencies were noted in communication from EU importers to FCM manufacturers in China regarding specifications of EU requirements as the majority of Chinese FCM manufacturers visited stated that they had not received such information.

FCM manufacturers do not always provide EU importers with information on product compliance with SML.

Information on EC requirements was provided to Chinese FCM manufacturers through training and guidelines.

## 5.5 TRADE INFORMATION ON FOOD CONTACT MATERIALS PRODUCTION

### Findings

There is no change since the previous mission regarding the main producing provinces of FCM. The main ports of export from the Guangdong province are Huangpu, Dongguan and Shenzhen.

According to the information provided by the AQSIQ in 2008, 751 ceramics manufacturers with a quality licence for export and 2410 plastic FCM producers under the supervision in the whole of China. The summary of Chinese manufacturers and exporters to the EU has been updated since the previous mission; see Table 1.

Table 1

Group	Numbers of manufacturers	Processors and exporters (particularly to the EU)
Domestic ceramics	751	439
Plastic packaging	2410	889
Metal containers	972	388

Data provided by AQSIQ

The Guangdong province is one of the major provinces producing FCM in China. The mission team met the local CIQ staff from Yangjiang and Dongguan and visited a number of FCM companies (see 6.2.3.3). In 2008, the Guangdong CIQ office supervised 339 ceramic producers (the majority classified as type III) who have obtained a quality license for export. With regard to plastics, 500

companies produce plastic FCM for export in this province categorised as follows: 40 companies as type I, 100 as type II and 360 as type III.

Table 2 sets out statistical data on the export of food contact materials, particularly to the European Union since the last mission.

Table 2

Group	Total numbers of consignments for export	Total amount of export. Ten thousand US dollar	Numbers of consignments for export to EU	Amount of export to EU. Ten thousand US dollar
Domestic ceramics	161943	286734.4	13409	23400.2
Plastic packaging	140011	190593.7	24294	90206
Metal containers	74348	195311.5	12160	38272.8

The data comes from statistics of the main regions of production, from January 2008 to June 2009.

The organisation of the FCM industry association in China has not changed since the previous mission.

## **Conclusions**

The main FCM producing provinces and organisation of the FCM industry association in China has not changed since the previous mission.

## **5.6 EXPORT PROCEDURES**

### **Findings**

Some changes to the export procedures for plastics have been made since the previous mission. For ceramic wares, the export procedures remain the same as the previous mission.

For plastics, the procedure is as follows: unlike ceramic producers, plastic producers are not subject to compulsory registration and do not need to apply for an export quality license. However, plastic companies that intend to export to the EU are required by the CIQ to submit analytical reports of raw materials and finished products. The analysis may be undertaken either by CIQ laboratories, private laboratories or in-house laboratories. All must be accredited according to ISO 17025. If the results meet the requirements of the country of destination, the company then applies to the CIQ for every shipment to obtain the customs clearance document by submitting an application form along with an analytical report of the finished product. CIQ inspectors then carry out a documentary check and, depending on the type of the company, a random physical check at the company takes place. If the above checks are satisfactory, the CIQ then issues the customs clearance document. The mission team noted that, with regard to nylon kitchen utensils, CIQ laboratory analyses generally cover analysis for overall migration and migration of PAAs and the migration of melamine and formaldehyde for melamine kitchenware.

Once the company has the above customs clearance document, the Customs procedure continues as

described in the previous report. The only difference now is that plastics cannot be released by Customs unless they have a CIQ customs clearance document.

For products that are not listed in the catalogue (e.g. metalware: sieves, ladles, and cutlery) no specific export requirements are needed from the AQSIQ, that is, the company does not need prior approval by the relevant CIQs (e.g. a customs clearance document) to the EU but companies can apply to the CIQ on a voluntary basis.

For FCM exported to the EU via Hong Kong, the procedure is as follows: some FCM exporters declare that these products are going to be exported only to Hong Kong. Therefore, these products are only tested by the CIQ on the basis of Chinese national standards, which in some cases mean that the products (e.g. nylon kitchenware) are not tested for compliance with certain EU requirements, such as PAAs. According to the RASFF database, a significant number of FCM consignments manufactured in China were exported to the EU via Hong Kong.

## **Conclusions**

In addition to ceramics, an export official control system is now in place for plastics, silicones and some metal FCM.

There is no equivalent export official control system for other FCM to the EU, in particular metalware, which is mainly subject to RASFF notifications.

When FCM are exported to the EU via Hong Kong and the exporter declares that the goods are only exported to Hong Kong, products are only tested against Chinese national standards. Since these do not include test on PAA, guarantees concerning the respect of EU limits for this substance cannot be provided.

## **5.7 RESPONSE TO RASFF NOTIFICATIONS**

### **Findings**

The procedure for receiving RASFF notifications has changed since the previous mission. Before January 2009, the AQSIQ received RASFF notifications from the Commission through the EU Delegation in China. Since January 2009, AQSIQ has direct electronic access to all RASFF notifications related to China (RASFF Window online application). The RASFF window allows the AQSIQ to monitor RASFF notifications the day after they are sent by the Commission. The AQSIQ then submits these notifications to the CIQs concerned, who undertake an investigation. The CIQs notify the AQSIQ of the outcome of the investigation.

In the Guangdong CIQ province, 8 RASFF notifications were received in 2008 and 9 to September 2009. According to the investigation carried out by this CIQ, the main findings are: 44 % of the FCM companies visited did not receive specifications on EU requirements from EU importers; most (81 %) of the notified products (mainly metal ware) were not included in the Catalogue, and lack of awareness of EC legislation and standards in some of the investigated companies.

The nylon kitchenware producer visited was notified 9 times according to the RASFF database (from 2005 to 2009). However, no investigation was undertaken for at least four notifications from 2007 to 2009.

The mission team examined another file of a company notified through the RASFF system in Dongguan. A letter from the AQSIQ to Dongguan CIQ through the Guangdong CIQ requiring an investigation was seen. Inspection and sampling were carried out by the Dongguan CIQ staff. The technical problems identified in the company during the investigation were reported back to AQSIQ and other plastic manufacturers were also informed to avoid these problems in the future.

RASFF notifications related to FCM products manufactured in China and exported via Hong Kong to the EU are sent to Hong Kong competent authorities by the Commission. However, the mission team was informed by AQSIQ that there is no communication of these RASFF notifications from Hong Kong authorities to AQSIQ.

### **Conclusions**

Full investigations were not carried out into the companies notified through the RASFF.

FCM products exported via Hong Kong are not subject to a RASFF investigation in China.

## **5.8 OFFICIAL CONTROL LABORATORY SERVICES**

### **Findings**

#### General Organisation

In report SANCO 7572/2007, 55 CIQ laboratories were authorised for testing FCM for export purposes all over China. During the mission, the mission team requested the AQSIQ to provide an update of the number of CIQ laboratories. At the time of writing the report, no information has been received.

In the Guangdong province, the mission team was informed that 15 CIQ laboratories in addition to the Guangdong Inspection and Quarantine Technology Center (GIQTC) had been authorised to perform an analysis of FCM for export purposes.

#### Laboratory visit

The mission team visited the GIQTC. Since the previous mission, no changes have been made regarding the scope of work of the CIQ laboratory or the sampling procedure.

The visited GIQTC is considered as a key national laboratory and is accredited according to ISO 17025 by the China National Accreditation Service for Conformity Assessment (CNAS). However, the method for PAA testing is not covered by the accreditation. The analysis of FCM is carried out within the Chemicals, Minerals and Metal Materials Testing division. Around 3600 samples of FCM were analysed last year (2008) in this laboratory, of which 2354 were for export to the EU. Most FCM-related tests were carried out in the GIQTC. The GIQTC laboratory is well equipped with analytical instruments and other devices and uses a LIMS system for data management. 43 employees work on FCM testing and are in general adequately qualified and trained.

During the visit, the mission team evaluated the analytical methods for PAAs and formaldehyde.

All requested documents related to the investigated samples were shown (e.g. sample form, SOP, chromatographic / photometric data).

In general, migration experiments are done according to EN 13130-1 and it was stated that the CIQ defines the individual parameters (e.g. time and temperature) for migration testing. If no specific parameters are given by the CIQ, migration tests of PAA and formaldehyde are performed with 3 % acetic acid for 4h at 100 °C. However, for repeated use articles, only a first migration experiment is carried out, whereas according to Directive 2002/72/EC and EN 13130-1 (chapter 10.8), migration tests should be carried out three times on a single sample and compliance checked on the basis of the level of the migration found in the third test. For formaldehyde migration from melamine articles in particular, it is known that migration levels may increase from the first to the third test.

To analyse migrating PAAs, a method comparable to the one used at EU level is used to analyse azo dyes (restricted to LOD less than 30 mg/kg). Quantification is done with GC-MS without using a suitable internal standard. The method so far covers 26 amines (amines related to prohibited azo

dyes and aniline). However, other PAAs may be relevant to nylon kitchenware. An SOP was established but it was not covered by the accreditation. It defines a calibration curve with 5 points and 0.01 mg/l as the lowest calibration level. No data were shown to the mission team to confirm the suitability of the method for analysing PAA in different food simulants in the µg/kg range.

An investigated nylon kitchenware sample to be tested for safety and hygiene requirements was analysed for PAA only, but no other parameters. Contrary to the presented SOP, the corresponding calibration curve was at a far higher concentration level and consisted of only three points. Taking the sample preparation steps as well as the performance of the GC-MS-system and the presented calibration data into account, the LOD of 0.01 mg/l as required by Directive 2002/72/EC was not reached.

For the demonstrated nylon kitchenware sample, the mission team also found some shortcomings in the use of GC-MS (e.g. interpretation of chromatograms).

The formaldehyde testing method used is compliant with EN 13130-23. A national proficiency test for formaldehyde was performed in summer 2009 but no report of the results has yet been received by the laboratory. The investigated melamine kitchenware sample was again only tested for formaldehyde and showed as a result of parallel testing a migration value of 10 mg/l on average for the first migration experiment. No single values were given and no second or third migration tests were performed.

For the other melamine samples, even with formaldehyde migration values (13.8 mg/kg, uncertainty to be added) very close to the SML (15 mg/kg), again no third migration tests were performed and no further analyses were carried out.

All test reports for plastic FCM by CIQ laboratories shown either at the laboratory or at the visited companies mentioned only very few parameters but documented full compliance with EU legislation (with more than 800 listed substances).

## **Conclusions**

There is no updated information available on the number of FCM laboratories authorised to test FCM nationwide for export purposes, despite the FVO's request.

Deficiencies identified in the previous mission in laboratories with regard to the use of food simulants have been addressed. However, the performance of the laboratory visited and the migration tests carried out for plastics intended to be exported to the EU are not yet equivalent to those laid down in Directive 2002/72/EC.

The above deficiencies may result in samples found to be negative by the Chinese being found positive by EU laboratories.

## **5.9 PROMOTION OF GOOD MANUFACTURING PRACTICE**

### **Findings**

As mentioned in report SANCO 7572/2007, there are no specific GMP guidelines for FCM process controls. The AQSIQ encourages companies to be certified according to ISO 9001:20001. Currently, some information on GMP has been distributed to local CIQ staff to pass on to the FCM industry. This is an ongoing process.

### **Conclusions**

The AQSIQ has distributed some information on GMP to the local CIQs to pass on to the FCM industry. This is currently ongoing.

## 5.10 FOLLOW UP TO MISSION 7572/2007

### Findings

The FVO undertook a mission to China in April 2007 with the objective of evaluating the official control system in place for FCM intended to be exported to the EU. This report made a series of recommendations to be followed up by the Chinese authorities.

Table 3 summarises the recommendations made, the response give by the competent authority and the follow up action taken.

Table 3

RECOMMENDATION OF SANCO 7572/2007	RESPONSE FROM CHINESE AUTHORITIES	FOLLOW UP IN MISSION SANCO 8156/2009
<p>(1) Continue with training and awareness campaigns to ensure that companies exporting plastic food contact materials are aware of the provisions set down in Commission Directive 2002/72/EC.</p>	<p>The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) will complete some training sessions before the end of 2007. CIQ staff and FCM manufacturing companies all across China will be trained following the three-level training mode of AQSIQ---direct affiliates of AQSIQ---local CIQs. The training will focus on the rules and regulations on food contact materials (e.g. Commission Directive 2002/72/EC). We hope that the EU could provide us with technical assistance and financial support for the training concerned.</p>	<p>Training and awareness campaigns are carried out on a regular basis. See 5.2.</p>
<p>(2) Ensure that FCM manufacturers for non-listed products including plastics are identified when exporting to the EU (Art 10 of Regulation (EC) No 852/2004).</p>	<p>AQSIQ hopes to sign a cooperation agreement with the EU on the establishment and implementation of a new system to ensure that FCM manufacturers are identified when exporting to the EU. In order to facilitate the establishment of the system, AQSIQ hopes to strengthen communication and exchange with the EU, being more knowledgeable of the existing identification system on exporting FCM manufacturers in EU Member States, and continues to improve the identification management system of plastics manufacturers.</p> <p>Additional information provided on 22 November 2007:</p>	<p>Plastics are included in the listed products. However, some metalwares are not listed products and therefore are not identified when exporting to the EU.</p>

	<p>The AQSIQ promulgated the Stipulation on Surveillance and Inspection of Import and Export Food Packaging vessels and Materials on 6 April 2006, a registration mechanism for manufacturers of Food Packaging Vessels and Materials presumed to be exported has been established since 1 August 2006 as so requested. Unfortunately, this information was not clearly given to your mission during the assessment.</p>	
<p>(3) Ensure that plastics FCM to be exported to the EU comply with the requirements at least equivalent to Commission Directive 2002/72/EC.</p>	<p>Manufacturers, importers and exporters shall bear liability in the event of safety problems concerning food contact materials exported to the EU. The central competent authorities of the importing country and exporting country are mainly responsible for the supervision of such commodities under legal authorisation. The AQSIQ will demand that FCM manufacturers produce and trade in accordance with the requirements of Commission Directive 2002/72/EC. The AQSIQ also requires local CIQs to carry out random inspections on plastic FCM to be exported to the EU in accordance with the requirements of Commission Directive 2002/72/EC. In order to convey the requirements of EU technical regulations when EU importers sign trade contracts with Chinese manufacturers, the EU is expected to take measures to train national importers on technical regulations and strengthen supervision. The AQSIQ and EU will pay more attention to the notification of unqualified FCM import and export operators, and reinforce safety supervision of food contact materials with mutual cooperation.</p> <p>Additional information provided on 22 November 2007:</p> <p>The AQSIQ and the General Customs Administration issued Joint Public Notice No 131 on the Compulsory Inspection of Some Export Products, which includes Plastic Food Contact Materials, on 30 August 2007. Kitchen and bathroom products made of plastics are subject to compulsory inspection since then. Conformity assessments will be based on the technical regulations and standards issued by</p>	<p>Plastics are included in the Catalogue and are tested batch by batch in accordance with some (selected) parameters of the plastic Directive 2002/72/EC.</p>

	<p>imported countries.</p> <p>Registration and inspection works have now been implemented by local CIQs. Testing standards equivalent to those of the EU have been drafted by CIQ laboratories and FCM testing has been conducted on these standards. We believe these two measures will safeguard the identification requirement in your second recommendation and conformity requirement in your third recommendation.</p>	
<p>(4) Ensure that methods for sample preparation and analysis are equivalent to Council Directive 82/711/EEC and Council Directive 85/572/EEC.</p>	<p>AQSIQ will complete the legislation of industry inspection standards on plastics FCM before the end of 2007, which are equivalent to those issued by the EU, including EN 13130, EN1186 serials and methods laid down in Commission Directive 82/711/EEC and 85/572/EEC. The AQSIQ hopes to strengthen technical exchanges with the EU and promote the coordination of inspection standards and methods.</p>	<p>Improvements have been made since the previous mission. However, some deficiencies have been found in relation to the methods for PAA and formaldehyde. See 5.8.</p>
<p>(5) Consider that FCM companies exporting to the EU implement Good Manufacturing Practice at least equivalent to Commission Regulation (EC) No 2023/2006.</p>	<p>The AQSIQ will help promote the implementation of ISO 9000 quality management system and ISO 14000 environmental management system in the FCM industry. Meanwhile, the AQSIQ will reinforce GMP promotion among FCM companies exporting to the EU and encourage companies to establish the GMP system on a voluntary basis.</p> <p>Additional information provided on 22 November 2007:</p> <p>Regarding the GMP certification recommendation, the AQSIQ wishes to cooperate with the EU in the technical field, to train technicians of Chinese manufacturers and local CIQs and to share the experience of the EU in the process of implementing GMP certification.</p>	<p>AQSIQ is promoting the implementation of ISO 9001 and information on GMP is being disseminated to FCM companies. This is an ongoing process.</p>

## Conclusions

Two recommendations have been fully addressed and three partly addressed with major improvements made in the relevant areas.

## 6 OVERALL CONCLUSIONS

The control system in place on FCM destined for export to the EU has improved since the previous mission, including the introduction of certain EU requirements on FCM. However, deficiencies regarding laboratory performance, the incomplete investigation of companies notified through the RASFF and the potential risk of non-compliant FCM exported to the EU via Hong Kong mean that equivalence with EU requirements cannot be guaranteed.

## 7 CLOSING MEETING

A closing meeting was held on 19 September 2009 with the central competent authority, AQSIQ. Representatives of the Guangdong CIQs, and one official from Unit E3 'Chemical, contaminants and pesticides' of DG SANCO were also present. At this meeting, the main findings and conclusions of the mission were presented by the inspection team.

The competent authorities made comments on some findings and also suggested stepping up cooperation between China and the EU on training for technical laboratory staff.

## 8 RECOMMENDATIONS

An action plan in response to the recommendations should be forwarded to the Commission within 25 days of receipt of the report. This action plan should clearly set out the manner and deadline by which the competent authorities will address each of the following recommendations:

Nº.	Recommendation
1.	Ensure that plastic FCM to be exported to the EU, and the methods used for their analysis, comply with requirements at least equivalent to Commission Directive 2002/72/EC.
2.	Ensure that FCM companies exporting to the EU implement Good Manufacturing Practice at least equivalent to Commission Regulation (EC) No 2023/2006.
3.	Consider systematically carrying out investigations at RFCM manufacturing establishments identified through RASFF notifications.

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

[http://ec.europa.eu/food/fvo/ap/ap\\_cn\\_2009-8156.pdf](http://ec.europa.eu/food/fvo/ap/ap_cn_2009-8156.pdf)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	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
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 1935/2004	OJ L 338, 13.11.2004, p. 4-17	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
Reg. 2023/2006	OJ L 384, 29.12.2006, p. 7578	Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
Reg. 282/2008	OJ L 86, 28.3.2008, p. 9-18	Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006
Dir. 84/500/EEC	OJ L 277, 20.10.1984, p. 12-16	Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs
Dir. 2002/72/EC	OJ L 220, 15.8.2002, p. 18-58	Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs
Reg. 372/2007	OJ L 92, 3.4.2007, p. 9-12	Commission Regulation (EC) No 372/2007 of 2 April 2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
		come into contact with foods
Dir. 82/711/EEC	OJ L 297, 23.10.1982, p. 26-30	Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs
Dir. 85/572/EEC	OJ L 372, 31.12.1985, p. 14-21	Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs
Dir. 78/142/EEC	OJ L 44, 15.2.1978, p. 15-17	Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs
Dir. 80/766/EEC	OJ L 213, 16.8.1980, p. 42-46	Commission Directive 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs
Dir. 93/11/EEC	OJ L 93, 17.4.1993, p. 37-38	Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers
Dir. 81/432/EEC	OJ L 167, 24.6.1981, p. 6-11	Commission Directive 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs
Reg. 1895/2005	OJ L 302, 19.11.2005, p. 28-32	Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food