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Governing Sustainable Food and Farming Production Futures Using Integrated Risk Assessment Approaches

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Abstract

Nanofoods, 'functional foods' and biopharming are three production futures that are strongly developing despite being characterised by significant gaps in knowledge and understanding, and a peculiar scarcity of proactive processes with which to seize opportunities and minimise and manage potential risks and public concerns which could negatively impact on the industry. In order to better assess benefits and risks and to build public trust, the paper suggests the establishment of an integrated health/food and environmental risk assessment regime that also incorporates and is responsive to the ethical concerns, socio-economic realities and local demands of various stakeholders – right from the beginning of a development. In order to have a global as well as a national practical effect, the assessment regime needs to conform to national and accepted international regulations and observe fundamental principles in bioethics and public sector ethics, such as integrity, access, autonomy and choice. Such a pro-active approach might lead to improved collaborations, to constructive communication channels and to enriched and more mutually acceptable futures.

Keywords

Integrated Risk Assessment, Ethics, Nanotechnology, GM Foods, Biotechnology

Introduction

Second generation biotechnology crops, so called 'functional foods' are beginning to enter the market promising benefits to consumers, such as foods with enhanced nutrient content and bioavailability, improved quality and taste, reduced allergenicity, or a higher satiety index. Another emerging production future uses plant and animal systems as living 'bioreactors' to produce pharmacologically active substances (biopharming), which may be more cost-effective than employing conventional bacteria, yeast or cultured mammalian cell systems. Straddling both, and still largely at the research stage, are the 'nanofoods' - food technologies that are associated with nanoscience and nanotechnology, a science that functions at the molecular and atomic level. In the food sector, one possibility being explored in this area is the development of nanosensors and nano-scale diagnostic devices that monitor the safety and quality of foods. Another area of applied research investigates how medicines or health supplements can be embedded in nanoparticles in order to deliver nanoscale nutrients or drugs directly to targeted cells, thereby maximising their health benefits and minimising their adverse effects. Currently more than 200 companies worldwide, including Unilever, Nestlé, and Kraft Foods, are reportedly involved in a rapidly developing nanotechnology industry. The value of its applications for foods alone is forecast to surge to US$20.4bn in 2010 (Helmut Kaiser Consultancy, 2004).

While the number of scientific papers addressing aspects of these emerging technologies is climbing, as with all emerging technologies, a lack of empirical data makes it difficult to accurately forecast their actual benefits and risks to human and environmental health. There is also a paucity of publications assessing their ethical and social impacts. Indeed, there is little evidence to suggest that their implications are being seriously discussed by either the scientific or civil community. Public knowledge about these novel production futures is generally low to almost non-existent. This is particularly the case for nanotechnology (Mnyusiwalla *et al*., 2003; International Risk Governance Council, 2005). Specific laws and regulations in this area are also largely absent. It is becoming apparent, however, that change is underway. For example, a newly funded program by the European Commission Research Directorate-General called "NanoBio-RAISE", aims to anticipate and then respond to ethical and social issues and concerns that might arise from nanotechnology (NanoBio-RAISE, 2006-2007) and in the US, the "21st Century Nanotechnology Research and Development Act", section 10 requires that "ethical, legal, environmental and other appropriate societal concerns" be considered and integrated into nanotechnology research and development programs (21st Century Nanotechnology Research and Development Act, 2003). Although change might slowly be underway, uncertainty and a lack of public debate makes solid risk assessments difficult to achieve.

Current issues with conventional risk assessment methodologies

Traditionally, risk assessment methodologies in the agroenvironmental sciences have focussed on scientific and technical multidisciplinary data and science-based risk assessment methods. For example, Codex Alimentarius principles (2003) guide the assessment of the safety and nutritional aspects of genetically modified (GM) foods, while the Cartagena Protocol on Biosafety (1992/2003) guides an assessment of genetically modified organisms (GMOs) on the environment. Both take a case-by-case empirical approach. Both refer to direct as well as indirect effects. The Codex includes an assessment of indirect effects of novel foods on human health and the environment (Codex 2003); and the Cartagena Protocol recommends an inclusion of "uncertain" effects with regards to the "conservation and sustainable use of biological diversity…taking also account of risks to human health" (Cartagena Protocol, 1992, Annex III).

When considering risk assessment for emerging agroenvironmental bionanotechnologies, a number of problems present themselves. Firstly, uncertainty has no numerical value. The existence and likely long-term persistence of scientific uncertainty, which would call Article 15 of the Rio Declaration on Environment and Development (1992) into action (defined as "the precautionary principle") demanding protecting the environment and human health. However, scientific uncertainty has no numerical value that is measurable and reproducible. Secondly, empirical scientific data are open to

interpretation. While scientific methods of data gathering may be objective and reproducible, empirical data are still open to interpretation with alternative explanations possible. In addition, there are often no universally accepted and reliable testing methods or standards yet available. At other times, any risk may not become apparent immediately or may be indirect, especially where the gathering of data is incomplete and still evolving. Furthermore, interpretations of data may be effected by social parameters. As discussed in detail by Kimmelman (2004), the interpretation of scientific data – even among scientific experts – is influenced by an individual's assumptions about risk acceptability, social affiliation, and political and social worldviews. Alternative interpretations could even lead to conflict until more data becomes available or a temporary consensus can be established. Thirdly, current conventional risk assessments largely ignore the human dimension and do not embrace ethical, cultural or social issues. Government-sponsored surveys in Australia indicate that a better informed public assesses risks arising from biotechnologies not so much by evaluating scientific data, but rather on outcomes and processes. For processes, not only do the various publics demand participatory decision-making, they also expect that technology providers present proof of benefits that trusted information sources can verify (Biotechnology Australia, 2003). Indeed, recent research tends to suggest that public disquiet and distrust regarding GM foods and feeds has become more differentiated in that a perception of distrust and unethical behaviour of researchers and companies connected to the industry also rank high in the public mind. Surveys conducted by Cormick & Ding (2005) indicate that for biotechnology, many policy decisions that were made by governments and industry in the past were based on an erroneous assumption that the public needed scientific facts to evaluate risks, when in reality the public was more interested in who would ensure their safety. Education campaigns designed to convince a sceptical public that a technology is safe does not appear to guarantee acceptance and quell public disquiet, indeed, a recent study investigating the acceptance of genetically modified foods has shown that exposure to information can alert people to potential dangers, even making people more distrustful of existing regulations (Poortinga & Pidgeon, 2004). According to Cormick & Ding (2003), the public is more likely to accept a new technology application if

- The information about an application is provided from a credible source
- It is morally acceptable and not harmful to people or the environment
- The application is regulated by government and not by industry
- The public has had some meaningful input in the development of a technology
- Consultations address major public concerns and public feedback is seen as having some effect
- Consultations occur before an application is developed and not afterwards
- Consumers can choose to accept or reject an application
- The application has clear individual or societal benefits
- The largest beneficiary is the public and not a multinational company

Adapted from Cormick & Ding (2005)

The aforementioned problems indicate that conventional risk assessments are insufficient in addressing the needs of the various publics who are asked to embrace emerging technologies and to trust researchers and governments although scientific uncertainty is common and risks and benefits difficult to ascertain.

Adopting an integrated risk assessment approach for emerging technologies

It has recently been recommended to adopt an integrative approach when assessing genetically modified organisms and GM foods and link health and food safety, and environmental considerations (World Health Organization, 2005; Haslberger, 2006). In the following, we suggest that an integrated approach is also taken for emerging food and biopharming technologies in order to better assess benefits and risks and to build public trust. Such integrative methodology would be holistic and include deliberate, multi-stakeholder public participation and an assessment of normative values. The approach would also not so much concentrate on endpoints but on various points of intersections,

preferably right from the beginning of a given research and development action (Kapuscinski *et al*., 2003) until the post-marketing phase.

When allowing normative values to enter risk assessment protocols, an immediate hurdle presents itself, namely how to measure and standardise them. Normative values cannot easily be measured, because they are multidimensional and affected by different variables, such as social forces, cultural practices and by moral codes, vulnerabilities and impact. While they might not lend themselves to scientific analysis, they can nevertheless be discussed and evaluated in a similar analytical and rational process. One possible "tool" with which to facilitate such assessment is the ethical matrix, introduced by Mepham (2000) and first applied by Kaiser & Forsberg (2001). The ethical matrix does not provide a numerical value. In its mechanics, the matrix is a grid of cells headed by a set of ethical principles first proposed in the 1970s by Beauchamp & Childress (2001) for the field of medical ethics. With respect to each ethical principle, the matrix identifies the most important impact of a particular technology for a given stakeholder group and transcribes it into its corresponding cell. Once every cell has been filled in, stakeholders consider and deliberate on all impacts, if necessary ranking them, so as to arrive at an ethically acceptable position. Furthermore, since each ethical matrix is constructed for a particular case/scenario, local as well as regional, national or international particularities and complexities could be addressed as soon as they arise and in a feedback loop inform subsequent development steps. When working under the guidance of an ethical matrix for assessing normative risks, the sharing of information could make complexities and interdependencies transparent, could foster a sense of co-responsibility for future outcomes and could bring about a sense of ownership of the technology.

However, this method is not optimal either. Similar to the shortcomings discussed above with regards to interpreting scientific data, bias and power relationships can influence processes and outcomes. One possible way to minimise bias and the effect of unequal power relationships is by agreeing on which ethical principles to use and by balancing stakeholder participation. Such standardisation might be difficult to achieve. For example, unlike in medicine, where the ethical principles first suggested by Beauchamp & Childress (2001) have long guided medico-ethical decision-making, their concept of 'autonomy' is not universally applicable across all cultures. However, there is some flexibility in which set of ethical principles is chosen for a given circumstance. For modern food biotechnologies with a potential global reach and impact, the following four ethical principles have already been proposed for a global code of ethics for modern food biotechnologies: the principle of beneficence (doing good), the principle of non-maleficence (avoiding harm), the principle of justice and fairness (which includes integrity and access), and the principle of choice and self-determination (Gesche *et al*, 2004). The latter replaces the principle of autonomy, which is contrary to the communal decision-making practices in many cultures. The four ethical principles could be extended by a fifth, such as 'respect for the law and the system of government' (Queensland Government, 2001), which would link the ethical framework to national and accepted international regulations.

It needs to be acknowledged that an integrated risk assessment would place an additional inconvenience on industry, which would embrace ethical and social issues as elements of their corporate strategic planning. Companies driving the evolution of emerging technologies expect to be constrained by a country's business norms and legal system. However, understandably, they try to negotiate minimal operational conditions to contain their costs and to maximise shareholder benefits. Already having to comply with at times stringent scientific regulatory requirements, they make a strategic decision where to locate their operations and to what extent they commit to corporate social responsibility (CSR as defined by McWilliams & Siegel (2001)). Their voluntary commitment may depend on the existence or absence of a competitive market (McWilliams *et al*. (2006), shareholder expectations and stakeholder demands. For the latter, it can be anticipated that in capacity-strong countries with vocal stakeholders and a tradition of strong regulatory oversight, companies will be more mindful of their ethical and social responsibility than in capacity-poor countries, where public objections and regulatory measures may be minimal. Two points stand out: regardless of capacity, without integration, ethical and social issues are likely to remain marginalised until public disquiet or fear brings them to the surface, potentially starting and repeating a cycle of conflict and distrust

similar to the one that has long plagued the GM biotechnology sector. Furthermore, without integration of other, equally valid non-scientific knowledges, scientific risk assessment processes are likely to result in uni-dimensional views regarding risk, with long-held beliefs and inferences becoming further entrenched and enforced by like-minded peers. If those beliefs and inferences are contrary to public opinion, rejection of the new technologies is a real possibility. Worse is to be expected if those interpretations turn out to be erroneous and the public comes to a conclusion that it has been misled.

A paradigm shift is needed from industry. In a recent survey conducted by the International Risk Governance Council (2005), most scientific nanotechnology experts on the panel from different economies in different continents saw no need for public engagement at this stage. Only a few recognised that civil society would make judgements on societal values rather than scientific facts. Only one expert went further and recommended "early citizen and stakeholder collaboration…as an essential step in preventing risk in the longer term". Whatever the misgivings or inconveniences, if industry aspires to develop these technologies further and to turn substantial investments into profits and if governments and civil society aspire to move towards a sustainable, equitable future, a more engaged, holistic, and integrated approach to risk assessment is necessary. By following an integrated risk assessment regime, the scope of assessment is widened and responsibility for developments, including adverse effects, shared between the scientific and public community.

Conclusion

Nanofoods, 'functional foods' and biopharming are three production futures which are strongly developing despite being characterised by significant gaps in knowledge and understanding. They have the potential to significantly contribute to feeding a rapidly growing world population and to respond to people's escalating medico-pharmacological needs in an affordable manner. However, while scientific discoveries and economic application leap ahead, the ethics and social science discourse lags dramatically behind. Remaining silent and waiting for the scale and economic force of the emerging technology to make public criticism ineffectual would be an unsatisfactory development. The preferred option is a proactive one that creates dialoguous relationships and shares knowledge and responsibilities. Reaching this goal will require synergy between scientists, industry, the government and the public. It requires international agencies to take the lead in developing new standards and to function as a repository and disseminator for analysis and exchange of data and experiences. It requires as its foundation one unifying global ethical framework whose principles guide different levels of conduct and interactions. It requires an integrated risk assessment approach that is systematic on the one hand and dynamic on the other, where the kinetics of scientific knowledge, technical change, difference in capacity and values, ecological, economical and political particularities and realities are being reconciled as best as possible for enriched and mutually accepted outcomes.

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