Responsible Innovation in GMO Governance: A way out of the Stalemate?

A case study of the assessment of MON810 in Norway

Amelie Riedesel
a.riedeselfreiinzueisenbach@student.maastrichtuniversity.nl

ABSTRACT
GMOs have caused controversy since their introduction to the European market. By relying on health and environmental risks assessment, decision-making in biotechnology excludes a diversity of concerns and stakeholders. Despite increasing efforts for public and stakeholder engagement the debate is highly polarized. *Responsible Innovation* might provide a way out of the stalemate. By conducting a case study of the assessment of MON810 in Norway, this paper explores the underlying elements of RI in existing frameworks in order to investigate how RI can offer an approach to open up new and more responsive governance options in regulating GMOs in Europe. The analysis has revealed that key to responsiveness is the institutionalization and integrations of all RI dimensions in the regulatory framework.

Keywords
Responsible Innovation, GMO governance, Norwegian Regulation Framework

INTRODUCTION
Although Genetically Modified Organisms (GMOs) might have the potential for feeding the world more sustainably, they have raised a polarizing controversy. Despite the complex und uncertain nature of the technology's impacts, by relying on scientific assessment of health and environmental risk, decision-making has narrowed down the debate about GMOs to one of "technical questions" (Gaskell *et al*, 2004). Notwithstanding the diversity of socio-economic, cultural and ethical concerns, preferences and attitudes, public skepticism has been framed as a risk issue and deviating concerns have been labeled as irrational fears, resulting from scientific ignorance (Torgersen, 2004; Wynne, 2001).Yet, initiatives to educate the public did not increase the acceptance and shifting the focus on public engagement has shown little success.

The debate about GMOs is stuck in a stalemate. If policy initiatives aimed at reforming the regulation keep narrowly focusing on a risk-benefit calculus, then it is likely that further attempts to achieve social acceptability will not contribute to finding a way out (Macnaghten, Carro-Ripalda & Burity, 2015). Instead of boiling down the discussion to one of risk and safety, different questions should be posed: Could GMOs contribute to sustainable development and societal utility? Who will benefit, who will loose? Do they have the potential to solve the "grand challenges of our time" (von Schomberg, 2013)?

Nevertheless, the question how governance should engage with issues which exceed the risk dimension, is a challenging one. Despite initiatives aimed to increase public participation, current forms of regulatory governance offer little capacity for reflection on the purpose of science or innovation or on wider ethical and social impacts. Nevertheless, by formulating questions about values, benefits and socio-economic aspects of a technology as well as questions about the very *purposes* of science and innovation (Jasanoff, 2005; Owen *et al*, 2013), the currently widely discussed concept *Responsible Innovation* (RI) might be a way forth. This thesis tries to explore the tools RI can provide to open up the debate, being guided by the following research question: How can the Responsible Innovation framework offer an approach to open up new and more responsive governance options in regulating Genetically Modified Organisms in Europe?

To answer this question, a case study has been conducted, aiming to detect underlying elements of RI in already existing frameworks. Integrating tools to assess sustainability, societal utility and ethical considerations, the Norwegian framework provides a comprehensive ground for analysis. In particular, the assessment of the *Bt*-maize MON810 is examined in order to explore how elements of RI are reflected in the Norwegian regulatory framework and what RI can add to these elements in order to make the governance framework more responsive. Owen *et. al*.'s (2013) *anticipation-reflexivity-inclusion-responsiveness* framework (ARIR-Framework[1]) will be applied to the Norwegian case, in order to examine if the four significant procedural dimensions of RI might reveal possible governance options that could be adopted by EU Member States as well.

Limits can be seen in the narrow range of practical experiences with the RI approach. Nevertheless, the aim is not to provide a RI tool kit but rather to contribute one input into a wider debate that is likely to shape policy in the near future.

A BRIEF INTRODUCTION TO RESPONSIBLE INNOVATION
RI emerged with the growing demand for public engagement in decision making processes regarding new technologies (Owen, Macnaghten, Stilgoe; 2012, p. 751). René von Schomberg's definition of the concept is widely referred to in RI literature, describing RI as:

"A transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)." (Von Schomberg 2011; p.9).

This definition reveals several important aspects of the concept: RI integrates a *product* and a *process* dimension of a technology, seeking to achieve acceptable and even desirable outcomes (Stahl, 2012, p.709). The product dimension incorporates the idea that science and innovation are steered to achieve desirable outcomes *for* society, seeking an inclusive, democratic way to answer the question *'what sort of future do we collectively want innovation to create for Europe?'* (Owen *et al*, 2012). For this, RI aims for innovation being targeted towards "right impacts", which, anchored in societal values, are supposed to solve societal challenges

[1] in the literature, the framework is referred to as the AIRR-framework by Macnaghten *et al.* (2015). Macnaghten *et al.* have arranged the dimensions in a different order (anticipation-inclusion-reflexivity-responsiveness) than initially set up by Owen *et al.* (2013). Since Owen *et al* have not named the framework but he order initially set up by Owen *et al.* is referred to in this paper, the anagram has been modified accordingly.

(Von Schomberg, 2013). The process dimension focuses on the procedural values of innovation that involve inclusive engagement *with* society. Owen *et al.* (2013) have developed a framework that integrates four dimensions:

- *anticipation* - understanding the complex interaction of a technology with its social and environmental surroundings;
- *reflexivity* - requiring scientists and policy makers to reflect on their responsibilities and the underlying values of their work
- *inclusion* - enabling early stakeholder and public engagement
- *responsiveness* - the capacity to change shape and direction in reaction to stakeholder and public values, new information about potential impacts, alternatives.

These dimensions are hardly new individually, however it is the emphasis on their integration and institutionalization that make the approach a novelty (Stilgoe, Owen & Macnaghten, 2013).

CASE STUDY - MON810 IN NORWAY

Case Selection and Method

Norway has been selected for the case study, as it is a pioneer in the holistic assessment of GMOs, evaluating both their physical and social impact since 1993 (Roger, 2015). The RI approach is present in the Norwegian Gene Technology Act[2], which uniquely requires a demonstration of social benefit and contribution to sustainable development being in line with ethical considerations , for GMOs to be approved for release.

MON810 is a Bt- maize that can be used to control maize insect pests including the larvae of the European corn borer, a moth that can seriously damage the corn harvest (Tefera *et a*l., 2016). The assessment of MON810 is analyzed as it remains the only GMO that is authorized for cultivation in Europe. Safeguard measures by European Member States caused controversy and concerns about the politicization of risk assessment. It is thus interesting to evaluate in how far the Norwegian model could be seen as an example for EU Member States.

The analysis is based on assessment reports by the Norwegian Environment Agency (NEA; Miljødirektoratet); GenØk – Centre of Biosafety, Scientific Committee on Food Safety (VKM), the Norwegian Biotechnology Advisory Board (NBAB) and the Norwegian Directorate for Nature Management (DN) as well on a range of secondary literature on the Norwegian assessment of GMOs.

Regulatory Context

As Norway is part of the European Economic Area (EEA), EU directives and regulations for the most part also apply to Norwegian assessments of applications for import, trade and cultivation of GMOs (Roger, 2015). In the event that a GMO application has been approved in the EU, Norwegian regulators can decide against it, if it presents potential health and environmental risk or if it violates the Norwegian Gene Technology Act (Rosendal, 2009). Like the European regulatory framework, the Act establishes that GMOs must prove to have no detrimental effects on the environment or human health, but further by stating that the deliberate release of genetically modified organisms should represent a "benefit to the community", enable "sustainable development" and is ethically justifiable[3].

In the case of MON810, the Norwegian Ministry of Environment (KLD) has commissioned the NEA to deliver a final assessment of the case of MON810 with an overall recommendation. After scientific risk assessment by the Norwegian Food Safety Authority (MT), based on the basis of the Scientific Committee on Food Safety (VKM) – which concluded that cultivation of maize MON810 is unlikely to have any adverse effect on the environment in Norway (VKM, 2013) - and a societal assessment conducted by the NBAB – which concluded that MON810 is unlikely to contribute to sustainably development and societal utility - the NEA suggested not to authorize cultivation of MON810 in Norway.

RESPONSIBLE INNOVATION IN ACTION?

The ARIR-Framework in assessing MON810

In the assessment of MON810, sustainability effects, socio-economic considerations and ethical concerns outweighed scientific risk assessments that suggested that the maize does not harm on environment and health (NBAB 2013). The Norwegian regulatory framework thus integrates product values of Von Schomberg's definition of RI, which emphasizes "ethical acceptability, sustainability and societal desirability" (von Schomberg, 2011). In order to examine the procedural dimension of the Norwegian regulatory framework, the assessment of the *Bt*- maize MON810 will be evaluated in the light of the ARIR- Framework.

Anticipation

The assessment of MON810 has revealed anticipation by going beyond the evaluation of short-term impacts and further involved studies of potential far-off future scenarios, addressing the potential long-term threat that might be posed if the target insect develops resistance to the released protein. In order to discover wether the Bt-maize will increase productivity, the NBAB compares it to its closest non modified relative (Miljødirektoratet, 2015). Moreover, after having evaluated the crop's necessity, the NBAB points out that since the insect MON810 is targeted against is barely found in Norway, the possible societal problems that can be solved by cultivating the maize are therefore not relevant (NBAB, 2013). Furthermore, the NBAB remarks that MON810 will lead to additional costs for society, farmers and other members of the production chain, as it would require a new set up of rules for coexistence and systems to keep MON810 separate from non-genetically modified maize (Miljødirektoratet, 2015). Taking this wide range of aspects into consideration, the NBAB concludes that – despite the positive outcome of scientific risk assessment - the cultivation of MON810 is a negative contribution to both community benefit and sustainability (NBAB, 2013).

A problem that became apparent in the analysis, is the lack of data and independent research in both safety and societal assessments (Myhr & Rosendal, 2009). To what extend the Gene Technology Act places the responsibility on Norwegian authorities for finding and collecting data on sustainable development and societal utility, thus remains an unresolved legal question.

Reflexivity

As demonstrated in the level of anticipation, the Norwegian regulatory framework shows reflexivity by moving beyond the predominant reductionist frame within crop science laboratory practice, which does not take into account the technology's integration in a broader socio-ecological system

---

[2] Act No. 38 of April 2, 1993 relating to the Production and Use of Genetically Modified Organisms

[2] Article 1 and 10

(Myhr & Rosendal, 2009). Reflexivity has also been revealed in reports of different agencies. The NEA acknowledges the complexity and unpredictability of the relation of MON810 and its social and ecological environment and points to a lack of societal information that prove its contribution to societal utility (Miljødirektorate, 2014).

Nevertheless, the analysis of the assessment of MON810 has illuminated some issues that can be attributed to a lack of reflexivity. While the NBAB's ecological sustainability assessment has revealed risks concerning resistance building of the target insect (NBAB, 2013), VKM's environmental risk assessment has acknowledged uncertainties in this regard, but concludes that the cultivation of maize MON810 is unlikely to have any adverse effect on the environment in Norway (VKM, 2013). This indicates different interpretation of uncertainties, while for NBAB the uncertainty is defined as a risk, VKM interprets the absence of certainty as safety[4] The interpretations illustrate the importance to reflect on the framing of the issue and underlying values that might be involved in the risk and societal assessments.

Furthermore, since scientific risk assessment of MON810, conducted by the VKM GMO Panel, is based on information provided by Monsanto, EFSA and other member states as well as on peer-reviewed scientific literature (VKM, 2013, p. 3), there is a lack of independent, transparent research.

Inclusion

Norway has various procedures to engage the public and a diversity of stakeholders in decision making. First, the Norwegian regulatory framework provides public access to information on applications for GM crops approval (Binimelis & Myhr, 2015, p.18). Second, as done in the case of MON810 after the first application in 1999 and during the renewal in 2008, the NBAB conducts national hearings for each GMO notification (Miljødirektorate, 2014). Third, the NBAB tries to provide for inclusion by interweaving expert and stakeholder inputs and forms of values and knowledge (Binimelis & Myhr, 2015). The composition of NBAB reflects that expertise is not exclusively possessed by scientists but also by other relevant stakeholders that contribute a diversity of knowledge and experience.

Responsiveness

Norway's regulatory system provides institutional structures and norms that have opened up the debate on the governance of GMOs and transcended it beyond their risk dimensions. It integrates societal advisory bodies parallel to the scientific advisory bodies and uses stakeholder and other public deliberative forums to consider the broader cultural, societal and ethical dimensions of the technologies (Macnaghten, 2015, p.237). This has been explicitly shown in the case of MON810, where societal utility and social values were taken into account through public consultations, research programs and stakeholder engagement (NBAB, 2013). Nevertheless, high level of anticipation and inclusion alone does not improve decision making, if it is not responsive to these processes (Stilgoe *et al*. 2013). Rosendal (2008) argues that it is not entirely clear in how far these concerns are actually taken into account in the final decision. The lack of reflexivity - in terms of scientists' and policy makers' values responsibilities - might become a problem in this regard.

It can be argued that the main reason for rejecting of MON810 in Norway is the lack of economic benefit rather than cultural and ethical concerns (Rosendal, 2008). Due to geographical conditions in Norway, proposed GMOs had little practical utility for Norwegian farmers. Thus, the GMO issue has not been very controversial in Norway (Rosendal, 2008). As the Norwegian public is generally against biotechnology and farmers advertise with "GMO-free zones", a GMO that might contribute to sustainable development and is economically beneficial for farmers might raise debate and controversy (Rosendal, 2008; Myhr & Rosendal, 2009). Learning from the European issues regarding GMO regulation, responsive governance options are a significant factor to prevent such controversy. The RI framework offers tools to better integrate the four dimensions in order to make GMO governance more responsive.

Towards Responsible GMO Governance

First, a tool offered by the RI framework that could enhance anticipation is an independent, publicly funded interdisciplinary research programme (Macnaghten, 2015) with social sciences and life sciences as equal partners. Such a program would help to investigate on how the Norwegian societal and scientific assessment could be better integrated to constructively arrive at a common ground. Furthermore, before thinking about how they could be otherwise configured, there is need to contextualize GM crop's social and ethical impacts. This involves discussions about the initial purposes of the technology in regard to the neoliberal political environment in which they were promoted. Second, reflexivity in the Norwegian regulation can be improved by initiatives that encourage scientists and policy makers to reflect on their own responsibilities and to be aware of the limits of their current knowledge and the framing of the issue (Stilgoe et al, 2013). As evident in the case of MON810, it is important that scientists and policy makers are mindful of the underlying values that frame their research. As has been done in NBAB, an advancement in scientific assessment may be the development of multidisciplinary collaboration and trainings that brings together social scientists and ethicists in scientific laboratories (Macnaghten, 2015). Third, the independent research program should aim to enhance inclusion by engaging a multiple range of stakeholders in the scientific assessment as well as societal assessment of GMOs. To enhance deliberation between different Norwegian interest groups, the program should help to identify common definitions, ensure wide and diverse participation and create support structures that allow people to form mature and informed perspectives and a sense of commitment for ongoing engagement. The enhancement and institutionalization of the anticipatory, inclusive and reflexive dimension will then lead to improved institutional capacities that can better respond to societal concerns and changing circumstances.

CONCLUSION

To conclude, this paper has investigated how the responsible innovation framework can provide tools for more responsive GMO governance in order to move the European debate on biotechnology out of its current sterile deadlock. By transcending the dimension of risk and addressing the complexity of the technology's socio-ecological context, RI seeks to steer innovation towards the "right impacts" in order to contribute to a desirable future. This involves deeply interrelated product and process dimensions. The case study revealed that arriving at more responsive governance options requires institutionalization and integration of both dimensions. While the Norwegian GTA establishes the product values sustainable development and societal utility, the regulatory framework has demonstrated shortcomings in the integration of the procedural values. Indeed, the Norwegian model has institutional capacities to ensure broad anticipation that transcends the dimension of risk and enables considerably wide stakeholder and public engagement. However, the framework lacks reflexivity, which includes the

[4] See Van Asselt & Vos (2008), "Uncertainty = risk tendency" (p.290)

capacity of researchers to be mindful about their responsibilities, values and limitations, which can result in a lack of responsiveness. Since the Norwegian public is generally against GMOs, vindication of an application - although gone through societal impact assessment - may raise controversy in the future. If the four dimensions anticipation, reflexivity, inclusion and responsiveness are integrated and institutionalized more deeply and coherently, the infertile GMO controversy that has been experienced in Europe, could possibly be prevented in Norway.

Having learned from RI, the Norwegian model could then function as an example for European Member States. Implementing regulations like the Norwegian GTA paired with RI tools that promote anticipation, reflexivity, inclusion and responsiveness in less responsive European regulatory contexts, might open up the sterile debate about benefits and risks of biotechnology and offer new possibilities for using GMOs responsibly. However, this requires constant and critical reflection on the underlying purposes of technology and the question how it can contribute towards a better future . Nevertheless, given complexity and uncertainty of its impacts, a critical reflection on the technology's purposes needs to be paired with consideration of less risky and more beneficial alternatives (Hartley *et al*, 2016). If the goal of the technology is to feed the world and to address the problem of malnutrition (Borlaug, 2000), alternatives to producing sufficient food for the entire world population need to be investigated. Therefore, it is time to open up the narrow debate on risks and benefits of biotechnology to a wide ranging discussion about sustainable food and agricultural systems.

ROLE OF THE STUDENT

Amelie Riedesel was an undergraduate student working under the supervision of Marjolein B.A.van Asselt, Ellen Vos and Denise Prévost in the MaRBLe Project *Law, Science and Uncertain Risks* when the research in this report was performed. The student worked in a research group with the students Milena Bulté and Ilaria Gliottone. The selection of the topic, the processing of the results as well formulation of the conclusions and the writing were done by the student.

I permit this thesis to be published in the scientific e-journal of the University College Roosevelt.

REFERENCES

1. Binimelis, R. & Myhr, A.I. (2016). Inclusion and implementation of socio-economics considerations in GMO regulations: needs and recommendations. *Sustainability* 8 (1),
2. Gaskell, G., Allum, N., Wagner, W., Kronberger, N., Torgersen, H., Hampel, J., Bardes, J. (2004). GM foods and the misperception of risk perception. *Risk Analysis* 24: 185–194
3. Hartley S., Gillund F., van Hove L, Wickson F. (2016). Essential Features of Responsible Governance of Agricultural Biotechnology. PLoS Biol 14(5): e1002453.
4. Jasanoff, S. (2005). Technologies of Humility: Citizen Participation in Governing Science. Wozu Experten?, 370-389
5. Macnaghten, P. (2015). A responsible innovation governance framework for GM crops: global lessons for agricultural sustainability. In: In;Macnaghten, P., & Carro-Ripalda, S. (2015). *Governing agricultural sustainability: global lessons from GM crops*. London: Routledge, Taylor & Francis Group. 225-23
6. Macnaghten, P.; Carro-Ripalda, S., Burity, J. (2015). Researching GM crops in a global context. In: In;Macnaghten, P., & Carro-Ripalda, S. (2015). *Governing agricultural sustainability: global lessons from GM crops*. London: Routledge, Taylor & Francis Group. 5-32
7. Miljødirektoratet (2015). Genmodifisert mais MON810: Helhetlig vurdering og anbefaling til vedtak. Rapport. M-272.
8. Myhr, A.I. & Traavik, T. (2003). Sustainabledevelopment and Norwegian genetic engineering regulations: applications, impacts, and challenges. *Journal of Agricultural* and Environmental Ethics, 16. 317-335
9. Myhr, A.I., Rosendal, K. (2009). GMO Assessment in Norway as compared to EU procedures: Societal Utility and Sustainable Development. Trondheim, Norway: The Directorate for Nature Management. http://www.dirnat.no/attachment.ap?id=10784
10. Norwegian Biotechnology Advisory Board (NBAB/ Bioteknologirådet) (2013). Sluttbehandling av den insektresistente, genmodifiserte maisen MON810: Vurdering av dyrking i Noreg. Dykkar
11. Owen R., Macnaghten P., Stilgoe J., Gorman M., Fisher E,, and Guston D., (2013). A framework for responsible innovation in Owen R., Bessant J., and Heitz M., (eds) *Responsible innovation: managing the responsible emergence of science and innovation in society*. John Wiley, Chichester 27–50
12. Rosendal, G. K., & Myhr, A. I. (2009). GMO assessment in Norway: societal utility and sustainable development. *EMBO Reports*, 10(9), 939–940. http://doi.org/10.1038/embor.2009.189
13. Roger, A. (2015). In the Public Interest? A Comparative Analysis of Norway and EU GMO Regulations. *Review of European, Comparative & International Environmental Law*, 24(3), 264-277.
14. Spök, A. (2011). *Assessing socio-economic impacts of GMOs, issues to consider for policy development*—final report. Federal Ministry of Health; Federal Ministry for Agriculture, Forestry, Environment, and Water Management, Vienna.
15. Stahl, B.C. (2013). Responsible research and innovation: The role of privacy in an emerging framework. *Science and Public Policy*. 40 (6): 708–716.
16. Stilgoe J., Owen R., and Macnaghten P., (2013) Developing a framework of responsible Innovation. *Research Policy* 42 1568–158
17. Tefera, T., Mugo, S., Mwimali, M., Anani, B., Tende, R., Beyene, Y., ... Prasanna, B. M. (2016). Resistance of Bt-maize (MON810) against the stem borers Busseola fusca (Fuller) and Chilo partellus (Swinhoe) and its yield performance in Kenya. Crop Protection (Guildford, Surrey), 89, 202–208. http://doi.org/10.1016/j.cropro.2016.07.023
18. Torgersen, H. (2004). The real and perceived risks of genetically modified organisms. *EMBO Reports*, *5*(Suppl 1), S17–S21. http://doi.org/10.1038/sj.embor.7400231
19. Van Asselt, M. B. A. & Vos, E. (2008) Wrestling with uncertain risks:EU regulation of GMOs and the uncertainty paradox. *Journal of Risk Research*, 11:1- 2, 281-300
20. VKM (2013) (Norwegian Scientific Committee for Food Safety. Environmental risk assessment of insect resistant genetically modified maize MON810 for cultivation, seed production, import, processing and feed uses under Directive 2001/18/EC (Notification C/F/95/12/02). 12/313 – final. http://www.vkm.no/dav/c758c03e41.pdf assessed: 28.06.2017
21. Von Schomberg, R. (ed.) (2011) Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields. Luxembourg: Publications Office of the European Union
22. Von Schomberg, R. (2013), A vision of responsible innovation. In: R.Owen, M. Heintz and J. Bessant (2013). *Responsible Innovation*. London: John Wiley