Accountability and Risk Governance:

A Scenario-informed Reflection on European Regulation of GMOs

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Table of Contents

1. Uncertain Risks, Organized Irresponsibility and Accountability Problems

Scientific and technological progress in an ever more globalized economy has resulted in new innovations, which have often contributed to improved living conditions (Archibugi and Iammarino 1999; Archibugi and Pietrobelli 2003; Castells 1999; International Monetary Fund 2000). Yet, the very same progress has produced unprecedented risks, which are often uncertain and incalculable in nature (Giddens 1991; Beck 1986, 1999). Such 'uncertain risks' are usually associated with large-scale, long-term and transboundary hazards with which society has no or only limited experience (van Asselt and Vos 2008; van Asselt et al. 2009). As a result, their risk potential is highly contested. An exemplary uncertain risk is posed by genetically modified organisms (GMOs).[1] As it is contested whether GMOs constitute a risk to the environment and/or human health, scholars have pointed out that GMOs should be conceived of in terms of uncertainty (ibid.; Lang and Hallmann 2005; Levidow et al. 2005). Indeed, even though scientific or historical proofs of harmful consequences with regard to GMOs are lacking, "suspicions cannot be fully refuted either" (van Asselt and Vos 2008, 281). A decisive question is thus how to take decisions in the face of uncertainty (Beck 1999; Löfstedt, 2009).

The European Union (EU) plays a central role in addressing and dealing with uncertain GMO risks (van Asselt et al. 2009; Borrás 2006). GMO regulation in the EU constitutes a salient issue of risk governance, as the topic is politically highly visible and decision-making is slow and contested (Lee 2008; Renn and Walker 2007; van Asselt and Renn 2011). We understand risk governance as "the identification, assessment, management and communication" of potential hazards in the complex network that produces collective binding decisions (International Risk Governance Council 2007; van Asselt and Renn 2011). The supranational system of multi-level governance in the EU implies that authority is dispersed among many actors. Hence GMO regulation is in need of adequate mechanisms ensuring that decision-makers justify and account for their behavior (e.g.: Fisher 2004; Harlow 2002; Bovens 2007a). It has been pointed out that "the shift from national, state-based policymaking to transnational and multi-level European governance is not being matched by an equally forceful creation of appropriate accountability regimes" (Bovens

1 The term GMO refers to organisms whose genetic makeup has been restructured during the process of genetic engineering in order to alter an organism's behaviour, its growth potential or its resistance to diseases and pesticides.

2007b, 104; Harlow 2002). Lee (2008) demonstrates that the absence of accountability arrangements in the GMO regulatory framework constitutes a real gap. She argues that "who is responsible if things go wrong should be a key element of the regulatory regime for any new technology" (p.107).

The EU's political attitude towards GMO regulation has been described as precautionary (Wiener 2011; Cantley and Lex 2011; Klinke et al. 2006; Levidow, Carr and Wield 2005). Since the introduction of GMOs in Europe in 1997, Member States such as Austria, Luxembourg and Italy repeatedly imposed national bans on GM crops authorized on a European level. In spite of political controversy, the European Commission (hereafter the Commission) continued to advocate the approval of GM crops. The Commission's behavior arguably raises accountability concerns, which might ultimately result in declining legitimacy of the entire supranational system of risk governance (Skogstad 2011). In fact, Member States in the Council of Ministers (hereafter the Council) threatened with the rejection of any further authorizations until the regulatory procedures of the existing system are improved. Consequently, regulatory reforms took place between 2002 and 2004 and resulted in the present-day legal framework of GMO regulation.

Yet, important legitimacy and accountability problems of GMO regulation on the European level remain. While legitimacy aspects of GMO regulation have already been widely examined (e.g.: Borrás 2006; Skogstad 2003; Bengtsson and Klintmann 2010; Tiberghien 2009), accountability relations within the field of GMO regulation have hitherto only been weakly explored (e.g.: Skogstad 2011).[2] Nevertheless, it has been pointed out that "accountability on the EU-level remains fragile and is not secured by a comprehensive formal accountability arrangement" (van de Steeg 2009, 3).

In this paper we analyze who can be held accountable under the complex system of supranational risk governance with regard to GMO authorization, should uncertain risks materialize. In conjunction with this question, we examine why a certain actor can or even should be held accountable. In order to develop a theoretically and empirically informed answer to these questions, we apply a conceptual framework of accountability to the specific case of the authorization of Bt-11 maize[3] in the EU. The Bt-11 case covers different authorization

2 Skogstad (2011) examines difficult-to-reconcile conflicts between the internal accountability standards of Member State citizens and external accountability obligations to fellow WTO (World Trade Organization) members. Yet, we focus on the accountability relations between different actors within the process of multi-level EU risk governance.

3 Bt toxin has a deadly effect on various insects and is produced by the soil bacterium *Bacillus thuringiensis*: "by means of genetic engineering, the genes for the active agent (Bt toxin) can be transferred from Bt bacteria to plants" (GMO Compass, 2012a). Thus, Bt-11 maize is able to produce the insect toxin on its own which is meant to protect it from damage from certain insect pests and moreover "show tolerance to glufosinate ammonium herbicides" (Syngenta n.d., available online at http://www.infogm.org/IMG/pdf/snif_bt11_renew.pdf).

streams for i) food and ii) food and feed additives, each of which reveals different regulatory dynamics.[4] This allows for a thorough analysis of accountability relations with regard to different regulatory streams. We first present a conceptual framework of accountability. We then briefly outline EU regulation of GMOs in general and the two authorization streams of Bt-11 in particular. The case subsequently serves as the basis for the development a hypothetical scenario, which is used to assess accountability mechanisms. Eventually, this analysis may serve as a first step towards better understanding accountability relations within the EU authorization framework for GMOs.

We claim that the mere adherence to the regulatory procedures during the decision-making process does not necessarily imply that overall accountability can be secured, even though certain 'piecemeal' accountability may exist. The fact that overal accountability on the European level remains a delicate issue and may not be easily established within the framework of supranational risk governance can be related to Beck's (1999) notion of organized irresponsibility, which can be understood as the paradoxical situation in which contemporary society is incapable of dealing with long-term impacts of unprecedented risks notwithstanding sophisticated decision-making structures in place. Indeed, the complex system of interwoven rules can lead to a situation in which "a conviction is blocked by the very thing that was supposed to achieve it" (54): adherence to the regulatory framework can make it difficult to hold a single actor accountable and might even lead to a void of accountability. In order to test accountability relations within the multi-level framework of GMO regulation, it is, as Bovens (2006) has pointed out, imperative to establish under what conditions a certain arrangement in fact qualifies as a form of accountability.

2. Conceptualizing Accountability

Accountability is a contested and often elusive concept of which several definitions exist (Romzek and Dubnick 1987; Flinders 2001; Mulgan 2000; Scott 2006; Dowdle 2006) and it can have numerous meanings (Curtin et al. 2010). Accountability can be defined as a relationship between two parties: "A is accountable to B when A is obliged to inform B about A's (past or future) actions and decisions, to justify them, and to suffer punishment in the case of eventual misconduct" (Schedler 1999, 13). In this paper, the focus is on

4 Note that there is also a stream for iii) cultivation, which has, however, not yet been finalized and will not be discussed in this paper.

ex-post accountability: the actor has to render account after the event has taken place (Bovens 2007b, 108; Harlow 2002). So the question is whether actors involved in the authorization of Bt-11 might retrospectively be held accountable might risks materialize. We, furthermore, concentrate on public accountability: those who govern are accountable to those who are governed (Joss 2001). Depending on the forum, accountability can be classified as political (e.g. if the forum is a parliament), legal (e.g. if the forum is a court) or even administrative (e.g. if the forum is an administration such as the Court of Auditors) (Bovens 2007b, 108). Nevertheless, the *principal* forum in democracies is the public, which should ideally be able to scrutinize and judge the conduct of those who govern. Put briefly, for public accountability, also referred to as overall accountability,[5] to exist, it should always be possible to trace back the whole accountability chain to the principal forum, the citizenry. Accountability is thus defined in terms of an explicit actor-forum relationship (Bovens 2006, 2007a, 2007b). Bovens (2006, 10) argues that the relation between the actor and the forum has to be structured according to the following criteria in order to be qualified as overall accountability:

" (1) there has to be a relation between an actor and a forum,
(2) where the actor is obliged to inform about,
(3) explain and justify his conduct to the forum,
(4) so that the forum can interrogate the actor,
(5) question the legitimacy of his conduct
(6) and pass judgment on the actor's conduct
(7) which might lead to sanctions of some kind"[6]

It is important to emphasize that only when *all* these criteria are met, overall accountability is established. Yet, Bovens' criteria are not beyond criticism. Whereas van de Steeg (2009) argues that the possibility of sanctions is an essential element, Harlow and Rawlings (2007) point out that it may "rather than 'thickening' accountability, act as a deterrent by creating incentives to deny responsibility" (546). But in contrast to wider and less wel defined frameworks used by other authors (e.g.: Mulgan 2000; Behn 2001), Bovens' criteria al ow for a focused analysis: his criteria can be used as a kind of checklist. Although Bovens does not concentrate on the active process of holding to account, his accountability criteria can be employed to examine multiple accountability relations.

Our overall research question is therefore: who can be held accountable under the complex system of supranational risk governance with regard to GMO authorization in

5 Throughout the paper, we will employ the term overall accountability.

6 We read this as including the possibility of informal or soft sanctions, such as the loss of reputation.

general and Bt-11 in particular should uncertain risks materialize? In conjunction with this, two main issues need to be explored. First: to whom is account to be rendered? Thus, to which forum is an actor required to render account? Often accountability has to be rendered to numerous different forums (Bovens 2007a, 455). This is referred to as the *problem of many eyes*. Second: who should render account? Thus, who among the multiple actors involved has to appear in front of the forum? This has been called the *problem of many hands* as "policies pass through many hands before they are actually put into effect" (457). In the case of GMOs, several actors (many hands) as well as several forums (many eyes) can be identified. Through the case of Bt-11, we will analyze whether all conditions for overall accountability have been met. Are the identified actors accountable to the identified forums and are these forums able to pass judgment on the actor's conduct?

3. GMO Regulation in the EU

The present EU regulatory framework of GMOs is the result of regulatory reforms that took place between 2002 and 2004. In general, the authorization of GMOs is based on comitology, which is defined as "delegation of powers to the Commission and the supervision of the Commission's use of these powers through Committees composed of Member States' representatives" (Christiansen and Polak 2009, 5). The two key legal documents are Directive 2001/18/EC[7] on the deliberate release of GMOs (experimental or on the market) in the environment, and the Food and Feed Regulation (EC) 1829/2003.[8] The objectives include, among others, ensuring a high protection of human and animal health, taking account of environmental and consumer interests, but also providing for the proper function of the internal market. Regulation (EC) 178/2002 also defines the role of the European Food Safety Authority (EFSA), which serves as the independent scientific advisory forum to the Commission. The Commission's draft decisions on the authorization of certain GMO are forwarded to the Standing Committee on the Food Chain and Animal Health[9] (hereafter the Standing Committee). If the Standing Committee is unable to deliver a decision within 3 months or cannot reach a decision by qualified majority voting (QMV), the Commission decision is passed on to the Council. If the Council, too, is also unable to

7 Directive 2001/18/EC replaced Directive 90/220/EC.

8 Regulation (EC) 1829/2003 replaced the 1997 Novel Food Directive.

9 Consisting of representatives of all Member States and chaired by a Commission representative.

reach a decision by QMV, the authorization decision reverts back to the Commission.[10] The Commission is then in a position to take the final decision.[11]

3.1 Authorization of Bt-11 Maize

The authorization of Bt-11 is subdivided into three different streams (see Table 1). The authorization stream for cultivation of Bt-11 (Table 1 stream 1, not discussed in more detail) is still pending at the time of writing as the Council has yet to act. Bt-11 as food (stream 2) and Bt-11 as food and feed additive (stream 3) have been authorized for import and marketing in the EU. Due to our interest in ex-post accountability, we focus on stream 2 and 3.

Stream	1) Cultivation	2) Sweet Maize as Food	3) Food and Feed Additive
Scope	Cultivation, feed and industrial processing	Sweet maize as food (freshly or preserved) and food additives	Food and feed additives
Status	Risk assessment report	Valid authorization granted	Valid authorization granted
Relevant Legal Framework	Submitted under Directive 2001/18/EC (and under earlier Directive 90/220/EC). Application appropriately expanded in 2003.	The application was submitted under previous Novel Food Regulation (EC) 258/97. Assessment and licensing under Regulation (EC) 1829/2003.	Submitted under earlier Directive 90/220/EC and Novel Food Regulation (EC) 258/97. Valid license transfer. Renewal: Regulation (EC) 1829/2003
Application Date	1996 in France	11/02/1999 in the Netherlands	1996 in the UK
Decision	No QMV in Standing Committee referred to Council, which has yet to act	19/05/2004 (authorized by Commission Decision) until 18/05/2014	1998 (authorized by Commission Decision) until 18/04/2007
		Renewal in one single decision: 28/07/2010 (authorized by Commission Decision)	
Expiry date of authorization	Pending	27/07/2020	

Table 1 The different authorization phases of Bt-11 Maize divided by product use (Table by authors based on GMO Compass (2012b))

10 For an analysis of votings concerning GMOs in the Standing Committee and the Council, see: Navah, Versluis and Van Asselt, forthcoming.

11 Note, that under the new comitology procedures the Commission's ability to make the final decision has been limited (Council Decision 2006/512/EC and Treaty of the Functioning of the European Union, Art. 290 and 291).

Initially, the producer Novartis launched the authorization process of Bt-11 by applying for registration concerning food and feed additives (stream 3) in the United Kingdom (UK) in 1996. While the competent authority in the UK forwarded the dossier to the Commission with a favorable opinion, other Member States voiced their objections (Commission Decision 98/292/EC). Yet, on February 12, 1998, the Scientific Committee on Plants[12] concluded that "there are no reasons to believe that [...] [the] maize grain is likely to cause any adverse effects on human health and the environment" (preamble). Accordingly, the Commission decided in April 1998, that "consent shal be given by the competent authorities of the United Kingdom to the placing on the market of the following product, notified by Novartis Seeds Inc" (Art.1(1)) and "[t]he consent shall cover the placing on the market of the product to be used as any other maize grain but not for cultivation" (Art.1(3)). Following Art.5 of Regulation 258/97/EC, Novartis notified the Commission about its intention to place food and feed additives containing Bt-11 on the market.[13] This finalized the authorization under stream 3 for the time being.

After Novartis' fusion with Astra Zeneca, in February 1999, the company applied to the Netherlands under its new name Syngenta for placing Bt-11 as food on the market (stream 2).[14] The application was first examined by the Dutch competent authority. The Dutch risk assessment, released in May 2000, described Bt-11 to be as safe as conventional maize (GMO Compass 2012b). After the Commission had forwarded the risk assessment to the Members States, some raised reasoned objections (Commission Decision 2004/657/EC, recital 5). Following the favorable opinion of the Scientific Committee on Food with regard to the safety of Bt-11 maize (recital 9),[15] the Commission passed a draft decision to the Standing Committee. However, the Standing Committee was not able to agree with QMV (GMO Compass 2012b). Likewise, the voting in the Council resulted in a stalemate. Thus,

12 In the beginning of the authorization procedures of Bt-11, EFSA had not yet been founded. Risks assessments and opinions to inform draft decisions were carried out by EFSA's predecessors the Scientific Committee on Plants and the Scientific Committee on Food.

13 The product was included in a summary of notifications received by the Commission in Commission Notice 1999/C 181/15. After a valid license transfer, Bt-11 was referred to in a list of April 2005 concerning 26 authorized GM products that had been approved (or did not require approval) before the new legislative framework had come into effect (Europa Press Releases RAPID. Register of existing GM food and feed products published (IP/05/439)).

14 The application was submitted under the outdated Novel Food Regulation 258/97.

15 Validation studies were carried out by the Joint Research Center (JRC) of the Commission working in collaboration with the European Network of GMO Laboratories (ENGL). Recital (9) Commission Decision 2004/657/EC.

the proposal was returned to the Commission, which in May 2004 granted approval until May 2014 (Commission Decision 2004/657/EC).

In a comparable way, the Commission also decided on the renewal of authorization of Bt-11 food and feed additives, whose first-phase authorization expired in April 2007. On January 28th 2009 EFSA's GMO-Panel gave its favorable opinion for renewal (GMO Compass 2012b). Yet, as neither the Standing Committee nor the Council could reach QMV, the authorization was renewed by the Commission in July 2010 for the next ten years. The same decision also extended the authorization for Bt-11 as food until the same date, and thus combined the second and third stream into a single decision.[16] This implies that Bt-11, authorized in the EU since 1998 (stream 3) and 2004 (stream 2), can be used as food and as food and feed additive till mid 2020.

4. Testing Current Regulatory Regimes against Future Events

When investigating innovative technologies such as GMOs, it is important to note that innovation is in itself a 'generator of uncertainty' (Nowotny 2008). In such a context, developing scenarios is helpful to imagine future situations (Bishop et al. 2007; Børjeson et al. 2006; Groves and Lempert 2007; van Notten et al. 2003; van Asselt et al. 2010). A hypothetical scenario can serve as a tool to explore how uncertainties could play out in the future and what impact these might have on accountability relations with regard to supranational risk governance.

Notwithstanding the favorable risk assessments produced in the authorization processes, there has been substantial disagreement in the scientific community as to potential adverse effects of Bt-11 (e.g.: Prasifka et al. 2007; Hilbeck and Schmidt 2006). It is therefore reasonable to explore a hypothetical scenario in which such uncertain risks would materialize. On the basis of the Bt-11 case history, each juncture of the authorization process will be identified, including the actors involved and the accountability

16 Commission Decision 2010/419/EU (28 July 2010). By repealing Commission Decision 2004/657/EC that granted authorization of sweet maize as food, the Commission provided a single decision for: foods and food ingredients; feed containing, consisting of, or produced from Bt-11 maize; products other than food and feed containing or consisting of Bt-11 maize for the same uses as any other maize *with the exception of cultivation*.

relationships between them. While several forums can be identified, the public remains the principal forum to which account should be rendered. The scenario investigates who might be 'blamed' by whom, for what reasons, and whether the accused actor can be held accountable by the forum in accordance with Bovens' criteria. To structure the analysis, actors are grouped according to their roles envisioned in the regulatory framework (compare Ravetz 2001; van Asselt and Vos 2008): Syngenta as the risk producer, EFSA as the risk assessor[17] and the Member States, the Commission and the Council as the risk managers Risk management can be understood as "the process of deciding what appropriate actions to take in order to avoid, reduce, or eliminate a risk when there is (or might be) one" (Charnley and Rogers 2011, 364).. As also van Asselt and Vos (2008) have observed in authorization processes concerning other GMOs (i.e. NK603, GT73 and MON863 x MON810), in practice role ambiguity reigns. While Syngenta is naturally the risk producer, it also functions as risk assessor as a result of procedures and resources, due to which EFSA and its predecessors actually merely review the risk producers' risk assessments (EFSA 2011). Due to the political deficit (no QMV and hence technocratic decision-making) and the Commission's rubberstamping of EFSA's opinions, EFSA's role extends to that of a risk manager as will be elaborated below. Nevertheless the default roles serve as a useful guidance in the scenario development.

4.1 Hypothetical Scenario: Adverse Effects on Human Health

30 years after the initial authorization, the consumption of GM maize, including Bt-11 gene products, is linked to an outbreak of new food allergies. As warnings from the scientific community are getting louder, the media and non-governmental organizations (NGOs) are quick in picking up the topic and increase public awareness. Suddenly, retailers and the manufacturer find themselves under sharp attack. Consumers are highly worried and start boycotting most GM products. Similar to earlier food scares,[18] which are generally associated with "spiraling public anxiety over food safety incidents and escalating media attention that supplements such events" (Knowles, Moody and McEachern 2007, 43), consumer consumption and purchase behaviors are negatively affected. As a result, many retailers quickly withdraw GM products from sale. Fearing bad publicity and damage to corporate reputation, Syngenta immediately publishes a press release stating that

17 Risk assessment is a "procedure for including science in decisions about whether and to what extend risks to health, safety, or the environment should be limited" (Charnley and Rogers 2011, 362). Yet, "in nearly all cases the science, and hence the RA [risk assessment], is beset by uncertainties" (ibid.).

18 For instance the BSE crisis in 1996, the Dioxin scandal in Belgium in 1999 or the EHEC in Germany in 2011.

it adhered to all legal rules and procedures. The company also emphasizes that EFSA at the time endorsed Syngenta's risk assessment. Member States inform the Commission of the need to take emergency measures, using the Rapid Alert System for Food and Feed (RASFF).[19] The Commission reacts by recalling all products containing Bt-11 from the market.[20] Who can be held accountable under the complex system of supranational risk governance with regard to GMO authorization?

Risk Producer: Syngenta

Since the authorization process was initiated with an optimistic risk assessment by Syngenta, the first focal point is the company itself. International NGOs and the media are quick in denouncing the company for its apparent detrimental health impacts and question the credibility of Syngenta's risk assessment. In addition, some consumers seek to hold the company liable for damages occurred to them. In fact, the company's track record is not clean. Between 2001 and 2004, Syngenta mislabeled and sold unapproved and experimental Bt-10 as Bt-11 to US farmers, resulting in international public outbursts and corporate reputation damage (Herrera 2005; Bahnsen 2005). Yet, in this scenario it is unlikely that the company can be sanctioned, as Syngenta at the time of authorization adhered to all relevant legal procedures and the European authorities approved its risk assessment.[21]

Risk Assessor: EFSA

As EFSA endorsed Syngenta's risk assessments and disqualified Member States' reservations, it is likely to be asked to justify its decision. However, holding EFSA accountable may prove difficult if not impossible, due to its largely independent status (Vos 2005). When creating EFSA, the Commission failed to distinguish between two models of delegation:

19 The legal basis of the RASFF is Regulation (EC) 178/2002, which provides for emergency measures in case that food or feed (imported or of Community origin) constitutes a serious risk to human health, animal health, or the environment. Art. 50(2) states that if Member States or the Authority have "any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system".

20 In case the Commission would fail to take measures, the Member States would have the opportunity to "adopt interim protective measures" (Regulation (EC) 178/2002, Art. 54(1)).

21 Private corporate liability is indispensable for fair market conduct and safeguarding consumers' interests, but the liability debate falls outside the scope of this paper. We would, however, like to emphasize that adequate and strict liability mechanisms could provide for a serious financial incentive for risk producers to conduct a more rigid risk assessment in the first place. This is of particular importance with regard to EFSA's reliance on the initial information provided by the applicant company (EFSA 2011).

1) a mechanism under which EFSA is accountable to the Commission and 2) a clear emphasis on EFSA's independence on the other (Collins 2003). The resulting inconsistency is visible in official EU documents. While the White Paper on Food Safety superficially states that the agency should be both, independent and accountable to the European institutions (European Commission 2000, para.41), Regulation 178/2002/EC merely stresses the principle of independence (Art.37) and does not mention accountability. In this sense, accountability relationships are neither part of the institutional structures of the Commission "nor is it [EFSA] answerable to it [the Commission] with regard to the quality of its scientific advice" (Kuiper 2009, 394).

Art. 6(2) of Regulation (EC) 178/2002 states that the Commission is required to base its decision on scientific risk assessment. However, as the Commission lacks the necessary resources and scientific expertise to conduct such assessments, it has been argued that it is difficult if not almost impossible for the Commission to deviate from EFSA's recommendation (Christiansen and Polak 2009). With the Commission simply following EFSA's opinion, the functional separation between risk management and risk assessment becomes diluted. This has led to much criticism, as EFSA, now de facto both risk assessor and risk manager, is consequently in a position to yield considerable power over the authorization process (van Asselt and Vos 2008; Bengtsson and Klintman 2010).

Notwithstanding the above, there are three relevant forums to which EFSA *should* in principle render account: the Member States, the Commission and the public. First, EFSA should in principle be partly accountable to Member States. Yet, the fact that Member States are not represented in EFSA's Management Board and are thus not directly involved in scientific processes, reinforces EFSA's independence. Scholars have, however, pointed to the significant role of the Advisory Forum. The agency's Advisory Forum, which serves as a platform for the exchange of scientific information, is comprised of representatives of national food safety authorities of all EU Member States and has to meet at least four times a year (EFSA 2012a). The 'conflict clause' laid down in Art.30(4) of Regulation 178/2002 holds that "where a substantive divergence of scientific issues has been identified [...] the Authority and the national body shall be obliged to cooperate". Both representatives of the Commission and the European Parliament are free to join the Forum's meetings as stipulated by Regulation 178/2002, Art. 27(7). Moreover, Art.30(4) holds, that the Forum is supposed to "address contentious issues and diverging opinions" and, if no compromise can be reached, it has to submit to the Commission a joint document in which controversial scientific issues are clarified. While the Advisory Forum has been seen as the Member States' important link with EFSA's executive director, who chairs the Forum (Groenleer 2009), the director in fact does not answer to either the Commission or the Member States. Rather, he

is merely accountable to the board, which can remove him from office by a majority vote (ibid.). As such, the Advisory Forum has in practice a rather limited role. Consequently, one might argue that while EFSA should in principle be accountable to the Member States, EFSA is in fact *not* formally required to render account to Member States. While Member States are able to ask for explanation and justification concerning EFSA's risk assessment and EFSA is required to cooperate with Member States in case of diverging scientific opinions, Member States are in no position to pass judgment, leading to sanctions.

A second forum to which EFSA should be accountable is the Commission. In principle, even though the Commission lacks legal supervision, it is able to partly control EFSA's activities through its representation in the Management Board. EFSA's Management Board includes one Commission representative as well as 15 members appointed by the Council after consulting the European Parliament on the basis of a list drawn up by the Commission (EFSA 2012b). In addition, the Commission "sees a role for itself in the approval of the annual reports, the budget and the financial control" (Vos 2005, 128). However, the fact that EFSA only delivers non-binding opinions based on its risk assessment implies that the agency does not necessarily need to provide justification concerning its risk assessment, as it is ultimately the Commission's decision whether to follow EFSA's advice. As EFSA's role as risk assessor is thus in principle divorced from the Commission's role as risk manager, EFSA is indeed *not* answerable to the Commission. In case uncertain risks materialize, EFSA may argue to be merely the risk assessor and that it is ultimately up to the Commission's judgment whether or not to follow EFSA's advice. While the Commission may question the legitimacy of EFSA's conduct, it is unable to pass judgment, leading to sanctions. At best, a loss of reputation concerning EFSA's credibility might occur.

Third, the last and most important forum is the public. Regulation (EC) 178/2002, Art.10 clearly assigns the duty to EFSA to inform the public in a transparent manner concerning potential risks stemming from food products. In particular, Art. 38 holds that EFSA should make public without delay "(a) agendas and minutes of the Scientific Committee and the Scientific Panels (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included (c) information on which its opinion is based." In addition, the Regulation requires EFSA to guarantee the inclusion of concerns of relevant stakeholders and develop "effective contacts with consumer representatives, producer representatives, processors and any other interested parties" (Art. 42). The agency has created online public consultation forums, in which members of the public and interested parties can express concerns with regard to specific scientific issues and submit relevant information and data (EFSA 2012a). Yet, even though the agency has developed a relatively open structure of public consultation procedures

and has willingly provided information in a transparent manner during the authorization process of Bt- 11, the public is unlikely to be able to ask for justification or to actively interrogate EFSA. Indeed, while the public may question the legitimacy of EFSA's conduct in case uncertain risks materialize, it is in no position to pass judgment, leading to sanctions.

In sum, although EFSA is a highly influential body due to its role as risk assessor and de facto risk manager, it seems to be hardly accountable to any forum. In case uncertain risks materialize, EFSA may refer to its primary de jure role as merely risk assessor and ignore its de facto role as risk manager. Although in regulatory practice a 'grey zone' between risk assessment and risk management has emerged, the strict separation between risk assessment and risk management is inscribed in the regulatory framework (Vos and Wendler 2006). This is likely to be emphasized by EFSA to reject responsibility and it might well be an effective defense.

Risk Managers: Member States, the Commission and the Council

Member States, the ministers in the Council and the Commission are other important actors during the authorization process of Bt-11. Member States were involved in the authorization process by voting in the Standing Committee and in the Council. In principle, Member States are accountable to their public, as national voters through parliaments can hold national ministers to account for their conduct in the Council (Gallagher et al. 2005). Yet, considering the time passed between the initial authorization and the outbreak of food allergies, the term of office of the responsible ministers is likely to have already elapsed. In theory, their successors are accountable for all their acts, but in practice it might be more difficult to hold individual ministers to account, e.g. when their party affiliations are different or the new minister was a critical MP at the time of authorization.[22]

During the authorization for Bt-11 as food, the vote in the Council resulted in a stalemate. The decision therefore reverted back to the Commission who in turn decided to rely on its initial draft proposal and subsequently authorized Bt-11 for consumption. This complicates the situation as the final decision was made by a technocratic body which is not as accountable as national ministers would be. The Commission inevitably took a decision not endorsed by QMV in the Council (van Asselt and Vos 2008; Christiansen and Polak 2009), which situation van Asselt and Vos (2008) qualify as a political deficit.

In principle, the Commission is accountable to the European Parliament (EP) as well as to the public. Although the European Parliament is not involved in the decision-making

22 It is beyond the scope of this paper to review the academic literature on (political) accountability at the national level in view of this elapse of term of office.

process of GMO authorization, it may retrospectively still act as an important forum to give voice to the European citizens.[23] Van Gerven (2005) shows that under current Community Law "members of the Commission are bound to explain their action to the European Parliament, and they can be held accountable by Parliament when those actions constitute wrongful behavior" (83). The European Parliament's right to interrogate Commissioners is stated in Art.230 of the Treaty on the Functioning of the European Union (TFEU): "The Commission shall reply orally or in writing to questions put to it by the European Parliament or by its Members". Moreover, the European Parliament is able to censure the Commission according to Art.234 of the TFEU, or even force the whole body of the Commission to step down.[24] Here again, the problem is that the term of office of the Commissioners responsible for the authorization might already have elapsed. So the accountability relationship between the Commission and the European Parliament in case of future materialization of uncertain risks seems weak.

Admittedly, the public has the opportunity to make comments to the Commission following the publication of EFSA's opinion as stated in Regulation (EC) 1829/2003, Art.6(7). However, "neither the scope nor the salience of such comments is outlined" and the Commission is "not specifically mandated to take these [comments] into account" (Scott 2004, 20). In fact, the Commission is merely required to take into account EFSA's opinion. Only if the Commission's recommendation on authorization differs from EFSA's opinion, explanations of the underlying reasons are indispensable (Skogstad 2011, 9). Yet, this was not the case regarding Bt-11 as food and food and feed additives (stream 2 and 3). As a result, the public is retrospectively not in a position to ask for explanation and justification or to actively interrogate the Commission. While it may question the legitimacy of the Commission's conduct, it is unable to pass judgment, leading to sanctions. As such, accountability relations between the Commission and the public are as good as nonexistent.

The members of the Council are individually accountable to the public and their national parliaments. However, since the emergence of majority voting with the Single European Act of 1986, in their national parliaments, ministers are able to justify taken decisions by claiming that they did their best to secure a particular policy, but were outvoted (Bogdanor 2007). While this of course does not always happen, in principle,

23 This has been demonstrated by the European Parliament's inquiry report with regard to the management of the EU BSE crisis (European Parliament, 1997).

24 In 1999, for example, the Santer Commission was successfully pressured into resigning after having been accused of serious mismanagement and corruption.

an individual minister "cannot be made accountable to his or her national parliament for a decision that has been taken by others" (6). Nevertheless, the Council missed the chance of representing Member States' interests (and thereby national public's interests) by having been unable to reach a compromise and left the decision to an unelected and bureaucratic body. This political deficit, which was already undermining the legitimacy of the decision (Borrás 2006) might thus have severe consequences also in view of ex-post accountability. Here again, the public as the principal forum is in a difficult position to hold the Council to account. Only national parliaments are able to ask for explanation and justification and to actively interrogate the Council. While both the public and national parliaments might question the legitimacy of the actors' conduct, neither of the two forums is in a position to pass judgment, which might lead to sanctions. At best, informal sanctions might entail a loss of reputation. Thus, at the supranational level, accountability relationships get diffused, which relates to the problems of many hands and many eyes, as regulatory decisions pass through many hands before being implemented, and as account has to be rendered to numerous forums. However, none of the forums seem able to pass a judgment and sanction in case uncertain risks of Bt-11 would materialize in the way envisioned in this scenario.

5. Conclusion

We attempted to explore accountability relations within the supranational multi-level framework of GMO risk governance by means of a hypothetical scenario on adverse effects associated with GMOs in general and Bt-11 in particular. Informed by the regulatory history and state of affairs pertaining to Bt-11, we tested current regulatory standards and future events against the accountability criteria as developed by Bovens. We focused on ex-post accountability to assess whether actors can be retrospectively held accountable: do the rules, regulatory procedures and institutional arrangements sufficiently provide for accountability in case that the outcome of the decision-making process is not satisfactory? While legitimacy of GMO regulation has frequently been discussed in the academic literature, accountability issues are rather underrepresented. Still, as accountability is a necessary prerequisite for legitimacy, its significance should not be underestimated. Decreased accountability may lead to weaker legitimacy.

Our findings can be summarized in three points: First, each actor in the authorization process can at best be partly held accountable for his conduct. Hence, overall accountability cannot be established. Second, each actor is able to point to its compliance with the legal

rules and procedures of GMO regulation at the times of authorization, which makes it difficult to pass a negative judgment. Third, each actor can refer to the involvement of other actors in reaching the final decision, by which the 'blame' can be shifted to other actors in the accountability chain. In sum, these points reflect Beck's hypothesis of organized irresponsibility: a situation where regulatory structures are unable to sufficiently address negative consequences and long-term impacts, notwithstanding that most actors adhered to the rules and procedures in place. Yet, we do not claim that no accountability is in place, as 'piecemeal accountability' can be established. We suggest the notion piecemeal accountability for situations in which one or more, but not al of the seven Boven's criteria are satisfied. In European GMO regulation, overall accountability, with al Bovens' criteria met, is not in place.

With these findings, we are able to demonstrate that uncertain risks resulting from technological progress and innovation pose a particular governance challenge. The current system of European GMO regulation is unable to sufficiently hold actors accountable, should uncertain risks materialize. This adds an important dimension to ongoing scholarly and societal debates on risk governance. Our scenario-informed reflection based on the authorization of one GMO provides a basis for agenda-setting the issue of accountability and for arguing that this kind of scenario thinking is productive to explore accountability relationships. It does, however, not provide a sufficient basis for concrete suggestions what is needed to improve accountability relations in the EU risk regulatory system. But it is clear that in the current European regulatory framework on GMOs in particular and probably on innovation induced risks more generally, the pursuit of accountability relations is simultaneous necessary but difficult to achieve.

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