Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	Impact Assessment of The Contaminants in Food (England) Regulations 2009	
Stage: Final	**Version:** 2	**Date:** May 2009

Related Publications: Commission Regulation (EC) No. 565/2008, Commission Regulation (EC) No. 629/2008 and 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

Available to view or download at:
http://www

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What is the problem under consideration? Why is government intervention necessary?
Contaminants in food can detrimentally affect consumer health. Most consumers are unable to assess the risk of contaminants in their food and therefore are unable to make fully informed choices about such risk. Government intervention is necessary to reduce the risk to health and also to provide greater clarity in enforcement..

What are the policy objectives and the intended effects?

1. To continue to reduce the long term health risks to consumers in England arising form chemical contaminants in food;
2. To reduce the burden on the agricultural and fishing industry;
3. To make enforcement provisions that enable the authorities to ensure that products placed on the market are safe and thus increase consumer confidence;
4. To introduce ambulatory provisions in the enforcing Regulations to reduce the burden on enforcement bodies as well as industry.

What policy options have been considered? Please justify any preferred option.

1. Do nothing;
2. Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulations;
3. Carry out policy 3 and in addition make ambulatory provisions in the domestic Regulations. This is the preferred option as it would achieve all the objectives outlined and fulfil the UK's requirement to make appropriate enforcement for directly applicable Commission Regulations.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The Commission, in discussion with Member States, reviews the EU measures put in place on an ongoing basis. It is anticipated that the domestic SI Regulations will be reviewed by June 2011.

Ministerial/CEO Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

..... Date: 14 may 2009

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2	Description: The Contaminants in Food (England) Regulations 2009

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 169,600	1
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups' Costs of reading and understanding the new legislation and guidance to industry (£11,300) and enforcement agencies (£33,300) and of developing and putting into place tests (£50,000 to the enforcement community and £75,000 to the government chemist).

Total Cost (PV) **£ 169,600**

Other **key non-monetised costs** by 'main affected groups' Laboratory equipment costs and costs of implementation of validated test methods.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£	1
Average Annual Benefit (excluding one-off)	
£	

Description and scale of **key monetised benefits** by 'main affected groups'

Total Benefit (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' Health benefits to consumers from the contribution to keeping contaminants at acceptable levels. Facilitation of trade through harmonising Member States measures. Some savings to the fish and mushroom industries due to the relaxation of maximum levels.

Key Assumptions/Sensitivities/Risks There will be no ongoing costs and some ongoing savings from the new maximum levels. Reading and understanding the new legislation will take 3 hours for the supplements industry and 2 hours for others. Implementing existing tests costs £10k per test and developing a new test costs £25k.

Price Base Year 2008	Time Period Years 1	**Net Benefit Range** (NPV) **£ -169,600**	**NET BENEFIT** (NPV Best estimate) **£ -169,600**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			1st July 2009	
Which organisation(s) will enforce the policy?			LAs and PHAs	
What is the total annual cost of enforcement for these organisations?			£ Negligible	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ Negligible	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ Decrease £ **Net Impact** £

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Summary: Analysis & Evidence

Policy Option: 3	Description: The Contaminants in Food (England) Regulations 2009 with ambulatory provisions

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 169,600	1
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups' Costs of reading and understanding the new legislation and guidance to industry (£11,300) and enforcement agencies (£33,300) and of developing and putting into place tests (£50,000 to the enforcement community and £75,000 to the government chemist).

Total Cost (PV) **£ 169,600**

Other **key non-monetised costs** by 'main affected groups' Laboratory equipment costs and costs of implementation of validated test methods.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£	1
Average Annual Benefit (excluding one-off)	
£	

Description and scale of **key monetised benefits** by 'main affected groups'

Total Benefit (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' As for option 2, plus a reduction in future regulatory burden on industry and enforcement agencies by removing the need for future amendments.

Key Assumptions/Sensitivities/Risks As for option 2

Price Base Year 2008	Time Period Years 1	**Net Benefit Range** (NPV) **£ -169,600**	**NET BENEFIT** (NPV Best estimate) **£ -169,600**

What is the geographic coverage of the policy/option?				England	
On what date will the policy be implemented?				1st July 2009	
Which organisation(s) will enforce the policy?				LAs and PHAs	
What is the total annual cost of enforcement for these organisations?				£ Negligible	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ Negligible	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ Decrease £ **Net Impact** £

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

Reason for Intervention

1. Contaminants in food can have an adverse effect on human health. Other negative consequences include the cost of any medical treatment. Consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of contaminants. Therefore, they cannot make informed choices about such risk. Government intervention is required to reduce these impacts on health and to address the lack of informed consumer choice.

2. The risk of contaminated products entering the market will be reduced by the new maximum levels set out:

   - in Commission Regulation (EC) No. 565/2008 for dioxins plus dioxin-like polychlorinated biphenyls (PCBs) in fish liver;
   - in Commission Regulation (EC) No. 629/2008 for lead, cadmium and mercury in food supplements; and
   - in the annex to 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 .

3. Enforcement of these maximum levels will increase consumer protection. Having correct enforcement provisions for the revised limits for lead, cadmium and mercury in certain aquatic species and fungi will avoid confusion for enforcement authorities and avoid any potential barrier to trade that may occur in attempting to enforce obsolete limits, whilst maintaining protection of human health.

4. In the case of the unavoidable carry-over into non-target animal feed of active substances contained in authorised coccidiostats and histomonostats, these are considered as undesirable substances in animal feed within the meaning of Directive 2002/32/EC and maximum levels for these substances in animal feed are therefore established by a Commission Directive amending Annex I to the 2002 Directive. These controls on animal feed, as opposed to food, are being implemented in domestic law by separate legislation.

Intended effect

- **To continue to reduce the long term health risks to consumers in England arising from chemical contaminants in food.**

5. Dioxins are a group of chemicals produced as a by-product of chemical processes, for example the manufacturing of chemicals, pesticides, steel and paints, pulp and paper bleaching, exhaust emissions and incineration. PCBs are a group of industrial chemicals widely used in the past but their manufacture and use is now banned. Some PCBs have dioxin-like properties. Dioxins and dioxin-like PCBs can enter the food chain through a number of routes, for example soils may be polluted by sewage sludge or composts, spills and erosion from nearby contaminated areas. The chemicals concentrate in the fatty tissues of beef and dairy cattle, poultry, pork or seafood. In general, food of animal origin contributes to the vast majorty of the overall human exposure.

6. Dioxins have a broad series of toxic and biochemical effects and some of them are classified as known human carcinogens, i.e. they cause cancer in humans. In laboratory animals they have been linked to endometriosis (severe effects on the uterus), developmental and neurobehavorial effects (learning disabilities), developmental reproductive effects and immunotoxic effects. These effects occur at much lower levels of exposure than carcinogenic effects. As regards dioxins and dioxin-like PCBs, the

Scientific Committee on Food (SCF) adopted, on 30 May 2001, an opinion on dioxins and dioxin-like PCBs in food, fixing a tolerable weekly intake (TWI) of 14 picograms World Health Organisation toxic equivalent (WHOTEQ) per kilogram body weight (bw) for dioxins and dioxin-like PCBs. This was endorsed by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) in October 2001 as a tolerable daily intake (TDI) of 2 picograms WHO-TEQ/kilogram bw.

7. As very high levels of dioxins and dioxin-like PCBs have been reported in canned fish liver recently, the European Commission, together with Member State countries including the UK, has established a Community maximum level for the sum of dioxins and dioxin-like PCBs in fish liver and processed products thereof to protect public health and to ensure a uniform approach in the internal market.

8. Lead, cadmium and mercury are all metal contaminants, which may be present naturally, e.g. lead in soil, but which are also introduced into the environment via human activity through industrial processes, vehicle exhaust emissions, as well as insecticide and fertilizer use. Levels of these metals are frequently found at higher levels in foods that are readily able to accumulate them such as fish, shellfish and offal, in comparison to staple foods such as wheat, rice and potatoes.

9. Lead is a cumulative poison which produces a series of effects on blood-forming tissues, the digestive and nervous systems, and the kidneys. The European Commission's now disbanded Scientific Committee on Food (SCF) adopted an opinion on lead on 19 June 1992. This opinion endorsed the provisional tolerable weekly intake (PTWI) of 25 µg/kg bw proposed by the WHO in 1986. Cadmium is also a cumulative poison that affects the kidneys even at relatively low levels of exposure. As regards cadmium, the SCF endorsed in its opinion of 2 June 1995 the PTWI of 7 µg/kg bw and recommended greater efforts to reduce dietary exposure to cadmium since foodstuffs are the main source of its intake by humans.

10. Mercury has toxic effects on animals and humans – pregnant women, nursing mothers and children are particularly sensitive to mercury poisoning. The most toxic form is methylmercury which causes damage to the central nervous system. Methylmercury is often found in fish because industrial effluents containing mercury are discharged into rivers or seas where they are converted by bacteria into methylmercury, which concentrates in the bodies of fish. As regards mercury the European Food Safety Authority (EFSA), the body that succeeded the SCF, adopted an opinion related to mercury and methylmercury in food and endorsed the PTWI of 1.6 µg/kg bw.

11. High levels of lead, cadmium and mercury have recently been found in certain food supplements and it has been shown that these food supplements can contribute significantly to human exposure to these metals. Maximum levels have not previously been set in Community legislation prior to the introduction of Commission Regulation (EC) No. 629/2008. In order to protect public health and to provide a uniform approach in the internal market, the European Commission together with Member State countries including the UK have now agreed maximum levels for them in food supplements.

12. Coccidiostats and histomonostats are substances intended to kill or inhibit protozoa, which may *inter alia,* be authorised for use as feed additives in accordance with Regulation (EC) No. 1831/2003 of the European Parliament and of the Council[1] on additives for use in animal nutrition. Authorisations of coccidiostats and histomonostats as feed additives lay down specific conditions for use such as the target animal species or categories for which the additives are intended. Feed business operators may produce, within one establishment, a broad range of feeds and different types of products may have to be manufactured one after another in the same production line. This may result in the unavoidable traces of a product remaining in the production line

[1] 22 September 2003 – OJ L268, 18.10.2003, p.29

and ending up as an ingredient of another feed product. This transfer from one product lot to another is called 'carry-over' or 'cross-contamination' and may occur for instance when coccidiostats or histomonostats are used as authorised feed additives. This may result in the contamination of feed and subsequently, by the presence of technically unavoidable traces of those substances in non-target feed, their resulting presence in derived foodstuffs.

13. In order to prevent the adoption by Member States of national rules addressing the issue of unavoidable carry-over of authorised coccidiostats or histomonostats in non-target feed and their resulting presence in derived foodstuffs, which would hinder the functioning of the internal market, the European Commission together with Member State countries including the UK have now agreed maximum tolerances for the presence of active substances contained in coccidiostats and histomonostats in food of animal origin originating from the non-target feed concerned. The provisions of Regulation (EC) No. 124/2009 are made under Council Regulation (EEC) No. 315/93 which lays down the Community procedures for contaminants in food. These contaminants are defined as:

    - "any substance not intentionally added to food which is present in such food as a result of its production and processing, preparation and treatment etc (including operations carried out in crop husbandry, animal husbandry and veterinary medicine) manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insects, fragments, animal hair, etc, is not covered by this definition".

14. The proposed Regulations will also revoke *The Contaminants in Food (England) Regulations 2007 and the Contaminants in Food (England) (Amendment) (No.2) Regulations 2007* (SI 2007/2983) and re-enact them with necessary amendments, thus implementing in one consolidated instrument.

- **To reduce the burden on the agricultural and fishing industry**

15. The intention of Commission Regulation (EC) No. 1881/2006 is to set maximum levels for contaminants including lead, cadmium and mercury that must be safe and as low as reasonably achievable based upon good manufacturing, agricultural and fisheries practices.

16. However, on the basis of new information, good agricultural and fisheries practices cannot keep levels of lead, cadmium and mercury in certain aquatic species and fungi as low as specified in the current annex of Commission Regulation (EC) No 1881/2006. The European Commission together with Member State countries, including the UK, have therefore agreed on higher maximum levels for those contaminants in order that industry may be able to comply while still maintaining a high level of consumer health protection.

17. As a consequence of this relaxation, UK industry will be able to offer more choice and extra varieties of mushroom species, for example, which will lead to more business for the commodity high volume product lines. There will also be the opportunity of selling medley packs which could make use of surplus products.

- **To make enforcement provisions to ensure that products placed on the market are safe and thus increase consumer confidence**

18. The requirements of Commission Regulation (EC) No. 1881/2006 and its amendments are 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 the requirements of the European legislation so as to give enforcement authorities in England the appropriate powers with which to ensure compliance of food business operators with Commission Regulation (EC) No.

1881/2006 as amended. In consequence, similar, parallel legislation will be made in Scotland, Wales and Northern Ireland.

- **To introduce ambulatory provisions in the enforcing Regulations to reduce the burden on enforcement bodies as well as industry.**

19. The introduction of ambulatory provisions in this Statutory Instrument (SI) for England will help to reduce the regulatory burden on enforcement authorities as well as industry as further SIs will not be necessary to introduce subsequent EU changes to these particular provisions in Commission Regulation (EC) No. 1881/2006. This practice will reduce the time and costs of enforcement authorities and industry in reading and comprehending the Regulations. It will also save them costs in terms of purchasing printed copies of the SI in which new or amending Regulations are contained. It will also significantly reduce the time and cost borne by central government in preparing new or amending Regulations. Stakeholders have previously welcomed the introduction of ambulatory references in food contact materials legislation. After formal consultation on this proposal, stakeholders fully supported the introduction of ambulatory references which will in future reduce the regulatory burden on businesses.

Background

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. The main provisions of Regulation 124/2009 are:

    i) *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.*

    ii) *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.*

iii) *Foodstuffs complying with the maximum levels set out in the Annex shall not be mixed with foodstuffs which exceed these maximum levels.*

iv) *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.*

v) *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.*

vi) *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.*

29. The proposed Contaminants in Food (England) Regulations 2009 have been revised to take into account the provisions of Regulation 124/2009 as follows:

1) regulation 2(1) – and 2(2) - interpretation

2) regulation 3(2)(c) – offences and penalties

3) regulation 4(1) and 4(2)(b) enforcement and competent authorities.

30. If these changes to the EC Regulations were not made, the unchanged or absent maximum levels may lead to increased exposure to the population of harmful contaminants and therefore contribute to an increase in health problems and subsequently a burden on health services. There would be a detrimental effect on the cost to fishing and agricultural industries if more stringent maximum levels were maintained in respect of lead, cadmium and mercury in certain fish species and certain mushroom species.

31. If the EC Regulations were amended as proposed, but the relevant changes to the Contaminants in Food (England) Regulations were not made, this may lead to the impacts set out in paragraph 39 and may also create a barrier to trade across the EU. It would contradict the important role the UK plays in agreeing EU harmonised measures and leave regulation of contaminants in England deficient in comparison with other EU Member States. It would also leave enforcement bodies without adequate statutory powers to prevent the placing on the market of those commodities which fail to meet the maximum limits laid down in the Commission Regulations.

Options

Option 1 - Do nothing.

32. This is what would happen if these changes were not made to the proposed Regulations, and provides the baseline to which other options are compared.

Option 2 - Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulations

33. This option would provide enforcement authorities with the necessary domestic legislation for the enforcement and execution of the amending Commission Regulations in England, which are binding in their entirety and directly applicable to all EU Member States.

Option 3 – Carry out policy option 2 and in addition introduce the use of ambulatory references in the domestic Regulations.

34. 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.

Costs and benefits of options[2]

Option 1 Do nothing.

35. This option is the baseline for comparison.

Option 2 Make appropriate domestic Regulations for the execution and enforcement of the amending Commission Regulations

36. This option would ensure that enforcement authorities within England, including 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.

Options 3 - Carry out policy option 2 and in addition introduce the use of ambulatory references in the domestic Regulations. This is expected to achieve all the objectives outlined above.

37. This would achieve the outcomes outlined in option 2 and in addition the introduction of ambulatory provisions in the domestic Regulations would reduce the regulatory burden on enforcement authorities as well as industry by ensuring that no additional amending Regulations or new Regulations would be required to make enforcement provisions for amendments made to the Annex to Commission Regulation (EC) No. 1881/2006.

Benefits

Option 1

38. There are no incremental benefits for option 1.

Option 2

39. This option fully meets the UK 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.

40. 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. Option 2 may even facilitate trade. It would prevent the UK from facing potential infraction proceedings from the European Commission and

[2] Note that all figures are rounded estimates and totals may not equal the sum of components due to independent rounding

consolidate the important role that the UK plays in negotiating and agreeing standards for contaminants in food within the European Union.

41. 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.

42. 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 toxicants 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

Option 3

43. 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.

44. 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.

45. 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.

Costs

Option 1

46. There are no incremental costs from option 1.

Option 2

47. 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

48. Each food authority in its area and each port health authority in its district are responsible for enforcing the legislation with respect to food safety and food hygiene. They have responsibility for enforcing the contaminants in food legislation and will, as outlined above, be affected by these proposals. There will also be ongoing and

unchanged administration costs to food authorities for monitoring and enforcing the new Regulations.

49. 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 389 Local Authorities and 39 Port Health Authorities in England. We have estimated that one Environmental Health Officer in each of the 389 Local Authorities (LAs) and the 39 Port Health Authorities (PHAs) 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[3]. 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 of factories, utilities and trading standards' as £14.95[4], which is uprated by 30% to give a cost of £19.44 per hour. These wage rates are average rates for all levels of EHOs and TSOs, and it is likely to be more senior staff who examine these Regulations, so the cost may be a slight underestimate. Multiplied by 389 LAs and 39 PHAs, and by 2 hours, this gives a total cost to enforcement agencies for reading and understanding the Regulations of approximately £33,300.

50. There will also be a one-off cost arising from test method development and validation. The consultation response from the LGC (see annex for detail) suggested that of the eleven coccidiostats and histomonostats, validated methods of testing exist 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 £158,300.

51. There may also be additional ongoing, relatively small, costs associated with testing foodstuffs to determine the presence of residues of these substances.

Costs to Industry

52. 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.

53. There are currently 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[5] businesses involved in food supplements.

54. 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) (England) Regulations 2009[6]) will be the main

[3] http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2008/tab14_6a.xls
[4] http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2008/tab14_6a.xls
[5] Food Safety Information Sheet (FSIS) 12/06 based on the number of UK supplement businesses contacted although 34 were no longer trading or unreachable
[6] These Regulations are designed to implement Commission Directive 2009/8/EC, OJ Ref, L40, 11.2.2009, pages 19-25

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 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/consulteng/2009/feedregseng2009

55. 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[7]	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'.

Option 3

56. The costs of option 3 would be the same as option 2.

Impact on other Government Bodies

57. 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.

58. 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 in the Commission Regulations. However, such testing would be risk based and the overall risk in the UK is low.

- **Public Consultation**

[7] 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.

59. The Food Standards Agency has consulted with all of its stakeholders including industry, trade bodies, enforcement bodies and other government departments consistently during negotiations with the European Commission and other EU Member States on the amendments to Commission Regulation (EC) No. 1881/2006. For example, it has released several Interested Parties Letters, notifying stakeholders as it has done so. These can be found at:

60. www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/.

Any comments received from stakeholders prior to the formal consultation detailed below have also been taken into consideration.

- **Results of the Consultation**

61. 800 stakeholders have been 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.

62. 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.

63. . 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.

64. 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.

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

66. 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) provided several comments in relation to costs associated with testing which are summarised below and also included in the Annex to the IA.

- **Consultation comments**

67. 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)).

68. 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) ranges and that the methods will also have to be shown to be flexible and or individually validated.

69. The LGC noted that the likely cost to enforcement authorities in this area would be in the region of £50k to put in place validated test methods for all the required

coccidiostats and histomonostats, in addition to which the LGC will incur costs in the region of £75k, which should be added to the Impact Assessment's estimate of the total burden on enforcement agencies.

70. In addition to the above the LGC provided the basis for estimating additional costs associated with testing (annex attached).

71. Comments provided by the LGC have been incorporated into the IA in relation to the costs associated with enforcement of the new Regulations. The LGC is also content to support local authorities in the testing regime and sharing methods of analysis to enable enforcement of the new Regulations in relation to coccidiostats and histomonostats.

72. 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's being discussed and drafted at EU level.

73. In relation to the guidance to the proposed Regulations, the authority felt that whilst it was less detailed than previous guidance, it was however, easier to read. They added that the loss of detail in the guidance was acceptable because it contained enough reference for the interested reader to source further information if required.

74. 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 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.

75. 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.

76. The TSSE commented that trading standards currently enforce the 2007 contaminants in food Regulations. The proposed 2009 Regulations introduce new limits for certain products that would incur an additional cost of testing for contaminants such as dioxins and dioxin like-PCBs to the new limits that will be a burden for local authorities, as tests on contaminants are expensive to carry out. The TSSE added that this problem will be more prevalent if an authority has an importer/manufacturer supplying products such as fish liver products for food supplements.

77. 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.

78. In relation to the guidance the TSSE felt that it would be helpful to highlight the potential links into the feeding stuffs as food businesses may direct rejected food into the feeding stuffs. If local authorities are expected to advise food businesses that food exceeding the levels in the proposed Regulations may be re-directed as feed; operators must be aware that such supply is caught by the feed legislation and they will be deemed to be a 'feed business operator'. The TSSE suggested that a statement like

'any food redirected as feed must not exceed limits for undesirable substances laid out in the Feed (Hygiene) and Enforcement Regulations 2005', would clarify the situation.

79. 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 and the ASHE figures do not contain a breakdown of specific grades for EHO's or TSOs and does not include a category for senior EHO's or TSOs. Therefore the costings could not be amended, but the point on senior staff has been noted in the text.

80. Comments from the PHA were on behalf of the City of London in its capacity as the London Port Health Authority. The PHA commented that they were content with the new levels established for certain contaminants and believed that this will ensure the continued high level of consumer protection. They also noted that the introduction of ambulatory references will allow future amendments to specific EC legislation to take effect in national law without new domestic Regulations. The PHA felt that this was a useful approach, as increasing knowledge and scientific advancements in maximum levels for certain contaminants in foodstuffs may change significantly in the near future. They also added that limits may also be necessary for additional contaminants in foods. The provisions should also reduce the varying amounts of information that an enforcement authority has to go through to clarify a decision. These changes can therefore, be implemented quickly and without usual regulatory burden, reducing costs to industry. It should also assist in future or further harmonisation of EC decisions if all countries are referring to the same decision rather than relying on the way it has been interpreted into national law.

81. The PHA also commented on the cost implications of implementing the new provisions for both industry and PHAs. They agreed that the proposals do not appear to have any significant 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.

82. The PHA added that with regards to industry, the increase of these levels is to ensure that the new MRL's are both safe for consumers and achievable. Only if companies can achieve these levels will they deem them to be reasonable. Should they fail to achieve these levels then the Commission will have to rethink their levels or face a potential conflict with industry.

83. The PHA briefly commented on the industry guidance. They said that the guide contained substantial information on the present provisions relating to the maximum levels for certain contaminants in foodstuffs. Information on the changes summarised in three short paragraphs, is lacking in depth and needs to be more comprehensive in order to provide useful and easily accessible guidance to industry. The PHA agreed however, that the guidance was well laid out, in good order, with useful links to the regulations and contact details for clarification.

84. 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.

Enforcement

85. The purpose of The Contaminants in Food (England) 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 on which we are consulting will provide the means by which this role can be extended taking into account the new requirements for enforcement of the new Regulations.

Sanctions

86. The criminal sanctions in the current Contaminants in Food (England) (No.2) Regulations 2007, as amended, would apply 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

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

Implementation and Review

88. 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.

89. The proposed Regulations are intended to come into force on 1st July 2009. We shall continue to regularly communicate with industry to ensure that no unforeseen difficulties arise from the proposed Regulations, which Agency will aim to review the Regulations and Guidance in 2011.

90. 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.

Summary and Recommendation

91. 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.

92. The Agency believes that the advantages of full implementation of the proposals that are the subject of this 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.**

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

Competition Assessment

We have fully considered the questions posed in the Office of Fair Trading Competition Assessment Test[8] and conclude that the proposed Regulations that implement the enforcement provisions of the Commission Regulations are unlikely to hinder the number or range of businesses of the ability of 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. The proposals do not contain a strong competition element or any significant new or additional burden. This is not expected to result in any reduction or change in businesses operating in this area, nor in their competitiveness or incentive to compete.

There is no current requirement for industry to carry out sampling and analysis within Commission Regulation 1881/2006, as amended. However, it may wish to do so (and may already be doing so) when carrying out its existing programmes of checks for contamination in excess of legal limits to gain the protection of the 'due diligence' defence under section 21 of the Food Safety Act 1990. This is applicable to all food businesses operating in the import, production, processing, storage, distribution and sale of food and in this respect is not likely to have a disproportionate effect on any business or group of businesses.

Small Firms Impact Test

Stakeholders, including the Enterprise Directorate in BERR, the Federation of Small Businesses and small businesses themselves, including those that are members of trade associations, have been consulted throughout the negotiations on the legislation via interested parties' letters. Any potential additional costs arising from checking compliance with the maximum levels will be proportionate to small businesses. It is the responsibility of individual food business operators to show how they satisfy compliance with the "due diligence" requirement under section 21 of the Food Safety Act 1990. For example, this may require that businesses specify requirements to be met by their supplier prior to receiving the product to ensure that the products are not contaminated above the permitted limits and would therefore not impact disproportionately on SMEs.

Sustainable development

The Food Standards Agency's remit is to protect the interest of consumers in relation to food safety, both now and in the future. In doing so, the Agency will take sustainable development into account in all of its activities and policy decisions. The proposal would have little if any impact on the deliver of the Government's five principles of sustainable development, on the environment or in relation to public health.

Race equality issues

Members of the ethnic communities are not affected by these proposals any differently to others. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Gender equality issues

There is unlikely to be any impact on gender equality.

Disability equality issues

Disable people are unlikely to be affected by these proposals.

Carbon Impact Assessment

The proposal is unlikely to have any significant impact on emissions of greenhouse gases.

[8] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf

Human Rights

It is not considered that this proposal will have a negative impact on the Human Rights of those affected by it.

Rural Proofing

The proposal is unlikely to have any significant impact on rural areas.

Annex: basis for estimating additional costs associated with testing

i) In order to enable enforcement of the limits proposed at 3(2)(c) of the draft England 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.

ii) 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**

iii) 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.

iv) 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.

v) 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.

vi) 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.

vii) 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.