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FROM RISK ASSESSMENT TO IN-CONTEXT TRAJECTORY EVALUATION

GMOs AND THEIR SOCIAL IMPLICATIONS

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FROM RISK ASSESSMENT TO IN-CONTEXT TRAJECTORY EVALUATION

GMOs AND THEIR SOCIAL IMPLICATIONS

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ABSTRACT

Purpose: Over the past twenty years, GMOs have raised enormous expectations, passionate political controversies, and an on-going debate on how should these technologies be assessed. Current risk-assessment procedures generally assess GMOs in terms of their potential risk of negatively affecting human health and the environment. Yet, is this risk-benefit approach appropriate to a deliver a robust assessment of GMOs? In this paper, we question the validity of current risk-assessment from both a social and an ecological perspective, and we elaborate an alternative approach, namely in-context trajectory evaluation
Methods: This paper combines frame analysis, context analysis and eco-social analysis to three different case studies.
Results: Applying frame analysis to Syngenta´s recent campaign "Bring plant potential to life", we first de-construct the techno-social imaginaries driving GMOs innovation, showing how the latter endorses the technological fix of socio-economic problems while reinforcing the neoliberal socio-political paradigm. Applying context analysis to biopharming in New Zealand, we then explore local practices, rules and formal and informal procedures, showing that to assess how safe is a technology it is necessary to address how "safe" is the context. Finally, drawing from the Italian case, we outline through eco-social analysis how the lack of long-term studies, further aggravated by current methodological deficiencies, prevent risk-assessment from considering not only how GMOs affect the environmental context but also, and most importantly, the way people live in, and interact with, this context.
Conclusions: Whilst it emerges that there might be a number of socio-political reasons to support a moratorium on GMOs in Europe even if they come to be considered technically safe, these results suggest that the integration of in-context trajectory evaluation with traditional risk assessment procedures may help promoting social compatibility, political accountability and ecological sustainability.

Keywords: Risk-Assessment, GMOs, social implications, eco-social analysis

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CONTENTS

1. INTRODUCTION

Over the past twenty years, biotechnologies have raised enormous expectations as well as passionate political controversies, paving the way to a strong polarization in European societies, to permanent tensions with the US about commercialization under WTO agreements, and to an on-going debate over risk assessment and risk management procedures. Mainstream risk assessment approaches conventionally understand risk assessment as "*a factually grounded, objective and value free analytic exercise*" (Busch et al. 2004). Accordingly, new technologies should be assessed in terms of their potential risk of negatively affecting human health and in terms of their environmental risks (Davies 2009).

Risk assessment procedures, however, have not driven out all concerns about GMOs, whilst doubts have been raised about the enormous pressures exerted by multinational corporations active in the fields of GMOs as well as about the conflict of interests that may potentially affect the scientific experts working for regulating authorities like the EFSA. The independence and reliability of risk assessment procedures have been contested not only because they have often been carried out by the same multinational corporations producing the GMOs under evaluation but also because the original data, for commercial reasons, have not been released to the academic community (Johnson et al. 2007).

Moreover, recent advances in genetics show that the genome is a complex system, which, far from being a mechanistic sequence of genes independent of each other, can be considered as an eco-system where all genes interact on a permanent basis (Buiatti 2004). This new understanding of the genome has raised important questions on long-term unpredictable consequences of genetic engineering, but the EFSA has not yet acknowledged the complexity and attendant uncertainty of GMOs (2009).[1] In addition, a number of independent studies on GMOs have generated results that raise questions about official assurances of safety (Le Curieux-Belfond et al. 2009; Seralini et al. 2009; Seralini, Cellier and Spiroux de Vendomois 2007; Gasnier et al. 2009; Heinemann, Sparrow and Traavik 2004; Traavik and Heinemann 2007).

The universality, objectivity and neutrality of risk-assessment methods have also been questioned, particularly in contexts of low scientific certainty, high stakes (Funtowicz and Ravetz 1992) and low social and political consensus (Winickoff et al. 2005). If "science and values interact dynamically in the process of risk analysis, even at early stages when risks are first being assessed" (Winickoff et al. 2005), then scientific uncertainty requires judgement calls to be made, which will inevitably reflects the values of those making the calls. These judgement calls are typically embodied in criteria for acceptable technical data and methods. As pointed out by a UN FAO expert on food safety, such criteria are imbued with values when, for

1 For more information, please refer to the EFSA Conference on "GMO risk assessment for Human and Animal Health and the Environment - 14-15 September 2009", http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902768091.htm

instance, choices have to be made whether hazard identifications should be based on mortality or morbidity, or whether they should be based on "best practice" or "typical use". Moreover, different extrapolation models may be required when moving from animal to human toxicity studies or when shifting from micro-ecosystems to farm-scale agricultural environments (in Winickoff et al. 2005 with reference to FAO 2002). Finally risk-assessment procedures also incorporate assumptions, obviously value-laden, on the significance given to the distribution of risks, on what constitutes a benefit worth taking a risk for, and what level of risk is acceptable.

Not only can risk assessment not be value-free, it also cannot be divorced from consideration of the context(s)—both biophysical and socio-political—in which the technology is to be implemented. That is, *assessing* risk—identifying and estimating the nature, magnitude and likelihood of potential harms—must include consideration of social context, including the attitudes and practices of those (individuals and institutions) involved in managing risk. Localised neglect or flouting of risk-management protocols, weak enforcement or monitoring procedures, ineffective norms, lack of transparency or reluctant authorities—all are relevant to risk assessment. In effect, risk-assessment and risk management cannot be really separated. This is why it has been argued that risk-assessment procedures cannot operate on the basis of technical expertise only: lay expertise, users' expertise and social science expertise need to be taken into account (Wynne 1992, Irwin 1995, Liberatore and Funtowicz 2003).

Finally, and crucially, risk-assessment and risk-management procedures typically operate only when the technology has already been developed and is ready for experimental and commercial authorization. Yet, this technology has already had an impact on society: public and private resources have been invested; universities, companies and start-ups have been involved; promises have been made; and social and political associations and movements have been mobilized (Van Lente and Rip 1998). All of these processes, which have led to the actual technology being developed, have changed the innovation regime, the research agenda priorities and the actual allocation of public resources and even the perception of the problem for which this technology was first developed. Social and political values, therefore, are not only embedded in risk-assessment procedures; they are also embedded in the very technology that risk-assessment procedures try to evaluate.

2. Frame analysis: GMOs are the solution, but what was the problem?

Narrowing down the debate to whether GMOs constitute a threat to human health and the environment, risk-assessment approaches have reduced the evaluation of GMOs merely to a question of how much risk a society can bear in exchange for the potential benefits claimed for the technology. Yet there is much more to the implications of GMOs than the risk/benefit relationship suggests. This will be illustrated here by an examination of the current public relations campaign by Syngenta, in particular, of the way Syngenta *frames* the issue of GMOs.

Frames, in the social sciences, are "principles of selection, emphasis and presentation composed of little tacit theories about what exists, what happens, and what matters" (Jasanoff 2003: 241, as quoted in Busch et al. 2004:16). Framing is active at all times and is a function of our desire to control and master events that look complex at first sight. Frames help the analyst to order their experiences of reality into patterns of causes and effects so that a given problem can be understood and addressed. As a consequence, frame analysis should constitute a fundamental tool of policy studies and policy-making, because a better understanding of the frames used to make sense of a given problem is essential to evaluate the solution suggested to solve that problem (Jasanoff 2003). It can, for example, help to identify when the proposed solution is an inappropriate "technological fix", through which problems that have social, economic or political causes are framed and addressed in terms of a technological "solution". Such a solution claims to address unwanted effects but leaves untouched their non-technical origins.

Recently, Syngenta has implemented a campaign to promote societal support of GMOs in Europe. Syngenta's posters can be found in various buildings across Europe, mainly airports and public places. There are three posters, related respectively to water scarcity, world hunger and child labor. The first poster (see Fig. 1) identifies the problem at stake as a growing scarcity of (fresh? unpolluted?) water and frames that problem as a function of water consumption by crops.

Source: www.singenta.com, "*Bring plant potential to life*" campaign

If this is the nature of the problem, then, it seems, we must choose between "grow[ing] less food" and "grow[ing] food that needs less water", and technological solutions to engineer plant varieties consuming less water not only make sense but appear as necessary and urgent:

"*Providing enough food, feed, fiber and fuel for the world's population now and confronting future demands depend on whether currently available agricultural technology can be fully accessed by the world's farmers*".

Framing water scarcity as a technical issue paves the way to a technological solution.[2] This obscures not only the whole array of social, economic and political factors that have resulted in the overuse of water, and in the pollution of water that makes it unfit for use, but also obscures the contribution to the problem of the very innovation regime of which Syngenta's strategy is a part. This regime, aimed primarily at industrialised agriculture in rich countries and deriving profits through intellectual property in those markets, has focused on the production of plant varieties that, in order to increase yield, require increased inputs in the form not only of pesticides but also irrigation. In many places such varieties and methods have displaced low-input varieties and methods developed locally (Jordan 2002). The technological frame allows Syngenta to claim that consideration of such social, economic and political factors, and what they are likely to mean for any technology developed under this regime, is the source of the problem: "*In effect, the rejection of sound science in assessing technology is denying food and income to those who would most benefit from new technologies"* (Syngenta website).

In this way, Syngenta illustrates how framing social, economic and political problems as a technical question can result in the delegation of essentially political decisions to expert committees, which effectively divert responsibility from political actors to techno-scientific networks and depoliticize controversial issues (Jasanoff 2003). Indeed, Syngenta advocates this:

What is needed:

- **Government officials must de-politicize their decisions on the use of technology in agriculture.**
- **Not only do we need governments to advance technology in developing markets, we also need governments to support the deployment of existing technologies across land currently under cultivation in order to raise yields and improve farming knowledge.**

Fig. 2: Source: www.singenta.com, "*Bring plant potential to life*" campaign

As Syngenta's campaign demonstrates, "objective" risk-assessment approaches tend to encourage a technocratic approach to science and technology policy, which has been criticized on a number of political and sociological grounds (Weingart 1999; Liberatore and Funtowicz 2003; Nowotny 2003; Felt et al. 2007; Levidow 2009; Ferretti 2009; Ferretti and Pavone 2009). For instance, such approaches neglect GMOs' impact on existing economic, political and social arrangements and on the developmental trajectory of the areas selected for implementation (Ferretti and Pavone 2009). As Sheila Jasanoff (2004) puts it, technology shapes society and it is shaped by it in a mutually constitutive process of co-production where science, technology and social order emerge side by side.

2 The same logic is applied to world hunger (*farmland is limited: how do we feed a growing population?*) and to the relationship between poverty and education (*our seeds enable children to spend more time in the classroom*).

The development of GMOs well illustrates this phenomenon because the production of GM crops could only be conceived in a socio-political context where genetic traits can be patented. Without the reinterpretation of patenting criteria that occurred in the Eighties[3], which extended patentability rights to plants and animal with modified genetic traits (Rouvroy 2008), the technique of genetic engineering may well have been developed as part of a larger basic research plan in molecular biology, but GMOs would have never been developed. GMOs have been possible only in a world in which western governments invest heavily in basic and applied research on biotechnologies in the attempt to build a "knowledge-dense" bio-economy (OECD 2009) that will maintain their competitiveness in relation to emerging economies like China, India and Brazil. In turn, GMOs become meaningful in a policy context where environmental and social problems are framed as technical so that technological (profitable) solutions can be elaborated, leaving unquestioned the actual causes of the problems at stake.

The point is that approaches focusing on risk do not call into question the visions and imaginaries that sustain a given technology's trajectory (Mcnaghten et al. 2005; Felt et al. 2007). Technological products are not neutral objects: they have been produced by specific actors, in specific contexts, in order to address a specific problem, which has been framed in such a way that given technologies make sense as solutions. As a result of the very process triggering their emergence, technologies are loaded with social and political values; they materialise certain paradigms, in fact, they "re-construct" social paradigms (ideas and assumptions about functioning) into physical matter – this is what could make the utility of a technology. It has to "fit" the social structures managing it, and resemble the material support a social setting organises to stabilise and maintain itself, which will remain completely undetected as long as the focus of technology assessment concentrates on their risk implications.

A thorough analysis of the ethical, social and political values and principles that each technology carries through the visions and imaginaries it promotes, thus, is a fundamental step towards a more robust assessment of technologies in general, and GMOs in particular. If social and political values are implicitly and explicitly embedded in a given technology's trajectory, risk-assessment and risk-management procedures need to bring into these decision-making contexts those who can identify these embedded values and their implications, making them available for public and transparent discussion and deliberation. In contrast, risk assessment procedures take technologies for granted, non-technical expertise is not considered relevant and socio-political analyses about technology implementation are addressed as a problem *per se.* Syngenta argues:

Regulation that is anything other than science-based will stifle innovation and limit the ability of farmers to grow more food with limited natural resources. Political pre-occupations are

3 See the key US Supreme Court decisions, e.g., Chakrabarty Vs Diamond case (1980) and the US legislation, the Bayh Dole Act (1980)

causing a crisis of governance in both the developed and the developing world.

Instead of considering public concerns about GMOs as an opportunity to reconsider the technology from a different perspective, producing a wider and more robust assessment of GMOs' implications, risk assessment experts keep considering the public as *the* problem, calling for solutions that aim at reducing this opposition rather than at learning from it (De Boer et al. 2005). Whilst governments continue relying on scientific expertise to legitimize their policies choices – shifting the responsibility of emerging social conflicts to a (constructed) uninformed, prejudiced and reluctant public – these questions remain largely unaddressed, when not bluntly ignored (Wynne 2006). Meanwhile, among the public, scientists are perceived not as neutral, but as influenced by the commercial environment described above, and awareness is growing of the conflict, in the scientific community, about the possible applications of biotechnologies (Bucchi and Neresini 2002; 2004). Yet public engagement exercises not only neglect these concerns but typically aim at getting support for science in exchange for dialogue (EC 2007).

Such approaches to public engagement have been challenged on a number of theoretical and empirical issues, which relate, for instance, to who is the public and how it has been constituted; who decides what is going to be talked about and on what grounds; and at what stage of policy making is participation set and why (Jasanoff 2005; Goven 2006a; Wynne 2006; Felt et al. 2007; Levidow 2007; Ferretti and Pavone 2009). In other words, "*the purpose is to hold science and industry answerable, with the utmost seriousness, to the fundamental questions of democratic politics* […] *Who is making the choices that govern lives? On whose behalf? According to whose definitions of the good? With what rights of representation? And in which forums?* (Leach, Scoones and Wynne 2005: 190).

Despite these criticisms, risk assessment and public engagement exercises keep addressing risk considerations made by the experts as 'scientific' and public views as 'perceptions', and the debate is highly restricted *"Risks are endlessly debated, while deeper questions about the values, visions and vested interests that motivate scientific endeavour often remain unasked or unanswered*" (EC 2007: 16). Meanwhile, current regimes of science and technology innovation, and "*the driving purposes and expectations shaping innovation and knowledge*" (Wynne 2006: 218), are not subject to public debate and deliberation. On the one hand, questioning public 'perceptions' remains a dominant concern of public engagement exercises, which maintain their original purpose of reducing conflict and securing support for scientific innovation and expert-based policy-making. On the other hand, questions about the reasons and the ways in which certain issues, and not others, have become objects of public policy; how and as a result of whose action has this happened; and what kind of society are we trying to achieve through current innovation directions and priorities are prevented from emerging as key issues in technology assessment procedures.

3. TECHNOLOGY ASSESSMENT IN CONTEXT

Perhaps easier for technocratic risk assessors to understand, but still neglected within risk-assessment processes, is the significance of the context of implementation for evaluating the risks and claimed benefits of a technology. Technologies never operate outside a biophysical and social context, and it is their interaction with their contexts that generates effects, impacts and implications. This is a statement of the obvious, yet its ramifications have yet to be fully recognised in risk assessment and other formal evaluations of technology. Put simply, in order to identify and evaluate the potential harms and benefits of a technology, we must know how it is likely to interact with its context, which requires knowledge of specific contexts as much as it requires knowledge of the technology itself.

Knowledge of specific contexts is unlikely to come from "risk experts" or those with detailed knowledge of the technology derived from laboratory investigations and modelling. The kind of detailed knowledge of context necessary is often more experiential than formalised. People who are unfamiliar with the technology in question may nonetheless have knowledge of context that is highly relevant to assessing that technology. Such people are typically not involved in formal risk assessment processes.

Formal risk-assessment processes for GMOs may make reference to the interaction of the GMO with its (implicitly, biophysical) environment, but have no requirements or methods in place for acquiring knowledge of specific contexts or evaluating the effects of the interaction (e.g., EU directive 2001/18/EC). In the US, the APHIS processes of notification and de-regulation assume that particularities of environment are irrelevant to the potential impacts of GMOs. Projects of harmonisation of GMO regulation, such as those championed by the OECD and WTO, tend to rule out *a priori* any genuine engagement with context.

What is true for potential hazards is true *a fortiori* for claimed benefits. The projected benefits of developing or applying a technology are rarely given the same scrutiny as its potential harms. Projected benefits are key elements in public funding agencies' (as well as private investors') decisions to fund the technology's development, and they are weighed against risks in regulatory agencies' decisions to permit the deployment of a technology. Insufficient scrutiny of benefit claims can thus lead to poor investment and regulatory decisions. As with risk, the assessment of (claimed) benefits, such as it is, rarely seeks detailed knowledge of the contexts with which the technology must interact if the benefits are to be realised.

There is ample evidence of the importance of contextual knowledge to evaluating risks. In Wynne's post-Chernobyl study of the interactions between Cumbrian sheep-farmers and techno-scientific personnel operating as risk managers, he found that the value placed by scientists on universally applicable models blinded them to the importance of local context. They ignored "farmers' own knowledge of their local environments, hill-sheep characteristics, and hill-farming management realities" (Wynne 1992: 287). This specialist hill-farming expertise, which was "not codified anywhere" and was "passed down orally and by apprenticeship" (Ibid., p. 295), in fact proved essential to predicting the behaviour of radioactive elements in the soil and to formulating competent strategies to manage the problem. Irwin's (1995) discussions of the risk assessment of the organo-phosphate pesticide 2,4,5-T again highlight "expert" blindness to local or experiential knowledge. In this case, the UK Advisory Committee on Pesticides (ACP) concluded that the pesticide was safe, provided it was used "in the recommended way." Farmworkers, with knowledge of actual farm practices as well as of the social (power) relations involved, argued that it could not be judged safe because the prescribed precautions could not be taken in the actually existing contexts of use: "the conditions envisaged by members of the [ACP] . . .are impossible to reproduce in the field" (1995: 17 - 18).

There is also evidence of the importance of contextual factors to the realisation of claimed benefits. Outcomes of attempts to evaluate the performance and economic impact of GM crops in developing countries have been highly inconsistent. This, as Glover has shown in his survey of evaluations of "pro-poor" effects of Bt cotton, is a result of abstraction from context:

The efforts of analysts have been largely confounded, though, not only by the sheer complexity of the factors involved, but because the external variables they have struggled to control and exclude are actually essential to understanding the impacts of new crop varieties on farms. In other words, the strenuous efforts to rule out the effects of 'externalities' can be seen as a reflection of a basic failure to recognise the fundamental importance of contextual factors in complex socio-technical systems. (Glover 2009: 37)

The relevant contexts include both biophysical factors (e.g., the local suitability of the background germplasm, seasonal rainfall, irrigation, soils, pest attacks and diseases) and socio-political factors:

[S]eed choices, pest-management strategies, cropping patterns and farming systems are embedded in a particular household's or farmer's wider livelihood strategy, which in turn is embedded in a set of social and institutional relationships and processes. (Glover 2009: 38)

The value of attending to specificities of context is illustrated here with examples from research exploring risks and potential benefits from implementing biopharming in New Zealand (Goven et al. 2008; Morris et al. 2009; Goven et al. 2009). Biopharming involves the production of plants and animals that have been genetically engineered to produce pharmaceutical substances (in, e.g., their leaves, seeds or milk) and the extraction and purification of those substances for use in humans. It is promoted as a lower-cost and more flexibly scalable production process. It is still unclear whether biopharming will be successful in these terms. Those who see biopharming as beneficial for New Zealand have portrayed it as a great opportunity for New Zealand farmers to add value to their products. The success of this strategy depends not only on the commercial success of biopharming as a drug-production process, but also on the practicalities of New Zealand farmers taking up biopharming.

Unlike other forms of drug production, biopharming poses the risk of contamination of the food supply, especially if the drug is made in a food-producing platform (such as food-crop plants or cow, sheep or goat milk). The prevention of contamination requires strict containment. Farmers and others with practical experience of managing plants and animals and their products are an excellent source of knowledge relevant to whether or not strict containment on a "biopharm" is feasible. Indeed, as suggested by Mauro and colleagues (2008, 2009), farmer knowledge would appear to be a valuable source of information for the evaluation of agricultural technologies, including GM technologies, in general, yet it remains neglected by policy-makers and researchers, especially in the global North.

The farmers and others associated with the types of farming most likely to "host" biopharming, that is, dairying and seed farming, identified a range of risk factors related to specificities of context. For example, the experience of those in seed farming suggested that complete containment in open-field conditions is impossible due to the impacts of wind, insects, birds and other animals. Most specialist seed farming in New Zealand is carried out in Canterbury, famous for its north-westerly winds, posing threats of cross-pollination. Although systems have been devised to minimise such contamination, local knowledge indicated that such systems are not adequate for the prevention of all contamination:

[I]n the Canterbury Plains, I don't know how you ever restrict that…. It's probably likely that the outcross is going to be not just 10 yards down the road, but probably 10k or 15k down the road. So 3k or 5k isolation's probably a waste of time.

It is often assumed that the risks posed by contexts can be mitigated by procedural requirements or controls imposed on the use of the technology. However, the New Zealand research also questions whether it is practical to assume that mandated controls will be consistently implemented. This, too, will be a function of context, both social and biophysical. Biopharming for farmers would be an economic activity like any other. This creates a situation in which there may be economic incentives to flout containment requirements. Farmers noted that rules are most often ignored when there is an economic incentive not to follow them. As with any product, increased market supply or reduced market demand may erode the profitability of the operation, whilst the existence of potentially competing production platforms[4] could bring about sudden increases in supply (and reductions in price). Biopharm animals may become ill, rendering them an economic liability. Costs to farmers may increase unexpectedly and render the contract less profitable. Such pressures experienced by a farmer directly or through his/her employer could provide an incentive not to follow the rules.

4 That is, biopharm crops would compete economically with each other and with biopharm animals as "production platforms" or "bioreactors"producing therapeutic proteins, and both would compete with laboratory (vat) production. At least to date, biopharming is an alternative method for producing drugs that can already be produced in other systems, rather than a source of new drugs.

A relevant example supplied by dairy farmers of non-adherence to risk-management rules involves herds containing tuberculosis-infected cows. Infected animals must be made readily identifiable, and there are restrictions on their movement. However, some farmers flout these rules, moving the infected herds without permission. Those involved in seed production noted that it is difficult to ensure that a combine harvester is completely clear of previously harvested plant material. Economic pressures might result in not cleaning harvesters as well as they perhaps should:

Are you going to spend another three hours [cleaning the combine] in the sunshine, [when] you could be combining and the rain's forecast for the next day? Probably not … I can give you the PC [politically correct] answer, 'no, no, we signed the documents and we'll do that.' I think in practical terms corners get cut.

Such incentives are intertwined with ownership and management arrangements and with farmers' own assessments of and attitudes toward risks. Farmers' and other operators' own beliefs regarding the riskiness of an operation affect the likelihood that they will meticulously follow risk-management protocols. That is, if a protocol is felt to be arbitrary or out of proportion to the risk as the farmer understands it, it may not be followed. This implies that the effectiveness of controls is to a significant degree reliant on farmer discretion. One example of this given by dairy farmers pertains to effluent disposal: *They think 'oh, this will do', you know, 'The rules are that strict, but if we do this and this, it might be all right'.*

In the seed sector, the demands of production and farmers' confidence in their own abilities may shape attitudes toward following rules:

Farmers tend – they're practical people cracking on with the job. So they're not looking at their ISO9000 quality control manual… It's not sloppiness or anything like that. But it's just the practical operation of things.

Interviews with farmers also highlighted the ubiquity of human error. Interviewees could relate a litany of human error that occurs in everyday farming practice. The milk of cows being treated with antibiotics, for example, is meant to be kept out of the milk sold off the farm, and these cows are marked to indicate this. However, farmers cited cases of such markings coming off or just being missed by the person responsible for milking. These errors occur *despite strong economic incentives to comply*: companies receiving the milk impose heavy financial penalties for farmers whose milk contains antibiotics.

Economic influences on farmers' and other operators' behaviour have implications for how risk is assessed. Rather than treating the economic dimensions of a proposed activity or organism as a separate issue, quantifiable in terms of economic cost and benefit, and human error as manageable through protocols and monitoring, *economic context and human error should be viewed as integral to environmental and health risks*. If, as Marvier and van Acker (2005) argue, "our evaluation of risk should assume that whatever transgene is being examined has a good chance of escaping", the question becomes: does the purpose of the technology—understood not in terms of claimed, unproven benefits, but in terms of the aims of the system that produced it— justify the risk that it is inevitably imposing?

As noted above, promoters of technologies rarely ground their claims of benefits in the specific contexts with which the technology must interact if the benefits are to be realised. As with potential harms, operators' understanding of their own situation is crucial to evaluating potential benefits. Biopharming is promoted to (and by) governments and regulators as bringing significant economic benefits to those jurisdictions and actors who engage in it. In New Zealand, biopharming has been framed as a solution to the problem of competitiveness in an economy dependent on commodity production, and consequently as a bringer of new options and benefits to New Zealand farmers. [5] On this basis, biopharming research and development have received generous public funding.

Specialty seed farmers and seed-production companies, however, described a distribution of market power that militates strongly against seed biopharming returning major benefits to New Zealand (Goven et al. 2009). With a similar distribution of power likely to obtain in the dairy sectors, dairy farmers, who doubted it would be possible to combine biopharm and conventional cows in the same operation, would be reluctant to leave their existing supply relationships to venture into biopharming (Goven et al. 2008). The practicalities of implementing biopharming, both in terms of measures to prevent contamination and in terms of relative distribution of market power, suggest that it is in fact unlikely that New Zealand farmers would benefit in any significant way from the introduction of biopharming. The likelihood and distribution of benefits is tightly linked not only to specificities of context, as argued here, but also to the processes of co-production discussed above: GMOs are a business strategy enabled through a particular intellectual property regime, and this drives both the framing of problems to which GMOs can be offered as a solution *and* the distribution (and nature) of benefits.

4. ECO-SOCIAL ANALYSIS

GMOs affect the agri-food production system and have an impact not only on the environmental context into which they are introduced, but also in the way people feel, live and interact with this context. Social and ecological impacts of products and technologies are related. Whatever has a social impact interacts, as well, with ecological elements to constitute what we call the environment. For example, in many European countries efforts have been made to support bio- and organic farming, small-sized farms, local products, and cooperatives. This kind of territorial

5 In other venues, particularly when in the midst of risk-assessment processes with public input, biopharming is promoted as the path to curing disease, even though to date biopharm R&D has focused on the production of generic versions of existing biopharmaceuticals.

marketing has created a new eco-social equilibrium in many rural communities, mitigating land abandonment and helping in the preservation of significant traits of so-called "vanishing traditional landscapes". In such a context, GMOs and their regime of production and innovation will inevitably interact not only with the ecological, but also the social equilibrium built on the ecological one. As a consequence, social analysis needs to be integrated with ecological studies on long-term environmental and eco-systemic changes affecting target farming areas. However, at least three main problems have so far prevented eco-social analysis into risk-assessment procedures: the lack of long-term studies, existing methodological deficiencies and a narrow, decontextualised approach to risks and benefits of GM crops.

The lack of long-term studies maintains a fairly high uncertainty in the assessment of risks for the environment and human health, strengthened by the unpredictability of some by-products of genetic manipulation (Schubert 2002). For instance, Bt-corn has been created through the insertion of the genes coding for the Cry-toxins of *Bacillus thuringiensis* under specific promoters that should have acted only in the green parts of the plant, or in the pollen, but not in the roots (Saxena et al. 1999). Therefore, the steady occurrence of the toxin in the roots and exudates of Bt Corn provides a good example of an unpredicted attribute (which also has potential long-term implications on the microbial fauna in the soil).

All the relevant literature on the environmental risks and benefits of the large-scale cultivation of GMOs compares the "environmental performances" of transgenic crops vs. the conventional ones, but little attention is deserved to the long-term consequences of the observed changes in the frequency and distribution of commensal species (target and non-target organisms) at the ecosystem scale. There has not been time enough to produce sound results on such issues (Pignatti & Guarino 2007). Modern agriculture became responsible of an ever-increasing trophic and ecological gap between cultivated areas and neighbouring ecosystems. This is regrettable not only for aesthetical or scientific reasons linked to biodiversity conservation, but also for the simple, utilitarian reason that the more we reduce and select the species co-occurring with the crops, the more we reduce the probability that there will be early bio-indicators of unanticipated risks and implications of the introduced technologies. In the last fifty years, natural early-warning signals were shown to be useful and effective instruments for the safeguard of human lives: for instance, the high toxicity and persistence of DDT and PCBs were identified in such way (Sheail 1985; EEA 2001).

Natural macro phenomena, and their changes and variations, may be considered, to a certain extent, predictable, but the more technology is able to transform the molecular characteristics of natural processes, the more the final outcome is unpredictable. This unpredictability proceeds from the existing gap between the pace regulating natural biological evolution, on the one hand, and the man-made technological evolution, on the other hand. Current nucleotide sequences are the result of biological evolution over three billion years. Changes in gene sequences may alter gene products, which have an impact on other genes and on other organisms: each gene mutation triggers a series of spill-over effects until a new equilibrium is reached in the homeostatic context of the eco-system. Molecules are connected to the eco-systems thanks to the intrinsic ability of living matter to connect, interact and move towards more and more complex levels of integration. These processes do not repeat themselves indefinitely, because the retroaction links responsible for preserving the homeostasis of the system are not completely self-contained but, rather, integrated in the evolutionary consistency of the biosphere.

In this respect, the eco-system is not a complicated but a complex system. Complicated systems, though difficult to analyse, can be completely explored, provided that enough time and proper tools are available. Yet, complex systems, like biological ones, cannot be exhaustively analysed because their evolution is not predictable. In other words, whilst it is certainly possible to insert exogenous genes into a chromosome, it is impossible to predict and calculate the outcomes and the interactions that will follow over long periods. Traditional engineering is used to derive its certainty from measures and deterministic descriptions that allow for predictable results. Genetic engineering, in contrast, may well understand and quantify the productive performances of GMOs or their advantages in terms of a reduced need for fertilizers, but cannot predict or even foresee the medium and long term risks of introducing species that are alien to the global homeostatic equilibrium of the biosphere. Only natural selection processes will reveal beyond doubt whether these organisms will have been, from an evolutionary point of view, incorporated without major damages. Yet this process is very slow, and its pace is certainly incompatible with market requirements.

From a methodological perspective, current risk assessment methods evaluate GM risks on the basis of risk/benefit analysis and short-term environmental impact in comparison to conventional crops. This type of evaluation, which focuses on a direct cause-effect approach, is inadequate to address environmental issues, for the homeostasis of the ecosystem is guaranteed by non-linear transformations. To date, we have accumulated significant evidence showing that environmental damage cannot be assessed through cost-benefit analysis, not only because the long-term impact cannot be easily predicted but also because the actual genetic modifications cannot be evaluated through simple calculations of causes and effects. Plant pathology, very much like human pathology, focuses more and more on degenerative alterations, which often emerge a long time after the exposure to the pathogenic agent has actually occurred (Lorenzini 1999). As a result, not only is it incorrect to link xenobiotics and the actual damage in a cause-effect relationship, it is also misleading to consider that a substance, or a genetic expression, is non-toxic just because it does not interfere with a given metabolic process (Cocucci 1996).

Facing these problems and considering that large fields cultivated with GM crops may have dramatic impact on the survival of the residual populations, plants and microorganisms existing in the agroecosystem, the EU is setting up a strategy aiming at preserving biodiversity through the creation of protected eco-systems. However, this approach is flawed for two reasons: first, it is problematic to confine biodiversity in restricted spaces, leaving the remaining agroecosystem permeable to GM crops and, second, the prospective protected ecosystems are not big enough to be unaffected by external influences. This typically applies to Italy, where farm properties are relatively small and fragmented and the geomorphology of the territory makes the approach based on protected eco-systems unfeasible.

The italian case is especially interesting because it presents a number of characteristics that potentially invalidate the outcomes of eisk assessment studies conducted in other nations. Italy, for instance, possesses a high biological diversity, which results from a great variety of climatical and environmental factors in a relatively small territory, mainly characterized by mountains, by the influence of the sea and by a prevalent orientation along the north-south line. It is generally accepted that to avoid cross-pollination and contamination it is necessary to place GM crops on big portions of flat land, contained by a belt of similar, conventional, crops. In Italy these conditions apply only to about 20 per cent of the territory. Moreover, in Italy still survives a significant variety of wild versions of cultivated crops, which makes the risk of contamination even higher than elsewhere.

As a consequence, the risk/benefit analysis, instead of focusing on the performance comparison between GM and conventional varieties, should rather consider the impact of GM crops on the local ecosystem and on the social and economic arrangements that have been so far built on that ecosystem. How convenient is to pave the way to GM crops in a country whose economy is based on local biodiversity, agricultural tourism, DOP productions, high quality wines and food? In fact, the economic success of these sectors rather suggests to follow the opposite strategy, declaring Italian territory GM-free and investing even more on these sectors to renew and strengthen the international reputation of a country where ecological biodiversity is no less attractive of historical and cultural diversity.

For all these reasons, it is increasingly important to think in terms of an eco-social equilibrium, whereby the ecological homeostatic equilibrium is part and parcel with the socio-economic equilibrium reached around given cultivations, eating habits and farming practices, which have evolved during decades and are repository of traditions, values, meanings and community life interactions.

5. CONCLUSION

GMO assessment is a complex issue (not a complicated one), and risk assessment studies, no matter how sophisticated they are, cannot produce definite and unquestionable results, because it is not merely an issue of scientific advancement. In fact, risk assessment procedures embody social and political values, and so do the technologies assessed. For a socially and scientifically more robust assessment, these values *must* be made explicit and taken into account when GM technologies are assessed. In this paper, thus, we tried to explore new approaches to GMOs from a broader perspective, which not only highlighted the cognitive limits and the political implications of current risk-assessment approaches but also took into consideration social, political, institutional and ecological elements.

First, we suggested the politics and ethics of a given technology be unpacked, by addressing the emergence, the socio-technical networks, the power relationships and the economic interests that are tightly interrelated in the process of innovation and implementation. In this step – which tried to answer the question: *what kind of future society is embedded in this technology*? – the techno-social imaginaries and visions driving and underpinning technology innovation and implementation of Syngenta have been de-constructed and scrutinized, not only per se but also in relation to dominant socio-political imaginaries. Whilst GM producers patent their discoveries and impose royalties on their products, GMOs are framed as solutions to world hunger and environmental degradation. The debate therefore shifts to costs and benefits of GMOs, whilst the basic question of why GMOs were developed in the first place remains unanswered and, actually, disappears into the background. Visions and imaginaries sustaining technological innovation do matter: scientists' and companies' values need to be unpacked and analysed. In addition, it is time to incorporate non-technical expertise: lay publics, social scientists and farmers have access to relevant societal knowledge that has to inform risk assessment.

In the second step – which addressed the question: *in what kind of society is this technology going to be implemented?* – we have shown the necessity of evaluating a technology in its proposed context of implementation, as well as the need to access locally based, experiential knowledge in order to do this. Social and institutional practices operating at local and national levels provide important information on how a given technology is likely to be implemented and to interact with other social and technical artefacts. Risk-assessment procedures should evaluate not only how safe is a technology, but also how "safe" is the context (Goven 2006b). In this respect, our examples suggest that not only the biophysical and social elements of context but also the fundamental purpose of the technologies – in the sense of their driving forces or economic logic of development – as much as their technical capabilities are relevant to assessing potential harms and benefits.

In the third step – which addressed the question: *how is this technology likely to affect the eco-social equilibrium of the area in which it is going to be introduced*? –eco-social analysis was suggested. Social meanings, actions and relationships arise and are enacted around specific local environments and around the local understanding and framing of it. Changing these environments will inevitably change the socio-relational domains constructed around them. Therefore, eco-social studies should study the impact of GMOs not only on the biophysical ecosystem but also on the social community that is part and parcel of that ecosystem.

In sum, we argue that frame analysis, context analysis and eco-social analysis should be performed along with the trajectory of the technology at stake, and accompany the traditional risk assessment procedures to ensure social compatibility and political accountability and ecological sustainability. These three steps may help consolidate a more robust social assessment, which we define as an *in-context trajectory evaluation*. From this perspective, it emerges that there might be a number of socio-political reasons to support a moratorium on GMOs in Europe even if they come to be considered, according to current risk-assessment approaches, as technically safe.

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