Explanatory Memorandum
The Contaminants in Food (Wales) Regulations 2009

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

1. Description

1.1 The purpose of the instrument is to revoke and re-enact with changes the Contaminants in Food (Wales) Regulations 2007 as amended and to provide the necessary measures to enforce three new European Commission Regulations introducing or revising maximum permitted levels (MPLs) for certain specified contaminants in food. The contaminants in question include dioxins, certain heavy metals and a group of veterinary products designed for use in animal feed.

1.2 The three new Commission Regulations mentioned in paragraph 1.1 are:

- Commission Regulation (EC) No. 565/2008 which amends Regulation 1881/2006 as regards MPLs for dioxins and dioxin-like polychlorinated biphenyls (PCBs) in fish liver;

- Commission Regulation (EC) No. 629/2008 amending Regulation 1881/2006 as regards MPLs for lead, cadmium and mercury in certain aquatic species and certain species of fungi and in food supplements; and

- Commission Regulation (EC) No. 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed.

2. Matters of special interest to the Subordinate Legislation Committee

2.1 None.

3. Legislative Background

3.1 Welsh Ministers have the powers to make the proposed Regulations pursuant to sections 16(1)(a), (e) and (f), 17 (2), 26(1)(a) and (3), and 48(1) of the Food Safety Act 1990 (as read with paragraph 1A of Schedule 2 to the European Communities Act 1972. Functions transferred to the National Assembly for Wales are now exercisable by Welsh Ministers by virtue of section 162 and paragraphs 28 and 30 of Schedule 11 to the Government of Wales Act 2006.

3.2 This Statutory Instrument provides for the execution and enforcement of Community legislation on food contaminants, including the new Commission Regulations detailed in paragraph 1.2. The instrument will also revoke the Contaminants in Food (Wales) Regulations 2007 (SI 2007/840 (W.73)) and the Contaminants in Food (Wales) (Amendment)

Regulations 2007 (SI 2007/3368 (W.297)) and re-enact them with necessary amendments.

3.3 European Community (EC) legislation on contaminants in food is made under the contaminants in food framework Regulation, Council Regulation 315/93/EEC. The Regulation lays down Community procedures for dealing with contaminants in food and it applies to those contaminants that are not covered by other specific Community legislation. In view of the disparities between the existing laws of Member States in regard to the maximum limits for contaminants in certain foodstuffs and the consequent risk of distortion of competition, Commission Regulation (EC) No. 1881/2006 was introduced under Council Regulation 315/93/EEC to ensure market unity while complying with the principle of proportionality. The provisions and requirements of Commission Regulation 1881/2006 (previously Regulation (EC) No. 466/2001) have applied across the EU since April 2002.

3.4 The intention of Commission Regulation 1881/2006 is to provide consumers with an increased measure of protection by setting EC maximum levels for mycotoxins and undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The Regulation aims to exclude seriously contaminated food from entering the food chain and harmonises Member States' existing measures, thus facilitating trade. Maximum levels for lead, cadmium, mercury, dioxins, polycyclic aromatic hydrocarbons (PAHs), nitrate, 3-MCPD, aflatoxins, ochratoxin A, patulin and inorganic tin have already been set under this legislation.

3.5 In view of the requirement to protect public health by keeping contaminants at levels that are toxicologically acceptable, the European Commission investigates whether limits should be set for additional contaminants and/ or foods and also reviews the maximum levels for those contaminants currently in the legislation.

3.6 In relation to Commission Regulation (EC) No. 565/2008, very high levels of dioxins and dioxin-like PCBs have been found in canned fish liver and reported through the Rapid Alert System for Feed and Food (RASFF) since 2006. No maximum level was established for fish liver and processed products thereof. In order to protect public health, competent authorities prohibited the placing on the market of those products because they were deemed to be unsafe. Thus it has been necessary to establish a Community maximum level for the sum of dioxins and dioxin-like PCBs in fish liver and its processed derivative products to protect public health and ensure a uniform approach in the internal market.

3.7 As regards Commission Regulation (EC) No. 629/2008, new information indicates that even good agricultural and fisheries practices are not sufficient to keep levels of lead, cadmium and mercury in certain aquatic species and certain species of fungi as low as is required in the Annex of Regulation (EC) No. 1881/2006. It is therefore expedient to revise the maximum levels fixed for those contaminants while also maintaining a high level of consumer health protection.

3.8 For Commission Regulation (EC) No. 629/2008, high levels of lead, cadmium and mercury have been found in certain food supplements and these have been notified through the RASFF. It has been shown that these particular food supplements - particularly cadmium which readily accumulates in seaweed - can contribute significantly to human exposure to these metals. In order to protect public health, it has therefore been necessary to set maximum levels for lead, cadmium and mercury in the particular food supplements. The maximum levels set are as safe and as low as reasonably achievable based upon good manufacturing practices. To allow Member States and food business operators' time to adapt to the new maximum levels for food supplements, the application of the maximum levels for food supplements has been deferred until 1 July 2009.

3.9 Commission Regulation (EC) No. 124/2009 was published in the Official Journal (OJ) of the European Communities on 11 February 2009 (OJ Ref: l40, 11.02.2009, pgs 7-11) setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed. The Regulation is applicable throughout the EU. It came into force on 2nd March 2009 and will apply from 1st July 2009.

3.10 Coccidiostats and histomonostats are veterinary medicines authorised for use in animal feeds. The occurance of unavoidable carry-over of coccidiostats and histomonostats in non-targeted feed, below maximum levels set under Directive 2002/32/EC may still lead to detectable residues of these substances in food products of animal origin. Because of the European Commission's concern about this possible carry-over into batches of feed that are not intentionally formulated with these veterinary medicines it has felt it necessary to introduce a Directive limiting the permissible amount of carry-over into feed, and at the same time, a Regulation limiting the resulting residue in food of non-target animals. This is intended to protect public health from the effects of adventitious carry-over. Until this point there has been no maximum residue limit (MRL) fixed for specific food in the frame of Council Regulation (EEC) No. 2377/90 that lays down MRL's for veterinary medicinal products in foodstuffs of animal origin. Nor has there been a provision in Regulation (EC) No. 1831/2003 that sets maximum tolerances for the presence of active substances contained in coccidiostats and histomonostats. Council Regulation (EEC) No. 315/93 laying down Community procedures for contaminants in food and it has therefore been amended to establish a provision for food of animal origin contaminated by the non-target feed concerned.

3.11 The main provisions of Regulation 124/2009 are:

- Article 1(1) provides that the foodstuffs listed in Annex to Regulation 124/2009 shall not be placed on the market where they contain a contaminant listed in this Annex at a level exceeding the maximum levels set in the Annex.
- In case of a finding of a significant residue below the maximum level set out in the Annex, it is appropriate for the competent authority to carry out investigations to confirm that the residue is present as a consequence of

unavoidable carry over in the feed and not as the consequence of illegal administration of the coccidiostat or histomonostat.

- Foodstuffs complying with the maximum levels set out in the Annex shall not be mixed with foodstuffs which exceed these maximum levels.
- Article 1(2) – when applying the maximum levels set out in the Annex to this Regulation to foodstuffs which are dried, diluted, processed or composed of more than one ingredient, changes of the concentration of the contaminant caused by drying, diluting or processing, as well as the relative proportion of the ingredients in the product shall be taken into account.
- Article 1(3) – the maximum levels established in the Annex to Regulation 124/2009 are without prejudice to the provisions and the MRLs (maximum residual levels) established by Council Regulation (EEC) No. 2377/90 and the MRLS established by Regulation (EC) No. 1831/2003.
- Article 3 provides that Regulation 124/2009 shall enter into force on the 20th day following publication in the OJ, will apply from 1st July 2009 and is binding in its entirety and applicable throughout the EU.

3.12 The proposed Contaminants in Food (Wales) Regulations 2009 have been revised to take into account the provisions of Regulation 124/2009.

4. Purpose and intended effect of the legislation

4.1 This Statutory Instrument assigns enforcement powers to the food authorities and port health authorities in Wales n respect of European Commission legislation on chemical contaminants in food. Doing so continues to fulfil the Government's commitment to implement EC legislation. In this case that commitment concerns the continuing protection of public health by keeping chemical contaminants in food at a safe level, while providing business operators with consistent, proportionate rules affecting their products.

4.2 Contaminants in food can have an adverse affect on human health. Most consumers are unable to identify the risks involved from ingesting chemical contaminants in food because they are unable to detect them and would be unable to assess the risk to their health over their lifetime of consuming contaminated products. Therefore, Government intervention on their behalf is required to reduce these impacts on health and to address the lack of informed consumer choice.

4.3 The intention of Commission Regulation 1881/2006 is to provide consumers with an increased measure of protection by setting EC maximum levels for mycotoxins and undesirable process and environmental contaminants in those foodstuffs that are significant contributors to the total dietary exposure of consumers to those contaminants. The Regulation aims to prohibit seriously contaminated food from entering the food chain and harmonise Member States' existing national measures, thus facilitating trade. Maximum levels for lead, cadmium, mercury, inorganic tin, dioxins, polycyclic aromatic hydrocarbons

(PAHs), nitrate, 3-MCPD, and certain mycotoxins including aflatoxins, ochratoxin A, and patulin among others have already been set under this legislation.

4.4 The proposed Regulations will apply in relation to Wales, the policy being enacted through these proposals in relation to the EU harmonised legislation, applies across the United Kingdom.

5. Implementation

5.1 It is intended that these Regulations should come into force on 1st July 2009. Parallel legislation is also being made to come into force in England, Scotland and Northern Ireland.

5.2 Guidance for business has been developed and formed part of the Stakeholder consultation on the proposed Regulations. Stakeholders were also asked to comment on the guidance, however no comments were received. The Guidance has been finalised and sent to stakeholders and has also been published on the Agency's website at www.food.gov.uk

6. Consultation

6.1 The Food Standards Agency fully consulted all stakeholders throughout the UK on the proposed Regulations. Within Wales over two hundred stakeholders were consulted. These ranged from food industry organisations to sector specific organisations, enforcement authorities and the National Assembly. There were no responses to the public consultation within Wales.

6.2 A total of 4 responses were received to the consultation in the rest of the UK; one from Laboratory of the Government Chemist (LGC), one from SEAFISH (the authority on seafood), one from Trading Standards, South East Group Ltd (TSSE) and one from a Port Health Authority (PHA (City of London))

6.3 All respondents have been thanked for their helpful comments and where necessary their views have been taken into account and appropriate actions taken. Where required, responses were sent.

6.4 A summary of the responses to the UK wide consultation exercise is contained in the Regulatory Impact Assessment below.

7. Regulatory Impact Assessment

8. Options

8.1 **Option 1:** Do nothing. Doing nothing contradicts the Government's commitment to meeting its EU obligations and fulfilling its policy on consumer protection in this area. It would also create potential for the UK to become liable for infraction proceedings and it would not be possible to

implement only parts of the proposal. It would contradict the important role the UK plays in negotiating the adoption of these rules to achieve it wider policy objectives for consumers and business and it would leave the regulation of contaminants in foodstuffs deficient in many ways in comparison with the main food legislation that now applies across the rest of the EU. Failure to fully implement the Commission Regulations would mean that prevailing national legislation would no longer accord with Community provisions. In addition, UK consumers would not have the same health protection as consumers in the rest of the EU.

8.2 **Option 2:** Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulations. This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the new Commission Regulations in Wales, which are binding in their entirety and directly applicable to all EU Member States.

8.3 **Option 3:** Carry out policy option 2 and in addition introduce the use of ambulatory references in the domestic Regulations. This option would fulfil all of the objectives achieved by carrying out option 2 and in addition would introduce ambulatory provisions (the use of ambulatory references will avoid the need to introduce a new statutory instrument each time the Annex to Commission Regulation (EC) NO. 1881/2006 is amended), to the domestic Regulations. This is the preferred option and is expected to achieve all the objectives outlined above.

9. Benefits

9.1 **Option 1:** There are no identifiable incremental benefits; (economic, social or environmental) associated this Option.

9.2 **Option 2:** This option would ensure that enforcement authorities within Wales, (local authorities and port health authorities), have adequate statutory powers to prevent the placing on the market of those commodities which fail to meet the maximum levels laid down in the Commission Regulations.

9.3 This option fully meets the Government's commitment to fulfil its EU obligations and contributes significantly to our agreed policy objective of protecting consumers from ingesting harmful levels of chemical contaminants in food. Commission Regulations are binding in their entirety and directly applicable in Member States from the date that they take effect. The UK has a legal obligation to ensure that provisions are in place to provide for their enforcement in full. Failure to do so may result in infraction proceedings against the UK government. This option would provide enforcement authorities with the necessary powers to enforce the European Regulations. Also, local authorities and port health authorities will benefit from the greater clarity provided by the European Regulations and from the power of enforcement devolved to them from these proposed Regulations.

9.4 This option would harmonise standards across Member States and prevent any barrier to trade occurring as a result of there being different Regulations in different individual Member States. It would prevent the UK from facing potential infraction proceedings from the European Commission and consolidate the important role that the UK plays in negotiating and agreeing standards for contaminants in food within the European Union.

9.5 It is also anticipated that some costs will be saved by the fish and mushroom industry as a consequence of maximum levels for lead, cadmium and mercury being relaxed.

9.6 Whilst the potential benefits to health are difficult to quantify they are likely to include reducing the risk of illness through exposure to cadmium, lead, mercury and dioxins. These chemicals have been associated with various adverse effects on human health, including carcinogenic, neurotoxic and immunotoxic effects. This option may therefore reduce such burden on the health service through prevention of chronic illness. In 1999, the Department of Environment, Food and Rural Affairs (DEFRA) published a report presenting economic evaluation of UK policy on chemical contaminants in food, which estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The aim of the evaluation was to assess whether current controls on chemical contaminants and naturally occurring toxins were cost effective and how these could be improved, taking into account the impact of such controls on consumers and the food supply chain. One of the report's conclusions was that the main beneficiaries were consumers, whilst the majority of the quantifiable costs had been borne by central government. The report is available on the DEFRA website at:
http://statistics.defra.gov.uk/esg/evaluation/chemcont/default.asp

9.7 **Option 3:** Benefits are maximised by option 3, as this will achieve all the policy objectives of option 2 and also make provision for the use of ambulatory references in the domestic legislation.

9.8 This will reduce the costs and time taken by enforcement authorities and industry to read and comprehend the Regulations. It will also save them money which would otherwise be spent on buying the amending Regulations from the Stationery Office. It will also significantly reduce the time and cost borne by central government in preparing amending or new Regulations.

9.9 The costs savings of policy option 3 are estimated to be the same as those calculated for one-off administrative costs to industry and enforcement authorities for reading and familiarising themselves with each new set of Regulations that are introduced (see below). Since a new or amending set of Regulations is required each time there is an amendment to Commission Regulation (EC) No. 1881/2006 and in light of the fact that this Regulation (including its previous publication as 466/2001) has been amended more than 20 times in the past 7 years, this is likely to be substantial.

10. Sectors and groups affected.

10.1 The primary business sector that will be affected by the Regulations will be mushroom producers, fishing businesses, supplements businesses, food and feed manufacturers and others with an in interest in chemical contaminants in foods. Only one comment was received from the business sector, which fully supported the proposal and its intended purpose.

10.2 These proposals have no particular impact on charities or voluntary bodies, nor on rural areas or members of any particular racial group.

10.3 The impact on the public sector is believed to be minimal. Some costs to the Exchequer may arise from the costs to local authorities and port health authorities in carrying out the sampling and analysis requirements in relation to coccidiostats and histomonostats provided for by Commission Regulation 124/2009.

10.4 There may also be some additional impacts. For example, the Food Standards Agency regularly carries out surveys to help protect and inform consumers, monitor trends and assess dietary exposure. The additional cost may involve having to carry out more research, including work to establish methodologies to ensure that the legislation is effective in protecting consumers from exposure to harmful chemical contaminants in food.

10.5 A competition filter assessment has been carried out and the results indicate that the proposed Regulations that implement the new Directive are unlikely to hinder the number or range of businesses or the ability for operators to compete. As such, the proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small and apply equally across all food contact industries. The proposals do not contain a strong competition element nor any new or additional burden as the new Directive they implement is amending existing legislation on food contact plastics. This is unlikely therefore to impact on businesses operating in this area, nor in their competitiveness or incentive to compete.

11. Costs

11.1 **Option 1**: European Community Regulations are binding in their entirety and directly applicable in all EU Member States from the date that they take effect. This option contradicts the UK Government's commitment to meeting its EU obligations and fulfilling its policy on consumer protection in this area. It would also create potential for the UK to become liable for infraction proceedings which in turn may result in financial penalties.

11.2 It would contradict the important role the UK plays in negotiating the adoption of these rules to achieve its wider policy objectives for consumers and business and it would leave the regulation of food contact materials

deficient in many ways in comparison with the main food legislation that now applies across the rest of the EU. Failure to fully implement the Commission Regulations would mean that prevailing national legislation would no longer accord with Community provisions. Businesses would have to comply with the proposals being made here for their goods to be legally compliant elsewhere in the EU. In addition, UK consumers would not have the same health protection as consumers in the rest of the EU.

11.3 **Option 2**: The cost analysis is based on the fact that Option 2 fully meets the requirements of the proposal.

Administrative Costs

11.4 There will be a small one-off cost to businesses and enforcement authorities for reading and familiarising themselves with the new Regulations. The Agency will also develop guidance for businesses on the proposed Regulations, which will help minimise costs of reading the new Regulations.

Costs to Enforcement Authorities

11.5 In Wales, Local Authorities and Port Health Authorities are responsible for enforcing legislation with respect to food safety and food hygiene. They have responsibility for enforcing contaminants in food legislation and will, as outlined above, be affected by these proposals. There will also be ongoing and unchanged administration costs to enforcement authorities for monitoring and enforcing the new Regulations.

11.6 We have estimated the time that enforcement authorities will typically invest in reading and familiarising themselves with the new single set of Regulations. There are 22 Unitary Authorities and 1 Port Health Authority in Wales. We have estimated that one enforcement officer in each of the 22 Unitary Authorities and the Port Health Authority is expected to read the Regulations and that it takes them 1 hour to do so. In addition we have estimated that each person uses a further hour for dissemination to key staff within the organisation. The 2008 Annual Survey of Hours and Earnings (ASHE) show that the median hourly pay, excluding overtime, for an Environmental Health Officer (EHO) is £14.94[1]. This is uprated by 30% for overheads, in line with the standard cost model, to give a cost of £19.42 per hour. It is assumed that the wage of Port Health Officers would be similar and can be proxied by the EHO rate. Consultation responses stated that Trading Standards Officers (TSOs) would also need to read and understand these Regulations. We assume that the time taken would be the same as for EHOs. ASHE 2008 gives median hourly pay, excluding overtime, for 'inspectors or factories, utilities and trading standards' as £14.95[2], which is uprated by 30% to give a cost of £19.44 per hours. These wage rates are average rates for all levels of EHOs and TSOs, and is likely to be more senior staff who examine these Regulations, so the cost

[1] http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2008/tab14_6a.xls
[2] http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2008/14_6a.xls

may be a slight underestimate. Multiplied by 22 Unitary Authorities and 1 Port Health Authority, and by 2 hours, this gives a total cost to enforcement agencies for reading and understanding the Regulations of approximately £1,800.

11.7 There will also be a one-off cost arising from test method development and validation. The consultation response from the Laboratory of the Government Chemist (LGC) (see annex for details) suggested that of the eleven coccidiostats and histomonostats, validated methods existed for five and the implementation costs for these five would therefore, be small. For a further five, the Community Reference Laboratory has methods available, so a cost would arise for validating these at the LGC and one UK Official control laboratory and this would be approximately £10.000 per analyte per body, giving a total cost of £100.000. Finally, one analyte (Diclazuril) currently has no method, so the estimated cost of developing and validating a method would be approximately £25.000. This gives a total one-off cost of developing and validating tests of £125.000. Added to the cost of reading and understanding, this gives a total cost to enforcement agencies of £158.000.

11.8 There may also be additional costs associated with testing foodstuffs to determine the presence of residues of these substances.

Costs to Industry

11.9 The affected industries themselves will determine the extent and regularity with which they check compliance with the new maximum levels, as they currently do with the existing maximum levels.

11.10 There may also be some costs for businesses from complying with new maximum limits, for example, additional cleaning required between production of feed lines.

11.11 On a UK basis there are known to be three mushroom businesses (this is estimated to grow to 15 (25% of the mushroom industry)) affected following the changes to the legislation and the effect on fishing businesses is negligible and there are 185[3] businesses involved in food supplements.

11.12 There is no anticipated burden on feed manufacturers from the proposed contaminants in food Regulation to which this Impact Assessment applies. The Feed (Specified Undesirable Substances) (Wales) Regulations 2009[4]) will be the main Regulations impacting on feed manufacturers in relation to coccidiostats and histomonostats. If this is implemented the food requirements are assumed to impose negligible additional costs on feed manufacturers. The associated costs for feed businesses detailed in the Impact Assessment at consultation stage have therefore been removed

[3] Food Safety Information Sheet (FSIS) 12/06 based on the number of UK supplement businesses contacted although 34 were no longer trading or unreachable

[4] These Regulations are designed to implement Commission Directive 2009/8/EC, OJ Ref, L40, 11.2.2009, pages 19-25

from this Impact Assessment as they are already taken into account in the consultation package for the Feed Regulations, which is available on the Agency's website at

http://www.food.gov.uk/consultations/consultwales/2009/feedregswales2009

11.13 The potential impact for a one-off cost to businesses is based on the same principles as those for LAs and port health authorities. The time and costs associated with each business are given in the table below:

Fig 1

Business/ Industry	Number of businesses	Time taken to read and understand				Costs per hour* £:p	Total estimated cost (rounded)
		Contaminants in Food Regulations 2009	Guidance on the Regulations	EC Regulations 629/2008, 565/2008 & and Regulation 124/2009	Total		
Mushroom businesses	3	45 mins	45 mins	up to 30 mins	2 hrs	15.33	£90
Fishing businesses	Negligible	45 mins	45 mins	up to 30 mins	2 hrs	N/A	Negligible
Supplements businesses	185	2 hrs	45 mins	15 mins	3 hrs	20.27	£11,200
Feed manufacturing businesses	348[5]	Negligible					

*Median hourly pay excluding overtime from ASHE 2008, uprated by 30% for overheads. For mushroom businesses: SOC 'Managers in Farming, Horticulture, Forestry and Fishing'. For supplements and animal feed businesses: SOC 'Production and process engineers'.

11.14 **Option 3:** The costs of option 3 would be the same as option 2.

[5] We use the number of manufacturing premises rather than number of businesses as it is likely that each premises will have a manager responsible for reading the regulations and disseminating the relevant information.

Impact on other Government Bodies

11.14 There may also be some additional impacts. For example, the Food Standards Agency regularly carries out surveys to help protect and inform consumers, monitor trends and assess dietary exposure. The additional cost may involve having to carry out more research, including work to establish methodologies to ensure that the legislation is effective in protecting consumers from exposure to harmful chemical contaminants in food.

11.15 The impact on the public sector is believed to be minimal. Some costs to the Welsh Assembly Government may arise from the costs to local authorities and port health authorities in carrying out the sampling and analysis requirements in relation to coccidiostats and histomonostats provided for in the Commission Regulations. However, such testing would be risk based and the overall risk in the UK is low. We quantify the risk as low on the grounds that existing feed legislation is very stringent within the UK. Feed business operators are already sampling and testing to ensure compliance with the existing zero tolerance requirement for the presence of coccidiostats in feed for non-target species.

12. Guidance on the proposed Regulations

12.1 Guidance on the new Regulations was issued for comment as a part of the consultation process. This guidance is currently being reviewed and amended as a result of comments received and will be published on the FSA website when this exercise is complete.

12.2 The purpose of the guidance is to help minimise the cost to enforcement authorities and businesses of reading the new regulations.

13. Consultation

Within Government

13.1 The Food Standards Agency (FSA) has sole policy responsibility for ensuring food safety. Other Government departments including the Devolved administrations in Wales, Scotland and Northern Ireland, Department of Health, The Department for Business Enterprise and Regulatory Reform, the Foreign and Commonwealth Office and the Cabinet Office were kept informed of progress throughout the negotiations relating to the Commission Directive through regular progress reports. To date, no adverse comments have been received from any department.

Public consultation

13.2 The Food Standards Agency fully consulted all stakeholders throughout the UK on the proposed Regulations. Within Wales over two hundred stakeholders were consulted. These ranged from food industry organisations to sector specific organisations, enforcement authorities and

the National Assembly for Wales. There were no responses to the public consultation within Wales.

13.3 During the course of negotiations with the Commission, the Agency's officials have frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities, public analysts, Federation of Small Businesses and other interested parties with an interest in policy issues related to contaminants in food.

Results of the Consultation

13.4 In the wider UK consultation over 800 stakeholders were consulted on these proposals. These ranged from sector specific such has mushroom producers, fishing businesses, supplements businesses, food and feed manufacturers and others with an in interest in chemical contaminants in foods.

13.5 Stakeholders, enforcement bodies in particular, were asked to comment with supporting evidence, of the cost of enforcing the new legislation and to comment on the assumptions that it will take 1 hour for enforcement authorities and businesses to read and familiarise themselves with the new Regulations. They were also asked to comment on any other costs that might be associated with the European Regulations and or the new Regulations and whether they introduce any additional burden; in particular any additional costs associated with testing.

13.6 Although no comments were received on the above specific questions from the enforcement authorities or businesses on the cost issue with either the Commission Regulations or the new Regulations. However, some comments were made about other matters and they are addressed in the 'consultation comments' section below.

13.7 Stakeholders were also asked to comment on the provisions introduced by Regulation 124/2009 on, a) the impact of tests showing that levels had exceeded; b) the monetary costs in relation to withdrawals for not placing the product on the market, c) the likely cost of any investigation by the competent authorities; and d) any cost to businesses and others of changes needed to avoid exceeding the limits, e.g. cost of any additional cleaning, keeping foodstuffs separate etc.

13.8 Stakeholders were asked to provide documentary evidence to support their views.

13.9 Although no comments were received from businesses on the new provisions of Regulation 124/2009 in relation to the above, the Laboratory of the Government Chemist (LGC) did however, provide several comments in relation to costs associated with testing which are summarised.

Consultation comments

13.10 Four responses were received; one from Laboratory of the Government Chemist (LGC), one from SEAFISH (the authority on seafood), one from Trading Standards, South East Group Ltd (TSSE) and one from Port Health Authority (PHA (City of London))

13.11 The LGC expressed concerns that the official food control enforcement analysts (Public Analysts (PA's)) may lack validated and operative test methods to support enforcement of the maximum levels for coccidiostats and histomonostats set by the European Regulation. They argued that highly sensitive methods of analysis will be needed to provide valid results in or below the parts per billion (ppb) range and that the methods will also have to be shown to be flexible and or individually validated.

13.12 The LGC noted that the likely cost to enforcement authorities in this area would be in the region of £75k to put in place validated methods for all the required coccidiostats and histomonostats and should be added to the Impact Assessment's estimate of the total burden on enforcement agencies, in addition to the £16,600 already quoted. In addition to which the LGC will incur £50k.

13.13 In addition to the above the LGC provided the basis for estimating additional costs associated with testing.

13.14 Comments provided by the LGC have been incorporated into the IA in relation to the costs associated with enforcement of the new Regulations.

13.15 The SEAFISH authority ("the authority") welcomed the introduction of the new limits for heavy metals in certain species and the new PCB limit for fish liver and derived products. They were also content with the introduction of ambulatory references that will reduce the regulatory burden in the case of food contaminants legislation, acknowledging that limits fixed by the European Commission are applicable without any variation in national legislation. The authority also felt that it would be encouraging for the Agency to persist with and, if possible, improve its programme of formal and informal consultations on European contaminant legislation when it is being discussed and drafted at EU level.

13.16 There were a number of comments from the TSSE, which centred around the regulatory burden on enforcement authorities. The TSSE were of the opinion that the cost and burden to enforcement authorities was underestimated. This was in reference to the estimate of one-off costs to environmental health officers (EHOs). The TSSE felt that although EHOs deal with food if deemed unsafe, any breaches of the limits was the responsibility of Trading Standards Officers (TSO's). The TSSE suggested that TSOs should also be included.

13.17 The TSSE also felt that the average hourly rates quoted for EHOs and/or TSOs were too low as senior officers are more likely to read the

Regulations and cascade the training to their staff. They also commented that as the proposed Regulations have new powers, extra costs need to be taken into account for updating authorisations for operational staff.

13.18 The TSSE were also of the opinion that as most local authorities have limited (and often decreasing) analytical funding and there is an increasing number of parameters which must be tested and enforced, it was important that the ambulatory provisions do not circumvent an Impact Assessment for any new controls in the future.

13.19 The Agency agrees with the suggestion to include TSO's in relation to enforcing the limits and have made the necessary revision to the cost analysis. Where specific comments have been made to revise certain aspects of the IA, these have been acted upon accordingly. However, in relation to the other costs, the TSSE neither quantified nor provided revised additional costs, which would have been helpful. The ASHE figures do not contain a breakdown of specific grades for EHO's or TSOs and does not include a category for senior EHOs or TSOs.

13.20 Comments from the PHA were on behalf of the City of London in its capacity as the London Port Health Authority. The PHA commented on the costs implications of implementing the new provisions for both industry and PHAs. They agreed that the proposals do not appear to place any significant extra financial burden on local authorities and PHAs as the only change is that of the Maximum Residual Limits (MRL's), which should not have any noticeable financial effect. In addition, the health benefits to consumers from the contribution to keeping contaminants at acceptable levels far outweigh the initial costs. It ensures a uniform approach in the internal market while enabling trade to continue. The PHA fully supported the adoption of the proposed Regulations.

13.21 All respondents have been thanked for their helpful comments and where necessary their views have been taken into account and the Impact Assessment amended accordingly. In particular the information provided by the LGC in relation to costs to local authorities has been very useful and has also been incorporated into the Impact Assessment.

14. Small Firms Impact Test

14.1 The Agency does not consider the impact on small businesses in general to be significant. This view has been supported by industry following earlier consultations (June and October 2007), which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness. Such businesses are always encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market. The Federation of Small Business were included in the consultation process and did not raise any concerns.

15. 'Test Run' of Business Forms

15.1 The Regulation requires that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation. This is not any new burden on industry, as this is an existing requirement under Regulation (EC) No. 1935/2004.

16. Enforcement, Sanctions and Monitoring

Enforcement

16.1 The purpose of The Contaminants in Food (Wales) Regulations 2009 is to provide enforcement authorities e.g. Environmental Health Officers, Trading Standards Officers and Port Health Officers with the necessary powers to prevent contaminated products from entering the market. They have done so with respect to the maximum levels for contaminants since 2002. In addition, the provisions for the new maximum levels for coccidiostats may impose new requirements on enforcement agencies; thus the proposed Regulations will provide the means by which this role can be extended taking into account the new requirements for enforcement.

Sanctions

16.2 The criminal penalty in the current Contaminants in Food (Wales) Regulations 2007, as amended, would remain unchanged in the case of prosecution against those in breach of the new Regulations. This is currently a fine not exceeding level 5 on the standard scale.

Simplification

16.3 The introduction of ambulatory provisions in the new Regulations represents a simplification measure being undertaken to reduce future burdens on enforcement bodies and industry.

Monitoring

16.4 The Food Standards Agency and local authorities in Wales routinely monitor foodstuffs on sale to the public to ensure compliance with regulations. The results of this work carried out by the Agency are published and are openly available on the Agency's website.

http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/

16.5 The Food Standards Agency shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The 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 the proposed Regulations, which will be reviewed in March 2010.

17. Implementation and delivery plan

17.1 We intend that the Statutory Instrument come into force on 1st July 2009.

17.2 As highlighted above, Local Authorities and Port Health Authorities are responsible for enforcing much food safety legislation, including the maximum levels for contaminants in food. The Local Authorities Co-ordinators of Regulatory Services (LACORS), the Association of Port Health Authorities and the Association of Public Analysts are consulted specifically through established Agency liaison mechanisms such as Interested Parties' letters during the development of the EU proposals and the formal consultations during the implementation process. In addition, the Agency is currently developing guidance on the Regulations in consultation with stakeholders.

17.3 The Agency shall continue to regularly communicate with industry to ensure that no unforeseen difficulties arise from the Regulations. As stated earlier, the European Commission investigates whether limits should be set for additional contaminants and also reviews the maximum limits for those contaminants currently in the legislation. Where these are specified, they are included in Commission Regulation (EC) No. 1881/2006. The Agency will consult stakeholders for information to inform these investigations, including data available from enforcement or industry testing, and any data from surveillance the Agency may undertake on these contaminants in food.

18. Post-implementation review

18.1 The Agency will aim to review the Regulations and Guidance in 2011.

19. Summary and recommendations

19.1 The proposals here provide for the effective enforcement of the Commission Regulations and they also provide businesses with harmonised rules that apply throughout the EU.

19.2 The Agency believes that the advantages of full implementation of the proposals that are 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. Industry fully supports the pursuit of Option 3 which has the desired effect in achieving the means of adequate enforcement of the EC Regulations. **Option 3 is therefore recommended as a means of achieving this.**

Annex: basis for estimating additional costs associated with testing

In order to enable enforcement of the limits proposed at 3(2)(c) of the draft Wales regulations - which apply to 11 coccidiostats and histomonostats in food - official control laboratories must put in place methods of analysis meeting the requirements established by Article 11 of Regulation (EC) No 882/2004. Known availability of analytical methods for the 11 coccidiostats and histomonostats LGC has put in place validated methods to determine the following in meat, eggs and liver:

1. Lasalocid sodium
2. Narasin
3. Salinomycin sodium
4. Monensin sodium
10. Nicarbazin.

However, the LGC may need to optimise and re-validate some of the above if called on to test compliance with the limits proposed by the draft regulations. The Community reference laboratory has methods for the following, but they have not been validated in LGC:

5. Semduramicin
6. Maduramicin
7. Robenidine
8. Decoquinate
9. Halofuginone.

There is no method (and a current Defra R&D requirement) for:

11. Diclazuril.

Cost estimate

In consequence of LGC's prior R&D, a sound scientific platform has been established within the UK for the determination of analytes 1-4 and 10. For the sake of simplicity, they will omit any costs relating to the further development, transfer and validation of analytical methods for these analysts from their estimate.

As far as they are aware, there has been little or no funding allotted to establish methods for analysts 5-9 and 11 in public sector official food control laboratories. So there is an outstanding requirement for at least one enforcement laboratory to validate and put in place such methods.

Validation is an activity that is particular to each laboratory putting a method into use. In LGC's experience, validation carried out to comply with the requirements of Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results costs £10k - £15k for each combination of analyte and food matrix; they are informed that it would be conservative to double this (£20k - £30k; midpoint £25k) if there were development required prior to validation.

However, from their direct experience, it costs a laboratory £3k - £10k to put in place a method if it has already been validated externally (such as by the CRL). So the cost to the LGC, together with one UK official control laboratory, of reducing methods for analytes 5-9 to practice may be of the order of £50k each.

No method is currently available so far as they are aware for determining diclazuril in food of animal origin to the limits laid down in the draft regulations, although it is understood this is the subject of a current Defra R&D requirement. The above midpoint figure of £25k may be appropriate (pending a more detailed reading of the Defra requirement).

Finally, the initial (set-up) costs associated with testing are likely to be in the region of £50k to the enforcement community, £50k to the LGC, and perhaps £25k for the establishment of one new method.