www.food.gov.uk

To: Interested Parties
(List attached)

Date: 23rd July 2008 Reference:

PUBLIC WRITTEN CONSULTATION

Proposal of the European Commission for a Regulation on Active and Intelligent Materials and Articles Intended to come into Contact with Food

Dear Sir/Madam

1. Informal discussions are taking place with interested parties at European Union (EU) level on a working document from the European Commission (EC) that could go on to form the basis of harmonised EU rules governing materials and articles in contact with food. The one that is the subject of this letter deals with a proposal for a specific Regulation on active and intelligent materials and articles intended to come into contact with food.

2. This letter describes the current state of play on the issue, the likely timetable as can be best judged at the moment and seeks your views on the idea being put forward. An earlier version of the working document was the subject of an informal consultation in August 2006; since then, it has been the subject of further discussion. The EC is now conducting its own consultation amongst Member States of the EU and other interested organisations on the latest version. That consultation will end in September 2008.

3. We are therefore seeking your views in accordance with Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council, laying down the general principles of food law, which requires open and transparent public consultation during the preparation of food law. Your views would be welcome while discussions remain active, but by **31st August 2008** to ensure that your comments/views can be weighed into the UK's negotiating line or in any case by 17th October 2008 when the consultation closes.

4. All comments and views should be sent to me: by e-mail at Nasreen.a.shah@foodstandards.gsi.gov.uk or telephone me on 020 7276 8553.

Draft Working Document on active and intelligent materials and articles intended to come into contact with food – EMB/1127rev3

5. The general principles on all food contact materials and articles intended to come into contact with foodstuffs are established in Regulation (EC) No. 1935/2004. It includes 'active' and 'intelligent' materials and articles, which are defined as:

   - 'active food contact materials and articles' means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;

   - 'intelligent food contact material and articles' means materials and articles which monitor the conditions of packaged food or the environment surrounding the food;

   - The provisions also include general safety, changes to the composition and properties of the food; release of substances into the food, labelling of released substances in accordance with rules on food labelling; labelling of non-edible parts and labelling to identify that the materials is active or intelligent;

   - Consumers must not be misled through changes in food or information given about the condition of food; and

   - Information for consumers and food packers on how to use active and intelligent materials and articles safely and appropriately in compliance with food law (see Article 8 below.

The full requirements contained in the working document are discussed below.

Detail

Article 1 – Subject Matter and Scope

6. Article 1(1) states that the Regulation shall apply to those materials and articles that are (a) active food contact materials and articles as defined in Article 2(2)(a) of Regulation (EC) No. 1935/2004 and (b) intelligent food contact materials as defined in Article 2(2)(b) of Regulation 1935/2004. Article 1(2) of the Regulation also provides for (a) additional requirements to Regulation 1935/2004, in relation to active and intelligent materials and articles; b) a Community list of substances, listing substances that may be used in active and intelligent components; c) additional rules on labelling; and d) information to be contained in a declaration of compliance.

Article 2 - Definitions

7. Article 2 gives the legal definition to particular expressions which are specific to their use in the proposed Regulation and these are:

- "component" means an individual substance or a combination of substances which cause the active and/or intelligent function of a material or article, including the products of *in situ* reaction of these substances. It does not include the passive parts, such as the material they are added to or incorporated into;

- "functional barrier" means a barrier consisting of one or more layers of food contact materials which ensures that the finished intelligent material or article complies with Article 3 of Regulation (EC) No. 1935/2004 and with this Regulation;

- "releasing active materials and articles" are those materials and articles designed to deliberately release substances into or onto the packaged food or the environment surrounding the food; and

- "released active substances" are those substances intended to be released from active materials and articles into or onto the packaged food or the environment surrounding the food and having a function on the food.

Article 3 – Community list of substances that can be used in active and intelligent components

8. Article 3 has the following provisions:

- Article 3(1) requires that active and intelligent materials and articles shall be placed on the market only if the substances which constitute the component of an active and intelligent material are included in the Community list of substances that may be used in active and intelligent components (hereinafter referred to as "Community list");

- Article 3(2) states that by derogation from paragraph 1 above, substances deliberately incorporated into active materials and articles to be released into food or the environment surrounding the food; do not need to be listed in the Community list. They shall be used in accordance with the relevant Community and national provisions applicable to food, and shall comply with the provisions of Regulation (EC) No. 1935/2004 and its implementing measures. The same shall apply to substances falling under the scope of Community or national provisions applicable to food, which are incorporated in active materials and articles by techniques such as grafting and immobilisation, in order to have a technological effect in the food;

- Article 3(3) states that by derogation from paragraph 1, intelligent materials and articles, in which the component is not in direct contact with food or the environment surrounding the food and is separated from the food or by a functional barrier, other substances than those included in the Community list may be used.

- The migration of the substances referred to in the above sub-paragraph into food shall not exceed 0.01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) No. 882/2004 of the European Parliament and of the Council[1]. This limit shall always be expressed as concentration in foods. It shall apply to a group of substances, if they are structurally and toxicologically related, in particular isomers or substances with the same relevant functional group, and shall include possible set-off transfer.

- The substances referred to in the first sub paragraph shall not belong to either of the following categories:

  (i) substances classified as proved or suspected "carcinogenic", "mutagenic" or "toxic' to reproduction" substances in Annex 1 to Council Directive 67/548/EEC[2];

  (ii) substances classified under the self-responsibility criteria as 'carcinogenic', mutagenic' or 'toxic to reproduction' according to the rules of Annex VI to Directive 67/548/EEC.

Article 4 – Conditions for inclusion of substances in the Community list

9. Article 4 requires that without prejudice to Article 3(2) and (3), substances which constitute the component of active and intelligent articles may be included in the Community list if, under the intended condition of use of the active and intelligent material and article in which they are used, the requirements of Article 3 and, where they apply, Article 4 of Regulation (EC) No. 1935/2004 are satisfied.

Article 5 – Authorisation procedure

10. Article 5(1) requires that substances which comply with the conditions set out in Article 4 of this Regulation shall be included in the Community list in accordance with the procedure for authorisation laid down in Articles 9 to 11 of Regulation (EC) No. 1935/2004. Article 5(2) requires that the Community list shall be amended in accordance with the procedure referred to in Articles 9 to 11 of Regulation (EC) No. 1935/2004.

Article 6 – The content of the Community list

11. Article 6 requires that where substances or a combination of substances are to be included in the Community list, they would need to specify the following: (a) the identity of the substance(s); (b) the function of the substance(s); (c) the register number; (d) if necessary, the conditions of use of the substance(s); (e) if necessary, restrictions and/or specifications of use of the substance(s); and (f) if necessary, conditions of use of the component or of the material and article to which it is added or into which it is incorporated.

[1] OJ L 1931 of 28.5.2004, p.1. as last amended by Council Regulation (EC) No. 1791/2006 (OJ L 363 of 20.12.2006, p.1.)
[2] OJ 196, 16.8.1967, p.1 as last amended by Directive 2006/121/EC (OJ L 396 of 30.12.2006, p.850)

Article 7 – Placing on the market of active and intelligent materials and articles

12. Article 7 lays down the conditions of placing on the market of active/intelligent food contact materials. In addition to the specific requirements for active and intelligent materials outlined in Article 4 and Article 15(1)(e), additional requirements are stated with which such products must comply and this is split into two categories:

1). Active and intelligent materials and articles shall only be placed on the market if:

a) they are suitable and effective for the intended purpose;
b) the substances which constitute a component of an active and intelligent material and article are included in the Community list;

c) they comply with the requirements of Article 3 of Regulation 1935/2004, as regards other substances present in the component such as impurities, or reaction products intermediates not be intentionally released, or decomposition products.

2) for releasing active materials and articles the following applies:

a) the amount of the released active substance(s) shall not be included in the value of the overall migration, in cases where an overall migration limit (OML) is established in a specific Community measure for the food contact material in which the component is incorporated;

b) without prejudice to Article 4(1) and 4(3) of Regulation 1935/2004, the amount of the released active substance(s) may exceed the specific restriction established for this substance in a specific Community of national measure on the food contact materials in which the component is incorporated as long as it complies with the Community provisions applicable to food, or if no Community provisions exist, the national provisions applicable to food.

Article 8 – Additional rules on labelling

13. Article 8 lays down the rules on labelling for active and intelligent materials and articles.

i) Article 8(1) allows for the identification by the consumer of non-edible parts, active and intelligent materials and articles or parts of it shall be labelled with the words “DO NOT EAT” and, always where technically possible, the symbol reproduced in Annex 1 shall be indicated.
ii) Article 8(2) provides that the information required by Article 8(1) shall be conspicuous, clearly legible and indelible and that it shall be printed in characters of a font size of at least 3mm.
iii) Article 8(3) prohibits retail trade of active or intelligent materials if the information required under paragraph 2 is not given in a language easily understood by purchasers.

iv) Article 8(4) provides that within its own territory, the Member State in which the material or article is marketed may, in accordance with the rules of the Treaty, stipulate that those labelling particulars required under paragraph 2 shall be given in one or more languages which it shall determine among the official languages of the Community.

v) Article 8(4) and 8(5) shall not prevent the labelling particulars from being indicated in several languages.

vi) Article 8(6) requires that a released active substance shall be considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC

Article 9 – Declaration of compliance

14. Article 9(1) requires that at the marketing stages other than the retail stage, active and intelligent materials and articles or components intended for the manufacturing of those materials and articles or the substances intended for the manufacturing of the components shall be accompanied by a written declaration in accordance with Article 16 of Regulation 1935/2004. Article 9(2) requires that the declaration referred in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex ll. Article 9(3) requires that appropriate documentation demonstrating that the active and intelligent materials and articles as well as the components thereof comply with the requirements of this Regulation be made available by the business operator to the national competent authorities on requests. The documentation provided should include information on the suitability and effectiveness, conditions and results of testing, calculations, other analysis and evidence on the safety or reasoning demonstrating compliance of the active and intelligent materials.

Article 10 – Establishment of the initial Community list

15. In five parts, this Article lays down what happens in the initial stages of the establishment of a Community list. In summary these are that: applications submitted by interested parties for inclusion of substances in the Community list should be made in accordance with Article 9 of Regulation 1935/2004. Deadline for submitting applications will be 18 months following the publication of the EFSA guidelines for the safety assessment of substances used in active and intelligent materials and articles, the guidelines will be issued at least 6 months after the publication of this Regulation. All substances for which a valid application has been submitted will be made publicly available by the Commission. The initial Community list will be adopted by the Commission in accordance with the procedure laid down in Articles 10 and 11 of Regulation 1935/2004. However by way of derogation from that procedure, (a) Article 10(1) of Regulation 1935/2004 shall not apply to the Authority's adoption of its opinion; b) the Commission will adopt its opinion on the initial Community list following the EFSA's adoption of its opinion on all the substances included in the register. The fifth part of this Article deals with the exclusion of a substance under consideration for the initial Community list, if during examination of the data and the applicant fails to submit supplementary information within the specified time limits.

Article 11 – Entry into force

16. Article 11 provides the entry into force day as the 20th day following that of its publication in the Official Journal of the European Union. It also stipulates that Article 3 shall apply from the date of application of the initial Community list. Until that date national provisions in force on active and intelligent materials and articles shall continue to apply. Article 9 shall apply after 6 months of the entry into force of this Regulation. This Article also states that until the date of application of the initial Community list, Article 4(2) of Regulation 1935/2004 remains applicable. The Article also provides that the Regulation shall be binding in its entirety and directly applicable in all Member States.

Annex I and Annex II

17. Annex I is the official symbol to be used under the labelling requirements of Article 8 of this Regulation. Annex II provides details of the information required in a written declaration of compliance.

Specific comments on cost implications

18. We would also welcome comments on any cost implications you might envisage arising from these proposals. More specifically we would welcome comments on the following:

- What numbers of companies are likely to be affected by these proposals and what is the financial impact?
- What are the benefits that can be identified?
- What are the likely policy and administration costs which can be identified? Do you believe that the proposals introduce any new administrative costs both for industry and enforcement authorities, over and above what a business would do commercially?
- Are these proposals likely to have an impact on sustainable development?
- Does any company have more than a 10%, 20% or 50% share of the market affected by these proposals?
- Would the cost of these proposals affect some businesses substantially more than others (e.g. small and medium sized businesses)?
- Are these proposals likely to affect the market structure, changing the number or size of the businesses?
- Are these proposals likely to affect the market structure, changing the number or size of the businesses?
- Would these proposals lead to higher set-up costs for new or potential firms that existing firms do not have to meet?
- Would these proposals lead to higher on-going costs for new or potential businesses that existing firms do not have to meet?
- Is the sector characterised by rapid technological change?
- What, if any, is the likely cost to the environment?

19. If you are commenting on any of the above issues, it would be helpful if they are shown under separate headings from those attributable to the Commissions proposal and those relating to costs. It would also be helpful if you are able to provide evidence to support your views.

Queries

20. Enquiries relating to the contents of this letter can be addressed to the contact given in section 4 on page one of this letter.

Publication of personal data and confidentiality of responses

21. In accordance with the Food Standards Agency's (FSA) principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of the responses, which may include personal data, such as your full name and contact address details. If you do **not** want this information to be released, please complete and return the Publication of Personal Data Form Annex B. Return of this form does not mean that we will treat your **response** to the consultation as confidential.

22. In accordance with the provisions of the Freedom of Information Act 2000 and the Environmental Information Regulation 2004 all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However we will take into account your views when making this decision.

23. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

24. A list of interested parties to whom this letter is being sent appears in Annex A. Please feel free to pass this document to any other parties with an interest in the subject matter, or send us their full contact details and we will arrange for a copy to be sent to them direct.

25. A copy of this consultation letter/package is available on our website at www.food.gov.uk where a summary of the responses received will be published approximately three months after the consultation.

26. This consultation has been prepared in accordance with the Cabinet Office's Code of Practice on Consultation, available at: http://www.cabinet-office.gov.uk/regulation/consultation/code.asp. The Consultation Criteria have been reproduced within Annex C.

27. For details about the consultation process (**not** about the content of the consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 115B Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 0207 276 8630.

28. Criterion 6 of the Cabinet Office Code of Practice states that a consultation must follow better regulation best practice, including carrying out an Impact Assessment. An Impact Assessment has not been prepared at this stage but will be included when a formal consultation is carried out in the future.

Comments on the consultation process itself

29. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to assist us to improve the quality of future consultations, please feel free to share your thoughts with us by using the **Consultation Feedback Questionnaire**, which is attached, in Annex D.

30. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Feedback Questionnaire.

31. If any of the mailing information used to send you this letter has changed, please advise us direct using the Feedback Questionnaire.

32. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully

Nasreen Shah
Policy Manager
Food Protection Division
Incident Prevention and Chemical Risk Management

Enclosures

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Annex A – Circulation list

Annex B– Publication of Personal Data Form

Annex C – Cabinet Office Consultation Criteria

Annex D – Consultation Feedback Questionnaire

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
E3 – Chemicals, contaminants and pesticides

EMB/1127rev3 (08.07.2008)

WORKING DOCUMENT: DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION

Working Document

on active and intelligent materials and articles intended to come into contact with food

Explanatory Note

BACKGROUND

The Framework Regulation (EC) No 1935/2004 on food contact materials establishes the general principles for all materials and articles intended to come into contact with foodstuffs ("food contact materials", FCM). It includes active and intelligent materials and articles. They are defined in the Regulation as follows:

- 'active food contact materials and articles' means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;
- 'intelligent food contact materials and articles' means materials and articles which monitor the condition of packaged food or the environment surrounding the food;

General provisions set out in Regulation (EC) No 1935/2004 for active and intelligent materials cover:

- General safety
- Changes to the composition and organoleptic properties of the food given that these changes comply with the Community provisions applicable to food
- Release of substances into the food only if they are authorised and used in accordance with the relevant Community provisions applicable to food.
- Labelling of released substances in accordance with rules on food labelling; labelling of non-edible parts and labelling to identify that the material is active or intelligent
- No misleading of consumer through changes in food or information given about condition of food
- Information to consumer and food packer on how to use active and intelligent materials and articles safely and appropriately in compliance with food law

The Regulation (EC) No 1935/2004 on FCM does not cover all necessary aspects in detail therefore further requirements for active and intelligent materials and articles need to be set in a specific Commission measure.

DRAFT SPECIFC REGULATION ON ACTIVE AND INTELLIGENT MATERIALS AND ARTICLES

The objective of this draft Regulation is to set down additional requirements to Regulation (EC) No 1935/2004 for active and intelligent materials and articles to ensure their safe use.

These cover in particular

1. Safety of substances used in active and intelligent materials
2. Relation to material specific requirements e.g. on plastic food contact materials
3. Labelling of parts that can be mistaken for food
4. Declaration of compliance

1. Safety of substances used in active and intelligent materials

1.1 Substances intended to be released into food with an intentional function in the food

According to Regulation (EC) No 1935/2004 substances released into food need to be authorised and used in accordance with the applicable food legislation. This principle is confirmed and applied in the specific measure in the following way: If a substance is added directly into the food or via the packaging, in both cases the same rules and legislation should apply. A duplication of authorisation should be avoided therefore no authorisation scheme is foreseen for these substances in the context of active packaging. Regulation remains within food legislation.

- Substances for which a Community authorisation scheme exists for use in food can only be released into food via an active packaging in compliance with the specific food legislation. E.g. food additives: only an authorised food additive can be released into the food in which it is authorised up to the authorised concentration. If a manufacturer intends to release a non-authorised food additive he has to seek authorisation via the Community authorisation scheme for food additives.
- Substances for which no Community authorisation scheme exists for use in food can be released into food via active packaging in compliance with the Community legislation or specific national legislation applicable. E.g. flavourings, nutrient sources, food ingredients.

If legislation on food provides for a limit in food for the "released active substance", the total quantity of this substance in food shall not exceed this limit independently from the source from which it derives (released via packaging or added directly to the food).

The released substances need to be listed in the declaration of compliance (see 4.) and adequate information has to be given to the consumer or food packer to be able to comply with food legislation.

The released substance needs to be listed in the ingredients list.

1.2 Substances that contribute to the active or intelligent function but which are not intended to be released into food and which don't have a function in the food

As these substances have not yet undergone a safety assessment and they might migrate into the food, a similar approach as for plastic materials is suggested. These substances should undergo a safety assessment by the European Food Safety Authority (EFSA) and a Community authorisation. An authorised substance will be listed in a Community list (positive list) specifying its identity, function and, if necessary, conditions or restrictions of use. In certain cases combination of substances may be inserted, e.g. when the safety

assessment is linked to this combination of substances due to their interaction. A generic authorisation is foreseen and not an applicant specific authorisation.

Exempted from the Community authorisation should be substances which are separated from the food by a functional barrier that reduces migration of the substance to a non detectable level if the substance is not classified as proved or suspected to be “carcinogenic”, “mutagenic” or “toxic to reproduction”.

The EFSA is drafting specific guidelines for the submission of applications for substances used in active and intelligent materials that is specifying the data to be provided by applicants.

To set up the Community positive list a transitional period of 18 months is proposed for applications to be submitted for the evaluation and authorisation. After all the valid applications have been evaluated by the EFSA, the Commission will prepare a draft measure for their authorisation or refusing their authorisation. The Commission will make available to the public a register of all substances for which a valid application has been submitted.

2. Relation to other material specific requirements e.g. on plastic food contact materials

This draft Regulation is only covering the component responsible for the active or intelligent function and is not regulating the basic material into which the component is incorporated.

This applies in particular to ceramics, regenerated cellulose films and plastics for which specific Community measures exist but also to paper, rubber, metals etc. which are regulated at national level. In the case of an active plastic absorber, the plastic material has to be manufactured in accordance with the plastics Directive and the active absorber component in accordance with this Regulation.

In the particular case of a "releasing active material": If the material specific measure e.g. the plastic Directive foresees an overall migration limit, the measured overall migration value shall not include the amount of the intentionally released substance.

3. Labelling of parts that can be mistaken for food

Non edible parts of active and intelligent materials, in particular sachets containing substances that can be mistaken for food, shall be labelled with the words ‘do not eat’ and shall be accompanied, where technically possible, by a symbol.

4. Declaration of compliance

- The active and intelligent materials shall not mislead the consumer. Therefore they need to be effective and suitable. Information as regards their effectiveness and suitability shall be included by the business operator in the declaration of compliance and demonstrated in the supporting documentation.
- The declaration of compliance shall contain adequate information relative to the substances for which restrictions are in place. This information shall allow the user of the material to ensure compliance with those restrictions;
- The declaration of compliance shall contain adequate information on the released active substances to allow the user to ensure compliance with the restrictions in the relevant food legislation including the labelling requirements of Directive 2000/13/EC;

1.	Regulation (EC) No 1935/2004[1] establishes that active and intelligent food contact materials and articles (active and intelligent materials and articles) are included in its field of application and, therefore, all the provisions provided for any type of materials and articles intended to come into contact with food (food contact materials) are also applicable to these materials. Similarly, other provisions provided for in other measures such as Directive 2001/95/EEC on general product safety[2] and its implementing measures, and Directive 87/357/EEC concerning products which, appearing to be other than they are, endanger the health or safety of the consumers[3] are also applicable, where appropriate. Therefore the relevant provisions of all these Community measures are not repeated in this Regulation.
2.	Regulation (EC) No 1935/2004 sets out the general principles for eliminating the differences between the laws of the Member States as regards, food contact materials. That Regulation provides in Article 5(1) for the adoption of specific measures for groups of materials and articles and describes in detail the procedure for the authorisation of substances at Community level when a specific measure provides for a list of authorised substances.
3.	Certain rules applicable to active and intelligent materials and articles are set out in Regulation (EC) No 1935/2004. These include provisions for released active substances that have to comply with Community and national provisions applicable to food and labelling rules. Specific rules should be laid down in a specific measure.
4.	This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004. This specific Regulation should establish the specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.
5.	Many different types of active and intelligent materials and articles exist. The substances responsible for the active and/or intelligent function can be contained in a separate container e.g. inclusion in a small paper sachet or, the substances can be directly incorporated in the packaging material e.g. incorporation in the plastic of a plastic bottle. Those substances, responsible for creating the active and/or intelligent function of that material (the components) should be evaluated under this Regulation. The passive parts, such as the container, the packaging into which that container is placed and the packaging material, in which the substance is incorporated, should be covered by the specific Community or national provisions applicable to those materials.
6.	The active and intelligent materials and articles may be composed of one or more layers or parts of different types of materials, such as plastics, paper and board or coatings and varnishes. Requirements for these materials may be either fully harmonised, or only partially harmonised, or not yet harmonised

1 OJ L 338 of 13.11.2004, p.4.
2 OJ L 11 of 15.1.2002, p.4.
3 OJ L 192 of 25 June 1987, p.1

	at Community level. The present rules should apply without prejudice to Community or national provisions that regulate these materials.
7.	The individual substance or, if relevant, the combination of substances which constitute the components should be evaluated to guarantee that they are safe and comply with the requirements set in Regulation (EC) No 1935/2004. In some cases, it may be necessary to evaluate and authorise the combination of substances, when the active or intelligent function implies interactions between different substances leading to an enhancement of the function or the generation of new substances responsible for the active and intelligent function.
8.	According to Regulation (EC) No 1935/2004, when specific measures include a list of substances authorised within the Community for use in the manufacture of materials and articles intended to come into contact with food, those substances should undergo a safety assessment prior to their authorisation. Where relevant, interaction of the substance with other substances, the materials in which it is to be incorporated and the efficacy of the component should be taken into account in the safety assessment.
9.	It is appropriate that the person interested in placing on the market active and intelligent materials and articles or the components, the applicant, should submit all the information necessary for the safety assessment of the substance or, of the combination of substances which constitutes the component.
10.	The safety assessment of a substance or of a combination of substances which constitutes the components should be carried out by the European Food Safety Authority (the Authority), after the submission of a valid application as set out in Articles 9 to 10 of Regulation (EC) No 1935/2004. In order to inform the applicant on the data to be provided for the safety assessment, the Authority should publish a detailed guidance concerning the preparation and the submission of the application. In order to enable enforcement of possible restrictions it would be necessary that the applicant provides an appropriate analytical method for detection and quantification of the substance. The Authority should evaluate if the analytical method is suitable for the purpose of enforcement of the suggested restriction.
11.	The safety assessment of a specific substance or of a combination of substances should be followed by a risk management decision as to whether the substance should be included in the Community list of substances that can be used in active and intelligent components (Community list). That decision should be adopted in accordance with the regulatory procedure described in article 23(2) of Regulation (EC) No 1935/2004 ensuring close cooperation between the Commission and the Member States.
12.	The Community list should include the name, conditions, restrictions or specifications or conditions of use of that substance or of a combination of substances and, where necessary, of the component or of the material and article in which they are added or incorporate into.

13.	Active materials and articles may deliberately incorporate substances, which are intended to be released into food. As these substances are intentionally added to the food, they should only be used under the conditions set out in the relevant Community or national provisions for their use in food. In case the Community or national provisions foresee an authorisation of the substance, the substance and its use should fulfil the requirements of the authorisation under the specific legislation on food e.g. legislation on food additives. Preservatives and enzymes could also be grafted or immobilised on the material and have a technological function on the food that is covered by legislation on food additives and enzymes. Therefore, these applications should be treated in the same way as released active substances.
14.	Intelligent packaging systems provide the user with information on the conditions of the food and should not release their constituents into the food. Intelligent systems may be positioned on the outer surface of the package and may be separated from the food by a functional barrier, which is a barrier within food contact materials or articles preventing the migration from behind this barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided they fulfil certain criteria and their migration remains below a given detection limit. Taking into account foods for infants and other particularly susceptible persons as well as the difficulties of this type of analysis affected by a large analytical tolerance, a maximum level of 0,01 mg/kg in food should be established for the migration of a non-authorised substance through a functional barrier.
15.	The specific Community measure covering the inert part of the active or intelligent material may set down requirements for the inertness of the material for example an overall migration limit applicable to plastic materials. If a releasing active component is incorporated into a food contact material covered by a specific Community measure, there may be the risk of exceeding the overall migration limit due to the release of the active substance. As the active function is not an inherent feature of the inert material the amount of released active substance should not be calculated in the value of overall migration.
16.	Article 4 (5) of Regulation (EC) No 1935/2004 provides that active and intelligent materials and articles already brought into contact with food shall be adequately labelled to allow identification by the consumer of non-edible parts. Consistency of such information seems indispensable to avoid confusion at consumer level. Therefore active and intelligent materials and articles should be labelled with a phrasing and accompanied, where technically possible, by the symbol reproduced in the Annex, whenever the materials and articles or parts of it may be mistaken as part of the food.
17.	Article 16 of Regulation (EC) No 1935/2004 provides that materials and articles shall be accompanied by a written declaration of compliance attesting that they comply with the rules applicable to them. In accordance with Article 5(1) (h) and (i) of that Regulation, to strengthen the coordination and responsibility of the suppliers at each stage of manufacture, the responsible persons should document the compliance with the relevant rules in a

	declaration of compliance which is made available to his customer. Furthermore, at each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities.
18.	Article 17(1) of Regulation (EC) No 178/2002[4] requires the food business operator to verify that foods are compliant with the rules applicable to them. Article 15 (1) (e) of Regulation (EC) No 1935/2004 provides that materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component so as to enable food business operators who use these materials and articles to comply with any other relevant Community provisions or, in their absence, national provisions applicable to food, including the provisions on food labelling. To this end subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration or intentional release from active and intelligent materials and articles to food complies with the specifications and restrictions laid down in Community or national provisions applicable to food.
19.	Since several active and intelligent materials are already on the market in the Member States, provisions should be established to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing market for those materials and articles. Sufficient time should be allowed for the applicant to make available the information necessary for the safety assessment of the substance or the combination of substances which constitutes the component. Therefore, an 18 months period, should be allowed, during which the information on active and intelligent materials and articles should be submitted by the applicants. It should also be possible to submit applications for authorisation of a new substance or of a combination of substances during the 18 months period.
20.	The Authority should evaluate without delay all applications for existing as well as new substances which constitute the components for which a valid application was submitted on time and in accordance with the guidance of the Authority during the initial application phase.
21.	An initial Community list of those substances for which authorisation is proposed should be drafted by the Commission after the completion of the safety assessment of all substances for which a valid petition was submitted in accordance with the guidance of the Authority, during the initial 18 months period. In order to ensure fair and equal conditions for all applicants, this initial Community list should be drawn up in a single step.

[4] OJ L 31 of 1.2.2002, p.1. as last amended by Regulation (EC) No 202/2008 (OJ L 60 of 5.3.2008, p.17.)

Article 1
Subject matter and Scope

1. This Regulation shall apply to:

(a) active food contact materials and articles as defined in Article 2 (2) (a) of Regulation (EC) No 1935/2004 (active materials and articles);

(b) intelligent food contact materials and articles as defined in Article 2 (2) (b) of Regulation (EC) No 1935/2004 (intelligent materials and articles)

which are placed on the market within the Community.

2. This Regulation provides for:

(a) additional requirements to Regulation (EC) No 1935/2004 in relation to active and intelligent materials and articles;

(b) a Community list of substances, listing substances that may be used in active and intelligent components;

(c) additional rules on labelling;

(d) information to be contained in a declaration of compliance.

3. The materials and articles to which active of intelligent components are added or into which they are incorporated shall remain subject to the Community or national provisions applicable to these materials and articles.

4. Unless provided otherwise hereafter, the finished active and intelligent materials and articles that fall within the scope of this Regulation shall remain subject to the Community or national specific measures applicable to these materials and articles.

Article 2
Definitions

For the purpose of this Regulation, the following definitions shall apply:

(a) "component" means an individual substance or a combination of substances which cause the active and/or intelligent function of a material or article, including the products of *in situ* reaction of these substances. It does not include the passive parts, such as the material they are added to or incorporated into.

(b) "functional barrier" means a barrier consisting of one or more layers of food contact materials which ensures that the finished intelligent material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with this Regulation.

(c) "releasing active materials and articles" are those materials and articles designed to deliberately release substances into or onto the packaged food or the environment surrounding the food.

(d) "released active substances" are those substances intended to be released from active materials and articles into or onto the packaged food or the environment surrounding the food and having a function on the food.

Article 3
Community list of substances that can be used in active and intelligent components

1. Active and intelligent materials and articles shall be placed on the market only if the substances

which constitute the component of an active and intelligent material and article are included in the Community list of substances that may be used in active and intelligent components (hereinafter referred to as "Community list").

2. By derogation from paragraph 1, substances deliberately incorporated into active materials and articles to be released into food or the environment surrounding the food, do not need to be listed in the Community list. They shall be used in accordance with the relevant Community and national provisions applicable to food, and shall comply with the provisions of Regulation (EC) No 1935/2004 and its implementing measures. The same shall apply to substances falling under the scope of Community or national provisions applicable to food, which are incorporated in active materials and articles by techniques such as grafting and immobilisation, in order to have a technological effect in the food.

3. By derogation from paragraph 1, intelligent material and articles, in which the component is not in direct contact with food or the environment surrounding the food and is separated from the food by a functional barrier, other substances than those included in the Community list may be used.

   The migration of the substances referred to in the above sub-paragraph into food shall not exceed 0,01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council[5]. This limit shall always be expressed as concentration in foods. It shall apply to a group of substances, if they are structurally and toxicologically related, in particular isomers or substances with the same relevant functional group, and shall include possible set-off transfer.

   The substances referred to in the first sub-paragraph shall not belong to either of the following categories:

   (i) substances classified as proved or suspected “carcinogenic”, “mutagenic” or “toxic to reproduction” substances in Annex I to Council Directive 67/548/EEC[6];

   (ii) substances classified under the self-responsibility criteria as ‘carcinogenic’, ‘mutagenic’ or ‘toxic to reproduction’ according to the rules of Annex VI to Directive 67/548/EEC.

Article 4
Conditions for inclusion of substances in the Community list

Without prejudice to Article 3 (2) and (3), substances which constitute the component of active and intelligent materials and articles, may be included in the Community list if, under the intended condition of use of the active and intelligent material and article in which they are used, the requirements of Article 3 and, where they apply, Article 4 of Regulation (EC) No 1935/2004 are satisfied.

Article 5
Authorisation procedure

1. Substances which comply with the conditions set out in Article 4 of this Regulation shall be included in the Community list in accordance with the procedure of authorisation laid down in Articles 9 to 11 of Regulation (EC) No 1935/2004.

2. The Community list shall be amended in accordance with the procedure referred to in Articles

[5] OJ L 191 of 28.5.2004, p.1. as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363 of 20.12.2006, p.1.)

[6] OJ 196, 16.8.1967, p. 1. as last amended by Directive 2006/121/EC (OJ L 396 of 30.12.2006, p. 850)

9 to 11 of Regulation (EC) No 1935/2004.

Article 6
The content of the Community list

The entry of a substance or of a combination of substances in the Community list shall specify:

(a) the identity of the substance(s);

(b) the function of the substance(s);

(c) the register number;

(d) if necessary, the conditions of use of the substance(s);

(e) if necessary, restrictions and/or specifications of use of the substance(s);

(f) if necessary, conditions of use of the component or of the material and article to which it is added or into which it is incorporated.

Article 7
Placing on the market of active and intelligent materials and articles

In addition to the specific requirements for active and intelligent materials set out in Article 4, Article 15(1)(e) those materials and articles shall comply with the following requirements.

1. Active and intelligent materials and articles shall only be placed on the market if:

(a) they are suitable and effective for the intended purpose of use;

(b) the substances which constitute the component of an active and intelligent material and article are included in the Community list;

(c) they comply with the requirements of Article 3 of Regulation (EC) No 1935/2004, as regards other substances present in the component such as impurities, or reaction intermediates not to be intentionally released, or decomposition products.

2. For releasing active materials and articles the following applies:

(a) the amount of the released active substance(s) shall not be included in the value of the measured overall migration, in cases where an overall migration limit (OML) is established in a specific Community measure for the food contact material in which the component is incorporated;

(b) without prejudice to Article 4 (1) and 4 (3) of Regulation (EC) No 1935/2004, the amount of the released active substance(s) may exceed the specific restriction established for this substance in a specific Community or national measure on the food contact materials in which the component is incorporated as long as it complies with the Community provisions applicable to food, or, if no Community provisions exist, with the national provisions applicable to food.

Article 8
Additional rules on labelling

1. To allow identification by the consumer of non-edible parts, active and intelligent materials and articles or parts of it shall be labelled with the words "DO NOT EAT" and, always where technically possible, the symbol reproduced in Annex I shall be indicated.

2. The information required by paragraph 1 shall be conspicuous, clearly legible and indelible. It shall be printed in characters of a font size of at least 3mm.

3. Retail trade of active or intelligent materials and articles shall be prohibited if the information required under paragraph 2 is not given in a language easily understood by purchasers.

4. Within its own territory, the Member State in which the material or article is marketed may, in accordance with the rules of the Treaty, stipulate that those labelling particulars required under paragraph 2 shall be given in one or more languages which it shall determine from among the official languages of the Community.

5. Paragraphs 4 and 5 shall not preclude the labelling particulars from being indicated in several languages.

6. Released active substance shall be considered as ingredients within the meaning of Article 6(4)(a) of Directive 2000/13/EC

Article 9
Declaration of compliance

1. At the marketing stages other than the retail stage, active and intelligent materials and articles or the components intended for the manufacturing of those materials and articles or the substances, intended for the manufacturing of the components shall be accompanied by a written declaration in accordance with Article 16 of the Regulation (EC) No 1935/2004.

2. That declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex II.

3. Appropriate documentation to demonstrate that the active and intelligent materials and articles as well as the components intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request. That documentation shall contain information on the suitability and effectiveness of the active and intelligent material and article, conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

Article 10
Establishment of the initial Community list

1. The initial Community list shall be drawn up on the basis of applications made pursuant to paragraph 2.

2. Interested parties may submit applications for the inclusion of a substance in the Community list according to Article 9 of Regulation (EC) No 1935/2004.

   The deadline for submitting applications shall be 18 months following the publication of the guidelines of the Authority for the safety assessment of substances used in active and intelligent materials and articles. The Authority shall at the latest 6 months after the publication of this Regulation publish guidelines for the safety assessment of substances to be used in active and intelligent materials and articles.

3. The Commission shall make available to the public a register of all substances for which a valid application has been submitted in accordance with paragraph 2.

4. The initial Community list shall be adopted by the Commission in accordance with the procedure laid down in Article 10 and 11 of Regulation (EC) No 1935/2004. However, by way of derogation from that procedure:

   (a) Article 10(1) of Regulation (EC) No 1935/2004 shall not apply to the Authority's adoption of its opinion;

(b) The Commission shall adopt the initial Community list after the Authority has delivered its opinion on all substances included in the register.

5. A substance shall be excluded from consideration for the initial Community list if during the examination of the data on that substance, the Authority calls for supplementary information and the applicant fails to provide the additional data within the set time limit.

Article 11
Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.

Article 3 shall apply from the date of application of the initial Community list. Until that date, national provisions in force concerning active and intelligent materials and articles shall continue to apply.

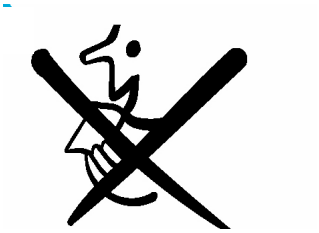
Article 9 shall apply after 6 months of the entry into force of this Regulation.

Article 4(2) of Regulation (EC) No 1935/2004 remains applicable until the date of application of the initial Community list.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

SYMBOL



ANNEX II

DECLARATION OF COMPLIANCE

The written declaration referred to in this Regulation shall contain the following information:

1. the identity and address of the business operator which manufactures or imports the active and intelligent materials and articles, or the components intended for the manufacturing of those materials and articles, or the substances intended for the manufacturing of the components;
2. the identity of the active and intelligent materials and articles or the components intended for the manufacturing of those materials and articles, or the substances intended for the manufacturing of the components;
3. the date of the declaration;
4. the confirmation that the active and intelligent material and article meets relevant requirements laid down in this Regulation, Regulation (EC) No 1935/2004, and in specific measures applicable;
5. adequate information relative to the substances which constitute the components, for which restrictions are in place under the Community or national provisions applicable to food and this Regulation; where appropriate, specific purity criteria in accordance with the relevant

Community legislation applicable to food and, the name and quantity of the substances released by the active component, to allow the downstream business operators to ensure compliance with those restrictions;

6. adequate information on the suitability and effectiveness of the active and intelligent material and article;

7. specifications on the use of the component, such as:
   (i) type or types of materials and articles in which the component can be added or incorporated into;
   (ii) conditions of use necessary to achieving the intended effect.

8. specifications on the use of the material and article, such as:
   (i) type or types of food intended to be put in contact with;
   (ii) time and temperature of treatment and storage in contact with the food;
   (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article.

9. when a functional barrier is used, the confirmation that the intelligent material or article complies with the requirements of Article 3(3) of this Regulation.

The written declaration shall permit an easy identification of the active and intelligent materials and articles or the component or the substance for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.

Circulation List

Name	Company
Mr Alan Turner OBE	
Julia Scott	
Mr Paul Anthony Taylor	
Nigel Barnwell	
Joy Hardinge OBE	AJH Consulting
Mr A J Newbould	AJN Solutions
Dr P Donnelly	APD Scientific Limited
Mr Stuart MacConnacher	AMDEA
Anton Davis	Alba Plastics
	Association of Consumer Research
	Association of Port Health Authorities
Mrs R McBrown	Avent Limited
Nicola Smith	Bird and Bird
Dr Steve Owen	Boots PDQ Centre
Mr A J Newbould	British Coatings Federation
	British Disposable Products Association
Dr Mercia Gick	British Plastics Federation
Sarah Plant	British Plastics Federation
Sally Barber	British Retail Consortium
Lucy Pearson	British Soft Drinks Association
Peter Vincent	BPIF
Mr Roger Hamby	CATRA
Alex Cole	Cadbury Schweppes
John Hammond	Campden & Chorleywood Food Research Association
Mr N Byrd	Campden & Chorleywood Food Research Association
Mr Keith Warren	Catering Equipment Suppliers Association
Dr S Parry	Centre for Analytical Research in the Environment
Dr Joanne Lloyd	Chemical Industries Association
Ms K Goodburn	Chilled Food Association
Victoria Sayer	Colormatrix Europe
Andrew Barnetson	Confederation of Paper Industries
Richard Whittaker	Crown Corporate Technologies
Mr J Begg	Dairy Industry Federation
Mr Brian McMullen	Danapak Flexibles Limited
Catherine Trueman	Department for the Environment, Food and Rural Affairs
Steve Ringer	Department for Business, Enterprise and Regulatory Reform
Mr John Askew	Dexter Packaging Products
Liz Fleming	Eclipse Scientific Group
	Enterprise Directorate
	Federation of Small Businesses
Ann Davison	FOODAWARE
Mr Richard Ratcliffe	Food Additives and Ingredients Association
Andrew Curtis	Food And Drink Federation

Dr Stephen Fellows	Food Policy Update
	Friends of the Earth
Ian Blakemore	Halton Borough Council
Mr R Colwell	H J Heinz
Mr Julian Stocker	H J Heinz
David Eaves	ICI Paints
Mr J Plaistowe	ICI Packaging Coatings Limited
	Industry Council for Packaging and the Environment
Mr Richard Armstrong	Innovia Films
Mr Jeff Graham	JEFPAC Limited
Mr Darren Prosser	Kenwood Limited
Mr John Webb-Jenkins	Kirkstone Plastics Limited
John Marriott	Laboratory of the Government Chemist
Mr Les Bailey	LACORS
Jon Averns	London Port Health Authority
Mr Christopher Sherlock	Lovell White Durrant
Peter Wight	Marks & Spencer Plc
Mr D A Smith	Metal Packaging Manufacturers Association
Mr A Woods	Metal Packaging Manufacturers Association
Sue Dibb	National Consumer Council
Mrs A Townshend	National Consumers' Federation
Katsuji Shibata	Nippon Gohsei
	Office of Fair Trading
Mr Roger Parry	Packaging and Films Association
Mr David Tyson	Packaging and Films Association
Robert Broughton	Packaging and Films Association
Martin Unwin	Packaging and Films Association
David Creek	Pillsbury Europe
Martin Addicott	Pulse Speciality Products
Mr I Cooper	PIRA International
Michael Burcher	Plastics Europe
Mr J Sidwell	RAPRA Technology Limited
Mr Roy Dixon	RDA Packaging Consultants
Mr Trefor Owen	Rexam Plastic Packaging
Ms L Creighton	SafePharm Laboratories Limited
John Figgins	Sainsburys Supermarkets Limited
Mr Stan Webb	Sinclair International Limited
Mrs L Freeman	Society of Chemical Industry
	Sustain
Mr John Swift	SCA Packaging
Ms Lynda Hamilton	Technical Indexes
Iain Ferguson	The Co-operative Retail Group (CWS) Ltd
Mr Ken Hardman	The Industrial Packaging Association
Mr Pete Watts	Toxicology Advice & Consulting Limited
Mr N Cull	Trading Standards Institute
Mr Barry Pamplin	United Biscuits (UK) Limited
Kay Flett	UNIVAR Limited
Mr D Finnegan	Weetabix Limited

Ms A Bristow	WHICH
Mr Ronald Pierre-Davis	Wilsanco Plastics Limited

Annex B

Privacy Statement

The **FOOD STANDARDS AGENCY** is totally committed to complying with the 1998 Data Protection Act principles that protect facts and opinions about the individual. Any personal information that you provide will only be used for a specific purpose. We will not pass on personal information to others outside of our organisation unless the Data Protection Act allows us to do so. *If you have concerns about your personal data please contact the Food Standards Agency Data Protection Officer at* Data.Protection@foodstandards.gsi.gov.uk

Publication of Personal Data

Please note that the Food Standards Agency may publish details that you supply in legitimate pursuit of the functions of the organisation.

As the publication of responses in full may include personal data (such as your full name and contact address details), would you please let us know if you object to us using this information.

Please tick the box below, complete the relevant details and return this form (together with your response) to indicate your objection.

☐ I **do not** agree to the publication of my personal details.

*** If no objection is received we will assume that you consent to full disclosure of your personal details and these may be published.**

Full Name	
Full postal address	

To comply with the *Data Protection Act 1998*, it is essential that we keep our records up to date. Would you therefore please inform us if your personal details change in any way.

This form has been issued by:	
If you have any queries, please contact:	

General information about the most recent Data Protection Act can be viewed on the Information Commissioner's Office website at www.dataprotection.gov.uk.
For general enquiries you may contact Tel: 01625 545745

Annex C

CABINET OFFICE CODE OF PRACTICE ON CONSULTATION

THE SIX CONSULTATION CRITERIA

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.

2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.

3. Ensure that your consultation is clear, concise and widely accessible.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.

5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator.

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

Annex D

PROPOSAL OF THE EUROPEAN COMMISSION FOR A REGULATION ON ACTIVE AND INTELLIGENT MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

Consultation Feedback Questionnaire

We would be interested in what you thought of this consultation package. We would be grateful if you could spend a few minutes to complete the following questionnaire and return it even if you do not intend to respond to the consultation itself. Please return the questionnaire no later than **31st August 2008** to:

Benjamin Nketiah
Food Protection Division
Incident Prevention and Chemical Risk Management
Room Area 4C, Aviation House
125 Kingsway, London WC2B 6NH
Tel: 020 7276 8339
Fax: 020 7276 8514

Or by email to: Benjamin.nketiah@foodstandards.gsi.gov.uk

1. How did you become aware of this consultation exercise?

Our consultation list included your/your organisation's name	[ ]
Via the Food Standards Agency website (www.food.gov.uk)	[ ]
Via the UK Online website (www.ukonline.gov.uk)	[ ]
Through a Food Standards Agency publication (please specify title)_____	[ ]
Other publication (please specify title)_____	[ ]
Other means (please specify)_____	[ ]

2. If you / your organisation are not responding to the consultation, is it because:

You are not working on this subject area	[ ]
The consultation topic is not relevant to you	[ ]
You do not have the time / resources to reply	[ ]
Other reason (please specify)	[ ]

3. Do you feel you were given enough time to respond to the issues / proposals in the consultation?

YES [ ]

NO [ ]

4. Were the issues / proposals clearly set out and easy to understand?

YES [ ]

NO [ ]

5. Do you have any suggestions on how the consultation package could have been improved?

6. Do you have any other comments about this consultation exercise? (Please continue overleaf if required)

7. If you received this consultation direct, were the contact and address details correct? If not please kindly provide the correct contact details for us to use in the future.

8. Do you still wish to remain on our consultation list?

YES [ ]

NO [ ]

9. Are there any other Food Standard Agency subject areas on which you would be interested in receiving future consultations?

Name: ……

Organisation: ……..
……
……
……
……

Date: ……..

THANK YOU FOR TAKING THE TIME TO COMPLETE AND RETURN THIS FEEDBACK QUESTIONNAIRE