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Delivering an Effective, Resilient and Sustainable EU-China Food Safety Partnership

Grant Agreement number:

727864 — EU-China-Safe

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This report forms part of the deliverables of the project "EU-China-Safe" which has received funding from the European Union's Horizon 2020 Research and Innovation programme under Grant Agreement No 727864 and from the Chinese Ministry of Science and Technology (MOST).

EU-China-Safe aims at reducing food fraud and improving food safety through focusing on improving food legislation, food inspection and increasing access to information across Europe and China. State-of-the-art technologies including a virtual laboratory will create a unique space to share and demonstrate best practice. The use of innovative technologies will result in improved detection of adulteration of food products as well as increased traceability and transparency of global supply chains.

The project runs from September 2017 to August 2021. It involves 33 partners and is coordinated by QUB (The Queen's University of Belfast, UK).

More information on the project can be found at www.euchinasafe.eu

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Nature of the deliverable		
ORDP	Open Research Data Pilot	
R	Document, report (excluding the periodic and final reports)	X
DEM	Demonstrator, pilot, prototype, plan designs	
DEC	Websites, patents filing, press & media actions, videos, etc.	
E	Ethics	
OTHER	Software, technical diagram, etc.	

Dissemination Level		
PU	Public, fully open, e.g. web	X
CO	Confidential, restricted under conditions set out in Model Grant Agreement	
CI	Classified, information as referred to in Commission Decision 2001/844/EC	

Table of contents

1. SUMMARY

This report (Deliverable 4.2) describes the ongoing activity to provide training to Chinese project partners such that the four main objectives of Work Package 4 are met. These are:

- To address current challenges and gaps in microbiological and chemical food safety testing through the implementation of new or improved analytical methods.
- To transfer analytical methodology and harmonise testing between China and the EU.
- To improve the safety and quality of food consumed in Chinese and European markets.
- To improve the food safety infrastructure in both China and the EU.

To date it has not been possible for the Chinese project partner for whom the training is planned (China National Center for Food Safety Risk Assessment - CFSA) to travel to the UK. The lead Fera scientist has however travelled to China to deliver training through meetings with CFSA, including at the 2019 International Food Contact Materials Safety Symposium organised by the Chinese NRL (Guangdong Inspection and Quarantine Technology Center - IQTC) and delivery of a lecture to Hong Kong Polytechnic University (PolyU) students and staff. In addition, meetings have been facilitated between Fera and the Chinese Academy of Inspection and Quarantine (CAIQ - not a Task 4.3 partner but a partner in the project overall) to provide an overview of the activity of the EU China-Safe project and Work Package 4 Task 4.3 specifically.

It is not currently known whether or not the CFSA scientist will be able to travel to the UK to receive the face to face laboratory based training. If this cannot take place within the project timeframe it is proposed that a series of on-line training materials is prepared for dissemination to CFSA and PolyU as well as other Chinese project partners to support knowledge development with respect to EU legislation and analytical methodologies required to demonstrate compliance of food contact materials and articles with the European Regulations.

2. INTRODUCTION

Any material or article which comes into contact with a foodstuff has the potential to cause chemical contamination. If chemicals transfer to the product, i.e. migrate, they may cause taint or odour problems and if the concentrations are high enough this may make the product unsafe to eat. The safety of materials and articles intended for contact with food is controlled within Europe by European legislation. Figure 1 provides an overview of the current EU legislation which can be found at:

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en
(accessed 20.03.2020).

Commission Regulation (EC) No 1935/2004 (EC, 2004) also known as the Framework Regulation sets out the general principles of safety and inertness for all Food Contact Materials (FCMs). The General Requirements are defined in Article 3 which states:

“1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

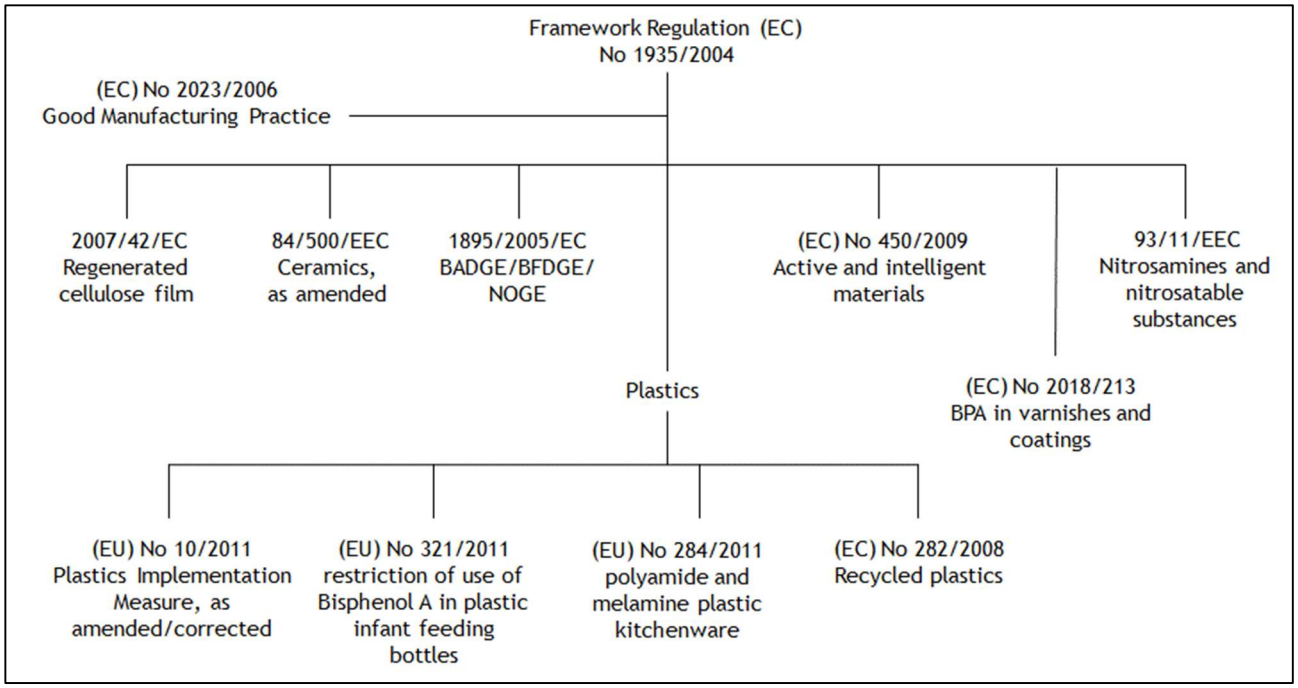
(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers."

Figure 1. EU legislation – materials and articles in contact with food



The Framework Regulation also provides for special rules on active and intelligent materials, good manufacturing practice and it empowers the Commission to develop and enforce additional measures for specific materials types (e.g. for plastics) or for specific substances (e.g. bisphenol A diglycidyl ether - BADGE).

Compliance with Article 3 (as above) requires measures (methods) to determine the safety, i.e. does the migration of any substances present in the final material or article transfer at concentrations that could endanger human health, as well as methods to determine inertness.

The range of material types used in contact with food is vast and new materials such as biobased/biodegradable/compostable are being developed at a rapid rate, and so the types of chemicals present and therefore the potential to migrate is extensive. There are several thousands of chemicals in inventory lists used by producers and of these several hundred find regular use in FCMs. To the best of our knowledge there is no comprehensive compendium of official analytical methods to be used for the analysis of foods for migrating substances. Nor indeed is there any compendium of unofficial methods. Given the huge number of different material types, substances and food types involved, this paucity of official methods for the analysis of foods for migrated food contact substances means that in many cases methods need to be developed and validated in-house prior to any enforcement campaigns being carried out. Rather than analyte specific methods attention has focussed on the standardisation of official methods for conducting migration or extraction tests using food simulants or solvents, i.e. on the process of the migration test itself. This usually involves placing the FCM in contact with a food simulant or solvent under strictly defined and controlled test conditions (as defined in the EU legislation) although foods may also be used. Food simulants are simple test media that are intended to mimic the migrating properties of the different categories of foods whilst at the same time being more straight-forward to analyse for the concentration of migrated substances. Methods to determine the inertness of a material (overall migration) have been developed in which the total mass of the migrating substances is determined and is compared to the overall migration limit. How to

conduct the migration tests is well defined in the legislation for plastic FCMs which specifies the food simulants applicable to each food type as well as the appropriate test contact conditions (time and temperature). Approaches for overall migration and specific migration of individual or groups of substances are given in Regulation (EU) No 10/2011 (EU, 2011) for plastic materials and articles. In the absence of specific measures for other material types the rules for plastics are often followed as a guide.

In addition to testing for the starting substances used to make, for example, a plastics FCM, the migration of any impurities or reaction/breakdown products formed during the manufacture of the FCM also needs to be considered. These substances are known as Non-Intentionally Added Substances or NIAS. Methods used to determine the NIAS differ between laboratories.

Differences in regulations and food testing methods have the potential to disrupt international trade and so the aim of Work Package 4 Task 4.3 is to transfer the know-how to carry out migration testing (overall migration for inertness, specific migration for known starting substances and NIAS for safety) to ensure that Chinese laboratories are able to determine compliance with EU rules. Given the large number and classes of compounds that may be used to manufacture FCM the full range of analytical methods are deployed in testing, i.e.:

- headspace gas chromatography-mass spectrometry (GC-MS) for the volatile substances;
- GC-MS for the semi-volatile substances;
- liquid chromatography (LC)-MS for the non-volatiles and the polar residues;
- inductively couple plasma-mass spectrometry (ICP-MS) for trace elements.

As mentioned above there are several approaches that can be used to test food contact materials. These include:

- Testing the food itself for undesirable chemical residues;
- Testing the FCM before it is used to ensure that it does not contain residues that could migrate at levels that could cause problems. Migration modelling can be applied too.
- Finally, uniquely for food contact materials, testing the FCM before use for its suitability in contact with food by employing food simulants that are intended to mimic the migration properties of different categories of foods. In this example standard methods and approaches are well defined with migration test methods being described as European standards.

The aim of Task 4.3 is to provide training on the migration test methods for FCMs following all of the above approaches as well as to select examples of analytical methods commonly used to demonstrate compliance with the migration limits defined in the legislation and the techniques to measure, profile and identify the NIAS. To support this and to provide context to the testing, training in the interpretation of the EU Regulations is also planned.

3. TRAINING

Task 4.3 of the project “Delivering an Effective, Resilient and Sustainable EU-China Food Safety Partnership” involves the training of staff from the China National Center for Food Safety Risk Assessment (CFSA) by secondment to FERA, the UK National Reference Laboratory for materials and articles in contact with food. Following on from the successful completion of the training, the intention is that the CFSA staff will transfer the methodologies and knowledge exchanged to colleagues in their laboratory.

Hong Kong Polytechnic University (PolyU) are also partners in Task 4.3 of Work Package 4 and although training of PolyU staff is not defined in the project outline the dissemination of information and provision of training material to this partner can only help to facilitate a more comprehensive understanding of European legislation and methodologies in that region.

3.1. TRAINING ACTIVITY

3.1.1. Plan

Training on the migration test methods for food contact materials, examples of analytical methods commonly used to demonstrate compliance with the migration limits defined in the legislation as well as techniques to measure, profile and identify the non-intentionally added substances is planned. Training in the interpretation of the EU Regulations will also be provided. Following on from the successful completion of the training, the CFSA staff will transfer the method to the China-EU laboratory.

The plan agreed with CFSA for the laboratory based training is:

1. Migration testing

- Migration test regulations in complex matrices (foods, food simulants and food contact materials and articles)
- Migration modeling (basic overview of available systems)
- Intentionally added substances (IAS) analysis technology (headspace GC-MS, GC-MS, LC-MS, GC-TOF-MS, LC-TOF-MS, ICP-MS)

2. Non-target analysis

Non-Intentionally added substances (NIAS) are known or unknown isomers, impurities, reaction products and breakdown product of these ingredients as well as possible contaminants from the manufacturing process such as recycled materials, irradiated materials or contamination from indirect food contact sources such as printing inks, external coatings, adhesives, secondary packaging. Training in the detection, identification and quantification of NIAS in a range of material types and their migration into food simulants and foodstuffs was planned.

3.1.2. Progress

An invitation letter was sent to CFSA in August 2018 and a visa application was submitted and approved.

Training was scheduled for October/November 2018 however the CFSA scientist cancelled a few weeks before due to other CFSA priorities.

The Fera science lead on FCM travelled to China in October 2019 and planned to meet with CFSA at the 2019 International Food Contact Materials Safety Symposium held in Guangdong and to visit the CFSA laboratories in Beijing following the event. The meeting at the conference took place (a copy of the presentation given at the conference and discussed with CFSA is provided in Appendix 1) however the subsequent visit to CFSA could not be accommodated at that time. Linked in with this visit the Fera science lead presented to staff and students at PolyU and to CAIQ (EU China-Safe project partners – although not directly involved in Task 4.3). Copies of the presentations given/provided to these EU China-Safe project partners are given in Appendices 2 and 3.

4. CONCLUDING REMARKS

Scientists from CFSA have not been able to travel to the UK to receive the training to date and it may not be possible for this to be arranged within the full project timeframe.

Instead we propose that a series of on-line training material is prepared for dissemination to CFSA and PolyU as well as other Chinese project partners to support knowledge development with respect to EU legislation and analytical methodologies. This approach has been proposed to the lead CFSA scientist.

5. ACKNOWLEDGEMENTS

We wish to acknowledge the contribution of all project partners who contributed to the completion of this deliverable.

6. REFERENCES

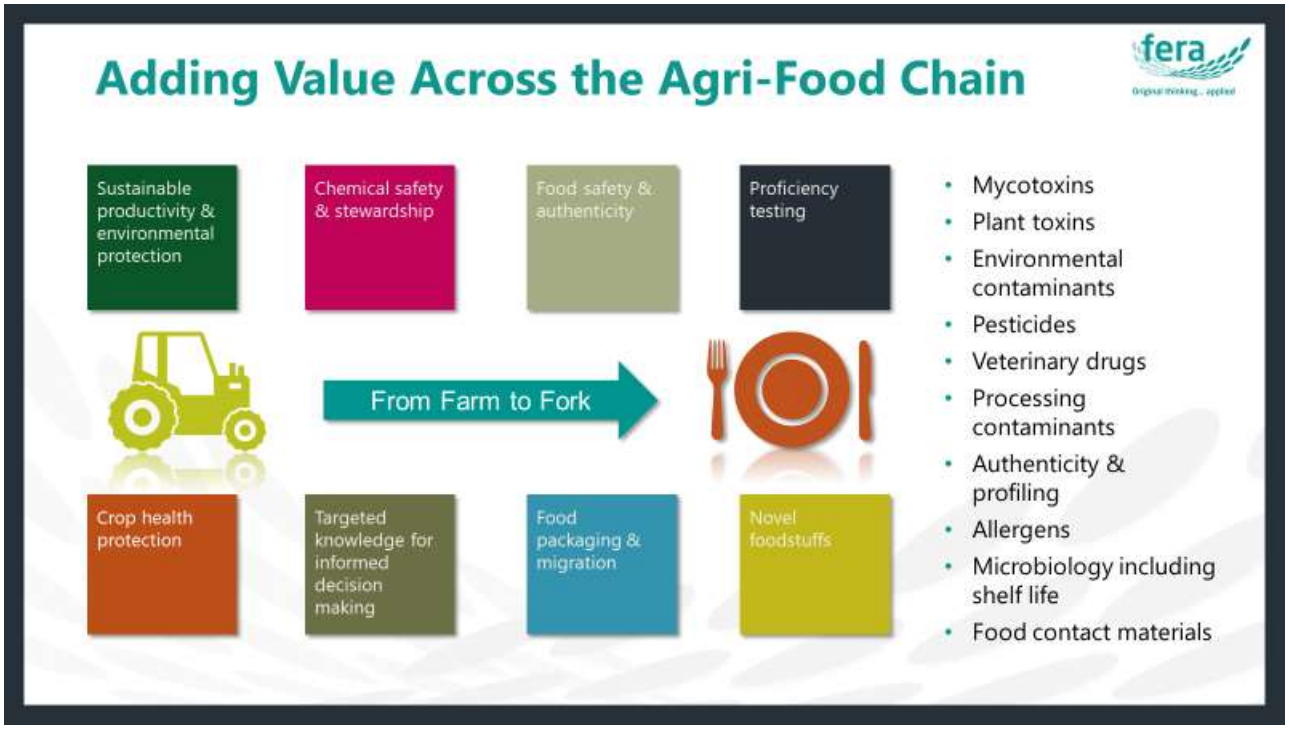
EC 2004. REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4.

EU 2011. COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.01.2011, p. 5.

7. APPENDIX

7.1. APPENDIX 1

2019 Food contact materials safety symposium presentation


Adding Value Across the Agri-Food Chain
fera
Sustainable productivity & environmental protection
Chemical safety & stewardship
Food safety & authenticity
Proficiency testing
From Farm to Fork
Crop health protection
Targeted knowledge for informed decision making
Food packaging & migration
Novel foodstuffs
Mycotoxins
Plant toxins
Environmental contaminants
Pesticides
Veterinary drugs
Processing contaminants
Authenticity & profiling
Allergens
Microbiology including shelf life
Food contact materials


fera
Food Contact Materials at Fera
Safety
Overall migration
Specific migration
Non-intentionally added substances (NIAS)
Shelf life
Food waste
Active packaging
Fraud
Reyclable and/or compostable and/or biodegradable?
Food contact materials at Fera
Standards and quality
fapas
cen
bsi.
Information systems
HorizonScan
Food Safety at your fingertips
Early warning systems – supply chain controls
UK National Reference Laboratory
Supporting the EURL, FSA, OCL's
EFSA
Working group on Bisphenol A
Provision of data to support EFSA evaluations
European Commission
Technical guidance
Evaluation of the Framework Regulation
State-of-the-Art facilities: The Thomson Suite

Why package food?

How Much Packaging is there?
Altogether around 10.8 million tonnes of packaging is used in the UK each year. Of that around 4.9 million tonnes ends up either in household bins or being recycled. Of the total packaging that we use within our homes most is used to protect our food and drink. Currently 8.3 million tonnes of food and drink is wasted by UK households each year.

www.wrap.org.uk/sites/files/wrap/why_do_we_need_A5_v6.48bc5cfd.10710.pdf

- Packaging is beneficial
  - Transportation
  - Provides essential information to the customer
    - Contents & ingredients
    - Health & safety - allergens
    - Storage & serving advice
  - Attracts the customer
    - Colour, surface effects, printing and branding
- Protects the packaged foodstuff
  - Increases shelf life of perishable foods
  - Reduces food waste – population growth

Consumers are not scientists

1955

https://time.com/3879873/throwaway-living-when-tossing-it-all-was-all-the-rage/

2019

Material options

Conventional plastics
high performance, well characterised, low cost, but....

Biobased plastics – high performance and renewables

Biobased and compostable – readily renewable and designed for organic recycling after use

Fossil derived and compostable – meet compostability standards

Table 1: Comparison of Industrial and Home Compostability

	Industrial Composting: BS EN 13432	Home Composting: Vinçotte Certification Programme
Biodegradation	Test performed at 58 °C +/- 2 °C, carbon dioxide at least 90 % compared with control within 6 months (approx 182 days)	Test performed at ambient temperature (20 - 30 °C), carbon dioxide at least 90 % compared with control within 365 days
Disintegration	Test performed at whatever temperatures are achieved in vessels, each at least 140 litre capacity. At maximum of 12 weeks (approx 84 days) no more than 10 % of original dry weight of test material > 2 mm.	Test performed at 20 - 30 °C in vessels each at least 140 litre capacity. At maximum of 26 weeks (182 days) no more than 10 % of original dry weight of test material > 2 mm
Current certification and logos	AFOR / DIN Certco	Vinçotte

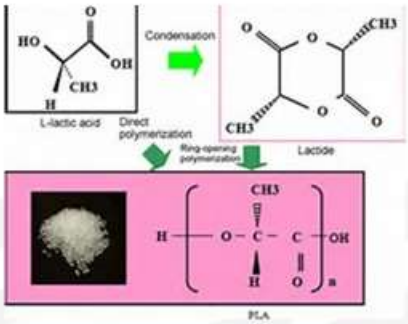
Source: https://www.bpf.co.uk/topics/standards_for_compostability.aspx

Examples – renewable biobased monomers

Produced by chemical synthesis using renewable bio-based monomers often obtained by microbial fermentation e.g. bioPET, polylactic acid (PLA)

Examples include: terephthalic acid, succinic acid, butanediol, adipic acid, various amino acids, acetic acid, acetone, 2,3-butanediol, butyric acid, isopropanol, propionic acid, lactic acid, ethanol and a range of fatty acids.

- Substitutes for existing fossil carbon-based plastics ('drop-ins')
- Not all are biodegradable or compostable
- Similar food contact and migration issues to fossil-based plastics
- Compatible with existing practices but enables a 'green' claim

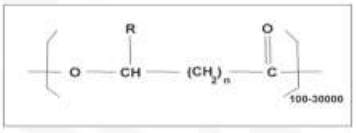


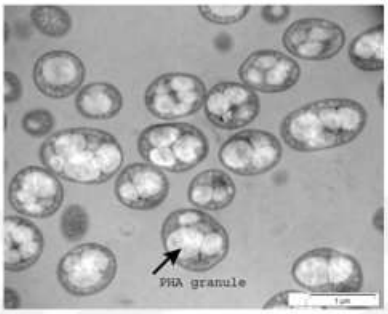
Examples – bacterial fermentation products

Synthesised by microorganisms including bacterial fermentation of sugars or lipids

Examples include:

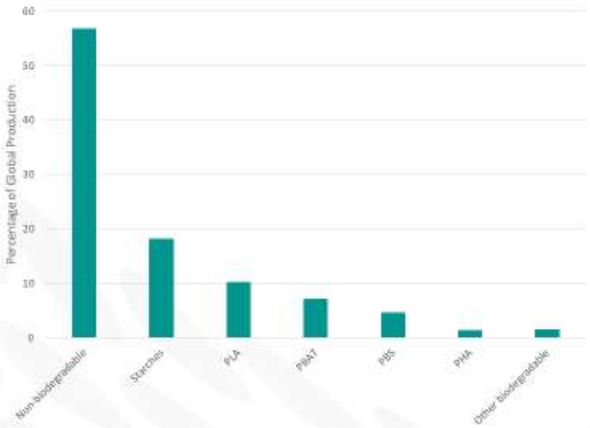
- Polyhydroxyalkanoates (PHA)
- Poly-3-hydroxybutyrate (P3HB)
- Poly-3-hydroxyvalerate (PHV)





PHA inclusion in Pseudomonas putida CA-3
Ward, P.G. de Roo, G. & O'Connor, K.E. (2005)
DOI: 10.1128/AEM.71.4.2046-2052.2005

Biobased FCMs in commercial use



Polylactic acid (PLA), polybutylene adipate terephthalate (PBAT), polybutylene succinate (PBS), polyhydroxyalkanoate (PHA).
Source: Nova Institute, 2019

Global bioplastic production 2018 = 2.112 million tonnes (biodegradable and non-biodegradable)

Projected increase by 1.288 million tonnes by 2023 (+41.2% growth)

Biodegradable materials – 0.912 million tonnes

Food Packaging applications – 0.516 million tonnes

Increase in polylactic acid (PLA) usage by 2023 >60%

Examples – plant based

Alginate from seaweeds

Just Eat trials seaweed-based sauce sachets as part of sustainability plan

by Lianne Taylor

955 Print

Just Eat, a marketplace for UK takeaways, has launched a trial of seaweed-based packaging for sachets of sauce as part of its sustainability strategy.

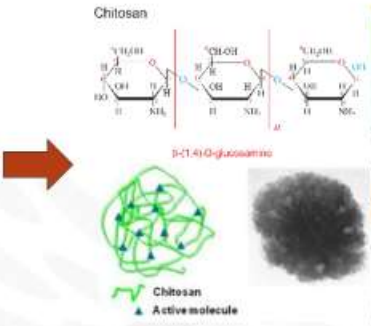
The six-week trial, in partnership with London-based packaging start-up, Skipping Rocks Lab, will see an alginate-based material, known as 'Ooho!' used for sachets of ketchup and garlic sauce.

They are said to open just like normal sachets and can be thrown into either home composting or domestic waste bins, to fully decompose in "a matter of weeks".

The sachets are being trialled in *The Fat Pizza*, a Just Eat partner restaurant in Southend, with a view to them being rolled out more broadly across the country.

Examples – chitin/chitosan

- Traditionally derived from processing crustacean by-products
- Sources also include mushroom waste and insects
- **Biodegradable, non-toxic, non-allergenic**



- Potential new insect sources such as black soldier fly (*Hermetia illucens*) are also a source of protein and oils

Examples – chitin/chitosan

- Traditionally d
- Sources also i
- Biodegradabl

New experimental packaging made out of waste langoustine shells shown to The Prince of Wales today as he opened the Waitrose & Partners Food Innovation Studio

https://waitrose.pressarea.com/pressrelease/details/78/NEWS_13/10946

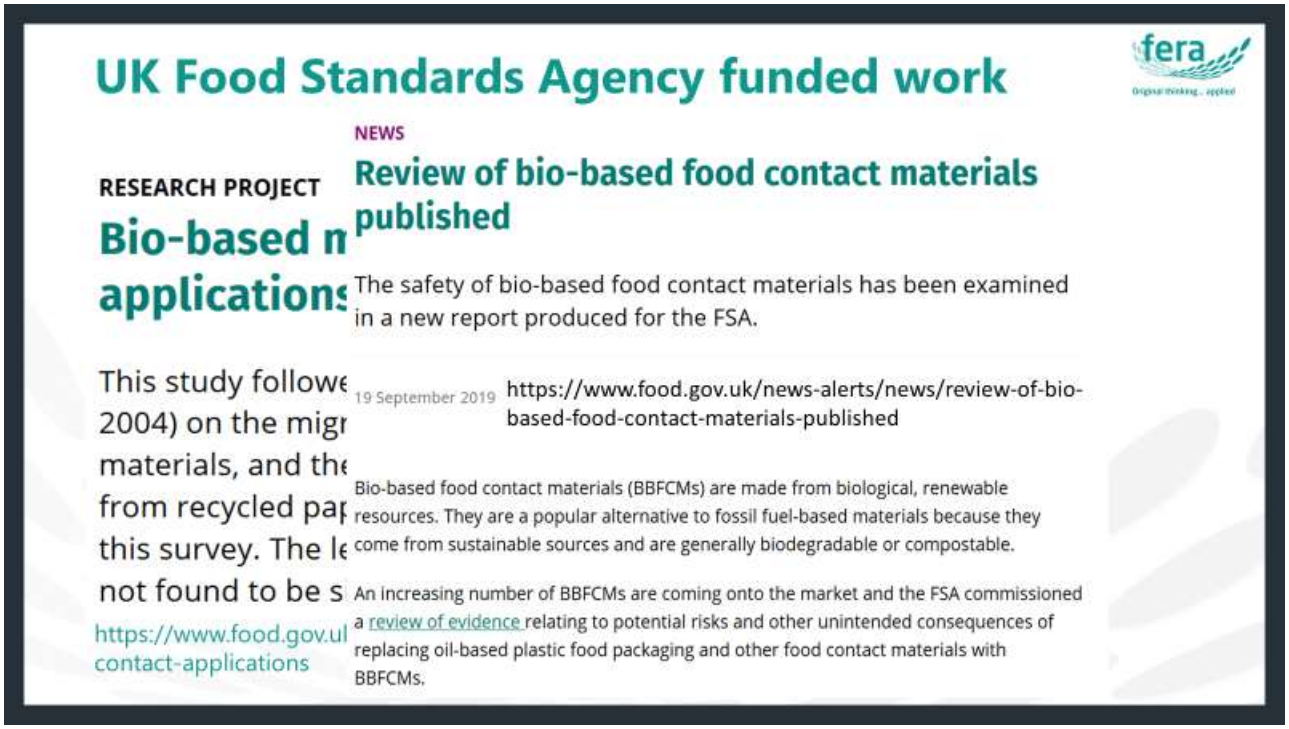
UK Food Standards Agency funded work

RESEARCH PROJECT

Bio-based materials used in food contact applications

This study followed on from an earlier one (A03040, published in 2004) on the migration potential from biodegradable food contact materials, and the findings of Agency-funded study on migration from recycled paper and board, A03021, (2005) were excluded from this survey. The levels of migration from bio based materials was not found to be significant.

https://www.food.gov.uk/research/research-projects/bio-based-materials-used-in-food-contact-applications


UK Food Standards Agency funded work
fera
RESEARCH PROJECT
Bio-based n
applications
This study followe
2004) on the migr
materials, and the
from recycled pap
this survey. The le
not found to be s
https://www.food.gov.ul
contact-applications
NEWS
Review of bio-based food contact materials published
The safety of bio-based food contact materials has been examined in a new report produced for the FSA.
19 September 2019
https://www.food.gov.uk/news-alerts/news/review-of-bio-based-food-contact-materials-published
Bio-based food contact materials (BBFCMs) are made from biological, renewable resources. They are a popular alternative to fossil fuel-based materials because they come from sustainable sources and are generally biodegradable or compostable.
An increasing number of BBFCMs are coming onto the market and the FSA commissioned a review of evidence relating to potential risks and other unintended consequences of replacing oil-based plastic food packaging and other food contact materials with BBFCMs.


Literature review
fera
Biobased FCMs publications 2013-February 2019
• 1267 Publications in peer reviewed literature
• 89 Grey literature publications
(excluding paper and board)
Search terms included:
Allergens, Bio-based, Bioplastic, Biopolymer, Contaminants, Food Contact Materials, Non-fossil fuel, Renewable, Packaging, Plant-based, Regulation, Risk, Safety, Toxicity
The bulk of recent published research addresses the development of composite materials, frequently employing both hard and soft or natural nanomaterials

Chemical residues and contaminants

Pesticides

- Food crops treated with pesticides frequently exhibit residues and subsequent processing may decrease or increase their concentrations, could the pesticides persist in any FCMs produced?

Natural toxins

- Toxins that occur naturally in food or feed and include mycotoxins (fungal toxins), phytotoxins (plant toxins) and algal toxins, could they persist in any FCMs produced?

Processing contaminants

- Could processing contaminants be formed during the manufacture of the FCM? Examples of process contaminants that are formed in foods often due to heat or other treatments include acrylamide, 3-monochloropropanediol, glycidyl esters, furan, PAHs and ethyl carbamate.

Findings from the literature review: No data reported to confirm whether or not biobased FCMs pose a risk of exposure to chemical residues and contaminants.

Chemical residues and contaminants

Environmental contaminants

- Could the materials contain persistent environmental contaminants such as dioxins and PCBs? If so could they persist in any FCMs produced?

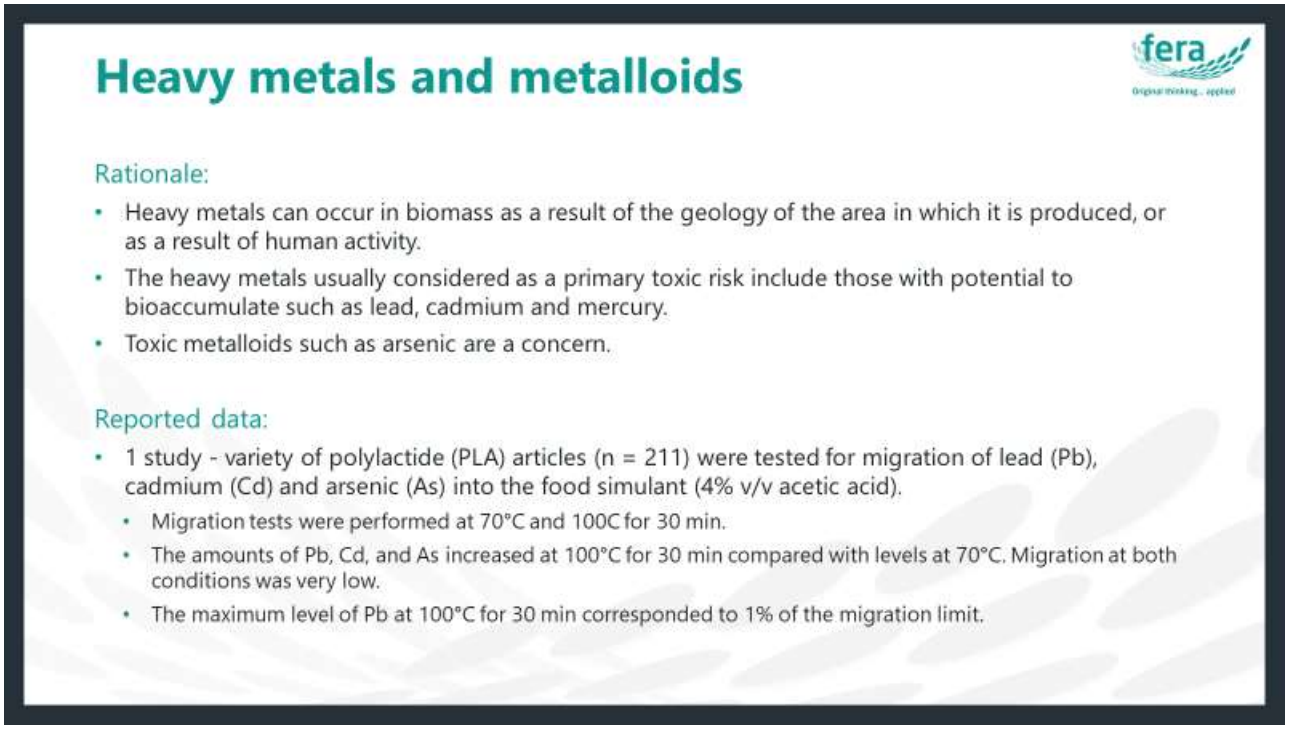
Genetically modified

- Could genetically modified materials be present in the biomass used for the production of biobased FCMs?

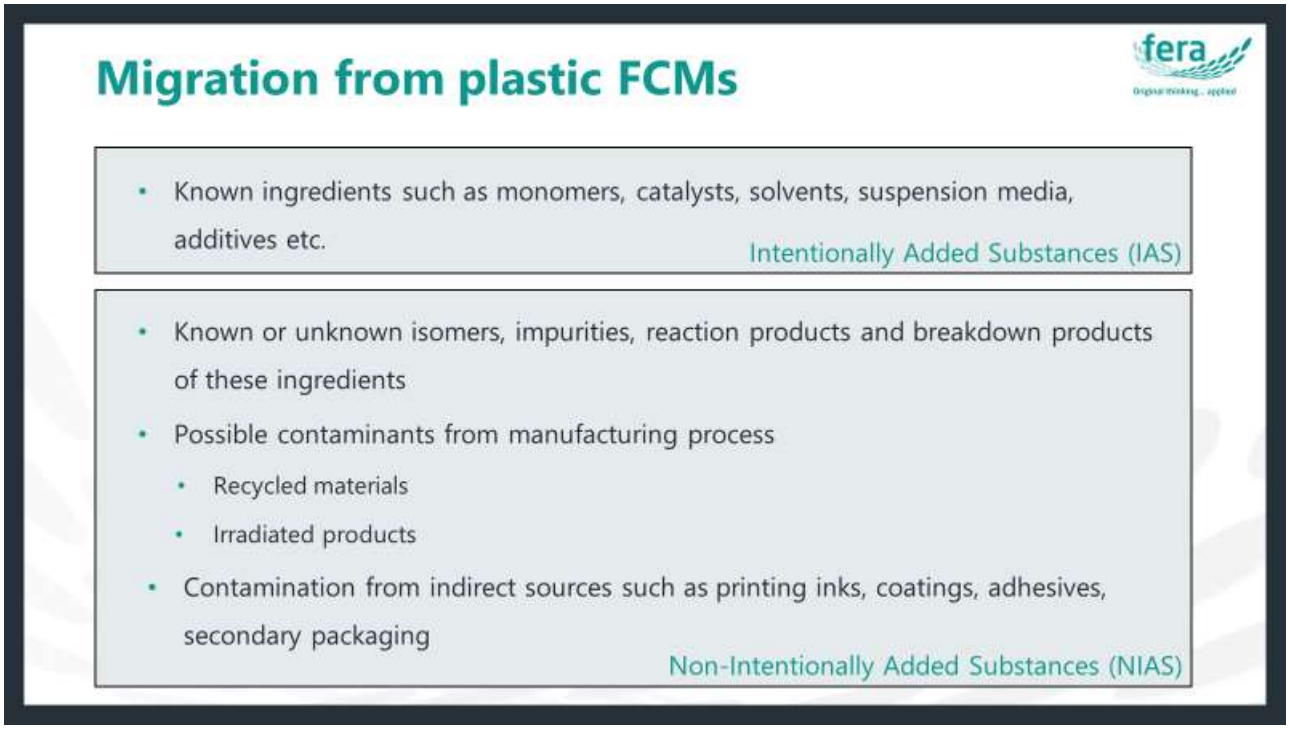
Veterinary medicines

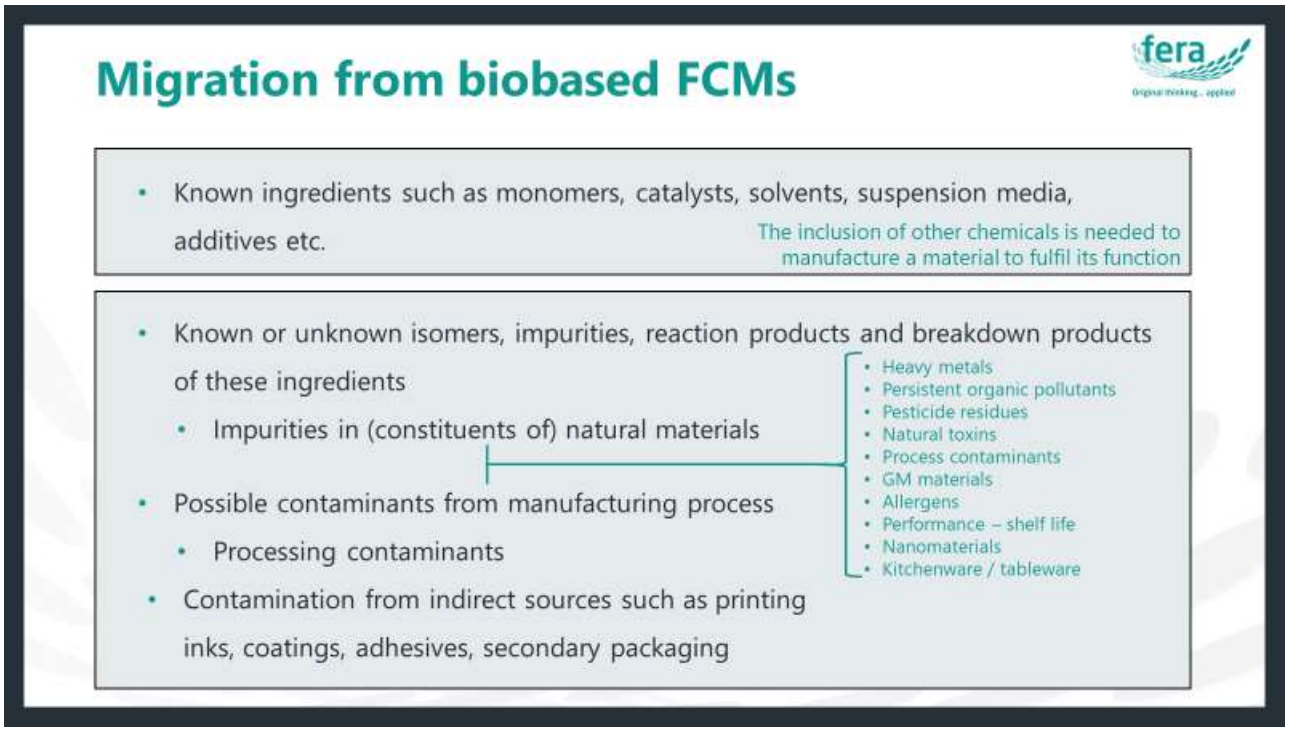
- Could residues of any veterinary medicines result in the presence of the parent compounds or their metabolites in tissues which are subsequently used in the FCM (e.g. crustaceans)?

Findings from the literature review: No data reported to confirm whether or not biobased FCMs pose a risk of exposure to chemical residues and contaminants.


Heavy metals and metalloids
fera
Rationale:
• Heavy metals can occur in biomass as a result of the geology of the area in which it is produced, or as a result of human activity.
• The heavy metals usually considered as a primary toxic risk include those with potential to bioaccumulate such as lead, cadmium and mercury.
• Toxic metalloids such as arsenic are a concern.
Reported data:
• 1 study - variety of polylactide (PLA) articles (n = 211) were tested for migration of lead (Pb), cadmium (Cd) and arsenic (As) into the food simulant (4% v/v acetic acid).
• Migration tests were performed at 70°C and 100C for 30 min.
• The amounts of Pb, Cd, and As increased at 100°C for 30 min compared with levels at 70°C. Migration at both conditions was very low.
• The maximum level of Pb at 100°C for 30 min corresponded to 1% of the migration limit.

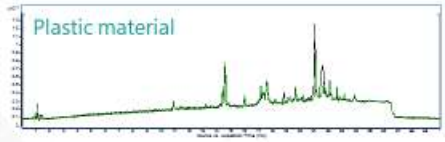

fera
Do any residues and contaminants migrate?


Migration from plastic FCMs
fera
Original thinking... applied
Known ingredients such as monomers, catalysts, solvents, suspension media, additives etc.
Intentionally Added Substances (IAS)
Known or unknown isomers, impurities, reaction products and breakdown products of these ingredients
Possible contaminants from manufacturing process
Recycled materials
Irradiated products
Contamination from indirect sources such as printing inks, coatings, adhesives, secondary packaging
Non-Intentionally Added Substances (NIAS)

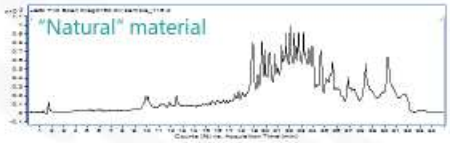

Migration from biobased FCMs
fera
Original thinking... applied
Known ingredients such as monomers, catalysts, solvents, suspension media, additives etc.
The inclusion of other chemicals is needed to manufacture a material to fulfil its function
Known or unknown isomers, impurities, reaction products and breakdown products of these ingredients
Impurities in (constituents of) natural materials
Heavy metals
Persistent organic pollutants
Pesticide residues
Natural toxins
Process contaminants
GM materials
Allergens
Performance – shelf life
Nanomaterials
Kitchenware / tableware
Possible contaminants from manufacturing process
Processing contaminants
Contamination from indirect sources such as printing inks, coatings, adhesives, secondary packaging

Plastics versus "natural" materials

- Intentionally added substances (IAS) - targeted
- Non-intentionally added substances (NIAS) – non-targeted



60 MFs



250 MFs

Databases of natural products are needed

Analytical approaches – what is present?

Specific extraction Clean-up Specific analysis		Generic extraction Minimal clean-up Generic analysis
Targeted	⟷	Non-targeted
IAS – Know exactly what to measure	Predictable NIAS – oligomers, impurities, literature references	NIAS – Complete unknowns

Mass spectrometry:
- 19 Triple-Quad LCMS
- 14 GCMS
- 3 Time of Flight (TOF) LCMS
- 2 High Resolution Orbitrap LCMS
- 3 High Resolution GCMS
- 2 Ion Ratio MS
- 3 Inductively Coupled Plasma MS

NMR capability:
- 2 500MHz, one equipped with a cryo-probe

Risk assessment – non-harmonised materials

- There is a lack of common guidelines and transparency in undertaking risk assessment work across Member States
- National measures can be difficult to access and are not always consistently structured or sufficiently detailed
- Measures are based on lists of authorised substances (with a total of close to 8,000)
- Testing methods are lacking for enforcement and compliance

Some biobased materials classed as non-harmonised

Framework Regulation

Article 3

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- endanger human health;
- bring about an unacceptable change in the composition of the food;
- bring about a deterioration in the organoleptic characteristics thereof

Methods to determine the safety of plastics food contact materials are expected to be applicable to biobased FCMs

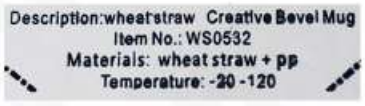
Other risks?

Allergens?

- The animal or plant origin of some biobased materials suggests there is an intrinsic risk of allergenicity
- Some of the proteins used to produce packaging materials and coatings are known food allergens (e.g. milk and egg proteins, soya, corn, gluten, crustaceans)
- Polymers directly extracted from biomass may be contaminated with allergenic proteins if purification is incomplete
- The physical, chemical and enzymatic treatments to produce packaging may induce denaturation, cross-linking and other chemical modifications that may alter the allergenic properties of the natural protein

Findings from the literature review: No data to confirm whether or not biobased FCMs pose an allergenic risk to consumers.

Claims?



- "Natural", "sustainable" or just a filler in a melamine-formaldehyde resin?
- Migration, e.g.

12/08/2019	Poland	migration of formaldehyde (60.5 mg/kg - ppm) from bamboo coffee mug from China, via Germany and via Slovakia	withdrawal from the market
06/09/2019	Lithuania	too high level of overall migration (31.7 mg/dm²) from bamboo dishes from France	destruction
10/09/2019	Norway	migration of melamine (3.33 mg/kg - ppm) from bamboo cups from China	recall from consumers

- Plastics?

RASFF and HorizonScan

Year	Number of alerts on migration from melamine ware
2018 to date	64 *

* Includes 34 bamboo containing products

Literature review – risks

- Limited research has been undertaken into the food safety risks associated with biobased FCMs
  - Information on the presence of inorganic contaminants such as heavy metals, persistent organic pollutants, natural toxins, pesticide residues, processing contaminants in biobased FCMs, and their capacity to transfer from the packaging into food, is required
- The risk of polypeptide-based materials that are known or suspected allergens or are extracted from matrices that contain allergens and used in biobased FCMs are not known
  - Impact of processing on the allergenic epitopes

Significant gaps in current knowledge relating to biobased FCMs

https://www.food.gov.uk/research/strategic-evidence-programme/bio-based-materials-for-use-in-food-contact-applications

Literature review – recommendations

- Determine the potential residues and contaminants in the biobased FCMs
- Confirm that analytical methods and risk assessment processes for establishing contaminant chemical transfer from fossil-based plastics to food are appropriate or adaptable for biobased FCMs
  - Use *in vitro* toxicology methods as a useful adjunct to traditional chemical analytical methods to establish safety?
- Scope for further method development e.g. HR-MS of allergen epitopes

https://www.food.gov.uk/research/strategic-evidence-programme/bio-based-materials-for-use-in-food-contact-applications

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Original thinking... applied

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7.2. APPENDIX 2

POLYU presentation

Fera Science Ltd

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Fera Science Ltd

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Original thinking... applied

Aim: to support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks

- A UK science business at the National Agri-Food Innovation campus, York
- Scientific heritage of over 100 years
- More than 350 scientists & technical specialists working across the agri-food supply chain

CAPITA

Department for Environment, Food & Rural Affairs

Institute for Plant Pathology, 1914

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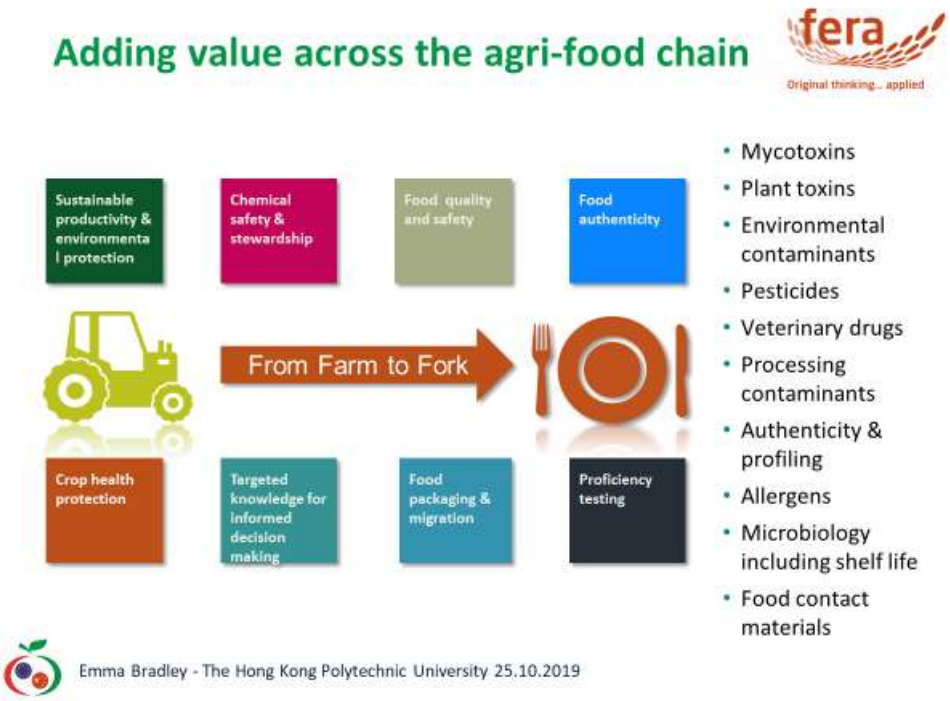
Adding value across the agri-food chain
fera
Original thinking... applied
Sustainable productivity & environmental protection
Chemical safety & stewardship
Food quality and safety
Food authenticity
From Farm to Fork
Crop health protection
Targeted knowledge for informed decision making
Food packaging & migration
Proficiency testing
Mycotoxins
Plant toxins
Environmental contaminants
Pesticides
Veterinary drugs
Processing contaminants
Authenticity & profiling
Allergens
Microbiology including shelf life
Food contact materials
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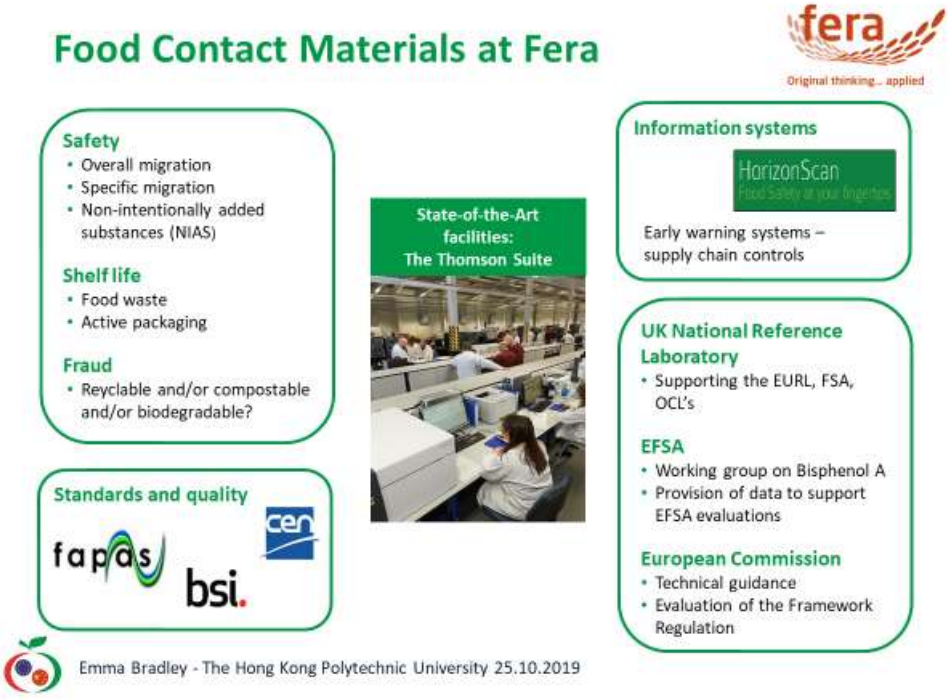
Food Contact Materials at Fera
fera
Original thinking... applied
Safety
Overall migration
Specific migration
Non-intentionally added substances (NIAS)
Shelf life
Food waste
Active packaging
Fraud
Reyclable and/or compostable and/or biodegradable?
Standards and quality
fapas
bsi.
cen
State-of-the-Art facilities:
The Thomson Suite
Information systems
HorizonScan
Early warning systems – supply chain controls
UK National Reference Laboratory
Supporting the EURL, FSA, OCL's
EFSA
Working group on Bisphenol A
Provision of data to support EFSA evaluations
European Commission
Technical guidance
Evaluation of the Framework Regulation
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EU China-Safe

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EU China-Safe – why?

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Original thinking... applied

In Europe and China, consumer trust in the food industry and regulatory authorities has been damaged by a large number of accidental and deliberate food contamination and adulteration incidents

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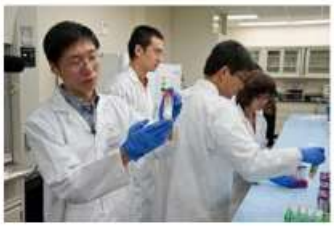
EU China-Safe

Laboratories in Europe and China are often working to different quality standards and using different analytical methods for producing for certification, which can result in protracted trade disputes



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EU China-Safe – what?

The project aims to develop & implement a shared vision of best practice between the EU & China

The key goals are to:

- Enhance food safety,
- Deter food fraud,
- Restore consumer trust,
- Deliver mutual recognition of data and standards and
- Support agri-food trade between the two trading blocks to promote economic growth

How?

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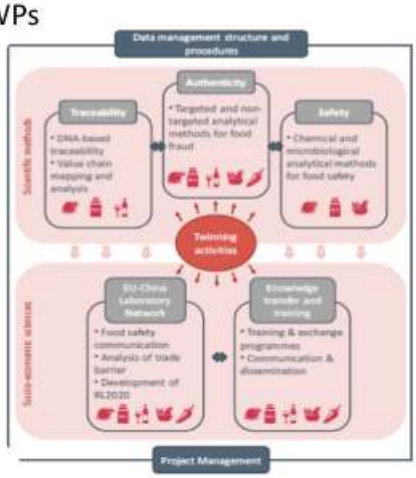
EU China-Safe work packages

Five Work Packages (WPs) supported by Data and Project Management WPs



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EU China-Safe WP4

Implementation of innovations in food safety

Nitrites and chlorate in milk and dairy powders……

Veterinary drug and feed additive residues in foods of animal origin …….

Food contact materials…….

Multi-analyte screening method for pesticide residues in fruits and vegetables, tea and fruit juices……

Tracking major microbiological food safety risks across infant formula supply chain……

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Migration from and safety of food contact materials

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What are food contact materials

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Original thinking... applied

Food comes into contact with many materials and articles during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles are called **Food Contact Materials (FCMs)**. Food contact materials are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use. **This includes direct or indirect contact.** Examples include:

- containers for transporting food
- machinery to process food
- packaging materials
- kitchenware and tableware

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

The term **does not cover fixed public or private water supply equipment.**

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1955

https://time.com/3879873/throwaway-living-when-tossing-it-all-was-all-the-rage/

2019

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Why package food?

How Much Packaging is there?
Altogether around 10.8 million tonnes of packaging is used in the UK each year. Of that around 4.9 million tonnes ends up either in household bins or being recycled. Of the total packaging that we use within our homes most is used to protect our food and drink. Currently 8.3 million tonnes of food and drink is wasted by UK households each year.

www.wrap.org.uk/sites/files/wrap/why_do_we_need_A5_v6.48bc5cfd.10710.pdf

- Packaging is beneficial
  - Transportation
- Provides essential information
  - Contents & ingredients
  - Health & safety - allergens
  - Storage & serving advice
- Attracts the customer
  - Colour, surface effects, printing and branding
- Protects the packaged foodstuff
  - Increases shelf life of perishable foods
  - Reduces food waste – population growth

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What is migration?

- The mass transfer from an external source into food by sub-microscopic processes
- May impact food in two ways
  - Food safety – migration of harmful substances
  - Food quality – migration of substances which impart taint or odour
- Migration occurs from
  - Food packaging
  - Materials and articles used in food manufacture, transport and storage
  - Materials and articles used in food preparation and consumption

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Factors affecting migration

- Migration is a diffusion and partitioning process that is dependent on:
  - The nature of the food contact material
  - The nature and concentration of the migrating substance
  - The nature of the foodstuff
  - The nature, extent and type of contact between the food contact material/article and the foodstuff
  - The temperature of the contact
  - The duration of the contact

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European legislation

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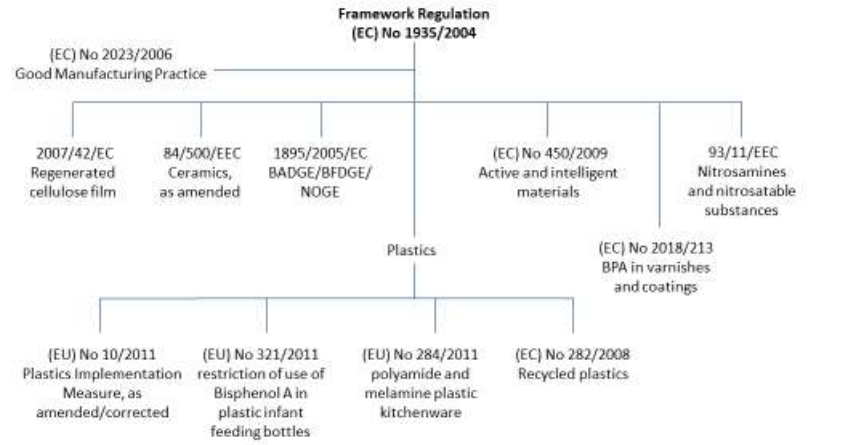
EU legislation



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Framework Regulation

- Article 3

  Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

  - endanger human health;
  - bring about an unacceptable change in the composition of the food;
  - bring about a deterioration in the organoleptic characteristics thereof

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Framework Regulation

- The Framework also provides
  - For special rules on active and intelligent materials (they are by their design not inert)
  - Powers to enact additional EU measures for specific materials (e.g. for plastics)
  - The procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority (EFSA)
  - Rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol
  - For compliance documentation and traceability

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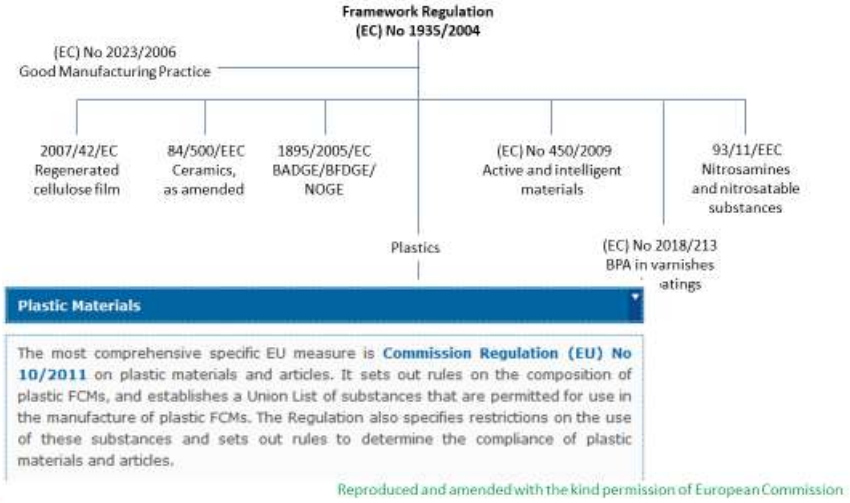
EU legislation - plastics



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What rules does the Regulation set?

- Union List of authorised monomers and additives for use in the manufacture of plastics
- Specific migration limits
  - Related to food
  - Based on toxicity
  - Assumption on exposure - 1 person of 60 kg ingests daily 1 kg of food in contact with 6 dm^2 of surface containing the substance at the maximum concentration permitted (SML)
- Overall migration limit
  - Expressed per food contact surface area = 10 mg/dm^2
  - For infant foods, expressed per kg/food = 60 mg/kg
- Rules on non-intentionally added substances (NIAS)
- Rules to test for compliance

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Migration testing

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Migration testing strategies

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Original thinking... applied

- Rules defined to test for compliance of migration from food contact materials and articles
- Regulation (EU) No 10/2011 states:
  - *"Official control should establish testing strategies which allow the enforcement authorities to perform controls efficiently making best use of available resources. Therefore it should be admissible to use screening methods for checking compliance under certain conditions. Non-compliance of a material or article should be confirmed by a verification method."*
  - Solvent extraction – easier to analyse
- Migration into food simulants
  - Select simulant based on food type
  - Select exposure type
  - Select exposure conditions
- Migration into food prevails

Food simulant
Simulant A - Ethanol 10% (v/v)
Simulant B - Acetic acid 3% (w/v)
Simulant C - Ethanol 20% (v/v)
Simulant D1 - Ethanol 50% (v/v)
Simulant D2 - Any vegetable oil containing less than 1% unsaponifiable matter
Simulant E - Poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm (Tenax)

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Examples

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Melamine-formaldehyde

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Original thinking... applied

- Sources in food contact materials and articles
  - Resins used to make picnic-ware and children's articles
  - Can coatings cross-linked with melamine-based resins
  - Used in paper making and adhesives
- Discovery
  - UK Food Standards Agency funded survey carried out by Fera

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Melamine-formaldehyde

- Exposure

- Test conditions – cups/bowls/plates
  - Intended to mimic worst foreseeable use – hot fill, all food types, depends on article type, repeat use
  - Polymer type and analyte solubility – 3% (w/v) acetic acid = worst case
  - "Hot fill" means the filling of any article with a food with a temperature not exceeding 100°C at the moment of filling, after which the food cools down to 50°C or below within 60 minutes, or to 30°C or below within 150 minutes – test conditions set at 2 hours at 70 °C

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UK surveillance

Simulant

Apple juice

Water

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Primary aromatic amines

- Sources in food contact materials and articles
  - Hydrolysis of isocyanates used in adhesives – if not allowed to cure correctly
  - Curing agents in epoxy based can coatings
  - Impurities in azo-dyes
- Discovery
  - 2004 - the black colour, suspected to be an azo-colour, led the Norwegian authorities to test black kitchen utensils made of polyamide (nylon)

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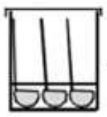
Primary aromatic amines

- Exposure



- Test conditions
  - Intended to mimic worst foreseeable use – hot foods, all food types, short term contact, repeat use
  - Polymer type and analyte solubility – 3% (w/v) acetic acid = worst case
  - Contact time – up to 30 minutes
  - Contact temperature > 100°C
  - Exposure conditions – 2 hours at 100°C

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UK surveillance

Original thinking... applied

Food Standards Agency food.gov.uk

FOOD SURVEY
INFORMATION SHEET

NUMBER 01/10 August 2010

A 4-YEAR ROLLING PROGRAMME OF SURVEYS ON CHEMICAL MIGRANTS FROM FOOD CONTACT MATERIALS AND ARTICLES, SURVEY 2: PRIMARY AROMATIC AMINE MIGRATION FROM NYLON KITCHEN UTENSILS

Summary

- This is the second of a 4-year rolling series of surveys on the chemical migration of substances from food contact materials and articles.
- In recent years, via the *Rapid Alert System for Food and Feed* (RASFF), many notifications have been issued for high migration of primary aromatic amines (PAAs) from nylon kitchen utensils imported from the Far East. This survey was commissioned to ascertain whether the UK market is now free from such non-compliant products.

Migration was detected in 35 of the 107 samples tested at levels above the limit of detection specified in the legislation.

	Total PAA migration (µg/dm²) MU = ±44%				Aniline migration (µg/dm²) MU = ±44%				4,4'-MDA migration (µg/dm²) MU = ±44%			
	A	B	C	Average	A	B	C	Average	A	B	C	Average
PAA_70 – analysis 1	652	508	538	566	< LOD	< LOD	< LOD	< LOD	897	634	537	690
PAA_70 – analysis 2	762	541	498	600	< LOD	< LOD	< LOD	< LOD	876	625	547	683

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Legislation and guidance

Original thinking... applied

23.3.2011 EN Official Journal of the European Union L 77/25

COMMISSION REGULATION (EU) No 284/2011

of 22 March 2011

laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 (1), and in particular Article 48(1) thereof,

Whereas:

(1) Commission Directive 2002/72/EC (2) lays down specific provisions relating to plastic materials and articles intended to come into contact with foodstuffs, including compositional requirements, and restrictions and specifications for substances that may be used therein.

(2) Several notifications and alerts have been received by the Rapid Alert System for Food and Feed pursuant to Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council (3) concerning food contact materials imported into the Union from the People's Republic of China (hereinafter 'China') and Hong Kong Special Administrative Region of the People's Republic of China (hereinafter 'Hong Kong'), releasing into food or food simulant amounts of chemicals that are not in compliance with the Union legislation.

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Legislation and guidance

http://publications.jrc.ec.europa.eu/repository/bitstream/JRC64903/lbna24815enc.pdf

EU guidelines on conditions and procedures for the import of polyamide and melamine kitchenware originating in or consigned from People's Republic of China and Hong Kong Special Administrative Region, China

https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_legis_china_guidelines_import-polymide-melamine.pdftreb

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Rapid alerts

- Issued by the European Commission through the Rapid Alert System for Food and Feed (RASFF)

Year	Number of alerts on migration from nylon utensils	Number of alerts on migration from melamine ware
2018 to date	43	64 *

* includes 36 from bamboo containing products

- Under control?

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Non-intentionally added substances (NIAS)

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What can migrate

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Original thinking... applied

- Known ingredients such as monomers, catalysts, solvents, suspension media, additives etc.

IAS

- Known or unknown isomers, impurities, reaction products and breakdown products of these ingredients
- Possible contaminants from manufacturing process
  - Recycled materials
  - Irradiated products
- Contamination from indirect sources such as printing inks, coatings, adhesives, secondary packaging

NIAS

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Early examples of NIAS reported

- Isomers and impurities of the known ingredients
  - Ethylbenzene in styrene
  - Di-(2-ethylhexyl) maleate in di-(2-ethylhexyl) sulfosuccinate
- Reaction products and breakdown products of these ingredients
  - Semicarbazide in gaskets - proposed to arise from the azodicarbonamide blowing agent used
  - BADGE derivatives in can coatings
- Impurities, especially from recycling
  - Substances in recycled paper and board

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EU legislation on NIAS

- Framework Regulation EC 1935/2004 Article 3 and Plastics Regulation EU 10/2011 Article 19
  - FCM manufacturers are obliged to ensure the safety of their products
  - Safety of NIAS must be assessed
- Presently, there are no levels of migration or exposure set for which compliance with this requirement can be demonstrated
- Regulation (EU) No 10/2011 states unauthorised substances may be used in FCM plastics, provided they do not migrate at levels above 10 µg/kg food, and this is often used for NIAS

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Non-targeted analysis for NIAS

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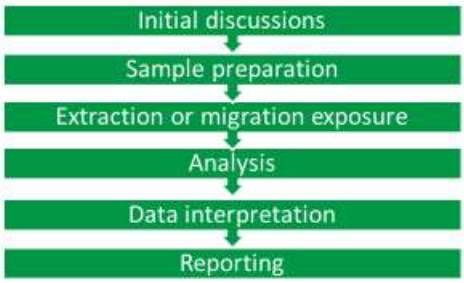
Protocols to follow….

- Presently no prescriptive guidelines on how to assess the safety of NIAS
  - ILSI Monograph - Guidance on best practices on the risk assessment of NIAS in Food Contact Materials and Articles (July 2015)
- What approach should be taken?



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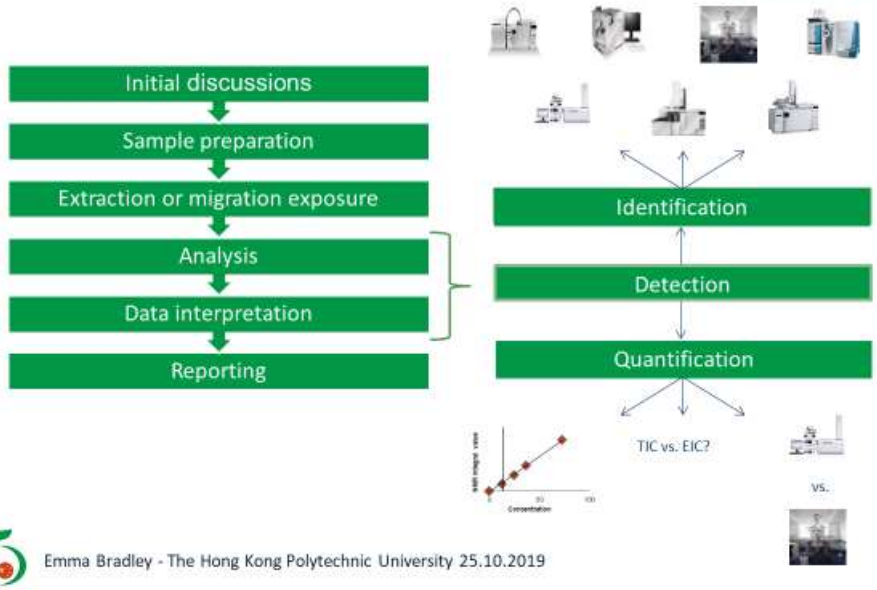
Analysis and data interpretation



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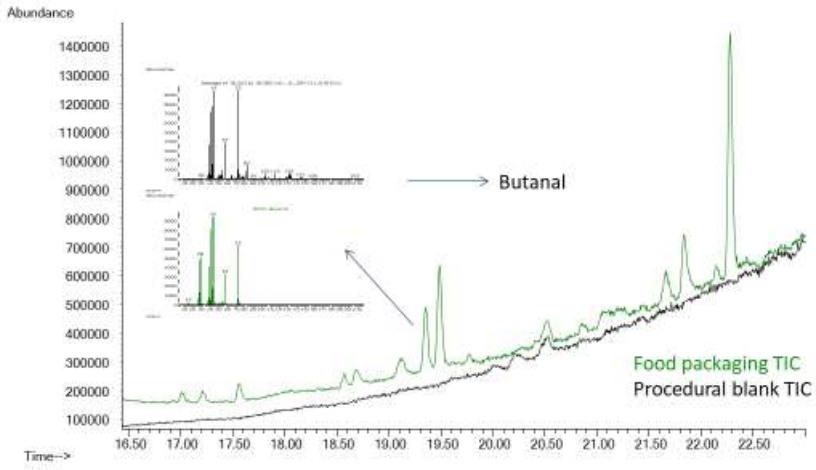
Headspace GC-MS



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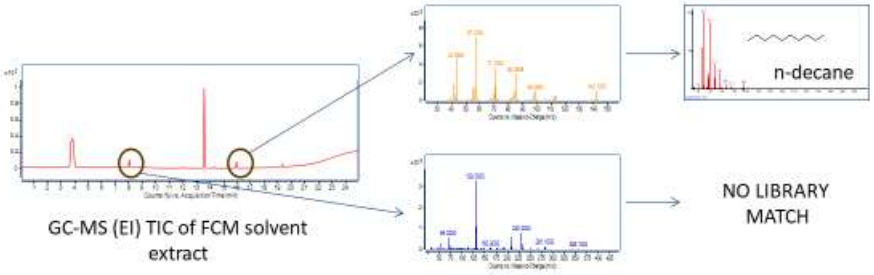
GC-MS

- Volatile and semi-volatile NIAS - GC-MS
- Identification can be carried out by comparison to electron impact (EI) MS libraries
  - Libraries contain many 10,000's of substances but often still unknown NIAS with no library match



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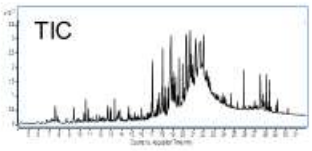
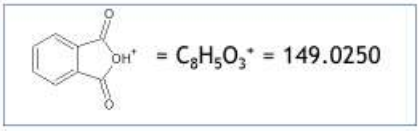
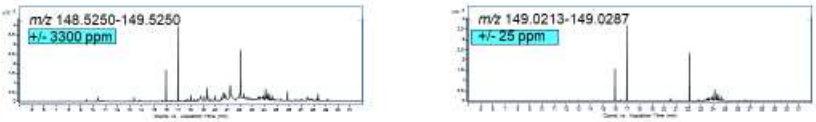
GC-TOF-MS

- High resolution – higher selectivity
- Accurate mass – potential chemical formulae for fragments (molecular adduct if using chemical ionisation)
- Some accurate mass libraries available but not as comprehensive as EI libraries





EICs at *m/z* 149.0250 with different mass windows



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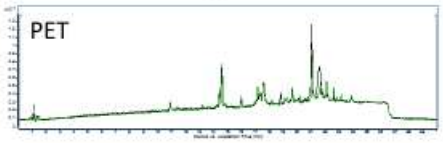
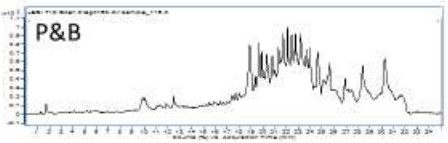
LC-HR-MS

- Non-volatile and polar NIAS detected by LC-MS
- HR-MS
  - Accurate mass, isotope information (spacing and intensity), fragmentation (in-source or MS/MS)
  - Positive and negative ionisation modes possible



60 MFs



250 MFs

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Database searching

- Comparison of list of accurate masses to theoretical database
  - Can include retention time, structures, MS/MS fragment data
- Theoretical oligomers and reaction products associated with starting materials (and impurities if known) below 1000 Da
  - Should consider simulant-oligomer interactions
- Can contain tens of thousands of compounds….
- Not confirmed unless compared to authentic standard

		AA	TMA	PA	CHDM	BD	EG	DEG	PG	HD	HMP	TMP	NPG	H2O	MW
PA+EG	linear			1			1							1	210.0528
EG+PA+EG	linear			1			2							2	254.0790
PA+EG+PA+EG	linear			2			2							3	402.0951
PA+EG+PA+EG	cyclic			2			2							4	384.0845
PA+EG+PA+EG+PA	linear			3			2							4	550.1111
PA+EG+PA+EG+PA+NPG	linear			3			2						1	5	636.1843
PA+EG+PA+NPG+PA+EG	linear			3			2						1	5	636.1843
PA+PG+PA+PG+PA+PG	linear			3					3					5	636.1843
PA+PG+PA+PG+PA+PG	cyclic			3					3					6	618.1737

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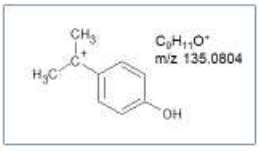
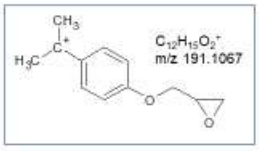
LC-QTOF-MS

- Controlled fragmentation experiments
- Can we use MS data to differentiate between linear and cyclic oligomers?
- Accurate mass information will be the same
  - BADGE.BPA = $C_{36}H_{40}O_6$, Cyclo-di-BADGE = $C_{36}H_{40}O_6$
- Fragment ions characteristic of the presence of an epoxy group?





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Quantification

- How can we quantify if we don't know what we are looking for?
- Internal standards
  - ^2H, ^{13}C analogues – not naturally occurring
  - Range of compounds to cover the mass range of interest?
  - IS that responds in positive and negative ionisation (for LC-MS)
- External standards
  - Chemically similar to substances of interest
  - e.g. BADGE or BADGE hydrolysis products for epoxy-related
  - e.g. Polyester diol urethane substance for polyester-related
- Synthesis of authentic standards to confirm identity
  - Retention time, accurate mass, fragmentation comparison
  - Expensive and time consuming

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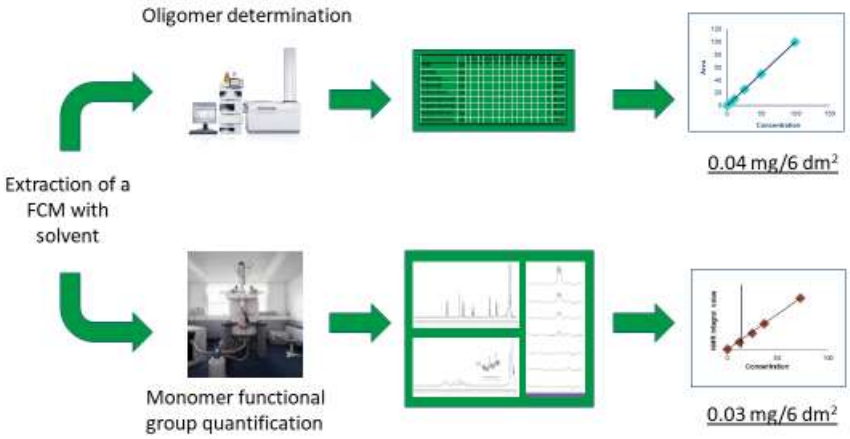
Quantification by LC-TOF-MS and NMR



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Summary

- Fera Science Ltd
  - Who we are and what we do
- EU-China-Safe Food Safety Partnership
  - Why and what?
- Migration from and safety of food contact materials
  - What is migration and why are we interested
  - What factors influence migration
  - What EU legislation is in place
  - Migration testing strategies – how do we test?
  - Examples of specific migration
  - Other aspects – NIAS

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www.euchinasafe.eu

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Disclaimer: The content of this presentation does not reflect the official opinion of the European Commission and/or the Chinese government. Responsibility for the information and views expressed therein lies entirely with the author(s).

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Thank you for your attention

Any questions?

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7.3. APPENDIX 3

CAIQ presentation

EUCHINASAFE 中欧食品安全

Delivering an Effective, Resilient and Sustainable EU-China Food Safety Partnership

EU China-Safe

Emma Bradley
Fera Science Ltd

fera
Original thinking... applied

EU China-Safe – why?

fera
Original thinking... applied

In Europe and China, consumer trust in the food industry and regulatory authorities has been damaged by a large number of accidental and deliberate food contamination and adulteration incidents

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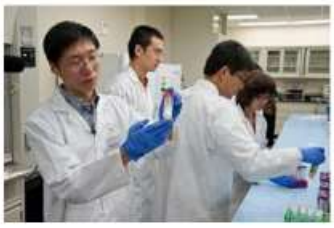
EU China-Safe

Laboratories in Europe and China are often working to different quality standards and using different analytical methods for producing for certification, which can result in protracted trade disputes



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EU China-Safe – what?

The project aims to develop & implement a shared vision of best practice between the EU & China

The key goals are to:

- Enhance food safety,
- Deter food fraud,
- Restore consumer trust,
- Deliver mutual recognition of data and standards and
- Support agri-food trade between the two trading blocks to promote economic growth

How?

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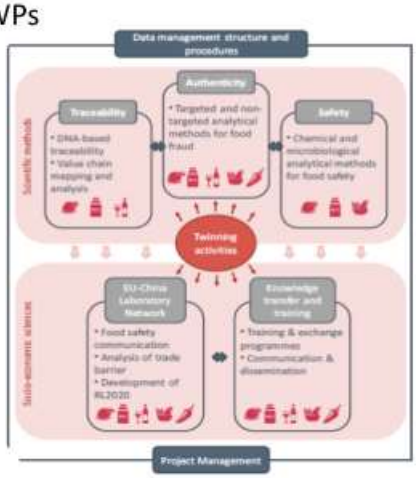
EU China-Safe work packages

Five Work Packages (WPs) supported by Data and Project Management WPs



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EU China-Safe WP4

Implementation of innovations in food safety

Nitrites and chlorate in milk and dairy powders……

Veterinary drug and feed additive residues in foods of animal origin …….

Food contact materials…….

Multi-analyte screening method for pesticide residues in fruits and vegetables, tea and fruit juices……

Tracking major microbiological food safety risks across infant formula supply chain……

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WP4 Task 4.3 - training

CFSA staff to be seconded to Fera for training on:

- European legislative framework and specific measures
- Migration test methods - Overall migration, specific migration
- Packaging extraction
- Application of migration modelling
- Targeted analysis for known migrants in simulants and foods
- Non-targeted analysis for the unknowns (NIAS)

Research project to identify and measure migrants in and migrating from Chinese food contact materials

- Implementing all of the above methods

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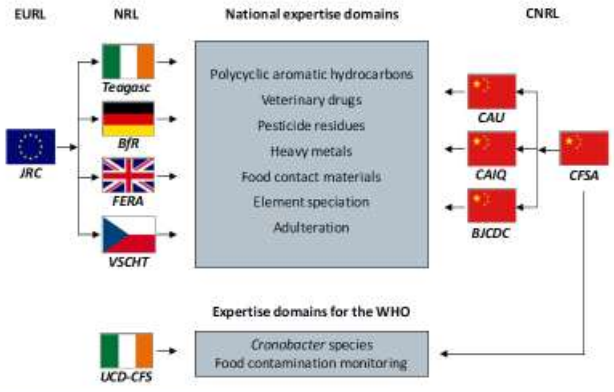
Confidence building

Harmonisation of analytical methods and standards

Creation of a virtual reference laboratory – transfer of FCM methods



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Food Contact Materials at Fera
fera
Original thinking... applied
Safety
• Overall migration
• Specific migration
• Non-intentionally added substances (NIAS)
Shelf life
• Food waste
• Active packaging
Fraud
• Reyclable and/or compostable and/or biodegradable?
State-of-the-Art facilities: The Thomson Suite
Information systems
HorizonScan
Food Safety at your fingertips
Early warning systems – supply chain controls
UK National Reference Laboratory
• Supporting the EURL, FSA, OCL's
EFSA
• Working group on Bisphenol A
• Provision of data to support EFSA evaluations
European Commission
• Technical guidance
• Evaluation of the Framework Regulation
Standards and quality
fapas
bsi.
cen
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