

REGULATORY IMPACT ASSESSMENT

The Contaminants in Food (Wales) Regulations 2003

1. TITLE OF PROPOSED MEASURE

The Contaminants in Food (Wales) Regulations 2003

Commission Directive 2002/69/EC of 30 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like polychlorinated biphenyls (PCBs) in foodstuffs.

2. PURPOSE AND INTENDED EFFECT OF MEASURE

(i) The Objective

The Contaminants in Food (Wales) Regulations 2003 extend to Wales only and revoke and re-enact with changes the Contaminants in Food (Wales) Regulations 2002 as amended. The Regulations-

- (a) make provision for the enforcement and execution of Commission Regulation (EC) 466/2001, as amended, setting maximum levels for certain contaminants in foodstuffs, and
- (b) implement Commission Directives 98/53/EC, as amended; 2001/22/EC; 2002/26/EC; and 2002/69/EC.

Commission Regulation 466/2001 as amended by Council Regulation 2375/2001 introduced maximum permitted levels for dioxins and furans in foodstuffs. The limits have applied since 1 July 2002. Specific limits for polychlorinated biphenyls (PCBs) have not yet been set, but the Regulation commits the Commission to reviewing this legislation by 31 December 2004 with a view to inclusion of dioxin-like PCBs in the levels to be set.

The intention of Commission Directive 2002/69/EC is to support the above legislation on unacceptable levels of these potentially harmful contaminants in food by ensuring effective and consistent enforcement procedures. In particular, it lays down the sampling methods and the methods of analysis for the official control of dioxins and the determination of PCBs in foodstuffs.

This RIA is concerned only with the implementation of Commission Directive 2002/69/EC, as Commission Regulation 466/2001 and the allied Directives 98/53/EC, 2001/22/EC and 2002/26/EC have already been implemented and dealt with in past RIAs¹. Directive 2002/69/EC relates specifically to the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs and applies to Enforcement Authorities only, as they are responsible for undertaking the official controls. The procedures introduced by the Directive are those already considered to be best practice by those

¹ Consultations on this Regulation and the Directives were carried out under The Contaminants in Food (England) Regulations 2002 in July 2002 (aflatoxins in spices) December 2001 (ochratoxin A) and March 2002 (lead, cadmium, mercury, dioxins, 3-MCPD and nitrate).

laboratories in the UK that are accredited to carry out dioxins analysis for enforcement purposes. In addition, Article 2 to the Directive makes provision for the adaptation of the methods of sampling and the methods of analysis to take account of advances in scientific and technological knowledge.

(ii) Devolution

The implementation of the Directive applies to the UK. The Contaminants in Food (Wales) Regulations 2003 transpose the Directive into national law in Wales and would revoke and replace *The Contaminants in Food (Wales) Regulations 2002*, as amended. Corresponding Regulations will be introduced separately in Scotland, England and Northern Ireland.

(iii) Background

Dioxins are toxic substances produced during various combustion and incineration processes and they are also unwanted by-products in the manufacture of certain chemicals. Dioxins are persistent organic pollutants that degrade only slowly and so are widespread in the environment. Levels in food reflect current and historical emissions of dioxins from industry and other sources, both man made and natural.

Risks to consumers from these contaminants are chronic and are assessed against long-term dose. In 2001, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) completed a review on dioxins and dioxin-like PCBs (a group of related chemicals that have similar toxicological effects). The COT recommended that the tolerable daily intake (TDI) of these chemicals should be reduced from 10 pg TEQ/kg bw/day to 2 pg TEQ/kg bw/day. According to estimates based on the average 1997 diet, about 36% of the UK population may exceed the TDI. Most young children are likely to exceed the TDI, primarily because they need to eat comparatively more than adults in relation to their body size. Reducing consumer exposure to these chemicals is an Agency and a European Commission priority. Setting maximum permitted limits forms part of a Commission strategy to reduce the presence of dioxins and PCBs in the environment and in food and feed. This measure protects consumer health by excluding grossly contaminated food entering the food chain as part of this overall strategy to reduce human exposure to dioxins.

Commission measures have been introduced under the contaminants framework Regulation, Council Regulation EEC 315/93², that set limits in food not covered by other specific Community legislation. Commission Regulation 466/2001, as amended, sets maximum levels for certain contaminants in foodstuffs and maximum permitted limits for dioxins and furans in certain foodstuffs have applied since 1 July 2002.

Commission Directive 2002/69/EC has been developed to meet the need for appropriate harmonised sampling and analytical methodology. Until the Contaminants in Food (Wales) Regulations 2003 come into force enforcement

² Council Regulation EEC 315/93 of 8 February 1993, laying down Community procedures for contaminants in food, allows the Commission to set limits for contaminants in food not covered by specific Community legislation. Commission Regulation 466/2001, as amended, was introduced under this procedure.

officials in Wales will continue to carry out sampling and analysis to ensure compliance with food safety legislation in accordance with the provisions of the Food Safety (Sampling and Qualifications) Regulations 1990.

(iv) Risk Assessment

The Food Safety (Sampling and Qualifications) Regulations 1990 make provision for national standards for the qualifications of food analysts and general sampling procedures but do not specify methods of analysis. Agreed harmonised methods of sampling and analysis are key to the consistent and effective enforcement of the limits introduced by Commission Regulation 466/2001, as amended. Commission Directive 2002/69/EC lays down the requirements and criteria for laboratories, sample preparation, analytical procedures and reporting of the results to be used for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. The procedures introduced by the Directive are those already considered to be best practice by those laboratories in the UK which are accredited to carry out dioxins analysis for enforcement purposes.

The introduction of harmonised statutory controls would help to reduce uncertainty or dispute in interpreting results against limits and would reduce inconsistency or dispute of sampling and analytical procedures. This would provide benefits to Industry and consumers in improved confidence in compliance testing. Failure to adopt harmonised sampling and analytical controls would undermine enforcement bodies' ability to effectively, and efficiently enforce the legislation. Inconsistent application of the law could result in trade barriers or dispute and undermine consumer confidence in consumer protection offered by the dioxins limits.

(v) Business Sectors Affected

The Directive relates specifically to the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. The draft Contaminants in Food (Wales) Regulations 2003 apply to Enforcement Authorities as they are responsible for undertaking the official controls. There are 22 Local Authorities (of which 4 are also Port Health Authorities) 1 stand alone Port Health Authority and 3 Public Analyst Laboratories in Wales, and it is these sectors that are likely to be directly affected by these measures. Industry is not obliged to follow the sampling methods or methods of analysis introduced by the Directive. The effects of this Directive on businesses will therefore be neutral.

The Directive does not specify any additional levels of enforcement sampling and analysis for dioxins in food. The maximum limits have applied since 1 July 2002 and Enforcement Authorities should already be carrying out tests for dioxins to ensure compliance with the EU legislation and national legislation under The Food Safety Act 1990. There is therefore no new burden on Enforcement Authorities. They will, however, need to make risk-based judgements on the relative priorities of this and other aspects of food law enforcement when deciding how to use their resources. We acknowledge that the current cost of analysis for dioxins in food is high and any programme of enforcement of the maximum limits is therefore likely to take up a

significant proportion of the budget Enforcement Authorities have available for food law enforcement. We acknowledge that local authority sampling across a range of food types for a range of parameters is important for effective food control.

The cost of analysis for dioxins is currently £400 to £500 per sample. These costs would apply to analysis for official control by enforcement authorities irrespective of whether the specific provisions of the Directive were implemented or not. We therefore believe that the cost to enforcement authorities of compliance, that is, the difference in costs now compared to the costs after this Directive is implemented, will be nil.

In addition, the new legislation provides that a screening method of analysis with proven, widely acceptable validation and high throughput could be used to select the samples with significant levels of dioxins. For example, bio-assay techniques, that meet the relevant quality criteria, may be used for screening purposes at a cost of around £150 per sample. This should reduce costs to Enforcement Authorities.

There are no laboratories in the UK that are accredited for these analyses. Public Analysts are responsible for enforcement testing but do not yet have the capability to carry out dioxins tests themselves. Analysis in a laboratory not having a Food Analyst can be undertaken, but only under the direction of the Public Analyst, who will need to take appropriate steps to ensure that the requirements of such direction are fully satisfied in order to avoid the potential for legal challenge.

Information provided by the Association of Public Analysts has suggested that in order for Public Analysts to carry out dioxins analysis themselves, significant costs would be incurred. In order for Public Analysts to make business judgements on whether to make this investment they will need information from Enforcement Authorities on their intended levels of sampling foods for dioxins.

Costs of equipping a laboratory to perform chromatographic analysis for dioxins in food

- Capital equipment £200,000
- Staff and training £150,000
- Consumables £50,000

Costs of equipping a laboratory to perform screening bio-assay for dioxins in food

A Public Analyst Laboratory could be equipped to carry out screening analyses using the bio-assay techniques, using the procedure under licence.

- Capital equipment £20,000
- Staff and training £10,000

(vi) Issues of Equity and Fairness

The legislation applies to the determination of one class of chemicals in a limited number of foodstuffs, for official control purposes. The scope of the legislation has implications for resource prioritisation by Local Authorities and Port Health Authorities responsible for enforcing the legislation.

3. OPTIONS

Option 1 Do nothing

Option 2 Develop non-statutory guidance for dioxins sampling and analysis for enforcement bodies

Option 3 Transpose Commission Directive 2002/69/EC into national law as *The Contaminants in Food (Wales) Regulations 2003*. Corresponding Regulations would be introduced separately in Scotland, England and Northern Ireland.

4. BENEFITS

Option 1

This is not a viable option since the UK has a legal obligation to implement the Directive. Non-implementation would:

- result in infraction proceedings against the UK government; and
- not promote effective and efficient enforcement of the dioxin limits laid down in Commission Regulation 466/2001, as amended.

Risks to health were addressed by Regulation 466/2001. The Directive supports this legislation by ensuring effective and consistent enforcement procedures across the EU. Non-implementation will leave the UK without specific statutory sampling procedures for the effective enforcement of the maximum limits for dioxins in foodstuffs. This could result in trade barriers or dispute and undermine consumer confidence in the increased levels of consumer protection intended by Regulation 466/2001.

Option 2

As highlighted in Option 1 above, the UK has a legal obligation to implement the Directive. Provision of non-statutory guidance rather than implementing the Directive would result in infraction proceedings against the UK government. The lack of national recognition of the effectiveness of harmonised official controls may have an impact on trade.

The costs of non-implementation are those highlighted above.

Option 3

Transposition of the Directive into national law would fulfil national obligations to implement this measure. The legislation would promote consistent and effective enforcement across the EU by reducing uncertainty or dispute in interpreting results against limits. This will benefit Industry and consumers through improved confidence in compliance testing.

There are no quantifiable health risks or benefits arising from implementation of the Directive.

5. COSTS FOR BUSINESSES, CHARITIES AND VOLUNTARY ORGANISATIONS

The Directive relates to enforcement testing only and therefore the primary implications of implementing this Directive are for Enforcement Authorities. Costs are those discussed at paragraph 2(v) above.

There is no requirement for general food manufacturing businesses to carry out additional sampling within the Directive or Commission Regulations, and Industry is not obliged to follow the sampling and analysis procedures in the Directive. However, they may wish to do so when carrying out their checks to satisfy the 'due diligence' requirement under the Food Safety Act 1990 and ensure compliance with the maximum limits set in Commission Regulation 466/2001, as amended.

6. SMALL FIRM'S IMPACT TEST

The Small Business Service, the Federation of Small Businesses and the British Chamber of Commerce were included in the consultation. The Small Business Service has indicated that it "is generally content with the measures as they do not appear to have an impact on small businesses".

7. COMPETITION ASSESSMENT

We would not expect Options 1 and 2 to affect competition for laboratory services since these retain the status quo. As highlighted above, the Directive introduces procedures that are already considered to be best practice by those laboratories in the UK that are accredited to carry out dioxins analysis for enforcement purposes. We would therefore not expect the implementation of the Directive under Option 3 to have a significant impact on competition.

The Directive sets certain requirements and criteria for the methods of analysis for the official control of dioxins. At present there are 3 Public Analyst Laboratories in Wales. Public Analysts are responsible for enforcement testing but are currently not set up to carry out dioxins and PCB testing. Where Public Analysts carry out this work they have to outsource to specialist non-control laboratories here and overseas. Currently there are no

laboratories in Wales accredited to carry out dioxins and PCB testing. Of these, only one is an Official Food Control Laboratory.

There are several existing barriers to entry for organisations wishing to enter the market for provision of dioxin and PCB testing. High-resolution gas chromatography coupled with high-resolution mass spectrometry is currently the reference methods used in the determination of very low concentrations of dioxins and PCBs. The purchase of this equipment has an initial high cost and is also very expensive to maintain. In addition, all laboratories that wish to carry out analysis for enforcement purposes must be accredited. Consequently, there are few laboratories carrying out dioxin and PCB testing. However, whilst the market for dioxin and PCB testing is concentrated and barriers to entry exist, the Directive should not create any new barriers to entry.

The Directive makes provision for the use of screening methods of analysis including bio-assay techniques which meet the relevant criteria. These have lower set-up costs. However, any positive result has to be confirmed by the instrumental procedures referred to above.

The Directive makes provision for adaptation of the methods of sampling and methods of analysis to take account of advances in scientific and technological knowledge. It is not possible to predict the nature of such advances and when they might arise. It is however, a reasonable expectation that such advances would lead to a reduction in analytical costs.

8. ENFORCEMENT AND SANCTIONS

(i) Enforcement

Local Authorities and Port Health Authorities are responsible for enforcing Food Safety Regulations.

(ii) Sanctions

Local Authorities and Port Health Authorities will be responsible for enforcing The Contaminants in Food (Wales) Regulations 2003. The criminal sanctions in these Regulations, a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding three months, would apply in the case of breaches of the limits.

9. MONITORING AND REVIEW

The Food Standards Agency will continue to consult with enforcement, Industry and other stakeholders to evaluate the effectiveness of and experience with the legislation.

10. RESULTS OF CONSULTATION

(i) Within Government

Other Government Departments including the Department for Environment Food and Rural Affairs, the Department of Health, the Department of Trade and Industry and the Cabinet Office were made aware of the Directive through Commission working group meetings reports and Interested Party letters. On 9 July 2002, the Agency also circulated an agreed draft copy of the Commission Directive.

(ii) Public Consultation

This is a technical issue and a limited consultation with Public Analysts was carried out via the Agency's Information Bulletins on Methods of Analysis and Sampling – Bulletins 14, October 2001; 20, June 2002; and 22, July 2002. In addition, the Association of Public Analysts, LACORS and the Association of Port Health Authorities were made aware of the Directive throughout the discussions on the proposed measures on dioxins through Interested Party letters.

Interested Parties including consumer groups were made aware of the Directive throughout discussions on the proposed measures on dioxins, through Interested Party letters, in particular of 5 December 2001 and 29 November 2001. On 9 July 2002, the Agency also circulated an agreed draft copy of the Commission Directive to Interested Parties including Enforcement Authorities.

During the formal consultation from 5 February 2003 to 30 April 2003, the Agency sent out nearly 400 consultation packages to stakeholders (including Enforcement Authorities, Consumer Groups, Trade Associations, Industry, the Small Business Service and Other Government Departments), including 85 in Wales. Only 9 responses were received, none of which came from Wales and these are summarised at Annex 3. In summary, respondents provided the Agency with up to date costs of analysis for dioxins and the costs of the bio-assay screening methods. Other comments included the possible implications for the Public Analyst system and those authorities operating a Public Analyst Laboratory. The APA stressed that Public Analysts are responsible for enforcement testing and that "irrespective of issues of long-term funding, a facility for testing will need to be set up within the Public Analyst service.

The Agency acknowledges that analysis for dioxins is expensive and that Public Analysts Laboratories are currently unable to carry out the work themselves. The Agency highlighted these issues in an earlier RIA on *The Contaminants in Food (England) Regulations 2002*. The Agency consulted widely throughout the negotiations on the maximum limits for dioxins and requested information from Enforcement Authorities on the implications that statutory limits would have on them. However, we received little quantified information at that time. The limits have applied since 1 July 2002 and the costs of analysis and the current situation with the Public Analyst service would apply irrespective of whether Directive 2002/69/EC was implemented or not.

11. SUMMARY AND RECOMMENDATIONS

Options are limited to those identified above. We expect there to be no significant differences in costs to Enforcement Authorities between the options. Option 3 is the only one that would avoid the potential costs to Government of infraction proceedings and costs to Industry posed by dispute in interpretation of enforcement testing results. It is therefore recommended that **Option 3 is supported**.

The Directive relates specifically to the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs. It lays down requirements and criteria for laboratories, sample preparation, the analytical procedures and the reporting of the results to be used for the official control of dioxins and the determination of dioxin-like PCBs in foodstuff. The procedures introduced by the Directive are those already considered to be best practice by those laboratories in the UK which are accredited to carry out dioxins analysis for enforcement purposes. The Directive also makes provision for the adaptation of the sampling and methods of analysis to take account of advances in scientific and technical knowledge.

There is currently a limited capacity for analysis of dioxins in food by suitably accredited laboratories in the UK, and the capital investment needed to increase this capacity is substantial. The current cost of analysis for dioxins in food specified in the Directive is high and any programme of enforcement of the maximum limits is likely to take up a significant proportion of the budget Enforcement Authorities have available for food law enforcement. However, the Directive does not specify any level of enforcement sampling and analysis for dioxins in food. There is therefore no new burden on Enforcement Authorities.

The new legislation provides that a screening method of analysis, with proven, widely acceptable validation and high throughput could be used to identify those samples with significant levels of dioxins. Bio-assay techniques, that meet the relevant quality criteria, may be used for screening purposes. This should help to mitigate Enforcement Authorities' concerns regarding the costs of enforcing the maximum limits.

Implementation of statutory controls would promote effective and consistent enforcement by reducing inconsistency or dispute on the appropriateness of sampling and analytical procedures. Transposition of the Directive into national law would fulfil national obligations to implement the measure; other options would result in infraction proceedings against the UK. The legislation would also facilitate trade by harmonising controls across the EU.

Explanation of Units:

A picogram (pg) is equivalent to one million millionth of a gram (g);

pg TEQ/kg bw – picograms of the equivalent amount of the most toxic dioxin per kilogram of bodyweight.

Definition of TEQ:

Dioxins and PCBs are found as a mixture of chemicals with differing toxicity - the sum of these chemicals, weighted on the basis of the most toxic dioxin, gives the Toxic Equivalent (TEQ). The Toxic Equivalent system devised by the World Health Organisation (WHO) is used, so the figures are referred to as WHO TEQ's.

Definition of TDI:

A TDI is the amount of a substance that can be ingested daily over a lifetime without appreciable health risk. It is expressed in relation to the bodyweight (bw) in order to allow for different body size, such as for children of different ages. A daily intake of 10 pg/kg bw/day is 600 pg for the average 60 kg person.

Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the balance between cost and benefit is the right one in the circumstances.

Signed by the responsible Minister _____

Date _____

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