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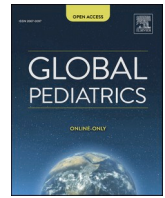
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## Good practices and ethical issues in food safety related research

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### ABSTRACT

After introducing a historical view of research ethics and the main schools of thought, the paper is structured around two main topics: On the one hand, the protection of the environment surrounding the research experiments conducted, which is a major aspect in food safety related research and includes the staff carrying out the research. On the other hand, collective decision aspects, which are involved in the construction of decision support systems for food safety enhancement. Based on a few examples in food safety related research, the paper reviews the ethical issues considered, the ethical principles applied, and the main measures taken in these cases.

### 1. Introduction

Birth of research ethics — Historically, the ethical principles of research emerged as a new formalized field, in the tradition of Hippocratic ethics, with the increasing concerns stemming from biomedical research. Their emergence was driven by the need for a balance between the benefits expected from the research conducted, and the risks to be taken, which in some cases led to major scandals [1].

The Nuremberg Code of 1947 first provided formalized safeguards to ensure accordance with ethical principles in research practices [2]. The various versions of the Declaration of Helsinki [3], promulgated by the World Medical Association since 1964, further developed the Nuremberg Code. They introduced in 1975 the need for review and validation of research protocols by an independent committee of ethics. Since these foundation stones of research ethics, numerous guidelines have been defined and specified for various cases and professions. These can be either advisory or have the status of legislations at the international, national or local level. However, codes and laws regulate practices but do not give comprehensive ethical advice. This is where ethical frameworks come into play.

Schools of thought in ethics — Different ethical frameworks have been developed. Among them, consequentialism, deontology-based ethics, and virtue ethics are major approaches [4]. As its name indicates, consequentialism refers to a family of ethical approaches

focusing on the consequences or effects of an action, i.e. an action is evaluated with regards to its overall consequences. A classic example of consequentialism is utilitarianism [5] for which an action is deemed morally good if it maximizes the utility of the society. In contrast to that, deontology-based ethics regroups different approaches to ethics that base morality of an action on its compliance with a set of normative rules or duties, regardless of their consequences. An iconic example of that kind of approaches is the categorical imperative introduced by Kant [6], where an action is morally allowed only if it can be elevated as a universal law. Finally, virtue ethics disregard consequences or duties in favor of virtues, i.e. traits of character that are deemed excellent and that need to be nurtured. In that sense, virtue ethics is more interested in how a life should be lived rather than what is the right action in a particular situation —see Vallor [7] for a recent account of virtue ethics.

The answers provided by the different frameworks do not necessarily converge. This raises the issue of how to solve this pluralism in practice, which also opened the way for different conciliation strategies. One of them, known as “principlism”, is widely referred to in biomedical ethics. It is based on both deontology and consequentialism, and lies on four principles [8]: respect for autonomy, non-maleficence, beneficence, and justice. As far as we are concerned in this paper, the principle of beneficence is the very basis of the research conducted to improve food safety. Indeed, food safety research aims to benefit consumers by preventing health issues of concern, but also the food industry and public

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authorities, by improving efficiency and reducing costs through the development of efficient high throughput technologies, thus avoiding adverse public health crises and increasing public confidence. As regards non-maleficence, justice and autonomy, these principles will be considered in Sections 2 and 3.

This paper proposes an overview of two ethical aspects which are prevalent in food safety related research, namely: 1) The protection of the environment surrounding the experiments conducted, which includes the research staff carrying out the experiments. 2) The ethics of collective decision, which is implied in the cost-benefit balance of the choices made to enhance food safety, with the involvement of different stakeholders and possibly personal data considerations. These aspects are developed in Sections 2.1 and 3.1, respectively.

## 2. Protection of the environment surrounding the research experiments conducted

Ethics related to environmental protection and safety concerns research activities that involve the use of elements that may cause harm to the environment, to animals or plants, or to humans, including research staff.

In food safety related research in particular, research labs must be aware of the possible harm to the environment caused by the research and the measures to be taken to mitigate the risks. Practically, they must ensure that appropriate health and safety procedures conforming to the legislation are applied for staff involved in the research.

The principle of non-maleficence is followed here, that is to say, avoiding causing harm is commented in the first example.

### 2.1. Example 1

*Description:* a research laboratory carries out microbiological or chemical hazard detection and control, involving the use of potentially infectious or toxic material that might accidentally impact the environment or cause harm to the research staff conducting the experiments.

*Ethical issue considered:* The kind of ethical issue that arise in relation to microbiological or chemical safety research lies in the risk of environmental health and safety impacts. The eventuality of accidental release of chemicals or pathogenic bacteria in the environment, of accidental contact with humans, has to be anticipated.

In this example, the risk considered primarily goes for the research staff itself—in contrast to research subjects or the general public in other cases. Although researchers may be assumed to have a good understanding of the risks involved, this is not necessarily straightforward when staff with different levels of responsibility, or students, are involved.

*Ethical principles applied:* This issue is in relation to the precautionary principle. Initially introduced in policies for environmental protection, the precautionary principle has now been much extended. Indeed, according to the European Commission, the principle additionally refers to potentially harmful effects on human, animal or plant health [9]. The principle states that in case an activity introduces a risk of harm, adapted measures should be taken to prevent or limit that harm, even in the absence of a precise assessment of the risk level.

To a lesser extent, and in addition to the precautionary principle, the issue considered is also in relation to the notion of informed consent. This is the most basic requirement originating from the Nuremberg Code [2]. Characterized as the most authoritative set of rules for the protection of human subjects in medical research, the Nuremberg Code has not been entirely adopted as law by any nation, nor as official ethics guidelines by any major medical association [10]. However, its basic requirement of informed consent has been integrated as international law in the International Covenant on Civil and Political Rights [11]. It is also the basis of the International Ethical Guidelines for Biomedical Research Involving Human Subjects, promulgated by the World Health Organization [12].

In reference to this requirement, in case a research activity introduces a risk of harm, the research staff are supposed to have consented to their involvement. Thus, measures to be taken include ensuring that the staff participating has a good understanding of the risk and ability to carry out the research adequately with regard to the risk.

*Measures to be taken:* legislations and guidelines, defined from the international and national levels until the local level at the scale of the lab, regulate the intake, storage, registration, handling and management of hazardous material. See to this regard. United Nations and WHO's position [13,14]. The protocols required include in particular the training of the staff to good laboratory practices, decontamination and waste management procedures, appropriate human protection equipment (gloves, masks, safety glasses, lab coats), use of biological and chemical hoods. Thus, to summarize, the security measures rely, on the one hand, on informational means, including training and procedure display, and on the other side on physical and chemical barriers to limit the risk of spread.

## 3. Ethics of collective decision

Addressing societal issues such as public health management through food safety control, involves several stakeholders with different visions of the system, different expectations from the research carried out, and possibly conflicts of interest [15]. Supporting decision-making in such a multi-actor context implies some ethics of decision and relies on the principle of justice in decision-making, since different points of view have to be reconciled [16]. In the case of food safety related research, experts from different disciplines are involved (e.g. food safety, nutrition, food processing), various stakeholders are consulted (e.g. consumers, food companies, public authorities, researchers). In bottom-up hazard control performed by food companies and top-down hazard control performed by food safety authorities, there is a common responsibility and interest in preventing public health problems related to the food chain and a common investment in the food chain safety. Nevertheless, expectations regarding the research carried out may differ. On the move towards modernized hazard control methods, food companies would possibly prioritize, as essential criteria, high-throughput tools and cost-efficiency for self-monitoring in routine use, ease of implementation, and affordable initial investment costs; while on the other hand, for safety authorities, the method capacity to discover unsuspected hazards could be salient.

When choices have to be made, whatever the method used to reconcile viewpoints (e.g. using risk-benefit analysis and multi-criteria decision [17,18]), it is based on underlying decision principles. Unfortunately, it is a well-known issue with voting rules (ways of making a decision based on the aggregation of stakeholders' preferences) that none is perfect and each one of them has some defects [19]. Importantly, the choice of the voting rule might impact the decision that is made, a decision that consequently might misrepresent the preferences of the actors. It is thus a matter of justice to acknowledge the bias associated with the decision-making mechanism that is chosen and try to address it. Example 2 addresses these considerations.

### 3.1. Example 2

*Description.* A decision support system is designed to analyze the costs and benefits of different food safety management strategies (which risks should be high-priority, which technologies should be chosen, etc.) by bringing in the views of the stakeholders concerned.

*Ethical issue considered:* The issue considered is the risk of providing an unequal representation of the different viewpoints in the decision process.

*Ethical principles applied:* This issue refers to the principle of justice in research. It is an issue known to the research community, especially in participatory approaches [20,21], that the research process itself induces concerns about: (i) The fair representation of the different groups

and stakeholders, offering the opportunity for all viewpoints to be expressed, and avoiding under- or over-representation of certain groups. (ii) The possible influence of the researchers themselves on the decision process, which should be avoided by keeping a neutral posture. These concerns are also shared with other research communities, in particular operational research, which produced a rich literature on the subject [22].

**Measures to be taken** — Although this issue is inherent to any decision process, adopting a formally well-defined decision methodology, explainable and interpretable, is a way of best addressing the issue. Moreover, providing the possibility to actors to understand and discuss the different aspects of the collective decision, will promote understanding and cohesion between the actors.

In addition to the ethical issues raised by the decision process, another related well-known issue in ethical guidelines is the respect of privacy. With the participation of different stakeholders representative of a range of situations and interest in the society, comes the question of the possible collection of personal data. Example 3 illustrates this issue.

### 3.2. Example 3

**Description.** A web survey is launched in order to collect the perceptions of end-users –parents, early childhood professionals, healthcare professionals– concerning the safety of infant food products.

**Ethical issue considered:** The issue considered is the risk of unconsented collection of personal information, in particular data allowing for the identification of a person, such as names, emails, IP addresses, etc.

**Ethical principles applied:** The ethical principle involved is the respect of privacy [23]. A recent approach to define privacy is to associate it with the protection of personal information. As it is the case in this example, this definition of privacy relates it to digital concerns such as data protection, at a time where data are valuable goods. This concept of privacy covers, on the one hand, the right to prevent others from obtaining information about oneself; on the other hand, the right to have control on information about oneself that may be registered e.g. on computers. Thus, privacy can be seen as part of the autonomy principle, in the sense that it refers to the right to decide whether and how data originating from oneself are used. With this broad meaning, privacy may not be exclusively restricted to identifiable data, but more generally to information about individuals. Views are however divergent about the scope of privacy [24].

**Measures to be taken:** The protection of personal data is regulated at the European level by the General Data Protection Regulation and by the Directive (EU) 2016/680 [25]. In the present example, the collection of identifiable data, if unnecessary for the study, can be completely avoided. Technically, this implies in particular the choice of a survey tool that allows the survey designer to block the collection of IP addresses. However, in case the study necessitates the collection of data that can, in some manner, allow one to identify the respondent, then participants should be informed beforehand and provide their consent. But even without the possibility of identifying the respondent, or in the case of anonymized data, good practices suggest to provide adequate information to the participants. Researchers would thus state any significant risks, the purpose of the research, any financial interests and external research funding, the opportunity to ask questions or to change one's mind, all items that directly arise from the Declaration of Helsinki statements.

## 4. Conclusions

This paper illustrates the challenge of adopting best practices for an ethical research, in the domain of food safety. Even in a restricted domain of research, it can be noted how diverse the issues raised are. Indeed, Section 2 addressed some issues related to the protection of the environment surrounding experimental research on food safety, including the research staff. This is probably the most straightforward

aspect of ethics in food safety related research. On the other hand, Section 3 illustrates how food safety related research becomes a societal issue when it comes to decision about food safety management. In this case, very different concerns are raised, in the field of ethics of decision-making and personal data protection.

By highlighting miscellaneous concerns regarding good practices and ethical issues in food safety related research, this paper aims at increasing awareness within academia, industry and other stakeholders, about the variety and complexity of research ethics and its tight imbrication with legislation.

## Declaration of Competing Interest

The corresponding author states on behalf of the co-authors that all Authors have no conflict or competing of interests to declare.

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