INITIAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1 These Regulations are to be known as The Materials and Articles in Contact with Food (England) Regulations 2007.

2. Purpose and Intended Effect

- **Objective**

2.1. The purpose of these proposals is to meet the Government's commitment to honour its EU obligations within the European Union; to reduce the risk to consumers of health effects arising from the consumption of harmful levels of chemicals in food.

2.2. Our proposal will make provision for the enforcement, in England, of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice (the GMP Regulation). They will also put in place offences that may be prosecuted before the Courts where alleged breaches of the GMP Regulations arise, defences against those alleged breaches under particular circumstances and penalties to apply on conviction of an offence under them.

2.3. The proposed Regulations will revoke and replace The Materials and Articles in Contact with Food Regulations 2005 (SI 2005 No. 898) in their entirety, in so far as they apply to England and re-enact their provisions taking into account the enforcement provisions of the GMP Regulation.

2.4. This Regulatory Impact Assessment (RIA) is concerned only with the enforcement of the GMP Regulation which will extend to England only.

2.5. The policy being enacted through these proposals in relation to the EU-harmonised legislation applies across the United Kingdom. In consequence similar, parallel legislation will be made in Scotland, Wales and Northern Ireland.

- **Background**

2.6. Under Article 3 of the Framework Regulation (EC) No. 1935/2004, the general requirement, all materials and articles falling within scope of that Regulation have to be manufactured in compliance with 'good manufacturing practice'. However, the term has not been further elaborated until now. The UK and some other EU member states have sought clarification of the term since the proposal for a framework regulation first appeared. The new GMP Regulation now does this and establishes the principles to be observed, proportionately, by businesses. It also lays down some specific requirements that apply to processes involving the application of printing inks to the non-food

contact side of a material or article. The inclusion of this Annex specifically on inks follows the discovery of widespread contamination of foodstuffs throughout the EU by isopropylthioxanthone (ITX) caused by set off from the non-food contact surface. Affected foodstuffs included fruit juices and infant and follow-on formulae. All EU countries were affected. Although there was no health risk arising from this incident, the presence of the chemical was undesirable and preventable.

2.7. Many sectors of industry have GMP guidelines in place and many businesses employ GMP measures in their manufacturing and processing. Trade associations have done much to promote the use of documented GMP systems by businesses in the UK. However, these may not always be observed or can be deficient, whilst in other cases businesses may have little or no GMP policy in place. The numbers involved are not known, but clarity of the requirement in law helps businesses know what is required of them. The UK, supported by other Member States and many UK industry sectors (see section 7.2) has therefore played a significant role in developing the European Commission's original proposal. The final proposal was subsequently adopted by The Standing Committee on the Food Chain and Animal Health as a specific regulation on 22 December 2006 and entered into force on 18 January 2007.

2.8. Commission Regulation (EC) No. 2023/2006 on GMP will apply from 1 August 2008 and is directly applicable in all EU Member States. The time between entry into force of the Regulation and the application of its provisions provides time for those businesses that are affected by the Regulation to ensure they have sufficient provision in place meet the Regulation's requirements on quality control systems, procedures and documentation.

2.9. The GMP Regulation applies to those materials and articles within the scope of Regulation 1935/2004 and lays down the detailed principles to be incorporated into GMP protocols to ensure uniformity and conformity amongst Member States across the European Union. The GMP Regulation seeks to ensure that materials and articles intended for use in contact with food are consistently produced and controlled to conform with the rules applicable to them and with quality standards appropriate to their intended use. This helps businesses to look at the intended use of their products to ensure that different uses do not lead to unexpected demands on the performance of the material used in their manufacture. This prevents higher than intended chemical migration arising from say, use in hot conditions during heating food than when use has been only anticipated in cool conditions, say in a refrigerator. Different food types also cause different migration behaviour among food contact materials and manufacturers have to ensure their products can cope with foreseeable food contact.

2.10. The GMP Regulation will apply to all sectors and to all stages of manufacture, processing and distribution of these food contact materials and articles, but excluding the production of starting substances used in their manufacture. The detailed rules set out in the annex to the GMP Regulation apply to the relevant individually mentioned materials and processes, as appropriate. Currently only requirements specific to printing inks are given.

- **Rationale for Government Intervention**

2.11. These proposals fulfil the Government's policies of meeting its EU obligations. These are to keep food safe by reducing the chronic long term health risks to consumers arising from chemical contamination of foodstuffs they eat, to reduce the potential for avoidable chemical migration resulting in food incidents and to meet the Lisbon agenda to improve the competitiveness of businesses in Europe by providing harmonised rules within which businesses can compete. To do nothing would leave enforcement bodies without adequate statutory powers to prevent the placing on the market of materials and articles intended to come into contact with food from entering the market.

2.12. The Food Standards Agency believes that the adoption of these proposals provides essential powers to enforce the modernised regulatory framework that removes trade barriers and allows for technological innovation. Consumer protection will continue in an area of food control where inadequate controls could have serious long-term implications or are seriously suspected of carrying, an unacceptable risk to consumer health, particularly among more vulnerable people. The proposal is the product of work by the UK in cooperation with the European Commission and other Member States. It requires that quality assurance control systems be put in place and documented. The documentation will be on paper or in electronic format and will be made available to the competent authorities on request.

3. Consultation

- **Within Government**

3.1. Departmental economists, the Small Business Service of the Department of Trade and Industry and the Office of Fair Trading are being consulted on these proposals.

- **Public Consultation**

3.2. Key European consumer and industry sector representative organisations have been involved in the development of the GMP Regulation that these proposals deal with in relation to England. In the UK all organisations on the Agency's database of contacts with an interest in the development of policy, issues and legislation on food contact materials were consulted on the initial development of

proposals in early 2006 and a further consultation took place in August 2006 when those proposals were last amended following the UK's intervention at EU level. To date, no comments have been received from stakeholders, which indicate any financial implications associated with the GMP Regulation.

3.3. Informal meetings with the key industry sectors have also taken place as the GMP Regulation that gives rise to these proposals for England was being negotiated. Formal consultation on these regulatory proposals for England will involve all organisations that are known to the Agency as wanting information about and/or involvement with developments and proposals on materials and articles in contact with food. These include manufacturers of food packaging, of food distributors and processors; those with an interest in food contact materials legislation; enforcement authorities and consumer organisations.

4. Options

- **Option 1 – Do nothing**

4.1 Doing nothing will not affect the requirements of the GMP Regulation as this is already legally binding and applicable throughout the EU. The GMP Regulation will still apply, but the obligation to put in place provisions to enable its enforcement, to provide for offences to be prosecuted, for defences for those that could have been prosecuted and to provide for penalties to be applied to those that could have been found to be in breach of those Regulations will not have been fulfilled and the Government would inevitably be cited in infraction proceedings by the European Commission.

- **Option 2 – Fully implement the necessary requirements that will support the European Regulation and provide for its enforcement**

4.2 This option meets the Governments commitment to fulfil its EU obligations and contributes significantly to providing for the up-to-date means of protecting consumers from ingesting harmful levels of chemicals that could have migrated from the materials or articles that were intended to be brought into contact with the food. As the GMP Regulation is already in force, we are required to provide for its enforcement in England, for offences to be created and defences to apply in particular circumstances and for penalties to apply upon conviction for an offence. This ensures that enforcement authorities can fulfil the requirements placed upon them and that the Courts can impose penalties that are in line with penalties that apply elsewhere in our food law. It also provides for defences in law for those against whom offences may be alleged in court.

NOTE FOR CONSULTATION

We would welcome comments on the assertions in this paragraph that option 2 has the desired effect in support of the proposal. If you disagree with this assessment, please provide evidence to support your view.

5. Costs and Benefits

- **Sectors and groups affected**

5.1 Typically, businesses affected by these proposals are those that manufacture food packaging, including those that use coatings, inks, adhesives etc, in the manufacture of materials and articles intended for food contact; distributors and processors.

5.2 Local authorities and port health authorities are responsible for enforcing legislation with respect to food safety and will therefore also be affected.

5.3 Consumers of foods placed in contact with the materials and articles subject to the provisions of the GMP Regulation will be assured that there are proper deterrent measures in place to dissuade manufacturers from breaching the GMP Regulation that seeks to protect their health.

Benefits

- **Option 1**

5.4 This is not a viable option and there are no foreseeable benefits.

NOTE FOR CONSULTATION

We would welcome comments on the assertions in this paragraph that option 1 does not have the desired effect in relation to the foreseeable benefits of the proposal. If you disagree, please provide evidence to support your view.

- **Option 2**

5.5 This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the GMP Regulation. It would also harmonise standards across the EU member states and ensure conformity and uniformity and prevent any barrier to trade occurring as a result of existing or future legislation in place in individual Member States. Consumers in the UK and throughout the EU will enjoy the same degree of protection from potential contamination of

foodstuffs from substances that might migrate from food contact materials and articles.

5.6 This option will ensure that the chance of consumers being exposed to harmful levels of substances migrating from food contact materials and articles, to the food itself, are minimised. This should increase consumer confidence. A 1999 report presenting the economic evaluation of UK policy on chemical contaminants in food estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million then. The report is available at:

http://statistics.defra.gov.uk/esg/evaluation/chemcont/default.asp .

5.7 Businesses involved in the manufacture of food contact materials and articles will gain from the Regulations by ensuring a non-discriminatory competitive environment, thus creating a level playing field both domestically and Europe-wide, which in turn may facilitate further trade.

5.8 Local authorities and port authorities will benefit from the greater clarity provided by the GMP Regulation and from the power of enforcement devolved to them by these Regulations that will apply to England.

5.9 The Agency considers that benefits will be maximised under option 2.

NOTE TO CONSULTATION

Stakeholders, particularly enforcement authorities are asked to comment on the proposal in relation to enforcement costs or benefits that can be identified. If you disagree with the assertion made in paragraph 5.9, please provide evidence to support your views.

Costs

- **Option 1**

Commission Regulations are binding in their entirety and directly applicable in all EU Member States from the date that they take effect. The UK therefore, has a legal obligation to ensure that the provisions are in place to provide for the enforcement of Regulation (EC) No. 2023/2006 in full. Failure to do so may result in infraction proceedings against the UK government. It would also leave the UK enforcement authorities without any domestic legislation for the enforcement and execution of the European Regulation.

- **Option 2**

5.10 These proposals place no new burdens on businesses; the requirement to manufacture in compliance with GMP has existed in law for nearly twenty years and they simply provide for the enforcement of the GMP

Regulation, for defences against alleged offences and for penalties upon conviction for an offence. Indeed, the informal consultation carried out in August 2006 showed that many businesses already had established GMP procedures, quality control and quality assurance systems in place sufficient to meet the requirements of the GMP Regulation. No pertinent comments on the specific costs to industry arising from these proposals were received by the Agency in the earlier consultation and we believe this still to be the case. As such, the Food Standards Agency does not anticipate any cost implications for businesses arising from these proposals.

Note for Consultation

We would welcome comments from stakeholders in our assertion that cost implications arising from these proposals are negligible. However, please inform us if you disagree with our assessment and provide evidence as appropriate on financial costs.

Summary costs and benefits table

5.11 The EC Regulation and as outlined in option 2 are negligible. The proposed Materials and Articles in Contact with Food (Amendment) (England) Regulations 2007, merely provide for the enforcement of Regulation (EC) No. 2023/2006 and the resources implications are negligible.

Option	Total cost per annum: - economic, environmental, social - policy and administrative	Total benefit per annum: economic, environmental, social	Groups affected
1	• Infraction proceedings against the UK Government • Possible financial costs to industry from lack of consumer confidence in the safety of food contact materials in the UK supply chain	• None	• None
2	• no quantifying information received by the Agency following the consultation in August 2006 in respect of the GMP Regulations • the cost implications for businesses arising from these proposals are likely to be negligible.	• fulfils the UK's legal obligations to make provision for the enforcement of the GMP Regulations • continued high level of public health and consumer confidence • the new English Regulations will ensure that measures, which are applicable throughout the EU are in place, thereby facilitating trade and creating a level playing 'field'	• Enforcement authorities and port health authorities • Manufacturers of food packaging, including those that use coatings, adhesives, etc in the manufacture of food contact materials and articles intended for food contact; distributors and processors.

Economic, Social and Environmental

5.12 The social and environmental costs arising from these proposals are negligible. The proposals apply equally to all areas of legislation on food contact materials and articles, thus, the provisions equally affect all businesses involved.

5.13 Rural areas, disabled people and members of the ethnic communities are not affected by these proposals, any differently to others. Charities and voluntary organisations are unlikely to be affected by these proposals.

Note for Consultation

We would welcome comments on our assertion that the economic, social and environmental costs arising from these proposals are negligible. However, please inform us if you disagree with our assessment and provide evidence as appropriate, to support your views.

5.14 These proposals are unlikely to have any specific impact on sustainability. Indeed, the elaboration of the requirement to follow GMP arguably ensures the best practice will contribute to reducing waste and loss in manufacturing.

5.15 The Food Standards Agency does not anticipate new or additional cost implications for enforcement authorities. Local authority enforcement bodies have always had responsibility for the enforcement of the food contact materials Regulations. Given that the English Regulations on which we are consulting merely provide the means by which this role can continue under the GMP Regulation, there is unlikely to be a significant resource implication to those enforcement authorities arising from these proposals.

NOTE FOR CONSULTATION

However, please inform us if you disagree with our assessment and provide evidence as appropriate to support your views. Enforcement in particular as asked comment in relation to enforcement.

Policy and Administrative Costs

5.16 The Food Standards Agency believes that the policy and administration costs are likely to be minimal. There will be a small administrative cost to business of reading the new legislation, however since there has been a requirement in law to manufacture in compliance with GMP for nearly twenty years now, this does not represent any new compulsory action,

thus there will be no administrative burden placed on business. Businesses are likely to benefit from the defined principles of GMP, which are currently not available. Indeed, the GMP Regulation requires that the rules applicable on GMP are proportionate to the business and thus avoid placing undue burdens on small businesses.

NOTE FOR CONSULTATION

We would welcome any comments on our view that any new administrative costs will be minimal. We would also welcome your comments and evidence if you believe that this regulation introduces any other new administrative costs, over and above what a business would do commercially.

6. Small Firms Impact Test

6.1. The companies involved in this area are represented through their national trade bodies to those at European level. The Small Business Service (SBS) and the Forum of Private Businesses (FPB) were consulted at this early stage. The FPB commented that, from a small business perspective, there are a number of considerations; for those businesses involved in the production of packaging materials, inks and printing machines, the GMP Regulation makes certain duties mandatory; for those businesses that use packaging, as such, the GMP Regulation should have little if any effect.

6.2. The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. In 2003[1], a study of the UK's packaging industry identified 13,000 packaging companies in the UK, combined they employ 250,000 people. The study also revealed that half of all packaging companies have a turnover less than £10 million, and that 85% are small to medium size enterprises.

6.3. In 2001, the industry employed approximately 100,000 people in around 2,700 companies – 85% of which are described as small-to micro-sized companies. The potential commercial impact of the proposals applies equally to all businesses involved small or large, however, the EU Regulation is explicit in charging businesses with the responsibility for proportionate compliance.

7. Competition Assessment

7.1. The Competition Filter Test has been completed and it has confirmed that none of the options raise competition concerns. The provisions for enforcement powers to the proper authorities in England do not place any hindrance on the competitiveness of business, nor does the alignment of penalties for offences with those that apply elsewhere in food law. As these proposals relate to offences where breaches arise,

[1] Mintel, April 2003

defences that might apply in the event of prosecution for alleged offences and penalties that apply on conviction for the offence, they are unlikely to raise any competition concerns. This view is supported by the Office of Fair Trading.

7.2. Economically, a lot depends upon the businesses profit margins as to whether there will be any effect on competition. Some firms may be able to compete in the industry because their costs are equal to, or only just below, their revenues. If their costs increase even a little, and they are unable to pass these costs on to the consumer, then their business will suffer. The true story is that those firms that are already conforming to the regulations should benefit from a level playing field, whilst there is a small chance those that are currently flouting them may be priced out of the market

7.3. Industry and businesses have been closely involved at European level in the development of these proposals and have not raised any issues that indicate a disadvantage to any particular business sector. The proposal presented to industry was one that was inspired by the UK in its efforts to define the principles of GMP that should be observed by businesses in establishing their own practices. The UK particularly sought to avoid prescribing to businesses how they should operate.

7.4. The consultation carried out in August 2006 highlighted that most businesses in the food packaging sector supported the proposal for a specific measure on GMP, thus creating a level playing field throughout the EU. The Confederation of Paper Industries (trade association representing the paper packaging industry), commented that they felt that an additional legislative document was unnecessary as they have developed guidelines on GMP. However, as indicated in 2.4, not all businesses have GMP in place and as such that would leave those businesses insufficient time in which to meet the compliance requirements of the GMP Regulation.

7.5. The proposals apply equally to all existing and new manufacturers of materials and articles intended to be brought into contact with food and will not therefore disadvantage any particular business sector, nor company.

8. Enforcement, sanctions and monitoring

- **Enforcement**

8.1. Local authorities and port health authorities are responsible for enforcing a large proportion of Regulations with respect to food safety and have done so in respect of the Framework Regulation 1935/2004, as sanctioned by The Materials and Articles in Contact with Food (England) Regulations 2005. Thus, the proposed Regulations on which we are consulting merely provide the means by which this role can continue under the GMP Regulation.

- **Sanctions**

8.2. The criminal sanctions in the Materials and Articles in Contact with Food (England) Regulations 2005, would apply in the case of prosecution against those in breach of the GMP Regulations. Any person who fails to comply with the requirements of Article 4 of the GMP Regulation is guilty of an offence under these and other regulations dealing with materials and articles in contact with food is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; on summary conviction to a term of imprisonment not exceeding 3 months or a fine not exceeding level 5 on the standard scale or both.

- **Monitoring**

8.3. The authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with regulations. The results of this work are published and are openly available. They shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Food Standards Agency will work with enforcement authorities where problems or suspected infringements of the Regulations arise. The effectiveness of the proposed Regulations will also be monitored via feedback from stakeholders as part of the ongoing policy process. We shall also continue to routinely talk to industry to ensure that no unforeseen difficulties arise from these Regulations.

Sections 9-12

[NB: Sections 9-12 will be completed after consultation and included in the full RIA.]

9. Implementation and delivery plan

10. post-implementation review

11. Summary and recommendations

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed ……

Date

Minister's name, title, department

Contact point

Richard Sinclair,
Food Standards Agency,
Chemical Safety Division,
Food Contact Materials Unit,
Room 515c,
Aviation House,
125 Kingsway,
London
WC2B 6NH
Telephone: 020 7276 8538
Fax: 020 7276 8514
Email: richard.sinclair@foodstandards.gsi.gov.uk

S T A T U T O R Y I N S T R U M E N T S

2007 No.

FOOD, ENGLAND

The Materials and Articles in Contact with Food (England) Regulations 2007

Made - - - -	***
Laid before Parliament	***
Coming into force - -	***

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), 2(a) and (3), and 48(1) of the Food Safety Act 1990([2]), and now vested in her([3]), [and under paragraph 1A of Schedule 2 to the European Communities Act 1972([4])].

[These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for certain references to Annexes to Community instruments as specified in regulation 2(4) to be construed as references to those Annexes as amended from time to time].

In accordance with section 48(4A) of [that/the 1990] Act she has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the

([2]) 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.

([3]) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act. **[DN: may need to add text to** explain **effects of GoWA 2006]**

([4]) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51).

European Food Safety Authority and laying down procedures in matters of food safety([5]), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Preliminary

Title, application and commencement

1. These Regulations may be cited as the Materials and Articles in Contact with Food (England) Regulations 2007, apply in relation to England only and come into force on [——].

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

"the 2006 Regulations" means the Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006([6]);

"Directive 93/10/EEC" means Commission Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with food([7]);

"Directive 2002/72/EC" means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs([8]);

"Regulation 1935/2004" means Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC([9]);

"Regulation 2023/2006" means Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food([10]);

"authorised officer" means any person, whether or not an officer of the authority having responsibility for execution and enforcement under regulation 14, who is authorised by that authority in writing to act in matters arising under these Regulations;

"food authority" does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple) nor a port health authority;

"import" means import in the course of a business from a place other than a Member State;

"plastics" means those materials and articles to which Directive 2002/72/EC applies;

"port health authority" means —

(a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984([11]) by section 7(1) of that Act), the Common council of the City of London; and

---

([5]) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended as at the date these Regulations are made by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

([6]) S.I. 2006/2687.
([7]) OJ No. L93, 17.4.93, p.27, as last amended by Commission Directive 2004/14/EC (OJ No. L27, 30.1.2004, p.48).
([8]) OJ No. L220, 15.8.2002, p.18. This Directive has been amended as at the date these Regulations were made by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45), 2004/19/EC (OJ No. L71, 10.3.2004, p.8) and 2005/79/EC (OJ No. L302, 19.11.2005, p.35).
([9]) OJ No. L338, 13.11.2004, p.4.
([10]) OJ No. L384, 29.12.2006, p.75.
([11]) 1984 c.22.

(b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act;

"preparation" in relation to food includes manufacture and any form of treatment or process;

"regenerated cellulose film" means a thin sheet material obtained from refined cellulose derived from unrecycled wood or cotton, with or without the addition of suitable substances, either in the mass or on one or both surfaces, but does not include synthetic casings of regenerated cellulose;

"sell" includes offer or expose for sale or have in possession for sale, and "sale" and "sold" shall be construed accordingly.

(2) Except in regulations 5 and 7, any reference in these Regulations to a numbered Article is a reference to the Article bearing that number in Regulation 1935/2004.

(3) Expressions used in these Regulations and in Regulation 1935/2004 or Regulation 2023/2006 bear the same meaning in these Regulations as they bear in those Regulations.

(4) Any reference to Regulation 2023/2006 or to an Annex of Directive 93/10/EEC or Directive 2002/72/EC is a reference to that Regulation or that Annex as amended from time to time.

Scope

3. The provisions of these Regulations do not apply to those materials and articles specified in sub-paragraphs (a), (b) and (c) of Article 1(3).

PART 2

General Requirements for Materials and Articles

Enforcement of Regulation 1935/2004

4. Subject to the provisions of Article 27 (transitional arrangements), any person who contravenes any of the following provisions of Regulation 1935/2004 is guilty of an offence —

(a) Article 3 (general requirements);

(b) Article 4 (special requirements for active and intelligent materials and articles);

(c) Article 11(4) and (5) (provisions relating to Community authorisation);

(d) Article 15(1), (2), (3), (4), (7) and (8) (labelling);

(e) Article 16(1) (declaration of compliance);

(f) Article 17(2) (traceability).

Enforcement of Regulation 2023/2006

5. Any person who fails to comply with the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.

Competent authorities for the purposes of Regulation 1935/2004

6. The following bodies are designated as the competent authorities for the purposes of the provisions of Regulation 1935/2004 as specified below —

(a) in respect of Articles 9 and 13, the Agency;

(b) in respect of Articles 16(1) and 17(2), the Agency and the authority having responsibility for enforcement pursuant to regulation 14(1).

Competent authority for the purposes of Regulation 2023/2006

7. The competent authority for the purposes of Article 6(2) and 7(3) of Regulation 2023/2006 is each food authority in its area.

PART 3

Requirements for Vinyl Chloride

Limits and migration limits

8.—(1) Materials and articles which are manufactured with vinyl chloride polymers or copolymers —

(a) must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram of the material or article as measured by the method of analysis specified in regulation 9(1); and

(b) must be manufactured in such a way that they do not transfer to foods with which they are in contact any quantity of vinyl chloride exceeding 0.01 milligrams of vinyl chloride per kilogram of food as measured by the method of analysis specified in regulation 9(2).

(2) No person may —

(a) sell;

(b) import; or

(c) use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food,

any such material or article that does not comply with this regulation.

Methods of Analysis

9.—(1) The method used in analysing any sample for the purpose of establishing the quantity of vinyl chloride monomer present in the material or article in order to determine whether it complies with regulation 8(1)(a) shall be the method specified in the Annex to Commission Directive No. 80/766/EEC (which lays 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)([12]).

(2) The method used in analysing any food for the purpose of establishing the quantity of vinyl chloride present in the food in order to determine whether a material or article which is or has been in contact with the food complies with regulation 8(1)(b) shall be the method specified in the Annex to Commission Directive No. 81/432/EEC (which lays down the Community method of analysis for the official control of vinyl chloride released by material and articles into foodstuffs)([13]).

PART 4

Requirements for Regenerated Cellulose Film

Controls and limits

10.—(1) This Part applies to regenerated cellulose film which —

(a) constitutes a finished product in itself; or

([12]) OJ No. L213, 16.8.90, p.42.
([13]) OJ No. L167, 24.6.81, p.6.

(b) is part of a finished product containing other materials,

and is intended to come into contact with food, or by being used for that purpose does come into contact with food.

(2) Except in paragraph (4), any reference in this regulation to Annex II is a reference to Annex II to Directive 93/10/EEC.

(3) Subject to paragraph (5), no person may manufacture any regenerated cellulose film intended to come into contact with food using any substance or group of substances other than the substances named or described —

(a) in the first column (denominations) of Annex II in the case of —

(i) uncoated film; or

(ii) coated film where the coating is derived from cellulose;

(b) in the first column of the First Part of Annex II in the case of film to be coated, where the coating will consist of plastics;

and other than in accordance with the conditions and restrictions specified in the corresponding entry in the second column of the appropriate Part of Annex II, as read with the preamble to that Annex.

(4) No person may manufacture any coating to be applied to film referred to in paragraph (3)(b) using any substance or group of substances except those listed in Annex II, III or IV to Directive 2002/72/EC and other than in accordance with the appropriate requirements, restrictions and specifications contained in those Annexes and in the 2006 Regulations.

(5) Substances other than those listed in Annex II may be used as colourants or adhesives in the manufacture of a film to which paragraph (3)(a) applies, provided that such film is manufactured in such a way that it does not transfer any colourant or adhesive to food in any detectable quantity.

(6) Subject to regulation 12 no person may —

(a) sell;

(b) import; or

(c) use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food,

any regenerated cellulose film which has been manufactured in contravention of the requirements of paragraphs (3) or (4), or which fails to comply with paragraph (8).

(7) No person may use in the course of a business in connection with the storage, preparation, packaging, serving or selling of food —

(a) where the food contains water physically free at the surface, any regenerated cellulose film containing bis(2–hydroxyethyl) ether, ethanediol or both these substances;

(b) any regenerated cellulose film in such a way that any printed surface of that film comes into contact with the food.

(8) Any material or article made of regenerated cellulose film, unless by its nature clearly intended to come into contact with food, at a marketing stage other than the retail stage must be accompanied by a written declaration attesting that it complies with the legislation applicable to it.

Migration limits for regenerated cellulose film coated with plastics

11.—(1) Subject to paragraph (2), no person shall manufacture or import any material or article made with regenerated cellulose film coated with plastics which —

(a) is intended to come into contact with food; and

(b) is capable of transferring its constituents to food in quantities exceeding an overall migration limit of 10 milligrams per square decimetre of the surface of the material or article in contact with food.

(2) In the case of any material or article made with regenerated cellulose film coated with plastics which —

(a) is or is comparable to a container or which can be filled with a capacity of not less than 500 millilitres and not more than 10 litres; or

(b) can be filled and for which it is impracticable to estimate the surface area in contact with food; or

(c) is a cap, gasket, stopper or similar device for sealing,

the overall migration limit shall be 60 milligrams of constituents transferred per kilogram of food.

(3) No person shall manufacture or import any material or article made with regenerated cellulose film coated with plastics manufactured with any substance listed in Section A or B of Annex II to Directive 2002/72/EC (authorised monomers) which —

(a) is intended to come into contact with food; and

(b) is capable of transferring its constituents to food in quantities exceeding the specific migration limits set out in column 4 of those Sections as read with the general introduction to that Annex.

(4) Where the migration limit for a substance mentioned in paragraph (3) is expressed in milligrams per kilogram, in the case of regenerated cellulose film coated with plastics which —

(a) is or is comparable to a container or which can be filled with a capacity of less than 500 millilitres or more than 10 litres; or

(b) cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the film and the quantity of food in contact with it,

the migration limit shall be divided by the conversion factor of 6 in order to express it in milligrams of constituents transferred per square decimetre of the material or article in contact with food.

(5) Subject to paragraph (6), the verification of compliance with migration limits shall be conducted in accordance with the provisions of Schedules 2 and 3 of the 2006 Regulations as read with regulation 11 of those Regulations and for the purposes of this paragraph any reference in those provisions to a plastic material or article shall be construed as a reference to regenerated cellulose film coated with plastic.

(6) Paragraph (5) shall not apply in any circumstances to which regulation 9(1) or (2) is applicable.

Saving and transitional provisions and defences

12.—(1) Notwithstanding the revocation of the Materials and Articles in Contact with Food Regulations 1987([14]), in relation to regenerated cellulose film manufactured before 29th April 1994 the defences in regulation 6A of those Regulations shall apply in relation to offences under these Regulations in like manner as they applied to offences under the equivalent provisions in those Regulations.

(2) In any proceedings for an offence of contravening regulation 10(3), (4), (6) or (7), or regulation 11(1) or (3) it shall be a defence to prove that —

(a) the act constituting the offence was committed in relation to a material or article made with regenerated cellulose film which was manufactured or imported into the European Community before 29th January 2006; and

(b) the act constituting the offence would not have constituted an offence under the Materials and Articles in Contact with Food Regulations 1987 immediately before the coming into force of the Materials and Articles in Contact with Food (England) Regulations 2005([15]).

([14]) S.I. 1987/1523, as amended by S.I. 1990/2487 S.I. 1991/1476 and S.I. 1994/979.
([15]) S.I. 2005/898. These Regulations were subsequently amended by S.I. 2005/2626, S.I. 2006/1401 and S.I. 2006/2687, but none of those amendments are relevant to this provision.

PART 5

General

Offences and penalties

13.—(1) Any person who contravenes the provisions of regulation 8(2), 10(3), (4), (6) or (7), or 11(1) or (3) is guilty of an offence.

(2) Any person guilty of an offence under paragraph (1) or under regulation 4 or 5 is liable —

(a) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both;

(b) on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both.

Enforcement

14.—(1) Each food authority in its area and each port health authority in its district shall execute and enforce —

(a) the provisions of Regulation 1935/2004 mentioned in regulation 4, and

(b) subject to paragraph (3), these Regulations.

(2) The Agency may also execute and enforce the provisions of Articles 16(1) and 17(2).

(3) Each food authority in its area shall execute and enforce the provisions of Regulation 2023/2006 mentioned in regulation 5.

Procedure where a sample is to be analysed

15.—(1) An authorised officer who for the purposes mentioned in regulation 14 has procured a sample under section 29 of the Act and who considers it should be analysed shall divide the sample into three parts.

(2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.

(3) The authorised officer shall —

(a) if necessary place each part in a suitable container and seal it;

(b) mark each part or container;

(c) as soon as reasonably practicable, give one part to the owner and notify him in writing that the sample will be analysed;

(d) submit one part for analysis in accordance with section 30 of the Act; and

(e) retain one part for future submission under regulation 16.

Secondary analysis by the Government Chemist

16.—(1) Where a sample has been retained under regulation 15 and —

(a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and

(b) the prosecution intends to adduce as evidence the result of the analysis mentioned above,

paragraphs (2) to (7) apply.

(2) The authorised officer —

(a) may of his own volition;

(b) shall if requested by the prosecutor (if a person other than the authorised officer);

(c) shall if the court so orders; or

(d) shall (subject to paragraph (6)) if requested by the defendant,

send the retained part of the sample to the Government Chemist for analysis.

(3) The Government Chemist shall analyse the part sent to him under paragraph (2) and send to the authorised officer a certificate of analysis.

(4) Any certificate of the results of testing transmitted by the Government Chemist shall be signed by him or on his behalf, but the testing may be carried out by any person under the direction of the person who signs the certificate.

(5) The authorised officer shall immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the defendant with a copy of the Government Chemist's certificate of analysis.

(6) Where a request is made under paragraph (2)(d) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

(7) In this regulation "defendant" includes a prospective defendant.

Application of various provisions of the Act

17.—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations —

(a) section 2 (extending meaning of "sale" etc);

(b) section 20 (offences due to fault of another person);

(c) section 21 (defence of due diligence) with the modification that in subsection (4) the references to "sale" shall be deemed to include references to "placing on the market";

(d) section 30(8) (which relates to documentary evidence);

(e) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (3) below;

(f) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (3) below;

(g) section 36 (offences by bodies corporate);

(h) section 36A (offences by Scottish partnerships).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the reference in subsection (1) to the Act shall be construed as including a reference to Regulation 1935/2004 or as appropriate to Regulation 2023/2006.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act shall be construed as including a reference to Regulation 1935/2004 or, as appropriate Regulation 2023/2006, and to these Regulations —

(a) section 3 (presumptions that food is intended for human consumption) with the modifications that the references to "sold" and "sale" shall be deemed to include references to "placed on the market" and "placing on the market" respectively;

(b) section 33(1) (obstruction etc. of officers);

(c) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub–paragraph (b);

(d) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

Amendment of the Ceramic Articles in contact with Food (England) Regulations 2006

18.—(1) The Ceramic Articles in Contact with Food (England) Regulations 2006([16]) are amended in accordance with paragraph (2).

(2) In Schedule 3 (declaration of compliance), for sub-paragraph (5) of paragraph 1 substitute the following —

"(5) confirmation that the ceramic article or articles meet the relevant requirements in —

(a) these Regulations; or

(b) (i) Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs([17]) as amended by Commission Directive 2005/31/EC([18]); and

(ii) Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC([19]).".

Amendment of the Food safety (Sampling and Qualifications) Regulations 1990

19. In the Food Safety (Sampling and Qualifications) Regulations 1990([20]), in Schedule 1 (provisions to which those Regulations do not apply) for the title and reference of the Materials and Articles in Contact with Food Regulations 1987 substitute the title and reference of these Regulations.

Consequential amendments to the 2006 Regulations

20.—(1) The 2006 Regulations are amended in accordance with paragraphs (2) and (3).

(2) In paragraph (1) of regulation 2 (interpretation) omit the definition of "the 2005 Regulations".

(3) In paragraph (1)(b) of regulation 11 (method of testing the capability of materials or articles to transfer constituents, and methods of analysis), for the expression "regulation 7(2) of the 2005 Regulations" substitute "regulation 9(2) of the Materials and Articles in Contact with Food (England) Regulations 2007([21])".

Revocations

21. The following Regulations or parts thereof are revoked —

(a) The Materials and Articles in Contact with Food (England) Regulations 2005;

(b) Regulation 24 of the Plastic Materials and Articles in Contact with Food (England) (No. 2) Regulations 2006([22]).

Signed by authority of the Secretary of State for Health

Caroline Flint
Minister of State
Department of Health

Nth Month 2007

([16]) S.I. 2006/1179.
([17]) OJ No. L277, 20.10.1984, p.12.
([18]) OJ No. L110, 30.4.2005, p.36.
([19]) OJ No. L338, 13.11.2004, p.4.
([20]) S.I. 1990/2463.
([21]) S.I.
([22]) S.I. 2006/2687.

Annex D

Circulation List

Name	Organisation
Mr Paul Anthony Taylor	
Mr Nick Mathys	
Mr R Pearce	
Julia Jackson	
Dr S Barlow	
Mr Alan Turner OBE	
Mr A Taylor	Albright & Wilson Limited
Robert Broughton	Alcan Packaging
Mr K Tomblin	Allied Bakeries Ltd
Dr David A Harris	Aluminium Federation
Richard Mahoney	Aluminium Federation
Mr Roger Parry	Amcor Flexibles
Ged Sweeney	Amcor Flexibles
Mr Stuart MacConnacher	AMDEA
William Whelan	Anglia Laboratories Limited
Dr P Donnelly	APD Scientific Limited
Mr R Allen	Arjo Wiggins Limited
	Association For Consumer Research
Prof G Phillips	Association for the International Promotion of Gums
Mr G Grenshaw	Association of British Health Care Industries
	Association Of Public Analysts
Mrs Rita McBrown	Avent Limited
Mr D Dulieu	Avesta Sheffield Information Systems
Agnes Howard	Bernard Mathews Foods Limited
Dr Diana Anderson	BIBRA International
Ms C Rostron	BIBRA International
Mr S Orszulik	Binne Environmental
Nicola Smith	Bird and Bird
Mr Forsyth	BM Polyco Limited
Mr Chris Bowden	BMRB
Mr D Lindsay	Bonar Polythene Films Limited
Dr Steve Owen	Boots PDQ Centre
Mr M Carter	BPB Paperboard Limited
Mr F Morrall	British Ceramic Confederation
Mr AJ Newbould	British Coatings Federation Ltd
Mr Frank Hauxwell	British Colour Makers Association
	British Disposable Products Association
Mr P Grayhurst	British Glass
	British Hardware and Houseware Manufacturers Association
	British Hardware Federation
Mr David Parker	British Non-Ferrous Metals Federation
Dr Mercia Gick	British Plastics Federation
Mr Mike Hopkins	British Printing Industries Federation
Mr P Raynor	British Retail Consortium
Dr G Smith	British Rubber Manufacturers Association Limited
Lucy Pearson	British Soft Drinks Association
Ms D Anderson	British Soft Drinks Association

	British Standards Institution
Ms C Kendall	BSI Information Centre
Mr John Horwood	Cadbury Schweppes
Dr Henman	Cambridge Polymer Consultant
John Hammond	Campden & Chorleywood Food Research Association
Mr N Byrd	Campden & Chorleywood Food Research Association FRA
Mr Ian Tomson	Canadian High Commission
Mr Keith Warren, Director	Catering Equipment Suppliers Association
Mr Roger Hamby	CATRA
Dr S Parry	Centre for Analytical Research in the Environment
Dr Joanne Lloyd	Chemical Industries Association
Mr J Tiffney	Chief Environmental Health Officer
Mr John Frater	Chief Executive
Ms K Goodburn	Chilled Food Association
Joe Smith	Clariant (UK) Limited
Mr B Rushbridge	CMB Group Technology
Dr Peter Oldring	Coates Coatings International
Dr A Boon	Coates Lorilleux Research
Victoria Sayer	Colormatrix Europe
Andrew Barnetson	Confederation of Paper Industries
Mr N Barnwell	
Steve Ringer	Consumer and Competition Policy Directorate, CCP5e
Ms Joy Bell	Cork Industries Federation
Mr Dennis Brangwyn	Corrugated Case Materials Association
Claire Hendy	Corus Packaging Plus
Julie Hayward	Council for Responsible Nutrition
Ms E Smith	Croda Adhesives Limited
Mrs K Briggs	Croda Chemicals Limited
Mr R Whitaker	Crown Corporate Technologies
Mr Brian McMullen	Danapak Flexibles Limited
Mrs Jenny Lewis	Danapak Flexibles Limited
Dr N Gault	DANI
Mr J Hewitt	Darex UK Limited
Dr L Gladden	Department of Chemical Engineering
Dr Stuart Fraser	Dexter Corporation
Mr John Askew	Dexter Packaging Products
Mrs Caroline Brown	Director Consumer and Food Issues
Mr John Swift	Director Regulatory Affairs
Dr Trevor Dines	Dundee University
Professor Alexander G	Dundee University
Liz Fleming	Eclipse Scientific Group
Dr D Edwards	Edwards' Analytical
Dr Colin Rogers	Eka Chemicals Ltd
Mr Smale	Elementis Specialities
Mr O'Grady	Enthone-OMI
Chris Dickson	Eurocool limited
Mandy Mills	European Information Centre
Mr Julian Stocker	European Legislation and Nutrition Services
Dr Helma Jotischky	European Resin Manufacturers Association
Mr R Ratcliffe	FAIA
Ms Sue Bridger	Farringdon Point

Annex D

Dr B Whitehouse	Federation of European Food Additives and Food Enzymes Industries
Mr William Marwick	Field Packaging
Martin Unwin	Flexible Packaging Association
Chris Whitehead	Flint Ink, Technical Sales Manager
Cherry Hannson	Foil Container Bureau
Mr J Wood	Food and Drink Federation
Dr D Bellamy	Food and Drink Federation
Dr Stephen Fallows	Food Policy Update
Ann Davison	FOODAWARE
Mr Richard Layton	Four D Rubber
	Friends of the Earth
Dr Adam Kelsall	Glass Technology Services Limited
Mr M Strutt	Greenpeace
Ms A Watts	Group Research and Development
Mr R Colwell	H J Heinz
	Halton Borough Council
Mr David Adams	Health Food Manufacturers Association
	Henry Cook Limited
Mrs J Mayall	HIPP Nutrition Ltd
Dr David Dunstan	Horticulture Research International
Mr P Allan	Hyperlast Limited
Mr P Fitzgerald	Hyperlast Limited Kemira Polymers
Mr J Plaistowe	ICI Packaging Coatings Limited
Dr S Harvey	ICI Plc Chemicals and Polymers Group
Dr Sally Pugh Williams	INCO Europe Limited
	Industry Council for Packaging and the Environment (INCPEN)
Mr Richard Armstrong	Innovia Films
	Institute of Food Science and Technology
	Institute of Wood Science
Prof P Lox	International Association Packaging Research Institutes
Mrs Sue Cain	International Institute of Synthetic Rubber Producers
Mr P Bullock	Interteck Testing Services
Mr D Coleman	James Cropper Plc
Mr W Robson	Jamont (UK) Limited
Mr P Harrison	John Waddington Plc
Mr J Millar	JRM Associates
Janice Peberdy	Kellogg's
Mr Darren Prosser	Kenwood Limited
Dr Sue Jickells	King's College London
Mr R Beal	Kingfisher Colours Limited
Mr John Webb-Jenkins	Kirkstone Plastics Ltd
Mrs G Cierech	Knoll Microcheck
Mr David Fox	Korsnas Paper Sacks Limited
Dr Julian Braybrook	Laboratory of the Government Chemist
John Marriott	Laboratory of the Government Chemist
Mr Les Bailey	LACORS
Dr Ian Ramsay	Laser Installations Limited
Dr D Wilson	Lead Development Association International
Mr B Cass	Linpac Plastics Limited
Dr Richard Marsden	LINX Printing Technologies plc
Mr H Galvin	LMG Smith Brothers

Mrs Phylla Wilson	Lyondell Chemical Europe inc
Ms L Hilsley	Margarine and Spreads Association
Christopher Sherlock	Main Library
Mr C.R. Hodge	Manager European Regulatory Affairs
Mr Peter Wight	Marks and Spencer PLC
Mr David Rogers	Meech Artx
Martin Addicott	Mirage Inks
Mr D A Smith	MPMA
Mr A Woods	MPMA
S Dibb	National Consumer Council
Mrs A Townshend	National Consumers' Federation
Helen Ferrier	National Farmers Union
Ms Helen Millar	National Federation of Consumer Groups
Julie Scott	National Starch & Chemical
Dr C. P. Cutler	Nickel Institute
Mr Alex Neal	Nikken UK Limited
Michael Evans	Nutritech
Mr David Tyson	Packaging and Industrial Films Association (PIFA)
Prof F Paine	Packaging Technology & Science
Dr Tina Walton	Paint Research Association
Mr R Philips	PERA Technology
Mr Nigel Barnwell	Phase Four Technical Limited
	Pillsbury Europe
Mr I Cooper	PIRA International Limited
Dr P Tice	PIRA International Limited
Dr H Vandenburg	Proctor Department of Food Science
Mr E Braxton Reynolds	Public Analyst Laboratory
Ronald Pierre-Davis	Quality Hygiene Manager
Mrs A J Hardinge OBE	Quest International
Dr J Waterson	RAPRA Technology Limited
Mr J Sidwell	RAPRA Technology Limited
Mr Roy Dixon	RDA Packaging Consultants
Dr B Baigre	Reading Scientific Services Limited
	Rexam Beverage Can Europe
Mr Trefor Owen	Rexam Plastic Packaging
Mr Colin Hamlett	RHM Technology
Ms Caroline Varley	Robinson Brothers Limited
Mr David Smith	ROCOUP
Ms L Creighton	SafePharm Laboratories Limited
Dr D Knight	Safepharm Laboratory
John Figgins	Sainsburys Supermarkets Ltd
Dr G Lawson	School of Applied Sciences
Dr N Ostah	School of Applied Sciences
Prof P Fryer	School of Chemical Engineering
Mr Peter Dryden	Selective Services (SSL)
Mr S Sidani	Seven Seas Limited
Mr David Stonor	Shell Chemicals Europe Limited
Mr Stan Webb	Sinclair International Limited
Mr R Arnold	SLF International
Maureen Beresford	Small Business Service
Mrs H Freeman	Society of Chemical Industry

	Somerfield PLC
Mr John Johnson	Spectra Masterbatch Ltd
Mr J Potter	Stainless Plating Limited
Mr D Spyropoulos	State General Chemical Laboratory
Mr A Osborn	STR
Ms J Longfield	SUSTAIN - National Food Alliance
Mr I Stewart	Synthomer Limited
	Tableware Distributors Association
Ms Lynda Hamilton	Tehnical Indexes
Mr Richard Hawke	Terinex Limited
Mr S Challenor	Tesco Stores Limited
D Pearce	The Environmental and technical Association for the Paper Sack
Mr Ken Hardman	The Industrial Packaging Association
Lesley Reid	The Tile Association
Mr M Klimes	Thomas and Green Limited
	Timber Research and Development Research Association
Mr Alan Skelding	Timcon
Mrs S Skone-James	TNO BIBRA International Limited
Mr Pete Watts	Toxicology Advice & Consulting Limited
Philip Becker	Trada Technology
Mr N Cull	Trading Standards Department
Mr Bob Crafts	Tun Abdul Razak Research Centre
G D Funnell	UK Steel Association
Mr A Crimes	Unilever Research Colworth
Mr Barry Pamplin	United Biscuits (UK) Ltd
K Flett	UNIVAR Limited
Ms S Beards	University Hospital Birmingham
Mr M H Edser	Vinamul Limited
	W R Grace Limited
Mr D Finnegan	Weetabix Limited
Ms A Bristow	WHICH
Ms S Davies	WHICH
Mr Sean Kerns	Willow Garth
Miss Spaapen	World Cancer Research Fund
Ms Dena Grabiner	WWF UK c/o The Toxics Policy Officer
Mr David Baron	Zinc Information Centre

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food [1], and in particular Article 5(1) thereof,

Whereas:

(1) Groups of materials and articles listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles should be manufactured in compliance with general and detailed rules on good manufacturing practice (GMP).

(2) Some sectors of industry have established GMP guidelines, while others have not. Consequently, it appears necessary to ensure uniformity among Member States as regards GMP for materials and articles intended to come into contact with food.

(3) In order to ensure such conformity, it is appropriate to lay down certain obligations on business operators.

(4) All business operators should operate an effective quality management of their manufacturing operations which should be adapted to their position in the supply chain.

(5) The rules should apply to materials and articles intended to be brought into contact with food, or already in contact with food and were intended for this purpose, or those which can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

(6) The rules on GMP should be applied proportionately to avoid undue burdens for small businesses.

(7) Detailed rules should now be set for processes involving printing inks and should be established for other processes as necessary. For printing inks applied to the non-food contact side of a material or article GMP should in particular ensure that substances are not transferred into food by set-off or transfer through the substrate.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food (hereafter referred to as materials and articles) listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.

Article 2

Scope

This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

The detailed rules set out in the Annex shall apply to the relevant individually mentioned processes, as appropriate.

[1] OJ L 338, 13.11.2004, p. 4.

Article 3

Definitions

For the purpose of this Regulation, the following definitions shall apply:

(a) 'good manufacturing practice (GMP)' means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof;

(b) 'quality assurance system' means the total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use;

(c) 'quality control system' means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system;

(d) 'non-food-contact side' means the surface of the material or article that is not directly in contact with food;

(e) 'food-contact side' means the surface of a material or article that is directly in contact with the food.

Article 4

Conformity with good manufacturing practice

The business operator shall ensure that manufacturing operations are carried out in accordance with:

(a) the general rules on GMP as provided for in Article 5, 6, and 7,

(b) the detailed rules on GMP as set out in the Annex.

Article 5

Quality assurance system

1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:

(a) take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them;

(b) be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business.

2. Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it.

3. The different operations shall be carried out in accordance with pre-established instructions and procedures.

Article 6

Quality control system

1. The business operator shall establish and maintain an effective quality control system.

2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

Article 7

Documentation

1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article.

2. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering the various manufacturing operations performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system.

3. The documentation shall be made available by the business operator to the competent authorities at their request.

Article 8

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 August 2008.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 December 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Detailed rules on good manufacturing practice

Processes involving the application of printing inks to the non-food contact side of a material or article

1. Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:

   (a) through the substrate or;

   (b) by set-off in the stack or the reel,

   in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:

   (a) through the substrate or;

   (b) by set-off in the stack or reel,

   in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

3. The printed surfaces shall not come into direct contact with food.