

**CONCORDAT BETWEEN
THE FOOD STANDARDS AGENCY AND
THE DEPARTMENT OF HEALTH**

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CONCORDAT BETWEEN
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Introduction

1. This Concordat sets out an agreed framework for co-operation between the Food Standards Agency (FSA) and the Department of Health (DH). It is not a legally binding agreement or a contract between the FSA and DH, nor is it intended to cover every detailed aspect of the relationship between the two. Rather, it is a statement of the principles which will guide relations between the FSA and DH to ensure sufficient communication and co-ordination to enable each to discharge its respective responsibilities effectively. The Concordat cannot override the statutory duties and powers of either the FSA or DH. It will be published.

Background

2. The FSA was established by the Food Standards Act 1999 (the Act) as a non-Ministerial UK government department headed by a Chairman and Board. It is accountable to the Westminster Parliament through Health Ministers and to the devolved administrations through their respective health ministers. The published Explanatory Notes to the Food Standards Act show that the FSA is to be "the primary source of policy advice in relation to food safety and associated areas to the Government as a whole, and to the devolved authorities. Most of the relevant expertise available to the Government and those authorities in the area of food safety and standards will therefore reside with the Agency and will not be duplicated within other government departments". It is therefore of paramount importance that Health Ministers have confidence in the advice and support they receive from the FSA and its officials in carrying out their Parliamentary duties.
3. Under s.19 of the Act the FSA has power to publish its advice to Ministers and others. The FSA discusses food policy in open meetings and policy advice to Ministers resulting from those discussions is published. In accordance with the Act, before publishing its advice, the FSA considers whether the public interest in disclosure is outweighed by confidentiality considerations. A typical model for FSA development of policy advice to Government is at Annex A.

General Principles

4. The Chief Executive of the FSA and the Permanent Secretary of DH jointly affirm their commitment, in the interests of good government, to develop effective working relationships so as to ensure that the best possible service is delivered. Officials of each organisation will continue to maintain regular contact (both formal and informal) in order to discuss business of mutual interest. Good communication in both directions will be essential to effective working within and between both organisations.

5. In the event of a dispute arising over the operation of this concordat, both organisations are committed to resolving the issue bilaterally at working level wherever possible. In the event that agreement cannot be reached, the matter will be passed to a senior level in each organisation, or, if necessary, to Chief Executive and Permanent Secretary level, for a decision.
6. In particular, the FSA and DH agree:
 - (i) to adopt a policy of 'no surprises' and to keep each other promptly and regularly informed about all work being undertaken by one organisation in which the other organisation has an interest, including the work of local authorities, where this is driven by one of the organisations or where relevant information is made available to one of the organisations, and bodies for which each is responsible. This will apply unless, because of the confidential nature of the information, it cannot be supplied from one organisation to the other;
 - (ii) to advise each other as far in advance as possible of any proposed announcement by one organisation which is of interest to the other;
 - (iii) where one organisation proposes to make an announcement which describes the responsibilities of the other, to agree with the other organisation how its responsibilities are described;
 - (iv) to give appropriate consideration to the other organisation's views on matters in which each has an interest;
 - (v) whenever possible to request advice in good time, and to provide an account of its expected use;
 - (vi) to inform the other organisation without delay of any relevant information which would require their action, particularly in order to ensure that public health interests are effectively protected;
 - (vii) to make available to each other full and open access to scientific, technical and policy information, and research and surveillance findings;
 - (viii) in line with our respective strategic aims to pursue opportunities for joint planning and joint funding of research and surveillance, and to co-operate fully where joint programmes are appropriate, for example on research with nutrition and other lifestyle elements;
 - (ix) to co-operate fully on public information and education programmes where the FSA and DH have shared responsibilities;
 - (x) to include representatives from each organisation in discussions on areas of mutual interest; and

- (xi) to co-operate fully on relationships with the food industry, relevant NGOs and academics.

Division of Responsibilities

- 7. The remits of the FSA and DH are as set out in Annex B. Where it is necessary to make changes to policy in which both organisations have an interest, the lead organisation will be responsible for the formulation of policy and the provision of administrative support essential to any legislative changes. Where the latter is necessary, the lead organisation will provide the other with instructions and guidance.

Parliamentary Business

- 8. The DH Parliamentary Clerk will be the principal point of contact for the House authorities on parliamentary business relating to matters within the remit of the FSA. The Clerk will be also responsible for managing relevant papers to and from Ministers' Private Offices and for communicating decisions, requests, details of business and other information to the FSA. The FSA Parliamentary Liaison Officer will be responsible for organising debates on Scrutiny of European legislation and for arranging, in liaison with the relevant Private Office and the Parliamentary Clerk, for written Ministerial statements to be made on areas of FSA's work attracting significant interest from MPs.
- 9. The FSA will be responsible for drafting and collating replies to Parliamentary Questions, briefing and other material in support of Health Ministers' participation in Parliamentary business concerning food safety and standards. The FSA's Parliamentary Liaison Officer will be responsible for conveying this to the DH Parliamentary Clerk. This officer will be the normal point of contact for any enquiries and requests from DH concerning the FSA's work on Parliamentary matters. This is without prejudice to the need for regular contact between the Private Offices of the Minister for Public Health and the FSA Chair and Deputy Chair.
- 10. The FSA will respond within agreed timescales to letters passed to it by DH from MPs and letters from members of the public. Monitoring of performance in these two areas will be maintained to measure levels of performance. This will cover performance by the FSA in meeting DH deadlines and by DH in ensuring letters concerning FSA business are given appropriate priority to enable them to meet agreed service standards

Nutrition

11. The FSA and the Department of Health both have important roles in nutrition. The FSA will be responsible, amongst other things, for the provision of readily intelligible, scientifically based information about the nutritional content of individual foods and impartial accurate advice on a balanced diet. DH will retain responsibility for the wider public health policy issues where nutritional status is one of a number of risk factors. The division of responsibilities is set out in more detail in Annex C to this concordat.
12. The FSA and DH will work closely together to ensure they discharge effectively their responsibilities in the area of nutrition. The FSA and DH will each publish objectives and targets, and report publicly on their work against these. In setting targets, each will consult the other in order to promote coherent working.

Foodborne Communicable Disease

13. The FSA and DH have a shared interest in communicable diseases although each has its own specific area of interest. DH has responsibility for overall communicable disease strategy as part of its wider responsibility for protecting public health. It will ensure that the strategy is developed with the full co-operation of all contributors to communicable disease control, including the FSA which is responsible for foodborne infections. The two organisations will also co-operate on emerging infections that may arise and may pose a potential threat to human health via food. The FSA and DH recognise the need to co-operate on such matters in order to achieve the best possible prevention and control of communicable disease.

The Health Protection Agency

14. The Health Protection Agency (HPA) was established on 1 April 2003 as a Special Health Authority sponsored by DH. Since 1 April 2005, it has operated as a non Departmental Public Body. Its functions, duties and powers are accorded to it by Parliament and the National Assembly for Wales. The HPA has responsibility for collection of statutory notifications of food poisoning and surveillance of the incidence of gastrointestinal infection, and providing or commissioning microbiological testing of food, water and environmental samples. As such, the FSA has established a clear relationship with the HPA, which is set out in a separate concordat.
15. The HPA will continue to receive its core funding from the DH and the National Assembly for Wales. In recognition of the FSA being lead Government customer of the HPA for food-related issues, DH will invite the FSA to its customer liaison meetings and relevant in-year reviews relating to the food work of the HPA. It will also consult the FSA, as of right, before the annual Ministerial Accountability Review of the HPA .

The Medicines and Healthcare Products Regulatory Agency

16. The Medicines and Healthcare products Regulatory Agency (MHRA) is an Executive Agency of DH established on 1 April 2003 to protect and promote public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.
17. The FSA and the MHRA have a shared interest in 'borderline' products which could be classified as either foods or medicines. They also share an interest in the safety and quality evaluation of substances which may become part of either foods or medicines, and in the evaluation of novel technologies (e.g. biotechnology) important for the development of both novel foods and new medicines. The FSA and the MHRA confirm their commitment to co-operate on such matters to allow each to fulfil their respective responsibilities effectively.

Public Bodies

18. The FSA and DH agree to inform each other about the establishment and operation of any bodies for which they have responsibility, whose work has implications for each other's activities. In addition, the FSA and DH confirm their commitment to ensuring that advisory committees, in which they both have an interest, operate effectively. Arrangements for handling joint committees will be agreed between officials of the two departments and may include such issues as appointments, provision of secretariat, agendas and briefing and payment of fees and expenses.

EU and International Arrangements

19. The FSA advises the Government as a whole on EU and international issues in the areas for which it has responsibility. In addition, its staff support Ministers in negotiating the agreed UK line in the EU Council of Ministers, whether or not this coincides with the FSA's original advice. The FSA and DH recognise the need to work in effective partnerships in pursuit of common interests in the formulation, negotiation, implementation and enforcement of EU and international policies, agreements, rules and legislation. This includes consulting and providing advice to each other. The FSA will aim to deliver the commitments across Europe and internationally set out in its Strategic Plan (2005-2010). In addition to working with the European institutions and other EU Member States, liaison between the two Departments involves work in the Codex Alimentarius Commission, the World Health Organisation, the World Trade Organisation, the Food and Agricultural Organisation of the United Nations, the International Office of Epizootics, the Council of Europe and other international organisations. The Agency will keep the MS(PH) informed on developments concerning its significant EU business, including via quarterly stocktake meetings, taking account of his/her comments. It will arrange for the MS(PH) to clear and sign letters to the EP Committee, Explanatory Memoranda and letters to the scrutiny committees and responses to key Commission consultations. It will ensure MS(PH) is informed and/or consulted at an early stage in all areas of formal disagreement with the Commission, including any proposed votes to

oppose or abstain over Commission proposals in Standing Committee. Beyond this, Agency and DH officials will exchange information and engage constructively over EU business with potentially mutual interests.

20. Whichever department has the main policy responsibility will normally take the lead, including providing official level representation at working level meetings. The lead Department will seek to provide the other with full information, as early as possible, on all relevant new developments and initiatives, including notifications of relevant meetings. The other department will be kept informed and fully consulted about any matter in which it has an interest. Where policy responsibility is shared between DH and the FSA, arrangements may be decided on an ad hoc basis. In some cases it may be appropriate for officials from both departments to attend these meetings.
21. DH and the FSA will consult over the preparation and handling of any matter of FSA business which appears on the agenda of a meeting of the Council which involves Health Ministers. The Food Standards Agency will continue to be party to the existing Whitehall-wide EU communication and co-ordination mechanisms, including use of the Cabinet Office machinery where there are disagreements between Departments.
22. Where necessary in response to international requests for information or inspection visits by officials from third countries, the FSA will provide technical input concerning its involvement in the UK regulatory system for food.

Arrangements for Handling Emergencies

23. The FSA and DH agree to inform each other immediately in the event of an emergency (or potential emergency) or serious incident which may have an impact on the other's responsibilities. They are also committed to working closely together to ensure that any emergency or serious incident is dealt with effectively, and agree to co-operate fully on any relevant action. Further details of FSA and DH roles and responsibilities in the event of an outbreak or food emergency are specified in Annex D to this concordat.
24. Both departments will work together in drawing up emergency and contingency plans and in planning and running appropriate major emergency exercises. This will include close liaison on strategies for media handling. The FSA and DH will provide each other with adequate notice of planned emergency exercises, with at least six weeks' notice if the participation of the other is sought.

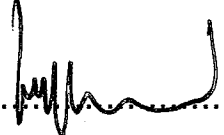
Charging

25. The FSA and DH may need to charge one another for some services although careful consideration will be given to that need and in the first instance consideration will be given to making a public expenditure transfer. When charging, HM Treasury guidance will be followed and payment will normally be made at full cost recovery.

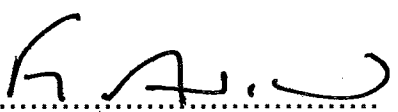
Operation and Review of Concordat

26. Amendments to this Concordat may be made at any time by agreement between the organisations. In addition, this agreement will be reviewed at intervals to be agreed between the FSA and DH, and be updated as necessary in the light of experience of its operation in practice.

Signed by
John Harwood
Chief Executive
Food Standards Agency



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Fiona Adshead
Deputy Chief Medical Officer
Department of Health



Date
04 Sep 2007

ANNEX A: MODEL FOR FSA DEVELOPMENT OF POLICY ADVICE TO GOVERNMENT

1. FSA Board gives steer on area of advice to be covered.
2. FSA gathers evidence.
3. Policy options worked up by FSA in consultation with stakeholders (external as well as all Government Departments with an interest).
4. Public consultation (written and, sometimes, public meetings) on policy options.
5. FSA Board discusses result of consultation in open meeting and decides on its advice to Government
6. FSA advice sent to Ministers (normally by letter from FSA Chair).
7. Minister(s) reach(es) decision on FSA advice (with involvement of relevant Cabinet committee if appropriate).
8. Government decision announced. If FSA advice has not been accepted, this announcement explains why.

ANNEX B: THE REMITS OF THE DEPARTMENT OF HEALTH AND THE FOOD STANDARDS AGENCY

The remit of the Food Standards Agency

The main objective of the Food Standards Agency is to protect public health from risks which may arise in connection with the consumption of food, including risks caused by the way in which it is produced or supplied, and otherwise to protect the interests of consumers in relation to food. Under the Food Standards Act 1999, the Food Standards Agency will have responsibility for the development of food policy and for the provision of advice, information and assistance in respect of matters connected with food safety, or other interests of consumers in relation to food, to public authorities (Ministers, government departments and their equivalents in the devolved authorities, local authorities or agencies of government), and to the general public or to individuals and bodies who are not public authorities.

The remit of the Department of Health

The Department of Health's overall aim is to improve the health and well being of the people of England through the resources available by:

- supporting activity at national level to protect, promote and improve the nations' health;
- securing the provision of comprehensive, high quality care for all those who need it, regardless of their ability to pay or where they live;
- securing responsive social care and child protection for those who lack the support they need.

ANNEX C: NUTRITION – ROLES AND RESPONSIBILITIES

The Food Standards Agency will be responsible for:

1. Providing the definition of a balanced diet for subsequent use in health education and training material, and promoting (where appropriate in partnership with other bodies) the availability and uptake of a balanced diet.
2. Providing authoritative factual information and advice about the nutrient content of individual foods and on the diet as a whole, as well as components thereof.
3. Monitoring and surveillance of the nutrient content of food and diet.
4. Proposing necessary legislation and voluntary action as appropriate relating to nutritional aspects of food, including labelling and claims, dietary supplements sold as food, fortified foods and functional foods.
5. Provide practical guidance and working with industry in relation to nutritional aspects of the food chain, including production, distribution, supply and promotion.
6. Representing the UK in international negotiations on issues relating to nutritional content of food (except when this relates to vulnerable groups such as mothers who are breastfeeding), on food and nutrition labelling and on foods for particular nutritional purposes. In the specific case of infant formula, the FSA leads on safety and nutritional content issues, and DH on policy on its use and promotion.
7. Formulating policy and providing advice to Ministers on the above issues. (1-6).
8. Commissioning research on food and diet appropriate to its responsibility for the above issues (1-7).

Health Departments will be responsible for:

9. Wider public health policy issues including nutritional aspects of clinical conditions (such as cardiovascular disease, cancer, osteoporosis or obesity) where nutritional status is one of a number of risk factors.
10. Consideration of vulnerable groups such as pregnant women and mothers who are breastfeeding. In the specific case of infant formula, the FSA leads on safety and nutritional content issues, and DH on policy on its use and promotion.
11. All links with the NHS and health professionals, breast-feeding promotion in the NHS, clinical nutrition and dietetics including hospital catering and nutritional therapy.
12. Health surveillance of the population.

13. Representing the UK in international negotiations on dietary issues relating to health and on issues relating to the nutritional content of food where this relates to vulnerable groups such as mothers who are breastfeeding, other than foods for particular nutritional purposes.
14. Formulating policy and providing advice to Ministers on the above issues (9-13).
15. Commissioning food and diet research appropriate to its responsibilities for the above issues (9-14).

FSA and DH will share responsibility for:

16. Providing the Joint Secretariat of the Scientific Advisory Committee on Nutrition.
17. Surveillance of the nutrient intake and nutritional status of the general population.
18. Health education on wider behavioural issues which include nutrition (such as obesity).
19. Policy formulation and advice to Ministers on these issues (16-18).

ANNEX D: OUTBREAKS AND FOOD EMERGENCIES

1. The Food Standards Agency is responsible for taking appropriate action in the event of outbreaks of foodborne infection and food hazards.
2. The Department of Health will retain responsibility for the public health aspects of outbreaks of gastro-intestinal infection where food is not, or is not thought to be, the vehicle of infection. These include outbreaks related to water, both tap water and recreational water, those related to direct contact with animals or with contaminated environments, and those caused by person-to-person spread.

The Food Standards Agency will:

3. Be responsible for maintaining the Food Alert system and for receiving RASFF transmissions from the European Commission.
4. Be the point of government contact for the HPA Centre for infection in relation to outbreaks of foodborne disease.
5. Deal, on behalf of CMO, with reports of serious outbreaks of disease, notified under the provisions of the Public Health (Infectious Disease) Regulations 1988, where these involve foodborne disease.
6. Liaise with Local Authorities, Health Authorities, Food Producers and Food Retailers to ensure that appropriate action is taken to protect public health in the event of food hazards or outbreaks of foodborne disease.
7. Be responsible for advising Ministers on outbreaks of foodborne disease.
8. Be the contact point for the WHO INFOSAN emergency system.

The Department of Health will:

9. Remain the point of government contact for the HPA Centre for infection in relation to outbreaks of non-foodborne disease.
10. Continue to deal, on behalf of CMO, with reports of serious outbreaks of disease, notified under the provisions of the Public Health (Infectious Disease) Regulations 1988, where these do not involve foodborne disease.
11. Determine who should take the lead in liaising with Local Authorities, Health Authorities, and other appropriate agencies to ensure that appropriate action is taken to protect public health until such time as the route of transmission is established.
12. Liaise with Local Authorities, Health Authorities, and other appropriate agencies to ensure that appropriate action is taken to protect public health in the event of outbreaks of non-foodborne disease.

13. Be responsible for advising Ministers on outbreaks of non-foodborne disease.
14. Be responsible for advising Ministers on issues associated with the international health regulations, taking advice from the Food Standards Agency on food-related aspects.

The Department of Health will share with the Food Standards Agency responsibility for:

15. Receiving information from the HPA Communicable Disease Surveillance Centre in relation to outbreaks where foodborne and non-foodborne transmission both remain possible routes of spread.
13. Determining who should take the lead in liaising with Local Authorities, Health Authorities, and other appropriate agencies to ensure that appropriate action is taken to protect public health until such time as the route of transmission is established.
14. Advising Ministers on outbreaks where foodborne and non-foodborne transmission both remain possible routes of spread. This will require close liaison between the two organisations.

ANNEX E: CORRESPONDENCE PROTOCOL

Protocol for working arrangements for Ministerial correspondence between the Food Standards Agency (FSA) and the Department of Health.

Introduction

This protocol recognises that the FSA is an independent organisation, and the protocol is designed to ensure that, as far as possible, smooth business processes are in place to get letters requiring a Ministerial signature into the Minister's office as quickly as possible so that FSA letters can be signed within the Whitehall Standard.

The responsibility for drafting letters and for reporting performance to Parliament remains with the FSA.

Responsibilities

The Department of Health's Customer Service Centre will :

- log on, scan in and keyword all FSA cases within 24 hours of receiving them;
- email all scanned images of FSA cases to the FSA Ministerial correspondence mailbox within 24 hours of receiving them (by day 2), including those letters from members of the public which the FSA deal with directly;
- print out and process all FSA letters through to the Minister's private office within 24 hours of receiving them, including standard cases with the Minister's electronic signature and those which the FSA has received directly from other Government departments;
- ensure each letter going into the Minister's is clearly marked with the latest date by which the letter should be signed (the Whitehall Standard date);
- deal with minor amendments of spelling, grammar etc required by the Minister and refer all matters of policy redrafts to the FSA;
- despatch the letters within 24 hours of being signed by the Minister;
- email to the FSA a scanned image of the signed final letter within 48 hours of the letter being signed; and

The Minister's private office will :

- forward all FSA letters received directly by the Minister's office to the Customer Service Centre within 24 hours of receipt; and
- ensure that at least 90 per cent of FSA letters are signed by the Minister by the day before the Whitehall Standard date, where letters are in private offices at least 8 days before the Whitehall Standard due date.

The Food Standards Agency will :

- have a central point for receiving all Ministerial and public correspondence from the Department of Health;
- have a central handling point for receiving all transfers for the FSA from other Government departments – with draft replies sent into DH through the Customer Service Centre with a note of the Whitehall Standard reply due date;
- return within 24 hours all letters which they do not feel are for the FSA to answer, so that they can be reallocated;
- answer directly letters from members of the public and campaign letters not requiring the Minister's signature;
- return draft letters for the Minister's signature within 10 days of receiving them;
- retain full responsibility for drafting and redrafting on matters of policy;
- retain full responsibility for advice to Ministers and all draft replies; and
- retain full responsibility for performance reports to the FSA and to Parliament.

Start dates and review processes

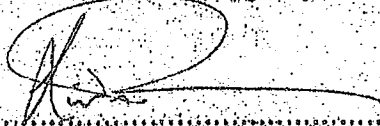
The effective start date for this protocol to be in place is 1 February 2007. Any correspondence drafts sent to the Department prior to that date will be dealt with by the FSA and the Minister's private office.

This protocol will be reviewed initially at 3 months from the date of commencement and 6 monthly thereafter, by meetings between the FSA and the Department.

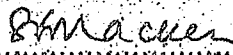
Signed :



.....
Sue Johns, Head of Private Office
For the Food Standards Agency



.....
Linda Percival, Customer Service Director
For the Department of Health Customer Service Centre



.....
Sarah Fisher-Mackey, Private Secretary
For the Department of Health Minister's office