

Explanatory Memorandum
The Materials and Articles in Contact with Food (Wales) Regulations
2007

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales.

1. Description

1.1 This Statutory Instrument provides enforcement measures in Wales for Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (“the GMP Regulation”) which establishes the principles to be proportionately observed by businesses and lays down specific requirements for the application of printing inks to non-food contact surfaces 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”).

1.2 This instrument revokes The Materials and Articles in Contact with Food (Wales) Regulations 2005 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.

2. Matters of special interest to the Subordinate Legislation Committee

2.1 None.

3. Legislative Background

3.1 Welsh Ministers have the required powers under section 16(2) and 17(1) and 2 and 26(1)(a), 2(a) and (3) and 48 (1) of the Food Safety Act 1990. The provisions of the Act were transferred from the National Assembly for Wales to Welsh Ministers under the provisions of the Government of Wales Act 2006. The Regulations are subject to the negative resolution procedure.

3.2 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.

3.3 The Regulations will provide for the enforcement, in Wales by local authorities and port health 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. Purpose and intended effect of the legislation

4.1 The Materials and Articles in Contact with Food (Wales) Regulations 2007 are being made to provide enforcement measures in respect of Commission Regulation (EC) No. 2023/2006. 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 effects 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. 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 for an offence under them.

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 The Regulations 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 Finally, the Regulations 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. 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. Implementation

5.1 It is intended that these Regulations will come into force on 6 December. Parallel legislation is being introduced in England to come into force on 29 October. Parallel legislation is also being made in Scotland and Northern Ireland to come into force during November.

6. Consultation

6.1 A formal consultation on the proposals with interested parties in Wales concluded on 4 August. There were no responses from over 50 interested parties in Wales. In England, some 207 organisations were consulted on these proposals, including representatives from food industry organisations to manufacturers of affected materials and articles, enforcement authorities, the Enterprise Directorate (formerly the Small Business Service (SBS)), Forum of Private Businesses (FPB), consumer organisations and other non-government organisations. Industry and enforcement authorities fully supported the proposals.

7. Regulatory Impact Assessment

7.1 A Regulatory Impact Assessment is included in this Explanatory Memorandum.

Regulatory Impact Assessment

8. Options

8.1 Option 1: Do nothing. Doing nothing will not affect the requirements of the GMP Regulation as this is already legally binding and will be 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.

8.2 Option 2: Put in place the domestic regulations which provide for the execution and enforcement of the Commission Regulation. 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 Wales, 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.

9. Sectors and groups affected.

9.1 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. Local authorities and port health authorities are responsible for enforcing legislation with respect to food safety and will therefore also be affected. Consumers of foods placed in contact with the materials and articles subject to the provisions of the GMP Regulation will also be affected.

10. Benefits

10.1 **Option 1:** There are no identifiable incremental benefits for this Option. Doing nothing provides no consumer protection because the requirements of the Commission Regulation cannot be enforced.

10.2 **Option 2:** 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.

10.3 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> .

10.4 Local authorities will benefit from the greater clarity provided by the GMP Regulation.

11. Costs

11.1 **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 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. No further incremental costs have been identified for this option.

11.2 **Option 2.** 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. 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.

12. Competition Assessment

12.1 The Competition Filter Test has been completed and it has confirmed that none of the options raises competition concerns. The provisions for enforcement powers for the proper authorities in Wales 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.

12.2 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.

12.3 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.

12.4 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, 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.

12.5 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.

13. Consultation

Within Government

13.1 The Food Standards Agency (FSA) has sole policy responsibility for ensuring food safety.

Public consultation

13.2 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 Wales. 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 who indicate any financial implications associated with the GMP Regulation.

13.3 Informal meetings with the key industry sectors have also taken place as the GMP Regulation that gives rise to these proposals was being negotiated. Formal consultation on these regulatory proposals was carried out 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.

13.4 In England, two hundred and seven 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 Enterprise Directorate (formerly the Small Business Service (SBS) – part of the Department for Business, Enterprise and Regulatory Reform), Forum of Private Businesses (FPB), consumer organisations and other non-government organisations. Only 5 responses were received and these were 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. One from the Laboratory of the Government Chemist (LGC), one from LACORS, one from the British Coatings Federation and one from the British Ceramic Federation. Consultation comments on drafting detail have been acted upon where necessary. . A formal consultation on the proposals with interested parties in Wales concluded on 4 August. There were no responses from over 50 interested parties in Wales.

14. Implementation and review

14.1 The majority of the provisions in the Statutory Instrument (SI) are intended to come into force on 6 December 2007. However, the provisions concerning GMP will not apply until 1 August 2008. Guidance for businesses has been developed and sent to all stakeholders consulted, informing them of the changes in these proposals. The guidance has also been 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.

14.2 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 Wales 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.

15. Summary

15.1 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. The Food Standards 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 Welsh 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 a means of achieving this.**

