
Guidance Note – Ethics and Food-Related Research

This document provides:

- guidance for applicants, reviewers and European Commission staff on core issues of ethical concern in the field of food-related research within the EC's ethics review process
- an appendix, which outlines broader concerns in the field of food ethics.

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Introduction

Research activities supported by the Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union and take into account opinions of the European Group on Ethics in Science and New Technologies (EGE).¹

Adherence to ethical principles is essential in all branches of research. Only ethically sound research can achieve public acceptance and demonstrate the integrity required of European researchers and their international colleagues.

This Guidance note aims to make food researchers aware of potential ethical issues that may arise in their work. Research involving food and nutrition is very diverse, ranging from interviewing children about their food preferences, to animal studies on contaminants, research on sustainable agriculture or the impact of certain foods on gene expression, to name just a few. As a result, research methods within the field vary widely. Furthermore, individual food and dietary decisions are often very personal and culturally or spiritually based. Therefore a guidance note such as this one cannot be exhaustive. What it can do is assist researchers in proper ethical conduct through awareness raising on many of the key issues of concern.

The following principles of the Charter of Fundamental Rights of the European Union² are relevant to all scientific endeavours supported by the Framework Programme and should serve as the basis for reflective deliberation.

- *Dignity*
- *Freedoms*
- *Equality*
- *Solidarity*
- *Citizens' rights*
- *Justice*

These principles are based, in particular, on the fundamental rights and freedoms recognised by the European Convention on Human Rights, the constitutional traditions of the EU Member States, the Council of Europe's Social Charter, the Community Charter of Fundamental Social Rights of Workers, and other international conventions to which the European Union or its Member States are parties.

¹ FP7 Getting Through Ethics Review. http://cordis.europa.eu/fp7/ethics_en.html

² The Charter of Fundamental Rights of the European Union.
http://www.europarl.europa.eu/charter/default_en.htm

Food Related Research Ethics Review – Generic Guidance

The European Commission provides information on the main ethical issues that may arise in research and indicates how each topic might be addressed to ensure compliance at: http://cordis.europa.eu/fp7/ethics_en.html. Here is a short overview, with the first two entries being likely to apply to all research covered in this document:

Informed Consent

Participation in research must be voluntary and it is the researcher's duty to ensure that research participants understand the scope and the details of the project. The minimum information given to potential participants must include: purpose and duration of the research, identity of the researchers, risks and benefits, information on data protection, privacy and data retention, the right not to take part, the right to withdraw, and contact details for questions. Evidence, usually in writing, of a completed informed consent process must be obtained. *It is important to emphasise that informed consent procedures must be followed by all researchers and are not restricted to medical research.*

Data Protection and Privacy

The right to privacy and data protection is part of the Fundamental Rights of the European Union.³ In order to respect this right, researchers must comply with the legislation on data protection within their Member State and carefully plan data storage, handling and retention so as to minimise the risk of confidentiality breaches. For a detailed description of this issue see: FP7 "Data protection and privacy ethical guidelines".⁴

Research on Animals

Food-related research, in particular with regard to health claims or safety assessments, may include research on animals. It is expected of researchers to use the "three Rs" as guiding principles in such research⁵.

- **Reduction** refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.
- **Replacement** refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim.
- **Refinement** refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals still used.

³ The Charter of Fundamental Rights of the European Union.
http://www.europarl.europa.eu/charter/default_en.htm.

⁴ FP7 Data Protection and Privacy Ethical Guidelines, <ftp://ftp.cordis.europa.eu/pub/fp7/docs/privacy.doc>

⁵ For ongoing information on the 3Rs see <http://www.nc3rs.org.uk>, <http://www.ecopa.eu/> or <http://www.forschung3r.ch/en/information>.

Food Related Qualitative Social Science Research



Example Topics:

Public perceptions and attitudes towards personalised nutrition

Dietary behaviour of defined groups (e.g. children, obese, low income)

Example Methods:

Interviews and focus groups

Food diaries, life histories

Observation

Social scientists are interested in a wide range of topics in connection with food. Some of these are of interest to public health (e.g. research on obesity), others are of particular interest to industry (e.g. marketing, public acceptance of novel foods), and yet others to development or agricultural science (e.g. livelihoods within fisheries). Unlike medical science, social science has not been strictly regulated through research ethics review for several decades. And attempts at applying procedures from medical ethics review to social science have proved challenging. Within social science research, it has been argued that:

[t]he quandary that the institutional discourse of ethical research confronts is that it is always/already vulnerable to being disconnected and dislocated from the relational ethics of the “real world” of research because the micropolitics of research practice are too messy and diffuse to be pinned down and regulated by systematized rituals and practices. Power is never innocent in the construction of research relationships.⁶

Social science researchers have found that it can be difficult to work with formalised codes of practice which inscribe rigid rules that do not take account of the breadth and complexity of empirical studies.⁷ Importantly, it has been argued that within some research methods (e.g. observation):

it is not possible for the [social science] researcher to specify in advance precisely what will be observed and the degree to which they will participate in the setting. Understandably, this lack of specificity raises challenges for research ethics boards.⁸

However, many professional associations have now drawn up codes of practice, such as the *Statement of Ethical Practice for the British Sociological Association*⁹ or the *Statement of Principles of Ethical Research Practice*¹⁰ by the UK's Socio-Legal Studies Association (SLSA). These and similar codes of practice usually distinguish between obligations towards

⁶ Christine Halse and Anne Honey (2007) Rethinking Ethics Review as Institutional Discourse, *Qualitative Inquiry* 13: 336-352.

⁷ Jacqui Gabb (2010) Home truths: ethical issues in family research, *Qualitative Research* 10: 461-478.

⁸ Carnevale et al (2008) Using participant observation in pediatric health care settings, *Journal of Child Health Care* 12: 18-32.

⁹ Statement of Ethical Practice for the British Sociological Association, <http://www.britisoc.co.uk/NR/rdonlyres/801B9A62-5CD3-4BC2-93E1-FF470FF10256/0/StatementofEthicalPractice.pdf>

¹⁰ SLSA Statement of Principles of Ethical Research Practice, <http://www.slsa.ac.uk/content/view/247/270/>

research participants, society as a whole, the discipline, as well as colleagues, sponsors & funders. In the following, the focus shall be on research participants.

In addition, some research councils have issued specific guidance for regulating social science research, such as the Canadian *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*, Chapter 10¹¹, launched in December 2010 or the *Australian National Statement on Ethical Conduct in Human Research*¹², Chapter 3.1 (2007).

In addition to the generic guidelines outlined at the start of this document, the following are relevant directly to social science food research employing qualitative methods.

Risks and Benefits

When assessing risks, the focus in medical research is mostly on physical *harms*, whilst the focus in protecting research participants in social science research is mostly on mental *distress*. It has been argued that the degree of risk in social science research is in no way equivalent to those in medical research and should therefore not be overestimated. "At most there is a potential for causing minor and reversible emotional distress or some measure of reputational damage".¹³ However, it is essential that potential research participants are made aware of the possibility for distress and that the researcher takes responsibility for reducing it to an absolute minimum.

A risk that applies to both medical and social science research is negative impact from a breach of confidentiality. For instance, a person interviewed on sensitive topics may risk detrimental consequences for his or her social status/employment/financial situation through a breach of confidentiality. Hence, as noted under generic guidelines, it is important to fulfil all requirements for data protection and to inform participants of such potential risks in advance.

One advantage social science research has over medical research is that the benefits are unlikely to be overestimated by potential participants; hence the therapeutic misconception¹⁴ poses less of a problem. The main benefit that research participants should expect is feedback on the outcome of the research.

Withholding the Truth – Covert Research

An important characteristic of social science research is that revealing detailed information about the scope and objectives of the study may heavily influence response behaviour (e.g. social desirability bias). Hence, one of the main differences between medical research and social science research is that covert research may be justifiable although it violates the principle of informed consent.

¹¹ Canadian Panel on Research Ethics, Chapter 10, Qualitative Research, <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/>

¹² Australian National Statement on Ethical Conduct in Human Research http://www.nhmrc.gov.au/publications/ethics/2007_humans/section3.1.htm

¹³ Robert Dingwall (2008) The Ethical Case Against Ethical Regulation in Humanities and Social Science Research. *Academy of the Social Sciences* 3(1)1-12.

¹⁴ A patient who takes part in non-therapeutic research may erroneously assume that the research will provide a cure.

Covert research should only be undertaken if it is impossible to obtain data with overt methods, if risks to research participants are minimal, if anonymity is guaranteed, if the project has societal importance and if the relevant research ethics committee has approved a detailed justification for the approach. In the context of covert, research ethics committees may impose a second postponed consent process, between the obtaining and the analysis/publication of data.¹⁵

Observation Research

One of the main ethical hurdles for social science research & data protection is observation research in public places. Within the area of food related research, this could for instance take place in restaurants or canteens. Observation research, which requires written consent from every individual present, even if there is only a minimal encounter, would render potentially important research impossible. However, the European Union's commitment to the protection of individual privacy must be upheld.

Research ethics committees should decide about the extent of informed consent requirements imposed prior to approving a study based on the risks and benefits of any individual study. For instance, it would be inappropriate to make the same demands on an observational study in a closed ward for anorexia and a busy fast food restaurant.

Inclusion of those Unable to Consent

By contrast to some medical research (which would then be termed 'therapeutic'), social science research is unlikely to benefit research participants directly, as noted before. This requires especially strong protections for persons unable to consent.

Social science research must only be carried out with those unable to consent if all of the following conditions obtain: the research cannot be carried out on those who are able to consent, consent by proxy/legal representative has been obtained, the person does not object, only minimal burdens are imposed, the research results are relevant to future persons in the same category, and the study has been approved by the relevant ethics committee.

New Technologies and Web-Based Research

Increasingly, social scientists collect data using new technologies (e.g. iPhones) and/or web based research (e.g. blogs, chat rooms). Many potentially vulnerable populations, who are the subjects of food research, for instance children and teenagers, make extensive use of such technologies and web-based forums. Data collection using new and web-based technologies is therefore becoming an important method in qualitative research and comparative international studies within food related research. For instance, people with eating disorders, ranging from anorexia to obesity, or their parents and family members may be reluctant to take part in face-to-face research but less so in web-based research.

¹⁵ For postponed consent in the medical context see: Han Boter, Johannes JM van Delden, Rob J de Haan, Gabriël JE Rinkel (2004) Patients' evaluation of informed consent to postponed information: cohort study, *British Medical Journal*, 329: 86. Angus Dawson (2004) Commentary: Methodological reasons for not gaining prior informed consent are sometimes justified, *British Medical Journal*, 329: 87.

Such use of technologies raises new ethical issues around recruitment, consent, privacy as well as authenticity of data. For example, it may be problematic to procure and verify the authenticity of parental consent for children; or the identities of individuals engaging in web mediums because their internet identity may not reflect the 'authentic persona'¹⁶.

It should be noted that web-based communications, where contributors can be identified, such as chat-rooms or self-help groups, require the obtaining of informed consent prior to taking part in research, even though they can be considered as public spaces.

Research Using Ethnography and Photographic Methods

Some research examining how families and groups engage with food and develop particular food behaviours involves ethnographic methods using observations, videos and photographs e.g. videoing of family meals, cooking. Such data can provide valuable social information and inform clinical diagnosis and family therapy programs in the treatment of eating disorders. Ethically, these methods raise issues of anonymity and confidentiality. Hence, as in other research, they need to be carefully balanced against the risks and benefits of the research, particularly since videos cannot be anonymised in the way interview data can.

¹⁶ Ward, G. (2002). *Crossing Cyber Boundaries: Where Is the Body Located in the Online Community? Reframing the Body*. London.: Palgrave MacMillan.

Interdisciplinary Food Related Research



Example Topics:

Assessing economic impact of food-related chronic disease.

Food-related quality of life research.

Example Methods:

Analysis of economic *and* epidemiological data.

As above plus interviews.

Food related research often employs interdisciplinary approaches, combining not only activities across the social sciences (for example qualitative social psychology research and quantitative economics research) but also across the natural and the social sciences (allergy studies, human nutrition, ethnography and public perceptions, for instance). Dealing with ethical issues may be complex when research fields with different ethical concerns and traditions collaborate.

In interdisciplinary research all interventions, which are medical in nature, need to comply with standard requirements as outlined on http://cordis.europa.eu/fp7/ethics_en.html. See also, Food Related Research Equivalent to Medical Research, below.

The main ethical issues in quantitative research fall under the generic issues raised at the outset (informed consent and data protection) plus the inclusion of those unable to consent (see section on qualitative research). The main ethical issue in this context that has not yet been discussed elsewhere in this document is secondary use of data or tissue.

Secondary Use of Data or Tissue

Most European countries allow the secondary use of data or tissue, if the data is fully anonymised, the research participant has not specifically objected to secondary use and approval for it has been obtained from the relevant research ethics committee. However, the value of research data can be compromised by anonymisation, for instance, when economic and epidemiological data are regularly updated and linked. In this situation, the expectation is that researchers obtain active consent for such data by contacting research participants again and discussing the new research project.

Nutrigenomics



Example Topics:

Interplay of genes and nutrition on the development of heart disease

Effect of polyunsaturated fat intake on "good cholesterol" (HDL) levels based on genetic make-up

Example Methods:

Bioinformatics

Genetics

Human clinical studies

Nutrigenomics studies how genetic and cellular processes relate to nutrition and health, including how people with different genetic variants respond to alternative dietary conditions and how diet can switch genes on or off. Food companies are interested in nutrigenomics because it can help them to develop and market new functional foods.

Guidelines by the European Nutrigenomics Organisation

The "European Nutrigenomics Organisation", a Network of Excellence funded by the European Commission, issued detailed guidelines on the ethical conduct of nutrigenomics research in 2007.¹⁷ The guidelines cover the following 19 topics:

1. Information during consent process
2. Content of the consent form for a nutrigenomics study
3. Informed consent for research involving research volunteers not able to consent
4. Informed consent for biobanks
5. Extent of informed consent for biobanking
6. Disclosure of genotype test results
7. Disclosure of genotype test results on an individual level
8. Ownership and governance
9. Storage of samples and data
10. Independent review of research using materials stored in a biobank
11. Benefit sharing
12. Fate of the sample and associated data if consent is withdrawn
13. Samples from deceased persons
14. Quality control
15. Potential legal successor in case the hosting institution closes down or the responsible scientist is not working for the biobank anymore
16. Access to biobanks
17. Disclosure of personal data
18. Use of biological materials and data in further research projects
19. Transfer of a biobank

Due to space restrictions, please see detailed information on all the above topics at:

<http://nugo.dife.de/bot/index.php>.

¹⁷ See also: Manuela M. Bergmann, Marek Bodzioch, M. Luisa Bonet, Catherine Defoort, Georg Lietz and John C. Mathers (2006) Bioethics in human nutrigenomics research. *British Journal of Nutrition*, 95:1024-27.

In this context, it needs to be borne in mind that:

- Potential nutrigenomic benefit claims to public health must be justified (see also legitimacy of publicly funded research).
- Priorities for public research spending on nutrigenomics should be informed by public engagement in order to achieve acceptance.
- When public funds are used to develop personalised genetic diets, the outcomes of the research should be accessible to all parts of the population and not just benefit the more affluent.
- Information provided to individuals from nutrigenetic tests should be accompanied by genetic counselling, where necessary.

Novel Foods, GM Foods and Health Claims



Example Topics:

Development of nutritionally enhanced functional foods for the elderly

Development of cultured meat

Example Methods:

Animal experimentation

Human clinical studies

Food-related research is particularly ethically sensitive if (a) it enlists human participants who are exposed to risks and (b) if the research itself develops new materials and techniques whose risks are unknown. The development of health claims will be given as an example for (a) and nano- as well as GM technologies as an example for (b).

Labelling and Health Claim Certification

The food market for foods that claim to contribute positively to health and well-being has been growing steadily in developed countries. Since December 2006 nutrition and health claims made on foods are regulated under harmonised rules across the European Union. The main aim of Regulation No 1924/2006 is "to ensure a high level of protection for consumers and to facilitate their choice" and to achieve "free movement of foods and create ... equal conditions of competition."¹⁸

The market trend and the regulatory move combined spur additional food research, (i) to develop novel products, the commercial viability of which depends on their supposed contribution to health and well-being, and (ii) to build the evidence base for health claims. As Regulation No 1924/2006 emphasises, the protection of the consumer is one of its main aims. Consumer rights in the area of food are usually associated with choice and thereby the possibility for "exit". Genuine "exit" is only feasible if the consumer receives all the information required to make an informed decision. Two main possibilities arise: First, consumers might *not* want to buy certain products. To make this choice possible, strict labelling regulations, which include process information, have to be in place. Second, consumers might *want* to buy the product with the most potent and reliable health effect. Again, strict health claim regulations, which ensure that claims are trustworthy, have to be in place.

For the development of health claims, interventions on human participants are likely to be necessary (e.g. blood sampling). These interventions have to be guided by the principles relevant to similar medical research. Details can be found on:

http://cordis.europa.eu/fp7/ethics_en.html. Hence, this type of research also falls under the section below, Food Research When Equivalent to Medical Research.

Up-to-date information on European Food Safety Authority (EFSA) requirements for health claims, can be found at: <http://www.efsa.europa.eu/en/nda/ndaclaims.htm>.

¹⁸ Regulation 1924/2006, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20080304:EN:PDF>

Nanotechnology and Food

Nanotechnology aims to produce materials or devices at the nanometre scale (a nanometre is one millionth of a millimetre). When nanotechnology is used within food production, its safety must be assessed as some of the chemicals used may have different characteristics and properties at the nano level than could be observed at the larger level.¹⁹

The European Food Safety Authority (EFSA) advises member states and public health officials on the potential risks of nanotechnology in food. An EFSA opinion commissioned by the EC established that international approaches to risk assessment can also be applied to nanomaterials. However, this must be done on a case-by-case basis and may be "very difficult and subject to a high degree of uncertainty", with current data limitations and the lack of relevant test methodologies.²⁰

In 2008, the European Commission committed to reporting again on the topic of nanotechnology regulation to the European Parliament and the European Council in 2011.²¹ At this point, important recommendations were included in the "Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research".²²

GM Foods

Foods whose DNA has been genetically modified (GM) to engineer certain characteristics (e.g. pesticide resistance) have been on the market since the 1990s. 20 years later, the controversies about GM foods are still ongoing. There have been many politically and economically motivated debates on this research field creating polarity both within and outside of the scientific community.

It is important to keep in mind that scientific uncertainty in itself does not raise ethical issues, but that commitment to safety must be evident. Any research using GM technologies or products must be accompanied by commitments to adhere to relevant EU and national legislation, namely: EU Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms (GMOs) and GMPs as well as Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs.

In this context, it would also be advisable for researchers to organise public consultations or engagement on the safety measures and public perception of their GM research.

Permissions obtained from relevant national authorities will need to be presented to the European Commission as part of the reporting requirements.

¹⁹ EFSA, Frequently Asked Questions on Nanotechnology, <http://www.efsa.europa.eu/en/faqs/faqnanotechnology.htm>

²⁰ Ibid.

²¹ Regulatory Aspects of Nanomaterials, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF>

²² Code of conduct for responsible nanosciences and nanotechnologies research, http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

Developing Country Research incl. Indigenous Peoples Research



Example Topics:

Developing nutrition packages for severely undernourished children

Developing Aboriginal Australian "bush tucker" for other markets

Example Methods:

Human clinical studies

Access to Traditional Knowledge

EC guidance on developing countries research is currently being developed. A cross-reference to this research for more detail will be given once it is available.

Equitable Partnerships

Research involving developing countries must take account of local research needs and potential benefits to local communities. It is unethical to undertake research in developing countries (for instance, because it is cheaper) when the results of the research will be of no benefit to local communities. Wherever feasible, the developing country perspective should be integrated into any research proposal in a way that makes them equitable partners. In practice, this means that they should be involved in setting the initial objectives of research as relevant to local populations, as well as in the implementation (e.g. analysis) and dissemination (e.g. publications).

Risks to Researchers

When undertaking research in some developing countries or in certain parts of other developing countries, researchers may face risks, which they would not encounter in a European setting (e.g. war zone, high risk of violent crime, malaria). Health and safety assessments by employers (e.g. European universities) need to precede such research so that researchers are fully aware of the risks and adequately insured and equipped if they undertake it.

The Convention on Biological Diversity²³

In 1992, The Convention on Biological Diversity (CBD) was opened for signature at the Earth Summit in Rio de Janeiro and has since been signed by 193 parties. Only Andorra, Holy See (the Vatican), and notably the United States of America (USA) are not party to it.²⁴ The convention has three objectives.

- the conservation of biological diversity
- the sustainable use of its components, and
- the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.²⁵

²³ This text is generic to the CBD, even though the FAO has issued some benefit sharing requirements for seeds only.

²⁴ Convention on Biodiversity, List of Parties, <http://www.cbd.int/convention/parties/list/>

²⁵ Convention on Biodiversity, Article 1, <http://www.cbd.int/convention/articles/?a=cbd-01>

According to the preamble of the CBD²⁶, non-human biological resources fall under the national sovereignty of states. This means that plants, animals, micro-organisms and traditional knowledge associated with these resources fall under the decision-making powers of national governments. Based on the sovereignty principle, each CBD party agrees to develop and implement national laws to govern access and benefit sharing of non-human biological resources.

When non-human genetic resources and associated traditional knowledge is used in food research, the CBD has to be respected. This requires at least:

- the obtaining of authorizations from national governments and of prior informed consent from the holders of traditional knowledge before using relevant genetic resources.
- the setting up of mutually agreed terms for access and benefit sharing.

Food-related Research in Emergency Situations

Food aid is one of the components of most development programmes. Its importance was emphasised in the Millennium Development Goals.²⁷

Target 1c: Reduce by half the proportion of people who suffer from hunger

1.8 Prevalence of underweight children under-five years of age

1.9 Proportion of population below minimum level of dietary energy consumption

However, giving food aid to mal- or undernourished and stunted children or adults to improve their health and prospects is not easy. Whilst some interventions have been tested sufficiently (e.g. micronutrient supplements such as iron or Vitamin A, fortified foods such as foods with iodised salts, or powdered micronutrients to be sprinkled on staple foods), others require further research (including genetic modification of crops or nutrigenomic solutions). Such research will be undertaken on highly vulnerable populations and is therefore particularly ethically sensitive. Double ethical review both in the North and in the South is therefore important.

Target populations for research in this area vary from mild to acutely malnourished individuals and from socially deprived to refugee and internally displaced groups. Their apparent extreme vulnerability at the individual level is sometimes compounded by social and political oppression, a fact that creates an additional requirement for protection as research participants. The relief community has entered an, as yet, unofficial dialogue on ethics guidelines for research undertaken in such situations. Guiding documents in this debate are not only the Declaration of Helsinki²⁸ and the relevant CIOMS Guidelines²⁹, but also the 1951

²⁶ Convention on Biodiversity, Preamble, <http://www.cbd.int/convention/articles/?a=cbd-00>

²⁷ Millennium Development Goals, Goal 1, <http://www.undp.org/mdg/goal1.shtml>

²⁸ Declaration of Helsinki, <http://www.wma.net/en/30publications/10policies/b3/index.html>

UN Convention on Refugees and its Additional Protocols³⁰. These provide basic guidance although they are not dealing with the apparent complexities that crisis settings are creating for research.

The ensuing discussion amongst humanitarian agencies has resulted in the first draft of guidelines for research in refugee and internally displaced populations. Recommendations include the following:³¹

- Undertake only those studies that are urgent and vital to the health and welfare of the study population.
- Restrict studies to those questions that cannot be addressed in any other context.
- Restrict studies to those that would provide important direct benefit to the individuals recruited to the study or to the population from which the individuals come.
- Ensure the study design imposes the absolute minimum of additional risk.
- Select study participants on the basis of scientific principles without bias introduced by issues of accessibility, cost, or malleability.
- Establish highest standards for obtaining informed consent from all individual study participants and where necessary and culturally appropriate from heads of households and community leaders (but this consent cannot substitute for individual consent).
- Institute procedures to assess for, minimise, and monitor the risks to safety and confidentiality for individual participants, their community, and for their future security.
- Promote the well-being, dignity, and autonomy of all study participants in all phases of the research study.

These guidelines represent the first step towards raising awareness in the research ethics communities of the need to consider crisis settings as deserving particular attention in the field.

²⁹ CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm

³⁰ UN 1951 Refugee Convention, <http://www.unhcr.org/pages/49da0e466.html>

³¹ Leaning, J. (2001) Ethics of research in refugee populations, *Lancet*, 357, 1432-3.

Food Related Research Equivalent to Medical Research



Example Topics:

Dietary-based cancer risks
Satiety mechanisms
Foodborne contaminants

Example Methods:

Animal experimentation
Human clinical studies

A range of food research can be regarded as equivalent to research in health care. The following gives some examples:

- As has already been noted above, medical interventions necessary to provide evidence for health claims (e.g. blood samples) fall under this category.
- In addition, human participants or animals may be involved in safety assessments or ingestion tests.
- Research on food allergies may include medical interventions.
- MRI use to understand the neuropsychological basis for satiety mechanisms or physiological responses such as gastric emptying.

Such research has to be guided by the principles of equivalent health research. We therefore refer to the main ethics pages of the European Commission's Ethical Review.

http://cordis.europa.eu/fp7/ethics_en.html

Appendix:

Broader Issues in Food Ethics

Food is fundamental to human existence. It is essential for survival, health, and well-being; it carries strong spiritual-symbolic significance (e.g. Buddhist vegetarianism) and it helps to form and maintain social relationships. Thus, it is unsurprising that food is intimately bound up with ethics, the study of norms, principles, or values that ought to guide human action. For instance, starvation and malnutrition pose some of the oldest questions about the duties of beneficence towards strangers. In addition to the issue of global hunger, food ethics faces a series of new questions that only emerged with the introduction of modern agricultural practices and biotechnologies. Is the exploitation of animals associated with intensive farming ethically acceptable? Do modern technologies produce safe, nutritious, and good quality food? Is food marketing ethically sound? What needs to be done about the detrimental effects of modern food production on the environment in terms of soil erosion, loss of biodiversity, and global warming? Or on a more general level: Where does state responsibility for citizen nutrition start and stop? Ought the health system to adopt punitive measures for those who put their health at risk through junk foods? The following section describes some of the most prominent issues that provide the context for research relating to food. In the context of this guidance document, this description is by necessity brief and of a general nature.

Food Security

Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life.³²

How we can feed a growing population that demands more resource-intensive diets, while tackling climate change and environmental degradation, is the key question of food security.

Over a billion people suffer from hunger³³ and climate change threatens to exacerbate this food insecurity further. However, sufficient food is available to feed the world population. *Access to food* is the primary problem. As Nobel Laureate Amartya Sen has shown in his seminal work "Poverty and Famines"³⁴, famines do not occur because of lack of food, but because no food entitlements for the poor are built into the mechanisms for distributing food. This means that increasing global agricultural productivity on its own cannot solve the problem. Likewise emergency responses to food shortages will always remain an unsatisfactory ad-hoc solution to more deep-seated problems. There is a need to look at distributional justice. At the individual and household level, the root cause of food insecurity - poverty - has to be tackled.

³² Food and Agriculture Organization (FAO). 1996. Rome Declaration on World Food Security and World Food Summit Plan of Action. World Food Summit 13-17 November 1996. Rome, <http://www.fao.org/docrep/003/w3613e/w3613e00.htm>.

³³ BBC, World Hunger hits 1 Billion, <http://news.bbc.co.uk/1/hi/world/europe/8109698.stm>

³⁴ Amartya Sen (1983) *Poverty and Famines*, Oxford: Oxford University Press.

Sustainable Food Production and Distribution

The sustainability and security of European agricultural, forestry, aquaculture and fisheries production is under threat from intensive production practices, global competition and climate change factors.

Agriculture, forestry and fisheries can no longer be viewed in a traditional sense and multidisciplinary, generic research from different disciplines must be applied.

It must...: reassess the “public good” role of life science research and its interactions with society and the environment, along with redefining the role of public research funding.³⁵

Climate Change

Climate change threatens global agriculture, particularly in countries already facing water shortages and areas vulnerable to rising sea levels and flooding. At the same time, agriculture is a considerable contributing factor to greenhouse gas (GHG) levels and therefore climate change.

In the EU, agriculture accounts for around 2% of gross domestic product (GDP) but contributes about 9% of GHG emissions, much in the form of methane (from digestion in ruminants and waste decomposition) and nitrous oxide (from fertilisers), which have a strong warming effect.³⁶ When one broadens the perspective to food in general and takes into account its production, packaging, transport, retail and preparation, the contribution to climate change is even greater.

- Mitigating agriculture’s contribution to climate change means embracing low-GHG farming practices, including less reliance on energy-intensive inputs.
- However, there is no benefit in reducing European agricultural emissions if Europeans offshore their contributions by substituting high GHG-emitting products with similar energy-intensive imports.

Meat Production³⁷

Farming animals on a large scale raises many ethical concerns, their contribution to GHGs being only one of them. Most of the 60 billion animals farmed for food worldwide every year are intensively reared with implications for animal welfare and consumer safety (e.g. increased occurrence of zoonoses, diseases that are associated with farmed animals and are transferable to humans such as salmonella, BSE, avian flu, swine flu). One could formulate the following ethical obligations or opportunities for action:

³⁵ Agriculture, forestry and fisheries: meeting tomorrow’s economic, social and environmental objectives An FP7 guide to sustainable production and management of biological resources from land, forest and aquatic environments, ftp://ftp.cordis.europa.eu/pub/fp7/kbbe/docs/fiche-agriculture-080305_en.pdf

³⁶ How will Farming in the EU be Affected by Climate Change, http://ec.europa.eu/agriculture/climate_change/index_en.htm

³⁷ Similar concerns apply to farmed fish.

- We have an ethical duty to treat farm animals in ways that respect their welfare and the environment.
- Meat-eating consumers in the developed world could signal their support for high animal welfare standards by choosing meat from farms where animals are extensively reared and their needs met.
- The EU could be a powerful force for good, by enforcing its animal welfare standards on all imports. FP7 already imposes EU ethical standards on all budget holders.

Food Miles or Long Supply Chains

Debates about sustainable agriculture and food production rarely stop on the field or at the processing plant. They reach into food distribution and supply chains. At the centre of public controversies over sustainable food supply has been the concept of "food miles", and the complicated logistics required to provide ever more choice to consumers in developed countries.

Taking the UK as an example, food is responsible for a quarter of lorry travel (by distance) and consumers drive around 19 billion kilometres a year to buy it. The UK Government puts the social and environmental costs of food transport at £9 billion a year.³⁸

There are concerns that long supply chains:

- Contribute excessively to climate change, especially when food travels by air, though food transport makes a smaller contribution to total GHG-emissions than agricultural production.
- Depend on dwindling oil reserves and are geopolitically vulnerable.
- Widen the gap in understanding between consumers and producers.
- Compromise animal welfare by transporting livestock long distances.
- Harm local economies and the communities they support.
- Go hand in hand with a deeper industrialisation of our food and food culture.
- At the same time, local food initiatives and campaigning can be parochial, downplaying the development benefits of international trade and alienating ethnic communities in Europe.

Food Waste

Food waste is costly, environmentally irresponsible and deeply troubling in a world where one billion people suffer from hunger. "The Dutch Ministry of Agriculture, Nature and Food Quality has estimated that Dutch consumers throw away approximately 8–11% of food purchased, equating to 43–60 kg of food waste ... per person per year."³⁹

Research in the UK⁴⁰ has shown that

- Every household in the UK wastes between £250 and £400 of food per year.

³⁸ Food Ethics Council (2008) Food Distribution, an Ethical Agenda, <http://www.foodethicscouncil.org/node/158>

³⁹ No detailed information is available for other EU countries, for more information see: Parfitt, J, Barthel, M and Macnaughton, S (2010) Food waste within food supply chains: quantification and potential for change to 2050, *Philosophical Transactions of the Royal Society B*, 365, 3065-3081

⁴⁰ Food Ethics Council (2009) Waste – Dishing the Dirt, <http://www.foodethicscouncil.org/node/329>.

- Avoidable waste of cereal-based food in the UK and USA could lift 224 million people out of hunger.
- Around 7 million tonnes of food ends up in landfill in the UK every year.
- Producing and distributing edible food that goes to waste accounts for around 5% of all UK GHG emissions.

Given the scale of the problem of food waste and its main concentration in individual households, considerable improvements to food efficiency could be achieved through behavioural change.

Fair Trade, Accreditation Systems

The slogan "We are what we eat", which is usually subscribed to Rousseau, is understood to have a health background. Healthy diets lead to healthy lives. However, increasingly it is also taken to express life-choices irrespective of health considerations. Food markets make it possible to express ethical values by consuming food correspondingly: the value of animal well-being is expressed by free-range and vegetarian products, the value of environmental protection by organic products and the value of social justice by fair trade products. We shall look at the latter as an example of this kind.

Millions of people around the world rely on agriculture for their livelihoods. In some poorer countries the majority of the population is fully or partly dependent on it.⁴¹ The growing market share and power of retailers has contributed to a situation where workers' rights and environmental standards are put under pressure by efforts to secure large quantities of products at the cheapest possible price.

Labelling and accreditation systems like *Fairtrade* and *Max Havelaar* have been crucial in raising the profile of ethical issues in food and farming. The problems that arise from accrediting some products as fairer than others include:

- Why are unfair products - for instance those made in illegal working conditions - on the shelves at all?
- Do 'ethical labels' live up to their promises - are they rewarding fair trade or just fairer trade?
- When large corporations buy into ethical standards, does that erode their value either in practice or in principle?
- Is competition in the 'ethical' foods sector creating too many different levels and types of 'ethical' standard, damaging consumer trust in the movement?

⁴¹ World Bank, Employment in Agriculture,
<http://data.worldbank.org/indicator/SL.AGR.EMPL.ZS/countries?page=1&display=default>

Food Science, Financial Conflicts and Scientific Integrity

*A conflict of interest is 'a conflict between the private interests and the official responsibilities of a person in a position of trust.' A conflict of interest thus arises when a person has to play one set of interests against another.*⁴²

FP7 encourages collaboration between academic researchers and private industry⁴³ to enhance European competitiveness. It is important to understand that collaboration with industry-partners does not represent an ethical issue *per se*. The potential for biases in research are numerous. But given public sensitivities and allegations of specific bias in the food industry⁴⁴, the following guidelines may be helpful.

In 2009, the International Life Sciences Institute in the United States issued "proposed conflict-of-interest guidelines, regarding industry funding to protect the integrity and credibility of the scientific record, particularly with respect to health, nutrition, and food-safety science".⁴⁵

These are⁴⁶:

1. conduct or sponsor research that is factual, transparent, and designed objectively, and, according to accepted principles of scientific inquiry, the research design will generate an appropriately phrased hypothesis and the research will answer the appropriate questions, rather than favor a particular outcome;
2. require control of both study design and research itself to remain with scientific investigators;
3. not offer or accept remuneration geared to the outcome of a research project;
4. ensure, before the commencement of studies, that there is a written agreement that the investigative team has the freedom and obligation to attempt to publish the findings within some specified time frame;
5. require, in publications and conference presentations, full signed disclosure of all financial interests;
6. not participate in undisclosed paid authorship arrangements in industry-sponsored publications or presentations;
7. guarantee accessibility to all data and control of statistical analysis by investigators and appropriate auditors/reviewers;

⁴² Coughlin SS, Soskolne CL, Goodman KW. (1997) *Case Studies in Public Health Ethics*. Washington: American Public Health Association.

⁴³ See for instance Marie Curie Industry-Academia Partnerships and Pathways (IAPP), http://cordis.europa.eu/fp7/people/industry-academia_en.html.

⁴⁴ Centre for Science in the Public Interest (2007) New Aspartame Safety Review 'Perfectly Predictable', <http://www.cspinet.org/new/200709122.html> and *Animals Australia (2008) Farming Critics Fault Industry's Influence*, http://www.animalsaustralia.org/media/in_the_news.php?article=132

⁴⁵ Sylvia Rowe, Nick Alexander, Fergus M Clydesdale, Rhona S Applebaum, Stephanie Atkinson, Richard M Black, Johanna T Dwyer, Eric Hentges, Nancy A Higley, Michael Lefevre, Joanne R Lupton, Sanford A Miller, Doris L Tancredi, Connie M Weaver, Catherine E Woteki, and Elaine Wedral (2009) Funding food science and nutrition research: financial conflicts and scientific integrity, *Nutrition Reviews*, 67(5)264-272.

⁴⁶ Ibid.

8. require that academic researchers, when they work in contract research organizations (CRO) or act as contract researchers, make clear statements of their affiliation; and require that such researchers publish only under the auspices of the CRO.

The drafting group of the above guidelines emphasised that financial conflicts of interest do not necessarily lead to bias, that a large number of well-known forms of scientific and personal bias exist and that *all* need to be kept in check. They also noted that whilst disclosure of conflicts of interest are an essential element of safeguarding research, it is not sufficient (hence the guidelines) and that the success of such guidelines rely on open communication between researchers and funding bodies in a spirit of collaboration.⁴⁷

A broader issue which is difficult to address through such guidelines, yet nevertheless warrants attention, is the issue of 'cultural bias' within scientific institutions. The heated controversies over issues such as GM foods illustrate how scientists may see the world differently from non-scientists, or how perspectives on problems may vary greatly between research disciplines. In addition, the regional cultural differences may impact. For instance, in Europe the precautionary principle is used to guide research involving GM organisms. At the same time, they are generally recognized as safe (GRAS) by the American Food and Drug Administration. This suggests the benefit of engaging stakeholders and members of the public in the process of defining research problems and subjecting research projects to ongoing critical scrutiny.

Legitimacy of Publicly-Funded Research / Societal Benefits

Much publicly-funded research relating to food aspires to deliver benefits to the population or to specific groups of people. Thus, a project in nutrigenomics may aim to benefit public health, or agricultural research may be intended to improve food security in developing countries. Claims about the potential public benefits of research are relevant to specific decisions on public sector research funding and also affect the broader licence to operate of the scientific community.

High-profile controversies over research in food and agriculture, for example the Golden Rice project to combat vitamin A deficiency through biofortification, have seen the legitimacy of such claims subjected to intense scrutiny. In particular, critics are concerned about the practical relevance and the opportunity costs of scientific projects to develop technical solutions to problems that also have social, economic and political dimensions.

The appropriate response to this concern is to ensure that any promises by researchers of potential public benefit are well-founded and take all foreseeable consequences into account. The first priority is therefore to ensure that the public interest elements of research problems are defined robustly and legitimacy. This entails that they:

⁴⁷ Ibid.

- Are intellectually robust. If research claims to have potential to contribute to addressing a real-world problem, then a robust problem definition is likely to depend on reviewing evidence from multiple disciplines across the social and natural sciences.
- Are informed by the demands of constituencies experiencing the problem in question. For example, a social science or plant breeding project may respond directly to the food security priorities of a rural communities in a region of sub-Saharan Africa identified through prior participatory research; or researchers may identify priorities for nutrigenomic research by working with patient groups. At best, projects should include governance mechanisms to ensure they are accountable to any groups they claim to benefit.
- Invite ongoing scrutiny by independent third parties. Many problems relating to food disproportionately affect marginal groups – people in poverty, ill-health or food insecurity – who have few resources to ensure their voices are heard in research decision-making or public debate. Inviting scrutiny from third parties that have a remit to represent the interests of such groups, such as civil society organisations, can help to ensure their definition of the research problem remains prominent throughout the research process.

With regards to developing country research relating to food, agriculture and rural development, a key resource and reference point is the report of the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD).⁴⁸ The IAASTD process involved 400 experts and civil society groups from around the world. Its report provides guidance on priorities relating to agricultural and food research, and methods for ensuring that aspirations to benefit food security, sustainability, rural livelihoods and poverty reduction are developed robustly and legitimately.

Food Habits and Public Health

Considerable research is being undertaken on eating disorders and food habits, which have a detrimental effect on public health. Here, obesity will be taken as an example.

According to the World Health Organisation (2005) approximately 1.6 billion adults worldwide are overweight and at least 400 million adults are obese, with predictions that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million obese. Obesity is a major risk factor for chronic diseases such as cardiovascular disease, diabetes, musculoskeletal disorders and some cancers. While obesity is sometimes characterised as a disease of affluence, many of the wide range of social, environmental, technological and other factors contributing to the rising incidence of overweight and obesity differentially affect individuals in lower socioeconomic groups. Globally, there are more obese people in developing and newly industrialised countries than there are in the industrialised world.

Unhealthy eating is one factor contributing to rising rates of obesity and overweight. However, changes in body shape are only one of the possible consequences of poor diet, and public health intervention seeks to improve dietary health for other reasons in addition to reducing

⁴⁸ IAASTD Reports, <http://www.agassessment.org/>

overweight and obesity. For example, consumption of fruit and vegetables is relevant to a wide range of health outcomes and varies considerably across EU member states, with per capita intakes in Greece more than five times higher than in the UK.⁴⁹ At the same time, considerable "junk food" consumption can outweigh the benefits of fruit and vegetable intake.⁵⁰

Ethical issues relating to healthy eating focus on the appropriate responsibilities of government, businesses and individuals. A key factor in this discussion is the level of autonomy that individuals are understood to experience as consumers in the marketplace. A relevant consideration is the degree to which socioeconomic inequalities explain poor diet and related health conditions. The balance of evidence suggests that while such inequalities do not fully determine differences in diet, they do provide an important explanation.⁵¹

The Nuffield Council on Bioethics has explored in depth the ethical issues relating to public health, including diet, outlining a 'stewardship model':⁵²

The concept of 'stewardship' is intended to convey that liberal states have a duty to look after important needs of people individually and collectively. It emphasises the obligation of states to provide conditions that allow people to be healthy and, in particular, to take measures to reduce health inequalities. The stewardship-guided state recognises that a primary asset of a nation is its health: higher levels of health are associated with greater overall well-being and productivity.

In this context, it is also important to bear in mind that food research often involves working with individuals and groups whose relationship with food and patterns of food consumption are entwined with more complex social, cultural, physical and psychological issues that extend beyond mere food 'behaviours'. For example, Western medicine and culture often attach moral overtones to the behaviour of overweight and obese individuals: they eat 'bad' and 'unhealthy' food; lack self-discipline and control; are negligent in caring and respecting their bodies and health.⁵³ However, food behaviours and attitudes differ across cultures. Among Australian Aborigines and Pacific Islander, for example, an older person who consumes lots of food and is physically large is viewed as a person who is comfortable with their own identity and who has a zest for enjoying life. While there are deleterious medical consequences to being overweight or obese, public health interventions designed to improve diet, weight and health problems within these groups are viewed as a cultural assault and form of cultural imperialism that seeks to erode the cultural values, heritage and identity of already oppressed native peoples. Hence, ethical research needs to consider the particularity of the specific populations involved in any food research.

⁴⁹ Martinez-Palou, A. and Rohner-Thielen, T. (2008) Fruit and vegetables: fresh and healthy on European tables. *Eurostat Statistics in Focus*. 60.

⁵⁰ Cohen DA, Sturm R, Scott M, Farley TA, Bluthenthal R. (2010) Not enough fruit and vegetables or too many cookies, candies, salty snacks, and soft drinks? *Public Health Rep.*;125(1):88-95

⁵¹ Food Ethics Council (2010) Food Justice, http://www.foodethicscouncil.org/system/files/FoodJustice_reportweb.pdf

⁵² Nuffield Council on Bioethics (2007) Case Study: Obesity, <http://www.nuffieldbioethics.org/public-health>, ppxvi-xvii.

⁵³ Gard, M., & Wright, J. (2005). *The obesity epidemic*. London: Routledge.

Food, Social Life and Personal Identity

*[T]he things we eat and drink play important roles in our social and personal (not just biological) life. To almost any citizen... food is connected with identity and social life. A good food research project should try to address these issues in advance, because neglecting them would almost certainly hamper the implementation.*⁵⁴

"Food lies at the centre of human sociability"⁵⁵ (Korthals 2002: 322). For instance, it plays an important role in family life and other forms of social bonding. "Drinks are for strangers, acquaintances, workmen... Meals are for family, close friends, honoured guests"⁵⁶. This is, of course, a simplification but having a meal with somebody often makes the difference between intimacy and distance. Meals, particularly at home, express close friendships. Common meals are meeting places for family members and friends.

With individualist eating either in terms of functional foods or foods tailored to one's genetic make-up, the social bonding function of food might be breaking down. Such foods:

can have detrimental effects on these social dimensions, because of their individualizing intake: what is healthy for me isn't for you, because of differences in genome, age, life style and ideals, and expectations. So in the end, the common meal, which, at least in European and Asian traditions of eating, is a cherished good in upholding relationships, could vanish.⁵⁷

Researchers need to be aware of potential public resistance to certain foods and may want to consider public engagement exercises to accompany their research.

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⁵⁴ Frans Brom, Marcel Verweij (2000) Food Research and IRBs, *Hastings Center Report*, 22(6)15-16.

⁵⁵ Korthals M (2001) The Struggle over Functional Foods: Justice and the Social Meaning of Functional Foods. In: *Journal of Agricultural & Environmental Ethics*, 15: 315-324, p.322.

⁵⁶ Douglas M (1997) Deciphering a Meal. In: Counihan C, van Esterik P (eds) *Food and Culture*. Routledge, London, pp. 36-54, p.41.

⁵⁷ Korthals M (2001) The Struggle over Functional Foods: Justice and the Social Meaning of Functional Foods. In: *Journal of Agricultural & Environmental Ethics*, 15: 315-324, p.322.