FRAMEWORK ON USE OF EXTERNAL DATA NOT IN THE PEER-REVIEWED LITERATURE AND CO-FUNDING OF RESEARCH WITH INDUSTRY AND INTEREST GROUPS

Summary

The General Advisory Committee on Science was asked to advise on the circumstances in which it is reasonable for the Food Standards Agency to use data generated by, or to fund research in collaboration with, industry or non-governmental organisations (NGOs).

The Committee identified five *guiding* principles that should be considered when addressing these questions.

Three scenarios are identified in which GACS judges that use of data collected by industry or NGOs is acceptable – where the data are submitted in response to the FSA consultations, where they are produced in the context of a rigorous system for monitoring compliance with safety requirements, and where they are submitted in support of regulatory risk assessment and the regulatory system is suitably robust.

In other circumstances, decisions on the use of externally generated data should be made on a case-by-case basis, balancing between the five guiding principles. Where this is done, the rationale for the decision should be clearly argued and publicly available.

Where the FSA does use data collected by industry or NGOs, they should be interpreted with care, paying particular attention to their representativeness as well as their validity. Moreover, the FSA should not accept findings from secondary research (systematic reviews and meta-analyses) by industry or NGOs without reviewing the primary research on which it was based.

Provided suitable systems of governance are in place, and the resultant gain in research capacity would offset any greater administrative burden and threat to the FSA's perceived independence, it would be acceptable for the FSA to fund research jointly with industry or NGO partners. Co-funding with commercial or NGO partners in other circumstances is not recommended.

Background

When developing policy and making regulatory decisions, the FSA sometimes uses data generated by industry (e.g. food producers and retailers) or non-governmental organisations (NGOs), which are not published in the peer-reviewed scientific literature. This can help to ensure that all relevant information is taken into account, and may also reduce costs. However, it must be done with care. Data provided by organisations with commercial interests or campaign objectives may be unrepresentative and misleading. And even if they are not, their use could compromise the FSA's perceived independence. To date, decisions on when and how to use external data of this sort have been made on an ad hoc basis without any explicit guiding policy.

In addition to using data produced by industry or NGOs, it could also be advantageous for the FSA in some circumstances to collaborate with partners from these sectors in funding research and the gathering of scientific evidence. For example, joint funding might make a project possible that could not otherwise be afforded. Again, however, care would be needed to ensure that the research was free from external influence, and that the FSA's reputation for independence was preserved.

Against this background, the FSA asked the General Advisory Committee on Science (GACS) to advise on the circumstances in which it is reasonable for the FSA to use data generated by, or to fund research in collaboration with, commercial or non-governmental organisations. This report sets out our conclusions.

1. Terms of reference

The questions that GACS was asked to address were:

1. In what circumstances and how should the FSA use data that have been collected by industry or NGOs and that are not published in the peer-reviewed literature?

2. In what circumstances and how should the FSA fund data collection or research jointly with industry or NGOs?

2. Principles

In determining whether and how to use external data, or to co-fund research with external partners, five principles must be considered.

1. Decisions made by the FSA and the advice that it gives should be based on the best available scientific evidence – if relevant data are ignored, there is a danger that decisions will be unsatisfactory, and may in some cases be susceptible to judicial review.

2. The FSA should be trusted by the public and perceived as independent of commercial and other external interests – the effectiveness of the FSA as a guardian of food safety depends importantly on the trust in which it is held.

3. The FSA's activities should be efficient, maximising value for taxpayers' money.

4. Commercial confidentiality and intellectual property rights should be respected, especially where there is a resultant public benefit – such benefit may arise, for example, from the innovation that is encouraged by opportunities for commercial exploitation of new ideas.

5. Costs for research should be distributed fairly across beneficiaries – there is a strong argument that those who profit from a product or activity should meet the costs of ensuring that it is acceptably safe.

None of these principles on its own is overriding. Often there will be tensions between them – for example, to maintain public trust, the FSA may sometimes have to generate data at its own expense rather than rely on information produced by the commercial organisations that profit from a food product. Thus, decisions on the best course of action will generally require a balance to be drawn between the principles. The next two sections consider how this might apply in a range of scenarios.

3. Use of external data

Decisions on the use of data produced by industry or NGOs will depend on the circumstances in which the data were generated, the form in which they are available (raw or processed) and the purpose to which they will be applied. A particular concern is the possibility of bias because the information that is available to the FSA is unrepresentative, either because of the way in which it has been collected, or because data holders withhold information that might be detrimental to their commercial interests or policy objectives.

Also important is the FSA's need to be open and transparent in its business. It may be difficult to use commercially sensitive data without placing them in the public domain. And even if the FSA agrees not to publish them until they cease to be sensitive, they may be open to discovery through requests under the Freedom of Information Act.

A number of scenarios can usefully be distinguished.

1. Responses to consultations

When developing policy, the FSA frequently consults with external stakeholders, including industry and NGOs. Where stakeholders provide data as part of their response, the FSA should of course give them due consideration (as is required under the cross government standard for impact assessment), although carefully taking into account any uncertainties about their validity and representativeness. Provided the process is open, and appropriate allowance is made for limitations of the data, this practice seems reasonable.

2. Compliance with safety requirements

Another situation in which the FSA makes use of externally generated data is in monitoring compliance with safety requirements. For example, to protect against poisoning by algal neurotoxins in bivalve molluscs, the FSA monitors areas producing these shellfish for levels of toxins, in accordance with EU regulations. If statutory limits are exceeded, the area is closed until subsequent tests show that levels have fallen to below the limits. Shellfish harvesters in Scotland can, however, submit evidence (such as the results of tests in products as sold) indicating that an area may in fact be clear of toxins. The FSA will consider such evidence, and may then allow additional official control samples to be taken. Such action can precipitate early re-opening of an otherwise closed area. In this case, the evidence presented by industry serves only as a trigger to further testing by the FSA, and any decision to re-open an area will depend on the results from the official samples.

In addition, the FSA has set out a clear protocol which producers can adopt if they wish their own results from *E. coli* monitoring to be considered in the hygiene classification of shellfish production areas in Scotland. The protocol, which must be followed by the harvester and verified by the local authority, specifies the test methodology to be used, and requirements for laboratory accreditation and sampling frequency. Furthermore, participating harvesters must agree to report all test results. Whilst such results are not used to replace the official control programme, they can influence it. Here the concerns about selective presentation of data are addressed because the protocol for sampling is clearly laid down, and there is an agreement to report all results. Moreover, laboratory methods are standardised and subject to appropriate quality assurance. In addition, there is scope for independent checks on the operation of the system, and for action if harvesters fall short of the prescribed standards for monitoring.

For these reasons, we see no objection to the FSA's using external data of this sort, provided the design of the monitoring system is available to the public.

3. Data provided to support regulatory risk assessment for product authorisation

Some products that are relevant to food safety (e.g. agricultural pesticides, veterinary medicines and food additives) are subject to regulatory risk assessments in which a notifier who wants approval for sale and marketing must submit scientific data demonstrating adequate reassurance of safety. Data are generated within a framework specified by the regulator, with prescribed requirements for quality assurance. Furthermore, there is a legal obligation on the notifier to inform the regulator of any data that might be considered adverse.

In this situation, therefore, there are again safeguards against presentation of data that are selective or of poor validity, and we consider that it is reasonable for the FSA to make use of such data (raw or summarised) provided they are subject to appropriate peer-review by the FSA or its advisory committees.

4. Use of other external data in risk assessment

More problematic is the assessment of risk using data generated externally outwith the context of a tightly controlled regulatory system. While the quality of data can be assured to some extent by critical review within the FSA or its advisory committees, their representativeness may be harder to establish. As a general rule, there seems no justification for the FSA accepting findings from secondary research (systematic reviews and meta-analyses) by industry or NGOs without reviewing the primary research on which it was based. Beyond that, we suggest that decisions about the use of external data in this situation should be determined on a case-by-case basis, applying the principles set out in Section 3 above. Moreover, where a decision is made to use such data, the rationale should be clearly argued and publicly available.

5. Surveillance and scoping

Externally generated data may also be of use to the FSA in scoping problems, monitoring trends, and horizon scanning for new sources of risk. For example, data collected by large retailers on the prevalence of *Campylobacter* contamination of meat supplied from other countries could be helpful in monitoring changes in the levels of such contamination, or provide early warning of a new problem with a particular source. There is, of course, the possibility that a retailer might hold back on data that it considered embarrassing or commercially damaging. However, where this happened, it is likely that the FSA would find out in due course, especially if adverse health effects occurred, and when publicising the problem, would have the option of naming the company that failed to disclose the information.

Another example is the FSA's use of data provided by industry on fortification of foods with dietary supplements. Data of this kind may be of value, for example, in scoping and prioritising assessments of risk from excessive exposure to the added nutrients.

Again, we consider that decisions on using external data for such purposes should be made on a case-by-case basis, taking into account in particular, the expected representativeness and validity of the data in relation to their planned use, the costs of alternative approaches (e.g. direct monitoring by the FSA), and the need for openness and transparency.

6. Public understanding, attitudes and behaviour

Some companies in the food industry own market research data (e.g. from supermarket loyalty cards) that they might be willing to share with the FSA, and which could be a useful supplement to other information that the FSA holds on public understanding, attitudes and behaviour regarding food. Such information might be used, for example, to prioritise foods for monitoring, or in the planning of publicity campaigns. These applications are less controversial than those which have direct impacts on regulation and enforcement, and as such may be a lower threat to public trust, provided they are clearly explained. Nevertheless, we do not think that use of such data could be endorsed in all situations. Rather, an assessment should be made on a case-by case basis, taking into account the expected validity of the data and their fitness for purpose, how much they will add to what is known from other sources, and how much they will cost. If they are used, they should be interpreted with appropriate care, and the FSA should be open about its methodology.

Use of confidential data
Given the public benefits of commercial confidentiality and intellectual property rights, there may be some circumstances in which it is appropriate for the FSA to use external data without making them publicly available, at least until they are no longer sensitive. Where the FSA decides that this is justified, it should agree in advance with the organisation providing the data what level of confidentiality will be maintained and how. Moreover, the justification for not making the data publicly available should be openly stated.

4. Co-funding of research

Co-funding of research has several possible advantages for the FSA. It may enable work to be undertaken that could not otherwise be afforded, or that requires expertise, methodology or equipment that is available only in industry. It could also encourage buy-in of co-funders to the findings from the research. On the other hand, co-funding is administratively more complex and expensive than support from a single funder; there is a danger that co-funders may try to influence the way in which studies and research teams are selected for support, and in which findings are subsequently interpreted and presented; and joint funding with commercial or NGO partners may be perceived as compromising the FSA's independence.

Some of these drawbacks can be addressed by the adoption of appropriate systems of governance for co-funded research. In particular, there is the option to establish an independent scientific committee to oversee the commissioning, conduct and reporting of studies, and act as a "firewall" between the funding bodies and research teams. This model has been followed successfully – for example, in the Mobile Telecommunications and Health Research (MTHR) programme, which is jointly funded by Government departments and the mobile telecommunications industry. Another case in which a "firewall" was usefully established between funder and researchers was a programme of research on Gulf War illness that was financed by the Ministry of Defence, but with the selection and monitoring of studies overseen independently by the Medical Research Council. Members of an independent oversight committee might be drawn from existing the FSA advisory committees or appointed according to a process analogous to that for co-opting members to advisory committees to assist in discussion of specific topics.

Most important in such arrangements is to have clear advance agreement from all stakeholders on the rules that will operate, and for this purpose, the FSA might find it useful to develop a standard format for a formal agreement, to be part of the contracting arrangements between funders (along the lines of Annexe A) that could be adapted to specific circumstances as appropriate. Among other things, this would cover the scope of the research to be commissioned, and the roles, responsibilities and rights of each stakeholder, including payment schedules for funders, how findings from the research will be published, whether funding bodies will have sight of draft reports before they are submitted for publication, and who has final responsibility for the editorial content of published reports. As with all research commissioned by the FSA, there should be a presumption that the data generated will at an appropriate stage be made publicly available, unless there are strong reasons for not doing this.

With suitable systems of governance to ensure that the FSA's perceived independence is not compromised, we consider that joint funding of research with commercial or NGO partners could be acceptable for the FSA, provided the gains in research capacity offset the increased administrative burden that would be entailed. This condition is more likely to be satisfied by larger scale studies. The rationale for co-funding and the governance arrangements to ensure the independence of research commissioned in this way should be publicly stated before the work is put out to tender.

Co-funding with commercial or NGO partners is not recommended in the absence of a robust "firewall" arrangement.

5. Conclusions and recommendations

GACS advises that it is acceptable for the FSA to use data collected by industry or NGOs, which are not published in the peer-reviewed scientific literature, in the following circumstances:

- the data are provided in response to consultations
- the data are collected to monitor compliance with safety requirements – provided the design of the monitoring system and its quality assurance are clearly and adequately specified by the FSA, and there are meaningful sanctions when compliance is unsatisfactory
- the data are provided in support of regulatory risk assessment for product authorisation – where data requirements are specified by the regulator, quality assurance is robust, there is a statutory obligation for notifiers to report all potentially adverse findings, and this can be enforced effectively.

In addition, it may be acceptable for the FSA to use data collected by industry or NGOs in the following circumstances:

- where the data are relevant to risk assessment and have been generated outwith a robust regulatory system
- for surveillance and scoping of problems
- to supplement other data on public understanding, attitudes and behaviour.

However, decisions in these situations would need to be made on a case-by-case basis, in the context of the five guiding principles set out in Section 3, and where the decision was to make use of the data, the rationale for doing so should be clearly argued and publicly available.

The FSA should not accept findings from secondary research (systematic reviews and meta-analyses) by industry or NGOs without reviewing the primary research on which it was based.

Where the FSA uses data collected by industry or NGOs, they should be interpreted with care, paying particular attention to their representativeness as well as their validity.

Where the FSA decides that it is justified to use external data without making them public, it should agree in advance with the organisation providing the data what level of confidentiality will be maintained and how. Moreover, the justification for not making the data publicly available should be openly stated.

Provided suitable systems of governance are in place, the FSA's perceived independence is not compromised, and the resultant gain in research capacity would offset any increased administrative burden, it would be acceptable for the FSA to fund research jointly with industry or NGO partners. Co-funding with commercial or NGO partners in other circumstances is not recommended. The rationale for co-funding and the governance arrangements to ensure the independence of research commissioned in this way should be publicly stated before the work is put out to tender.

Annexe A Issues to be covered in a standard template for agreement between funders

Issue	Principle/FSA objective
Scope of research and technical specifications for the work	• Will need to reflect agreement on shared objectives • Scientific content must be fit and scientifically robust for the intended purpose • Subject to external expert review
Commissioning	• To follow established principles of open tendering and independent expert evaluation of tenders • Subject to FSA procedures for strategic evidence prioritisation
Costs and payments	• To be agreed up front • Consistent with principles for other FSA- commissioned evidence work
Management	• Needs to maintain integrity of the scientific objectives; no undue influence on the direction of research • Arrangements must be cost-effective and benefits much outweigh any additional administrative burden • Could be done by third party (e.g. independent committee or panel) if arrangements can be agreed in advance
Evaluation of results	• Independent expert peer review • Partners should not exert editorial control over presentation of results by the researchers • Could be done by third party (e.g. independent committee or panel) if arrangements can be agreed in advance
Reporting and publication	• As with other FSA-funded research, there should normally be an expectation that results will be openly published, preferably in the peer-reviewed scientific literature • To include what information is fed back to different parties and at what stage • FSA will need to have rights of access and use of results in line with our legal obligations and policies on openness • Could be done through a third party (e.g. independent committee or panel) if arrangements can be agreed in advance
Rights and responsibilities and other terms and conditions	• To be agreed up front • Consistent with principles for other FSA- commissioned evidence work.