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Safety, Security and Quality: Lessons from GMO Risk Assessments

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1. Introduction

Assessing the impact of new techno-sciences on our life supporting systems and on our present and future common wealth is a complex and controversial issue that involves the relation between science and governance, and more generally, between science and democracy (Gallopin *et al.*, 2001).

Indeed, governments find themselves in the contradictory role of *speeding up* techno-scientific innovation, in order to maintain market share and hence economic survival in the globalized competition system, and of *slowing down* the very same process, in order to keep ensuring one of the main pillars of modern states: safety. Concurrently, as we will see, scientific research carries out the equivalent conflicting task of producing knowledge for innovation *and* for regulation. Finally, citizens demand safety, but the very reassuring certainty they require, paradoxically undermines the confidence they hold in the capacity of modern state to ensure this fundamental right; indeed, admitting a danger seems more trust worthy than declaring the absence of risks, especially after major crises in the regulatory system, such as the one of bovine spongiform encephalopathy (BSE). In these epistemic and normative tensions - defined as a "Triple Catch 23" by the British philosopher Jerome Ravetz (Ravetz, 2003) - new relationships between science, society and governance need to be investigated and implemented (De Marchi & Ravetz, 1999).

As we will articulate, the modern ideal of grounding our decision-making processes on the certain, objective and exhaustive knowledge, produced by an independent community of scientists - in other words the principle of 'science speaking truth to power'- is inadequate when applied to our contemporary open-field, irreversible experimentation, characterized by intrinsic complexity and controversy.

C*omplexity* entails the paradoxical epistemic situation according to which the more we know about the interaction between social and environmental systems and the more there is to know. Lack of certainty, namely uncertainty and ignorance, is therefore not temporary or accidental, but intrinsic and unavoidable. On the other hand, *controversy* implies the inherent and inextricable coupling between facts and values, and therefore the existence of

mutually incompatible and indispensable epistemic and normative perspectives. Under these conditions, typically 'post-normal' (Funtowicz & Ravetz, 1993) a certain, objective and exhaustive knowledge for a rational decision can never be achieved nor even conceived of.

In this chapter, we would like to propose some critical reflections on the underlying assumptions and consequences of the conception and use of risk assessment techniques, by contextualizing them to this broader scenario.

As exemplary cases, we will focus our attention on the role and impact of biotechnologies on the global food production systems. More specifically, we will proceed by reviewing and analyzing, in this more extensive epistemic and normative context, different open questions about the impact of genetically modified organisms in agriculture (Guarnieri *et al.*, 2008) and in aquaculture (Barbiero *et al.*, 2011).

We will first start from clarifying the main critical aspects inherent in defining and assessing the risks of these techno-scientific processes and products. Complexity and controversy will be explored in terms of the unavoidable presence of ignorance, the coexistence of multiple disciplinary perspectives and epistemic cultures, and the aims and stakes dependency of any framing of risk.

Innovation, precautionary and regulatory science, namely the three modes of scientific research involved in the production, impact evaluation and regulation of biotechnology will be then defined and examined, in relation to their corresponding epistemic and normative cultures and *praxis*. The driving argument will be to show that both production and regulation are driven by the epistemic culture of innovation, based on the principles of certainty, objectivity and exhaustiveness, and enclosed in a modern, evidence-based epistemic and normative black box. We will also argue that three grand narratives of innovation, founded on the ideals of control, power and urgency, are in charge of normalizing whatever comes from out of the box, i.e. complexity and controversy.

In this scenario, by focusing on the so called negative and liminal knowledge (Kastenhofer, 2010, Knorr Cetina, K. 1999), the key role of *precautionary science* is to peak in, and ultimately to break in the box of the whole innovation and regulation process (Jasanoff, 2005), leaving room for a democratized, open and post-normal evaluation of bio-technologies.

A first step in shading some light through the actual complexity involved in the genetic engineering endeavor will be to examine the crisis of the central dogma of molecular biology, as emerged from the past two decades of research. The founding pillars of the biotech production system - determinism, reductionism and mechanism - are indeed facing a deep challenge, given the numerous evidence of the actual complexity of the genome's physiology. When fully acknowledged the repercussions of this crisis could destabilize the entire edifice of *biotech* industry, including the normative foundations of genetic engineering's patenting law.

We will then deepen and extend our reflection on the impacts of Genetically Modified Organisms (GMOs) by analyzing some of the main controversies involved in the open-field agri-food implementation, correlating them with the notions of food (bio)safety, security and quality.

(Bio)safety is traditionally associated with the absence of possible environmental and health hazards, and therefore correlated to and defined *by* risk assessments[1]. We will explore this correlation and its relations with the grand narrative of control.

We will then move to the global issue of food security, commonly referred to as the availability of and the stable access to healthy food supplies. In this respect, we will examine the grand narrative of power according to which (only) biotechnology enhanced crops and animals can and will feed our overpopulated world. As we will see, on the one hand GMOs are evaluated and regulated in terms of their *safety*, on the other hand they are promoted in terms of their necessity for achieving food *security*. The latter argument is improperly utilized to reinforce the former, according to the third grand narrative of innovation, namely urgency. In this view, GMOs can and should be considered *safe enough*, given their role in tackling present and future global hunger. Indeed, both the possible correlation between safety and security and the actual need for GMOs in dealing with food security are highly controversial (Altieri & Rosset, 1999; Francescon, 2006; Giampietro, 2009; Waltner-Toews & Lang, 2000).

Finally, we will step into the necessity of moving from safety and security to the issue of food *quality* in its crucial connection with the development and use of new *narratives of humility* (Jasanoff, 2003), grounded on a thoughtful diagnosis of the *present* distribution of techno-scientific, cultural, economic and political power and of local and global vulnerability to change (Funtowicz & Strand, 2011).

This analysis will lead us to outline a number of paradoxes embodied in the conception and use of risk assessment techniques. The traditional western reaction to paradoxes is to try to solve them, but we believe that another fruitful approach, typical of other cultural traditions and revitalized in the post-normal scenario (Ravetz, 2001), can be useful in this case: to accept the paradoxes and to constructively and creatively learn from them about the limitations of our own existing intellectual structures.

2. Deciding under lack of knowledge: From experiment to experience

2.1 High-power open-field experimentation: Complexity, irreversibility and controversy

Over the last century, the intensity, the time scale and the diffusion of our technological intervention on natural, cultural and social systems have grown exponentially. We are now able to act on socio-ecological systems with an unprecedented power. In a more literal sense, we are manipulating matter and energy over shorter and shorter time frames, interfering locally and globally with the bio-geo-chemical cycles of our planet (Elser & Bennet, 2011; Rockström *et al.*, 2009; Townsend & Howarth, 2010).

At the same time, the boundaries of disciplinary science and technological enterprises and profits have been steadily blurring, with the oligopolization of industrial production systems. Corporate know-how has been gradually expanding at the expense of common

[1] We will utilize the synthesizing term of (bio)safety to refer to both health and environmental risks, focusing our specific attention on the latter, but keeping in mind the existence of equivalent debate about the former.

knowledge. From the epistemic and normative closure of our simplified, controlled and reversible scientific laboratory practice, we have been stepping into a variety of open-field techno-scientific direct experimentations.

This overall transition entails at least three kinds of consequences (Benessia, 2009). First, the interaction between socio-ecological systems and technology itself is characterized by emergent and reflexive complexity (Funtowicz & Ravetz, 1994). Radically different from the mere simplifiable complication of laboratory settings, emergent complexity implies tight coupling between different levels of organization, interacting and influencing each other through highly non-linear dynamics, critical dependence from initial conditions, and self-organizing emergent properties. Concurrently, the presence in the socio-environmental systems of elements provided with individuality, intentionality, autonomous aims, foresight, symbolic representations and morality entails a level of reflexive complexity. Knowledge about the evolution of complex systems is therefore always incomplete and surprise is inevitable (Gallopin, 2001). In this situation, our ability to predict the outcomes of our actions is radically undermined by the quality and the magnitude of what we do not and cannot possibly know. Indeed, when dealing with emergent and reflexive complexity, the kind of knowledge we lack is intrinsically different from quantifiable risk: uncertainty, ignorance and indeterminacy dominate our cognitive endeavours about future developments. Following Smith and Wynne's (1989) classification of the lack of knowledge relating to different decision-making modalities, one speaks of risk when the main variables of the problem are known and the respective probabilities of different outcomes are quantifiable and quantified. A typical example is the risk of losing when playing roulette, characterized by a known, closed, finite and discreet information space. Uncertainty is associated with a situation in which the main variables of the problem are known, but the quantitative incidence of the relevant factors is not and it is therefore impossible to assign different probabilities to different events. It can also be defined as a probability of second order, in which different risks assessment scenarios associated with different distributions of probability are compared (Bodansky, 1994; Tallacchini, 2005). Lack of knowledge is defined as ignorance when even the main variables of the problem are unknown and therefore the probabilities of negative outcomes are also unknown. Ignorance is unavoidable when dealing with evolving systems, in which the information space is open and expanding (Giampietro, 2002; Prigogine, 1978). Finally, as we will further explore, indeterminacy is correlated with the presence of multiple and non-reducible epistemic and normative perspectives (Sarewitz, 2004).

The second relevant consequence of our contemporary high-power techno-scientific implementation is that direct open-field experimentation is by definition irreversible. If something goes wrong we cannot run a second test. This mere fact implies that, unlike what happens in the laboratory practice, we cannot proceed by iterative approximations to the result we want, avoiding on the way what we do not want. In other words, just like with life experiences, we don't have the luxury of painlessly learning from our mistakes.

When considered together, these two consequences amount to the possibility of unforeseen, unpredictable and unrecoverable negative outcomes. Contemporary techno-science is then supposed to deliver ever-new 'goods', but it is also concurrently exposing socio-environmental systems to ever-new possible corresponding 'bads'. In his prescient book on "normal accidents", Charles Perrow reflects on the inexorable occurrence of harmful events

– accidents – as a consequence of the reflexive complexity and the tight coupling inherent in our high-power technologies (Perrow, 1984). A few years later, in defining our contemporary techno-scientifically driven way of life as "risk society", Ulrich Beck refers to this controversial condition of modernization, in which risks are woven into the very fabric of progress (Beck, 1986).

Finally, whereas the supposed benefits of techno-scientific processes and products are 'built in' within industrially optimized and controlled systems, their possible serious drawbacks cannot be addressed by a single scientific discipline and framework, or more generally by techno-science alone. These problematic circumstances, which were effectively captured by Alvin Weinberg's as "transcientific" in the early seventies (Weinberg, 1972), lead us to the third fundamental consequence of open-field, high-power experimentation: the absence of a predefined scientific disciplinary framing, setting and method of inquiry, in foreseeing and managing the effects of techno-scientific implementation over the systems involved. Multiple and incommensurable perspectives, such as modes of questioning, detecting, measuring, even identifying relevant data, are meant to coexist indefinitely precisely because the objects of inquiry do not emerge from a predetermined laboratory and disciplinary set up. This plurality of relevant, indispensable and often incompatible standpoints determines a level of indeterminacy (Smith & Wynne, 1989) in the very definition of the issues at stake. Moreover, as we will further explore, different epistemologies, ontologies and methodologies involve as many normative stances. In Daniel Sarewitz's words: "The necessity of looking at nature through a variety of disciplinary lenses brings with it a variety of normative lenses, as well" (Sarewitz, 2004). In this inherent and inextricable coupling between facts and values, which we will refer to as controversy, negotiation and most often competition between disciplines - and their related normative power - becomes a founding criterion for choosing what kind of knowledge is "scientifically relevant" for the issue at stake.

In this overall scenario, if we cannot accurately predict, exhaustively describe, and effectively remove the consequences of our action, then a deep reflection on the grounds and methodologies of what we call responsible decision and conduct is needed.

2.2 From the modern model to post-normal science

When complex socio-environmental systems are involved, the modern ideal of founding our decision-making processes on the neutral knowledge produced by an independent community of scientists – in other words of 'scientists speaking truth to power' (Wildavsky, 1979) - becomes inadequate. Complexity, irreversibility and indeterminacy radically undermine the idea that science can provide a single, certain, objective and exhaustive perspective from which a straightforward decision can be taken at a political level.

A first acknowledgement of this kind of procedural inadequacy was internationally made in 1992, in the Principle 15 of Rio Declaration on Environment and Development, in which a precautionary approach was invoked: "In order to protect the environment the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environment degradation".

The precautionary approach introduces the idea that science can be temporarily unable to produce a certain and exhaustive body of knowledge suitable for a rational decision. A political stance has then to be introduced in order to minimize the chance of harming people and the environment, over the chance of an economic loss, due to a technological restriction. The fundamental consequence of this normative step is an epistemic shift from a two values theoretical science, based on the evaluation of the truth/falsity of a hypothesis, to a three value science 'applied to risks', which includes uncertainty as a possible outcome of a scientific assessment. This in turn implies a deep change in the modern relationship between scientific truth and the correspondingly right political decision, by introducing the notion of risk acceptability through a normative action (Shrader-Frechette, 1996; Tallacchini, 2005). Indeed, in the 2000 Communication from the European Commission, the precautionary principle is qualified as a principle of political responsibility, namely a principle that considers certain risks as "inconsistent with the high level of protection chosen for the Community" (Communication from the European Commission, 2000).

The precautionary model represents a substantial improvement over the inherent positivism of the modern ideal, in that uncertainty and the need for an eminently political choice are explicitly taken into account. Nonetheless, the privileged nature of scientific knowledge is not challenged at its roots: lack of full knowledge is still regarded as technical uncertainty, a provisional condition ascribable to temporary methodological difficulties in collecting and managing data.

In the same Communication from the European Commission, the precautionary principle is associated with risk management: it can be invoked only when a scientific assessment provides evidence of risk and when the precautionary measures are in line with a proportionality principle between cost and benefits (Funtowicz, 2007). In other words, in this model, lack of knowledge is recognized but improperly reduced to a temporary and statistically manageable condition. Therefore, the presence and the epistemic and normative consequences of emergent complexity, namely ignorance, indeterminacy and controversy, are not fully acknowledged.

In 1993 , around the same time as the Rio Declaration, Silvio Funtowicz and Jerome Ravetz developed a radically new way of conceiving the relationship between science and policy, deeply challenging the modern ideal of the autonomous and privileged 'republic of science' providing 'the facts' to policy makers (Merton, 1968). In this framework (Figure 1), defined as post-normal science, the complexity, irreversibility and indeterminacy involved in contemporary socio-environmental issues are fully acknowledged in all their consequences (Funtowicz & Ravetz, 1993).

The starting point of their reflection is that in the majority of cases in which techno-science is called into question by the normative sphere, facts are uncertain, values are in dispute, decisions are urgent and stakes are high. From the one-dimensional incremental ideal of progress towards certainty, typical of the modern model and of its precautionary development, here we step into a two dimensional representation space, where uncertainty is correlated with decision stakes. This correlation allows discriminating between three fundamentally different kinds of scientific research. In the scenario that we have so far outlined, the transition from one area to the next is determined by incrementing techno-scientific power and therefore the complexity involved.

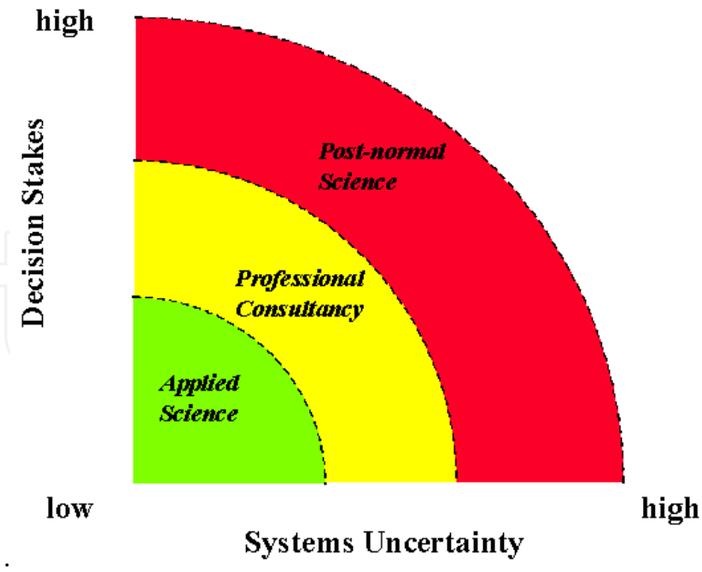

Fig. 1. The framework of post-normal science (Funtowicz & Ravetz, 1993)

The first type of research is *applied science*, essentially laboratory science, in which risks are predictable and under control. The information space is closed and knowable and reductionist approaches can be useful. It is the condition in which the modern model has emerged and it has been easily applied.

When complexity grows and both decision stakes and uncertainty increase, we get into the area of *professional consultancy*, where specifically selected experts advice is required to inform policy makers in order to orient the decision in the most rational and responsible way. As we will later specify, regulatory science and the attempts to extend the modern ideal by protecting scientific knowledge from uncertainty, indeterminacy and abuse can be ascribed to this area (Funtowicz, 2006). In particular, the precautionary approach and the related risk assessment and cost benefits analyses are invoked in this context.

Extending further techno-scientific power, we get into the post-normal science scenario, characterized by the paradoxical situation in which knowing more entails new levels of complexity and therefore more uncertainty, indeterminacy and ignorance. This dynamic implies the necessity of developing new methods of knowledge production and new criteria for assessing their quality (Funtowicz & Ravetz, 1990).

In the modern model of applied science, relevant knowledge is scientific by definition and the quality of scientific knowledge is identified with its degree of "truth", which is autonomously evaluated within the scientific community itself, through the peer review procedure. The implicit assumption is that the normative sphere can and has to be kept apart from the quality assessment process.

In the precautionary approach, typical of professional consultancy, relevant knowledge is still scientific and the quality assessment procedures based on peer review are integrated with new ways to evaluate the degree of acceptability of risk. Despite this wider set of criteria, the separability and the need to preserve the ideal modern separation between the description of the relevant facts, provided by science, and the values of politics is still firmly

reconfirmed. In this sense the actual application of the precautionary principle is reduced to a technical fix based on scientific *consensus* rather than truth (Sarewitz, 2011).

But in the context of complex and controversial socio-environmental issues, as expressed in the post-normal model, facts and values are not separable and therefore no form of knowledge, including a scientific one, can be evaluated on the basis of a univocally predefined concept of truth. New forms of public control of knowledge production have then to be elaborated (Funtowicz & Ravetz, 1990). This entails the necessity, not only ethical or political, but primarily epistemic and methodological, to extend the public participation in the decision making processes. From the logical demonstration of evidence-based matter-of-fact, validated by a disciplinary peer review system, we should step into open dialogues including extended facts and collectively validated by extended peer review processes. In this new context: "Science is considered as part of the relevant knowledge and it is included as a part of the probative evidence of a process. The ideal of rigorous scientific demonstration is thus replaced by an ideal of open public dialogue. Inside the knowledge production process, citizens become both critics and creators. Their contribution has not to be defined as 'local', 'practical', 'ethical' or 'spiritual' knowledge, but it has to be considered and accepted as a plurality of rightful and coordinated perspectives with their own meaning and value structures" (Liberatore & Funtowicz, 2003, p. 147, as cited by Tallacchini, 2005).

2.3 Biotechnology for food production: An open debate

In light of what we have outlined so far, let's now turn our attention to one of the most intense and pervasive open-field experimentation of the last few decades: biotechnology for food production. The debate about the impact of this kind of techno-scientific innovation on our socio-ecological systems, over local and global scale, is indeed highly complex and controversial. Moreover, as we will be exploring in the following, it is still rooted in the modern model of interaction between science and policy, despite the numerous attempts to democratize the debate about its consequences.

We will start our investigation on the impact of GMO's in the agri-food system by embedding this issue in the larger context of the dominant epistemic and normative strategies used for assessing and managing the complexity and controversy involved. As we will see, these strategies are essentially founded on a black boxing mechanism, defended through a set of standardizing strategies and narratives of modernity, whereas post-normal approaches are mostly needed but far from being widespread.

3. Biotechnologies in context

3.1 Modes of research and epistemic cultures

As any other techno-scientific endeavour, food related biotechnology depends on science in (at least) three ways: for its production, impact evaluation and regulation.

These three distinct phases, which are all equally crucial, correspond to three distinct modes of scientific research: innovation science, precautionary science and regulatory science. These types of research define and are embedded in a variety of corresponding epistemic cultures (Kastenhofer, 2010), interlinked with a range of disciplinary frameworks and implying distinct normative assumptions, such as evidence framing and detection, focus of interest, quality assurance methodologies and most of all uncertainty management.

Innovation science (Wynne quoted by Jasanoff, 2005) is typically carried out by private industries, not rarely granted with public funds (Goldenberg, 2011), with the explicit aim of developing and introducing new (bio)technological products in the market. The prevalent goal of this type of endeavour is to make things work. This, in turn, entails a methodology founded on laboratory trial-and-error iterative approximation to the desired result, through the design and management of linear cause-effect relationships between a limited or limitable number of variables (i.e. a specific gene for a specific property, according the central dogma ideal which we will discuss in the following section). The corresponding epistemic culture of innovation science is therefore essentially based on determinism, reductionism and mechanism, applied *in vitro*, to small and de-contextualized temporal and spatial horizons, and resulting in the production of so-called hard facts, namely new goods, characterized by a given set of properties, with the externalization of uncertainty.

In the scheme of post-normal science, this kind of epistemic approach evokes the first quadrant, what we referred to as applied science. The main *caveat* to be kept in mind at this point is that, in the case of biotechnology, just as in any other techno-scientific global and direct experimentation, we are not in the modern scenario of laboratory science, as the result of experimenting over living systems in all their intrinsic emergent complexity, and because these products are meant to be diffused and tested directly into open socio-ecological systems. Molecular biology and genetic engineering are the leading disciplines of this type of research.

Precautionary science (Ravetz, 2004) is normally undertaken within research institutions such as universities, and it involves the understanding and the management of the consequences of large-scale techno-scientific implementation. Its main focus is therefore the complexity of interaction between the organisms involved - this time conceived and treated as processes- and the environment. The correlated epistemic culture of this type of scientific research is based on observation *in situ*, through systemic approaches over large population systems and extended temporal and spatial horizons, involving highly non-linear causal links, such as retroaction mechanisms, dependence on initial conditions etc.

Precautionary science also involves an experience-oriented epistemic culture, with middle range temporal and spatial horizons, observation, communication and intervention, strong reliance on individual case history and professional rather than scientific identity (Kastenhofer, 2007)

The disciplinary set up of this mode of research includes ecology, epidemiology, toxicology, plant breeding science, system and population biology.

Whereas innovation science mainly concentrates on producing consistent - and profitable - objects in a controlled way, precautionary science is interested in the so-called negative or liminal knowledge (Kastenhofer, 2010; Knorr Cetina, 1999), implying the extremely ambitious task of investigating the absence of specific – or even unspecified - object characteristics, namely unwanted and harmful properties, the absence of causal relations and the absence of natural processes and mechanisms including such causal relations. Therefore, this kind of epistemic endeavor entails the recognition of complexity and ignorance, and the attempt to manage indeterminacy and irreversibility. As we will see, the main problem with the liminal knowledge of precautionary science is its impractical relation with decision-making processes, still based on the modern model, which requires incontrovertible evidence and hard facts.

This evidence-based ideal is actively pursued by regulatory science (Jasanoff, 1990), within public agencies such as the Food and Drug Administration, by endorsing the innovation science epistemic approach, in most cases even with the aid of the very same people, through the so-called "revolving door" phenomenon between regulatory agencies and industry (Mattera, 2004; Meghani & Kuzma, 2011; Revolving Door Working Group [RDWG], 2005). Leaving aside the most basic issue of conflict of interests and biased epistemic and normative positions, the main critical issue is that regulatory science is characterized by an intrinsic ambivalent position towards uncertainty. On the one hand, just like precautionary science, its aim is to deal with the possible impacts of technological implementation, therefore openly assuming a given lack of knowledge. On the other hand, in order to be credible in the modern scenario, it has to deliver by default a certain, objective and exhaustive factual position towards the issue at stake.

As a result of this tension, the main strategy of regulatory science is to ask only scientifically answerable questions, and then to equate a narrowly defined risk assessment with scientific assessment. The European's implementation of the Precautionary Principle in terms of risks/costs/benefits analyses goes precisely in this direction. This black-boxing epistemic and normative procedure to externalize complexity, indeterminacy and controversy evokes the so-called lamppost paradox, where one searches for the lost keys, at night, only under the lamppost just because it is the only place where one can see (Funtowicz & Strand, 2011). Thus, from the laboratory closure of innovation science, here we step into a form of institutional closure, with the aid of authoritative expert advice, the professional consultancy in the post-normal diagram, belonging to the epistemic culture and – at least in the US - to the actual community of the biotech industrial system.

3.2 The normative implications of regulatory processes and risk assessments

A number of authors have analyzed in details the nature and the implications of this lack of openness. In a seminal work on risks and regulatory processes, Sheila Jasanoff refers to the risks assessment procedures in regulatory frameworks as "technologies of hybris" for three reasons (Jasanoff, 2003, 2007). First, they focus on the known at the expenses of the unknown, on short-term quantitatively manageable risks, leaving in the shadow long-term indeterminate and possibly ignored consequences - the so-called unknown unknowns (European Environmental Agency, 2001).

Second, their capacity to internalize challenges that come from outside their framing assumptions is limited, as in the case of chemical toxicity assessments that continue to rest on "the demonstrably faulty assumption that people are exposed to one chemical at a time" (Jasanoff, 2003: 239).

Third, the specialized language and knowledge used to elaborate and to make use of these technologies in the context of policy tend to preempt an open discussion with all legitimate stakeholders. More specifically, the normative assumptions of these analytic models are not subject to general debate and the modern ideal of objectivity is used as a tool to obscure the boundary work that is needed to design them.

Indeed, a starting point for a deeper reflection on the foundations, functions and aims of regulatory risks assessments is the recognition that they are not and cannot be value-neutral, as they inherently depend on normative assumptions in a variety of ways (Kuzma & Besley

2008; Lewenstein, 2005; Meghani, 2009): in the formulation of the problems to face, in the definition and identification of the possible hazards, in the detection and measurement of the exposure, in the characterization of possible effects. Moreover, explicit normative commitments (i.e. choices shaped by cultural, ethical, economic and political considerations) are made when prioritizing and weighting risks in the cost-benefits analyses (Kastenhofer, 2010).

As Sandra Harding effectively points out (Harding, 2004), the main strategy to defend the standard notion of objectivity, despite this complex and intrinsic blending of facts and values, is to appeal to and make use of a homogeneous epistemic culture: if the values and interests at stake in shaping what is considered as relevant knowledge are shared by the members of the regulatory community, they don't stand out: they are neutral within a seamless background.

Both innovation science and regulatory science are therefore embedded in the modern ideal of "scientists speaking truth to power", and enclosed in an epistemic and normative black box. The closure mechanisms are based on preserving the principles of certainty - in the statistically manageable variant of risk assessment -, objectivity - suitably borrowed from epistemic and normative homogeneity- and exhaustiveness - declined in the form of the lamppost paradox.

3.3 Defending the modern ideal: The three grand narratives of innovation

As we will explore in the following sections, these quite effective stabilizing strategies are supplemented with three "grand narratives" of innovation (Wynne *et al.*, 2008), responsible of reassuring citizens about the "proper" - i.e. modern - functioning of the whole governance system regarding techno-scientific research and implementation. These standardizing narratives can be defined in terms of power, control and urgency. They are in charge of normalizing whatever comes from out of the box, namely complexity, controversy and irreversibility.

The grand narrative of power is rooted in the ideal of scientists as inventors of new entities, committed to extend indefinitely the limits of human being and agency through the creative manipulation of life, energy and matter. Either by reaching new territories on the macro, micro or nano scales, by intervening on organic and inorganic matter, or by converging nano, bio, information and cognitive science technologies, the power of human agency on its surroundings consists on a constant exercise of techno-scientific creative enhancement of the known and prompt treatment of the unknown. In line with the narratives of the green and the blue revolutions, in our context, the narrative of power is directly connected with the issue of food security. Indeed, the "gene revolution" is founded the idea that, with the aid of agri-biotechnology, we can tackle and solve the issue of global hunger, by dramatically increasing our yields and protecting our crops from climatic stresses and diseases. Likewise, with biotechnological aquaculture, we can cheaply provide the needed animal proteins to the hungry world.

Power is nothing without control: safely driving the impressively powerful car of innovation means being able to govern at will the inherent complexity of the interaction between the human techno-scientifically enhanced species and its 'natural' surroundings. In our framework, the narrative of control is declined in terms of (bio)safety, i.e in terms of the

capacity to contain the possible health and ecological drawbacks of GMOs, by implementing a variety of barriers (Guarnieri *et al.*, 2008): genetic, ecological, physical, environmental, and last but not least, normative.

Finally, the grand narrative of urgency is based on the assumption of a morally binding necessity to bypass any delaying post-normal knowledge production and decision-making process, in favor of a silver-bullet technoscientific and technocratic approach, in order to effectively confront and solve the pressing socio-environmental problems that afflict the planet, on local and global scales. In this future oriented narrative, lack of time and high stakes produce allegedly compelling mono-causal framings, in which techno-scientific expert knowledge emerge as a "deus ex machina" from the grand narratives of power and control. In other words, in the context of this narrative, one needs to reject any ethical or precautionary controversy about (bio)safety, if one wants to meet the challenge of food security.

In this overall framework, as we will articulate in the following, the main role of precautionary and post-normal science is to confront the epistemic and normative closure of both innovation and regulatory science, attempting to peak in and ultimately to open the black box they are enclosed in.

We will devote the following two sections to explore a variety of relevant open questions raised within the epistemic culture of basic science, in the field of system biology and ecology, starting by analyzing and discussing the fundamental epistemic grounds of the biotechnology enterprise: the central dogma of molecular biology.

4. The central dogma of molecular biology

As we have mentioned, reductionism, determinism and mechanism are the founding pillars of genetic engineering's epistemic culture. According to this view, the ultimate understanding of the living can be attained by reduction to the system's elementary constituents, whose dynamics is simplifiable and from which the whole can be deterministically deduced, that is predicted with certainty. The organisms can then be treated as predictable and controllable mechanisms or, according to the updated version of this metaphor surging from information technologies, as manageable programs. The foundation of corporate biotechnology relies on the normative translation – or, more specifically, of co-production (Jasanoff, 1990 and 2005) - of this paradigm in patenting law: just like any other "novel" and "not-obvious" reproducible mechanical contraption, GMOs are legitimately ascribable to the ontological cosmology of intellectual property rights.

The founding stone of this whole metaphysical (Dupré, 1993), epistemic, and normative structure is the central dogma of molecular biology (Crick, 1958). At the time of its formulation, the dogma appeared to be an extremely solid basis on which the building of new biotechnologies could be constructed. The central dogma is, in itself, relatively simple: the 'genes' are imagined as sequences of nitrogenous bases along the double-stranded DNA helix. The DNA sequences are transcribed into messenger RNA (mRNA) molecules which travel to the sites of protein synthesis where they are translated into a sequence of amino acids (polypeptides or proteins) according to a code – the universal genetic code - which allocates each triplet of nitrogenous bases (codon) a specific amino acid or a stop codon.

By definition, a dogma does not admit exceptions. A scientific dogma describes a regularity in the set of facts by combining two or more categories of observations into what is known as an invariant association. An invariant association allows a significant reduction in the number of particulars needed to describe the perception that we have of reality at that given level. And this is exactly what happened in the formulation of the central dogma, which aims to construct an invariant association – through a hierarchical relationship represented by the one-way flow DNA → RNA → protein – between the nucleic acid category (DNA and RNA) and the protein category. Since, at the time of its formulation, it appeared certain that the relationship between DNA, RNA and protein was always, inevitably the same, the idea of a 'dogma' stuck. The central dogma was, after all, an expression of that golden age of genetics that was the 1950s and the sense of satisfaction that came from having discovered the molecular nature of genes. As Evelyn Fox Keller put it, the dogma, in all its beauty, dazzled minds (Fox Keller, 2001). The double helix soon became the icon of science and DNA the metaphor for the book of life: all that remained to be done was to develop technologies suited to sequencing the genomes of living beings as quickly as possible.

4.1 The Human Genome Project and the crisis of the central dogma

The results recently achieved in the field of genomics have, however, cast doubts over the central dogma, thereby causing a severe crisis in the grounds of genetic engineering's epistemic culture. One of the findings that appeared to be most immediately significant in the conclusions of the human genome project (International Human Genome Sequencing Consortium [IHGSC], 2001; Venter et al., 2001) was the drastic reduction in the estimated number of genes that constitute human genetic make-up: a mere 35,000, that later dropped to 24,000, in any case far fewer than expected (Ast, 2005). The relationship between genome complexity and size was known: a human DNA molecule is 26 times longer than that of a relatively simple organism like yeast (*Saccharomyces cerevisiae*). It was therefore equally likely that the number of codifying human genes was far higher than the 5,800 forming the genetic make-up of yeast. However, gene density, evaluated as the number of codifying genes per million base pairs, was found to be far higher in yeast (483) than in humans (11). This can mean only one thing: the complexity of the organism does not depend on the number of genes, rather on the type and quantity of the DNA sequences that do not code for protein (Ast, 2005). Some 98.5% of the human genome appears to be made of non-coding DNA and only the remaining 1.5% is made up of gene sequences that code for protein (Barbiero, 2004).

The scientific community has now started to realize that the respect for the orthodoxy of the central dogma has caused us to underestimate the non-coding portion of the genome (Shapiro, 2009), known until recently, in that hubris that characterised genetics in the 20th century, as nothing but 'junk' DNA. Here we see how the framing of any specific epistemic culture entails a normative discrimination between relevant knowledge and superfluous epistemic noise.

It is likely than in what we previously considered 'junk', we will find gems of incomparable beauty (Gibbs, 2003a), the key for starting to understand the holarchic nature of genetic information (Barbiero, 2002).

4.2 The hidden molecular layers of genetic information

The central dogma has come to be besieged by a multitude of accompanying problems. It is not the factual evidence that DNA transcribes into RNA or that RNA is translated into protein that is questioned, but the status of dogma and the hierarchical idea implicit to the one-way flow: DNA → RNA → protein. It would undoubtedly be more appropriate to talk about the 'central law of molecular biology' since, by definition, a law of nature describes in more simple terms a highly significant regularity in the set of facts (Ziman, 1984), thereby contemplating a certain number of related exceptions, restrictions and conditions. A special creative commitment is therefore required to update our conceptual tools in order to achieve an overview of molecular genetics that is closer to the empirical evidence brought to light by experimental research. What were originally perceived by scientists as abnormalities and exceptions to the dogma, are increasingly proving to be the manifestations of an extraordinary system of hidden – yet very present and active - layers of genetic information (Ast, 2005; Buiatti Marcello & Buiatti Marco, 2001; Gibbs 2003b; Shapiro, 2009; Storz, 2002; Travis, 2002)[2].

What we referred to as "liminal knowledge" is then fundamental for shifting our view on the living structure and functioning.

4.3 The crisis of genetic engineering's epistemological system

The crisis of the central dogma is entailing the necessity for a deep reconsideration of genetic engineering's epistemic foundations. Contemporary genetic engineering is, indeed, based on the deterministic certainty that the gene product obtained from a sequence of DNA is unique and incontrovertible, i.e. it cannot undergo post-transcriptional modification.

The discovery of hidden molecular layers of genetic information undermines this certainty and makes scientists more aware of the limits of a technology that would need a deep revision. The doubts and questions become pertinent when the uncertainty is such as to condition the outcome of important research programmes. However, in line with what we mentioned so far, this awareness has not been taken on board by regulatory agencies, such as the U.S. Food and Drug Administration (2009).

The genome is proving to be a cosmos apart, dominated by complexity, in which we should move with great caution. Perhaps we are lacking the very conceptual tools needed for exploration: the determinist, reductionist and mechanistic tailor metaphor – the 'cutting and stitching' that is so commonly used amongst biotechnologists – is proving to be excessively simple and misleading (Barbiero, 2002; Dodman *et al.*, 2008). This explains why, after 40 years of promises, embedded in the grand narratives of power and control (Lewontin, 2000),

[2] The most significant of these hidden layers include: *Transposons* (McClintock, 1950; Princeton University, 2009; Wicker *et al.*, 2007); *Reverse Transcriptase* (Baltimore, 1970; Skalka & Goff, 1993; Temin & Mizutani, 1970); *RNA interference* (Daneholt, 2006; Ecker & Davis, 1986; Siomi & Siomi , 2009); *RNA editing* (Brennicke *et al.*, 1999; Covello & Gray, 1989; Grosjean & Benne, 1998; Pring *et al.*, 1993); *Mitochondrial Genetic Code* (Elzanowski & Ostell, 2008; Jukes & Osawa, 1990); *Pseudogenes* (Balakirev & Ayala, 2003; Hirotsune *et al.*, 2003; Mighell *et al.*, 2000; Poliseno *et al.*, 2010); *RNA splicing* (Black, 2003; Clancy, 2008; Matlin *et al.*, 2005;); *Riboswitch* (Cheah *et al.*, 2007; Tucker & Breaker, 2005; Vitreschak *et al.*, 2004); and *RNA decoy* (Cesana *et al.*, 2011).

gene therapy sets the pace and continues to be a hope beyond reach. Not that there has been a lack of progress. Quite the opposite, each new piece of knowledge has shed light on an aspect of the system whose complexity we continue to underestimate. Essentially, the more we know the more we realize the vastness of our ignorance about the genome's physiology. We currently have a powerful – albeit anything but refined – instrument for introducing gene sequences into various organisms, however we know next to nothing about what this ability implies within the genome as a whole. And, above all, our experimentation is eminently irreversible: no one knows how to correct possible errors (Camino *et al.*, 2009).

Apparently, all this debate is still placed within the first quadrant of the post-normal diagram, the one of applied science, but, as anticipated, even within the epistemic closure of the laboratory, we are facing the consequences of our direct experimentation on living systems: complexity, irreversibility and controversy dominate our biotechnological endeavour, deeply challenging its epistemic culture. This fact is fraught with consequences both within innovation science, in terms of revising the very idea of the safety and consistency of corporate know-how, and within its regulatory counterpart, in terms of the normative foundations of patenting and on the possibility of quantifying, assessing and managing the impact of our experimentation. All this even before stepping out of the laboratory walls.

Let's now examine some of the main controversial issues related to the impacts of biotechnology in open fields, namely in the agri-food production.

5. GMOs and food production: (Bio)safety, security and the silver-bullet

Research, development and large-scale farming of genetically modified crops are rapidly altering the agriculture scenario worldwide. In 2010, GM seeds worth 11.2 billion US dollars which represents 22% of the global seed market were planted covering a total of 148 million hectares, corresponding to a market value of harvested crops estimated at 150 US dollars (James, 2010).

The proposed benefits of the biotech crop industry vary from specific kinds of resistance - to herbicides, pests and extreme weather conditions - to an enhanced nutritional power, such as the highly controversial Golden Rice, engineered to produce pro-Vitamin A. The possible negative consequences of GM crops for food production include human health issues, negative effects on non-target species and organisms, and irreversible genetic pollution.

In the past few years, GM animals have made their way not only within the pharmaceutical industry – with the emergence of the so-called pharming (Caruso, 2007) –, but also within the food industry. An aquaculture company, the Aqua Bounty Technologies Inc. (ABT), has recently applied for authorization to market a GM Atlantic Salmon as food product for human consumption (Pollack, 2010). In case of approval, this salmon would be the first transgenic animal to be marketed for US dinner tables and it would clear the way for a whole set of redesigns, from fast-growing tilapia and carp (FAO, 2002) to the Enviropig™, engineered to reduce phosphorous pollution (Pollack, 2007; Saenz, 2010).

The making of GMOs for food production introduces a whole new type of ecological hazard, in terms of a possible large-scale and irreversible alteration of genetic information in

ecological systems[3]. Indeed, genetically engineered crops have the biological potential to propagate outside of the labile borders of their cultivated fields through seeds, pollens or DNA fragments, with the help of bacteria, and variously interact with other species, both wild and farmed, in their proximity[4]. In the case of aquaculture, as we will later explore, GM fishes could, in principle, evade their breeding infrastructure, and interact with the wild populations, with a very small, but not null, chance of irreversibly altering the eco-systemic balance and the genetic makeup of these latter[5].

As mentioned so far, the structure of the debate around ecological risks of agri-food biotechnology is characterized by the coexistence of different epistemic cultures and strategies, with a variety of normative implications. The innovation science approach is focused on optimizing the products for their declared benefits and on minimizing the deterministically predictable drawbacks. The normative framework of regulatory science is founded on defining dangers in the restricted, quantifiable terms of risks, leaving to precautionary science the burden of proving the existence of possible hazards.

In this scenario, precautionary science is engaged in the arduous task of exploring the complexity of interaction between GMOs and socio-ecological systems, entailing a number of controversial problems.

5.1 Precautionary science open questions

5.1.1 GM crops: Gene flow and introgression

Ecologists are discussing the possibility that a transgene belonging to GM plants could spread to native populations through a process known as introgression – the stable incorporation of a gene in the host genome able to generate a differentiated population. The ecological consequences of a transgene introgression in plants or bacteria are not yet fully understood, but could be significant (Smith & Smith, 2006).

In a recent critical review, we considered vertical and horizontal introgression, we analyzed the biochemical and genetic constraints and the environmental factors that limit the possibility of transgene spread and we illustrated cases in which the natural barriers are overcome (Guarnieri *et al.,* 2008). In the meantime, these concerns have been empirically confirmed, highlighting the relevance of a post-normal framing and management of complexity.

Let's now revisit a crucial debate about introgression, in which precautionary and innovation science had a close and direct confrontation, and a post-normal kind of extended peer review was proven to be essential.

In late 2001, the journal *Nature* published an article by Berkeley scientists Ignatio Chapela and his student David Quist about a possible case of introgression of Bt transgenes in landrace maize, in the Mexican region of Oaxaca, despite the government moratorium on GM maize imposed in 1998 (Quist & Chapela, 2001). The article fuelled a heated debate as it implied that normative barriers were not sufficient to prevent uncontrolled and potentially

[3] We will leave aside in this context the possible impacts on human health.
[4] The very notion of 'proximity' is naturally highly controversial in itself (Guarnieri *et al.,* 2008).
[5] For more details, see section 5.1.2 and 5.2.1.

irreversible genetic contamination in the center of origin of this stable crop. In a very short time, *Nature* received a number of outraged criticizing letters, by molecular biologists and biotechnologists, claiming that the results were unacceptable, as the inverse polymerase chain reaction (iPCR) used to amplify and analyze small DNA quantities was extremely sensitive and thus prone to false positives. Chapela's experimental methods were then accused of not meeting the due – i.e. molecular biology - accuracy standards (Kaplinsky *et al.,* 2002; Metz & Fütterer, 2002). One scientist called the paper "a testimony to technical incompetence," another termed it "so outlandish as to be pathetic," and a third dismissed it as "trash and indefensible" (Metz & Parrott, quoted in Lepkowski, 2002). Quist and Chapela's published response was considered inadequate and, although officially only science quality was at stake, the case became rapidly ideologically polarized: the authors were accused of environmentalist biases, their detractors of improperly defending the industrial biotech lobby. The journal itself was forced to justify the whole publication process[6]. As Jasanoff eloquently points out, the article was subject to a greater degree of scrutiny than the crops themselves had undergone in the passage from lab to field to commercial cultivation (Jasanoff, 2005).

As a result, in April 2002, *Nature*'s editor Philip Campbell took the unprecedented step of officially withdrawing the journal support to the contested paper, leaving the readers to judge the science for themselves (Campbell, 2002). In this way, for the first time, the subjectivity of scientific judgment under conditions of uncertainty was formally acknowledged in the science community.

Indeed, in this inherently post-normal issue, characterized by lack of full and certain knowledge, the absence of a predefined and agreed upon assessment methodology, the high stakes and the inextricable link between facts and values, the modern-based peer review system was doomed to failure. Although the argument of ideological biases regrettably and improperly occupied the scene, the main issue here is that, when assessing biosafety risks and their potential normative consequences, a level of indeterminacy emerges from the coexistence - and antagonism - between different epistemic cultures, which implicitly legitimate different sampling methods, statistical analyses, and analytical techniques. In this case, the innovation science approach of molecular biology ended up prevailing, with the help of the actual methodological weakness of the Berkeley scientists. A black boxing mechanism was set in place at this point. Indeed, the inadequacy of their sampling methods was incorrectly identified with the actual absence of possible introgression. In other words, the absence of incontrovertible evidence was conveniently identified with the incontrovertible evidence of absence (of introgression), applying the so-called *argomentum ad ignorantiam* (Kastenhofer, 2010).

A later extensive survey performed between 2003 and 2004 in the same region suggested the same line of argument, concluding that transgenic plants were rare or absent in the sampled fields (Ortiz-García *et al.,* 2005). As we have anticipated, the liminal knowledge, typical of precautionary science, can be easily dismissed and normalized.

[6] For an extended account of the entire controversy, see Lepkowski (2002), and for an interesting perspective on the ideological charges and delegitimation of the two scientists involved see Monbiot (2002).

It took another four years and the involvement of several different disciplines, such as plant evolutionary ecology, applied statistics, and population ecology to make new measurements, re-examine the 2001 and 2004 samples and find out that the transgenes were indeed present and they had always been there. Interviews with local farmers about seed exchanges indicated that transgenes most likely persisted in the communities after 2001, rather than having been re-introduced. Moreover, new simulation models, based on this experience-based data collection, showed that when pollen and seeds are limited, as in the Oaxaca region, transgenes are likely to be highly aggregated geographically, therefore challenging the statistical methods for calculating the probability of detecting rare events- again liminal knowledge - based on assumptions of random or uniform geographical distributions (Piñeyro-Nelson *et al.,* 2009; Snow, 2009).

Thus, local knowledge was essential for challenging the standard hypotheses of statistical analyses and the experience-based epistemic culture of the scientists involved was crucial for asking the proper questions to the proper agents, namely the local farmers. This decade-long open debate can therefore being interpreted as an illuminating example of how the complexity implied in high power techno-scientific experimentation involves indeterminacy, irreversibility and inherent controversy.

Extended peer community and extended facts, such as the relevant local knowledge of Mexican farmers, was then decisive for re-frame the issue at stake and finding clearer results.

Before exploring the innovation science framing narratives of introgression, let's examine the main biosafety open questions associated with a different type of biotechnological endeavor: the GM salmon.

5.1.2 GM salmon: Trojan gene effect and ethology

ABT succeeded in injecting into the genome of an Atlantic salmon a gene construct constituted by the promoter and termination region from the Ocean Pout (*Zoarces americanus*) antifreeze gene and the growth hormone (GH) gene sequence of Chinook Salmon (*Oncorhynchus tshawytscha*). The corporation has patented the procedure and the resulting fish under the trademark AquAdvantage® Salmon [AAS] (Aqua Bounty Technologies Inc., 2010).

GH stimulates cell division, muscular and skeletal growth, hepatic synthesis of insulin-like growth factor (IGF) and the immune system. GH production is in turn inhibited by the presence of glucocorticoids, which have an anti-inflammatory function, and somatostatin, which inhibits insulin synthesis. In wild-type salmon, the promoter of the gene that regulates GH production is only expressed in response to certain environmental stimuli, such as temperature and the duration of daylight (Bjornsson, 1997), whereas the promoter of genetically modified salmon is continuously active (Devlin *et al.,* 1995). Since gene expression systems are regulated by negative feedback, it would appear clear that the choice of a promoter from a non-*Salmonidae* species has precisely the purpose of preventing the Atlantic Salmon's development regulators from working, thereby effectively isolating the GH production system from the salmon's physiology. The GH of Atlantic Salmon and Chinook salmon are in fact very similar, without being exactly the same. The mRNA nucleotide sequence is 90% identical (1013/1126 nucleotides) and the protein expressed is

94% identical (198/210 amino acids): just 5 amino acids are effectively different (Bodnar, 2010).

During the integration process, the gene construct – known as EO-1α – underwent promoter rearrangement, which reduced its expression potential. Despite this, when the transgenic salmon was backcrossed to a wild-type Atlantic Salmon, the EO-1α gene construct appeared to be stable in the second (F2) and fourth (F4) generations (Yaskowiak *et al.,* 2006). The data released by ABT – which, despite being devoid of independent review (Veterinary Medicine Advisory Committee - Food and Drug Administration Center for Veterinary Medicine [VMAC], 2010), was accepted as reliable by scientific literature (Fox, 2010) – show that AAS gains weight about 3 times faster than wild-type Atlantic Salmon (Aqua Bounty Technology Inc., 2010). The idea is then to develop a fish product that is materially equivalent to its wild-type counterpart, but it is functionally different, namely more efficient, as it requires less time to grow and be ready for the market.

The evaluation of the risks and impacts of this techno-scientific experimentation is highly controversial and some of the main issues raised within the precautionary science framework involve again possible ecological hazards, emerging from the relations between the communities of GM and wild-type salmon. The debate hinges around two questions: whether the transgene's presence alters the fitness of the GM salmon compared to that of the wild-type salmon and what happens if a GM salmon mixes with a wild-type population. Three main topics of experimental investigation can therefore be defined: (1) the possible competition between GM and wild-type populations; (2) the potential transfer of the transgene to the wild-type population; and (3) the evaluation of the predatory behavior of the GM salmon on the wild-type homologue.

Since the assessment of fitness in natural environments is difficult to assess experimentally, a number of theoretical models have been developed. One of the most interesting is the one devised by Muir & Howard (1999), who articulated the "Trojan Gene Effect", where the mingling of the populations of GM salmon with the wild-type salmon populations can lead to increases or decreases in GM salmon fitness, however, in both cases to the detriment of the ecosystem. In another theoretical model, the increase in frequency of the GM genotypes in any case corresponds to a reduction in the fitness of the wild-type population (Hendrick, 2001). When considered together, these models, show that the GM salmon can also have poorer overall fitness than its wild-type homologue, that is often related to malformations and physiological problems of various kinds (Deitsch *et al.,* 2006; Eales *et al.,* 2004; Hu & Zhu, 2010; Leggat *et al.,* 2007; Roberts *et al.*, 2004). In any case, when a GM salmon is introduced into a natural environment, the modelled risk is that it will lead to the extinction of the wild type.

These theoretical models are backed by a number of experimental papers. Various studies indicate that the GM salmon are effectively less fit, either because they grow too fast (Devlin *et al.*, 1994; Devlin *et al.*, 1995) or because mortality rises in certain conditions, such as the presence of predators or a shortage of food (Sundström *et al.*, 2004). However, in natural conditions, what are the real availabilities of food for any escaped GM Salmon? Sundström *et al.* (2007) compared salmon raised in tanks with salmon raised in an environment simulating natural conditions. The GM Coho Salmon grow larger, up to three times longer than the wild type. In pseudo-natural conditions they only grow 20% longer. In this context,

it is interesting to consider the findings of Devlin *et al.* (2004), who report that when the GM salmon are raised in the same tanks as the wild type, they live together peacefully whilst there is plenty of food. However, when food becomes scarce, the GM salmons demonstrate dominant behavior, and even cannibalism, thereby leading to the extinction of both populations. In the same food shortage conditions, the wild-type salmon would have survived without any real problem.

In general, all these studies point out a recurrent issue in the precautionary science epistemic approach: even minimal changes to the initial conditions can lead to very different results that are difficult to compare, thereby making it arduous to evaluate the risk associated with the introduction of the GM salmon into aquatic ecosystems in experimental conditions.

5.2 Innovation science normalizing strategies

5.2.1 The narrative of control: (Bio)safety and the myth of containment

In light of what we have experienced so far, the phenomena of gene flow and introgression are highly complex and controversial. Nonetheless, a powerful narrative of control, based on the notion of barrier is dominating the innovation and regulatory framework.

A clear example in which the lack of knowledge involved in open field biotech experimentation was reduced to statistically manageable risk assessment, is a study by the American plant biologist and biotechnologist Neal Stewart, later extended in a book for the general public (Stewart, 2003; 2004). The vertical (i.e sexual) introgression phenomenon is subdivided in a finite and numerable set of discreet steps that can be isolated and individually analyzed. These steps are essentially the minimum known linear cause-effect conditions under which gene introgression can occur between any given GM plant and a relative population. In order to overcome these natural barriers the two species must: (1) be sexually compatible, (2) grow near one another, and (3) have partially overlapping flowering times. Moreover, (4) the first generation F1 hybrids must persist for at least one generation and be sufficiently fertile to produce backcross hybrids (BC1). Finally (5) the transgene must have a selective advantage for the wild relative and (6) backcross generations must progress to the point at which the transgene is incorporated into the genome of the wild relative. Each barrier depends on a limited number of variables and interactions. Moreover, a one-to-one correspondence can be established between any given barrier and a corresponding probability distribution of being crossed (Guarnieri *et al.*, 2008). This determinist, reductionist and mechanist approach extend the epistemic culture of innovation science from the controlled *in vitro* regime, to the complex *in vivo* open field. The crucial normative implication of this framing is the possibility of applying specific counter-measures, allowing for regulatory principles – such as the European framework of co-existence (Commission of the European Communities, 2003) - and consequent modeling and policy implementations based on environmental and geographical confinement (Commission of the European Communities, 2006). Moreover, this biotech framing allows for the implementation of genetic barriers in the secured laboratory set up, in terms of programmed seed sterilization, through the highly controversial Gene Use Restriction Technology (GURT) methods. These sterilizing methods, born as normative barriers for copyright protection and highly contested by the civil society as forms of commons

misappropriation (Shiva, 1997)[7], are therefore recycled as techno-scientific barriers, in the scenario of risk management.

Let's now move to the GM salmon case, in which the same kind of framing is applied.

In a recent report on the risk assessment and mitigation of AquAdvantage Salmon (Bodnar, 2010), the complex and controversial biosafety issue of possible genetic flow and perturbation in wild populations, is reduced to the implementation of a series of counter-measures, namely biological, physical and environmental barriers, characterized by a statistically quantifiable margin of uncertainty, as emerging from the laboratory set up and procedures.

The first biological barrier consists in breeding only sterile all-female salmons. Sterility is achieved by triploid induction through pressure shock (Benfey, 1988). Indeed, having three copies of each chromosome, triploids fishes cannot produce gametes and therefore they are sterile. Nonetheless, the percentage of infertility induction is never certain (Devlin, 2010) and moreover triploid fishes grow slower (Devlin, 2004) and have a higher chance of manifesting aberrant phenotypes (VMAC, 2010). In ABT laboratories, the success rate of this techniques is guaranteed at 98,9%, leaving only 1,1% diploid eggs. Nonetheless, some concerns emerge in the ABT report, as they feel the need to explicitly declare that each sterilized eggs batch will be sampled and destroyed if the diploid eggs percentage is 5% or more (Aqua Bounty Technology, 2010). AquAdvantage salmon genetic females that are homozygous for the EO-1α gene are induced with 17-methyltestosterone to produce male gonads (neomales). The male gametes (deriving from chromosomic females and therefore without male chromosomes) so produced are used to fertilize wild type salmon eggs. As a result, all newborns are females, with a copy of the EO-1α gene (Bodnar, 2010).

Given the small, but existing probability (1.1% at most) of diploids salmons being grown, ABT plans to isolate the structure through a number of physical barriers, such as fencing, on-facility living quarters for security personnel, 24 hours a day surveillance with the help of security cameras, plus filters, nets and other containment device. Here, biosafety becomes a matter of surveillance, directly borrowing the real and metaphoric epistemic culture of security services, contrasting techno-scientific uncertainty with active control measures. But, like any other of this kind, such a complex and expensive system is inherently prone to accidents, as indeed documented in a vast literature about Atlantic Salmon's escapes (Crozier, 1998; Gausen & Moen, 1991; McKinnell *et al.*, 1997).

Finally, the AquAdvantage Salmon land-based production facilities are located in Canada (Prince Edward Island) and in Panama, where a number of environmental barriers are already in place. The fresh bodies of water of eastern Canada have been one of the natural habitats of Atlantic Salmon. But today this fish is extinct, due to overexploitation, acid rain and barriers to migration. According the ABT, in case of escape, AquAdvantage Salmon would find the same environmental problems that drove its wild counterpart to extinction (Bodnar, 2010). Nonetheless, even if highly degraded, those waters are indeed salmon's natural habitat. On the other hand, in Panama, the facility is located at a high altitude, near a river that drains to the Pacific Ocean. Much of the river water is utilized for power

[7] The most famous patent associated with this kind of transgenic technique was quite ineffectively called Terminator and rapidly withdrawn from the market (US Patent 5, 723, 765, 1998).

generation and the numerous canals that control water flow to power generation facilities are not suitable for salmons. Moreover the river water is used up to a 100% for 4-5 months a year. The nearby waters could sustain a young salmon for some time but the elevated water temperatures near the ocean would make it very hard to survive. Escape to the Pacific Ocean is therefore highly unlikely (Bodnar, 2010).

As we can see, a principle of deterministically controlled redundancy is used to ideally, asymptotically, reduce the unavoidable presence of uncertainty. However, as was demonstrated in the case of GM crops introgression, even if barriers are strict and redundant, in accordance with the law of large numbers, over long term and for large populations, they are inevitably overcome (Guarnieri *et al.,* 2008). Moreover, in this overall "lamppost" paradoxical scenario, indeterminacy and ignorance are completely dismissed, as not "scientifically" - i.e. statistically - manageable, and thus not functional to the modern framing of regulatory processes.

5.2.2 The narrative of power: Food security and the myth of enhanced yield

The issue of (bio)safety has been threatening the successful introduction of GM crops in the food production system since the beginning, in the early-nineties. Moreover, in the then globalizing market, the biotech industry had to face the difficult task of confronting its products with a variety of cultural, political, historical and economic configurations, belonging to the different targeted affluent countries. Overall, these patterns were converging in diversified civic epistemologies, implying contrasting epistemic and normative framings of the biotechnological endeavor (Jasanoff, 2005).

While the established regulatory notion of substantial equivalence[8] (OECD, 1993) was ensuring a fast expansion in the US market, when the move was made across the Atlantic Ocean, GM products encountered a strong opposition in European countries, related to a number of factors, including the threat of losing market shares and the relatively fresh memory of the BSE food safety shock (Ibrahim, 1996). In 1998, The European Union resolved to adopt a precautionary approach and impose a moratorium on new biotechnological products. This decision challenged the US export patterns and opened new kinds of regulatory oversight within the globalized free market set up of the WTO.

Around the same time, in a quite unsettling circular loop, the biotech industry was facing raising concerns back in the US. In 1999, a new heated biosafety controversy regarding possible adverse effects on non-target insects (Losey, 1999) appeared in the news media. Indeed, disturbingly evoking Rachel Carson "silent spring" (Carson, 1962), the potentially 'innocent victims' of GM Bt cotton were the highly symbolically beautiful monarch butterflies, whose images and costumes ended up dominating the scene at the 1999 anti-globalization riots that occurred in Seattle and Washington, USA.

[8] Endorsed by the FAO and the WHO in the early 1990s, the notion of substantial equivalence essentially frames the food safety regulatory process in the controversial reductionist terms of biochemical profiling. This type of assessment reduces the costs- and the time-to market of GM food products. Born as a compromise between science and the market the substantial equivalence principle was assumed by the law as a certain scientific procedure, grounding in this way the consequential normative justification for not labeling GM foods as such in the USA (Tallacchini, 2000).

Strong counter-measures were thus needed (Barboza, 1999) and a renewed effort was made by the main biotechnology corporations to emphasize the potential benefits of their genetically engineered food products. A number of industry-wide alliances were set in place at that time - such as the Alliance for Better Foods - financing scientific research, organizing educational forums, lobbying legislators, regulators and farms organizations and using their own web sites to promote the benefits of GM products (www.betterfoods.org). In this way, a narrative of power took shape and was diffused through specialized literature, as well as the mass media (Fernandez-Cornejo & Caswell, 2006; McLaren, 2005). Great expectations were placed on the capacity of the emerging biotech industrial production system to improve crop yields and, in the very near future, to provide nutritionally enhanced food products, such as the Golden Rice, which made the cover picture of Time Magazine in 2000, and initiated a still ongoing scientific, regulatory and cultural controversy (Time, 2000; Pollan, 2001; Potrykus, 2010).

In response to biosafety concerns, this narrative of power brushed up the questionable Malthusian assumption that correlates hunger with a gap between food production and population growth, shifting in this way the attention to the issue of global food security. In line with a culturally granted endorsement of the "green revolution", considered in that context as a key innovation triumph in the agri-food system, the prospects of genetic engineering applied to food production were purposefully named as "gene revolution". Not only this upgraded techno-scientific application would raise agricultural productivity, but also it would significantly help to reduce the chemical inputs, cleaning up some of the main inconveniences of the previous version.

Twenty years later, an extensive review by the Union of Concerned Scientists on the actual aggregate yield improvement in the US agriculture system reveals quite a different scenario about the alleged promises genetic engineering (Union of Concerned Scientists, 2009).

The report evaluates in detail the intrinsic and the operational yield of two primary GE food and feed crops, namely corn and soy. Intrinsic yield, the highest that can be achieved, is obtained when crops are grown under ideal conditions; it may also be thought of as potential yield. By contrast, operational yield is obtained under field conditions, when environmental factors such as pests and stress result in yields that are considerably less than ideal. Genes that improve operational yield reduce losses from such factors. In order to live up to the food security challenge, not only potential but also intrinsic yield has to be improved. The key finding of the analysis is that the raising of intrinsic yields, both of soy and corn, during the twentieth century are not ascribable to the genetically engineered traits but to the successes of traditional breeding. Concurrently, out of several thousand field trials, many of which have been intended to raise operational and intrinsic yield, only Bt corn has succeeded and only as far as operational yield. Moreover, the gains delivered were minimal compared to the overall gains within non GM crops: insect-resistant Bt corn varieties have provided an average yield advantage of 3-4% compared to conventional practices, but overall the conventional breeding methods have increased yields of the major crops of 13-25% (Union of Concerned Scientists, 2009).

As to the prospects for the future, the report interestingly argues that, even granting the very optimistic possible margin of a 50% yield increase, estimated by theoretical research on the limitations of plant physiology and morphology, the actual projections for the potential contribution of genetic engineering should take into account the fact that most of the trans-

genes under current exam may succeed in raising intrinsic yield, but may never reach the market. Indeed, these second-generation GMOs are characterized by greater intrinsic genetic complexity: unlike the ones currently commercialized, they have the potential to influence a number of other genes, therefore entailing multiple and unpredictable side effects on a crop. The systemic approach of precautionary science and the crisis of the central dogma suggest that, once again, ignorance and indeterminacy are highly significant and would require, as the report recommends, a radical revision of the regulatory processes involved. Thus, keep betting on genetic engineering for addressing food security will have unavoidable consequences in terms of food (bio)safety. Clearly, the objection coming from the epistemic culture of innovation is that these new possible harmful side effects will be managed through more powerful risk assessment technologies and will be effectively balanced with the needed countermeasures. Once more, we see how the black boxing mechanism can be at work and how these two narratives of innovation, control and power, are closely depending on one another.

A fully analogous line of argument can be retraced in the case of GM salmons. In this context, the narrative of power rests on further enhancing the alleged remarkable performances of the aquaculture "blue revolution" (Vassallo *et al.*, 2007) and on tackling the issue of food security by effectively responding to the globally growing need for healthy and cheap animal proteins. Again, indefinite (bio)safety risks are explicitly weighted up against definite food security benefits. In a recent article published on the journal *Science* (Smith *et al.*, 2010), a whole dissertation on US salmon market aggregate prices is made, arguing that the FDA regulatory processes should take charge of the changing patterns of animal protein consumption, induced by technologically driven declining costs. In particular, for a "full impact assessment" of GM salmons, the regulatory agency should compare the possible minor nutritional and health drawbacks of GM fishes, with the major substantial public health benefits of eating more salmon instead of other proteins, such as beef. In this context, the AquAdvantage salmon is reductionistically framed as a product: in terms of its alleged lower production and market costs – a benefit of being GM - and of its healthier nutritional power – a benefit of being substantially equivalent to a wild type salmon. Both statements are endorsed as evidence-based, i.e. objective, within the black boxing innovation and regulatory epistemic culture. The framing data statements such as: "For American adults eating no fish, consumption of just one serving of salmon per week can reduce coronary death of 36%", are as narrowly selected as purposefully effective (Smith *et al.*, 2010).

5.2.3 The narrative of urgency: The silver-bullet for global hunger

Having set in place a narrative of control - in charge of defending (bio)safety - and a narrative of power - in charge of enhancing food security-, a third fundamental narrative of innovation was developed, in order to make GM products, not only safe and desirable but also urgently needed.

At the turn of the century, world leaders pledged to halve hunger and extreme poverty by 2015, as the first of eight fundamental Millennium Development Goals (MDG). The UN Millennium Declaration, adopted by 189 nations, provided a specific timeframe for measuring results and draw public attention to the issue of global food security. In the meantime, in the affluent world, the biotechnological food market was relatively confined to North America, given the Mexican moratorium on corn and the European ban on new GM

products, as we have seen, both established in 1998. The so-called developing countries represented a large and less regulated market-share to occupy. A new form of controversy was then emerging, again between different epistemic and normative cultures, about the role of genetic engineering in tackling and solving the problem of global hunger. The founding assumptions of the innovation approach can be located in an extensive report by the Consultative Group on International Agricultural Research, published in 1999 (CGIAR, 1999): given the major socio-economic differences between the countries where the debate about GMOs is taking place and the countries where they are actually needed, the positions and the conclusions of the formers are largely irrelevant to the latter (Persley, in CGIAR, 1999). Moreover, a silver-bullet high-power technology is needed to fight the enemies of health and wealth. In Gabrielle Persley's words: "The innovation science of molecular biology and other tools of biotechnology add elegance and precision to the pursuit of solutions to thwart poverty, malnutrition, and food insecurity in too many countries around the world. In agriculture, these enemies are manifest as pests, diseases, drought and other biotic and abiotic stresses that limit the productivity of plants and animals" (Persley, in CGIAR, 1999, p. 3).

Risks and benefits of genetically engineered food processes and products should be thus weighted against the urgent needs of the poor. The regulatory debate was to be considered as a privilege of affluent nations, not applicable to developing world: where extreme poverty and hunger are prevalent discussing about uncertainty is a luxury that can't be afforded.

A study published in 2004, on the environmental (bio)safety of a transgenic nematode resistant variety of potato, documented gene flow towards wild relatives that grow in the proximity (Celis *et al.*, 2004). The problem was deepened by the fact that the transgenic variety was grown in one of the most important areas of biodiversity conservation (The Central Andes), where 130 wild species of potatoes that are sexually compatible with transgenic crops had been documented. The similarity with the Chapela case could have initiated a similar long-term controversy. Nonetheless, the scientists who conducted this research followed the Nuffield Council of Bioethics position, whereby the risk of compromising biodiversity by introgression is not a sufficient reason for banning the use of GM crops in developing countries, where a response to denutrition (Nuffield Council on Bioethics, 2004) is an urgent issue. "The Nuffield Council on Bioethics, suggests that introgression of genetic material into related species in centres of crop biodiversity is an insufficient justification to ban the use of genetically modified crops in the developing world. They consider that a precautionary approach to forgo the possible benefits invokes the fallacy of thinking that doing nothing is itself without risk to the poor" (Celis *et al.*, 2004, p. 223). As we can see, the main argument is founded on a dualistic normative approach according to which either we deploy the most advanced techno-scientific implementation, i.e. the silver-bullet, regardless of the possible (bio)safety consequences, or they are left with nothing.

This technocratic normative assumption can be found in the Nuffield Council on Bioethics' actual recommendation: "[…] it is easier to forgo possible benefits in the light of assumed hazards, if the existing *status quo* is already largely satisfactory. Thus, for developed countries, the benefits offered by GM crops may, so far, be relatively modest. However, in developing countries the degree of poverty and the often unsatisfactory state of health and

agricultural sustainability is the baseline and the feasibility of alternative ways to improve their situation must be the comparator" (Nuffield Council on Bioethics, 2004, p. 58). In 2004, a few years have passed already from the first optimistic statements about future yield increase and in affluent countries the food security arguments are not as effective. In the Nuffield Council's vision, yield enhancement may not be so significant in our context, but in the developing countries, it still have to prioritized over (bio)safety. As a result, the narrative of urgency can then be interpreted as an effective epistemic and normative strategy to fill up the gaps of both the narrative of control and of power[9].

6. Concluding remarks: From predicting risks to diagnosing needs

As we have seen, when applying genetic engineering to our food production system, we are faced with emergent and irreducible complexity, implying the presence of ignorance and indeterminacy. Moreover, as articulated earlier (see section 2), our direct and high-power experimentation can be considered as fundamentally irreversible with unknown long term consequences.

The impact of these biotechnologies has been, and still is, prominently evaluated in terms of possible future consequences and the latter are in turn declined in the restrictive framework of quantifiable risks and benefits. So far, we have explored the fundamental epistemic and normative limits of risks assessments in this context, and the normalizing strategies to keep them operational.

We would like to conclude our reflections by concentrating on the logically former, fundamental premise of this whole framework of analysis, namely the strong and implicit normative stance according to which we identify impact evaluation with future developments. This assumption is the grounding pillar of the modern principle of responsibility, according to which we need to predict the future in order to justify our action in the present (Funtowicz & Strand, 2011).

When fully acknowledged, the complexity and irreversibility of our techno-scientific experimentation lead necessarily to a revision of this principle. Indeed, we are left in the paradoxical situation in which we need to know about the future consequences of our implementation in order to act, but we are prevented from knowing the future developments, as a consequence of the intrinsic nature of the very same implementation (Benessia *et al.*, 2012). A way out of this inherent contradiction is to shift our attention back to the present and to divert our analytical and reflective capacity from prediction to diagnose and from responsibility under risk to commitment in times of change (Funtowicz & Strand, 2011).

Sheila Jasanoff articulates this kind of paradigm change by advocating the need for new "technologies of humility", directed to alleviate known causes of people's vulnerability to harm, to openly address the issue of equity and the socio-economical realignments implied by the new emergent technologies, and to reflect on the social factors that promote or discourage learning from our (technological) past and present experience (Jasanoff, 2003; 2008).

[9] A more recent version of this narrative of urgency is applied to the climate change emergency, in terms of both mitigation and adaptation.

When applied to our case study, this approach actually allows opening up the black box of the overall narratives of innovation, and reconsidering the whole biotechnology enterprise as the tip of the iceberg of the industrial agriculture and breeding main paradigm – the basis of the green and the blue revolution - with all its long-term inherently dysfunctional properties.

Indeed, this model of food production is based on the linearization of flows of nutrients, requiring a progressive depletion of stocks – such as fossil energy, soil erosion, loss of biodiversity – and the progressive filling of sinks – in terms of environmental pollution and greenhouse gasses (Folke *et al*., 1998; Giampietro, 2009). Moreover, the prime purpose of this paradigm is to maximize production and to increase efficiency – accordingly defined in the restrictive terms of quantity and total output -, temporarily externalizing social, cultural and environmental costs. In fact, augmenting efficiency in this context intrinsically collide with the preservation of diversity, and therefore of flexibility and adaptability, the two main evolutionary strategies for a sound long-term stability of terrestrial ecosystems (Giampietro, 1994).

In more concrete terms, in order to maximize efficiency, industrial agriculture and breeding increasingly replaces traditional biological varieties with hybrid seeds and breeds - produced by a few big commercial corporations - and traditional knowledge and practices with standardized, corporate techno-scientific know-how.

This transformation necessarily reduces our collective natural resilience and progressively forces our reliance on further (bio)technological fixes, alimenting yet another – destructive - Catch 22 situation. The modern narratives of control, power and urgency applied to the agri-food biotechnology enterprise are embedded in this sterile epistemic and normative circular loop, and therefore they lead to unsustainable processes.

Once again, a way out of the paradox is to reconsider our relation with food and food production altogether and move to a more complex model (Waltner-Toews & Lang, 2000), in which what we eat is not defined in the generic terms of yet another commodity, nor in the reductionist terms of needed calories and nutrients, but it is embedded in a democratized constellation of social, cultural and ecological public values. In other words, we need to move from food (bio)safety and security assessment to a complex and democratic food quality evaluation.

7. References

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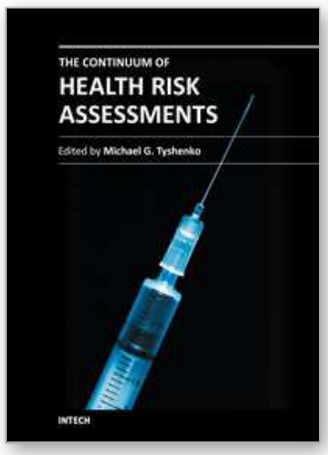

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This book presents a collection of health risk assessments for known and emerging hazards that span a continuum. Case studies for existing health risks include psychoactive drug usage in delivery truck drivers and using look-back risk assessment for accidental syringe re-use in healthcare settings. Case studies for emerging risks include precautionary actions to safeguard blood supplies; nanoparticle deposition in the lung; and the epistemic issues surrounding genetically modified organism risk assessments. The final section of the book deals with advancing health risk assessment analyses through a post-genomics lens and provides case studies on personalized genomics, new data analyses and improving in silico models for risk assessment. These case studies provide much insight into the ongoing evolution of health risk assessments.

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