FOOD STANDARDS AGENCY
SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

EXECUTIVE NOTE

The Materials and Articles in Contact with Food (Scotland) Regulations 2007 S.S.I. 2007/471

Description

1. The above instrument was made in exercise of the powers conferred by sections 16(2), 17 (1) and (2), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990 and paragraph 1A of Schedule 2 to the European Communities Act 1972. The instrument is subject to negative resolution procedure.

2. Policy Objective

2.1 This instrument provides for the enforcement in Scotland of Commission Regulation (EC) No. 2023/2006 (the "GMP Regulation"), on good manufacturing practice for materials and articles intended to come into contact with food, and implements Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with food ("the RCF Directive").

2.2 This instrument revokes The Materials and Articles in Contact with Food (Scotland) Regulations 2005 (SSI 2005 No. 243) as amended ("the 2005 Regulations") in their entirety, and re-enacts them with additional provisions for the enforcement of the GMP Regulation and with amendments where necessary to implement the RCF Directive. The implementation does not introduce substantive new provisions, but simply brings legislative references up to date.

3. Legislative Background

3.1 Under Article 3 of the Framework Regulation (EC) No. 1935/2004 general requirements, all materials and articles falling within the scope of that Regulation have to be manufactured in compliance with 'good manufacturing practice (GMP)'. However, the term has not been further elaborated upon until now. The UK and some other European Union (EU) Member States have sought clarification on 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.

3.2 This instrument will provide for the enforcement, in Scotland by local authorities, of the GMP Regulation, which will apply from 1 August 2008 and is directly applicable in all EU Member States. The time between entry into force of the GMP Regulation and the application of its provisions provides time for businesses that are affected by the Regulation to ensure they have sufficient provision in place to meet the Regulation's requirements on quality control systems, procedures and documentation. Provisions relating to this enforcement include identifying offences that may be prosecuted before the Courts where alleged breaches of the regulations arise, and providing for defences and transitional arrangements in accordance with the GMP Regulation.

4. Policy Background

4.1 It is the intention that the law on materials and articles intended to be brought into contact with food should protect human health from any chronic acute health effect over a person's lifetime arising from the consumption of food that could be contaminated with chemicals used in the manufacture of the materials and articles. The intention is particularly to protect consumers from substances that might be carcinogenic, mutagenic or toxic to reproduction. It also aims to protect the nature and quality of the food concerned and to provide the industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty seven EU Member States.

4.2 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 an Annex specifically on inks follows the 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.

4.3 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 EU. The GMP Regulation seeks to ensure that materials and articles intended for use in contact with foods are consistently produced and controlled to conform with the rules applicable to them and with quality standards appropriate to their intended purpose.

4.4 This SI will also implement the provisions of the RCF Directive. This Directive was adopted by the Standing Committee on the Food Chain and Animal Health and published in the Official Journal of the European Communities on 30 July 2007 (OJ L172, 30.7.2007, p.71-82) and entered into force on 20 July 2007. The new Directive consolidates the provisions of Directives 93/10/EC and 2004/14/EC on regenerated cellulose film and repeals and the two Directives it replaces. Their provisions were formerly implemented by the 2005 Regulations, which are being replaced by this instrument and references to those Directives will be changed by this SI. There are no new substantive provisions being implemented by this exercise, but merely an update.

4.5 Lastly, the SI makes provisions for references to certain EC instruments or parts of them to be construed as references to that instrument as it may be amended from time to time. The Legislative and Regulatory Reform Act 2006 makes such ambulatory references permissible where it seems necessary or expedient to the Scottish Ministers. The ambulatory references specified in the Regulations are to the GMP Regulation and to two Annexes to Directives which contain lists of chemical compounds and technical specifications that are subject to regular updating and amendment by the European Commission. Use of the ambulatory references will obviate the need to introduce a new SI each time these Annexes or the GMP Regulation are updated.

5. Consultation

5.1 One hundred and sixty eight stakeholders were consulted on these proposals, from food industry organisations to manufacturers of affected materials and articles. We included others interested such as enforcement authorities, the Scottish Federation of Small

Businesses, consumer organisations and other non-government organisations. Industry and enforcement authorities fully support this proposal.

6. Other Administrations

6.1 This instrument applies in relation to Scotland only. Separate but parallel legislation is being enacted for England, Wales and Northern Ireland.

7. Impact

7.1 The Food Standards Agency fully consulted all stakeholders on the proposed Regulations. 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 on 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. Although the consultation confirmed that the measures proposed have no specific extra requirements that lay any identifiable new financial burdens on business, the Packaging and Films Association (PAFA) indicated that there may be some incidental costs to businesses arising as a result of the need to verify that their operations conform to the specific requirements laid down in Articles 5 and 7 of the GMP Regulation. However they were unable to quantify these.

7.2 LACORS (Local Authorities Coordinators of Regulatory Services) commented that whilst they were unable to quantify the additional costs involved as a result of enforcement authorities having to spend more time during inspections to assess how the principles of GMP were being applied by businesses, these costs were not likely to be significant.

7.3 Rural areas, members of ethnic communities of any particular racial group and disabled people are unaffected by these proposals. Charities and voluntary organisations are also unaffected by these proposals. This view is echoed by industry.

7.4 A Regulatory Impact Assessment has been prepared and is available at the address below.

Food Standards Agency Scotland
19 October 2007

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FINAL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

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

2. Purpose and Intended Effect

- **Objective**

2.1 The purpose of these proposals are to meet the Government's commitment to honour its EU obligations within the European Union; and 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 Scotland, of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice (the "GMP Regulation"). It will also put in place offences that may be prosecuted before the Courts where alleged breaches of the GMP Regulation 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 (Scotland) Regulations 2005 (SSI 2005 No. 243) as amended in their entirety, re-enact their provisions with amendments where necessary in relation to the provisions on regenerated cellulose film (RCF) and taking into account the enforcement provisions of the GMP Regulation. The provisions of RCF are not new provisions, but existing ones which will bring legislative references up to date.

2.4 This Regulatory Impact Assessment (RIA) is concerned only with the enforcement of the GMP Regulation so far as it applies to Scotland and does not cover provisions on RCF (see 2.12 below).

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 England, Wales and Northern Ireland.

2.6 The Regulations being proposed will be in place on 16th November 2007, but in relation to the enforcement provisions of the GMP Regulation, these will not apply until 1st August 2008.

- **Background**

2.7 Under Article 3 of the Framework Regulation (EC) No. 1935/2004, general requirements, 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 upon 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 the European Food Safety Authority concluded that there was no health risk arising from this incident, the presence of the chemical was undesirable and preventable.

2.8 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.

2.9 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 to meet the Regulation's requirements on quality control systems, procedures and documentation.

2.10 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 are capable of complying with the applicable legal requirements in respect of chemical migration under foreseeable conditions of food contact.

2.11 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.

- Regenerated Cellulose Film (RCF)

2.12 Commission Directive 2007/42/EC on materials and articles made of regenerated cellulose film intended to come into contact with food was adopted by the European Commission's Standing Committee on the Food Chain and Animal Health. The amending Directive was published in the Official Journal (OJ) of the European Union on 30 July 2007 (OJ L172, 30.7.2007, p.71-82). Full details of are available at the following website address below:

http://europa.eu.int/eur-lex/lex/JOHtml.do?uri=OJ:L:2007:172:SOM:EN:HTML

2.13 This Directive consolidates Commission Directives 93/10/EC and 2004/14/EC on regenerated cellulose film, which were implemented by The Materials and Articles in Contact with Food (Scotland) Regulations 2005 (SSI 2005 No 243). At the same time the Commission has codified the provisions of these two Directives in the newly adopted version by bringing legislative references up to date. The new Directive entered into force on 20 July 2007 and the two Directives that it replaced are repealed.

2.14 The substantive provisions of the new codified Directive were implemented in Scottish law when the original Directives it replaces were implemented. There are no new provisions to be implemented by the proposed Regulations or to be assessed by this RIA. References to the original Directives are being changed to refer to the new codified Directive. Given that this is only a technical change of detail, which does not need a formal consultation, the changes will be undertaken in the proposals contained here. Similar provisions are being proposed by the other administrations in England, Wales and Northern Ireland.

- **Rationale for Government Intervention**

2.15 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 that do not conform to the requirements deemed necessary to assure protection of the health of consumers.

2.16 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 Other government departments included in the informal consultation process were the Scottish Government DG Health & Wellbeing and DG Rural Affairs & Environment. To date, no adverse comments have been received.

- **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 Scotland. 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 September 2006 when those proposals were last amended following the UK's intervention at EU level. To date, no comments have been received from stakeholders who indicate any financial implications associated with the GMP Regulation.

3.3 Formal consultation on these regulatory proposals for Scotland was carried out in May 2007, and involved 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.

- **Result of Consultation**

3.4 One hundred and sixty eight stakeholders were consulted on these proposals. These ranged from food industry organisations to sector specific organisations such as those manufacturers of materials and articles intended to come into contact with food and others with an interest in food contact materials legislation. We also consulted enforcement authorities, the Scottish Federation of Small Businesses, consumer organisations and other non-government organisations.

3.5 Only 3 responses were received two of which were no comment, the other one was from Packaging and Films Association (PAFA), which is one of the trade associations representing major UK manufacturers of plastic and cellulose films, as well as companies that print and convert speciality packaging materials. Consultation comments on drafting detail have been acted upon where necessary.

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 Government's 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 food. At the time the GMP Regulation becomes applicable, we are required to provide for its enforcement in Scotland, notably 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.

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; their distributors; and processors.

5.2 Local 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 also be affected.

Benefits

- **Option 1**

5.4 There are no identifiable incremental benefits for this Option.

- **Option 2**

5.5 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. This view is supported by PAFA, who commented that pursuit of option 2 will be beneficial for businesses involved in the manufacture of food contact materials and articles, as the Regulations will indeed provide for a non-discriminatory competitive environment, both on the domestic front and across the EU area, which can enhance opportunities for trade.

5.6 Consumers in the UK will enjoy the same degree of protection from potential contamination of foodstuffs as other countries throughout the EU. This option will ensure that the chances 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 Local authorities will benefit from the greater clarity provided by the GMP Regulation.

Costs

- **Option 1**

5.8 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 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.

5.9 No further incremental costs have been identified for this option.

- **Option 2**

5.10 By enabling enforcement of the GMP Regulation, for defences against alleged offences, and for penalties upon conviction for an offence, enforcement authorities will incur additional resource costs. However, LACORS (Local Authorities Coordinators of Regulatory Services) commented that they were unable to quantify the additional costs involved as a result of enforcement authorities having to spend more time during their inspections to assess how the principles of GMP were being applied by businesses. These costs are not predicted to be significant.

5.11 There may be some incidental costs to businesses arising as a result of the need to verify that their operations conform to the specific requirements laid down in Articles 5 (requiring businesses to have in place quality assurance system) and 7 (specifying appropriate documentation) of the GMP Regulation. 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.

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.

5.14 Stakeholders were asked in particular to comment on the social and environmental costs arising from these proposals. These include rural areas, disabled people, and members of the ethnic communities; charities and voluntary organisations. PAFA commented that they were in full support of the Agency's assessment that resource implications would be negligible.

5.15 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 that will contribute to reducing waste and loss in manufacturing. This view was supported by PAFA.

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 Scottish Federation of Small Businesses and the Forum of Private Businesses (FPB) were consulted. 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. No further comments have been received from the FPB following the end of the consultation.

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.

[1] Mintel, April 2003

6.3 In 2001, the plastic film 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 'TEST RUN' OF BUSINESS FORMS

7.1 There are no forms associated with this piece of legislation.

8. Competition Assessment

8.1 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 Scotland 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, 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.

8.2 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.

8.3 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. This view was supported by PAFA, who believe that the objectives of protecting consumer health, facilitating fair competition in the area of food contact materials and articles and minimising burdens placed on the regulated community, are adequately fulfilled by the agreed text of the GMP Regulation.

8.4 The consultation carried out in September 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 2.7, 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.

8.5 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.

9 Enforcement, sanctions and monitoring

- **Enforcement**

9.1 Local 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 currently enforced by The Materials and Articles in Contact with Food (Scotland) Regulations 2005. Thus, the proposed Regulations on which we have consulted merely provide the means by which this role can be extended to cover also the GMP Regulation, which will be enforced by local authorities.

- **Sanctions**

9.2 The same level of criminal sanctions that currently exist in the Materials and Articles in Contact with Food (Scotland) 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 the proposed Regulations and is liable 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 6 months or a fine not exceeding level 5 on the standard scale or both.

- **Monitoring**

9.3 The authorities in Scotland 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.

10 Implementation and delivery plan

10.1 The majority of the provisions in the Statutory Instrument (SI) are intended to come into force on 16th November 2007. However, the provisions concerning GMP will not apply until 1st August 2008.

10.2 Guidance for businesses has been developed and will be sent to all stakeholders consulted, informing them of the changes in these proposals. The guidance will also be published on the Agency's website at www.food.gov.uk. Information about the new Regulations will also be disseminated in an explanatory note, which covers current issues on food contact materials and any future ones. This note is updated periodically and is a useful tool, which is designed to provide a general introduction to EU harmonised legislation and its implementation in the UK.

11 Post-implementation review

11.1 Member States are obliged under the provision of the GMP Regulation to ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with the GMP Regulation. The authorities in Scotland routinely monitor foodstuffs on sale to the public to ensure compliance with regulations. The results of this work are published and are openly available. We shall, therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations and work with enforcement authorities where problems or suspected infringements of the Regulations arise. The effectiveness of the SI 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.

12 Summary and recommendations

12.1 The proposals here provide for the effective enforcement of the GMP and they also provide businesses with harmonised rules that apply across the European Union.

12.2 The Agency believes that the advantages of full implementation of the proposals that the subject of this regulatory impact assessment will benefit industry, enforcement authorities and consumers. The measures proposed are important in providing the means for improved enforcement and essential consumer health protection and improved products. We recommend that the GMP Regulation is enforced and implemented in Scottish law and the 2005 Regulations are revoked and consolidated taking into account the provisions of the GMP Regulation. Industry fully supports the pursuit of Option 2 which has the desired effect in achieving the means of adequate enforcement of the GMP Regulation. **Option 2 is therefore recommended as a means of achieving this.**

- **Summary costs and benefits table**

12.3 The cost implications arising from the EC Regulation and as outlined in option 2 are negligible. The proposed Materials and Articles in Contact with Food (Scotland) Regulations 2007, merely

extend existing statutory controls so as to 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	• Possible infraction proceedings against the UK Government	• None identified.	• Enforcement 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. • Consumers
2	• No quantifiable information was received by the Agency following the consultation in August 2006 in respect of the GMP Regulation • The cost implications for businesses include a small administration cost of reading the new materials. However, since this is already a legal requirement, this is not a cost burden. • By enabling enforcement of the GMP Regulation, for defences against alleged offences, and for penalties upon conviction for an offence, enforcement authorities will incur some additional resource costs.	• Increased level of consumer confidence as the UK will enjoy the same enforced level of protection as the EU. • The new Scottish Regulations will ensure that measures, which are applicable throughout the EU are in place, thereby creating a 'level playing field' and facilitating further trade.	• Enforcement 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. • Consumers

13 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

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THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2007 ("THE REGULATIONS")

TRANSPOSITION NOTE FOR COMMISSION DIRECTIVE 2007/42/EC RELATING TO MATERIALS AND ARTICLES MADE OF REGENERATED CELLULOSE FILM INTENDED TO COME INTO CONTACT WITH FOODSTUFFS ("THE DIRECTIVE")

The Directive is transposed by Part 4 of the Regulations. The Regulations also provide for enforcement and administration of Commission Regulation (EC) No. 1935/2004 and Commission Regulation (EC) No. 2023/2006 and for the application of Articles 2, 7 and 8 of Commission Directive 2002/72/EC.

The following table demonstrates how each relevant provision of the Directive has been given effect in the Regulations:

Article	**Implementation**
Article 1 and Annex I: Article 1 to the Directive applies the directive to regenerated cellulose film. Annex I defines regenerated cellulose film.	 Article 1 is implemented by regulation 10(1). Annex I is implemented via regulation 2(1) (Interpretation).
Article 2: Article 2 specifies the types of regenerated film to which Article 1 applies.	 Article 2 is implemented by regulation 10(3).
Article 3 and Annex II: Article 3 and Annex II (as it relates to Article 3) set out the requirements for manufacture of uncoated regenerated cellulose film and coated regenerated cellulose film with coating derived from cellulose. Article 3(2) permits derogation from Article 3(1) in relation to colourings and adhesives provided that there is no trace migration of substances into or onto foodstuffs.	 Article 3 and Annex II (as it relates to substances used for manufacture) are implemented by regulation 10(3)(a) which makes reference to Annex. Article 3(2) is implemented in regulation (10)(5).
Article 4 and Annex II: Article 4 and Annex II (as it relates to Article 4) set out the requirements for manufacture of coated regenerated cellulose film with coating consisting of plastics. Article 4(3) requires that coated regenerated cellulose film with coating consisting of plastics should also comply with Articles 2, 7 and 8 of Directive 2002/72/EC.	 Article 4(1) and (2) and Annex II (as it relates to Article 4(1) and (2)) are implemented by regulation 10(3)(b) which makes reference to the First Part of Annex II. Article 4(3) is given effect to by regulation 10(4) and by regulation 11 which writes out the requirements of Articles 2, 7 and 8 of Commission Directive 2002/72/EC insofar as they relate to regenerated cellulose film.
Article 5: Article 5 specified that printed surfaces of regenerated cellulose film must not come into contact with foodstuffs.	 Article 5 is implemented in regulation (10)(7)(b).
Article 6: Article 6 requires that materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs should be accompanied by a written declaration.	 Article 6 is implemented by regulation 10(8).