Report of the Research Evaluation Panel

GenØk – Centre for Biosafety

EXECUTIVE SUMMARY

Norwegian

GenØk - Senter for biosikkerhet har nylig vært gjenstand for evaluering av vitenskapelig kvalitet basert på senterets publikasjoner i perioden 2010-2018. I denne rapporten presenteres evalueringspanelets konklusjoner. Innledningsvis beskrives GenØks arbeid og utvidete rolle innenfor norsk politikkutforming på dette området, før rapporten tegner et bilde av GenØks vitenskapelige fokus, bemanning og publikasjonsnivå. Spesifikke evalueringer presenteres under fire tematiske overskrifter: miljø/toksikologi; virologi/immunologi; mikrobiologi/molekylærbiologi og ELSA - Etiske, rettslige og samfunnsmessige aspekter ved ny teknologi/samfunnsvitenskap. Den generelle vitenskapelige kvaliteten på GenØks publikasjoner er vurdert som "meget god" (karakter 5 på en 7-punkts skala). Avslutningsvis viser rapporten hvordan GenØks arbeid har bidratt til identifisering av både synergier og kunnskapshull og hvordan GenØk har levert unike bidrag til et fagfelt med vesentlige vitenskapelige og samfunnsmessige utfordringer.

English

This report represents the output from the Research Evaluation Panel into the scientific quality of the publications generated by GenØk – Centre for Biosafety. The analysis covers the period from 2010-2018. Following an introduction to the work of GenØk and the larger context of Norwegian policy in this area, the report summarizes GenØk's scientific focus, staffing and publication levels. The Research Evaluation Panel presents its specific research evaluation under four thematic headings: environment/toxicology; virology/immunology; microbiology/molecular biology; ELSA – Ethical, legal and social aspects of new technologies/social sciences. The overall scientific quality of GenØk's research output is rated as 'very good' (a grade of 5 on a 7-point scale). Finally, the report identifies some areas of synergy and knowledge gap identification in GenØk's work before noting GenØk's unique contribution to a field of significant scientific as well as societal concern.

Section 1: INTRODUCTION AND BACKGROUND

Purpose

GenØk – Centre for Biosafety was founded in 1998. It is a non-commercial foundation located at UiT - The Arctic University of Norway and SIVA Innovation Centre in Tromsø, Norway.

GenØk's vision is *Safe Use of Biotechnologies*. Its current mission focuses on research, capacity-building and advice on risk assessment and management of Genetically Modified Organisms (GMOs) and emerging biotechnologies. Accordingly, the research institute conducts research on the environmental, health and social consequences of genetic engineering and genetic modification. GenØk also conducts informational activities, advisory work and consulting within its area of competence.

GenØk receives funding from a number of sources, including the Ministry of Climate and Environment, the Ministry of Foreign Affairs, the Norwegian Environment Agency, Norad, Norec and

DiKu, plus the Norwegian Research Council and European sources such as Horizon2020 and Marie Curie Actions. Advisory activities have included work with the Norwegian Environment Agency, the Biotechnology Advisory Board and the Norwegian Scientific Committee for Food Safety. GenØk has also undertaken public involvement and science communication activities: including seminars, workshops, school visits, research days, blogs, exhibitions and contributions to national and international debate. Courses, workshops and conferences have been organised both within Norway and internationally – very notably in developing countries.

As of 2018, the Institute had a total of 12 employees, including 9 full-time equivalent researchers (forskerårsverk). In 2007, GenØk was recognised as the national competence centre in biosafety. Please refer to GenØk's home page for further information: genok.com/about-genok/

GenØk has not previously been subject to a research evaluation of this kind. However, in 2016 a review of GenØk's Biosafety Capacity Program was conducted by KPMG. The main aim of that review was to assess the goal achievement and sustainability of the programme. In 2018, the Research Council of Norway (RCN) was requested by the Ministry of Climate and Environment to organise an evaluation of the quality of the Institute's scientific production. The Norwegian Environment Agency (NEA), the main recipient of GenØk's research, was at the same time asked to conduct an evaluation of the societal relevance and impact of GenØk's research. The two evaluations are formally separate from each other and carried out in parallel. There has been some communication between the two evaluations, but no formal coordination. NEA's evaluation is intended to investigate the degree to which GenØk's work supports the prioritised knowledge needs of the Norwegian authorities. The task of the scientific evaluation – as reported on here - is to determine the scientific quality of GenØk's research based on the Institute's published outputs.

From the Ministry of Climate and Environment:

<u>The Norwegian Policy on GMOs</u>
Norway has been relatively restrictive with regard to GMOs over the years. According to the Ministry, various governments have received broad support for this policy from consumer and environmental organisations, and also the agricultural industry. The Storting (Norwegian Parliament) recently confirmed the Standing Committee on Business and Industry recommendation concerning the White Paper on agricultural and food policy. In this, the committee states that Norway "…must continue to pursue a restrictive GMO policy." In line with this, by a recent Royal Decree (July 2017), living products from a GM maize line and three GM oilseed rape lines are prohibited in Norway for use in industrial processing and as feed.

In Norway, production and use of genetically modified organisms (GMOs) are regulated by the Gene Technology Act. The main purpose of the Act is to ensure that the production and use of genetically modified organisms do not result in adverse effects on health and the environment. At the same time, the Norwegian Act differs from legislation in most other countries in that it also includes ethical considerations, sustainability and benefit to society as assessment criteria that must be given considerable weight. Thus, Norway has a wide-ranging set of assessment criteria under the Gene Technology Act, which gives more latitude in treating proposed innovations than is the norm under EU legislation.

A guiding principle is that to the greatest possible extent, decisions should reflect the Norwegian people's moral views and the ethical norms of Norwegian society, as these have been expressed in the responses from consultation bodies, studies and other forms of enquiry. The Government

attaches importance to maintaining consumer trust in the ability of the public administration to put the Gene Technology Act into practice in keeping with its intentions.

Excerpts from Ministry yearly allocation letters to GenØk:

Tasks concerning research in 2018:

The knowledge base for the assessment of GMOs according to the Gene Technology Act
In accordance with the mandate given by the Ministry of Climate and Environment, and the Norwegian Environment Agency, GenØk shall conduct investigations/research on specific GMOs submitted for approval through the EU's legislation system for GMOs (Directive 2001/18/EC on the deliberate release of GMOs into the environment and Regulation (EC) 1829/2003 on genetically modified food and feed). The Ministry asks GenØk to explore these issues and through additional activities contribute to expanding the knowledge base for GMO assessments under the Norwegian Gene Technology Act, including the basis for assessments of sustainability, societal utility and ethics. The Ministry also welcomes Genøk's contribution to the development of a knowledge base for the assessment of gene-edited organisms.

Tasks concerning research in 2010:

The knowledge base for the assessment of health and environmental effects of GMOs
GenØk shall contribute to expand the knowledge base for the assessment of health and environmental effects of GMOs. Genøk shall (by assignments from the Ministry of Environment and the Directorate of Natural Management) conduct investigations/research on specific GMOs submitted for approval through the EU's legislation system on GMOs (Directive 2001/18/EC on the deliberate release of GMOs into the environment and Regulation (EC) 1829/2003 on genetically modified food and feed). It is further assumed that priorities and allocation of the remaining funds will be discussed accordingly with the Ministry of Environment and the Directorate for Nature Management.

Use of the evaluation
The Ministry intends GenØk to explore the knowledge base for GMO assessment under the Norwegian Gene Technology Act, including the basis for assessments of sustainability, social benefits and ethics. The Ministry also expects that GenØk will contribute to the development of a knowledge base for assessment of gene edited organisms. Based on the two previously-mentioned evaluations, the Ministry will assess to which degree the scientific production matches the societal needs. As already noted, the two evaluations are presented separately and not coordinated. The Ministry will use the reports in its future deliberations with respect to GenØk.

Composition of the Research Evaluation Panel
The composition of the evaluation panel reflected the four thematic areas. Due to the difference in volumes of the four thematic areas, one panel member was assigned to each of the areas, Environment/ecotoxicology and Virology/immunology, and two members each to Microbiology/ molecular biology and ELSA (ethical, legal and social aspects) of new technologies/social science. The Chair was in addition to his role as Chair assigned as expert in the ELSA (ethical, legal and social aspects) of new technologies/social science area.

The members of the Research Evaluation Panel were brought together by the Research Council of Norway. Some of the evaluation panel members were suggested directly by colleagues at RCN. Some members were found through a general search for researchers with the appropriate background, particularly in terms of thematic research experience. The Research Evaluation Panel was formally appointed by the RCN.

The Research Evaluation Panel consisted of the following members:

Chair
Alan Irwin, Copenhagen Business School, DK

Environment/ecotoxicology
Pia Lassen, Aarhus University, DK

Virology/immunology
Martin Pfeffer, University of Leipzig, DE

Microbiology/molecular biology
Wendy Harwood, John Innes Centre, UK
Lorenzo Brusetti, Free University of Bozen-Bolzano, IT

ELSA (ethical, legal and social aspects) of new technologies/social science
Alan Irwin (also Panel Chair)
Pierre-Benoît Joly, Institute for Research and Innovation in Society, FR

The material evaluated consisted mainly of peer-reviewed international journal papers, but also non peer-reviewed scientific reports and book chapters. The following volumes of publications were made available through SharePoint to the expert panel members. The publications made available to the panel were published up to November 1st 2018:

	Journal articles	Book chapters	Reports	Sum per category
Environment/ecotoxicology	23	4	3	30
Virology/immunology	18	1	2	21
Microbiology/molecular biology	53	6	10	69
ELSA (ethical, legal and social aspects) of new technologies/social science	60	29	10	99
Sum per publication type	154	40	25	219

Methods

The outline of the evaluation was initially discussed between the Ministry and RCN. The evaluation panel was established taking into account the various thematic areas to be covered.

GenØk was asked to make an inventory of journal articles, book chapters and reports in the 2010-2018 period. This material was made available to the panel members by SharePoint prior to a physical meeting in Oslo on October 26, 2018. However, the official work started in the first meeting.

The Norwegian Environment Agency was contacted at the onset and took part as observers in the physical meeting. No results from their evaluation were presented to the Research Evaluation Panel

or the RCN then or at any subsequent point during the preparation of the Research Evaluation Panel report.

GenØk was asked to give a presentation of the Institute and its work to the panel at the beginning of the Oslo meeting.

Section 2: GENØK'S SCIENTIFIC CONTRIBUTION

GenØk's Scientific focus and scientific goals
As noted above, GenØk's vision is safe use of biotechnologies. The Institute conducts research on environmental, health and social consequences of genetic engineering and genetic modification. GenØk also conducts information activities and consulting within its area of competence.

Prioritised areas are:
Biosafety in genome editing
Antimicrobial resistance in the environment
Responsible and sustainable biotechnologies

GenØk has programmes/teams in the following main areas:
Ecotoxicology/ecology and ecosystems
Virology and vaccine research
Molecular and microbial research
Society, ecology and ethics (SEED)

Employment and staffing
Figures supplied by GenØk indicate total staffing as follows. According to the evidence presented to the Research Evaluation Panel by GenØk in October 2018, the figure for research staff has now fallen from 9 to 7. This is obviously a very dramatic decline since 2010.

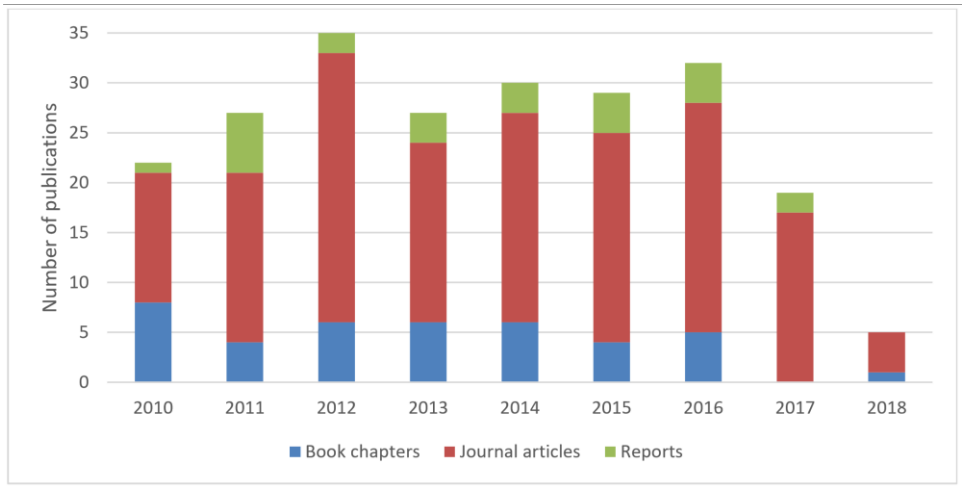
	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total employees	37	43	40	26	33	30	30	25	12
Total person-years	32	34	30,6	22,9	22,5	27,4	24,2	20,8	11,5
Researcher FTEs (full-time equivalent)	29	29	26	18,9	19	23,8	21,4	16,8	9

Bibliometric analysis

NIFU – Nordic Institute for Studies in Innovation, Research and Education Publication performed a bibliometric analysis of the period 2010-2017 on GenØk's production. Their report (presented in July 2018) serves as background to the evaluation of the institute. This bibliometric study is based primarily on the Web of Science database (it should be noted that the specific research evaluations in section 3 have chosen to supplement this by use of GoogleScholar).

Below are some extracts from the report.

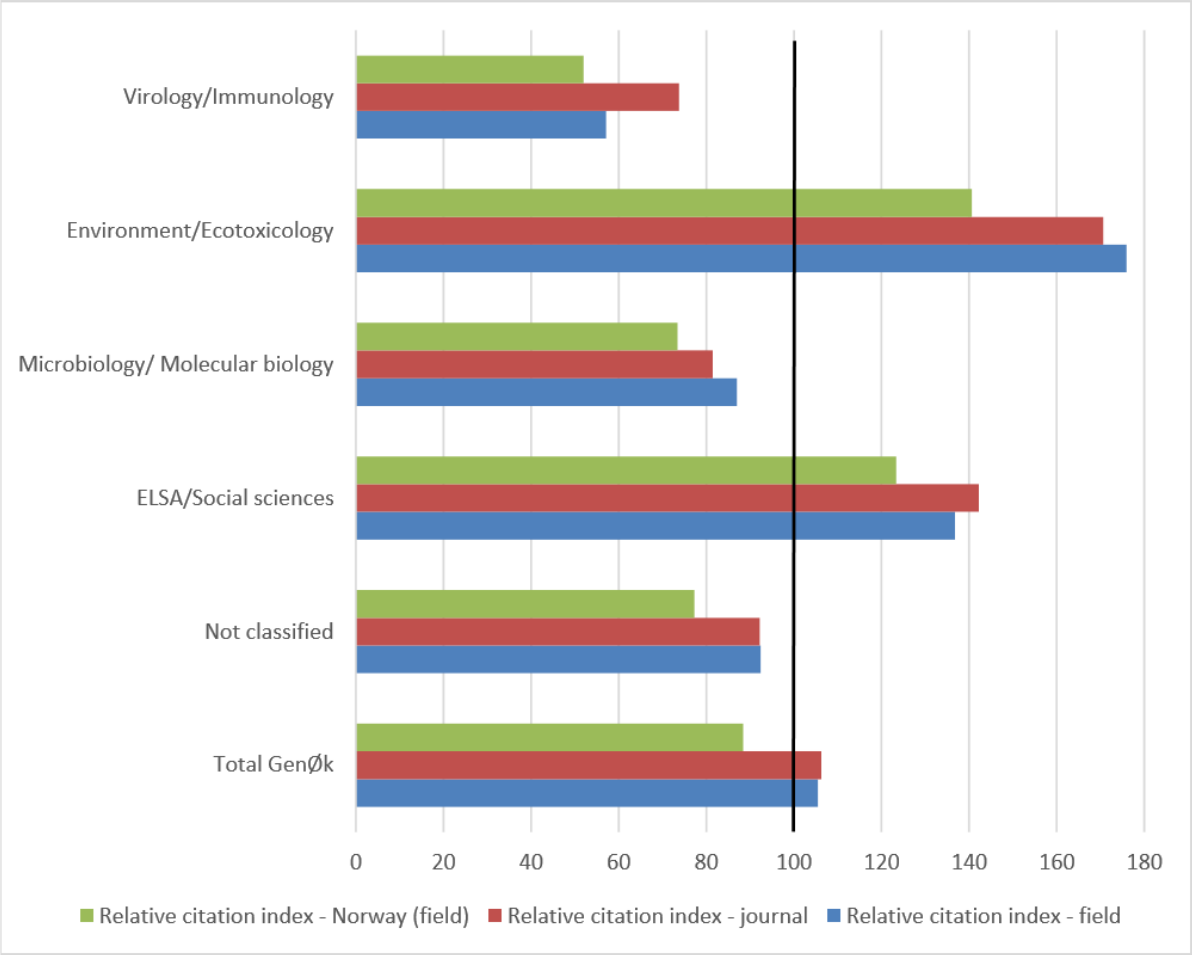
Number of publications by publication type and year (Note: The NIFU report covers publications from the beginning of 2010 until June 2018).



The submitted publications have been classified by research areas: ELSA/Social sciences, Microbiology/Molecular biology, Environment/Ecotoxicology, Virology/Immunology. This classification has been provided by GenØk. Some publications (21 articles in total) have not been field classified.

ELSA/Social sciences has the highest publication volume and accounts for 41 per cent of the publication of GenØk, followed by Microbiology/Molecular biology with 28 per cent and Environment/Ecotoxicology with 13 per cent. The NIFU report notes that: 'Overall, in terms of citation rates, GenØk performs slightly below the national average but on par with the world average. There are large internal differences in citation rates, varying across research areas from very high to low.'

The relative citation index for GenØk compared with the averages for Norway and the world, 2010-2015 articles is presented in the NIFU report as follows:



As it is stated in the NIFU report:

'Generally speaking, the citation rate of scientific articles is very skewed. Most articles are little cited or not at all, while a few get an extremely high number of citations. In the last decade, there has been an increasing interest in using highly-cited articles as an indicator in the research policy context. One reason is the strong attention towards scientific excellence. In this context highly-cited articles have been considered as a relevant indicator.

In order to analyse GenØk's score on this citation indicator, articles which are among the 10 per cent most cited articles in their fields have been identified. In total there are 10 such articles from the period, which means that 12.3 per cent of the publication output appear within the 10 percentile. This is close to the corresponding overall average for Norway, which is 12.8 percent.'

The full NIFU report is included in the appendices.

<u>Overview</u>

The Research Evaluation Panel was very specifically struck by three general features of GenØk.

First of all, this has been a most unique initiative in combining the natural and social sciences in one shared environment with a common mission and vision. In terms of interdisciplinary collaboration alone, this has been a very ambitious and innovative development. Our focus is on the scientific quality of outputs rather than larger impact. However, we can say that GenØk has attracted considerable scientific attention world-wide for its original and innovative approach to

interdisciplinary co-working. In that sense also, this evaluation has consequences for scientific research – and especially interdisciplinary research – beyond the Norwegian border.

Secondly, and in very close relationship to this point, GenØk has focused on an issue of significant scientific importance but which is also a matter of widespread public, economic, political and environmental concern. In that way too, the existence of GenØk has been a remarkable innovation. The Evaluation Panel can imagine that this has created challenges for the Institute: balancing across different scientific fields, working with a variety of scientific journals and outputs, combining a research role with responsibilities in the area of public engagement and advisory work. However, this should not detract from the uniqueness of GenØk in scientific composition and purpose.

Thirdly, and as the staffing figures above clearly demonstrate, GenØk has contracted considerably over the period between 2010 and 2018 – to something like 30% of its original size in terms of employed researchers. It has not been our job to examine the reasons for this and we have not seen any prognosis of future funding or plans for development of the Institute. However, this staffing contraction provides an un-ignorable background to our evaluation. In the individual evaluations that follow, we have attempted both to assess the quality of research outputs over the whole period and to take stock of the current situation. The latter task is clearly extremely difficult when the current researcher level is so very low (especially considering the breadth of GenØk's scientific focus). This means that the timing of this research evaluation (in 2018 rather than for example in 2015 or 2016) inevitably has consequences for our findings.

Section 3: SPECIFIC EVALUATION REPORTS

Introduction

The full assessment criteria used in preparing this report are available in an appendix below. As already noted, our report was centrally focused on the scientific quality of the published research and not, for example, on its societal relevance or larger impact. Scientific quality was further defined within the assessment criteria with regard to such factors as: originality and the development of new knowledge, the specification of research questions and objectives, theory and methods, documented knowledge, the scientific basis of projects, and matters of multi- and inter-disciplinarity. In this section, following a report and overview of each evaluation, the four thematic areas are ranked on a 7-point scale: ranging from 1 (poor) to 7 (exceptional). The 7-point scale was adopted from the RCN's standard guidelines for evaluation of research grant proposals.

At the beginning of section 4, we summarize the four evaluations and then rank the quality of the Institute's work overall.

Environment/Ecotoxicology

<u>Overview</u>

Environment/ecotoxicology at GenØk is a very small research group. According to the employment list, four persons have been part-time in the research group from 2010 to 2018. None of these persons is employed at GenØk today. However, it can be difficult to estimate the precise size of the group as several authors from the publication list had stated a relation to GenØk but were not employed according to the information we were given. The group might have been larger in some periods.

The research focus has been quite narrow but that is to be expected with such a small group: the toxicity of GMO maize and soybeans towards the aquatic arthropod, *Daphnia magna,* which is a common model organism in ecotoxicological studies. The research group has used life cycle tests on *Daphnia magna* with both glyphosate resistant crops and Bt-crops producing toxin from *Bacillus thuringiensis* to study their toxic effects. Especially soybeans are used in agricultural fish farming so investigating the aquatic ecotoxicology of GMO crops is very relevant. The research results showed that the juvenile and young animals of D. magna are affected by GMO crops. Conventional risk management of GMO crops uses short-term tests with adult D. magna where no effects have been found.

Another important finding from the group was that glyphosate-tolerant GMO crops contained glyphosate after being treated with the pesticide. The group compared samples from commercial fields with either conventional crops or GMO crops using standard procedures for pesticide application for the specific crops. Fields with conventional crops were treated with glyphosate before planting and did not contain glyphosate. However, GMO crops treated with glyphosate during the growth season were found to contain high quantities of glyphosate and AMPA. The research group had with these findings documented that that there are not sufficient tests and procedures for the ecotoxicological risk assessment of GMO crops at the moment.

This research is very relevant in scientific terms given GenØk's particular scope and focus.

Publication summary

The bibliometric analysis shows that environment/ecotoxicology has the second lowest volume of publications, 13%. Three papers are among the most cited articles in their field and the average citation index is approximately equal to the average world-wide citation index. The level of international collaboration is high, around 78% for environment/ecotoxicology.

Table 1. Scientific papers published by GenØk, Environment/Ecotoxicology

Reference	GenØk members	Journal	Year	Citations Google Scholar	Contribution of GenØk
Bøhn et al. 2010	Bøhn, Traavik	Exotoxicology	2010	80	high
Kahilainen et al. 2011	Bøhn	Evol Ecol	2011	83	low
Amundsen et al. 2012	Bøhn	Biol Invasions	2012	30	low
Bøhn et al. 2012	Bøhn, Traavik	Environmental Sciences Europe	2012	18	high
Herrmann et al. 2012	Nolde Nielsen	J. Northw. Atl. Fish. Sci.	2012	0	low
Cuhra et al. 2013	Cuhra, Traavik, Bøhn	Ecotoxicology	2013	92	high
Van den Berg et al. 2013	Bøhn	Crop Protection	2013	54	medium
Bøhn et al. 2014	Bøhn, Cuhra, Traavik	Food Chemistry	2014	193	high
Chura et al. 2014	Cuhra, Traavik, Bøhn	Aquaculture nutrition	2014	7	high
Gillund et al. 2014	Gillund, Nordgård, Bøhn, Wikmark, Hilbeck	Potato Research	2014	4	high
Cuhra 2015a	Cuhra	Environ Sci Eur	2015	22	high
Cuhra 2015b	Cuhra	Journal of Biological Physics and Chemistry	2015	2	high
Cuhra et al. 2015	Cuhra, Traavik, Bøhn	Journal of Agricultural Chemistry and Environment	2015	10	high
Fagan et al. 2015	Traavik, Bøhn	Environ Sci Eur	2015	9	high
Holderbaum et al. 2015	Holderbaum, Cuhra, Wickson, Bøhn	Journal of Toxicology and Environmental Health	2015	21	high
Bøhn et al. 2016a	Bøhn, Rover, Semenchuk	Food and Chemical Toxicology	2016	25	high
Bøhn et al. 2016b	Bøhn, Bones	Scientific reports	2016	na	medium
Cuhra et al. 2016	Bøhn	Frontiers in Environmental Science	2016	22	high
Venter et al. 2016	Bøhn	Environmental Toxicology and Chemistry,	2016	7	high
Bøhn 2017	Bøhn	Food and Chemical Toxicology	2017	0	high
Bøhn et al. 2017	Bøhn	Frontiers in Environmental Science	2017	na	high
Cuhra et al. 2017	Bøhn	Scientific reports	2017	na	high
Sevcu et al. 2017	Eltemsah	Environ Sci Pollut Res	2017	4	low

Between 2010 and 2017, 23 papers were published: which is a very high number for this small research group. However, of these, 11 papers were critical reviews, discussion papers or short communications. The focus in these critical papers is on the inadequacy of the present risk management of GMO crops and pesticides. Even though they are published in scientific journals, they do not include novel research data. The Evaluation Panel understands that GenØk should participate in the public debate. However, from a scientific point of view it is difficult to assess these papers.

Three papers in 2011 and 2012 have a focus on fish with different scopes in the natural environment and not on matters of biotechnologies. These are not within the remit for GenØk but are considered

a spin off from previous employments. This leaves eight research papers in the research area of GenØk in eight different journals.

The impact factor for these journals ranges from 0.5 to 4.9. Number of citations range from 0 to 193. In general, the contribution from GenØk is high and a substantial proportion of the 23 papers have GenØk researchers as first author.

Analysis

A distinctive key feature of the research group is the development of an alternative approach to investigating the aquatic ecotoxicology of GMO crops as well as a critical approach to the existing risk assessment of GMO crops.

It is a little difficult to evaluate the scientific level in the period from 2010 to 2018. There is a period of high-level research around 2010-2014. After that period, it seems that the research activities did not develop to the same degree. However, as mentioned, only four people have been employed in the research group from 2010 to 2018. Of these four persons, one left in 2010, the second in 2014 and the third in 2016, so this can be the explanation for the decline in the research. The last person in the research group environment/ecotoxicology ceased employment at the beginning of 2018.

Evaluation and grading

As mentioned above, the number of researchers in this group has declined over the years. Depending on the specific year, the grading of environment/ecotoxicology will vary. Given this history, it could be questioned whether this research area should be evaluated apart from the other thematic areas.

As this evaluation has to consider the whole period (2010-2018) **the scientific merit will be graded as 5**: Very good. The science is of very good quality and has contributed to scientific innovation and new knowledge. Publication has been achieved in recognised scientific journals.

Virology/Immunology

Overview

In this section, a total of 18 scientific papers, one book chapter and 2 reports are considered for evaluation. Thus the output under this topic is less than that of the other topics. This mirrors the small number of scientists within the virology/immunology group. The majority of the papers appeared in open access journals which is desirable in order to enhance visibility of the work. There is a striking heterogeneity regarding the different fields being addressed with the main exception being a relative concentration on work on poxviruses. With some of the papers one might get the impression that participation of GenØk members was more by chance or accidental but not conceptional. For many papers this is reflected by two or more affiliations including GenØk, which in turn made it difficult to judge the true contribution of GenØk.

Publication summary

The papers published in this section covered many different aspects of virology and immunology. One area of strength is represented by a total of 5 papers dealing with poxviruses, which are within the scope of biosafety/biosecurity after the eradication of smallpox was declared in 1980. The immune response to transgenic food was monitored in a mouse model in three papers; two papers were addressing the fate of naked plasmid DNA and other DNA vaccines in fish. Other topics covered aspects of human endogenous retroviruses (1 paper), the discovery of novel viruses/description of new isolates of known viruses (3), a cell line as model for cancer research (1), the immune response to recombinant vaccines (1), the immune response in co-infected human individuals (1), and the antibacterial impact of citrus extract (1). The book chapter provides an environmental risk

assessment of genetically engineered viral vector vaccines with emphasis on poxviruses, while the two reports address the relation of climate change and the emergence of viruses in wildlife. Finally, at least 13 papers contained original research while the others were reviews.

Analysis

The metrics of the publication activity mirror the broad scope of topics covered by the scientific papers. The impact factor of the journals listed in Table 2 ranges from <1 to about 6 with the vast majority between 2 and 4, which is good to very good in this field. Although publications start in 2010, only 7 papers have been cited a minimum of 10 times, 2 of which were cited more than twenty times (28 and 36 times). Five out of the 18 papers were mainly driven by GenØk members, three had a medium contribution, while this was low in the remaining 10 papers, representing more than half of the overall publications. Nevertheless, this shows a fair amount of national and international collaborations. Publication activity was surprisingly continuous with almost exactly two papers per year. Regarding the relevance for the scope of GenØk, most but not all papers fall within that remit. The latter are mainly papers where the contribution of GenØk is marginal and where more than one, sometimes even three, affiliations are listed for the authors from GenØk. In about half of the papers (8 out of 18) GenØk researchers are first authors.

Evaluation and Grading

Many aspects have to be considered when evaluating the scientific merit of a small and recently assembled group of researchers. This is particularly challenging in the wide fields of virology and immunology. With regard to the big issues in this field concerning safety, recombinant viral vaccines and new technologies to construct these, newly emerging viruses, impact of climate change, change in the host range and host tropism of viruses, immune response and allergenic potential of GM food, most of these aspects have been covered and made subject to at least one publication. However, only the latter and the poxviruses lead to more than one paper, so a continuous focus on particular subjects or issues is not visible. Some of the papers show no relevance to the mission of GenØk and seem to have got a GenØk co-authorship on an *ad hoc* basis. Scientific relevance as reflected by the citation of the papers in the scientific literature was rather low with a few exceptions.

The grading of this evaluation was made on a scale from 1 (poor) to 7 (exceptional). The science has generated new knowledge and publications in scientific journals have been generated. **For this reason we recommend an overall grade of 4 for virology/immunology.**

Table 2. Scientific papers published by GenØk, Virology/Immunology

Reference	GenØk members	Journal	Year	Citations Google Scholar	Contribution of GenØk
Ortiz-Catedral et al. 2010	Kurenbach	Arch Virol	2010	28	low
Tryland et al. 2011	Tryland, Okeke, Traavik	Emerg Infect Dis	2011	9	low
Okeke et al. 2012	Okeke, Traavik	Infect Genet Evol	2012	9	high
Piasecki et al. 2012	Kurenbach	Arch Virol	2012	20	low
Krelle et al. 2013	Okoli	J Cancer Therapy	2013	13	low
Smits et al. 2013	Tryland	PLoS One	2013	10	low
Andreassen et al. 2014	Andreassen, Bøhn, Rocca, Wikmark, Traavik	Food Agr Immunol	2014	18	high
Bendiksen et al. 2014	Olsen, Tümmler	BioMed Res Inter	2014	10	low
Hølvold et al. 2014	Myhr	Vet Res	2014	36	medium
Okeke er al 2014	Okeke, Okoli, Tryland, Bøhn, Traavik	Virol J	2014	8	high
Andreassen et al. 2015	Andreassen, Bøhn, Wikmark, Traavik	Scand J Immunol	2015	8	medium
Okeke et al. 2015	Okeke, Okoli	Pak J Pharma Sci	2015	9	low
Andreassen et al. 2016	Andreassen, Bøhn, Wikmark, Traavik	BMC Immunol	2016	7	medium
Seternes et al. 2016	Myhr	Sci Rep	2016	2	low
Ngu et al. 2017	Okoli	Immun Inflamm Dis	2017	0	low
Okeke et al. 2017	Okeke, Okoli, Tryland, Bøhn	Viruses	2017	1	high
Okoli et al. 2018	Okoli, Okeke, Tryland	Viruses	2018	4	high
Priso et al. 2018	Okoli	BMC Infect Dis	2018	0	low

Microbiology/Molecular Biology

Overview

In this section we consider a total of 53 papers and 6 book chapters as well as relevant information in 10 reports. These publications fall mainly into two subject areas: GM safety and Horizontal Gene Transfer. They are therefore considered under these two broad headings.

Under the topic of GM safety there is work on transgene detection, transgene spread, transgene stability as well as extensive use and evaluation of a range of profiling techniques for GM risk assessment.

Work on Horizontal Gene Transfer includes the study of antimicrobial resistance and screening for antibiotic resistant isolates. Part of GenØk research has been related to the investigation of the ecological behavior of antimicrobial resistance genes in cells and environments. Also included in this area are studies of natural bacterial transformation, DNA uptake and other microbiological studies.

In the assessment of this area, it was clear that work involving molecular biologists and/or microbiologists together with input from social scientists led to higher impact outcomes than would have been possible without this unique collaborative environment.

Publication summary

1. GM safety

Under the broad area of GM safety, GenØk has made significant contributions using a range of profiling techniques in GM risk assessment. Profiling expertise within GenØk covers metabolomics,

proteomics and molecular profiling technologies. In some cases, more than one profiling technique has been applied in a single study. Several studies examined either herbicide-tolerant GM maize or insect-resistant GM maize, as well as stacked variants. The only GM crop grown within Europe is an insect-resistant GM maize (MON 810), which is also being widely grown worldwide. In stacked variants, the herbicide-tolerant trait has been stacked with other traits and the crop has been grown under a range of different environments. This was the background to studies looking at the biosafety implications of stacked transgenes and of growing GM maize under conditions of environmental stress. Molecular profiling expertise featured in a number of papers as well as some excellent review articles. It was good to see a discussion on the merits of targeted verses untargeted profiling and consideration of molecular profiling as a way of addressing risk assessment gaps. It was also good to see the case made for the prudent use of profiling in GMO risk assessment.

The impact of environment and/or abiotic stress on metabolism and protein expression in GM crops featured in several papers. Generally, it was found that environment explained the majority of the differences seen. It was suggested that GM plants should be grown under different environmental conditions as part of the risk assessment process. One study attributed metabolism 'disturbances' to the transformation process. The authors were isolated in their interpretation and conclusions, with critics suggesting that omics technologies should be used cautiously in safety assessments. However, even in this study the need for further work under different environmental conditions was acknowledged.

Studies on the detection, spread and stability of transgenes were also undertaken. Transgene detection focused on the flow of transgenes into wild relatives and landraces of maize. One paper that nicely illustrated the benefit of a combination of expertise in biotechnology and social science included a socio-biological analysis across different farmer communities in Mexico. The presence of transgenes in local maize varieties from South Africa was also examined in another study. An excellent review paper looked at the challenges of detecting transgenes in landraces and wild relatives.

In terms of transgene stability, some studies suggested that staked transgenes may impact the expression of endogenous genes, may lead to higher mutation rates and a changed proteome. However, the need for further study was acknowledged to determine if these findings have any relevance for safety assessment.

One additional research area concerned the quantification of Bt protein and Cry1A toxin in Bt maize. It was found that stressful environmental conditions and different genetic backgrounds affected Bt protein concentration, a finding of potential importance.

2. Horizontal gene transfer

GenØk activities have been largely dedicated to understanding how Horizontal Gene Transfer (HGT) occurs and what consequences it could have regarding health and the environmental sector. Eight papers were related to the detection and the description of antimicrobial resistances in environments (seal or rat gut, pristine soils, water sediments) or organisms (like *Enterococcus faecium*). Most of these papers were published between 2010 and 2012, but others appeared later. All these papers have been produced by one leading group, with the group leader as corresponding author or involved in some other way, clearly having played an important role in a network focusing on HGT. On the one hand, part of the research has been dedicated to the exploration of antR-related plasmids in clinical isolates. On the other, research has concerned the search for AntR genes or transposons carrying gene cassettes in the environment.

A second research frame is related to the fate and uptake of food-derived DNA into the gut system and the local microbiota. This is a natural progression of the previous research, but with more focus on evaluation of the consequences in terms of biosafety and evolution. This aspect had been

investigated in two principal papers by senior members of GenØk. An additional paper showed the role of membrane vesicles in the uptake and transfer of gene information between bacterial cells.

A third frame is related to the exploration of the behavior of mobile genetic elements and natural bacterial transformation and the consequences for recombination. This appears to be a very important research path mostly driven by one principal group, who produced at least one paper per year. The network involved mainly the Dept. of Pharmacy, at the Arctic University of Tromsø, but also research groups in Coimbra (Portugal), Harvard and Yale Universities. The main aims were the description of the mobile element structure, in terms of harbored genes or of the position and types of flanking regions. The consequences in terms of HGT from an ecological point of view was also evaluated, with particular emphasis on the stability of the transformants and the consequential fitness or biological costs. Most recently, novel mechanisms of DNA integration and replacements into the bacterial genome have been described.

3. Other microbiological studies

GenØk researchers have contributed to work on the evaluation and characterization of the bioflocculant production capabilities of isolated bacterial strains. The focus was on understanding their potential in water purification systems and as an alternative to chemical sources. The work principally involved one GenØk member who was also responsible for studies on *Helicobacter hepaticus* and links to hepatitis and hepatocellular carcinoma. This work is somewhat outside of the main priority research areas.

Table 3. Scientific papers published by GenØk, Microbiology/Molecular Biology

Reference	GenØk members	Journal	Year	Citations Google Scholar	Contribution of GenØk
Glad et al. 2010a	Nielsen	BMC Microb	2010	53	medium
Glad et al. 2010b	Nielsen	Microb Ecol	2010	32	medium
Johansen et al. 2010	Coucheron	New Biotechnology	2010	21	low
Rosvoll et al. 2010	Nielsen	FEMS Immunol Med Microbiol	2010	85	high
Sletvold et al. 2010	Nielsen	J Antimicrob Chemother	2010	45	high
Aguilera et al. 2011	Nielsen	J Appl Entomol	2011	7	high
Domingues et al. 2011	Nielsen	J Antimicrob Chemother	2011	14	high
Grønsberg et al. 2011	Grønsberg, Nordgård, Hegge, Nielsen, Traavik	Food and Nutrition Sciences	2011	10	medium
Heinemann et al. 2011	Heinemann, Kurenbach, Quist	Environmental International	2011	40	high
Johnsen et al. 2011	Bøhn, Nielsen	J Antimicrob Chemother	2011	49	high
Li et al. 2011	Gilna	Plant and Soil	2011	53	low
Sistiaga et al. 2011	Nielsen	Can J Fish Aquat Sci	2011	23	medium
Székács et al. 2011	Quist, Swain	Food and Agricultural Immunology	2011	28	medium
Zeng et al. 2011	Gilna	Nutr Cycle Agroecosyst	2011	16	low
Domingues et al. 2012	Nielsen	PLOS Pathogens	2012	95	high
Graef et al. 2012	Myhr, Catacora-Vargas, Bøhn, Quist	Biorisk	2012	16	medium
Heinemann and El-Kawy 2012	Heinemann	Environmental International	2012	4	medium

Nordgård et al. 2012	Nordgård, Traavik, Nielsen	BMC Research Notes	2012	14	medium
Okoli et al. 2012a	Okoli	International Journal of Hepatology	2012	7	medium
Okoli et al. 2012b	Okoli	Proteome Science	2012	12	medium
Rizzi et al. 2012	Nordgård, Nielsen	Critical Reviews in Food Science and Nutrition	2012	73	medium
Starikova et al. 2012	Nielsen	PLOS Pathogens	2012	40	high
Townsend et al. 2012	Bøhn, Nielsen	Frontiers in Microbiology	2012	25	high
Aguilera et al. 2013	Nielsen	iForest	2013	7	low
Madi et al. 2013	Quist	Eur Food Res Technol	2013	4	low
Overballe-Petersen et al. 2013	Nielsen	PNAS	2013	87	high
Starikova et al. 2013	Nielsen	J Antimicrob Chemother	2013	42	high
Agapito-Tenfen et al. 2014a	Agapito-Tenfen, Wikmark	Proteome Science	2014	29	high
Agapito-Tenfen et al. 2014b	Agapito-Tenfen, Traavik	BMC Plant Biology	2014	30	high
Ben Ali et al. 2014	Quist	Int J Mol Sci	2014	7	low
Iversen et al. 2014	Iversen, Grønsberg, Bøhn	PLOS ONE	2014	11	high
Nielsen et al. 2014	Nielsen, Bøhn	Frontiers in Microbiology	2014	43	high
Okaiyeto et al. 2015a	Okoli	Int J Mol Sci	2015	48	low
Okaiyeto et al. 2015b	Okoli	Environmental Technology	2015	10	low
Okaiyeto et al. 2015c	Okoli	Microb Biochem Technol	2015	0	low
Okeke et al. 2015	Okoli	Pak J Pharm Sci	2015	9	low
Trtikova et al. 2015	Wikmark, Hilbeck	PLOS ONE	2015	32	medium
Utnes et al. 2015	Nielsen	The ISME Journal	2015	12	high
Woegerbauer et al. 2015a	Nielsen	Frontiers in Microbiology	2015	7	high
Woegerbauer et al. 2015b	Nielsen	Environmental Pollution	2015	13	high
Borruso et al. 2016	Nielsen	Science of the Total Environment	2016	8	high
Harms et al. 2016	Nielsen	PNAS	2016	2	high
Mesnage et al. 2016	Agapito-Tenfen	Scientific reports	2016	16	high
Nascimentto-Gavioli et al. 2016	Agapito-Tenfen	Journal of Proteomics	2016	5	high
Okaiyeto et al. 2016a	Okoli	Microbiology Open	2016	18	low
Okaiyeto et al. 2016b	Okoli	Pol J Environ	2016	4	low
Vilperte et al. 2016	Vilperte, Agapito-Tenfen, Wikmark	Environ Sci Eur	2016	4	high
Agapito-Tenfen et al. 2017a	Agapito-Tenfen, Wickson	Biodivers Conserv	2017	2	high
Benevenuto et al. 2017	Benevenuto, Agapito-Tenfen, Wikmark	PLOS ONE	2017	7	high

Domingues et al. 2017	Nielsen	Current Opinion in Microbiology	2017	13	high
Ntozonke et al. 2017	Okoli	Int J of Environ Res and Public Health	2017	0	low
Agapito-Tenfen et al. 2018	Agapito-Tenfen, Traavik	Environ Sci Eur	2018	0	low
Ali et al. 2018	Agapito-Tenfen	European Food Research and Technology	2018	0	low

Analysis

Publications in the area of microbiology and molecular biology made up 28% of the total publications over the review period and were predominantly journal articles together with a few reports. The articles were published in 35 different journals with no clear preference for a particular journal with a maximum number of 4 papers being published in the *Journal of Antimicrobial Chemotherapy* (impact factor 5.2). The area covering microbiology and molecular biology had the highest number of articles with international co-workers demonstrating the very collaborative nature of this area of research.

1*. GM safety*

In the GM safety area, the average impact factor from 18 papers was 3.67, somewhat lower than for the area of Horizontal Gene Transfer. There were another 4 papers without impact factors. The average number of citations in this area was 13.52 (1.93/year). Within this group, the highest impact publications were 2 reviews, published in *Environment International* during 2011/2012. These gave comprehensive and balanced coverage of the use of omics tools in GMO risk assessment. Papers evaluating GM crops for genetic instabilities or under different environmental conditions or involving data from animal feeding studies tended to have the lowest impact factors. Papers authored by, or with contributions from one key member of GenØk staff feature prominently and focus on using a range of techniques for transgene detection. Some of the important contributions in this area are highlighted above. One study attracted criticism over flaws in design and methodology. The claims made by the authors that the transformation process causes metabolism disturbances were perhaps over-sensationalist and at odds with the vast majority of the published literature.

GenØk is rather unique in having access to both scientific expertise and expertise in socio-economics and ethics. This combination has allowed some really well-designed studies that would have been difficult to undertake elsewhere. It is evident that the unique combination of expertise has been a strength. In general, the conclusions reached have been measured and have advised on sensible future risk assessment approaches. Things have moved on considerably since the start of this review period. The previous focus on using a range of 'omics' technologies in untargeted ways to profile GM crops has been replaced by more targeted approaches looking specifically at the trait being introduced or modified.

2. Horizontal Gene Transfer

Regarding the HGT-related papers, they have been published in peer-reviewed journals often with very high impact factors (IF). The average IF for these papers is 5.28. However, excluding the two worst IF-performing papers, the IF average raises to 5.69. Only one paper has been published in a journal without IF. To date, the average number of citations of the papers within this topic is 33.45 (average 4.78 citations per year). The best performing papers in terms of bibliometrics are from 2015 published in *ISME J*., and two papers from 2013 and 2016 published in *Proc. Natl. Acad. Sci. USA*. Despite the low citation scores, the recognition of the scientific quality of these papers is very well represented by the successful publication in those renowned journals. In this sense, the performance of the leading group is outstanding. In particular, the topic related to the exploration of the behavior

of mobile genetic elements and natural bacterial transformation, was the most successful in terms of IF scores and citations. These papers could be helpful in defining a new ecology of gene dynamics, with potential implications in the understanding of gene evolution, antibiotic resistance mechanisms, biosafety risks, and ecological modeling.

3. Other microbiological studies

Concerning GenØk's activities in other areas of microbiology, the average IF of the papers was 2.18. Only one paper was published with an IF of more than 3.00 (Int. J. Mol. Sci.). However, some papers have been published in journals without an assigned IF. The approaches used by the researchers included techniques ranging from strain plating, physiological analysis, polysaccharide chemical analysis, TGA and IR spectroscopy and SEM observation. Research on hepatocarcinoma was conducted with different techniques including cDNA-based Real Time-PCR or protein extraction and characterization. However, overall the work appeared to have limited impact within the scientific community, with very low numbers of citations, with the exception of the paper published in *Int. J. Mol. Sci.* with 48 citations (16 per year).

Evaluation and grading

Evaluation was made on a 7-point scale with 7 being exceptional and 1 poor. An evaluation of 4 is good and recognizes that the science has generated new knowledge and led to publications in scientific journals. An evaluation of 5 is very good and requires that the science is of very good quality and has contributed to scientific innovation and led to publication in recognized journals. We underline that some of the material under review clearly deserves an evaluation of 5 or even up to 7 (with leading-edge journals such as ISME J), but this was mostly related to only a specific area of research (HGT and DNA recombination). Most of the other outputs, included in the parallel research areas, fall below this standard. **For this reason, we recommend an overall grade of 4 for this area but with recognition that the HGT area should be graded 5.**

ELSA – Ethical, legal and social aspects of new technologies/ social science

Overview

GenØk offers a unique academic environment for a group of social scientists – both in terms of the focus on biosafety but also the co-location with natural scientists. We cannot think of a similar research cluster elsewhere in the world. The group's contribution to scholarly and policy-related work on responsible innovation should be specifically commended.

This point is supported by the 2016 KPMG review. As noted in that report: 'All respondents concur that no other institutions would have taken the place of GenØk had the programme not existed. GenØk is a unique type of institution, combining science with a socio-economic approach and engaging with a wide range of stakeholders.' (p.1) This statement certainly applies to the research team working on ELSA/social sciences.

The ELSA group is in close touch with research and policy developments world-wide and can also claim a leadership role in developing this broad and interdisciplinary field. Certainly, GenØk researchers have identified and contributed to a range of key issues related to the governance of new and emerging sciences and technologies (NEST). While research on GMOs is central and has had a high scientific impact, the group has also worked on nanotechnology, synthetic biology, and more recently, gene editing. Across these substantive areas, GenØk researchers have made a contribution on several issues, including: political dimensions of risk assessment methodologies; the role of public engagement in the governance of NEST: and the definition, enactment and development of responsible research and innovation (RRI). The ELSA/social science group has also made important

contributions in areas such as: sustainable agriculture; the local application of GMOs (including co-existence of GM and non-GM crops); local and global governance of biodiversity.

Across a broad range of topics, this group has developed a clear voice, demonstrated substantial creativity and made a real contribution to both understanding and practice. The group has dealt with a series of challenging 'real world' issues: often bringing together empirical and conceptual materials in an innovative and engaging fashion. The contribution is not merely instrumental but opens up original research perspectives and contributes to the reflexivity of actors engaged in the analysis and governance of science and technology - including the self-reflexivity of ELSA researchers.

Publication summary

As evidenced by the large output of high-quality publications over the period in question, this is a very productive group of researchers. As noted in the bibliometric analysis (Aksnes: 2018), ELSA/Social Sciences has the highest publication volume within GenØk – accounting for 41% of publications in the 2010-2018 period. The bibliometric report also indicates that ELSA/Social Sciences publications are generally highly-cited (based on Web of Science). In the social sciences, Google Scholar is usually regarded as a better indicator and we have conducted some further analysis using this (Table 4).

Table 4. Scientific impact of papers published by GenØk ELSA/Social Sciences Group (Google Scholar – search on 21/11/2018, n>= 10)

Reference	GenØk members	Journal	Year	Citations Google Scholar	Contribution of GenØk
Carew and Wickson 2010	Wickson	Futures	2010	111	High
Delgado et al. 2010	Wickson	Public Understand Sci	2010	233	High
Gillund and Myhr 2010	Gillund, Myhr	J Agric Environ Ethics	2010	14	High
Myhr 2010	Myhr	J Agric Environ Ethics	2010	28	High
Olesen et al. 2010	Myhr	J Agric Environ Ethics	2010	50	High
Wickson et al. 2010a	Wickson	Nature Nanotechnology (commentary)	2010	39	High
Wickson et al. 2010b	Wickson	iJETS	2010	23	High
Myhr and Myskja 2011	Myhr	Nanoethics	2011	16	High
Wickson and Wynne. 2012a	Wickson	Ethics, Policy and Environment	2012	32	High
Wickson and Wynne. 2012b	Wickson	EMBO Reports (Science&Society)	2012	43	High
Hofmann et al. 2013	Myhr	BMC Medical Ethics	2013	34	High
Jacobson et al. 2013	Myhr	Journal of Environment & Development	2013	21	High
Myskja et al. 2014	Myhr	Life Sciences, Society and Policy	2014	17	High
Wickson et al. 2014c	Wickson	Journal of Responsible Innovation	2014	55	High
Miller et al. 2015	Wickson	Review of Policy Research	2015	21	High
Wickson et al. 2015a	Wickson	Sci Eng Ethics	2015	11	High
Wickson et al. 2015b	Wickson	Sci Eng Ethics	2015	12	High
Hartley et al. 2016	Gillund, van Hove, Wickson	PLOS Biology	2016	12	High
Preston et al. 2016	Wickson	Technology in Society	2016	10	High
Pascual et al. 2017	Wickson	Current Opinion in Environmental Sustainability	2017	194	Low

Since 2010, the ELSA/social science group has published 20 papers with 10 or more citations. This is a very high impact if we take account of the size of the group, and a mark of substantial scientific recognition by the academic community. Some researchers in the group are especially productive and well-regarded. Many of the papers are co-authored by GenØk colleagues, and also very often with international researchers. In general, we estimate the contribution of GenØk colleagues to the produced papers as essential (rather than secondary or minor). This also demonstrates that GenØk research is highly integrated in international networks.

It is noticeable that the ELSA group publishes across an unusually wide range of journals and across a range of fields (including *Nanoethics*, *Journal of Agricultural and Environmental Ethics*, *Sustainability*, *Nature Nanotechnology* and *Science and Engineering Ethics* plus many more – often only once). On the one hand, this seems an inevitable characteristic of the group's commitment to multi-disciplinary work and indicates the range of audiences they have sought (also including book chapters and other publications). On the other, it does raise questions about the group's publication strategy and some of the key journals in the ELSA/Social Science domain do not appear (especially *Social Studies of Science* and *Science, Technology, & Human Values* but also *Research Policy* and well-regarded social scientific journals e.g. in policy and politics, or sociology).

Analysis

Some of the key distinctive features of this group of ELSA/social science researchers are as follows:

- They are amongst the internationally leading groups within research into the governance of GMOs;
- The group has more specifically explored the limitations of current frameworks for risk assessment and risk management, and they have conducted some very original explorations of alternative frames, such as more participatory ways of assessing and implementing RRI or care-based perspectives;
- The research group has developed a unique way of conducting interdisciplinary research which specifically fosters productive interactions between the social sciences, environmental sciences and (molecular) biology;
- The group does not focus only on laboratory studies and analyses of regulatory sciences and regulation, but has been conspicuously successful in taking account of specific farming practices and associated socio-economic issues within particular empirical settings.

We understand that the group was not invited to provide a self-assessment as part of the evaluation process. This would have been useful. In particular, it would have clarified the overall research strategy of GenØk – including the social science group. It could also have specifically addressed the issue raised above concerning whether the group has at least considered a more targeted publication strategy or left this to individual researchers on a more *ad hoc* basis. This also links to the unaddressed question of the group's wider intellectual ambitions beyond the (admittedly broad) area of responsible innovation.

Evaluation and grading

A grade of 6 represents 'excellent': 'The science is in the forefront of its field and contributes to scientific innovation as well as generates important new knowledge'. If one takes the field as 'social aspects of biosafety' (or similar), then that is a reasonable description of the publications we have read and the outcome of the publication analysis. 'Publications in leading scientific journals' is more open to question – but the descriptor for grades 5, 6 and 7 with regard to scientific journals moves between 'recognised' (5), 'leading' (6) and then 'top' (7). **On that basis, and taking account of the level of productivity, originality and impact, we recommend an overall grade of 6.** Given the size of the group and the seniority of its staff, they have performed to an extremely high level. GenØk

should be commended for bringing a talented, productive and ambitious group of researchers together in a location which was not previously renowned for work of this kind.

Section 4: OVERALL CONCLUSIONS AND RECOMMENDATIONS

Summary of evaluation and overall grading

The Research Evaluation Panel has ranked GenØk's scientific merit across the four thematic areas according to a 7-point scale: ranging from 1 (poor) to 7 (exceptional). The grades awarded (along with the descriptors for each grade) are as follows:

Environment/Ecotoxicology: 5. ***Very good****. The science is of very good quality and has contributed to scientific innovation and new knowledge. Publications in recognised scientific journals.*

Virology/Immunology: 4. ***Good.*** *The science has generated new knowledge, but has some qualitative deficiencies. Publications in scientific journals.*

Microbiology/Molecular Biology: 4. ***Good****. The science has generated new knowledge, but has some qualitative deficiencies. Publications in scientific journals.*

ELSA – Ethical, legal and social aspects of new technologies/social science: 6. ***Excellent.*** *The science is at the forefront of its field and contributes to scientific innovation as well as generates new knowledge. Publications in leading scientific journals.*

The Panel considers this to be a very good performance and **awards an overall grade of 5** for the scientific quality of GenØk over the period covered by this evaluation. As noted in the individual evaluations, there is considerable variety in the quality of research outputs from the different groups. Nevertheless, and taking account both of the interdisciplinary range and the pronounced downsizing of the Institute between 2010 and 2018, we consider that this positive assessment is fully merited.

The current mission of GenØk focuses on research, capacity-building and advice on risk assessment and management of GMOs and emerging biotechnologies. The evaluations above broadly indicate that GenØk has been successful in making a scientific contribution to this area. This is clear across all four thematic groupings, representing also a unique and innovative scientific initiative in an important domain of technical, social and public interest. We would add at this point also that the combination of social science with the other scientific disciplines has been specifically helpful in addressing the broad goals and ambitions of the Institute.

Synergies among thematic areas and GenØk's capacity to fill knowledge gaps

In the opinion of the Research Evaluation Panel, the common focus of GenØk on the safe use of biotechnologies has allowed a number of cross-disciplinary synergies to develop. This is especially striking between the social and natural sciences. The Panel has identified several areas where GenØk has been able to address knowledge gaps which have been at least partly neglected by research centres with a less-specific focus on genetic engineering technologies. Examples here include:

- Research groups in GenØK have adopted a critical approach to the current risk management of GMO crops and pesticides. A significant strand of the research has documented inadequate and insufficient risk management protocols. This is an issue of obvious scientific as well as societal significance;

- Another area where GenOK has contributed to filling a specific knowledge gap is in understanding the extent of, and reasons for, transgene introgression into local maize varieties in Africa. By conducting interviews with farmers, researchers were able to describe the likely origin of seed batches and how it was distributed within the community. Combining this information with molecular analysis allowed evaluation of the extent of unintended mixing of GM and non-GM maize;

- Research within GenØk has been able to contribute both to the international debate over topics related to Responsible Research and Innovation (RRI) and to contextualise this fully in the case of biotechnology governance. In this way, empirically-based knowledge of the practical realities of agricultural application, a theoretical grasp of the underlying themes (for example, regarding a 'politics of care') and close co-operation with scientists working in this area has allowed new perspectives and research horizons to emerge.

In making this positive point about GenØk's performance, we must also note that the current scale of the Institute makes critical mass a substantial challenge for such a complex and cross-cutting area. With the current level of research staffing, the possibilities for future synergies and inter-disciplinary collaborations are clearly very restricted.

Final remarks

A scientific evaluation of this kind over a substantial time period and combining rather different areas of expertise is not without its challenges. Certainly, no member of the Panel claims expertise across all the areas covered in this report. In addition, we have throughout our work attempted both to evaluate specific thematic areas but also to consider the overall quality of the Institute's collective research activities.

In the opinion of the Research Evaluation Panel, GenØk is a unique institute with a shared focus and a broad range of cross-disciplinary competences. Certainly, it has a special place within the global community of researchers addressing matters of the risk management of emerging biotechnologies. In our scientific judgement, the Institute has lived up to most of the expectations placed upon it and achieved some very good, and even excellent, results. This is a substantial achievement for Norwegian research in a field of great international significance.

As we have already noted in Section 2, however, we are also very aware of the decline of the numbers of research staff at GenØk: making the level of activity today very different to even as recently as 2016. This does make the timing of this evaluation crucial. Eight years is a long period for an evaluation to cover – especially when this is taken together with the decrease in the Institute's research capacity. In making this point, we should however also stress that KPMG did complete a separate review in 2016: although this had a focus on capacity building rather than scientific quality. The Research Evaluation Panel is specifically concerned about the future viability of this Institute. International experience is that it is particularly difficult to recover from the loss of key researchers and the geographical location of the Institute may not make the recruitment of established researchers particularly easy.

The future development of GenØk is however beyond the remit of this Panel. Instead, we will conclude by observing that it has been especially interesting for this inter-disciplinary panel to evaluate an activity with this particular organisational form, level of ambition and scientific purpose. Whatever lies ahead for GenØk, it is very important that there is serious reflection on what can be achieved – and what has been achieved – by an innovative cross-disciplinary activity of this sort. We

hope that our report will make a contribution to that larger process of national and international reflection.

Appendix 1. Mandate

Appendix 2. List of Documents

Appendix 3. Assessment criteria used to evaluate GenØk

Appendix 4. NIFU bibliometric analysis