Chapter 3

Science, Uncertainty and GMOs

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Introduction

The question of how public authorities should deal with risks and uncertainties has become a dominant concern in the wake of the 1992 programme on the creation of the internal market. A key question that can be derived from Ulrich Beck's (Beck 1986; Beck 1997)[1] agenda-setting critique and provoking notion of 'organised irresponsibility', is one of how to deal responsibly with situations in which there are suspicions that hazards may exist, although (sufficient) scientific or historical evidence for them is lacking, i.e. situations that deal with 'uncertain risks'. Prominent risk scholars have made very clear that dealing with such 'uncertain risks'[2] is a key challenge in current societies (e.g. Ravetz 2001; Wynne 1995; Beck 1986; Jasanoff 1990; Renn 2006; Löfstedt 2005; Nowotny *et al.* 2001 and Harremoës *et al.* 2002). These uncertain risks concern situations of suspected, possible hazards, which are usually associated with complex causalities, large-scale, long-term and trans-border processes, and which are generally difficult to control and also transcend human sensory capacities.

This contribution aims to understand the role of science and knowledge in the regulation of uncertain risks by examining how various actors deal with science, knowledge and uncertainty in the field of EU risk regulation. Our analysis may help to identify the difficulties of dealing with uncertain risks and to discern some ways to address these problems. In such situations, since scientific knowledge is perceived or portrayed to be limited, experts, stakeholders or the public have or create doubts about the possibility or severity of hazards (Van Asselt 2005). At the same time, regulators habitually turn to science and experts in these cases in order to justify their decisions (Hilgartner 2000; Jasanoff and Wynne 1998; Ravetz 1990; Van Asselt 2005; Van Asselt *et al.* 2006). This situation, which we term the 'uncertainty paradox' (Van Asselt and Vos 2005, 2006), raises important questions about the role of science, knowledge and experts in the regulation of uncertain risks. To date, attention paid to this issue has been scant: even legal literature on the precautionary principle, legitimating decisions and actions in situations characterised by uncertainty (Faure and Vos 2003), often treats science and expertise as unproblematic in nature.

The notion of uncertain risks refers to possible, new, imaginable hazards, with which society has no or limited experience. It is uncertain whether the particular activity, product or phenomenon constitutes a risk to humans and/or the environment, because causalities are complex, the possible multiple effects are heterogeneous and extend to the long-term and/or the global scale and risk perceptions clash. The use of genetically modified organisms is an example of uncertain risk. As Lang and Hallman (2005) phrase it: "the potential for risk in using [GMO] (..) remains just that – potential. There has yet to be an event that would allow institutions and experts to move [it] (..) from an uncertain risk to a quantifiable hazard" (p. 1243).[3] Scientific or historic proofs of harmful consequences are lacking, but suspicions cannot be fully refuted either. Uncertain risks need to be distinguished sharply from traditional, simple risks that can be calculated by

means of statistics on frequencies and actual impacts. Approaches, tools, routines, procedures and structures that work quite well in the regulation of simple risks are not just inadequate, but may even hamper dealing responsibly with uncertain risks. In the case of uncertain risks, basic, seemingly simple, questions as to whether there is a 'real' risk or whether there is 'enough' safety cannot be answered by science. The presence of uncertainty challenges, or at least complicates, the role of experts as risk assessors.

Without doubt, governance of uncertain risks is difficult, and inherently political. In this context, Beck (1986) provocatively coined the notion 'organised irresponsibility'. We understand organised irresponsibility as a situation in which society is unprepared for, and unable to deal adequately with, inevitable surprises, negative consequences and/or long-term impacts associated with uncertain risks, notwithstanding all institutions and procedures in place and the pretence of certainty and control. Yet, before even considering sensible and effective alternative ways of dealing with uncertain risks, we need to comprehend the essence of the challenge being faced. To this end, we propose to examine various decision-making processes on uncertain risks so as to understand which mechanisms bring about, contribute to, and sustain the uncertainty paradox. In case-study research on EU GMO regulation, we examine how various actors actually deal with science, knowledge and uncertainty. With this, we aim to infer patterns and mechanisms illustrating the governance of uncertain risks.

Three Case Studies

We analysed three cases relating to EU Regulation of GMOs[4] that all pertained to the import of genetically modified organisms (GMOs), i.e.:

- NK603, a genetically modified maize made resistant to a particular herbicide to increase farmers' control of weed;

- GT73, a genetically modified maize made resistant to the same herbicide as NK603;
- MON 863 X MON 810, a maize composed of two genetically modified maize variants containing insecticidal proteins;

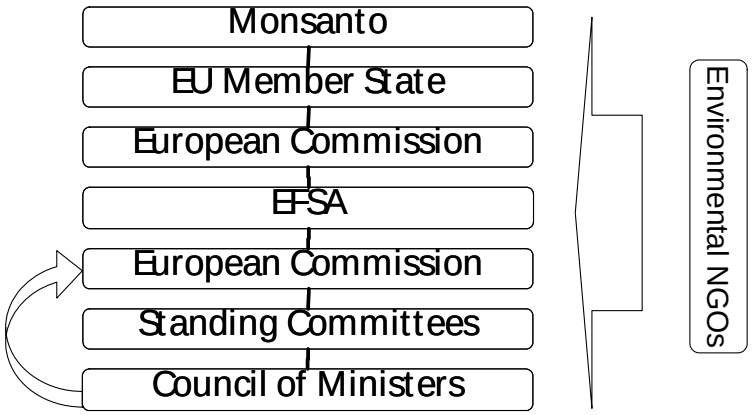
Our analysis has been informed by analysis of all kinds of documents and views produced by the relevant actors and we benefited from complementary research on the same cases and/or EFSA, which involved interviews and participant observation (e.g. Chalmers 2004; Vos and Wendler 2007) as well as earlier analyses on EU regulation of GMOs.[5] All three cases developed around applications for authorisation for import into the EU by the US-based biotechnology company Monsanto. The cases are particularly interesting because of the complex regulatory procedures and decision-making and societal controversies involved. In our analysis, we use the following notions inspired by Ravetz (2001) to refer to specific main actors, i.e.:

- **risk producers** - those pursuing potentially hazardous activities or technologies: Monsanto.
- **risk assessors** - experts seeking to analyse risks, e.g. the GMO-panel of the European Food Safety Authority (EFSA).
- **risk managers** - those charged with deciding on and controlling risks: the European Council and Commission and the member states.
- **risk protesters** - those objecting to new technologies or activities on behalf of potential risk victims: Greenpeace and Friends of the Earth. These risk protestors do not have a formal role, but they aim to influence the regulation process through lobbying, protesting and critical reports.

The risk regulation process (see Figure 1 for a schematic overview) began with an application by the risk producer Monsanto to one of the EU member states to market a GM product in that country. Not only did

Monsanto initiate the risk regulation process, it is legally required to carry out an assessment. Monsanto is thus not only the risk producer, but is also the first to assess the risks. Their assessment had been submitted to the relevant competent authority of the member state. When the national assessment was completed, it was forwarded to the European Commission. The Commission then asked the GMO Panel of the European Food Safety Authority, established in 2002 as an independent body for science-based risk assessment, to consider the risks of the GM product in question. The GMO Panel has to operate within strict time limits[6] and it lacks the resources and facilities to test products. Our analysis demonstrates that this means that EFSA's risk assessments are *de facto* meta-reviews of Monsanto's assessments instead of an independent examination (van Asselt *et al.* in press). The claimed independency of EFSA is compromised by reliance on Monsanto's research facilities, tests, knowledge and willingness to disclose information.

Figure 1:
Schematic overview of the decision-making procedure on GMOs.



The panel's advice was forwarded to the relevant standing committees comprised of representatives from each member state. Yet, they could not agree with the proposed authorisation of the products and failed to give an

opinion. This meant that the Commission had to refer the draft decision to the Council of Ministers of the EU. Similarly divided on these issues, the Council too failed to reach agreement and could not adopt a decision. This meant that in turn the final decision was up to the Commission which functions in these cases as 'deal breaker'. This procedure has been intended to serve as a provision for incidental deadlocks. Yet, in the three GMO cases that we analysed, this turned out to be the *de facto* standard operating procedure.

Our analysis furthermore indicates that in the case of EU regulation of NK 603, GT 73 and MON 810 x MON 863, the uncertainty paradox is sustained and reinforced by the interplay of four mechanisms: 1) uncertainty intolerance, 2) boundary work, 3) the inclination to equate uncertainty with risk, and 4) technocratic provisions. In the following sections we will briefly discuss these mechanisms.

Uncertainty Intolerance

Our case study research on EU regulation of GMOs revealed that both the risk producers and the risk assessors expressed an intolerant attitude towards uncertainty. By uncertainty intolerance we mean that uncertainties are not acknowledged, are deemed irrelevant, or are simply evaded, instead of genuinely and systematically investigated.[7] Uncertainty intolerance is associated with an unwillingness to demand and produce uncertainty information. In this section, we will detail how Monsanto and the EFSA GMO Panel framed uncertainty as well as their assessment behaviour.

Monsanto's Framing

Our impression is that Monsanto's safety assessments are deliberate efforts to transform any uncertainty about risk into absolute certainty about safety. To

this end, they avoid uncertainty in their communication, they define it away in their reports and they seem to attempt to suppress tests that may question absolute certainty. This behaviour will be detailed below.

The risk producer seems deliberately to avoid the vocabulary of risk and uncertainty. In the case of NK 603, uncertainty is not even mentioned once in their 37-page report. Monsanto only used the term 'risk' in contexts not directly related to NK 603, or in contexts in which Monsanto claims that the risks are similar to or even less than those of conventional maize, implying that their product is as safe or even safer. In this way, Monsanto claimed that its GMO does not pose any risks to humans and the environment, albeit indirectly and implicitly, as it refused to frame its assessment in those terms. Instead of risk assessments, Monsanto conducts what it called 'safety assessments'. This 'safety framing' is not just a matter of wording. We would like to argue that the choice of "safety" instead of "risk" symbolises Monsanto's uncertainty intolerance. The notion of 'framing' refers to 'schemata of interpretation' (Goffman 1974), which are enablers to organising experience and to setting boundaries, and which serve as 'bias for action' (Perri 6 2005), i.e. they push particular styles of decision-making and/or behavioural responses (compare Benford and Snow 2000). Framings impact on risk assessment, as "frames define what counts as relevant for attention and assessment" (Perri 6 2005 p. 94)[8]. Monsanto's safety framing reinforces a focus in the risk assessment on demonstration of no effect, which pre-empts, hampers or even derails any attempt to systematic analyse uncertainty.

Monsanto's Assessment Behaviour

Monsanto also displayed uncertainty intolerance in its assessment behaviour. Informed by an interview with Mr Morley,[9] UK environment minister, the Guardian journalist Paul Brown stated that Monsanto did not immediately and voluntarily share test results indicating that MON 863 caused

unexplained kidney damage to rats (Brown 2005). A German law court in Münster ordered Monsanto (20 June 2005) to disclose the suppressed report on rat feeding trials related to MON 863. The court case was inspired by a Greenpeace campaign (Greenpeace 2005). The full rat study report (eleven hundred pages) and a summary document were subsequently made available on Monsanto's website.[10] The rat study was dated December 2002, while the MON 863 assessment was released in August 2003. In the MON 863 assessment, these rat study results were not reported: it was suggested that these tests were not performed and no anomalous results had been found. Viewed against the background of this chronology, it is clear that the test results, which could have been interpreted as uncertainties about effects, were indeed suppressed.

Surprisingly this obvious violation by Monsanto of the obligation to disclose all relevant research seemed to have no consequences for EFSA's attitude towards Monsanto's applications. The authorisation procedure prescribes that companies carry out the risk assessment, which needs to be reviewed by EFSA. EFSA is thus dependent on Monsanto's assessments. In such a situation of dependency, trust and trustworthiness are critical, especially in a so-called post-trust era (Löfstedt 2005). Trust is not a matter of belief, but it involves a system of checks and balances. Trust should not be given naively or relied on blindly. And failure to adhere to an atmosphere of mutual trust and openness should at the very least have negative consequences for the risk producer. At it stands now, the regulators' attitude towards Monsanto was not affected by the affair concerning the missing rat study. Whether this missing data was a lack of due diligence or a deliberate attempt to hide uncertainty information was apparently unimportant to the risk regulators. How can one expect trustworthy behaviour when abuse is so easy?

Apart from the fact that the rat study report was held back, it is also worthwhile looking at the assessment behaviour in the contested study.

According to the rat study report, the tested rats had less mineralised kidney tubules than average. Without motivation or justification, Monsanto claimed that this finding is of "no biological significance" (p. 11). The observed effects are dismissed by Monsanto as irrelevant. Van Asselt (2005) observed that in many practices claims of irrelevance enable experts to suggest certainty. Uncertainty intolerant assessors seem inclined to claim irrelevance, while uncertainty tolerant assessors would have investigated the uncertainty and would have sought to share the uncertainty information. Monsanto furthermore stated that the effect cannot be considered "test related" (p. 11). This is a quite puzzling statement. So there is an adverse effect, however, Monsanto claims that this is not caused by the intake of GM maize. It is not explained how this is possible in a control study set-up: the only difference between the two groups of rats was that the rats with altered kidneys were fed GM maize. Here, uncertainty intolerant assessment behaviour entailed creating a smoke-screen with the aim of keeping the uncertainty out of sight. It is intriguing that although Monsanto neutralised the uncertainty in the report itself through claims of irrelevance and a smoke-screen, it still decided to conceal the rat study report. The combination of these assessment behaviours – claiming irrelevance, creating a smoke-screen and suppression of the report – provide further evidence for our evaluation of Monsanto's stance: uncertainty intolerance is both manifest in the framing and the assessment behaviour.

EFSA's Stance

In our cases, we also observed uncertainty intolerance on the part of EFSA's GMO panel, which is in line with the earlier observations of Levidow *et al.* (2005): the opinions of EFSA's GMO Panel "generally indicate no uncertainty" that might trigger extra risk management measures (p. 270) and they "have framed scientific uncertainties in such a way that they can be

resolved by extra information, or can be readily manageable, or can be deemed irrelevant to any risk" (p. 273). The risk assessor partly inherited Monsanto's uncertainty intolerance, as EFSA's risk assessments were in fact meta-reviews of Monsanto's assessment. This arrangement, which is laid down in the relevant legislation, did not only introduce dependency on the willingness of the applicant to disclose all relevant information, but also introduced it in terms of framing and the willingness to disclose uncertainty information. EFSA's room for manoeuvre is determined by Monsanto's framing and information about uncertainties. The behaviour of Monsanto with regard to the tests with adverse effects indicates that this dependency is not a theoretical issue, but a practical difficulty. Another illustration is that during the assessment of MON 863 x MON 810 (EFSA 2004a), the applicant had repeatedly to provide EFSA with additional data for a variety of reasons. Though Monsanto apparently satisfied the panel in the end, it is clear that the company lingered with the information.

However, the uncertainty intolerance of EFSA's GMO Panel cannot only be explained by inheritance of uncertainty tolerance from Monsanto. It is noticeable that EFSA's GMO Panel often sides with Monsanto's evaluations and interpretations of data, and even explicitly "agrees with the applicant", without further explanation or critical discussion of uncertainties that might have been overlooked by Monsanto. We did not find any signs that the rat study affair prompted more explicit requests for uncertainty information. EFSA did frame its assessment activities as risk assessment, but its actual assessment behaviour is very consistent with a safety, i.e. an uncertainty intolerant, orientation. Chalmers (2004) characterises EFSA's style of reasoning as providing "its own corpus of proof" to find no evidence of risk.

In all cases, the Commission asked EFSA's panel to "consider whether there is any scientific reason to believe" that the placing on the market of the GMOs "is likely to cause any adverse effects on human health and the environment" (EFSA 2003; EFSA 2004a; EFSA 2004b). The particular

formulation "whether there is any scientific reason to believe" is relevant if we compare it with the closed question (i.e. whether or not the activity constitutes a risk) the Commission asked in the virginiamycin case (van Asselt and Vos 2005, 2006). It can be argued that the terms of reference to EFSA in relation to GMOs were more uncertainty tolerant in the light of the following two elements: 1) instead of asking for a decisive answer and proof on whether the risk is a hazard, the Commission asked for indications that hint at adverse effects, and 2) instead of referring to science as the source of absolute truth and certainty, with the notion "to believe" the Commission seemed to accept that science cannot provide certainty about uncertain risks.[11] The terms of reference could therefore have been read as an invitation to discuss the uncertainties involved systematically and to provide uncertainty information. Interestingly, however, in all three cases, EFSA provided clear, 'certain' answers phrased in the following terms: the GMO is *as safe as*[12] the conventional counterpart and it is "unlikely to have an adverse effect on human and animal health and (..) the environment". "Unlikely" can be read as "low risk". Combined with the claim "as safe as", it can be argued that the effective message of EFSA's assessment is a plausibility proof, although such non-risk contention was arguably not requested by the Commission. This production of plausibility proofs can be read as an uncertainty-intolerant interpretation of the goal of the assessment. Our observations are consistent with findings of Stahl and Cimorelli (2005) about policy analysts involved in ozone risk assessment. They argue that:

> "Even when uncertainty is discussed, policy analysts attempt to limit its consideration, address only uncertainties in specific pieces of data, indicate that uncertainties may be very large and produce impacts to the final conclusion that are not part of the analysis, or, in other cases, list the assumptions of the analysis so as to avoid specifically addressing some troubling uncertainties" (Stahl and Cimorelli 2005 p. 1110).

Wynne (2001) attributes to experts involved in risk assessment "the inability (..) to recognise the limits of their knowledge". In his observations, they instead forward "claims that the risks and consequences are (or soon will be) adequately known" (p. 447). These observations and analyses suggest that EFSA's uncertainty intolerance is not unique, but rather widespread among risk assessors institutionalised in the policy domain.

Monsanto's safety assessment and EFSA's risk assessment breathed a similar spirit due to shared uncertainty intolerance. This resemblance, which was also noted by others, led to accusations of bias and relationships with biotech industry, complot theories, etc. Friends of the Earth (2004), for example, argued that EFSA is used by the Commission to force GMOs onto the market. We do not agree with such views. Building upon our analysis, we argue that EFSA was as uncertainty intolerant and safety-oriented as Monsanto, with the consequence that it is understandable that EFSA felt at ease with Monsanto's arguments and that the assessments were very similar. We want to emphasise that we neither suggest nor argue that EFSA is deliberately defending or advancing Monsanto's stakes. But, because of the shared uncertainty intolerance, their lines of reasoning were very similar. This similarity is not the point of departure, but in part the *effect* of EFSA's attitude towards uncertainty.

Boundary Work and Plausibility Proofs

How did EFSA construct plausibility proofs about uncertain risks? Evading uncertainty, which enabled the declaration of GM products to be safe, was made possible through boundary work. Boundary work, a notion coined by (Gieryn 1983; 1999), is a strategic and purposeful act in which boundaries are drawn between realms, for example, between science and non-science and between science and politics. Boundary work involves drawing and maintaining contrasts through selective attributions, which effectively

demarcate in order to construct "self-evident justification" and "superiority in designated terrains" (Gieryn 1999). It has been convincingly demonstrated that boundary work is not just a matter of formal responsibilities, but that it is an ongoing negotiation process on roles and tasks and how these are portrayed to others. Tactics and intentions are involved and boundary work has particular effects (Bal *et al.* 2002; Halffman 2003, 2005; Hoppe and Huijs 2002; Jasanoff 1990, 2005).

EFSA explicitly stated that it had been requested to consider scientific objections and not to assess non-scientific ones (EFSA 2003: 4). The GMO panel used the constructed boundary between science and non-science to argue that possible uncertainties about interference with the European environment and regular maize crops are non-scientific concerns. In this way, the scope of the risk assessment could be minimised. In a similar vein, EFSA constructed a boundary between risk assessment and risk management. Such boundary work enabled the GMO Panel to disqualify and dismiss member states' concerns, which could have been read as uncertainty issues (compare Levidow *et al.* 2005), as "non-scientific" and "issues of risk management".

The GMO Panel's responses to concerns regarding the risk of cross-contamination illustrate the dynamic nature of boundary work. With NK 603, it refused to consider the possibility that the GMO could contaminate regular maize crops. It argued that the question of contamination was one of risk management, not of risk assessment and thus was felt to be beyond the limits of the panel remit (EFSA 2003). Landfried (1999) (quoted in Levidow *et al.* 2005 p. 263) argued: "the difficulty of distinguishing between political and technical questions also provides an opportunity to those who might wish to reduce political questions to technical ones". In our case, issues of uncertainty were recast as political topics. In this way, boundary work helped EFSA to minimise the scope of the assessment. The same point concerning cross-contamination was raised with regard to GT 73. This time, however, the panel did engage in what it had previously argued to be questions of risk

management. Concerns regarding contamination were still quickly dismissed with the reasoning that spillage of the GT 73 plant would likely only occur in ports located in industrial areas. Since these industrial areas offer little room for agricultural cultivation, contact with, and contamination of, other plants was portrayed as highly unlikely. Similar reasoning was employed when contamination concerns were raised with regard to MON 810 x MON 863. Also in that case, the panel appeared more willing to addresses issues it dismissed in the NK 603 case. Chalmers (2004) argues that in the case of NK 603 the panel interpreted its role in the narrowest and most formal sense and thus carried out a very minimal risk assessment. However, if mere import excludes the possibility of interference with the environment and regular maize crops in the European Union, we argue that the whole issue actually concerns a non-risk and that it would not be necessary to engage in any 'boundary work' to exclude these types of concerns.

Boundary work enabled EFSA to construct superiority, which facilitated the production of authority claims. The Panel often mobilised 'the scientific literature', but without specific references, or they just agreed with some particular findings or conclusions, without providing further justification. Through this *ex cathedra* style, EFSA presented itself as an authoritative voice. "Believe us, we are scientists", is the implicit message. The constructed authority is then used as an anchor to evade uncertainty. In the GT73 assessment, the Panel investigated the potential allergenicity of two genetically modified proteins (EFSA 2004b). Concerning one of these proteins, EFSA stated that no indications of allergenicity could be found in Monsanto's data (EFSA 2004b p. 9), nor in the previous panel assessment for NK 603 (EFSA 2004b p. 9). Yet, neither references nor details were provided. Our analysis of the NK 603 assessment reveals that in that assessment EFSA merely stated that an allergy risk evaluation had been performed previously by the national competent authorities and the EC Scientific Committees. Again, neither references nor details were provided.

In the GT 73 assessment, the panel argued that new information on allergenicity would be required to change the panel's opinion (EFSA 2004b p. 9). The boundary work brought about self-evident justification for EFSA's role in deciding what counts as 'new science'. The 'new' requirement (compare Chalmers 2004) in combination with the self acclaimed authority in this domain, enabled the panel to be satisfied with a reference to earlier assessments. In sum, boundary work facilitated the production of certainty about non-allergenicity.

Some further illustration of boundary work and its crucial role in constructing plausibility proofs can be found in the second opinion on MON 863 x MON 810 (EFSA 2005). On the basis of new rat study results, the panel straightforwardly concluded that there are no safety concerns. However, that particular rat study yielded some anomalous results in organ weights of the rats fed the hybrid maize: the weights were statistically significantly lower. The significance of these results was immediately disarmed by the unmotivated assertion that "this difference did not exhibit a dose-response relationship" (p. 22). This is another example of authority claims used by EFSA to evade uncertainty.

Dynamic boundary work between risk assessment and risk management (or as Levidow *et al.* (2005) phrase it: "judgements in the grey area between risk assessment and risk management" (p. 273)) as well as between science and non-science facilitated the construction of claims of irrelevance and of authority claims, which were used as building blocks in creating certainty. EFSA's boundary work in is an example of what Jasanoff (2005) refers to as "less transparent, politically significant boundary work".[13] It is beyond the scope of our expertise to assess the content of the GMO panel's claims: we only want to describe the assessment behaviour. Our analysis demonstrates that in instances that could have been read as uncertainty (member states' concerns, adverse effects, open questions), the GMO panel actively evaded uncertainty through boundary work, instead of discussing these uncertainties

and exploring whether and how they might matter. Let alone that the possibility of other and "unknown" uncertainties was systematically considered with an open mind (compare Wynne 2001; Levidow *et al.* 2005).[14]

An 'Uncertainty = Risk' Tendency

Our case-study research reveals another mechanism contributing to the uncertainty paradox. We discovered that various actors tend to equate uncertainty with risks. Although the notion "uncertain risks" points to situations where risks are highly uncertain, this does not mean that *all* risks are highly uncertain and, importantly, not all uncertainties inhibit dangers. Not all uncertainties are by definition relevant or critical for every aspect in a risk assessment. Equating uncertainty with risks implies that any uncertainty is interpreted as a signal of risk.

We observed that both the risk producer (Monsanto) and the risk protestors (Greenpeace and Friends of the Earth) tend to equate uncertainty with risk, notwithstanding the fact that they have opposite positions in the GMO debate. Monsanto's uncertainty intolerance and the associated desire to prove no effect, seem to be grounded in the following reasoning:

zero uncertainty = zero risk = 100% safe

As a consequence they seem to fear uncertainty, as it threatens the idea of absolute safety.

The risk protestors also tend to equate uncertainty with risk, but in a different way. Their reasoning seems to be:

uncertainty = risk = 100% hazard

The actual behaviour of the risk protestors is consistent with this logic, which is illustrated by the following example. Shortly after EFSA's opinion

on GT 73 became public, Greenpeace published a short critique, in which it concluded that irregularities in the molecular characterisation of GT 73 oilseed rape had not been investigated satisfactorily (Greenpeace 2004 p. 2). Greenpeace highlighted that in EFSA's report, it was stated that besides the genes added by Monsanto, there was a small fragment of DNA present in GT 73 that was not present in its unmodified counterpart, and it also lacked some DNA normally found in oilseed rape (EFSA 2004b p. 5). It argued that not investigating these differences was an error on part of the panel. The risk protestor seems to believe that insufficient molecular characterisation implies uncertainty which means risk. Greenpeace apparently did not consider the possibility that the uncertainties pertaining to the altered DNA structure could also be "safe uncertainties" (RMNO 2004; van Asselt 2004). The same logic seems to motivate the stance of Friends of the Earth. These risk protestors explicitly attacked the lack of uncertainty information in EFSA's assessment:

> "By failing to frame its opinion within the context of continuing scientific debate and uncertainty about fundamental issues relating to its conclusions, the Panel has failed to provide decision makers with an adequate analysis of scientific uncertainty" (Friends of the Earth 2004 pp. 15-16).

This argument is used to discredit EFSA. Such equating of uncertainty with risk may be interpreted as a way to politicise uncertainty. Politicisation of uncertainty refers to the phenomenon of politicians, stakeholders, special interests groups and/or the public highlighting, amplifying or attenuating uncertainties in order to serve other interests (e.g. Funtowicz and Ravetz 1990; Pollack 2003; Smithson 1993; Stocking and Holstein 1993). Levidow *et al.* (2005) suggest that in the GMO case such politicisation of uncertainty is taking place: "[p]olicy actors play down or emphasise various uncertainties – to challenge evidence of risk or safety, to justify their stances (..), to pursue greater rigour in demonstrating safety, to mediate among conflicting views

and/or to delay (..) decisions" (p. 273). [15] That is not the point we want to raise here. We would like to point to the fact that the risk producer tried to avoid uncertainty in order to demonstrate safety, while the risk protestors highlighted uncertainty to demonstrate risk. This tendency to equate uncertainty with risk sustains the uncertainty paradox as it hampers the production and sharing of uncertainty information. Those who adhere to the absolute safety logic (i.e. zero uncertainty = zero risk), do not welcome uncertainty information. On the other hand, actors who consider uncertainty as a sign of risk tend to politicise uncertainty information, which is, according to Frewer *et al.* (2003), one of the reasons why experts hesitate to communicate uncertainty.

Technocratic Provisions

Finally, we may observe how technocratic regulatory provisions put the risk assessor, i.e. EFSA, centre stage. EFSA's role in the decision process is magnified, with the consequence that the role of EFSA's uncertainty intolerance is further increased. In all three cases, deadlocks[16] occurred because no agreement pro or against import was reached in the relevant Committees and/or the Council. To avoid procedural standstill, in such situations the Council delegates political powers to the Commission: the relevant legislation stipulates that it is the Commission that ultimately is empowered to adopt a decision.[17] Despite the resistance of several member states, the Commission could issue consents for the placing on the market of NK 603[18] and GT 73 oilseed[19] under Directive 2001/18, taking EFSA's opinion as its justification. This provision designed for extraordinary circumstances was the *de facto* standard operating procedure and it gave the leeway to adopt authorisation in line with EFSA's opinion. The Commission's decisions were a matter of rubberstamping EFSA's plausibility

proofs. As a consequence, EFSA was the *de facto* risk manager in the NK 603 and the GT 73 cases.

In the MON 810 x MON 863 case, the decision-making process was more complex, because of disagreement within EFSA's GMO panel. In 2004, the member states could not reach a majority in favour or against authorisation, but this time the Commission could not rely on a plausibility proof. So the decision-making process temporarily evaporated, partly due to changes in the regulatory regime. In 2005, EFSA issued a new opinion, this time it succeeded in producing a plausibility proof, which was again the basis for a Commission proposal to be discussed in the Committee, but again the member states could not reach a majority, so it was referred back to the Council. However, the Council did not react in the appropriate period, with the consequence that also in this case, the Commission authorised MON 863 x MON 810 in line with EFSA's plausibility proof.[20]

In view of the societal and political controversies in Europe pertaining to genetic modification (e.g. Durant *et al.* 1998; Gaskell *et al.* 2000; Gaskell *et al.* 2004; Horlick-Jones *et al.* 2007; Jasanoff 2005; Levidow 2001; Levidow *et al.* 2000, 2005, 2007; Wynne 2001), it is striking that notwithstanding the political turbulence about possible authorisation of these three GMOs, in the end the decisions about the import were taken in a technocratic manner: the Commission could simply authorise these products. Our analysis provides further evidence for Borrás' conclusion (Borrás 2006) that scientific experts continue to have a central, undisputed position in actual EU regulation of GMOs, notwithstanding rhetoric and institutional changes after the BSE crisis. So there is a clear political deficit. It is exactly such technocratic division of responsibility, and associated credibility and legitimacy questions, which were the main political concern after the BSE crisis and the *raison d'être* of EFSA (Vos 1999; Vos 2000). Our analysis adds another dimension to the old concerns: technocratic provisions sustain or even reinforce the

uncertainty paradox in situations of uncertainty intolerance on behalf of the risk producer and the risk assessor.

Conclusion

Our findings reveal that the uncertainty paradox is also manifest in the case of EU regulation of GMO imports. Our analysis indicates that in the case of EU regulation of NK 603, GT 73 and MON 810 x MON 863, the uncertainty paradox is sustained and reinforced by the interplay of four mechanisms: 1) uncertainty intolerance, 2) boundary work, 3) the inclination to equate uncertainty with risk, and 4) technocratic provisions.

The first pattern is *uncertainty intolerance* on the part of Monsanto and EFSA. EFSA's uncertainty intolerance was accompanied by *boundary work* that enabled it to claim irrelevance and to construct authority claims which served as building blocks in creating plausibility proofs. In addition, the third mechanism is the *tendency to equate uncertainty with risk*, which (further) confined risk producers and risk assessors to the role of uncertainty-intolerant producers of plausibility proofs. Finally, *technocratic provisions* resulted in an even stronger, and *de facto* political, role for EFSA, with the consequence that its uncertainty intolerance became a critical and decisive factor in the interplay. Our analysis also demonstrated that in this way the political responsibility for a highly sensitive risk dossier got lost, notwithstanding all institutions and procedures being in place and the pretence of certainty and control. Only the future will teach us whether as a consequence European society is unprepared and unable to deal with possible surprises, negative consequences and long-term impacts in the event that GMOs should turn out to have such effects. Yet, it must be emphasised that it is too early to conclude that the current situation is indeed one of organised irresponsibility.

The identification of different, although interacting, uncertainty paradox mechanisms contributes to a further understanding of the

complexities of the governance of uncertain risks and as such it provides input for theory development in the field of risk governance. The key question from a policy perspective is whether these insights can de translated into recommendations for risk regulation. The main challenge for risk governance is to break (out of) the uncertainty paradox and to rethink the role of science and expertise in risk regulation (compare Wynne 2001; Levidow *et al.* 2005 and Jasanoff 2005). Our analysis provides insights into the ways in which actors wrestle with uncertainty. What would be more responsible ways of dealing with uncertainty in the context of risk regulation? Before we share some ideas about first steps, we would like to reflect on the political discussion on EU regulation of GMOs.

The case studies discussed in this contribution lend further importance to the issue of dependence on the risk producer, which is also raised in the current political debate on the regulatory procedures in GMO authorisation.[21] The current arrangement does not only introduce dependency on the willingness of the applicant to disclose all relevant information, but also introduces dependency in terms of framing and the willingness to disclose uncertainty information. Uncertainty intolerance on behalf of the risk producer is easily inherited, which on its turn contributes to sustaining the uncertainty paradox. Especially the rat study affair illustrates that dependence is not just a theoretical issue, but an actual concern. We would recommend to policy actors to develop mechanisms that enable them to investigate and punish violations of trustworthy behaviour. It should not be so easy to hide (uncertainty) information. Furthermore, it seems necessary to develop incentives that invite risk producers to be more uncertainty tolerant.

Our analysis suggests that uncertainty intolerance is a core problem. Recognising and addressing uncertainty can inform knowledge-generation (Levidow *et al.* 2005). To counteract uncertainty intolerance, uncertainty training is needed. In current education programmes, science is presented as a body of certainty (Pollack 2003; see also Collins 1987), which nourishes

uncertainty intolerance. In all scientific education, more explicit attention should be paid to the uncertainty aspects of science (van Asselt and Petersen 2003). Our own experience with uncertainty training suggests that it changes attitudes towards uncertainty and creates openness for communicating uncertainty, without hampering the willingness to bear responsibility and take decisions. Another aim of uncertainty training is to facilitate awareness of uncertainty paradox mechanisms among people involved in risk regulation.

Furthermore, risk assessment bodies, such as EFSA, should not only include experts on issues relevant with regard to specific uncertain risks, but should also welcome uncertainty tolerant experts who are aware of mechanisms associated with the uncertainty paradox in order to organise resistance to the production of plausibility proofs. In addition to this, it might prove fruitful to organise realms where risk producers, risk assessors, risk managers and risk protestors meet, besides indirect communication through formal reports. Such two-way exchanges might help to discuss uncertainties in a different way, and might enable risk regulators to gain an understanding of what science can and cannot provide.

Informed by our research, we are convinced that the uncertainty paradox is deeply ingrained in current risk regulation arrangements and the broad socio-political order. So it will be difficult to break (out of) the uncertainty paradox. Insights into, and broader awareness of mechanisms that bring about, and sustain, the uncertainty paradox are only first, but necessary steps. When looking at the current debate on EU GMO regulation, we observe that most critics continue to frame EFSA's role in terms of the uncertainty paradox: EFSA's GMO Panel is expected resolve diverging scientific opinions and is still cast as "a body responsible for supplying *unimpeachable* scientific advice and guidance" (Randall 2006 p. 413, emphasis added). It is not recognised that the problems arise from the great burden placed on science as the basis for decisions (Levidow *et al.* 2005). In this way, an artificial certainty that glosses over any uncertainty regarding the risks of

GMOs is asked for, which only encourages and reinforces "the self-delusions of institutional science" (Wynne 2001 p. 457) and the "lack of reflexivity about the quality of the knowledge it provides" (*ibid.* p. 458). This direction further reifies the uncertainty paradox. We would like to argue that any regulatory reform is doomed to fail if the uncertainty paradox is not recognised, let alone addressed.

Notes

[1] Beck's sociological conclusions are mirrored by risk scholars (Wynne 1982; Ravetz 1996; Jasanoff 1993; Jasanoff 2005; Löfstedt 2005; Hajer 1995; Klinke and Renn 2002).

[2] Notwithstanding Knight's famous distinction between uncertainty and risk, it has been convincingly argued that risk implies uncertainty (Vercelli 1995; RMNO 2004; van Asselt 2000; van Asselt and Vos 2005, 2006; van Asselt *et al.* (in press)). However, in the case of many risks there is certainty that a particular activity yields detrimental effects (such as smoking and lung cancer), notwithstanding uncertainties pertaining to when health effects will manifest themselves, by whom, to which degree and/or where and to which extent environmental impacts will materialise. In such cases, uncertainty is limited to the contingencies of the occurrence. But there is another category of risks in which there is not only uncertainty with regard to the contingencies of the occurrence. In many controversial risk dossiers there is also uncertainty with regard to potentially complex causal relationships as well as uncertainty pertaining to kind of negative impacts, if any. In such cases, usually ambiguity also reigns, for example, with regard to the evaluation of the activity, benefits and risks. To emphasise the impossibility of calculating such risks with classical risk assessment methods, we prefer to refer to the latter class of risks as 'uncertain risks'. The notion can be considered a tautology, but tautologies do have meaning: just as 'a large giant' emphasises that even for a giant this particular one is very large, the notion 'uncertain risks' emphasises that uncertainty is a prominent feature of this category of risks.

[3] Compare Hunter (1999), Siegrist (2003) and Levidow *et al.* (2005) who also explicitly refer to gene technology in terms of "unknown risks" / "unknown, unquantifiable and (..) undiscoverable risks", "a very unknown risk" (p. 46) and "uncertain risks" respectively.

[4] For in-depth treatment and detailed overviews of the EU regulation of GMOs, see Hunter 1999; Grossman 2000; Guehlstorf and Hallstrom 2005; Vos and Wendler 2006; Borrás 2006 and Levidow *et al.* 2007.

[5] There are many scholars studying the European GMO debate and regulation of GMOs in Europe. Analyses of the GMO debate usually focus on risk perceptions among the public (see, for example, Tulloch and Lupton 2002; Siegrist 2003; Gaskell *et al.* 2004). Other studies discuss GMO regulation with an emphasis on the precautionary principle (see, for example, Levidow *et al.* 2005). For comparative studies on regulatory regimes, e.g. EU versus the United States, see e.g. Jasanoff 2005; and Guehlstorf and Hallstrom 2005. Some of these colleagues, e.g. Brain Wynne, Sheila Jasanoff and Les Levidow and his co-authors, share our special interest in how actors deal with science, knowledge and uncertainty in the GMO debate and/or regulation of GMOs. See also de Wilde and Reithler 2006.

[6] As per Directive 2001/18/EC (OJ [2001] L 106), the EFSA has to provide its opinion within 90 days of the European Commission's request.

[7] See Wynne (2001) who argues that already the framing of the issue at stake in terms of "what are the risks?" tends to narrow down to the questions "what are the scientifically demonstrable risks?", which implies excluding 'unknown' and unanticipated effects, i.e. the uncertain risks.

[8] This is the reason that Renn (2006; Renn and Walker 2008) includes framing as an important element in the pre-assessment phase.

[9] Further sources were not specified.

[10] At the time of our research, the rat study report and its summary were available on Monsanto's website on http://www.monsanto.com/monsanto/content/sci_tech/prod_safety/ratstudy.pdf. Since this website had been revamped in June 2006, this link is no longer functional and the reports are no longer available.

[11] Also in the regulatory documents related to the directives relevant for the regulation of GMOs and in additional guidelines, the Commission expresses openness to uncertainty or even explicitly calls for the description and explicit treatment of uncertainty (Levidow *et al.* 2005).

[12] It is noteworthy that this phrasing is very much in line with what Jasanoff (2005) describes as the "product" perspective on biotechnology (i.e. whether the GM product is different from the natural product) as opposed to the "process" perspective on biotechnology (i.e. whether biotechnology as such is acceptable). Jasanoff (2005) argues that the product perspective dominates in the United States, while the process perspective dominates in Europe. Our analysis suggests that the product perspective is promoted in EU regulatory practice, which provides another angle for explaining the discontent among risk protestors with the regulatory

state of affairs. In the EU, the product and the process perspectives seem to collide. It is beyond the scope of the current paper to substantiate this view on EU regulation of GMOs.

[13] Compare also Cranor (1990) who argued that "the supposedly objective scientific studies used for estimating risks to human health for regulatory purposes can be considerably (..) political" (p. 126). It can furthermore be argued that earlier boundary work in the processes of setting up the regulatory structures, enabled EU policy to define "agribiotechnology as an expert scientific issues (..) kept separate from socio-ethical issues" (Levidow *et al.* 2005: 266) which facilitated EFSA's boundary work.

[14] We did not include members of the public in our analysis. Frewer *et al.* (2003) reveal that risk experts assume that information about uncertainty will cause panic. It is beyond the scope of this study to investigate this hypothesis. However, informed by an analysis of the GMO debate in the UK and more broadly in Europe, Wynne (2001) qualifies such portrayal of the public in terms of "a naïve 'demand for zero uncertainty'" as "grotesque" (p. 476-7). He argues that the public recognises that uncertainty is inevitable, that it is not as intolerant as suggested and that "they actually recognise a more radical uncertainty (indeed indeterminacy) than that admitted by science" (p. 477). Wynne's claim is further supported by observations from focus group research: "not only did focus groups recognise the inherent uncertainties present in the GM-agriculture and food issue, they were particularly troubled by the failure of expert institutions to acknowledge [these] (..) uncertainties" (PABE report 2001 p. 7 as cited in Guehlstorf and Hallstrom 2005 p. 338). These observations suggest it is not uncertainty information that causes problems, but the experts' inability to acknowledge uncertainty.

[15] See also Levidow *et al.* (2007) in which they argue that "[c]ompeting policy agendas framed scientific uncertainty in different ways" (p. 26).

[16] Interestingly enough, these 'regulatory delays have been often called "the de facto EU council moratorium" – a misnomer for a period of intense activity' (Levidow *et al.* 2005 p. 262). Our cases demonstrate that contrary to the idea of an EU moratorium, GMOs were actually authorised for the EU market.

[17] Article 58 (2) Regulation 2002/178/EC (OJ [2002] L31/1) refers to the procedure laid down in Council Decision 1999/468/EC (OJ [1999] L 184), establishing the procedure to be followed.

[18] Commission Decision 2004/643/EC (OJ [2004] L 295).

[19] Commission Decision 2005/635/EC (OJ [2005] L 228).

[20] Commission Decision 2006/47/EC (OJ [2006] L 26).

[21] *EU Food Law Weekly*, no. 247, 10 March 2006.

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