

WORKING PARTY ON MATERIALS AND ARTICLES IN CONTACT WITH FOOD OR DRINK

DISCUSSION PAPER: FUTURE FOOD STANDARDS AGENCY-FUNDED RESEARCH ON CHEMICAL MIGRATION FROM MATERIALS AND ARTICLES IN CONTACT WITH FOOD

PURPOSE

This paper sets out the general background to FSA-funded research on chemical migration and the associated role of the Working Party. It seeks the views of the Working Party on possible future work.

By way of background this paper includes a list of research projects completed in the past year and currently in progress (Annex I), and gives details of further work which may be commissioned in FY 2006 (Annex II).

The paper also suggests topics for projects which could be commissioned in FY 2007 (Annex III). The examples given in Annex III are intended to stimulate discussion, and Members are asked to comment on these. **The Secretariat would welcome other ideas from Members.**

Annex IV looks at the wider picture. **Members are requested to consider whether they agree with the assessment in Annex IV.**

**SECRETARIAT
OCTOBER 2005**

BACKGROUND

1. The Working Party advises the Food Standards Agency on cost-effective research on materials and articles in contact with food. Chemical contaminants get into food in many ways and the challenge for those involved in food production and its control is to work together to ensure that contaminants from a wide range of packaging types do not threaten health. The information generated in this research programme can be used to assess the possible contamination of food or drink from the migration of chemicals from packaging, cookware, and other materials and articles that are intended to come into contact with foodstuffs. This research is necessary to ensure that UK consumers are effectively protected from chemical migration from such materials and articles into food or drink. The Working Party also considers the results of such work.
2. The Food Standards Agency funds research and surveillance projects, by open competition, to underpin current and future policy on food contact materials. Periodically potential contractors receive Requirements Documents, which invite bids for new scientific work. The criteria on which bids are selected include relevance to policy requirements, overall scientific quality and potential value for money.
3. The results of the projects inform policy work in a number of ways. At one level they serve to protect public health in the UK and to increase technical knowledge. They also inform reviews of European Commission (EC) Directives on food contact materials, for example on plastics, and the results of projects inform UK input into discussion of future possible specific EC Directives/Measures e.g. active and intelligent, biodegradable or secondary packaging.
4. This research work provides information about the nature and the levels of chemical migrants and develops methods of analysis. It also increases understanding of the factors that influence chemical migration.

CURRENT RESEARCH PROJECTS

5. A list of Food Standards Agency-funded research projects on food contact materials and articles completed in the past year and projects currently in progress is at Annex I.

FUTURE WORK

PROJECTS FOR COMMISSIONING IN 2006

6. Details of projects, which may be commissioned in FY 2006, are at Annex II. Invitations for bids for these projects are included in the latest Food Standards Agency Research Requirements Document, published in September. The deadline for bids is December 2005.

PROPOSALS FOR PROJECTS FOR POSSIBLE COMMISSIONING IN 2007

7. Areas of work in which projects might be commissioned in FY 2007 need to be identified now for detailed review and possible inclusion in next year's Requirements Document. Some possible topics are listed at Annex III.

STRATEGIC CONSIDERATIONS

8. Annex IV looks at this research programme in terms of likely future needs. In part 1 of this Annex there are examples of possible net needs for information at the moment: paper and board; plastics; packaged food intake and general method development. It would be very helpful if Members could comment on the priorities that provisionally have been assigned in Annex IV.

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ANNEX I: PROJECTS COMPLETED SINCE THE NOVEMBER 2004 WORKING PARTY MEETING AND CURRENT RESEARCH

Reported projects*

| PROJECT TITLE | Contractor |
|--|--|
| Migration from recycled paper and board to dry foods. Research into the factors involved, leading to practical avoidance and amelioration measures | Central Science Laboratory, York (CSL) |
| Development of multi-methods for determining the migration of additives included in the proposed 6th amendment of Directive 90/128/EEC | RAPRA, TNO Netherlands |
| Assessment and quantification of latex protein (LP) transfer from LP-containing contact materials into food and drink products | Leatherhead Food International (LFI) |
| Substances migrating from ion-exchange resins | RAPRA |
| Chemical migration from silicones used in connection with food contact materials and articles | RAPRA |
| Method development for the analysis of nonylphenol in different types of packaging | CSL |
| An investigation of the breakdown products of curatives and antidegradants used to produce food contact elastomers | RAPRA, TNO Netherlands |

* Reports for these projects are available in the Food Standard Agency's Library, Aviation House, 125, Kingsway, London, WC2B 6NH or electronically from edward.potter@foodstandards.gsi.gov.uk

Current Research Projects

| PROJECT TITLE | Contractor |
|--|-----------------------------------|
| LC-MS method development for the screening of non-volatile and polar compounds present in paper and board and plastic food contact materials | CSL |
| Chemical migration from adhesives used in food contact materials and articles | CSL |
| To identify chemicals that could migrate into foodstuffs from pigments and dyes and measure migration of these chemicals into food simulants | PIRA |
| Investigation of migration from decorative shrink-sleeves | PIRA |
| An investigation of functional barriers currently used by the food industry and an assessment of their efficacy | CSL |
| An investigation of the stability of BADGE in foods and the reaction products formed | CSL |
| Measurement of packaged food intake by children by kilogram body weight to include type of packaging and foodstuff | University of Newcastle-upon-Tyne |
| Monomer and other chemical migrant levels in food grade plastic | PIRA |
| An investigation into the reaction and breakdown products from starting substances used to produce food contact plastics | CSL |
| An assessment of the potential for migration of substances from inks and coatings | RAPRA |

Current Surveillance Project

| PROJECT TITLE | Contractor |
|---|-------------------|
| Survey of the migration of benzophenone and 4-hydroxybenzophenone from food packaging into foodstuffs | CSL |

ANNEX II: RESEARCH PROPOSALS FOR PUBLICATION IN ISSUE 19 OF THE FOOD STANDARDS AGENCY'S REQUIREMENTS DOCUMENT (SEPTEMBER 2005)

Further work on the analysis of nonylphenol in food contact materials and assessing any migration into simulants and foods

A recently reported, Agency-commissioned research project (A03047) developed a method of analysis for the mixture of substances, generally referred to as nonylphenol, in a range of food contact materials and articles. This allowed initial evaluation of food packaging materials as a potential source of this mixture of substances in food. The method, based on gas chromatography-mass spectrometry and internally standardised by ¹³C-labelling, is capable of detecting ppm (1 in 10⁶) or possibly ppb (1 in 10⁹) levels of nonylphenol if present in plastics, rubbers or paper.

Further validation of this method is now required, concentrating on selected materials and involving a check exercise with a second laboratory. Consideration should be given to the variation in occurrence and concentration of nonylphenol in plastics, rubbers or paper, taking into account methods of manufacture as well as possible sources of nonylphenol. There is also a need to investigate migration from materials found to contain nonylphenol into simulants and foodstuffs. This work will require cautious interpretation of the results to take account of environmental sources of nonylphenol.

Assess new and potential applications of nanotechnology for food contact materials in the UK, considering the consumer safety and regulatory implications of their possible use

The use of nanotechnology in food contact materials and articles is an emerging science. It has been said that engineering at the nanoscale creates new opportunities for the packaging industries, and various potential applications of the technology are being suggested. These include:

- Improved barrier properties.
- Better temperature performance.
- Thinner films for flexible packaging.
- Nanoscale pigments for inks.

Research is now needed to gather more information on new and potential applications of this technology to food contact materials and articles in the UK, specifically in the context of chemical migration into food. Both consumer safety and regulatory implications will need to be considered.

Experimental work to identify the chemicals that are specific to active and intelligent packaging on the UK market and the extents to which they migrate into food

A new Framework Regulation 1935/2004/EC (replacing 89/109/EEC) recently introduced the concept of active and intelligent packaging into EU-wide legislation on materials and articles intended for food contact. Some practical work is needed to help the UK formulate its approach to likely future discussions on chemical migration from these newer types of packaging. The Food Standards Agency has already funded a desk-based study on UK trends in active and intelligent packaging (project A03039). This looked at future experimental needs to measure the chemicals that could migrate into food from such packaging. Some practical work is now needed to identify the chemicals that are specific to active and intelligent packaging on the market in the UK, and the extents to which they migrate into food. For example are spoilage indicators scavenged?

Investigate the application of HPLC-MS methodology to the determination of individual primary aromatic amines where there is a high packaging:food mass ratio

Primary aromatic amines may arise in materials intended for food contact as a result of the presence of impurities or breakdown products from aromatic isocyanates to make polyurethanes or colourants prepared by diazo-coupling.

Traditionally the BGVV colourimetric test is used to screen for the presence of aromatic amines based on the response for aniline. However, a number of primary aromatic amines give a weaker response than aniline. It is therefore important to be able to identify which specific aromatic amines are present. This is possible with the advent of high pressure liquid chromatography-mass spectrometry methods of analysis.

Testing is also based on the traditional assumption that 1 kg of food is packaged in 6 dm² of material. With the introduction of more single portion packs such as vinegar and tomato sauce sachets, this may no longer hold true.

Work is required to explore the application of liquid chromatography-mass spectrometry to the determination of individual primary aromatic amines and in particular to assess whether the traditional packaging/food mass ratio is appropriate for the determination of this type of analyte in cases such as single portion packs and sachets.

ANNEX III: PROPOSALS FOR PROJECTS FOR POSSIBLE COMMISSIONING IN FY 2007

Improvement of CEN methods

Methods previously developed and validated by CEN (Comité Européen de Normalisation) for the analysis of certain monomers in food simulants, have been used in recent Agency-funded surveillance to assess compliance with statutory limits on composition and migration (project A04009). During this surveillance, several of the methods were modified to enable them to be applied to test food samples for possible monomer migration or to develop the stated confirmation criteria for the methods. However, should work be carried out to apply other CEN methods intended for use with food simulants, to test samples of food for monomers?

In view of the long list of substances with restrictions in EC Directive 2002/72/EC as amended, as well as the recognition that multi-methods are helpful to analysts, is there a need to commission further work to develop and validate methods/multi-methods for substances listed in the plastics Directive. The Directive lists over 100 substances with specific migration limits, of these 30 have been included in the Agency's recent surveys on plastics. For the remaining substances:

- How widely are they used in relation to packaging for food sold in the UK?
- How many already have CEN methods of analysis?
- How many of the already established methods are suitable for use with food as well as food simulants?
- Is further confirmation criteria work required for simulants and/or foods?

Colourants

A recently completed Agency-commissioned project (A03045) has provided an important first step in obtaining information about substances considered most likely to migrate from colourants (pigments and dyes) commonly used in plastic packaging for food. In that project specially prepared test articles of plastics compounded with colourants were prepared. Some migration of substances identified as potential migrants in extraction tests was found, but in general these were at low levels.

When the colourants were blended into the specially prepared test articles, no additional additives such as slip and anti-static agents were added. This was because it was felt the wider range of additives available might over complicate the migration picture in the first instance. However, slip and anti-static agents may be added in commercial operations and it is possible that colourant migration could be increased by their presence in the plastic packaging. Should further analytical work be undertaken to determine whether migration could be increased by their presence?

Further research to investigate packaged food intake

The conventional European Union (EU) approach to assessing exposure of migrants from food contact materials and articles uses an intake of 1 kg of packaged food per 60 kg person per day. An on-going, Agency-commissioned project (A03051) is investigating

whether this approach should be modified to ensure specific protection against chemical migration into food marketed for children. This project was reviewed favourably at the Spring meeting of the Working Party on Materials and Articles in Contact with Food or Drink and the importance and validity of such work was recognised. This project has also led to the creation of a packaging database providing information on pack formats, intake and food-to-pack area ratios. Such data is limited at present but is very important for accurate exposure calculations.

Should further work be commissioned to look at other vulnerable groups such as the elderly, pregnant women, students or ethnic minorities? For example, work reported by Leatherhead Food Research Association asserts that within the next 25 years, it is projected that the percentage of the population over 60 will be over 25% in Europe. Do the elderly use a higher volume of single portion packaged foods? Sociological factors such as single person households can reduce the enthusiasm to cook, which in turn increases the consumption of convenience foods and single-portion packs. An expansion of the current work to cover other groups would not only lead to a further assessment of the applicability of the EU approach but also result in a much larger database providing vital packaging related exposure information.

Irradiation of food packaging

Packaging can be irradiated during its manufacture, for example as part of the main polymerisation cross-linking process or for the curing of printing inks onto the substrate. Alternatively irradiation may be used to sterilise packaging either before or after filling with foodstuff to eliminate spoilage organisms.

While the use of irradiation to cause cross-linking is likely to reduce migration, it may also cause decomposition to lower molecular weight substances which may migrate more readily. The effects of irradiation on packaging materials have been studied, but information appears less complete on the effects of irradiation on additives present in plastics used for food packaging, particularly with respect to migration.

Organotins

In recently published, Agency-funded work a gas chromatography-mass spectrometry method was developed and validated for a range of organotin stabilisers (Project A03031/32). This work concentrated on six organotin substances: a mon- and di-ethyl tin compound, a mon- and di-octyl tin compound and a mono- and di-dodecyl tin compound.

Since this project work was carried out, EFSA have agreed with a CSTEE opinion on the lowering of the group TDI for 14 dioctyltin compounds for use in food contact materials, from 0.0006 mg/kg bw to 0.0001 mg/kg bw. If taken forward by the Commission, this may result in the reduction of specific migration limits by a factor of 6. Should work now be carried out to:

- Improve the methodology already developed.
- Expand the method to include a wider range of di-octyl tin compounds.
- Improve detection limits.

Multi-layered materials

It is possible that the EU Commission may bring multi-layered materials and articles, which have a plastic layer in contact with food, within the scope of the rules on food contact plastics (currently EC Directive 2002/72/EC, as amended). This is being considered within a proposed 'plastics implementation measure,' formerly known as the plastics 'super-regulation.'

Within Article 13 of a working document for this measure it is stated that the finished article shall comply with the Overall Migration Limit, the Specific Migration Limit and the other specific restrictions of the substances contained in the different layers. Thus any migration through the plastic layer which is in contact with the food must comply with any restrictions that are in place in the plastics legislation.

Should work be commissioned to investigate whether the rules for testing plastics, in terms of migration into simulants, can be applied to multi-layers that contain a plastic layer in contact with food?

ANNEX IV: STRATEGIC OUTLOOK ON FSA-FUNDED RESEARCH ON MATERIALS AND ARTICLES IN CONTACT WITH FOOD

LIKELY POLICY NEEDS FOR RESEARCH OUTPUTS IN NEXT 5 YEARS

Part 1: By type of material/requirement:

| | Policy need | Main focus | Available info. | Therefore: current need for new projects |
|---------------------|-------------|------------|-----------------|--|
| Paper & board | +++ | EU | Much | Possible need re: multilayers (see Annex III) |
| Can coatings | +++ | EU | Much | No |
| Elastomers | +++ | UK | Much | No |
| Adhesives | +++ | UK | Little | Entry re. primary aromatic amines in Sept. 2005 Requirements Document (see Annex II) |
| Recycled packaging | +++ | EU | Much | No |
| Plastics | +++ | EU | Growing amount | Project started 2005. Possible need (see Annex III) |
| Ion exchange resins | ++ | EU | Some | Project published in 2004 |
| Inks | ++ | UK | Some | Project started 2005 |
| Secondary packaging | ++ | EU | Growing amount | No |
| Kitchenware | ++ | UK | Growing amount | No |
| Wood | ++ | UK | Growing amount | No |

| | | | | |
|----------------------------------|----|----|----------------|--|
| Glass | ++ | UK | Much | No |
| Ceramics | ++ | UK | Growing amount | No |
| Cork | ++ | UK | Growing amount | No |
| Metals/alloys | + | EU | Much | No |
| Silicones | + | UK | Some | No |
| Active and Intelligent Packaging | ++ | EU | Growing amount | Entry in Sept. 2005 Requirements Document (see Annex II) |
| Biodegradable | + | UK | Some | No |
| General method development | ++ | EU | Growing amount | Possible need (see Annex III) |
| Latex allergens | + | UK | Little | Entry in June 2005 Requirements Document |
| Packaged food Intake | + | UK | Little | Project started 2004 Possible need (see Annex III) |
| Functional barriers | + | EU | Little | Project started 2004 |
| Nanotechnology | ++ | EU | Little | Entry in Sept. 2005 Requirements Document (see Annex II) |

Part 2: By main area of policy work:

| | |
|---------------------|-----|
| UK | Yes |
| European Union (EU) | Yes |

