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PathoSeq Project Report, WP5

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ABBREVIATIONS

AGES	Österreichische Agentur für Gesundheit und Ernährungssicherheit (NRL for *Lm* in Austria)
BGBl.	Bundesgesetzblatt
CJEU	Court of Justice of the European Union
FBO	Food business operator
FHI	Folkehelseinstituttet (the Norwegian Institute of Public Health)
FSA	Food safety authority
GFL	EU General Food Law Regulation
FHR	EU Food Hygiene Regulation
HI	Havforskningsinstituttet (the Norwegian Institute of Marine Research)
HOD	Helse- og omsorgsdepartementet (the Norwegian Ministry of Health and Care Services)
Lm	*Listeria monocytogenes*
LMSVG	Lebensmittelsicherheits und Verbraucherschutsgesetz (Austrian Food Safety and Consumer Protection Act)
MCR	EU Microbiological Criteria Regulation
MT	Mattilsynet (the Norwegian Food Safety Authority)
NOU	Norsk offentlig utredning
NRL	National reference laboratory
Ot.prp.	Odelstingsproposisjon
OCR	EU Official Controls Regulation
Rt.	Norsk Retstidende
RTE	Ready-to-eat
RV	Regierungsvorlage
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
VI	Veterinærinstituttet (the Norwegian Veterinary Institute)
WGS	Whole genome sequencing
ZMD	EU Zoonosis Monitoring Directive

1 Report Background, Remit and Methodology

1.1 Introduction

This report is the outcome of legal research conducted under the aegis of the project 'Food Safety with High Precision—Pathogenomics for the Food Industry' (short title: PathoSeq).[1] The report elucidates some of the legal implications of whole genome sequencing (WGS) of bacterial pathogens in the food industry, using *Listeria monocytogenes* (*Lm*) as a case study. Its focus is on the Norwegian context, although account is also taken of the experiences and practices of certain other European states, particularly Austria.

A central purpose of the PathoSeq project has been to prepare the Norwegian food industry for challenges accompanying the introduction of WGS technology, as well as facilitating exploitation of the technology's benefits for surveillance and control of foodborne bacteria in the food industry. The project has been led by the Norwegian food research institute Nofima, in cooperation with the Unit of Food Microbiology at the University of Veterinary Medicine in Vienna and the Norwegian Research Center for Computers and Law (NRCCL) at the University of Oslo. In addition, multiple industry actors, from both the meat and salmon processing industry, have partaken in the project. The Research Council of Norway provided the project funding.[2]

The bulk of the research and writing involved in producing this report was carried out by members of the NRCCL, more specifically, Christiane Hunsbedt aided by Lee A. Bygrave and Tommy Tranvik, during the period 2021 to 2023. Researchers at Nofima—primarily Annette Fagerlund and secondarily Solveig Langsrud—have provided useful technical insight, particularly regarding the mechanics of WGS in the food industry context.

Legal regulation and interpretations often struggle to keep up with technological advancements. This makes it crucial to stay up to date on multiple fields at once. The PathoSeq project has been an interdisciplinary endeavour, encompassing technological research (including the sequencing and categorisation of numerous *Lm* isolates), empirical research (involving interviews with food industry actors) and a work package (WP5) on legal issues. This approach has enabled enhanced understanding of the possible impact of using WGS data as part of food safety management. Research contributing increased knowledge about *Lm* and what can be learned from WGS data about the origin and properties of individual *Lm* isolates is important for comprehending how WGS may affect the application of legal rules, also in the future. This can be

[1] For further information on the project, see https://nofima.com/projects/pathoseq/.

[2] Project number 294910. See further https://prosjektbanken.forskningsradet.no/project/FORISS/294910.

decisive for how legal regulation should be adapted and developed, to ensure better accordance with newly uncovered potentials, challenges and needs arising from the technology.

1.2 Research Aim

The overarching aim of the report is to elucidate legal rules that may hamper or otherwise affect the implementation of WGS of *Lm* originating from the food industry. This is an exercise of high practical relevance, as the questions explored are central for the activities of numerous actors in the food industry—including both food business operators (FBOs), food safety authorities (FSAs) and food testing laboratories—in frequently performed tasks. At the same time, many of the questions are challenging to address conclusively as the applicable law is often broad and vague, making it difficult to determine its application to specific situations. That difficulty is exacerbated in the present case because many of the situations considered in the report have not yet unfolded, or only barely been experienced.

The food industry is naturally worried about any risk of having to withdraw their products from the market. Even more do they fear the possibility of their products causing illness. Thus, there is ample motivation in the industry to minimise the chances of either of these outcomes, by making thorough efforts to keep *Lm* under control. To this end, many FBOs express willingness to apply WGS in order to learn more about *Lm* in their factories and other production facilities, and to implement better control measures.[3] Yet, there are barriers to large-scale WGS implementation, as elaborated in this report. Legal uncertainties surrounding, for instance, the extent to which FSAs can access and use WGS data from FBO facilities play a role in this regard.

1.3 *Listeria monocytogenes*

Listeriosis is a serious infectious disease caused by the bacterium *Listeria monocytogenes*. Almost all human cases of listeriosis are foodborne, placing food production in the spotlight for identifying the cause of outbreaks and for seeking to prevent contamination altogether. *Lm* is widely distributed in the environment, creating a risk for it to enter our food at any stage throughout the production chain. Both legal requirements and the approach towards it by authorities and food producers reflect that *Lm* is a highly prioritised food safety risk. The main reason for this is the severe risks it poses to human health. Patients who are diagnosed with listeriosis may display serious symptoms, suffer miscarriage if pregnant, or even die. The seri-

[3] See further Chapter 3.

ousness of the disease and the relatively high mortality rate (13.7% in the EU in 2020) designates *Lm* as a highly prioritised bacterium in the context of food safety, despite a low incidence compared to other foodborne pathogens (0.43 per 100,000 population in the EU in 2020).[4]

The likelihood of severe outcomes among healthy people is fortunately low and most people ingest small numbers of *Lm* frequently feeling no or only light symptoms. Pregnant women, elderly individuals, infants and those with a weakened immune system face significantly increased risks, as their tolerance for *Lm* is considerably lower, resulting in a higher susceptibility to illness.

The probability of developing listeriosis after consuming contaminated food is highly dependent on the dose, and 92% of listeriosis cases are caused by foods containing more than 100 000 *Lm* per serving.[5] The initial contamination of the products is low in most cases, and listeriosis is therefore primarily caused by foods in which the bacterium can grow for a long time (long shelf life, no preservatives). *Lm* can grow even at refrigeration temperatures and without oxygen (eg, vacuum packaged products); it also survives freezing. Examples of high-risk foods are ready-to-eat (RTE) meat products, soft cheeses, and cold smoked salmon. Heat inactivates *Lm*, but listeriosis is still associated with products made from cooked meat or pasteurized milk, because the food can be contaminated after the heating step.

Lm strains can establish in niches in the food processing environment (eg, in drains, floor cracks or processing equipment) and may survive there for years or even decades—this property is usually referred to as 'persistence'—and from there spread to food products. Clinical cases of listeriosis can therefore sometimes be traced via food products back to a persistent *Lm* strain residing in a specific factory environment.

The properties of *Lm* vary. Some variants seem to survive better in food processing environments and are more frequently found on foods, and some variants are more likely to cause illness (ie, be hypervirulent). In summary, a typical case of listeriosis is a vulnerable person consuming a high-risk food product contaminated with a common or hypervirulent *Lm* that has been stored at abuse temperature (>5°C) and/or been consumed after the due-by date.

As elaborated later in the report, the legal framework distinguishes between RTE foods and food that is supposed to be cooked before consumption, and between foods supporting growth

[4] European Food Safety Authority (EFSA), 'The European Union One Health 2021 Zoonoses Report' (2022) 20(12) *EFSA Journal* 7666.

[5] European Food Safety Authority (EFSA), '*Listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU' (2018) 16(1) *EFSA Journal* 5134.

of *Lm* and not supporting growth. Stricter requirements are therefore applied for foods like smoked salmon, sushi, deli meat (without preservatives) and soft cheeses.

The elevated risks associated with RTE products entail a larger economic burden for the FBOs producing this type of food, in ensuring that the food is safe. This burden includes expenses of collecting and analysing samples and resources to prevent and eliminate *Lm*, along with financial and reputational costs should recalling contaminated products become necessary.[6] In addition, there could be legal costs if it is proven that the food has led to illness.[7] FBOs producing RTE products thus have a particularly strong interest in optimising their approach to controlling *Lm*, such as by finding ways to realise potential benefits of WGS.

1.4 Whole Genome Sequencing and its Potentials

WGS reveals the genetic code of an organism and has taken over as the 'gold standard' to identify microorganisms. The genome sequence of *Lm*, as for other microorganisms, is not constant, but will evolve over time. Bacteria grow by division of a mother cell into two identical daughter cells, but over time, mutations will arise. Therefore, when two bacterial isolates have identical or almost identical sequences, it is deemed likely (but not certain) that they share a common ancestor rather close in time and therefore also originate from the same source. Genome sequencing can therefore be used not only to assign a microbial isolate to a specific species or to say something about its properties (eg, if it contains antibiotic resistance or virulence genes), but also to track spreading routes and identify likely contamination sources. Such tracking is commonly used by health authorities to study spread of infectious diseases in the population (eg, during the COVID-19 pandemic) and find likely food sources during outbreaks. However, the approach can also be used by food companies to link pathogens on their products to certain raw materials and investigate spread within their food production facilities.

Whole genome sequencing is the most discriminatory method available for determining the genetic relatedness of organisms. The approach is based on unraveling the genetic identity (genome) of an organism, as encoded in its deoxyribonucleic acid (DNA). DNA is composed of a series of nucleotides—adenine, thymine, cytosine and guanine—represented by the four letters A, T, C and G. Thus, WGS provides a sequence of letters (nucleotides) revealing the genetic code of an organism. The genome of an *Lm* isolate is around 3 million nucleotides in length, and encodes around 3000 genes.

[6] K Jordan and others, *Listeria monocytogenes in the Food Processing Environment* (Springer 2015) 29-30, 35.
[7] Ibid.

In the pre-genomic era, pulsed-field gel electrophoresis (PFGE) technology was the 'gold standard' laboratory method for determination of bacterial relatedness, also in respect of *Lm*.[8] The PFGE-based method is based on digestion of genomic DNA with selected restriction enzymes, followed by separation of the resulting fragments using pulsed-field gel electrophoresis. Comparisons are finally made between the banding patterns obtained for different isolates and interpreted according to the number of observed dissimilar restriction fragments. There can be significant genetic diversity between isolates having identical PFGE patterns.

Due to its superior analytical capacity to discriminate between bacterial types, WGS has now taken over from PFGE as the state-of-the-art technology for analysing *Lm*. In some countries, such as Austria, this development occurred already quite a number of years ago.[9]

In practice, WGS constitutes both a laboratory procedure employing a sequencing machine to generate raw sequencing data (in the form of FASTQ files) from individual organisms (eg, *Lm* isolates), and the mathematical analysis of the generated raw WGS data (bioinformatics). The bioinformatic analysis involves comparing the genome sequences of two or more organisms to each other to count the number of genetic differences between them and estimate their evolutionary relationship. The results are often presented as a phylogenetic tree. The bioinformatic analysis of raw WGS data can be performed at different levels of 'resolution', depending on the purposes of the analyses and the relatedness of the organisms to be compared.

The two main approaches currently used during WGS analysis of *Lm* and other foodborne pathogens are genomic MLST and SNP analysis. Traditional MLST (multilocus sequence typing) of *Lm*[10] is relatively simple to perform and involves comparing the sequence of seven (out of ~3000) genes. It is used to assign isolates to sequence types (STs) and clonal complexes (CCs). For isolates within the same CC group, an expansion of this gene-by-gene comparison may be conducted with cgMLST (core genome MLST), which takes into account ~1700 *Lm* genes,[11] while wgMLST (whole genome MLST) takes into account 'all' genes in the *Lm* genome. These methods naturally provide progressively higher 'resolution' and more detail. When comparing closely related genomes (differentiated by few genetic differences), the wgMLST approach

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[8] See eg B Félix and others, 'Building a molecular *Listeria monocytogenes* database to centralize and share PFGE typing data from food, environmental and animal strains throughout Europe' (2014) 104 *Journal of Microbiological Methods* 1.

[9] See A Pietzka and others, 'Whole Genome Sequencing Based Surveillance of *L. monocytogenes* for Early Detection and Investigations of Listeriosis Outbreaks' (2019) 7 *Frontiers in Public Health* 139. See further Chapter 5 (Section 5.5) below.

[10] M Ragon and others, 'A new perspective on *Listeria monocytogenes* evolution' (2008) 4(9) *PLoS Pathogens* e1000146.

[11] A Moura and others, 'Whole genome-based population biology and epidemiological surveillance of *Listeria monocytogenes*' (2017) 2 *Nature Microbiology* 16185.

provides the same level of discriminatory power as the SNP (single nucleotide polymorphisms) analysis method, which determines differences between genomes at the level of the individual nucleotides (letters).

In addition to providing information about the similarity of different isolates, WGS data can be used to predict characteristics of individual bacterial strains or subgroups, eg, by detecting the presence of resistance or virulence genes. Different subtypes of *Lm* have been found to exhibit distinct properties. For instance, some CCs predominate among those that cause disease and outbreaks, while others are common in food and food processing environments but less frequently associated with clinical cases.[12] These may have achieved resistance to certain disinfection agents, more easily form biofilm, or show increased tolerance to stress conditions. The use of this type of information as part of risk-based food safety management is anticipated to increase in significance in the forthcoming years.[13]

1.5 Benefits and Challenges with Implementation of Whole Genome Sequencing

Use of WGS for surveillance and outbreak investigation of microbiological food pathogens is expanding,[14] and its relevance is increasing, also for the Norwegian food industry. This is partly due to WGS becoming quicker and simpler to perform, making it progressively more accessible and affordable.

As indicated above (and further on in the report),[15] detailed genomic sequences can allow FBOs to map the bacterial variants within their factories and discover sources and spread, thereby enabling more informed risk assessments, plans and responses. Accordingly, WGS can be a valuable tool for FBOs to manage pathogens such as *Lm* preventatively in a more efficient manner and thereby to fulfill better their food safety obligations.[16]

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[12] United Nations Food and Agricultural Organization (FAO) and World Health Organization (WHO), '*Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring' – Meeting report (2022), Microbiological Risk Assessment Series No 38, Rome.

[13] Ibid.

[14] See eg V Michelacci and others, 'European Union Reference Laboratories support the National food, feed and veterinary Reference Laboratories with rolling out whole genome sequencing in Europe' (2023) 9(7) *Microbial Genomics* 001074.

[15] See Chapter 4.

[16] L Baert and others, 'Guidance document on the use of whole genome sequencing (WGS) for source tracking from a food industry perspective' (2021) 130 *Food Control* 108148.

WGS data from FBOs can be useful also for food safety authorities. The latter are tasked with verifying FBOs' compliance with the food safety framework, monitoring foodborne pathogens in the food chain, and identifying food-related sources and causes of outbreaks. Generating, or gaining access to, a wider arsenal of WGS analyses could provide FSAs with insights to support these purposes and improve their mapping and tracing of *Lm* along the food chain. Increased use of WGS can thereby contribute to improved targeting of official food safety activities.

However, there are multiple challenges for the implementation of WGS in the food industry.[17] Some of these are legal—in particular, uncertainties and lack of clarity in food safety legislation can act as barriers for FBOs to start applying WGS on a more regular basis.[18]

Yet other challenges arise from the duration and expense of WGS. Such sequencing currently takes days or weeks to perform, which is too long time for analyses to be useful as part of daily hygiene monitoring programmes. Additionally, the cost of analyses may be considered too expensive by FBOs, especially compared to only considering presence or absence of *Lm*, as is sufficient for compliance with current regulations. Thus, even FBOs wishing to utilise WGS are likely not to apply it to all isolates they detect, due to the costs.

Concerns may relate to the use of WGS data, particularly how it may be interpreted and acted upon by regulatory authorities. FBOs are worried about how much specific information the authorities would hold about their *Lm*, and—perhaps even more—what other FBOs or customers might find out about their factories and food safety controls.[19]

The extent of associated metadata ('data about data') that accompanies WGS data is an important point to consider in this context. Metadata describes the origin of the sequenced isolate and may include eg, collection date, factory name, sample location, and sample type. The issue of data sensitivity pertaining to data sharing and WGS often boils down to the amount of shared or required metadata and the notion that WGS data may never be completely anonymised as long as the key that links the WGS data with the metadata exists.

Although WGS provides considerable useful information, the data (including metadata) needs to be interpreted by competent experts, and there are risks of misinterpretation or misjudging how much weight can be put on WGS data compared to other information sources. It is important to take into account that since *Lm* is a genetically quite stable bacterium, highly similar

[17] See further AD Klijn and others, 'The benefits and barriers of whole-genome sequencing for pathogen source tracking: A food industry perspective' (2020) *Food Safety Magazine* 6696.

[18] Ibid.

[19] See further Chapter 3.

Lm may exist independently in multiple locations at once, eg, as a consequence of complex food distribution chains or transfer of equipment.[20] It is also important to take into account that biases may arise due to sampling not being performed to an equal extent or in an equal manner by all actors.

WGS data may provide clear answers with respect to the similarity of isolates, but not necessarily to their source of origin. Furthermore, errors might occur during sequencing, and the quality of the analyses can vary. The standards for how to assess the data may also differ, for instance regarding how many genetic differences one considers can exist between isolates while still concluding that they originate from a common contamination source.

In practice, these concerns may directly hinder the potential for data sharing between different actors. They highlight the importance of building competence within all relevant sectors, to ensure proper interpretation of the data at hand. The concerns are elaborated upon later in the report, particularly Chapter 3.

1.6 Methodology

The research underlying this report has consisted of a mixed methodology combining doctrinal analysis of the law as it is (*lex lata*) with an empirical mapping of stakeholder attitudes, and thereafter a relatively brief normative analysis of the law as it should be (*lex ferenda*). Relevant existing legal provisions and the possible interpretational room they provide for have been examined and held up against stakeholders' expressed attitudes and needs, to identify legal shortcomings or legal focus areas that ought to be addressed in the future.

Put simply, doctrinal legal analysis entails asking 'what the law is in a particular area'.[21] Put less simply, doctrinal analysis 'aims to give a systematic exposition of the principles, rules and concepts governing a particular legal field or institution and analyses the relationship between these principles, rules and concepts with a view to solving unclarities and gaps in the existing law'.[22]

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[20] A Fagerlund and others, 'Pervasive *Listeria monocytogenes* is common in the Norwegian food system and is associated with increased prevalence of stress survival and resistance determinants' (2022) 88(18) *Applied and Environmental Microbiology* e00861-22.

[21] I Dobinson and F Johns, 'Qualitative Legal Research' in M McConville and W Hong Chui (eds), *Research Methods for Law* (Edinburgh University Press 2007), 16, 18-19. Doctrinal analysis is also often flagged using a variety of alternative terms such as 'legal dogmatics' or 'black-letter law' analysis.

[22] JM Smits, 'What is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research' in R Van Gestel, H-W Micklitz and EL Rubin (eds), *Rethinking Legal Scholarship: A Transatlantic Dialogue* (Cambridge University Press 2017) 207, 209.

The principal focus of doctrinal research in this study has been Norwegian food law. As this law is largely based on EU legal instruments, law at the EU level is also considered. Norwegian legal provisions are interpreted in conformity with Norwegian doctrine concerning interpretation of legal sources ('rettskildelære'),[23] whereas EU legislation is interpreted according to EU doctrinal methods.[24]

Furthermore, comparisons are made with Austrian food law, which, although also based on the approach taken at the EU level, differs in significant respects from the Norwegian regulatory approach. The purpose of this comparison is primarily to observe the different systems and their functioning, to gauge what lessons or inspiration Norway might derive from the Austrian approach. No full comparative analysis is performed in this respect. However, elements of comparative method occur. Sacco describes the comparative method, distinct from the doctrinal method, as 'founded upon the *actual observation* of the elements at work in a given legal system'.[25] Herein, stakeholder interviews on how, for instance, the relevant regulatory approach functions and is perceived, constitute a central part of the discussions in Chapters 3-6.

A recurrent problem with the doctrinal legal analyses in this report is that food law at both EU and national levels contains many vaguely phrased rules, the semantics of which are difficult to determine conclusively. This is intentional from the side of the legislator. Vagueness caters for flexibility in how to comply with the legislation. It also holds the advantage of making the rules more dynamic and resilient to technological and organisational developments. Food law is designed to provide such interpretational room, taking its point of departure in diffuse standards like 'safe food', which are then specified either to some extent in more detailed regulatory instruments, or left to various 'softer' standards, such as guidelines or codes of practice. Under Norwegian 'rettskildelære', valid aids for interpreting legislative text include preparatory works (*travaux préparatoires*), court decisions ('case law'), administrative practice, secondary or delegated legislation (typically 'forskrifter'), legal scholarship and factors rooted in considerations of what is a reasonable, practicable or sensible interpretative result in a broader societal perspective ('reelle hensyn').[26] These aids are applied to the extent available. A challenge is that some of these aids—for instance, legal scholarship and case law—provide little help for tackling many of the questions examined herein.

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[23] As traditionally elaborated in T Eckhoff, *Rettskildelære* (5th edn with J Helgesen, Universitetsforlaget 2001).

[24] For an authoritative exposition, see K Lenaerts and JA Gutierrez-Fons, 'To Say What the Law of the EU Is: Methods of Interpretation and the European Court of Justice' (2014) 20(2) *Columbia Journal of European Law* 3.

[25] R Sacco, 'Legal Formants: A Dynamic Approach to Comparative Law (Instalment I of II)' (1991) 39(1) *The American Journal of Comparative Law* 1, 25 (emphasis added).

[26] See generally Eckhoff (n 23).

Vague legislative phrasing often leads to lower predictability of how law shall apply, and this problem is typically exacerbated in the context of new technologies or practices. WGS and the questions generated by its use are scantly reflected in legal texts or administrative practice. Furthermore, use of WGS is still not prevalent among FBOs. There is also uncertainty about how WGS technology will evolve and be used in the future.

These factors, along with the scarcity of helpful interpretative sources on legal aspects of WGS in the food industry, make assessments of legal developments and perceived regulatory needs particularly difficult. Thus, the report's conclusions as to how the relevant law is to be properly understood in a WGS-related context are often formulated in a relatively tentative way. Reflections in terms of *lex ferenda* are also necessarily limited. Nonetheless, understanding the law *lex lata* is a necessary precondition both to consider whether current law has the capability of addressing developments like those brought on by implementation of WGS and to identify possible reform measures.

The mapping of food industry actors' viewpoints has focused primarily on FBOs, particularly the potentials they envisage, hindrances they anticipate, and needs they express to facilitate reaping the benefits offered by WGS technology. Efforts were also made to map the viewpoints of other important stakeholders, such as FSAs and National Reference Laboratories (NRLs) tasked with *Lm* testing in food products. Despite all stakeholders having a common aim to ensure safe food, they also bring quite different perspectives to the regulatory 'mix'. The report tries to convey this variation justly while at the same time recognising that use of WGS by private actors and regulatory authorities is—and will be—connected and interdependent to a considerable extent, also on the legal plane. Thus, the report attempts to keep in mind the larger picture of public health and food safety systems in conjunction, including both government efforts and each FBO's own food safety control measures.

The mapping of stakeholders' perspectives has involved interviews and e-mail correspondence mainly conducted during the period 2021-2022, the analysis of which makes up central parts of the research conveyed in this report. As presented in Chapter 3 particularly, interviews have been conducted with various Norwegian FBOs. Furthermore, an Austrian FBO was interviewed for the purposes of gaining some insight into the industry perspective while examining Austrian law. Most of the Norwegian FBOs that were interviewed are relatively large actors within their sectors of the Norwegian food industry who have showed some interest in and knowledge about WGS. A possible bias in this regard is that these FBOs are more interested in and informed about WGS than the 'average' Norwegian FBO. In other words, one cannot assume that the views expressed by the interviewed FBOs are representative for the entire Norwegian food industry.

The interviews were qualitative and conducted in a manner comparable to what Ringdal refers to as conversation interviews ('samtaleintervjuer'). In other words, they were conducted in a flexible manner with considerable variations from interview to interview, as opposed to more strictly structured interviews.[27] Still, there was a clear underlying structure, and a list of questions was prepared as a basis to be asked to all interviewees. Thus, one might refer to the interviews as semi-structured, with considerable flexibility for the interviewees to contemplate problems presented to them. They were encouraged to speak freely, and this affected the focus and follow-up questions of each interview differently. Follow-up questions were, thus, partially planned and partially improvised, as described by Ringdal.[28] However, the aim was always to return eventually to the planned list of questions. Each FBO interview usually lasted for approximately two hours, ensuring the possibility to explore various relevant topics at considerable length.

A challenge with this approach is the difficulty of analysing qualitative data, as there are no standardised techniques to do this, unlike for numeric data.[29] As already stated, the purpose of the research has been mainly to map attitudes and needs, opinions and reflections on the part of food industry actors. The authors of the report have thus chosen, to the best of their ability, to convey statements that appear most representative for the actors involved and most relevant to the report.

As for other stakeholders, some interviews were conducted similarly to those with the FBOs, while contact with other actors was limited to e-mail correspondence due to practicalities or interviews not being possible. An interview was conducted with an employee of the Norwegian NRL responsible for *Lm* analyses of samples from agri-food and feed, and a simpler conversation took place with the NRL responsible for *Lm* analyses of samples from seafood. The first-mentioned person made clear that their views or opinions did not necessarily represent those of the NRL but were based on own experiences and knowledge. The Norwegian microbiology reference laboratory for *Lm* responsible for diagnostic testing of clinical samples of human origin was not available for interview, but e-mail correspondence took place. Contact with the Danish NRL for *Lm* for food was also restricted to e-mails, while the Austrian Health Ministry and Austrian NRL for *Lm* participated in interviews.

[27] K Ringdal, *Enhet og mangfold. Samfunnsvitenskapelig forskning og kvantitativ metode* (Fagbokforlaget 2007) 217-218.

[28] Ibid, 222.

[29] Ibid, 221.

1.7 Report Structure

Following this introductory chapter, the report provides a short overview in Chapter 2 of relevant Norwegian and EU law concerning food safety. This is in order to provide necessary background information for understanding the more detailed and often complex regulatory issues taken up in Chapters 4, 5 and 6.

Chapter 3 sets out key findings from stakeholder interviews, in particular with FBOs regarding their attitudes towards WGS. Note that, while Chapter 3 contains much of the interview discussions, certain interview topics are instead included in Chapters 4-6 where the relevant questions are discussed more thoroughly in connection with concrete regulatory processes.

Chapters 4, 5 and 6 are dedicated to parsing the implications of WGS under current law. Three issues are in focus: (i) the role of WGS data in assessing the safety of food; (ii) access by food safety authorities to WGS data, or isolates on which to perform WGS, from the food industry; and (iii) FBOs' ability to receive isolates and sequences held by the authorities. Chapter 4 deals with the first-listed matter, Chapter 5 with the second-listed matter, and Chapter 6 with the third.

Chapter 7 draws together key observations and conclusions from the preceding chapters, pointing to some apparent regulatory shortcomings. The chapter then advances some proposals for possible legal approaches (*lex ferenda*) that could hopefully make it more attractive for FBOs to apply WGS while also offering better utilisation of WGS data.

2 Relevant Law: A Brief Overview

2.1 Basic Constituents of Food Law

Legal requirements concerning food safety constitute a sub-category of what is typically termed 'food law'. This area of law comprises multiple legislative instruments, some of which are international in origin and scope of application, others of which are adopted by national legislatures to cater predominantly for the needs and conditions of a specific country. Together, these instruments form the cornerstones of an enormous public law framework codifying basic rules and principles for food safety management. An essential element of the framework is the establishment of independent regulatory authorities (ie, FSAs) to monitor, refine, supplement and enforce the legislative rules.

For the European Union (EU), the overarching public law framework for food safety is provided by Regulation 178/2002/EC—usually called the 'General Food Law' (GFL).[30] The regulatory principles of the GFL provide the basis for more customised food safety norms, such as rules concerning hygiene, animal health, use of pesticides and food additives. Two important examples are Regulation 852/2004/EC,[31] which lays down general rules on hygienic food production, and Regulation 853/2004/EC,[32] which sets out specific hygiene rules for food derived from animals.

Another important example—and one particularly relevant for this report—is Commission Regulation (EC) 2073/2005.[33] This Regulation lays down, *inter alia*, the maximum thresholds for *Lm* presence in food products,[34] along with requirements for *Lm* sampling in the processing environment.[35] Especially noteworthy here is the requirement that producers of RTE products must adhere to *Lm* limits of either maximum 100 cfu/g[36] at the end of shelf-life or absence in

[30] Regulation 178/2002/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2000] OJ L 31/1 (hereinafter 'General Food Law' or 'GFL').

[31] Regulation 852/2004/EC of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2004] OJ L 226/3 (hereinafter 'Food Hygiene Regulation' or 'FHR').

[32] Regulation 853/2004/EC of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [2004] OJ L 226/22.

[33] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [2005] OJ L 338/1 (hereinafter 'Microbiological Criteria Regulation' or 'MCR').

[34] MCR Annex I, Chapter I.

[35] MCR Art 5(2)(2).

[36] The cfu (colony forming unit) is an estimate of the number of living cells.

25 grams (for food samples).[37] They must also 'sample the processing areas and equipment for *Lm* as part of their sampling scheme'.[38]

Norway's principal statutory instrument in the field is the 2003 Food Act (matloven).[39] This is supplemented by a voluminous amount of secondary legislation in the form of 'forskrifter' (regulations). The food safety legislation adopted at EU level is routinely incorporated into the 1992 Agreement on the European Economic Area (EEA), an agreement to which Norway is a party. Norway's food safety regime accordingly embodies and reflects the requirements of the GFL and other central EU rules in the field.[40]

The national regulatory authority for food safety in Norway is the Norwegian Food Safety Authority (Mattilsynet; MT). Similar to its counterparts in other European countries, MT is given broad discretionary powers when pursuing its remit, subject to the requirement that its exercise of powers be necessary and proportionate.[41] This includes the power to require information from FBOs—as elaborated in Chapter 5.

Other significant actors in the field are the Norwegian Institute of Public Health (Folkehelseinstituttet; FHI), the Norwegian Veterinary Institute (Veterinærinstituttet; VI) and the Norwegian Institute of Marine Research (Havforskningsinstituttet; HI). FHI plays a central role in mitigating outbreaks of illness or disease that threaten public health. VI is designated Norway's National Reference Laboratory (NRL) for *Lm* in agri-food and feed, while HI is designated NRL for *Lm* in seafood. FHI houses the Norwegian microbiology reference laboratory for *Lm* responsible for diagnostic testing of clinical samples of human origin.

2.2 General Principles and Regulatory Mechanisms

The central rule in food law is that food be 'safe'. In the words of the GFL, '[f]ood shall not be placed on the market if it is unsafe'.[42] Complying with this norm is primarily FBOs' responsibility. To this end, EU food law has adopted what is often termed the 'food chain approach'—that is, an approach mandating that FBOs at all stages of the supply chain ensure and verify that

[37] MCR Annex I, Chapter I, 1.2-1.3.

[38] MCR Art 5(2)(2).

[39] Lov 2003-12-19-124 om matproduksjon og mattrygghet, mv. (hereinafter 'matloven'). There is no official English translation of the Act. We base our English versions of the Act's provisions on a translation available at: https://app.uio.no/ub/ujur/oversatte-lover/data/lov-20031219-124-eng.pdf.

[40] See particularly the 2008 Food Law Regulations (Forskrift om allmenne prinsipper og krav i næringsmiddelregelverket, FOR-2008-12-22-1622; matlovsforskriften) § 1; 2008 Food Hygiene Regulations (Forskrift om næringsmiddelhygiene, FOR-2008-12-22-1623; næringsmiddelhygieneforskriften).

[41] Matloven § 23.

[42] GFL Art 14(1).

their products meet relevant food law requirements. The key provision here is GFL Article 17(1) which states:

> 'Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met'.

Management of risk is integral to this approach, where 'risk' means 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard'.[43] According to the GFL, 'food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure' (Article 6(1)). Thus, food law embraces a pre-emptive, *ex ante facto* regulatory stance that prompts FBOs to anticipate and mitigate food-related risks, as opposed to a reactive, *ex post facto* strategy geared to allocating responsibility and liability after adverse health effects occur.

European food law also operates with a 'precautionary principle', expressed as follows:

> 'In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'.[44]

Adherence to the precautionary principle buttresses food law's anticipatory, pre-emptive character.

Another key feature of the European food safety regime is its use of meta-regulation. The latter term denotes 'ways that outside regulators deliberately—rather than unintentionally—seek to induce targets to develop their own internal, self-regulatory responses to public problems'.[45] As already noted, European food law sets out particular goals and stipulates a risk-based, food chain approach for reaching them. It also stipulates basic elements for this approach.[46] Yet FBOs are otherwise given considerable leeway to develop their own compliance regimes

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[43] GFL Art 3(9).

[44] GFL Art 7(1).

[45] C Coglianese and E Mendelson, 'Meta-Regulation and Self-Regulation' in R Baldwin, M Cave and M Lodge (eds), *Understanding Regulation: Theory, Strategy, and Practice* (2nd edn, Oxford University Press 2011) 147, 148.

[46] See eg GFL Art 18 (laying down registration and traceability requirements).

through private standards. These meta-regulatory characteristics promote 'buy-in' and private rulemaking from FBOs, albeit within the dictates of an overarching public law framework.

The rules for ensuring hygiene in food production provide an apt illustration of meta-regulatory mechanics. In keeping with the GFL's 'food chain approach', the Food Hygiene Regulation (FHR) states that '[f]ood business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation'.[47] The Regulation then states that meeting these requirements must involve implementing 'Hazard Analysis Critical Control Point' (HACCP) principles.[48] These are globally recognised principles for identifying, monitoring and mitigating food safety hazards and for documenting the remedial measures applied. However, they provide little more than a procedural backbone for the development by FBOs themselves of internal rules and procedures for hazard mitigation. Thus, the legislative references to HACCP principles constitute a form of meta-regulation intended to shape and spur industry-led rule development in the field.[49]

At the same time, FSAs have a key role to play in determining the degree to which FBOs' food safety procedures pass legal muster. While compliance with specific legislative criteria may give rise to an industry presumption that the food is safe, an FSA may still impose corrective measures if it has reason to believe that the food is nevertheless unsafe.[50] Thus, FSAs possess an 'industry override' power. This is ancillary to their more general mandate of monitoring and verifying FBOs' compliance with the legislative requirements.[51] In consequence, FSAs' viewpoints and practices are central for FBOs' understanding of food safety law.

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[47] FHR Art 3.

[48] FHR Art 5.

[49] In a similar vein, see P Verbruggen, 'Private food safety standards, private law and the EU: exploring the linkages in constitutionalization' (2020) in MC Gamito and HW Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes*, Edward Elgar, 54-79, 64 (noting that the introduction of HACCP principles in EU food safety law created demands for industry guidance for European FBOs—particularly smaller operators—on how to operationalise the principles).

[50] See GFL Art 14(8) ('Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe').

[51] See eg GFL Art 17(2).

2.3 Legal Specifics on *Lm*

Current food safety law does not take account of different properties between subtypes of *Lm*, as may be revealed by WGS. It focuses on the *Lm* bacterium as such, be it by posing limits for *Lm* presence in foods,[52] or requirements for testing and hygiene.[53] Whether such variations in properties may nevertheless have relevance (more indirectly) under the current system, appears more a question of its use in risk assessments.[54]

Account is taken in the legislation of *Lm* being a widespread bacterium. Therefore, both in the EU and many other regulatory frameworks around the world, it is considered a hazard to keep under control rather than one to eliminate. EU legislation contains no zero-tolerance. Instead, it focuses on minimising the prevalence and level of *Lm* in foods to decrease the disease burden of *Lm*. Getting completely rid of *Lm* is regarded as unrealistic,[55] and efforts to achieve such an aim likely not proportional. The legislation thus reflects an aim of keeping amounts at an acceptable level.

Further, there is no explicit obligation under EU law for FBOs to notify the authorities upon detection of *Lm* in their processing environments. Cases of listeriosis in humans, when detected, have to be reported.[56] For FBOs, the requirement to notify relies on whether the finding gives reason to believe ('grunn til mistanke') that the food or ingredients are injurious to health.[57] *Lm* in the processing environment is in practice not considered to meet this threshold. Notification takes place primarily if foodstuff with *Lm* above the legal maximum levels has been sent to the market. Thus, the food safety authorities usually have no complete overview of *Lm* across various food production sites. Norwegian FBOs may choose to inform the FSA about some such detections, but MT does not keep complete records of FBOs' *Lm* detections.

[52] MCR Annex I, Chapter I.

[53] See eg MCR Art 5(2)(2).

[54] See further Chapter 4 on the role of WGS data in assessing food safety.

[55] See M Zwietering and others, 'All food processes have a residual risk, some are small, some very small and some are extremely small: zero risk does not exist' (2021) 39 *Current Opinion in Food Science* 83-92.

[56] See Forskrift om Meldingssystem for smittsomme sykdommer (FOR-2003-06-20-740; MSIS-forskriften) Chapter 3.

[57] Matloven § 6(1).

2.4 Soft Law and Policy

A variety of 'soft law' codes (eg, guidelines, standards, codes of practice) complement the legislative rules. Some such codes are developed by FSAs, others by private actors in the food industry.

An influential instance of the latter is the Global Standard for Food Safety adopted and published by the British Retail Consortium (BRC).[58] Despite its UK origins, it has become an internationally recognised benchmark for best practice in food safety management.[59] The BRC offers both audit and certification services that are widely applied across food industry sectors in many countries.

Finally, it is worth noting that, in parallel to increasing uptake of WGS, a more holistic policy approach is emerging to tackle *Lm* incidence. In Europe, this policy is commonly referred to as 'One Health'. It considers the whole of *Lm* detected in human patients, in foods, as well as in animals and the environment. Recognising the close interconnectedness of health across these dimensions, the policy is aimed at improving outbreak investigations. An important example is the EFSA One Health WGS System, enabling comparisons between, *inter alia*, *Lm* from humans, food, feed, animals and the environment to be compared at the EU level.[60] Such tendencies highlight the importance of data sharing to optimise health improvement strategies. They encourage in turn greater interdisciplinary collaboration and communication across traditional sectors.

[58] See further https://www.brcgs.com/our-standards/food-safety/.

[59] The standard is approved by the Global Food Safety Initiative (GFSI), a consortium of consumer and food industry actors dedicated to assessing, approving, and improving food industry standards across the world. See further https://mygfsi.com/who-we-are/overview/.

[60] See G Costa and others, 'Guidelines for reporting Whole Genome Sequencing-based typing data through the EFSA One Health System' (2022) 19(6) *EFSA Supporting Publications* EN-7413.

3 Stakeholder Attitudes and Perceived Needs for Regulatory Reform

3.1 Introduction

As stated in Chapter 1, a variety of industry actors have been interviewed during 2021-2022 as part of the legal work package (WP5) in PathoSeq. The primary purpose of the interviews was to map FBOs' attitudes to, envisaged use of, and experienced or envisaged challenges with, applying WGS. This chapter sets out the main results of these interviews, with a view to providing an enhanced comprehension of food industry perspectives on WGS. When applicable, insights from the interviews are incorporated into the legal deliberations in Chapters 4-6.

3.2 About the FBOs Interviewed

The FBOs interviewed produce foodstuffs with varying *Lm* risk-levels. This variation largely hinges on the degree to which they produce RTE food. As previously noted, for RTE products, such as deli meat, sushi and smoked salmon, there is an elevated need to monitor, test for, and control *Lm* along the production process. Among the interviewees were also fish slaughterers that do not themselves produce RTE foods but prepare fish for further processing by others, where the end-product may be RTE foods that also does not undergo any heat preparation throughout the processing chain.

Some producers have multiple production sites and adhere to over-arching requirements for the whole corporation with quality control personnel placed locally at the various locations, so that *Lm* mitigation may be organised across multiple levels. The division of tasks can thus vary between FBOs. For example, HACCP, risk analyses, and daily follow-up might be at the local level, where there is in-depth knowledge on the processes and products, with central support should a problem emerge and escalate.

While Norwegian meat producers generally do not produce for export, the fish slaughterers and producers of salmon and trout products export much of their produce, and they do so globally. This includes countries such as Japan, China, Australia and the US. One producer of RTE fish products explained that it used to export to the US but had ceased to do so due to unpredictability, since should any *Lm* be detected during a control, the whole container would be either returned or destroyed, presenting too high an economic risk for the FBO.[61] While a few countries, like the US and China, operate with zero *Lm* tolerance, it will be recalled from the previous

[61] Interview H.

chapter that EU law permits small amounts of *Lm* up to the limit of 100 cfu/g at end of shelf-life in RTE products.

3.3 Experiences with Particular *Lm* Challenges

The FBOs interviewed had varying experiences with *Lm* as a challenge. This variation could depend on differences in their products and associated risks, their differing sizes and production volumes, as well as mere ad hoc *Lm* incidence.

Some interviewees had not experienced any persistent *Lm* challenges,[62] as cleaning and disinfection had been effective to eliminate the bacterium. Others again had experienced greater challenges, either being subject to outbreak investigations, or faced persistent *Lm* in their factories. Those who had experienced such challenges described having learned from them. They referred to the value of tracing sources and making targeted efforts continuously over time, eg, through increased cleaning.[63] Detections of *Lm* also provided an opportunity to discover a bad practice or flaws in routines, prompting adjustments of the routines to improve safety.[64]

3.4 Adherence to Required Limits

As noted in Chapter 2, producers of RTE products must adhere to *Lm* limits of either 100 cfu/g at the end of shelf-life or absence in 25 grams (for food samples). This is with respect to the samples of the product, not product surfaces or the processing environment. When asked about which requirement they adhere to, a majority of the interviewed FBOs stated that they adhere to absence in 25 grams.[65] Those adhering to absence in 25 grams would retain the product if *Lm* had been detected or recall it if the product had already left the factory. Qualitative tests can be used as a tool for release of products, such that sampled products are not released until they have tested negative.

A meat producer remarked that if it were to adhere to 100 cfu/g, the *Lm* would grow sufficiently quickly as to significantly reduce the product's shelf-life.[66] This FBO stated that it would not speculate about whether it would manage to stay beneath 100 cfu/g, adding that at least one of its major customers applied a zero tolerance for *Lm*.[67]

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[62] Interviews D, G.

[63] Eg interview E.

[64] Interview B.

[65] Interviews A, B, C, D, G, H.

[66] Interview B.

[67] Ibid.

A couple of FBOs described adhering to 100 cfu/g at the end of shelf-life, based on data modelling or shelf-life studies. In this regard, it appears that relevant industry guidelines ('bransjeretningslinjer') are considered a useful tool and adhered to. One FBO stated that it categorises its products based on their potential for *Lm* growth, where the guidelines lay out various product categories that determine the degree of intensity of testing regimes to which the products are subject.[68] Where, for any product, studies for the potential of *Lm* growth have not been performed, the product will be categorised such as to undergo the highest intensity of sampling (even if it should otherwise have belonged to a more lenient category).[69]

One of the fish slaughterers remarked that it is supposed to adhere to *Lm*-requirements for non-RTE products, but that it in practice adheres to 100 cfu/g at the end of shelf-life for whole fish, based on modelling.[70] This was due to the customers (exporters) tending to take the 100 cfu/g approach, causing the FBO to adapt accordingly.[71] The FBO stated that, in its experience, it never reaches those limits anyway (the measurements would usually be less than 10 cfu/g). The FBO had therefore agreed with the exporter to apply this limit value. This FBO also referred to MT having applied some pressure in this direction.

Another fish slaughterer, adhering to absence in 25 grams, stated that it does not base its practice on the EU regime's distinction between RTE and non-RTE products because China and USA apply a zero-tolerance policy regardless.[72] This is despite most other countries having less strict policies that are more in accordance with the EU rules.

3.5 Results from FBOs' Testing

The FBOs would usually receive qualitative test results (presence/absence) within one to two days.[73] One more day was indicated for quantitative results (indicating the number of cfu/g in the sample).

For production of certain foodstuffs, it is imperative to receive the results quickly, particularly for RTE foods of short shelf-life, or fish exports that will become RTE. Already within one to two days, the fish may have advanced far along in the production process. Early results can then

[68] Interview F.
[69] Ibid.
[70] Interview E.
[71] Ibid.
[72] Interview A.
[73] Interviews A, B, C, D, E, F.

enable re-routing the fish upon *Lm* detection, so that it can be sent to a producer that will apply a heating step during processing.[74] Some FBOs therefore receive indications of any positive at the earliest point possible,[75] to be ready to deal with detection without delay. Some producers used qualitative tests as a tool for product release.[76]

A couple of FBOs described delivering samples for analysis once a week and receiving the results approximately a day and a half after such delivery.[77] A week may then pass before they learn about presence of *Lm*, at which point the produce has come quite far. One of these FBOs is a fish slaughterer (but not producing RTE products itself). That FBO assumed that the receiving FBO performs more extensive sampling upon obtaining the fish, and before supplying it to the market.[78] Testing by the receiving FBO was also considered more manageable, as it operates with smaller batches.

It bears emphasis that WGS is a method that would be applied later and for different purposes. Receiving WGS results may take weeks. WGS is thus not suitable for product release purposes. Application of WGS would rather be an addition to already applied analyses.

3.6 Customer Requirements for Testing and Information

Specific customer requirements (beyond industry standards) appear not to be very prevalent. One FBO stated that its Norwegian and European customers only require adherence to the legal rules, and nothing stricter.[79] Another FBO stated that it has an important customer with zero-tolerance for *Lm*, but that the customer poses no requirements on how to perform the testing (beyond the legal requirements for this); the customer trusts the FBO to conduct risk-based testing as it sees fit.[80]

However, many customers would require certified adherence to a relevant standard, such as the BRC Global Standard for Food Safety, and this would be accepted as adequate.[81] Adherence to a standard could also reduce the need for customer audits, unless the FBO experiences many discrepancies with its products. Customer requirements for certification appear common: a fish

[74] Ibid.
[75] Interview F.
[76] Interview B.
[77] Interviews D, H.
[78] Interview D.
[79] Interview H.
[80] Interview B.
[81] Interviews A, C, D, F.

slaughterer commented that all customers require certification.[82] They may require adherence to any relevant standard,[83] or to a specific one. Certification is then a customer requirement preconditioning the FBO's delivery to that customer, and it may entail stricter requirements than prescribed by legislation.

3.7 Information Sharing in the Food Chain

3.7.1 Perceived Sensitivity of the Data

From the interviews, it seems clear that the FBOs consider WGS data derived from isolates from their facilities to be relatively sensitive information for their businesses. Several of the FBOs gave the impression that it is sensitive even to share the fact that they have detected *Lm* at all. The reason for this appears mainly rooted in fears of reputational consequences and possible critique that the FBOs should have handled hygiene and *Lm* mitigation differently.[84]

Regarding potential information sharing with its customers, one FBO indicated that it would be very reluctant to disclose information 'about something that it obviously could have done something about, or that indicated very obvious poor production hygiene, or something similar', concluding that 'I think it would take a lot before we shared that sort of information'.[85] Another interviewee remarked that the sensitivity of WGS data would depend greatly on the situation, particularly whether it may somehow be used against the FBO.[86] This appears truly one of the greatest concerns among the FBOs in regard to disclosing WGS data.

3.7.2 *Lm* Notifications from Suppliers

Most of the interviewees stated that they would not be notified by their suppliers upon detection of *Lm*.[87] Suppliers are not legally required to provide such information, and there appears little practice (regarding raw materials) to arrange for this through agreements. Neither do FBOs necessarily sample every batch of raw materials they receive. One FBO referred to this practice as trust-based.[88] Conversely, notice from suppliers appears common for detection of *Salmonella*

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[82] Interview A.

[83] A prerequisite being that the standard is approved by the Global Food Safety Initiative (GFSI).

[84] Interview B.

[85] Ibid ('det hadde jo ikke vært noe artig å dele [med kundene] informasjon om noe som vi helt klart kunne ha gjort noe med, eller at det hadde vært helt opplagt dårlig produksjonshygiene, eller noe sånt. […] Jeg tror det sitter langt inne å dele den informasjonen').

[86] Interview H.

[87] Interviews B, F, G, H.

[88] Interview C.

spp. and antibiotic resistance. The difference hinges on different rules and likely also the fact that *Lm* is more commonly detected.

At the same time, a fish slaughterer stated that it would be notified if its supplier tested positive for *Lm*, eg, on production surfaces.[89] Another fish slaughterer also stated that the fish farmers may notify detections, although they perform *Lm* sampling relatively rarely.[90] The purpose is to improve management of *Lm* risks: the recipient still receives the fish, but may, for instance, process it at the end of the production day, immediately prior to cleaning, in order to minimise the risk of spreading.[91] This provides an opportunity for the recipient to take appropriate measures. However, the FBOs had no written agreement mandating such notifications.

Although transparency is generally perceived as positive, if *Lm* is detected on raw materials, it may depend on the production and risks whether the materials are then received and processed. One FBO remarked:

> 'It's a question as to what we shall use [the material] for. There is always a risk when taking in *Lm*-infected material into our production. That risk exists in other places as well. […] We are very sceptical to taking in *Lm* and using it in our production, in such a case. That is something we would assess quite carefully. We are extremely concerned about *Lm*'.[92]

It is interesting to observe that this FBO is a meat producer, while the other FBOs referred to above, were fish slaughterers and thus subject to different risks and obligations in respect of *Lm*. This point is elaborated upon directly below.

3.7.3 *Lm* Information to the Recipients

Attitudes to sharing information about *Lm* appear to be shaped by quite different considerations and needs in the Norwegian fish industry compared to in industries processing other products like meat. Fish constitute a central part of Norwegian food production, including export of fish that may be further processed elsewhere to high-risk RTE products, such as smoked salmon or sushi.

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[89] Interview A.

[90] Interview D.

[91] Interview A.

[92] Interview C ('Det spørs jo hva vi skal bruke den til, da. Det er jo alltid en risiko å ta inn en *Lm*-befengt vare i produksjonen vår. Det er det også andre steder. […] Vi er veldig skeptiske til å ta inn *Lm* og bruke det i produksjonen vår, i så fall. Det er noe vi ville ha vurdert ganske nøye, i så fall. Vi er meget redde for *Lm*').

An FBO engaged in fish processing remarked that it would inform the exporters upon detection of *Lm* in products.[93] It also notifies the exporters if *Lm* is detected in the processing environment in such a way that there is a risk of presence also in or on the fish, even if no *Lm* has been detected in or on the fish.[94] The FBO can then notify the exporters of the fish of a slight challenge in the environment and indicate to the exporter a certain caution in respect of what of their customers receive the fish.[95] This would allow the exporters to then adjust their decisions as to whom they send the fish,[96]—for instance, that it should not be sent to China due to the latter's zero-tolerance policy. The FBO explained that it sends analysis results as to whether *Lm* is detected, continuously and immediately from the lab to its two major exporters.[97]

Another fish producer perceived MT to mandate that it should notify about 'everything', even detection on equipment, to its customers.[98] The interviewee remarked that the consequence might be a reduced frequency of sampling and testing, and thus a decreased probability of *Lm* detection, to lower the risk of having to notify.[99]

Yet another FBO explained that lack of detection of *Lm* in its randomly performed fish sampling programme is not equivalent to a guarantee against *Lm* presence: *Lm* may still exist on the next fish.[100] On this basis, the FBO thought it a bit pointless to notify customers, referring also to the fact that the customers also perform their own sampling upon reception, and that those tests hold much higher potential to harm their reputation, should they discover large amounts of *Lm*.[101] A couple of FBOs also stated that environmental detection of *Lm* is generally not notified.[102]

Another hindrance mentioned was scant knowledge among the exporters, such that they cannot use the information,[103] or that it may easily be misunderstood and cause overreaction.[104]

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[93] Interview E.
[94] Ibid.
[95] Ibid.
[96] Ibid.
[97] Ibid.
[98] Interview A.
[99] Ibid.
[100] Interview D.
[101] Ibid.
[102] Interviews D, H.
[103] Interview D.
[104] Interview A.

It seems that for at least some fish producers, conveying information of *Lm* detection to their customers, although not legally mandated, is not avoided, at least when detections are rare and notification perhaps takes place towards different customers. The relevant FBOs were slaughterers preparing the fish mainly for export. Thus, they do not produce RTE products, possibly rendering the information perceived as less sensitive.

A meat producer, on the other hand, explained that it has no agreements to contact its customers about *Lm* detection in the processing environment, and that such agreements are not common.[105] Should *Lm* be detected in the environment, the products might be retained,[106] but it was clearly stated that the FBO will not inform its customers about *Lm* detection in the processing environment, as long as the products themselves are not contaminated.[107]

In general, many FBOs limit providing *Lm* information to a 'need-to-know'-basis—that is, the information is not provided unless necessary due to a recall or delivery problem.[108] Customers usually do not require information on *Lm* findings.[109]

3.7.4 Notifications to the FSA

All FBOs stated that, as long as there is no danger to public health, they would normally not notify MT about detection of *Lm* in the processing environment, most of them even if detection occurred repeatedly; however, they follow up internally.[110] As one interviewee remarked, 'as long as we have control within our own facilities, we do not notify'.[111] Multiple FBOs perceived this as a matter of trust—MT trusts the FBOs to handle *Lm* according to their responsibility to ensure that the food is safe. This is a consequence of the flexible meta-regulatory character of the current legal framework as described in Chapter 2.

In the face of a long-lasting *Lm* challenge in their facilities, some FBOs would inform MT about this and how it is being handled, but managing it would still be left to the FBO.[112] Information may also be sent to MT when *Lm* is found in products retained at the facilities, despite this not being required.[113] For whole fish, it appeared considered unnecessary to alert MT.[114] Findings

[105] Interview C.
[106] Ibid.
[107] Interview B.
[108] Interview F.
[109] Interview B.
[110] Interviews A, B, C, D, F.
[111] Interview C ('så lenge vi har kontroll i eget hus så varsler vi ikke').
[112] Interview B.
[113] Interviews B, C.
[114] Interview E.

in products sent to the market are notified. MT would also receive information when it requests this. So far, according to interviewees, MT has not asked for *Lm* isolates or copies of sequences in these contexts, beyond whether *Lm* is detected.[115]

3.7.5 Potentials for Sharing WGS Data

Whole genome sequencing is still in its infancy among FBOs. In respect of sharing WGS data between industry actors, this appears (at least for now) to occur primarily in connection with research projects. One FBO expressed uncertainty as to whether it would want to continue sharing outside of these projects.[116] In general, the possibility of such sharing seems still not thoroughly explored or discussed among FBOs.

An FBO stated that it would certainly be useful if everyone in the production chain partakes in WGS data sharing, including that suppliers are transparent, so that the origin of *Lm* can be traced back throughout the food production chain.[117] Another FBO thought it would not make much difference to share WGS information between FBOs as it considered that the handling of *Lm* (hygiene measures, etc) would remain the same.[118] This FBO, however, thought it would be interesting to receive information on fish it receives, since it comes into contact with its production equipment, making relevant knowledge about any specific strains among the suppliers.[119]

Likely more realistic, at least in the near future, is sharing between facilities within the same corporation. Such facilities may often send each other ingredients or foodstuffs, and already be fairly adept at sharing information. There would not be the same risks associated with sharing business sensitive data, as towards competitors. Some FBOs thus envisaged sharing WGS data between their corporation's various facilities, to get a better overview of how pathogens move internally within and between these facilities.[120]

Several of the interviewees recognised that there would be advantages to increased openness and transparency in the food chain.[121] At the same time, FBOs expressed scepticism. One FBO stressed that any such data, if shared, would need to be shared in a pedagogical manner, clearly

[115] Interview B.
[116] Interview C.
[117] Ibid.
[118] Interview D.
[119] Ibid.
[120] Eg interview C.
[121] Eg interview H.

explaining the 'whats, whys and hows'.[122] Another FBO expressed doubts about the utility of access to information concerning what *Lm* other FBOs detect, since it did not envisage having the capacity to spend time analysing such information.[123] The important information would be that the product is compliant or 'safe' when leaving the FBO, often expressed in terms of an analysis certificate; *Lm* detected at a later stage, regardless of where it originated, is the responsibility of the FBO that detects it.[124]

A fish slaughterer clearly stated that it does not share WGS data with anyone.[125] The reason expressed was concerns about scant knowledge of WGS (eg, in the event of traceback from Europe to an FBO in Norway for strains that may be very similar in multiple FBOs, of which not all perform WGS).[126] At the same time, the FBO was not certain whether increased knowledge and use of WGS could make WGS data sharing more relevant: according to the FBO, there is still a concern that if one notifies a customer in a different country about *Lm*, that the customer panics, alerts the authorities, and returns the products—even if those products were actually to be heat treated before consumption.[127] The same concern was raised for sharing with the authorities; that a perceived low level of knowledge created a risk of overreaction.[128] At least for now, this FBO therefore considered it best to contain WGS results to the extent it may. The FBO thought any change in its stance on this matter would lie far ahead in time.[129]

3.7.6 Attitudes Towards a WGS Database on *Lm*

The interviewees were asked to contemplate the potential for creating a shared database of WGS data of *Lm* from Norwegian FBOs. Databases containing such data already exist to some extent. FHI keeps a database of all sequences from clinical isolates as well as sequence data it receives in connection with *Lm* outbreak investigations. The NRLs (VI and HI) have their databases. In addition, other actors, like commercial laboratories or research institutions, keep databases. However, current databases are sectoral, and information is shared according to what is strictly necessary. In theory, a more comprehensive database routinely including new WGS data from Norwegian FBOs, could provide a better overview of the diversity of *Lm* in production facilities and increased knowledge of the spread and characteristics of specific strains. Such a database could be administered by an authority or as a cooperative endeavour between FBOs. It could be based on data from outbreak investigations only, surveillance programmes, or even routine

[122] Interview H.
[123] Interview B.
[124] Ibid.
[125] Interview A.
[126] Ibid.
[127] Ibid.
[128] Ibid.
[129] Ibid.

submission from the FBOs' own food safety control programmes. This possibility was raised in the interviews first and foremost as a hypothetical thought experiment to gauge FBOs' willingness to share such data and have it organised in a database, what concerns they might have about such a possibility, and what conditions appear most favourable for them to accept a database of this kind being implemented.

The FBOs were generally positive to increased research and knowledge on *Lm* and WGS. They could see the usefulness of a database, eg, for improved mapping both nationally and internationally,[130] provided that it includes all or most FBOs. One FBO also thought that an authority-administered database might increase the attention FBOs pay to food safety challenges, as (particularly among fish slaughterers) it may be tempting to prioritise volume and speed over food safety and quality beyond the bare minimum.[131] This FBO therefore imagined that an extensive authority-managed database of FBOs' *Lm* genome sequences could be a potential incentive to improve overall food safety practices.[132]

Nonetheless, all interviewees asked expressed some form of scepticism or concern regarding how such a database would be implemented and used.[133] A database would entail information sharing—albeit to differing degrees and forms of compulsion, depending on the model followed. The previous section indicates that the willingness to share data appears to vary between FBOs. As pointed out by one interviewee, some FBOs find it difficult even to admit to detection of *Lm* in their facilities, as it can raise suspicions of poor hygiene routines;[134] sharing WGS data, with the level of detail it entails, can then seem unthinkable. There has also so far not been any practice to share *Lm* data within the industry.[135]

The main concern, however, appears to be how such a database would be used, particularly if it is to be accessible also for private actors.[136] The FBOs appeared particularly concerned that other FBOs (their competitors) might get access.[137] The concern rests largely on the unwillingness to share sensitive or detailed information with competitors, as well as a worry that other actors might find a way to highlight negative information to the detriment of specific FBOs.[138]

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[130] Interviews B, F.
[131] Interview D.
[132] Ibid.
[133] Eg interview B.
[134] Interview E.
[135] Interview G.
[136] Interview F.
[137] Eg interview F.
[138] Interview F.

A related concern mentioned was the reputational consequences if an FBO is linked to a known outbreak of *Lm*, such that customers may refuse to receive their products.[139] Large production volumes, like in the salmon industry, increases the severity of such consequences. An FBO expressed concerns that any publicly accessible database containing such information can lead to loss of customers, and that risks of this would increase with WGS.[140]

The interviewees also expressed uncertainty about the potential value of sharing WGS data between FBOs.[141] The fact that they are competitors appears decisive, despite there being a certain degree of crossing supply or production chains, which could be an incentive to cooperate on a database that could provide knowledge about how *Lm* travels within the food chain. Adding to this, there appears to be a general expectation that no other FBOs would share WGS data with other industry actors.[142]

Some level of anonymisation and limitation of the amount of accompanying associated metadata might be envisioned to ameliorate these concerns, as it should then not be possible to identify specific FBOs. One FBO suggested that sharing between FBOs would require pseudonymising the data, where perhaps a neutral stakeholder could possess the (re-)identification keys.[143] Another interviewee, however, thought that anonymisation might deprive the data of any value at all.[144]

In general, the interest in any industry-initiated database for sharing of data between FBOs appeared low. The attitude was different towards data sharing within corporations and between their own localities. The desirability and utility of these internal arrangements were greeted with a much higher degree of positivity by interviewees, both with regards to sharing data and to discussing findings and their implications in order to learn.[145] In such a setting, concerns about competitors' access to sensitive business data, or misuse by other FBOs, are to a large extent eliminated.

As for the potential for an expanded authority-administered database, the main concern appears a lack of trust in how the authorities would use the data, and in their competence to assess it in

[139] Interview E.
[140] Ibid.
[141] Eg interview F.
[142] Eg interview E.
[143] Interview G.
[144] Interview F.
[145] Eg interviews E, G.

an appropriate manner (eg, that they might jump to conclusions that are not adequately founded).[146] The prospect that the authorities might be able to simply compare any sequence from clinical patient isolates with a database of *Lm* sequences from the food industry raised concerns that adequate investigations might then not be performed. This appears to be perceived as a completely different matter than if epidemiological examinations lead to a suspicion which then cause the authorities to come to an FBO to collect samples and compare sequences.[147] Furthermore, fears were expressed that the authorities might use the data without adequate critical thinking and understanding of what information can and cannot be derived from the data.[148]

A pertinent question is how data should be gathered for such a database. One FBO stated that it would of course not hinder MT in collecting samples and performing WGS on any *Lm* isolates contained in these samples and building a database from these elements, but that the FBO would not be submitting data voluntarily for that purpose.[149] Data from outbreak investigations, having been collected in a more dire situation, appear more accepted by the FBOs to be used in this way (such data is already incorporated in FHI's database). At the same time, several FBOs raised a concern that there needs to be equality in the data foundation if a new database is to be introduced.[150] This points to including more sequences from isolates gathered by the FSA (eg, through surveillance programmes) or submitted by FBOs. A couple of FBOs said they thought it would be good for the FSA or NRLs to have *Lm* isolates and information available, but that they were concerned whether that information would represent all or most, or just a few, FBOs.[151] As stated by one FBO:

> 'I think that if they [MT] are going to take tests and sequence, then there must be a requirement that they do not choose [just] a couple of factories in Norway. They must approach every factory and take tests. And then there'll be a type of database that they can use if there is an outbreak. […] But that we are meant to share our sequences with them would not be quite right, as what if a factory in Rogaland [county] has the same sequences but does not share them because they have not performed WGS?'.[152]

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[146] Eg interview F.

[147] Interview F.

[148] Ibid.

[149] Interview D.

[150] Interviews C, D, G, H.

[151] Interviews C, D.

[152] Interview D ('Jeg tenker at hvis de [MT] skal ta prøver og sekvensere, så må det være et krav om at de ikke velger [kun] et par fabrikker i Norge. Da må de gå til alle og ta prøver. -Og da blir det en sånn database som de har, og som de kan bruke videre hvis det blir utbrudd […] -Men at vi skal dele med dem våre sekvenser blir litt feil, for hva hvis en fabrikk i Rogaland har samme sekvenser, men ikke deler sekvensene sine fordi de ikke har helgenomsekvensert?').

Some FBOs pointed to the fact that *Lm* isolates found at different FBOs' facilities may be very similar,[153] leading to risks of misleading results from comparing with the database if it does not contain a wide selection of WGS data from all FBOs. It was therefore thought that a database could only be 'fair' if it was based on testing of every facility, until *Lm* was actually detected,[154] to avoid that some FBOs sample more than others and thereby contribute disproportionate amounts of results to the database. At the same time, there was an understanding that the data foundation can never be completely equal, in part because *Lm* samples are collected in different ways,[155] whether performed by MT or the FBOs themselves (eg, some FBOs sample more diligently than others). As discussed in Chapter 5, this is likely a challenge also in Austria, where some FBOs clearly submit much higher numbers of isolates than others, apparently due to more extensive testing. Complete equality thus appears not realistically achievable. Nevertheless, some guidelines could be enacted to decrease the inequalities. To this, an FBO pointed to the BRC requirement (for those certified) to find *Lm* (in their own food safety control programme),[156] and that such a standard can foster a higher level of equality.

A related point raised by a fish slaughterer with large volumes of exports, is the importance of global equality if a database is to be made accessible, seeing as various countries may have different requirements.[157] The concern is that FBOs in countries where WGS is more prevalent and where more WGS data exists in databases, would be more vulnerable to being pointed to as a source of *Lm*, and thus suffer negative consequences, than FBOs in countries with a less stringent or less utilised WGS regime (even if they handle the same products and *Lm*).[158]

Comments were made that guidelines for authority use of a database ought to be clear and not overly discretionary.[159] FBOs need assurance that the use will be appropriate. Increased transparency on how the authorities will use such data, and the limits for their use, can foster FBO acceptance. Lack of predictability, on the other hand, generally seems a considerable contributor to FBO scepticism. Indeed, uncertainties about authority use and fears of the consequences of being included in a database where data is being overly shared, may also lead FBOs to decrease their sampling in order to avoid *Lm* detections altogether.[160]

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[153] Eg interview G.
[154] Interview D.
[155] Ibid.
[156] Ibid.
[157] Interview E.
[158] Ibid.
[159] Interview C.
[160] Interview E.

3.8 FBOs' Experience with WGS

From the interviews, it appears that Norwegian FBOs generally do not (yet) apply WGS as part of their internal *Lm* control programmes. Most of the FBOs stated that they had not applied WGS outside of the PathoSeq project,[161] or that they had used it also in connection with other projects, but never on their own initiative.[162] One FBO stated having tried it once a long time ago: this amounted to five to six analyses motivated by curiosity rather than any concrete *Lm* challenges at the time.[163] Yet another FBO had tried WGS on its own initiative prior to the PathoSeq project, years earlier, on four occasions.[164] This FBO had ordered it due to experiencing specific *Lm* challenges in the hope that it would provide the FBO more information to aid in handling those challenges.[165] It never actually made practical decisions based on the WGS results, as it resolved the relevant challenges before receiving them.[166]

Another FBO said that it had never applied WGS prior to the PathoSeq project, but that it had now started to submit samples for WGS beyond the project.[167] This was motivated by comparing with project analyses to learn whether they still had challenges with the same strains as detected in the project.[168] This FBO specified that this data was only for internal use, to gain knowledge on various persistent strains it might have, and to better target its control measures.[169]

The general impression is thus that most FBOs are highly interested in WGS and the information it can contribute to their *Lm* control and handling. At the same time, at least at the time of the interviews, the FBOs seemed to have scant experience with this tool. The understanding of how they may use WGS results and what competence is necessary for performing the analyses and interpreting them, appeared generally low. Several of the interviewees also expressed that they still had not thought much about challenges relating to WGS. Nevertheless, they appeared interested to learn more.

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[161] Interviews D, F, G.
[162] Interview C.
[163] Interview E.
[164] Interview B.
[165] Ibid.
[166] Ibid.
[167] Interview A.
[168] Ibid.
[169] Ibid.

3.8.1 FBOs' Perceptions of the Utility of WGS Results So Far

When asked about the use of WGS based on having tried it in the PathoSeq project, FBOs described it as useful to obtain increased information about the *Lm* detected in their factories, such as the pathogenicity of persistent strains.[170] A couple of FBOs, however, said that they still had not used the PathoSeq WGS results for any practical purposes or looked further into them.[171] The expected advantage, should a case of *Lm* arise, was nevertheless that they now believed that they had the means to check whether it was linked to a strain in their processing environment.[172]

Another FBO stated that it had derived much use from knowing what persistent strains it has in its facilities, and whether they were hazardous or not, and that it had already taken measures based on results it had received.[173] For instance, it aimed to use WGS results actively in training personnel, to make them aware of the risks and to explain to them the importance of routines, to improve their understanding.[174]

One FBO had started applying WGS to trace *Lm* within its processing facilities, something for which it previously had no method.[175] In addition to sequences from the PathoSeq project spanning over three years, the FBO wished to continue generating and analysing WGS results to compare isolates and define any problem areas.[176] A follow-up interview with this FBO to evaluate its use of WGS was unfortunately not possible. However, the FBO had arranged for a commercial laboratory to perform WGS and to store isolates with the opportunity of requesting WGS from specific isolates at a later date, should this be desired or needed.[177] The timeframe for storage of isolates would depend on what is agreed between the FBO and the laboratory. While some strains remain in the bacterial strain collection, for potential WGS at a later stage, other strains from this FBO are sequenced on a continuous basis.[178] This illustrates flexibility for the FBOs in how to implement WGS in a manner adapted to their needs. Another FBO

[170] Eg interviews C, D.

[171] Interviews B, C.

[172] Interview C. In practice, the FBO would not get access to an outbreak strain or associated WGS data and thus could not undertake such comparisons itself, but it could share its own strain(s) or sequence data with the authorities and hope to be excluded as a suspect.

[173] Interview D.

[174] Ibid.

[175] Interview A.

[176] Ibid.

[177] Ibid.

[178] Ibid.

described having been offered a similar commercial agreement (for a laboratory to store isolates and perform WGS on a selection of these) and expected it would also take up the offer.[179]

3.8.2 FBOs' Knowledge of WGS Initiated by Other FBOs

A fish slaughterer stated that it is not aware of many others applying WGS in the Norwegian food industry at present.[180] It thought that this was largely due to the high costs involved.[181] Another fish slaughterer said there was not much WGS taking place in the fish industry.[182] The interviewee mentioned one major actor it knew to perform this on a relatively large scale, but had not heard of anyone else using WGS.[183] A comment was made that the COVID-19 pandemic led to fewer physical meetings between fish industry actors, meaning in turn fewer conversations between FBOs to discuss and share this kind of knowledge and experience, compared to what would normally be the situation.[184]

An FBO in the meat industry had not heard about anyone else in that industry applying WGS, adding: 'I have actually heard that people were negative until we started to talk about it'.[185] Another FBO in the meat industry remarked that each FBO in that industry would mostly figure things out themselves, and that there is little sharing of information or experience across the industry: 'We prefer to manage for ourselves in our own respective domains'.[186] This FBO stated that it was somewhat 'taboo' to talk about detection of *Lm* at all due to fear about information being divulged that could cause reputational harm.[187] Such an attitude may come to amplify the effect of no one wanting to be 'first' in using WGS. The same FBO surmised that there is much more openness and cooperation on these issues within the salmon industry, due to a larger extent of similar aims and less competition on quality.[188]

3.8.3 FBOs' Expectations of WGS Utility

When considering how WGS may be useful for them, FBOs express the desire to find out what strains they have within their facilities, whether or not they are persistent, and perhaps which strains are more challenging to deal with or more hazardous to health.[189] Furthermore, they

[179] Interview D.
[180] Interview A.
[181] Ibid.
[182] Interview D.
[183] Ibid.
[184] Ibid.
[185] Interview C ('Jeg har egentlig hørt at folk er negative til vi begynte å prate om det').
[186] Interview B ('Vi vil helst klare oss selv på hver vår tue').
[187] Ibid.
[188] Ibid.
[189] Eg interviews B, C, D, G.

wish to trace *Lm* within their facilities,[190] and some FBOs also envisage comparing *Lm* between various facilities within their corporation, to trace and understand the pathogen's transmission patterns.[191] A main hope thus appears to be for the FBOs to gain an increased understanding of the reasons why they have *Lm* and learn about their associated properties, such as which strains are more likely to cause disease.[192] Another valuable use of WGS would be to examine the diversification of strains within their facilities, over time.[193] This could involve spatial mapping of *Lm* detected in their factories to gain a good overview of transmission.[194] Furthermore, an interest was expressed to learn about how *Lm* moves within the food chain and between different facilities, and also internally within a facility.[195]

There were also desires to compare results with suppliers, to understand where *Lm* came from, eg, whether the presence of bacteria might be the result of poor barriers to the facility's immediate surroundings (soil, air, ventilation, etc), have followed raw ingredients from a supplier, or be a persistent strain in the facility over time.[196] This knowledge could enable tackling *Lm* at the source location, or at least hinder its entrance into the facility.

For corporations with multiple production facilities, there is an interest in using WGS to find any connection between various facilities, with WGS applied on a continuous basis, but perhaps not with the same frequency at each facility (as some locations will have higher risks or otherwise a higher need for testing than others, also depending on who delivers to whom).[197]

In general, there appears to be a desire to learn more about *Lm*,[198] for practical use purposes in the FBOs' own food safety control programmes.

There was variation between the FBOs regarding what they see as the most pressing reason to apply WGS. For one FBO, this was to make comparisons internally within the corporation;[199] for another, it is to trace *Lm* backwards to understand where it came from.[200] Yet another FBO described the most useful purpose of WGS for FBOs to be enhancement of *Lm* mitigation

[190] Eg interview G.
[191] Interviews C, F.
[192] Interviews C, G, H.
[193] Interview F.
[194] Interview H.
[195] Interview C.
[196] Interviews C, E, F.
[197] Interview F.
[198] Interview G.
[199] Interview F.
[200] Interview E.

measures in food production and at problematic points along the production line (eg, a machine that constantly is associated with *Lm*, or tracing a strain that may have spread throughout the production process).[201] Of course, these aspects are all connected.

A couple of FBOs indicated applying WGS to rule out producers as potential sources in the event of an outbreak—that is, to 'clear their names'.[202]

One FBO expressed that it might become interested to try applying WGS in the event of a change in its *Lm* situation—eg, if *Lm* shows up somewhere the FBO has never previously detected it.[203] The purpose would then be to learn whether the *Lm* was a new strain starting to establish itself, or one of the already present persistent strains that has spread further.[204]

3.8.4 Scepticism Towards Use of WGS

As indicated in the previous section, there were many reasons for FBOs to apply WGS. The interviewed FBOs did, however, also express various reservations. These are key to understanding FBOs' actual willingness to implement WGS and the form that such implementation is likely to take. The reservations also point to some of the regulatory challenges that are elaborated in the subsequent chapters.

A central concern is authority access to WGS data derived from FBO testing procedures, combined with uncertainty as to what the authorities may do with such data. As expressed by one FBO representative, 'I think it is quite scary if MT can ask us about our strains and that they can extract the data',[205] either from the FBO itself or from the laboratory it uses. The interviewee stated that it would have been easier to decide to apply WGS if the FBO knew that it could keep that information to itself.[206] This FBO clearly stated that it would not currently consider starting to apply WGS, due to a lack of certainty over what may happen with those samples, sequences, and analyses, combined with economic factors.[207]

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[201] Interview A.

[202] Interviews C, H.

[203] Interview D.

[204] Ibid.

[205] Interview C ('Jeg synes det er ganske skummelt, da, hvis MT kan spørre om våre stammer og at de kan hente ut de opplysningene').

[206] Ibid.

[207] Ibid.

Exacerbating this concern is the likelihood that not all FBOs will be supplying the authorities with this kind of information. Thus, those FBOs that frequently perform WGS and systematically keep track of their strains, do so at higher risk of having to share their data, and thus at a higher risk of being pointed to as an outbreak source.[208] This challenge applies even when the source might in reality be a different FBO that does not perform WGS, since very similar strains can exist in different places.[209] Taking this risk appears little attractive to the FBOs.

3.8.5 FBOs' Envisaged Approaches to Implementing WGS

Those FBOs that considered implementing WGS on a more routine basis had varying thoughts on how this could be carried out. Sequencing everything, continuously, was perceived as exaggerated and too expensive. FBOs therefore envisaged more targeted approaches. For example, several FBOs envisaged to start with an extensive mapping, which they could then apply as a baseline.[210] Based on information gained from the mapping, the WGS focus could then be made more targeted (eg, by choosing particular focal points where analyses are made relatively frequently) or related to specific *Lm* challenges. More specifically, this approach would first sequence isolates immediately to get an overview of *Lm* in the facility concerned, and then, when the picture becomes clearer, to sequence less and instead store isolates in the laboratory for future sequencing as becomes necessary.[211] Choosing samples for WGS based on risk assessments was a prevalent idea.[212] An interviewee stated that one cannot perform WGS 'just in case', but that it is necessary to have a plan for what one samples and why, choosing the most interesting isolates for WGS in a 'tactical' manner.[213]

Some FBOs envisaged applying WGS to a selection of isolates from both product and processing environment samples.[214] For positives on a product, one would wish to trace where it came from. Otherwise, the FBOs generally focused on the preventative aspects: eg, to avoid outbreaks rather than having to trace the source and cause after an outbreak occurs.

One FBO thought it would become more relevant to conduct WGS continuously but recognised that this would also be quite expensive.[215] If the prices were lower, it would likely be more feasible to send samples for WGS on a continuous basis. Usually, the FBOs would get offers

[208] Ibid.
[209] Ibid.
[210] Eg interview F.
[211] Interview F.
[212] Eg interview B.
[213] Interview D.
[214] Interview A.
[215] Interview D.

for sequencing where the relative price decreases incrementally with the number of samples submitted, such that it becomes beneficial cost-wise to collect isolates for a while so that more isolates could be sequenced at once. At the same time, an interviewee remarked:

> 'If one is going to collect everything and whole genome sequence this afterwards, then one cannot do anything whilst an outbreak is happening. One can of course conjecture later when one has received information about the direction of infection, the type etc. The result is a sort of hindsight'.[216]

[216] Ibid ('Hvis man skal gå og samle opp alt og helgenomsekvensere i etterkant, da kan man ikke gjøre noe mens utbruddet pågår, og så kan man jo gjøre seg tanker senere når man har fått informasjon om smitteveien, type, osv. Det blir sånn etterpåklokskap').

3.9 Possible Barriers to FBO Use of WGS

Generally, the decision of the part of an FBO to implement WGS will depend on an assessment of costs and benefits. FBOs perform the weighing up of costs and benefits differently, according to their individual circumstances. For example, one FBO stated that it produces very few products associated with significant *Lm* risks, and that although it seeks to tackle *Lm* should this be detected, it had therefore not so far considered using WGS on a routine basis.[217] Another FBO indicated that applying WGS might be perceived to suggest that the FBO cares about food safety.[218] At the same time, this FBO commented that knowledge about WGS was still low among its customers, such that it did not expect any direct effect on its reputation if it applied WGS.[219] The focus on prices and visual quality would, according to this FBO, usually be more highly prioritised by customers.[220] The FBO added:

> 'Perhaps the smokehouses in Europe can have thoughts like "wow, they are diligent if they perform WGS", but at the same time "wow, if they have so much to perform WGS on, maybe they have a problem there". It is difficult'.[221]

Relatively subjective factors may come into play in these individual cost-benefit assessments. For instance, one FBO remarked:

> 'In my opinion, having a good picture is valuable in itself, both in relation to discussion with the authorities and in relation to understanding one's own microflora from a risk assessment perspective'.[222]

Another FBO remarked that, despite multiple challenges and uncertainties around WGS, the technology holds great promise for an industry concerned with doing things 'right':

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[217] Interview G.

[218] Interview D.

[219] Ibid.

[220] Ibid.

[221] Ibid ('Kanskje røykeriene i Europa kan ha noen sånne tanker rundt at "oi, de er jo flinke hvis de helgenomsekvenserer", men samtidig "oi, har de så mye å helgenomsekvensere, kanskje de har et problem der". Det er vanskelig').

[222] Interview F ('Jeg mener at det har en verdi i seg selv å ha et godt bilde, både i forhold til diskusjon mot myndighetene og i forhold til å forstå egen mikroflora farevurderingsmessig på anleggene').

> 'On the other hand, it [WGS] is after all a fantastic means to try and get things right. And we want to get things right. We don't want to let out dangerous infectious material'.[223]

Yet another FBO stated that it would not consider implementing WGS until the industry association had discussed challenges with MT of how results may be accessed and used.[224]

Despite the individualised subjective elements of many of these assessments, several factors were repeatedly present as potential barriers to WGS uptake. One barrier is economic cost. As pointed out earlier, the economic costs of implementing WGS are currently considerable, although expected to decrease. Several FBOs pointed to financial resources being a major hindrance against applying WGS at any substantial scale, at least if only out of interest or increased knowledge, as WGS would require considerable resources.[225] When one FBO was asked to point to barriers, it replied: 'barriers, those are just money'.[226] This FBO pointed out that the currently negative pressures of the world economy have a big impact on what tests and analyses FBOs perform, referring in particular to WGS.[227] The interviewee added that, should WGS become less expensive, one could use it more actively.[228] Another FBO remarked that the better and more rapid WGS becomes, the easier it will become to apply it.[229] Evolution and accessibility of the technology, thus also plays a role for the FBOs' WGS uptake.

Another frequently flagged barrier was lack of WGS-related competence. Several FBOs emphasised the importance of having access to the necessary expertise to make good use of WGS analyses.[230] When an investment in WGS is made, an FBO should be able to get maximum out of it and to follow it up effectively.

Other frequently mentioned barriers to WGS uptake were the unpredictability of whether and how an FSA (primarily MT) may access and use WGS data, at least as long as use of WGS is voluntary,[231] along with doubt as to whether MT has adequate WGS-related competence.[232] In

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[223] Interview G ('på den annen side: det [WGS] er jo et fantastisk hjelpemiddel for å prøve å få ting riktig. Og vi ønsker jo å få ting riktig. Vi ønsker jo ikke å slippe ut farlige smittestoff').

[224] Interview C.

[225] Interviews D, E.

[226] Interview D ('Barrierer, det er jo bare penger').

[227] Ibid.

[228] Ibid.

[229] Interview H.

[230] Interview G.

[231] Interview D.

[232] Interviews A, B, D, F, H.

effect, perceived low FSA competence in this regard, appears a major hindrance for FBOs' trust in the ability of MT to interpret and use WGS data in an appropriate manner.[233] Thus, it also becomes a potential barrier for the FBOs to implement WGS, as they experience uncertainty over how the data might be used or interpreted. With this trust deficit, the FBOs are not comfortable with MT having their WGS data.[234]

Part and parcel of these competence and trust deficit barriers is a fear that MT may misinterpret WGS results, potentially leading to incorrect conclusions on the sources of *Lm*.[235] There is a fear that too quick and too definite conclusions could be made, based on WGS.[236] In the words of one FBO, there is 'a great danger that there can be a quick-fix if one finds in a database the same profile that is indicated through illness and thinks that it comes from that particular factory—and that very rapid conclusions may be drawn'.[237]

This sort of worry is exacerbated by the fact that a strain found in one location can genetically match a seemingly unrelated strain somewhere else. This was a concern raised by several FBOs. The risk applies, but is not limited to, situations where many FBOs have the same supplier. Furthermore, a particular strain may live in multiple facilities with no apparent connection between them. If then only one or few of the FBOs perform WGS, their findings may become the centre of FSA attention, while other FBOs who do not perform WGS, might escape this attention.[238] There is a concern of potentially increased vulnerability for some FBOs if there is an imbalance in what FBOs the authorities would have strains from, particularly if very few FBOs apply WGS.[239]

Such an imbalance may arise due to a preference by larger corporations to sequence themselves, while smaller FBOs do not have their own laboratories, such that some FBOs may end up having large amounts of data, while others have very little.[240] The FSA may then have a more clear picture of the larger FBOs' *Lm* situation than that of the smaller FBOs, and thereby could more easily point their fingers at them.[241] Thus, differences in testing regimes may constitute a barrier to WGS uptake.

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[233] Interviews B, F, H.

[234] Interview C.

[235] Interviews A, H.

[236] Interview H.

[237] Interview F ('Det er stor fare for at det kan bli en quick-fix hvis man i en database finner samme profil som er påvist ved sykdom og tenker at det er fra den fabrikken—og at det kan bli trukket veldig kjappe konklusjoner').

[238] Interviews A, G.

[239] Interviews B, F.

[240] Interview F.

[241] Ibid.

Even where there might be sufficient competence within the FSA to avoid the scenarios envisaged by the FBOs, it is also important that the FBOs believe in and can trust the presence of that competence. Such trust hinges on FBOs being given a proper understanding of how the authorities perform outbreak investigations, and what weight they place also on other factors like epidemiological data. The authorities must also nurture trust in their appropriate execution of these investigations in practice. In this regard, an FBO noted that it is usually up to the local MT to make decisions towards the FBOs, and that, therefore, the competence would either have to be improved there (risking local variations), or cases involving account of WGS data would have to be centralised to someone trained in assessing that kind of data.[242]

Concerns that their sequences might become commonly known as linked to an *Lm* outbreak (eg, by being made part of a publicly available list or database) were considered by some FBOs to potentially outweigh the advantages of implementing WGS for preventative purposes.[243] Such concerns were taken to the next level by one FBO's worries about potential public blacklisting, primarily with regard to other countries' acceptance for export.[244] The scenario proposed was that another country might require the FBO to have its strains analysed and share them with that state, for use in case of an outbreak, and that if the FBO is circled out as a likely source, it might be blocked from that country for a couple of years.[245] This highlights also the need to find good solutions in accordance with other states, particularly for FBOs who export—both to improve the understanding of WGS and ensure suitable approaches.

The interviewees generally claimed that they would like to know if they are the cause of an outbreak.[246] They had an awareness of the potentially grave consequences of listeriosis, and there was universal agreement that food contaminated with *Lm* at a level likely to cause listeriosis needs to be recalled. Concomitantly, the FBOs generally feared being incorrectly pointed to and suffering the financial and reputational consequences of this if they were not actually the source.[247]

[242] Interview B, F.
[243] Interview E.
[244] Ibid.
[245] Ibid.
[246] Eg interviews A, G, H.
[247] Interviews B, F, G, H.

At the same time, it might also be disadvantageous for those who do not use WGS, if the public comes to learn that the authorities lack analysis data only from a few, named FBOs.[248] Furthermore, a concern was raised that if knowledge on *Lm* strain properties increases and is refined in the future, and this knowledge becomes more prevalent and even considered in assessments by FSAs and FBOs, it might become easier to criticise an FBO for not having done enough if it knew it had a particularly pathogenic persistent strain in its facilities.[249] In other words, this information might increase the requirement and expectations for the *Lm*-mitigation measures taken by that FBO.

Legal uncertainties were also a barrier to WGS uptake and can be regarded as indirectly adding to the 'cost' side of FBOs' cost-benefit assessment of the technology. Indeed, one interviewee stated, with reference to legal uncertainties particularly regarding FSA access to and use of WGS data, that it might be best to stop any kind of sequencing and have as few results as possible describing their *Lm*.[250] Another FBO raised the need for clear guidelines for the purpose of predictability about what MT can and cannot do.[251] There was also a wish for requirements or common guidelines, eg, from food industry associations, to ensure correct use at similar frequencies, with fairly equal implementation of WGS across each sector.[252]

[248] Interview B.
[249] Interview E.
[250] Interview B.
[251] Interview C.
[252] Interviews B, D.

4 Role of WGS Data in Ensuring Food Safety

4.1 Introduction

This chapter concerns the role of WGS in assessments of when food is 'safe' for the purposes of food law. There is currently no express legal requirement in Norway or in the EU that FBOs apply WGS. If they do so, it is by choice, to help support their compliance with legal obligations, yet such compliance is still possible without the application of WGS.[253]

As highlighted in the previous chapter, when FBOs consider implementing WGS, their core objective is to improve their own food safety control measures to ensure safe food. This objective is reflected in the law, which provides that a foodstuff may not be traded if it is unsafe.[254] That a food is unsafe, means that it is 'injurious to health' or 'unfit for human consumption'.[255] In cases of *Lm* outbreaks, it is the first option that is most relevant. Thus, food may be considered 'injurious to health' ('helseskadelig') if, for example, it is contaminated with *Lm* above the applicable thresholds set out by legislation.[256] Currently, *Lm* detected in production facilities is primarily subject to qualitative analyses confirming whether *Lm* is present, possibly followed by quantitative analysis for detections in food products. Whether the latter themselves can be considered 'safe' or not after *Lm* detection is (at least under current law) subject to quantifiable *lex specialis* regulation that applies regardless of the type of *Lm* strain involved.[257] Thus, in respect of foodstuff itself, there is less of a role for WGS to play in respect of compliance.

It is possible that the legal limit values of acceptable *Lm* for RTE products might, in time, become affected by WGS in the sense that they might be made dependent on known properties of various *Lm* subtypes. This possibility was flagged by one FBO.[258] It is also worth noting that FAO and WHO recently proposed that 'a virulence ranking of *L. monocytogenes* obtained by determining and analysing subtyping data could be informative to improve risk assessments and thus make for better and more informed risk management decisions'.[259] Nonetheless, they also recommended 'that the control of *L. monocytogenes* globally should continue to use an

[253] See eg GFL Art 17(1).

[254] See GFL Art 14(1), which is replicated in § 16 of Norway's Food Act (matloven): 'Det er forbudt å omsette næringsmiddel som ikke er trygt'.

[255] GFL Art 14(2); see also matloven §16(1)(2) which refers to the criteria 'helseskadelig eller uegnet for konsum'.

[256] See Chapter 2 (Section 2.1).

[257] MCR Annex I, Chapter I, 1.1-1.3.

[258] Interview D.

[259] FAO and WHO (n 12) 67.

approach that does not consider subgroups (ST/CC) of *L. monocytogenes* but allows risk managers in some countries to use *L. monocytogenes* subtype information to inform risk management'.[260] It would seem then that availability of WGS data is unlikely to incur changes to the legal limit values of acceptable *Lm* for RTE products in the near future.

How to control *Lm* in the processing environment is left largely to the FBOs and their individual assessments. It is for this kind of measure that WGS is truly interesting to consider, particularly from the FBO perspective. The ensuing parts of this chapter consider first the possible impact of WGS on FBOs' risk assessment and thereafter the possible impact of WGS on FSA regulatory approaches, primarily in respect of *Lm* controls in food processing environments. The implications for FSA regulatory approaches are considered in light of FSA handling of a concrete case of listeriosis outbreak in Norway in 2022.

4.2 WGS in Risk Assessment

As noted in Chapter 1, WGS can provide FBOs with a deeper understanding of the genetics of *Lm*, associated virulence factors and potential transmission patterns. There can be little doubt that this information will be relevant for determining the level of risk presented by the sequenced *Lm*. Thus, if an FBO has performed WGS, the data generated will likely become part of the FBO's risk assessment.[261] A central question then is whether and how the existence of WGS data (or, alternatively, the lack of it) may affect the assessments or threshold for when food is considered 'safe', hereunder what control measures the FBO must take.

The WGS data may enable more discriminating and efficient *Lm* control efforts—a possibility envisioned by FBOs.[262] If a detected *Lm* strain is found to be of the more dangerous kind, increased control efforts towards it would generally be desirable for food safety. The increase in control efforts could also be deemed legally necessary, as the risk can be considered higher. Thus, WGS data may raise the legal threshold for what efforts are expected of FBOs to fulfil their food safety responsibilities. A more contentious issue is whether it would be legally acceptable or desirable that knowledge of an *Lm* strain in the processing environment being less pathogenic or virulent would allow for the FBOs to take a more relaxed approach towards it.

[260] Ibid.

[261] See GFL Art 3(11).

[262] See Chapter 3.

One interviewed FBO stated that knowledge of the strain being less pathogenic would not change the measures it would apply.[263] Amongst other interviewees there seemed little consensus, let alone thought, on the issue. At the same time, they generally seemed not to foresee any relaxation of approaches from the FSA based on WGS data.

Summing up, the potential impact of WGS appears mainly as a contribution to more targeted and accurate measures for *Lm* control conducted by FBOs in their own facilities, within their granted flexibility. WGS is not considered likely to cause more lenient requirements or expectations. Whether it might sometimes intensify requirements, appears a more open question. The FBOs expressed a desire for clearer rules and guidelines both for the FBOs and for the FSA.[264]

4.3 Implications of WGS for FSA Assessment

The implications of WGS for FSA assessments are far from easy to gauge. The wide discretion granted to FSAs makes it difficult to draw up clear guidelines for their assessments. Furthermore, seeking empirical insight into the analyses they have conducted is challenging as they take the form of administrative decisions that can sometimes be hard to track down and access. Nonetheless, looking more closely into a concrete case may serve as a useful example in considering the possible role of WGS data in FSA assessments. The following case concerns a recent listeriosis outbreak in Norway.

4.4 2022 Listeriosis Outbreak in Norway

Information on the following case of listeriosis outbreak in Norway was gathered primarily from case documents, press releases, and a report from the health authorities. Reservations must be taken as for the case's representability; it is presented for illustrative purposes.

4.4.1 Case Summary

On 7 September 2022, FHI (the Norwegian Institute of Public Health) was notified about three cases of listeriosis with the same genotype.[265] A week later, FHI was notified about yet another

[263] Interview E.

[264] Eg interview H.

[265] FHI, 'Utbrudd av *Listeria monocytogenes* ST121 februar – oktober 2022. Sluttrapport for utbrudd av *Listeria monocytogenes* ST121, 2022' (1 March 2023) 5. The cases were discovered by the Norwegian microbiology reference laboratory responsible for diagnostic testing of clinical samples of human origin for *Lm*—a laboratory operated by FHI.

case, with a further patient being reported in October.[266] All up, five patients had fallen ill between February and October of an *Lm* strain belonging to sequence type (ST) 121.[267]

This caused the official declaration of an outbreak, and FHI, in cooperation with municipal medical officers ('kommuneleger'), the FSA (MT), and the NRLs (VI and HI), started work to trace its origin.[268] Part of their effort involved (as is common)[269] studying epidemiological information from patient interviews. Four of the patients revealed that they had consumed smoked salmon or trout during the relevant period, three of them from the same producer.[270] The interviews otherwise indicated few common denominators in their diet and no common food establishments.[271] Smoked salmon or trout was therefore considered the most relevant product to suspect, also in light of the fact that it is a known high-risk product for *Lm*.

WGS was applied in the investigations. FHI's microbiology reference laboratory for diagnostic testing of clinical samples of human origin performs WGS and cgMLST analysis on a routine basis on all clinical *Lm* isolates it receives and compares the results with what it already holds in its database.[272]

An unopened package of smoked salmon from the producer that had been mentioned in patient interviews was collected from one of the patients. It was tested, but no *Lm* was detected.[273]

When the outbreak was declared, VI and HI started examining samples from previous MT surveillance programmes. Two relevant *Lm* samples from a salmon surveillance programme of 2020 and 2021 were sequenced and compared with the outbreak strain, but they did not match.[274]

Two relevant *Lm* samples from a 2022 surveillance programme on RTE foods were also sequenced. The suspected FBO had been visited by MT as part of this surveillance programme

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[266] Ibid, 5.

[267] Ibid, 3.

[268] Ibid, 5.

[269] See G Kapperud, *Utbruddsveilederen* (last updated 8 October 2019) Chapter 9.

[270] FHI interviewed three patients (one did not wish to be interviewed, another was too ill, so that they could only be asked the most basic questions): FHI (n 265) 9.

[271] Ibid.

[272] Historical clusters from 2010, 2014 and 2018 were found to be genetically close to the outbreak strain (up to six cgMLST allele differences): ibid, 9-10. However, the persons involved then were never interviewed and were not considered part of the ongoing outbreak.

[273] Ibid, 10.

[274] Ibid, 10.

on 4 April, and three product samples had been collected from it.[275] Analysis results from early June showed that one of these samples tested positive for *Lm*, quantified to <10 cfu/g (ie, within the legal threshold). MT had then remarked that the results were satisfactory.[276] MT had also tested a product from this FBO bought in a store on 6 April 2022, as part of the same surveillance programme.[277] The product tested positive, but with *Lm* amounts below the legal threshold.[278] Accordingly, the findings had not caused a product withdrawal.

When the outbreak was declared in September 2022, these two isolates were sequenced, and the data was shared with FHI. It was then discovered that one of them (from cold smoked salmon) had the same genotype as the outbreak strain (one cgMLST allele difference), while the one from the other (bought) salmon product sample did not match (although it matched historic clinical *Lm* isolates from the period 2010-2015, and later also an environmental isolate obtained from a drain sample by the FBO in October 2022).[279] These findings caused the authorities to notify the relevant FBO that its smoked salmon was a suspected source. Further investigations were then directed towards this FBO.

MT visited the FBO's factory for a control inspection on 4 October 2022 as part of the outbreak investigation, and on this occasion they collected environmental samples for analysis.[280] The FBO had not received any notices about *Lm* from its supplier. However, the FBO could not confirm that it had performed sampling for *Lm* in the processing environment in 2022, as legally required.[281] MT then made an urgent decision ('hastevedtak') on 6 October 2022 requiring the FBO to perform environmental sampling daily for a limited period.[282] In MT's inspection resumé, it is noted that the NRL (VI) had performed WGS on positive *Lm* isolates from the RTE surveillance programme, and that one of these isolates matched the genotype of the four patient isolates.[283] This caused MT to suspect that a persistent *Lm* strain had established itself in the FBO's production facilities.[284]

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[275] Samples taken 4 April 2022 (MT 2022/74468-3).

[276] 'Analyserapport viser tilfredsstillende resultat' (MT 2022/74468-7). The sequence of this isolate was later found to be similar to the outbreak strain.

[277] MT 2022/216829-30.

[278] Ibid. This was later found not to be the same strain as the outbreak strain. Note that MT seems not to have informed the FBO about the test result shortly after the testing (although it should have). Gauging the real significance of this omission for subsequent events is difficult, but it did deprive the FBO of an opportunity to deal with the *Lm* found then.

[279] FHI (n 265) 11-12.

[280] MT 2022/216829-2.

[281] See MCR Art 5(2)(2).

[282] MT 2022/216829-2.

[283] Ibid.

[284] Ibid.

Presumably adding to MT's concerns was the failure of the FBO to follow its own plan for environmental sampling, a plan which was also found to be too generally formulated.[285] The fact that the FBO had not performed sampling in the processing environment resulted in a very meagre data foundation for MT's assessments regarding the FBO's *Lm* situation. This prompted the urgent decision compelling daily environmental sampling, and also later updating and adding of detail to the FBO's sampling plan.[286]

The FBO's environmental sampling resulted in three *Lm* positives, all from drains.[287]

On 14 October (ten days after MT first collected samples from the factory), it informed the FBO that it had made another urgent decision, this time to withdraw products from the market.[288] MT did this after finding one *Lm* positive sample among those it had collected, of which it had informed the FBO on 10 October.[289] The FBO itself remarked that, of all the samples MT collected on 4 October (a total of 14), the production line on which *Lm* had been detected was the only place in which products did not come into direct contact.[290] The FBO commented on 14 October that it had therefore had no reason to believe there to be a problem in the production, and that based on the limited information available at that point in time, it was still of the opinion that its products were safe.[291] This contrasts with the opinion of MT expressed on 12 October that the finding of *Lm* on the production line entailed a risk that the products might be unsafe.[292] MT suspected indirect contamination, from the line via personnel to the product.[293]

The urgent decision banning sale and requiring withdrawal from the market, was conveyed to the FBO and effectuated by it on 14 October (although the decision was formally made on 17 October).[294]

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[285] Ibid.
[286] Decision of 25 October 2022: see MT 2022/216829-16.
[287] MT 2022/216829-17.
[288] MT 2022/216829-5.
[289] Ibid.
[290] Ibid.
[291] Ibid.
[292] Ibid.
[293] MT 2022/225009-1.
[294] Ibid.

MT apparently considered there to be sufficient grounds to believe that products on the market were not safe.[295] The ban on sale and withdrawal from the market applied to all products produced and packed on the two packaging machines related to the production line where *Lm* had been detected on 4 October, until cleaning and disassembly of that line had been performed.[296] As mentioned, MT considered that contamination might have occurred indirectly via personnel, creating a risk of contaminated products being on the market.[297]

When making the decision, MT referred to the precautionary principle and the need to protect consumers.[298] The press release from 19 October mentions the decision being based on the precautionary principle because of *Lm* findings in the processing environment that did not match the outbreak strain but nevertheless represented a discrepancy ('avvik').[299] However, FHI's final report on the outbreak indicates that MT chose, based on the precautionary principle, to require withdrawal of certain products *before* the WGS results from the isolates obtained from the processing environment samples were ready.[300]

The main reason for the urgent decision appears (both from MT's decision and the accompanying press release) to have been the detection of *Lm* in the production facility.[301] Detection of *Lm* in production facilities does not usually cause forced withdrawal. The limited information foundation likely contributed to MT leaning on the precautionary principle, due to the scarcity of *Lm* sampling performed as part of the FBO's own food safety control programme from the relevant time period (combined, then, with *Lm* detections in October, as well as a certain urgency due to the ongoing outbreak). Yet, at the time of the urgent decision, MT had already been aware of the *Lm* positive environmental samples for a few days, whilst knowing that WGS analysis results were imminent.

New information emerged already within the next few days. On 18 October 2022, MT wrote that WGS had revealed that the *Lm* strains found on the production line and in drains did not match the outbreak strain.[302] They differed from the outbreak strain with more than 70 alleles.[303] However, they were very similar to the bought product sample collected by MT in

[295] Ibid.

[296] Ibid.

[297] Ibid.

[298] Ibid ('Ut i fra et føre var prinsipp og vår plikt til å beskytte forbrukerne fatter vi vedtak om at dere må stoppe salget og trekke tilbake produktene fra markedet').

[299] Matportalen 19 October 2022.

[300] FHI (n 265) 14.

[301] MT 2022/225009-1; Matportalen 19 October 2022.

[302] MT 2022/216829-14.

[303] FHI (n 265) 11.

April 2022.[304] They were also similar to five historical human isolates in FHI's database.[305] (Since no interviews were conducted with those historical patients, FHI took great caution in interpreting the implications of that match in its report, remarking that genetically similar *Lm* can survive over time in different geographic locations).[306]

VI also performed SNP analyses of isolates from the product and environmental samples from the FBO, which supported the cgMLST analysis results obtained by FHI. They found that the difference between the isolates from the environmental samples collected in October and the bought product sample from April to be maximum 17 SNPs, which was considered very similar and, according to FHI's report, a strong indication that the strain had been in the FBO facility throughout the whole period.[307] This strengthened the suspicion of a persistent strain in the FBO's facilities.

4.4.2 Legal Basis

The urgent decision of 17 October 2022 was made based on § 23 of the Norwegian Food Act (matloven), providing that MT can make necessary decisions to ensure implementation of Norwegian food law, hereunder forbid sale or require withdrawal of products from the market.

To require the products withdrawn, MT considered there to be a risk of *Lm* contamination rendering the products unsafe. Part of the assessment was the FBO's lack of compliance with the environmental sampling requirements of MCR Article 5(2) (see also Norway's Food Hygiene Regulations (næringsmiddelhygieneforskriften) § 2). As already noted, MT also explicitly referred to the precautionary principle and the protection of consumers.

The outbreak involved multiple patients, but no certain link was established to conclude that the suspected FBO was the source of the outbreak. The suspicion that it might be, appears a central factor for the decision made—a suspicion that appears largely based on the match between isolates from patients and the cold smoked salmon product sample from April, as well as patient questionnaires or interviews.

As noted in Chapter 2, it is the FBOs' responsibility to ensure their compliance with relevant food law requirements.[308] If an FBO has reason to believe that food is injurious to health, the

[304] Analysis results of 19 October 2022: see MT 2022/216829-11.
[305] Ibid.
[306] FHI (n 265) 14-15.
[307] Ibid 13.
[308] See also matloven § 5.

FBO is to notify the FSA immediately,[309] and to put in place necessary measures, for example product withdrawal.[310] In this case, the FBO concerned did not consider there to be reasonable grounds to believe that the food was unsafe.[311] MT concluded differently.

If the food law requirements had been complied with, there would have been a presumption that the food was safe.[312] When requirements are not complied with, it would depend on the requirements in question and the severity of possible consequences whether such non-compliance amounts to food being regarded unsafe. This is subject to a concrete assessment by the FSA.

While the FSA has considerable discretion in this context, its decision (eg, requiring withdrawal of products) should be necessary and proportionate.[313] For instance, the health risk should be considered against the negative effects for the FBO. Indeed, the Norwegian Food Act, in addition to having health and consumer protection objectives,[314] mentions the need to ensure consideration of the industry stakeholders.[315] In this regard, it is instructive that MT, upon finding in July 2022 that the FBO failed to perform product sampling of n=5,[316] ordered the FBO to correct this so as to become compliant but did not then deem the food 'unsafe'. However, when more factors later started pointing towards a link to an outbreak, compliance shortcomings, like the lack of sampling from the processing environment, seem to have combined with other factors in the subsequent assessment of the food's safety.

As noted above, the precautionary principle played a role in MT's urgent decision. Regarding this role, FHI remarked in its final report on the outbreak that:

> 'The Food Safety Authority [Mattilsynet] ordered producer A to withdraw certain products from the market applying a "precautionary principle". Later one saw that these *L. monocytogenes* isolates had a different genetic profile than the outbreak strain, but that they were similar to a sample taken from producer A in the authority's surveillance programme for RTE products in 2022, as well as with historical patient isolates …'.[317]

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[309] Matloven § 6(1).

[310] Matloven § 6(3). See also GFL Art 19(1).

[311] See MT 2022/216829-5.

[312] GFL Art 14(7).

[313] Matloven § 23.

[314] Matloven § 1(1).

[315] Matloven § 1(3).

[316] MT 2022/137252-3.

[317] FHI (n 265) 3 ('Mattilsynet påla produsent A å trekke enkelte produkter fra markedet i et 'føre-var-prinsipp'. I etterkant så man at disse *L. monocytogenes* isolatene hadde en annen genetisk profil enn utbruddsstammen,

Questions may be asked about how widely the precautionary principle may be applied in such instances, particularly given the presence of already vague thresholds like 'safe' and 'suspicion', as well as the fact that WGS data was imminent (communicated to the FSA the day after its urgent decision was formally dated), and about how it might have affected the decision had the WGS results arrived sooner.

4.4.3 Summary of Factors That May Have Been Considered

The factors (explicit and otherwise possibly considered) in this case were a combination of epidemiological and microbiological data which included the following:

- Patient interviews indicating this type (and to some extent brand) of products.[318]
- Five patients ill with an *Lm* strain matching the one found in the FBO's product tested 4 April 2022.
- A lack of *Lm* environmental sampling from 2022, resulting in little *Lm* information from the FBO.
- A non-compliant testing regime (previously n≠5 over x time) (also, not in accordance with the FBO's own sampling plan).
- The only existing product sample of a product then on the market, was a sample (negative) taken of a product on 30 August 2022.[319]
- *Lm* detected in the facility in October (although not on any direct product contact surfaces).
- A suspected possibility that products might have been indirectly contaminated from the production line via employees.[320]
- The FBO itself considered that the food was safe.
- *Lm* can cause serious disease.
- The precautionary principle.
- Protection of consumers.

The following information appears still not to have been available to MT at the time of the decision (although imminent):

men var like en prøve tatt fra produsent A i Mattilsynets overvåkningsprogram for spiseklare produkter i 2022, samt historiske pasientisolater (ST121 og CT1708)').

[318] Matportalen 19 October 2022.

[319] MT 2022/225009-1.

[320] Ibid, 2 ('personell kan være i kontakt med båndet og deretter fisken. Det er derfor fare for at fisken kan bli indirekte forurenset, selv om fisken ikke er direkte i kontakt med transportbåndet').

- WGS demonstrated that the strain from the production line and drain isolates from October did not match the outbreak strain.
- WGS did, however, show a match between the production line and drain isolates from October and the bought product sample from 6 April 2022 (not a strain related to the outbreak). This seems to have strengthened the suspicion that the FBO was struggling with persistent *Lm* strain(s), although—at the risk of spelling out the obvious—this suspicion on its own would not have been sufficient to warrant withdrawal of the food products concerned.

4.4.4 Some Reflections

In Norway, WGS is currently applied by the authorities for outbreak investigations. The illustration case demonstrates first the role of WGS in contributing to raise suspicion towards an FBO, and then how analysis results have—together with other factors—become part of the knowledge held by the FSA. The existence or absence of WGS results was likely a relevant factor in the food safety assessments.

The case also demonstrates some central questions and possible exploitations of WGS. One question of practical significance is whether a case like this affects FBOs' perception of WGS and their trust in how the FSA uses such data, and thereby how eager FBOs are to apply it. As indicated in Chapter 3, it seems clear from food industry interviews that trust in the FSA's competence and use of WGS data is low and fragile, at the same time as being important for FBOs' willingness to themselves implement WGS. The FBO under suspicion experienced a sense of unpredictability,[321] which could also become a signal effect in relation to other FBOs. This is largely due to the meagre information foundation for a decision on withdrawal, sparse explanations of reasons towards the FBO at the time,[322] and how the precautionary principle was applied.

Another question is whether the same decision would have been made regardless of the availability of WGS results at the time of decision-making. In other words, whether confirming that isolates from the environmental samples did not match the outbreak strain could have reduced the suspicion against this FBO (considering the otherwise scant *Lm* information basis for the decision and the use of the precautionary principle).

The non-compliance with environmental sampling requirements likely played a central role for the decision. A couple of alternative situations can be imagined to illustrate some possibilities:

[321] Interview with the FBO 19 December 2022.

[322] Ibid.

(i) Had the FBO been compliant and able to demonstrate environmental sampling results to MT (and/or more product samples from the FBO's own food safety control programme), MT would have had more knowledge on which to base its decision, at least regarding presence of *Lm*. (The FBO could then also have had reason to put in place measures earlier—as is the intention of sampling requirements in the first place—should samples have tested positive for *Lm*.) This might have diminished the need to apply the precautionary principle.

(ii) Had the FBO gone one step further and, as part of its internal risk approach (in addition to regular sampling), performed WGS on at least some *Lm* isolates collected from its environment (and possibly product or raw material) samples, it would have been in possession of more detailed information on what *Lm* strains existed or had existed in its facilities, as well as their internal distribution and whether any of them persisted in the environment. Access to such information would have enabled the NRL to quickly compare and confirm or exclude strain matches, and it would have given MT a better overview and information basis for its assessment. Had there been no match, this might have contributed to clear the FBO from suspicion. Another question is what would happen had a match been made with such WGS data generated by the FBO. An important factor is then the FSA's competence to make appropriate assessments to reach correct conclusions, and the FBOs' trust in its competence to do so. If they really are the source, FBOs would normally wish to know as soon as possible,[323] to act quickly and reduce their losses. Nevertheless, it is crucial that the FBOs feel they can trust the FSA to take all uncertainties and factors into account. Otherwise, the industry would likely be reluctant to share WGS data. Since they would probably have to share such data in an ongoing outbreak situation, they might find the safest choice is not to generate WGS information at all.

4.4.5 Further on the FBO Perspective: Expectations, Opportunities, Concerns

More concrete information about the strains of *Lm*, their properties, and where they originate in the food chain, might affect the FSA's assessments. Interviewed FBOs anticipated that such information might become relevant in FSA decisions in the longer term, in the sense of affecting what they require from the FBOs' risk assessments and management, or for inducing stricter or more detailed requirements.[324] The FBOs, however, did not expect this to happen soon. An interviewee considered it unlikely, if an FBO could document its persistent *Lm* strains to be less pathogenic, that this would affect authority assessment relating to it, although it still perceived

[323] See Chapter 3.

[324] Interviews B, D, F.

this a possibility in the future.[325] This might indicate a lower likelihood that FBOs would implement WGS for the purposes of alternative ii) above.

At the same time, a possible advantage of WGS for FBOs is that it might be used to indicate that they can be cleared of suspicion. WGS information could reduce the chances that they are falsely pointed to and minimise negative effects for the FBO where the uncertainty as to whether patient strains might originate from them might otherwise (without such data) be considerable.

The potential for more information might also enable use of less burdensome measures, in accordance with the proportionality principle. In the case described, WGS data was imminent. The need for quick decisions to protect human health is understandable, and it is of course possible that MT in this case would have considered the products unsafe regardless (although having to apply the precautionary principle could be taken as an indication that any additional information would have been useful for the assessment). At the same time, MT could have considered rather holding back the products (eg, in the stores) until WGS data arrived to provide a more complete picture. Such an option depends, of course, on the time perspective and the durability of the food, and on whether other factors would otherwise render sufficient belief that the food is unsafe. Still, the need to base decisions on the precautionary principle might be reduced in some situations.

4.4.6 Summing Up

Through describing a concrete case of outbreak investigations towards an FBO, this chapter has shed light on the role played by WGS, and what part WGS could have played, in that context. It must be stressed that the point of the above discussions is not whether the suspected FBO was or was not the outbreak source. The exercise set out with the purpose of understanding what information the authorities had at any given time when decisions were made, and how the presence or absence of WGS data to inform those decisions may (or might) have influenced the assessments made.

Authority assessments of when food is 'unsafe' are highly discretionary. WGS can contribute to raise suspicions and create hypotheses. However, as a ground for decisions, it must be used with consideration also of other possible explanations for matches and other potential sources for the outbreak strain.

Increased application of WGS both by the authorities during outbreak investigations, and by FBOs in their own food safety control programmes, can contribute to create a better picture of the relevant *Lm* status. A danger is the potential that too much weight is placed on the WGS

[325] Interview F.

data. When assessing food safety, it is essential that the data foundation is sufficient and balanced (eg, based on examinations beyond just one or perhaps two FBOs, and based on multiple data sources), and that industry trust is nurtured to ensure their willingness to contribute and cooperate.

5 Access to WGS Data by Food Safety Authorities

5.1 Introduction

The basic issue taken up in this chapter concerns FSAs' legal power to require FBOs to provide them with isolates, sequences and analyses of foodborne pathogens. This power is examined primarily in respect of the current legal situation in Norway. At the same time, the chapter endeavours to impart a deeper understanding of the Norwegian regulatory regime by exploring the regulatory approach in another state, Austria. Austria is subject to the same EU framework as Norway, whilst also widely performing whole genome sequencing of *Lm* isolates from FBOs. Thus, Austria provides a useful point of comparison when assessing possibilities for future (alternative) regulatory approaches in Norway.

The main topics considered are the legal obligations for FBOs and laboratories to send in isolates or WGS data, and the corresponding legal rights for the authorities to claim them. The notions of 'obligations' and 'rights' are important to qualify at the outset. The perspective taken may appear to focus on the authorities as the mandating part, where FBOs and laboratories are left to comply with their requests. In reality, the legal picture is more complex. It bears reminding that EU food safety law is based on the premises that food may only be placed on the market if it is safe and that FBOs bear the primary responsibility to ensure such safety. A system taking this starting point must necessarily afford FBOs some flexibility for how they achieve the requisite safety level. The FSAs' mandate is to control that the FBOs comply with obligations, as well as to ensure public health. For this, they are given powers under administrative law (in Norway, primarily the Food Act (matloven) and its attendant regulations) to enforce food safety rules and carry out inspections and investigations targeting FBOs. These powers are, however, limited by the mandates given as well as by general principles for the exercise of administrative authority, such as the requirement of proportionality.

5.2 FBO Viewpoints

It will be recalled from Chapter 3 that interviews with Norwegian FBOs revealed disparate expectations and opinions on MT's ability to require WGS data from them. Some FBOs expected that MT might come to require WGS data from FBOs that have this, similarly to how MT may currently require access to analysis results from the FBOs' own or external laboratories.[326] One FBO stated that requests by MT for WGS data are likely to remain seldom for the

[326] Eg interview G.

near future since the authority so far has neither requested such results, nor asked about whether the FBO has performed WGS at all.[327]

In any case, MT's power to require this data likely depends on the context. Several FBOs thought they would have to share isolates or data they have with MT in the context of an outbreak investigation.[328] One of them remarked that it would cooperate with MT regardless and provide it with what is asked for.[329] Another FBO thought WGS data to be data the authorities do not need, due to the level of detail in the data.[330] (For outbreak investigations, however, this is the level of detail with which the authorities operate). A couple of other FBOs stated that they did not think MT could require WGS data from FBOs that have performed such sequencing.[331] One of them explicitly said it thought that MT cannot require WGS data, not even in an outbreak situation, because there is no current requirement to perform WGS.[332] Another FBO reasoned that MT could not require WGS data because this would be the FBO's property since the FBO would have paid for the sequencing.[333] Indeed, multiple FBOs considered such data to be the FBOs' property,[334] and stated that they would not share it with MT until sharing becomes necessary,[335] likely referring to a formal decision that requires sharing. However, they admitted that outbreak situations entail a particular challenge.[336]

As highlighted in Chapter 3, the main concern of FBOs in this context appears to be the potential for WGS data to be used to blame an FBO as causing an outbreak without sufficient foundation for the accusation. However, FBOs were not uniformly negative to disclosure of WGS data or submission of *Lm* isolates to MT. Several expressed support for such measures, provided there are assurances for appropriate use of the data or isolates.[337] Multiple FBOs stated that they wish to be transparent and to learn of illness that they could be causing, in order to stop it.[338] Nonetheless, there was a general attitude that sharing data with MT would require clearer guidelines

[327] Interview B.
[328] Interviews B, F.
[329] Interview F.
[330] Interview G.
[331] Interview A, E.
[332] Interview A.
[333] Interview E.
[334] Interviews D, H.
[335] Interview H.
[336] Interview E.
[337] Eg interview F.
[338] Interviews B, G.

on how the data is to be used, as well as guarantees for a high level of equal or non-discriminatory treatment of all FBOs, rather than MT meting out special attention to those operators that expend considerable resources on WGS.

5.3 MT's Legal Power to Access WGS Data

The relevant legal basis for MT's ability to require data (hereunder analysis results) from FBOs can be found in Norway's Food Act (matloven) and Norway's Official Control Regulation (kontrollforskriften).[339] The latter incorporates the rules of the EU Official Controls Regulation (OCR),[340] which governs FSAs' official control activities in EU law.

Matloven § 13(3) provides that an FBO 'shall at the request of the supervisory authority provide the necessary samples or results of completed analyses free of charge'.[341] The provision omits a detailed specification of what 'results of completed analyses' ('resultater av gjennomførte analyser') comprise, but the term would certainly include whether a pathogen is detected and in what amount (if quantitatively analysed). These kinds of analysis results have been most relevant for *Lm* so far. WGS data may also qualify as analysis results under the provision, as it is an outcome of analyses. From the wording, the analyses must already have been performed. Thus, if the FBO has not performed WGS, MT is limited to request other analysis results that the FBO may have (qualitative or quantitative), or to collect samples itself and subject any isolates it finds to WGS.

Matloven § 13(3) is augmented by provisions in matloven § 14(1)(1) stipulating that an FBO must, upon MT's request, 'make available or submit any necessary information or samples'.[342]

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[339] Forskrift om offentlig kontroll for å sikre etterlevelse av regelverket for mat, fôr, plantevernmidler, dyrehelse og dyrevelferd (FOR-2020-03-03-704; kontrollforskriften).

[340] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) [2017] OJ L95/1 (hereinafter 'EU Official Controls Regulation' or 'OCR'). Kontrollforskriften § 2 incorporates the OCR in Norwegian law.

[341] In Norwegian: 'Virksomheten skal på anmodning fra tilsynsmyndigheten vederlagsfritt avgi nødvendig prøvemateriale eller resultater av gjennomførte analyser'. See also OCR Art 14(h).

[342] In Norwegian: 'Virksomheten skal når tilsynsmyndigheten krever det, gi eller sende inn nødvendige opplysninger og prøvemateriale'.

While the scope of the term 'information' ('opplysninger') is not specified, there can be little doubt that it is sufficiently broad to encompass WGS data, particularly in light of statements in the preparatory works that the obligation to provide information must not be perceived too narrowly.[343]

To the extent matloven § 13 applies, its specific phrasing about analysis results can make it preferable as a foundation for requiring WGS data. Otherwise, both §§ 13(3) and 14(1) seem to provide similar access in respect of WGS. One noticeable difference is that §14(1) contains an additional sentence empowering MT to decide how the information is to be given, hereunder its form and level of detail. This seems to provide MT wider scope to require FBOs to adapt the information according to MT's preferences, compared to § 13(3) which lacks any equivalent phrase. In the case of WGS, MT might, for example, want the data provided in a particular format.

Article 15 of the EU's Official Controls Regulation sets out an obligation for FBOs to 'give staff of the competent authorities access to', amongst other items, equipment, premises, animals, information management systems, as well as 'their *documents and any other relevant information*',[344] to the 'extent that this is necessary for the performance of official controls or of other official activities'.[345] This bears similarity to matloven § 13 and corresponds well with concrete investigation settings. The phrasing 'access to' could suggest that the FSAs must settle with examining 'documents and other relevant information' in the form these already exist. Furthermore, 'access to' need not entail handing over the information to the authorities, as much as allowing them to see and examine it (eg, at an FBO's physical location).[346] OCR Article 15(1), thus, may not necessarily be used to require copies of the FBO's WGS data, yet it may also be interpreted to include such an obligation.[347]

Under matloven §§ 13(3) and 14(1), the obligation to provide analysis results and sample material is placed on the FBO ('virksomheten'). The term 'virksomhet' is broadly defined as any private or public-sector business undertaking or private person engaged in the production, processing and distribution of intermediate inputs at the level of primary production and of food,

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[343] Ot.prp.nr.100 (2002-2003) 146.

[344] OCR Art 15(1)(d) (emphasis added).

[345] OCR Art 15(1).

[346] Likely corresponding with 'examination' in OCR Art 14(1)(e) or 'verification' in Art 14(1)(g).

[347] Cf OCR Art 14 providing methods and techniques of official controls. Article 14 seems less aimed at placing obligations on the operator and less suited for the challenges raised herein than the provisions discussed above. The objects of control (eg, 'documents', 'records' and 'results of controls' (OCR Art 14(e), (a)) do not correspond as well, and FSAs' access is limited to 'examination' and 'verification', which appear narrower than under the forementioned provisions. Article 14 is therefore not further assessed herein.

including drinking water, or involved in the production of materials and articles that are intended to come into contact with or that may have an effect on intermediate inputs and food, except for activities undertaken for private and non-commercial purposes.[348] Laboratories performing analyses on behalf of FBOs or others managing data for FBOs, are not encompassed.[349]

If the analyses required are not stored by the FBO itself, it may need to provide them from actors operating on its behalf.[350] However, particularly if there is a pressing need for rapid provision of the data, or if the FBO should fail to comply, it is relevant also to consider the authorities' access rights towards those other actors. For this, matloven § 14(2) provides: 'Any person may be ordered to produce or submit information and samples if this is necessary in connection with the control of imports or for transmissible disease surveillance'.[351] Again, under this provision, the authorities must actively request the information. The obligation extends to laboratories and other enterprises. Laboratories were also central in the legislator's intentions behind the provision.[352] Thus, laboratories would, upon request, need to provide, *inter alia*, necessary information about performed analyses.[353] However, the relevant purposes for MT to require WGS analyses from laboratories are narrower than from FBOs: information for import control and disease surveillance is encompassed, but not other official controls or activities.

5.3.1 Necessity and Proportionality

MT's powers under matloven §§ 13 and 14 are qualified by the term 'necessary'. The term functions both as a justification to require data from FBOs, and as a limitation on MT's authority. It provides that MT can demand, *inter alia*, analysis results that it needs for its purposes.[354] At the same time, MT's claim should not be excessive. Thus, 'necessary' restricts the purposes for which MT can require access, and the level of detail and extent of information it can claim.

On its face, the criterion 'necessary' does not directly signal a broader proportionality assessment of MT's exercise of powers. Nonetheless, there are solid grounds for reading such an

[348] Matloven § 4(1) in combination with matloven § 2.

[349] While the activities performed by such actors are indirectly related to production and processing, the preparatory works make clear that the legislator has not considered laboratories encompassed under 'virksomheten' in the first paragraph. See eg Ot.prp. nr. 100 (2002-2003) 146-147 (referring to 'andre foretak som ikke er omfattet av lovens virksomhetsdefinisjon, eksempelvis laboratorier').

[350] Ibid, 146 ('også det å fremskaffe eller utarbeide opplysninger vil omfattes av bestemmelsen').

[351] In Norwegian: 'Enhver kan bli pålagt å fremlegge eller sende inn opplysninger og prøvemateriale når dette er nødvendig av hensyn til kontroll med import eller av hensyn til smitteovervåkning'.

[352] Innst.O.nr.36 (2003-2004) 1.8.

[353] Ot.prp.nr.100 (2002-2003) 146.

[354] For sample material, the proposition comments that 'necessary' entails that it should be in sufficient amounts (ie, the amount necessary): ibid, 145.

assessment into the criterion, particularly in light of the preparatory works for the legislation combined with general administrative law doctrine.

In respect of matloven § 13(2) concerning MT's power to require FBOs to make available facilities, equipment, etc, the preparatory works indicate a requirement for proportionality between the task at hand (for MT) and the obligations it triggers (from the FBOs).[355] As the purposes and considerations behind all of the sub-paragraphs of matloven § 13 are essentially similar, it makes sense to apply a corresponding proportionality assessment to MT's powers under § 13(3). Beyond those provisions, the necessity criterion also qualifies MT's authority under matloven § 23 to make decisions in general (including decisions under matloven §§ 13 and 14): MT can make 'necessary decisions' ('nødvendige vedtak').[356] The preparatory works elaborate that 'necessary' entails a requirement that measures must be suitable to realise the purpose,[357] and, furthermore, that the purpose is not achievable by equally effective, less intrusive means.[358] The preparatory works also refer to the need for proportionality between objectives and means for interferences in persons' rights and interests.[359]

These aspects correspond well with the general principle of proportionality in Norwegian administrative law, which mandates administrative bodies (including MT) to consider the proportionality of decisions they make.[360] This requirement is procedural: MT must consider affected interests and the proportionality between purpose and means before taking measures.[361] The

[355] Ibid, 145; see also 85.

[356] Matloven § 23(1).

[357] Cf Ot.prp.100 (2002-2003) 157, see also 103.

[358] Ibid.

[359] Ibid, 157. Regarding proportionality and caution from the side of MT under matloven, more explicit regulation on a duty of care ('aktsomhetsplikt') in Norwegian food law was proposed in NOU 1996:10, Annex I (§ 5-5) as a specification of the proportionality principle mandating MT to choose the alternative that is least burdensome for the FBO (provided the legal objectives were still fulfilled). This codification was not adopted: see Ot.prp.nr.100 (2002-2003) 86.

[360] See eg T Eckhoff and E Smith, *Forvaltningsrett* (10th edn, Universitetsforlaget 2014) 404-405; HP Graver, *Alminnelig Forvaltningsrett* (4th edn, Universitetsforlaget 2015) 130.

[361] Eckhoff and Smith (n 360) 404-405.

assessment itself is discretionary,[362] but it must be made,[363] and it should thereby function as a limitation on the authorities' exercise of power.

The core of the proportionality principle consists of a three-pronged assessment: whether the measure in question is appropriate or suitable ('egnet') to realise its objective; whether it is necessary ('nødvendig') or if the purpose can be attained by less intrusive means; and whether the measure is altogether too burdensome compared to the aim to be realised ('forholdsmessig').[364]

The suitability requirement refers to the measure's ability to achieve its defined purpose.[365] The purpose should relate to the legislative objectives, both of matloven and international obligations such as the EEA Agreement.[366] Matloven aims to ensure safe food and promote health, quality, and consumer interests along the whole production chain, as well as to protect environmentally friendly production,[367] and to promote good plant and animal health.[368] The GFL sets out similar objectives in its 'general principles of food law': to achieve a 'high level of protection of human life and health and the protection of consumers' interests'.[369]

The central aim of matloven §§ 13 and 14 is facilitation of MT's performance of its tasks to achieve these overarching legislative objectives. MT actions related to *Lm* will typically have

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[362] See Ot.prp.nr.100 (2002-2003) 157. For the *content* of the decisions made, there is likely not sufficient basis to assume a generally applicable proportionality principle in Norwegian administrative law: see Rt 2011, 304, para 56. See also Eckhoff and Smith (n 360) 405. In other words, a discretionary administrative decision cannot usually be overruled by the courts based on a lack of proportionality (unless it is highly unreasonable: see Eckhoff and Smith (ibid) 399-401). Proportionality requirements extending also to the content of decisions do apply within certain areas of administrative law, including where EU law is binding on Norway, as is the case for food law: see EEA Agreement Art 6 and ODA (Agreement between the EFTA States on the establishment of a surveillance authority and a court of justice) Art 3; TEU Art 5(4). See also Ø Rasmussen, 'Forholdsmessighetsprinsippet i forvaltningsretten' (1995) 5-6 *Lov og Rett* para 2.7. The proportionality principle in EU law, as set out in TEU Art 5(4), applies as an overarching norm. See also GFL Recitals 66 and 99. If a decision entails a restriction on the fundamental freedoms of EU law, the proportionality assessment can be fully tried and overruled by the courts (see Graver (n 360) 131-132), although there will be a margin of appreciation for the EU member states.

[363] That a balancing has been properly performed can be tried by the courts: see Rt 2011, 111. See also Ot.prp.nr.100 (2002-2003) 157. A decision that is made without an attempt at balancing could be found invalid: see further Graver (n 360) 131.

[364] See eg Eckhoff and Smith (n 360) 404. This corresponds with the three-pronged approach applied also in EU law: see P Craig and G de Búrca, *EU Law. Text, Cases, and Materials* (7th edn, Oxford University Press 2020) 583.

[365] See eg Graver (n 360) 128.

[366] Agreement on the European Economic Area (EEA), 1992.

[367] Matloven § 1(1).

[368] Matloven § 1(2).

[369] GFL Art 5(1). The aim of free movement of food and feed is promoted in GFL Art 5(2).

health objectives, within which more concrete purposes can be defined for the specific measure. A claim from MT for WGS data under §§ 13 or 14 requires that such access enables them to attain those defined purposes.

The measure must also not go beyond what is necessary in the relevant situation. This entails that there should not exist other, less onerous means capable of attaining the same purposes with equal efficiency.[370] The alternative to requiring WGS data would be either for MT to fulfil its tasks based on other types of or less detailed information from the FBOs, or to perform the analyses itself (based on requiring or collecting samples). The adequacy of such alternative means must then be considered.

In addition to assessing the existence of other, less intrusive means, the scope of the relevant measure must be considered. In other words, MT must ensure that the extent and level of detail of data requested, is not excessive.[371]

Even if the measure is found to fulfil both the suitability and the necessity criteria, it still must pass muster in terms of its proportionality in a strict sense. This third category of assessment involves a balancing of interests—typically a weighing of societal interests codified in the legislation (here primarily health) against the interests of those affected (eg, FBOs)[372]—to ensure that the advantages of the measure outweigh the disadvantages. As the assessment tends to turn on incommensurable interests, it is typically left to administrative discretion.[373] The threshold for proportionality is thus difficult to ascertain precisely.

In the balancing, any affected interests can be considered, also beyond the explicit legislative objectives. Accordingly, the weight attributed to the different interests will naturally vary. Nonetheless, in the field of food law, certain interests will weigh heavier than others. These interests are 'human life and health' and 'consumer interests' which are set out in GFL Article

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[370] See eg Graver (n 360) 128.

[371] Matloven § 14(1)(3) states that MT may determine the level of detail of information to be provided (ie, the provision relies on MT's discretion), albeit within the necessity requirement. As indicated above, a similar sentence is not included in § 13(3). Considering the detail and potential sensitivity of WGS data, it is worth noting that NOU 1996:10 proposed codifying that MT ought not to demand especially sensitive information about production processes and the like which is not required for realising the goals of the legislation ('bør avstå fra å kreve særlig sensitiv informasjon om produksjonsprosesser e.l. som ikke er påkrevet for at lovens formål skal realiseres'). Although not adopted, the proposed rule highlights that account should be taken (under a proportionality assessment) of the information's sensitivity (under which must also be considered the risk, despite confidentiality and secure storage, of such information being spread).

[372] See Graver (n 360) 129.

[373] Ot.prp.nr.100 (2002-2003). The consequence of this wide discretion is that the strict proportionality assessment is unlikely to be overruled unless it appears highly unreasonable: see Rt 1995, 738, 740-741.

5(1) as the central objectives of food law. The paragraph's failure to mention other interests,[374] can be read as limiting the significance of other (competing) objectives.[375] Yet, while less significant or salient, the latter are far from irrelevant here. For instance, GFL Article 5(2) specifies the aim of free movement of food and feed within the EU. This also points to proportionality in accordance with Treaty on European Union (TEU) Article 5(4). Moreover, several food law instruments reference industry interests. The OCR recitals comment that FSA activities should be organised and conducted 'taking their [FBOs'] interests into account and limiting the said burden to that which is *necessary* for the performance of efficient and effective official controls'.[376] Matloven explicitly mentions industry interests in its objectives.[377] The preparatory works, however, specify that matloven is not to promote industry interests in general, as this could conflict with the other legal objectives.[378] In accordance with the order in which objectives are listed in matloven § 1, the proposition further provides that, upon a balancing of interests, decisive weight should be given to health as the main legal purpose.[379] This both acknowledges industry interests as relevant and provides guidance for their weighing. The threshold appears high for FBO interests to have significant impact compared to other food safety interests, indicating a considerable margin of appreciation for MT to justify measures based on health objectives.[380]

5.4 Situations Where Access Might be Relevant

Based on the objectives and tasks of MT discussed above, the potential contexts in which matloven §§ 13(3) and 14(1) might be relevant reach rather wide. In the following, three very gen-

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[374] Note that 'other objectives' was included in the proposal for the GFL (see COM(2000) 716 Art 5), but was removed in the adopted version of the GFL.

[375] Cf van der Meulen reads GFL Art 5(1) as providing a 'limited and closed set of objectives' for all of food law; that it must pursue either or both of the two explicit objectives of 'human life and health' and 'consumers' interests', and therefore that 'commercial interests seem to be excluded from the legislature's balancing of interests': Bernd MJ van der Meulen, 'The function of food law: On objectives of food law, legitimate factors and interests taken into account' (2010) 5(2) *European Food and Feed Law Review* 83. However, he acknowledges the possible relevance of commercial interests through GFL Art 6 and TEU Art 5(4): ibid 88.

[376] OCR Recital 34 (emphasis added). See also OCR Recital 39. Note that recitals are not legally binding: see eg Case C-136/04 *Deutsches Milch-Kontor GmbH v Hauptzollamt Hamburg-Jonas*, judgment of 24 November 2005 (ECLI:EU:C:2005:716) para 32.

[377] Matloven § 1(3) ('ivareta hensynet til aktørene langs hele produksjonskjeden'), although this objective is intended as secondary and is largely aimed at ensuring Norwegian food export: see Ot.prp.nr.100 (2002-2003) 134.

[378] Ibid.

[379] Ibid.

[380] Also, the EU and EFTA courts have usually afforded EU member states a considerable margin of appreciation with regards to achieving objectives like public health: see eg F Sejersted and others, *EØS Rett* (Universitetsforlaget 2011) 339.

eral (and potentially interrelated) situations for when use of these provisions might be considered, are drawn up and related to WGS analyses: (i) verification of FBO compliance (official controls)[381]; (ii) outbreak investigations; and (iii) surveillance of *Lm* in the food chain. The aim is not to provide any precise template for when MT may require WGS data, but rather to point to relevant considerations and perhaps indicate in what situations access is more likely to be required. In the end, these are case-by-case assessments subject to considerable administrative discretion.

5.4.1 Verification of FBO Compliance through Official Controls

As already pointed out, there is currently no provision in EU or Norwegian law mandating FBOs to perform WGS.[382] Neither are there any obligations for which WGS data is necessary to assess compliance. How to comply with, for instance, HACCP-based procedures is flexible; FBOs can use WGS to better identify and assess risks, but the FSA should be able to assess their compliance without access to the WGS data.

Even if, for example, an FBO's risk assessment, or tracing for *Lm* sources,[383] or trending[384] is heavily based on information from WGS, it should suffice, as a maximum, that MT sees a less detailed report of the FBO's WGS findings and how they have been taken into account. Access to the complete whole genome sequence datasets (ie, FASTQ files or assembled genome sequences) should not be 'necessary' in the legal sense elaborated in the previous section. If the FBO bases fulfilment of legal obligations on WGS, and MT suspects that the FBO fails to use the WGS information correctly or expediently, MT could alternatively refer the FBO to consult external expertise rather than setting out to examine the full details themselves.

Accordingly, access to WGS data seems of little relevance and unnecessary for MT to verify FBOs' compliance.

5.4.2 Outbreak Investigations

Outbreak investigations generally have two main objectives: finding the source and identifying the cause.[385] Both are central to stop the outbreak and prevent further cases of illness. They thus both correspond strongly with the objective of safeguarding human life and health.[386]

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[381] For further definition, see Chapter 6, Section 6.8.1.

[382] Requirements, for example, to sample are merely qualitative/quantitative, and analysis results showing presence or amount of *Lm* should suffice to demonstrate compliance. See MCR Annex I, Chapter I, no 1.1.-1.3.

[383] MCR Art 7(1)(2).

[384] See MCR Art 9.

[385] Kapperud (n 269) 12.

[386] GFL Art 5(1).

In an outbreak situation, the threshold for what is 'necessary' will change considerably, much due to the need for rapid detection. During an outbreak, MT and the NRLs will collect and analyse samples. Time will be of the essence. If the FBO is already in possession of relevant WGS data, this could allow FHI to compare suspected food-related isolates to patient isolates more quickly. Access to those sequences thus seems both suitable and necessary, at least to the extent sampling by the authorities alone is not equally efficient for performing the investigations. MT can then likely require sequences or analyses under matloven § 13(3), and possibly § 14(1) and 14(2).[387]

In an outbreak situation with a high risk to health, there can be an elevated necessity of requiring complete sets of WGS data. In this context, the health objectives highlighted both in the legislation and in the preparatory works (as pointed out above) will receive heightened priority.

Sequence data held by the FBO (or their laboratories) may correspond with different strains of *Lm* than any *Lm* MT may find through collecting samples. Requiring access to these sequences can thus contribute to a better data foundation for the authorities in their investigations. Still, claims to receive WGS data should correspond with isolates from samples from the relevant period and from relevant products or production areas.

5.4.3 Surveillance of *Lm* in the Food Chain

MT monitors *Lm* for the purpose of surveillance and mapping of its status in the food chain. WGS employed in this context can increase the knowledge on *Lm*, improve MT's basis for decisions and activities, and contribute to prevent or solve future outbreaks. Nonetheless, a measure is only 'necessary' when no other, less intrusive means can achieve the purpose sought by MT in an equally beneficial or superior manner.[388] For example, to the extent collecting samples can efficiently achieve the purpose, requiring WGS data from FBOs is unlikely to fulfil the necessity criterion here. For purposes of surveillance of *Lm*, MT's need for WGS data would be less acute compared to during an outbreak, thereby allowing time for it to itself perform WGS, should it need to.

One could argue that sampling by MT provides better assurance that the FBOs examined are representative, avoiding the risk of making FBOs that utilise WGS more prone to extensive data

[387] MT can also require that microbiological laboratories that detect *Lm* in a foodstuff, send the pathogen ('smittestoff') to the relevant NRL, and if an outbreak is suspected, also directly to FHI's laboratory (where it will undergo WGS), see MSIS-forskriften § 2-4a(3). The wording of this provision does not encompass environmental samples, and it only refers to the pathogen (not analyses of it). For further discussion of this obligation, see Section 5.6.2.

[388] See eg Graver (n 360) 128.

collection. Also, sampling arranged by MT could contribute to comparability and an equitable data foundation across factories, avoiding bias caused by different sampling regimes.

Nonetheless, MT's collection of samples and sequence data can fulfill different purposes. The collection of sequences could, for example, include *Lm* sequences generated by an FBO over time. However, such historic insights may struggle to clear the proportionality test.

One may ask how much more onerous it would be for an FBO were MT to require WGS data from the FBO, as opposed to MT collecting samples or isolates and performing WGS itself. The advantage of MT having access to sequences from isolates from the FBO's facilities would be similar whether MT claims access to WGS data from the FBO or generates the WGS data from samples it collects itself, although the latter would be based on less investment from the FBO's side. However, a requirement that FBOs perform WGS and send the results to MT (or, rather, the NRL on their behalf) would probably enable MT to utilise the sequence data more quickly and with lower costs and resources from MT. Furthermore, WGS data from FBOs may be more extensive (eg, covering more sampling locations, also over time), thereby providing a fuller picture of *Lm* in the food chain.

As pointed out several times earlier in the report, MT gathering WGS data only from some FBOs (ie, those who perform WGS) can create inequalities between those who apply the technology and those who do not. FBOs applying WGS may then feel more vulnerable to adverse implications of the authorities having extensive data on the *Lm* detected in their facilities. Worries about MT access claims and how the data might be used, may then deter FBOs from applying WGS. The main aims pursued by MT in accessing information (ie, safe food, health) may be negatively affected if its approach hampers industry uptake of WGS and thereby the potential benefits it would bring to the food safety regime. Setting the threshold for requiring access to FBOs' WGS data too low may ultimately be irreconcilable with either step of the proportionality assessment.

A different matter is when the NRLs might wish to perform WGS on isolates detected in samples from surveillance programmes on their own initiative and outside the scope of official activities, eg, for research purposes. That situation is outside the scope of this section, but it is touched upon in Chapter 6.

5.4.4 Conclusions

This section has attempted to shed light on the legal basis for MT's ability to require WGS data from FBOs. Matloven provides such legal basis, subject to requirements of necessity and proportionality. Before requiring WGS data, MT must therefore assess the suitability and non-

excessiveness of the measure, and it must consider and weigh all interests involved. The outcomes of such assessments rely much on the specific situation and purpose, for which reason three types of scenarios have been reflected upon. It seems likely that collection of simpler analysis results, or of samples for analyses, often can fulfil MT's objectives adequately compared to requiring a full set of WGS data from FBOs. MT may not always 'need' access to highly detailed genetic information at the level WGS provides for purposes of routine surveillance and regular official controls. For these purposes, analysis results stating presence or absence of *Lm* should suffice for the authorities to fulfill their responsibilities (as MT itself indicates; see Section 6.3). An exception may pertain for outbreak investigations.

In any case, the various interests involved must always be carefully weighed against each other. MT is afforded considerable discretion here. At the same time, the food law system is built on a certain amount of trust and respectful collaboration between MT and FBOs. Perception by the latter that MT takes due account of their interests is important for their willingness to cooperate expediently. It is therefore important that MT stays attentive to possible adverse effects of requiring information from FBOs. As flagged in earlier parts of the report, extensive MT information gathering practices beyond what FBOs find reasonable, could engender their reluctance to implement WGS. If FBOs for such reasons decide against applying WGS technology, this would be far from an unequivocal 'win' for food safety. This points to a need for finding measures that, in total, best serve the legal objectives. Thorough assessments under the necessity criterion are an important component in ensuring that MT's access rights do not engender more adverse effects than the purposes they aim to serve.

5.5 The Austrian Approach

The previous section focused primarily on access to WGS data generated by FBOs. As another possible scenario is for the authorities to perform WGS on isolates from FBOs, the possibilities for collecting such isolates, particularly on a routine basis, calls for examination. Collection of isolates for WGS is the main topic of this and the following section.

This section presents the legal and practical situation in Austria regarding authorities' ability to receive *Lm* isolates from FBOs and their performance of WGS on these. Austria is interesting to consider because its approach deviates from other European countries. While in Norway and most other states, WGS of *Lm* from the food industry is far from routine, Austria currently performs WGS on, in principle, all *Lm* found in FBOs. Austrian FBOs are required to submit to the NRL all *Lm* isolates they find through their own food safety control programmes, be these from food, food contact surfaces or the processing environment in the wider sense. The NRL then performs, and covers the costs of, WGS on all *Lm* isolates it receives. It then constantly compares sequences to enable efficient tracing and handling of detected cases of illness. Thus,

Austria represents a functioning example of how the authorities (and, to some extent, the FBOs) may reap benefits offered by WGS. For states still in the early phases of implementing WGS of food-related samples in their systems, and also for FBOs that consider using WGS, examining the Austrian approach can provide inspiration and insights on how WGS may be exploited—or not—when deciding upon future ways forward.

Another factor making Austria interesting for comparison with Norway, is the common EU legal foundation. Despite differences in the legal (and factual) traditions—from organisation of public administration and relevant agencies to the prevalence of different foodstuffs in production—both countries' food safety regimes have a basis in EU law. This entails application of common concepts, such as the principle that food must be safe, placing food safety responsibility on the FBOs, and considering the whole food chain ('from farm to fork') under the same framework. The similarities that spring from this common foundation should better enable both comparisons and potential transfer value between the EU/EEA states.

This section examines the approach taken in Austria, seeking to understand not only the applicable rules *lex lata*, but how they are practiced, their background, and how they are perceived by relevant stakeholders. Part of the aim is to uncover advantages and possible disadvantages of the approach. This should also facilitate assessment against the situation in Norway (see Section 5.6). While acknowledging the need to consider as many factors as possible to acquire a comprehensive picture, the following examination seeks to do so within reasonable limits, taking its starting point in the rules that require FBOs to submit *Lm* isolates and their subsequent whole genome sequencing.

5.5.1 Austrian Food Law: An Introduction

The general responsibility for food safety in Austria is placed with the Ministry of Health (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz). This is the competent authority at the national level. On the sub-national level, Austria consists of nine federal states (or provinces), each with their own government. The local food safety authorities in each of the nine federal states are responsible for implementing and enforcing the food safety legislation in their respective regions. They carry out tasks, such as official controls and administrative measures towards the FBOs. The local authorities are nevertheless coordinated by the Ministry of Health, and they report back to the ministry when carrying out, for instance, surveillance campaigns on its behalf.

For technical and scientific tasks, there are designated laboratories. The NRL for *Lm* in Austria is AGES (Agentur für Gesundheit und Ernährungssicherheit). It performs laboratory analyses and related tasks on behalf of the ministry, to which it reports back. AGES does not perform

official controls as such, as these are carried out by the authorities as described. It does conduct, however, the scientific work and risk assessments.

AGES is tasked with receiving isolates from all positive *Lm* samples taken in Austria, be they from humans, animals, food, processing environments, or something else. AGES sequences the isolates, perform analyses, and sends quarterly reports to inform the ministry. These reports provide updates on the current situation in Austria, such as which strains (or subtypes) are prevalent, and which companies submitted (and which did not submit) isolates. The ministry then decides how to act based on the information it receives.

AGES was established in 2002, merging 18 federal institutes related to agriculture, food control, veterinary medicine and public health. Gathering such various competencies is in accordance with a development that occurred throughout EU/EEA states (Norway included) in the early 2000s as a result of the then new EU framework. Nevertheless, it is noteworthy that Austria has encompassed also public health under the same NRL as food. In other states, food and human epidemiology are often placed under separate authorities (for instance MT and FHI in Norway). This provides AGES with a different starting point for working interdisciplinary and obtaining a comprehensive overview over foods as well as plant, animal, and human health.[389]

An AGES employee interviewed referred to this combination of human and environment/food origin under one NRL (both for *Lm* and many other bacteria) as 'typically Austrian'.[390] The interviewee also regarded this a major advantage.[391] Advantages are easily conceivable: for example, the data can be kept in the same database or databases within the same agency, facilitating more efficient comparisons across sectors, without the need to share data and coordinate between various involved bodies.

The central food safety legislative framework in Austria is provided by the 2006 Food Safety and Consumer Protection Act (Lebensmittelsicherheit- und Verbraucherschutzgesetz; LMSVG).[392] Austria joined the EU in 1995, and the GFL and several of its *lex specialis* regulations are therefore directly applicable. Despite being based on EU food law, Austrian food legislation contains some domestic particularities.

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[389] See generally K Udagawa and others (eds), *EU Food Safety Almanac* (2021) German Federal Institute for Risk Assessment (BfR).

[390] AGES: interview 20 July 2022.

[391] Ibid.

[392] Bundesgesetz über Sicherheitsanforderungen und weitere Anforderungen an Lebensmittel, Gebrauchsgegenstände und kosmetische Mittel zum Schutz der Verbraucherinnen und Verbraucher (Lebensmittelsicherheits- und Verbraucherschutzgesetz – LMSVG).

In accordance with the EU framework, the LMSVG covers the entire food chain and bases itself on EU food law principles. It also explicitly places the obligation to ensure food safety and comply with food law on the FBOs (see LMSVG § 21), in accordance with the FBO responsibilities under GFL Article 17.

The legal obligation discussed in the following concerns submission of isolates. Submitted isolates are subsequently subjected to WGS. The decision to perform WGS on all isolates received is not prescribed by the legislation but made by AGES, in cooperation with the Ministry of Health.[393] The sequencing is funded partly through financial contributions from the ministry.[394] All the WGS data is kept in one database,[395] and comparisons take place continuously. Any links between human and food isolates are thus quickly uncovered by AGES.

AGES transitioned to using WGS already during 2015-2017. Prior to this, PFGE was applied between approximately 2008 and 2016.[396] According to the AGES interviewee, AGES would analyse anything it received also back when PFGE was being applied.[397]

Since all *Lm* detected in the Austrian food industry is already (at least in principle) undergoing WGS by AGES, there is inherently less of a need for FBOs to perform and finance WGS themselves. Neither is there any indication that Austrian FBOs themselves perform WGS to any considerable extent.[398]

5.5.2 Central Provisions

Focusing on the topic at hand—submission of isolates that subsequently undergo WGS—two legislative provisions are of particular interest: LMSVG §§ 38(1)(6) and 74. In short, they mandate FBOs and laboratories to routinely send in all positive isolates of, *inter alia*, *Lm* within the scope of those provisions.

It bears emphasis that these provisions themselves do not directly involve WGS. They oblige FBOs and laboratories to submit isolates, without prescribing for the authorities' use of these; in other words, subsequent WGS performed by AGES takes place separately. Still, this obligation is a necessary precondition for the WGS that AGES performs on the isolates it receives.[399]

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[393] AGES: interview 20 July 2022.

[394] Ibid.

[395] Ibid.

[396] Further on PFGE, see Chapter 1, Section 1.4.

[397] AGES: interview 20 July 2022.

[398] Ibid.

[399] See https://www.ages.at/mensch/krankheit/krankheitserreger-von-a-bis-z/listerien.

The main consideration behind the obligation to submit all *Lm* isolates is public health. The provisions concerned are based on implementation of the EU's Zoonosis Monitoring Directive (ZMD),[400] particularly Article 6. These obligations in Austria, however, are more extensive than those required by the directive, making the Austrian approach stand out in the European setting.

ZMD Article 6 lays down 'Food business operators' duties'. These fit in as part of the wider EU framework, including the responsibility under GFL Article 17 for FBOs to ensure that their food be compliant, the duty under FHR Article 5 to have in place HACCP-based procedures, and the requirement under MCR Article 5 (see also Article 3) for FBOs that produce RTE foodstuffs posing a risk to public health, to perform necessary *Lm* sampling as part of their own food safety control programme, including samples of equipment and the environment where the food is processed. The obligation in ZMD Article 6 is aimed at FBOs and concerns samples taken in connection with their own food safety control programmes.

That the obligation in Austrian law is more extensive compared to what is prescribed by EU law, partly follows from the LMSVG's legal phrasing, and partly from ministry decrees specifying the obligation. Whereas ZMD Article 6(1)(b) refers to communicating 'results' *or* providing isolates, the LMSVG requires submission of *isolates*. Where the ZMD's obligation (in Article 6(1)(b)) is submission 'on request', leaving it for the member states to decide what isolates to require and how routinely, there is no qualifying word in the LMSVG limiting when submission should take place in Austria. This indicates more extensive, routine submission than in the directive. In addition, ministry decrees specify relevant sample origins for submission, currently including all *Lm* isolates from samples of any source from FBOs' internal food safety control programmes. Furthermore, Austrian legislation has added a similar, independent obligation also for laboratories (LMSVG § 74), as elaborated further below.

LMSVG § 38 is phrased as follows (emphasis added):

> '*Unternehmer* sind *verplichtet* […] (6) *im Rahmen der Eigenkontrollen* betreffend das Vorliegen von Zoonosen und Zoonosenerregern gemäß Art. 4 ff. der Richtlinie 2003/99/EG […] die *Ergebnisse* zu *verwahren* und *unverzüglich*, längstens jedoch binnen zwei Tagen, die *Isolate* dem gemäß § 75 zuständigen *Referenzlabor* zu *übermitteln* oder deren unverzügliche Übermittlung *durch das untersuchende Labor unter Nennung des Unternehmens* zu veranlassen'.

[400] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents [2003] OJ L 325/31.

This is the current wording, which is the result of a few changes having been made to the original phrasing from when the Act entered into force in 2006. The first change occurred in 2010, adding the phrases 'unverzüglich, längstens jedoch binnen zwei Tagen' and 'oder deren unverzügliche Übermittlung durch das untersuchende Labor zu veranlassen'.[401] These changes entail specifications. Firstly, 'unverzüglich' specifies an upper time limit set to two days for when the isolate must be sent to the relevant reference laboratory.[402] In addition, the alternative of fulfilling this obligation by sending in the required data through the examining laboratory (which is often the most sensible approach in practice) is made explicit.

A third change occurred in 2014, with the inclusion of a specification in the last part of the provision: the words 'unter Nennung des Unternehmens'.[403] This made explicit that laboratories sending in isolates on behalf of an FBO must name the FBO. This clarification was made to avoid interpretational challenges.[404] Interesting in this regard, is the apparent confusion over how this should function against the anonymity requirement in § 74 (see further below). During the public consultation accompanying the change, several stakeholders commented that the change would conflict with § 74 and thus require an adjustment of the latter's anonymisation obligation.[405] This is further discussed in Section 5.5.4.

As already intimated, the § 38 obligation was included in the law already when the LMSVG was originally adopted. It appears to have attracted little documented attention or controversy during the legislative process.

The obligation in LMSVG § 38 is directed at FBOs, not laboratories. This must likely have been perceived as a shortcoming, seeing as it was decided in 2010 to introduce LMSVG § 74, which came into force 1 January 2011.[406] This provision created an independent duty for laboratories to send in isolates, seemingly aimed at instances when FBOs fail to fulfil their obligation. It reads (emphasis added):

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[401] Added by Bundesgesetzblatt (BGBl.) I 95/2010.

[402] See RV649, 4.

[403] Added by BGBl. I 67/2014.

[404] See RV184, 7.

[405] See consultation responses ('stellungnahme') submitted by Amt der Vorarlberger Landesregierung 20 May 2014, 2; Amt der Niederösterreichischen Landesregierung 20 May 2014, 2; Amt der Wiener Landesregierung 22 May 2014, 2.

[406] BGBl. I Nr. 95/2010.

> '*Labors*, die *im Rahmen von § 38 Abs. 1 Z 6* das Vorliegen von Zoonosen und Zoonosenerregern untersuchen, haben *Isolate* unverzüglich, längstens jedoch binnen zwei Tagen, dem gemäß § 75 zuständigen Referenzlabor *anonymisiert* und *unter Hinweis auf die Produktgruppe* zu übermitteln. Diese Verpflichtung *entfällt*, sofern die Isolate bereits auf Veranlassung des Unternehmers gemäß § 38 Abs. 1 Z 6 übermittelt wurden'.

The introduction of this provision was perceived as necessary for tracing food-related outbreaks of disease.[407] It has remained unchanged since its introduction, except for the addition in 2014 of the last sentence, which was not there originally.[408] This sentence frees the laboratories from their obligation set out in the first sentence, if it has already been fulfilled by the FBO. In other words, there is no need for double submission.[409]

LMSVG § 74 entails the same obligations for laboratories as for FBOs under § 38(1)(6) with respect to submission of isolates and the time requirement for sending them. However, there are some differences between the two provisions. One difference is the inclusion in § 38 of the obligation to store results ('Ergebnisse'). This can similarly be found in ZMD Article 6(a). In both provisions, that obligation rests solely on the FBO (who can of course arrange for this with its laboratory). Another difference, already hinted at above, is that isolates submitted under § 74 are to be anonymised (at least according to the § 74 wording), indicating their origin by the product group. This appears, in theory, to entail not naming the FBO (see further on this in Section 5.5.4).

Regardless of § 74, the main responsibility to submit isolates remains on the FBOs under § 38(1)(6), where laboratories' submission—at least from the wording—is to be based on a request by the FBO to their laboratory or an agreement between these two parties. The laboratory is then, as described in the provision, to name the FBO. LMSVG § 74 is relevant (at least after the 2014 addition) only if the FBO does not fulfil its obligation.

5.5.3 Decrees

The above-described legal provisions provide for further specification through decrees by the Ministry of Health. These decrees are not systematically published but are rather considered

[407] Regierungsvorlage RV649, 6 ('Zur Abklärung lebensmittelbedingter Krankheitsausbrüche ist es erforderlich, über die Bestimmung des § 38 Abs. 1 Z 6 hinaus die Übermittlung von Isolaten durch eine entsprechende Verpflichtung der Labors sicherzustellen').

[408] BGBl. I 67/2014 ('Diese Verpflichtung entfällt, sofern die Isolate bereits auf Veranlassung des Unternehmers gemäß § 38 Abs. 1 Z 6 übermittelt wurden').

[409] Cf RV184, 8 ('wenn das Labors bereits über Veranlassung des Unternehmers die Isolate übermittelt, eine nochmalige anonymisierte Weiterleitung nicht erforderlich').

internal documents conveyed to the local, executing food authorities, which can then provide the FBOs within their jurisdiction with the necessary information for them to comply.

In respect of LMSVG § 38(1)(6) and § 74, there seems to have been issued a total of three decrees, in 2010, 2016, and 2021, each replacing the previous. The first decree specified that mandatory submission of *Lm* isolates applied to samples from food, smear water, brine water, and food contact surfaces.[410] The necessity of requiring submission of these isolates was justified based on the then current epidemiological situation and scientific insights.[411]

More interesting for present purposes is the decree from 2021, which entailed an extension of what isolates need to be submitted (ie, from which sources). The extension encompassed environmental samples from food-related areas (such as drains, floors, protective aprons, door handles, seals);[412] in practice encompassing all isolates found through the FBOs' own food safety control programmes. This expansion was justified first by the importance of environmental samples, as they are 'ein wichtiges Instrument im Rahmen der Guten Hygienepraxis'.[413] For the objective of rapidly solving foodborne outbreaks,[414] it was furthermore concluded that '[d]aher ist die Übermittlung der Isolate von Umfeldproben an das NRL sehr sinnvoll'.[415] The result is an unusually wide obligation to submit compared to other EU/EEA states.

According to the AGES interviewee, the 2021 expansion was prompted by a specific outbreak,[416] eventually traced back to processed meat products. This outbreak lasted from January 2020 to September 2021 and involved five patients. The interviewee stated that:

> 'during the outbreak analyses, we saw that we did not receive some samples which were positive, because they were not in contact with food. […] These isolates would have been very important, because if we knew that, at the time, that *Listeria* was found in this company, a lot of cleaning would have been started much earlier, and some people wouldn't have gotten ill. […] Because of this, the ministry said that it's very important

[410] Erlass (decree) BMG-75360/0055-II/B/13/2010, 3 ('(1) Lebensmitteln, (2) Schmierwasser, (3) Salzbadwasser, (4) den Oberflächen, die mit Lebensmitteln in Berührung kommen').

[411] Ibid, 2.

[412] Erlass (decree) No. 2021-0.771.143, 4 ('Umfeldproben aus den lebensmittelasoziierten Bereichen (wie zum Beispiel Gully, Fußboden, Schutzschürzen, Türgriffe, Dichtungen …').

[413] Ibid, 2.

[414] Ibid, 2: ('Im Rahmen der Abklärungen bei mehreren Listerioseerkrankungen hat sich gezeigt, dass die Isolate von Umfeldproben […], die an das NRL übermittelt wurden, hilfreich waren und zu einer schnellen und effizienten Ausbruchsabklärung beigetragen haben').

[415] Ibid.

[416] AGES: interview 20 July 2022. This is likely at least some part of the experience referred to in the decree when stating that it 'hat sich gezeigt' in Erlass (decree) No. 2021-0.771.143, 2.

> to send all the isolates. Food isolates were detected much, much later, and we could have prevented a lot: cleaning, setting back food from the market, and also the patients'.[417]

In a follow-up e-mail, the interviewee added: 'Environmental and food-associated isolates with the outbreak strain could be traced back to 2017'.[418]

It is difficult to assess industry attitudes to this adjustment, as the expansion was based on a decree that formally did not change the legislative text, and FBOs are thus not given the same opportunities to comment or object. Indeed, they may not even learn about the change until a considerable time after adoption. Regardless, the expansion can contribute to improved monitoring, as *Lm* tends to be found earlier and more easily in, *inter alia*, drains than on direct food contact surfaces. An Austrian FBO head of quality management stated that the clear consequence is that one more efficiently learns about the strains of a certain plant if one takes everything into account: 'The more data you've got, the more you know'.[419]

5.5.4 Anonymity

AGES keeps the data in its database for current and future comparisons. The metadata is not shared with anyone else—eg, a company's name is never mentioned in a research project.[420] The genome sequences and WGS data are themselves are not considered sensitive, and they are considered identifiable only based on knowledge of the internal, confidential metadata.[421] However, AGES knows the identity of the FBO from which an isolate originated.

As touched upon in Section 5.5.2, some confusion can easily arise in seeking to understand when the FBO must be identified or not as the origin of an isolate. LMSVG § 38(1)(6) has never contained a reference to anonymity. The explicit requirement to name the FBO was added later. LMSVG § 74, however, does contain the word 'anonymisiert'. From the wording, one might presume this to entail that the laboratory is not to mention the FBO. This seems, however, not to be in accordance with practice. Both the interviewed FBO and AGES employee have conveyed their experience to be that submission of isolates is not—and cannot be—anonymous. Nevertheless, the reference to anonymity remains in the text of § 74. This is also despite the

[417] AGES: interview 20 July 2022.
[418] AGES: e-mail 22 July 2022.
[419] Austrian FBO: interview 22 June 2022.
[420] AGES: interview 20 July 2022.
[421] Ibid.

fact that the 2016 decree specifying § 74 removed reference to 'anonymisiert' and required simply that 'die Produktgruppe' needs to be mentioned.[422]

The 'Einsendeformular' (which is a form to be completed and submitted along with submitted isolates) confirms the claims of the FBO and AGES.[423] There, the categories for who submits the isolate include FBOs under § 38(1)(6), laboratories on their behalf under the same provision, and submission under § 74 (not on behalf of the FBO). Furthermore, official control is a category. Interestingly, naming a contact person and who submits, as well as the FBO, seems required information to include in the form, also for § 74 submission. Based on the Einsendeformular, the latest decrees, and what is sent and received in practice, submission thus appears not to be anonymous. This prompts the question why 'anonymisiert' is still in the legislative wording, as decrees are presumably meant to stay within the frames of what the legislation prescribes.

An evolution seems to have taken place since the obligations were first introduced. According to the FBO interviewee, 'at the beginning, everything was very anonymous. It was only product samples, and it was very anonymous'.[424] Today, however, 'it's not anonymous'.[425] This appears to have happened through changes in the ministry's specifications and practice. AGES also remarked that the ministry wants to know who sent the isolate.[426] At some point, the ministry is likely to need to identify where the data came from.

It bears reminding that LMSVG § 74 is relevant only if the FBO fails to fulfil its § 38(1)(6) obligation. This may possibly also be the reason for its anonymity requirement: if the laboratory needs to submit under § 74, this indicates that the FBO is neglecting its legal duty, in which case the legislator may have considered receiving the isolate as more important than asking the laboratory to point fingers at their contracting FBO. Such a motivation, however, is not explicitly stated. And, in practice, § 74 submission does not seem to be anonymous anyway.

5.5.5 Further Background to Austria's Approach

The Austrian approach stands out compared to Norway and most states, particularly regarding the extent of samples submitted and the extent to which they are whole genome sequenced. For

[422] Erlass (decree) BMG-75360/0012-II/B/13/2016, 3.

[423] AGES, '*Listeria monocytogenes* Einsendeformular'. Version 'gültig ab 05.11.2019' appears to still be the current version as of late 2023, when this report was finalised.

[424] Austrian FBO: interview 22 June 2022.

[425] Ibid.

[426] AGES: interview 20 July 2022.

properly understanding the implementation and feasibility of this approach, it can be useful to examine aspects of its background in more detail.

A question that springs to mind is why Austria would have such a strong focus on *Listeria monocytogenes*, a focus that it seems to have had already since the 1980s when the realisation first emerged of *Lm* as a foodborne risk. The focus then was centered upon cheese and other dairy products, as the first known *Lm* outbreaks (globally) with identified sources were dairy-related.[427]

Cheese is a much produced and much consumed product in Austria.[428] As many cheeses entail a high risk for *Lm*, this led to a heightened cheese and dairy focus in countries like Austria and Switzerland. According to the AGES interviewee, in their experience, it is mostly meat and cheese products that are involved in outbreaks.[429] Although the initial focus of the Austrian *Lm* monitoring programme (see further below) was on cheese producers, Wagner and Stessl note the increasing participation in the programme also among meat producers.[430] Meat is another food much produced and consumed in Austria.

From 1988, Austria established a voluntary *Lm* monitoring programme for dairies and cheese factories. The programme was launched by the Institute of Food Safety, Food Technology, and Veterinary Public Health in Vienna, Austria.[431]

These early initiatives could be seen as an emerging change in how to consider and approach food safety.[432] Wagner and Stessl point to the superiority of the procedure applied (under the monitoring programme developed)—eg, using drain samples, smear and brine samples, that provide information on a whole batch rather than just a random sample.[433] Indeed, there seems

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[427] A Baumgartner and H Schmid, '*Listeria monocytogenes* in genussfertigen Lebensmitteln: eine Auswertung der amtlichen Untersuchungen in der Schweiz der Jahre 2006-2008' (2013) 8 *Journal für Verbraucherschutz und Lebensmittelsicherheit* 109-117.

[428] Based on data from the survey period 2020/21 (2020 for animal products), Austria has a particularly high level of self-sufficiency for meat (112%) and dairy products, eggs, potatoes, and also cereals. The numbers are lower for vegetables (58%), fruits, and particularly fish (7%)—seeing as Austria has no coastline. See https://info.bml.gv.at/en/topics/food/degree-of-self-sufficiency-with-food.html.

[429] AGES: interview 20 July 2022.

[430] M Wagner and B Stessl, 'Sampling the Food-Processing Environment: Taking Up the Cudgel for Preventive Quality Management in Food Processing (FP)' (2021) in EM Fox and others (eds), *Listeria monocytogenes. Methods and Protocols*, vol 2220, Humana, New York, NY, 233-242.

[431] Ibid.

[432] See also K Koßdorff, 'The new Austrian Food Safety and Consumer Protection Act: "Lebensmittelsicherheits- und Verbraucherschutzgesetz – LMSVG"' (2006) 1(5) *European Food and Feed Law Review* 286.

[433] Wagner and Stessl (n 430) 239.

to have been a special focus on environmental samples in Austria, from well before the 2021 decree expansion.[434] Thus, the 2021 expansion could be seen as reflecting a long-lasting focus that was already deeply entrenched in the Austrian context.

Yet, it also reflects first-hand experience with listeriosis outbreaks, particularly an outbreak in 2009-2010. The outbreak involved Austria, Germany and the Czech Republic, and in total 34 cases were connected to it.[435] Eventually, it was traced back to an Austrian producer of an acid curd cheese (Quargel).[436] At the time, PFGE was routinely applied, which is how the relevant laboratory (the binational Austrian-German Consiliar Laboratory for *Listeria*) first discovered the connection between the human isolates involved.[437] The routine use of PFGE was regarded as crucial for identifying the outbreak. This bolstered general faith in the considerable potential of molecular subtyping (then PFGE) to play a decisive role in Austria's *Lm* control strategy.[438]

There appears to be agreement that the Quargel case was a considerable game changer for the Austrian *Lm* approach. The interviewed Austrian FBO commented that it led to the decision that the NRL should collect all these data to have them in case they would need them.[439] Krejci describes what she refers to as an 'improvement of the legal situation' taking place 'as a consequence of the outbreak': it led to the amendments made in the LMSVG in 2010, as well as the 2010 decree.[440]

While PFGE was used in the Quargel outbreak, WGS and cgMLST (using a scheme referred to as MLST+, encompassing 2 298 genes) were applied in a slightly later outbreak in Austria and Germany which took place from 2011 to 2013.[441] All the isolates tested (apart from a control strain) provided indistinguishable PFGE and fluorescent amplified fragment length polymorphism patterns,[442] while cgMLST was able to clearly separate between German and Austrian cases.[443] In this outbreak, there was never any definitive proof of the causative vehicle, but measures were taken at the main suspect factories, after which no more cases were reported.[444]

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[434] Ibid, 237.

[435] R Fretz and others, 'Listeriosis outbreak caused by acid curd cheese "Quargel", Austria and Germany 2009' (2010) 15(5) *Euro Surveillance* 19477.

[436] Ibid.

[437] Ibid.

[438] Ibid.

[439] Austrian FBO: interview 22 June 2022.

[440] C Krejci: presentation 22 March 2022.

[441] D Schmid and others, 'Whole genome sequencing as a tool to investigate a cluster of seven cases of listeriosis in Austria and Germany, 2011-2013' (2014) 20(5) *Clinical Microbiology and Infection* 431.

[442] Ibid.

[443] Ibid.

[444] Ibid.

5.5.6 Acceptance and Trust

The smooth functioning of mandating submission of isolates from all FBOs relies on their willingness to comply with the mandate. The precise degree and nature of this willingness is challenging to examine without a broader basis of interviews with Austrian FBOs than has been possible as part of the current work, or access to other material reflecting industry opinions. There have not been any easily available sources providing a representative overview of industry attitudes in Austria and how these attitudes have evolved over the last few years. Neither have there been easily available statistics as to how many isolates are submitted under the requirements of LMSVG § 74 rather than § 38(1)(6). Thus, it has been beyond the capacity of the current study to acquire the details that would be desirable to examine industry acceptance. The following account is based primarily on the indications provided by a single FBO, as well as the FSA and NRL.

With these shortcomings in mind, FBOs' acceptance appears to have evolved since the provision was first adopted, and the general impression is that acceptance is currently high. There is, of course, a risk that FBOs, when placed under an obligation to submit all isolates detected, will seek to detect less *Lm*—a risk broached in earlier parts of this report. Again, however, there seems to be little evidence of this risk being realised in Austria: a significant number of industry isolates are submitted there each year, and the current system seems to have contributed to solving several outbreaks.

Despite this, the number of isolates AGES receives indicates that not all *Lm* isolates obtained through the FBOs' own food safety control programme are actually being submitted. AGES receives a total of 1600-2200 *Lm* isolates per year from all sources; most of them are food-associated, and only relatively few of them (approximately 40-60 per year) are clinical.[445] AGES receives isolates from both internal and official controls, although isolates from FBO's internal controls dominate.[446] The AGES interviewee considered the amount that AGES receives to be a lot, although presumed it not to encompass all *Lm* isolates detected.[447] The extent of, and reason(s) for, FBOs' failure to submit *Lm* seem not to have been thoroughly examined.

The Austrian FBO described submitting isolates as part of its obligation to ensure food safety, stating:

[445] AGES: interview 20 July 2022.

[446] Ibid.

[447] Ibid.

> 'At the beginning, I would clearly say that there was a high reluctance in [finding *Lm* and then having to submit it]. […] When that was introduced, there was a lot of discussion of "Is this necessary?", "It needs to be anonymous", and "why?", and "what is done with the results", etc. There was high reluctance in doing so, because there was fear that this data is misused to some extent, and possibly used not in the way it is supposed to be, etc., etc. – because, as you say, you open yourself'.[448]

This parallels the concerns raised by Norwegian FBOs to increasing use of WGS in Norway. The Austrian FBO concluded that, after some time with the current Austrian approach:

> '[j]ust from a gut feeling, I would guess that there is [currently] more the understanding of the fact that the public health aspect *can only be tackled if the data is available*, and the data *can only be collected on a routine basis* with certain *rules that are valid for everybody*, to be able in the case of a foodborne outbreak *to quickly track down the root cause*'.[449]

The importance of FBO acceptance has attracted attention since the beginning. Upon adoption of the LMSVG, Koßdorff raised the concern that it might take time to achieve more full and functioning cooperation in Austria as set out under the (then) new framework:

> 'In Austria, the relationship between industry and authority can generally be described as good and constructive. Several cases do exist where active information and cooperation already has helped to solve problems before a crisis or emergency occurs. Still, the new approach requires a "new spirit". This means that the roles of the parties concerned need to be actively shifted towards the type of partnership which is necessary to implement effective emergency or crisis management procedures. The FSCPA [=LMSVG] provides an appropriate basis for getting this new concept started'.[450]

In other words, the LMSVG—in accordance with the then new EU approach—is built on a necessary presupposition of active and functioning cooperation and understanding between the industry and authorities. LMSVG §§ 38(1)(6) and 74 are examples of obligations for which a constructive, cooperative relationship between the authorities, AGES and FBOs is decisive for their functioning.

[448] Austrian FBO: interview 22 June 2022.

[449] Ibid; emphasis added.

[450] Koßdorff (n 432) 289.

As remarked by the Austrian interviewees, and in accordance with the above-mentioned need foreseen by Koßdorff, there appears to have been a development in FBO attitudes towards these requirements. In parallel with this development, the duty to submit has become increasingly more extensive: from an obligation to submit a narrower category of samples and (at least in certain situations) to do so anonymously, to the obligation being expanded to involve all detected *Lm* isolates and never (at least apparently not in practice) anonymously. Continuous expansion reflects needs perceived by the authorities, but it may also indicate decreasing scepticism from the industry.

The lesson and effect from the Quargel case seem to have been an FBO expectation that the root cause will anyway eventually be found, combined with the deterring example of the potentially devastating effects for the FBO if the situation has then already gone too far.[451] The Quargel outbreak is recurringly pointed to as a game changer for Austria: 'It was a game changer for both sides',[452] FBOs and authorities. Particularly for FBOs, the Quargel outbreak appears to have highlighted the advantage of early detection rather than finding out later.

As for the situation today, the Austrian FBO expressed the perception that there is a high level of trust on both sides:

> 'of course, both sides have their interests, but what I guess is characteristic for the Austrian approach, is that *we try to understand the constraints and the interests of the other side, and how to come to a win-win situation*.'[453]

The FBO remarked also the benefit that it 'can be advantageous for a food business operator having the whole genome sequencing data, because it's also very quickly approved that you're not involved at all' if the strains do not match.[454] The FBO regarded, in sum, the Austrian approach to be currently advantageous and well-functioning: 'There's definitely a huge benefit, […] and once you have that obligation, I mean, there is no reason not to work with the state, I would guess'.[455]

The AGES interviewee also considered that the current level of acceptance of the system and obligations is quite good, due to the FBOs seeing their benefits, especially that the current approach enables earlier detection that can (compared to the Quargel case) prevent companies

[451] Austrian FBO: interview 22 June 2022.
[452] Ibid.
[453] Ibid; emphasis added.
[454] Ibid.
[455] Ibid.

from having to close down, and instead allow for them to start producing again after a necessary break of targeted hygiene and cleaning measures.[456]

5.5.7 Advantages and Challenges

The above attitudes rest upon some fairly obvious advantages of the Austrian approach. The main advantage is the ability to perform very quick analyses in the case of an outbreak. Since AGES routinely compares food industry isolates with human isolates and already has a considerable number of genome sequences in its database, the sequence of a specific strain found in a clinical patient sample can rapidly be compared to sequences of *Lm* originating from food and food production facilities found in the database.

Another benefit, particularly from an FBO perspective, is that FBOs do not pay for the analytical service of WGS.[457] FBOs get access to WGS data of *Lm* from their own facilities for a minimum of costs. In Norway, if an FBO wishes that *Lm* isolates collected through its food safety control programme undergo WGS, it would have to pay for this itself. As already pointed out, the costs are relatively high, functioning as a barrier for extensive industry uptake. Thus, the Austrian approach provides the FBOs with increased opportunities for more extensive WGS data to apply as part of their *Lm* risk management programmes.

Nonetheless, the financial costs of WGS, particularly when performed at the Austrian scale, present challenges. AGES has prioritised WGS, which is currently the only method it applies for *Lm*.[458] This requires financial prioritisation. AGES has so far managed to raise sufficient funding for this, apparently partly from the Ministry of Health. Also, it expressed a hope that WGS would get cheaper, particularly by implementation of sequencing machines with higher capacity and centralising the sequencing to one location.[459]

From AGES' side, no other challenges (apart from the costs) were expressed with the Austrian approach. The AGES interviewee could also not think of any challenges arising from the fact that while Austria takes this approach, most other states do not. However, the FBO interviewee did see this disparity as a challenge at the international level:

> 'I think the legal challenge would be actually to have the other European countries to get to the level where we are. Because, for example, for [our FBO] – if [our FBO] takes

[456] AGES: interview 20 July 2022.
[457] Austrian FBO: interview 22 June 2022.
[458] AGES: interview 20 July 2022.
[459] Ibid.

> the decision to increase the sampling plan for *Listeria* in the different sites, then it's imminent that the more you look, the more you find; that I will have to send in the strains I find, and there is no way to avoid this'.[460]

In other states, the FBOs would also usually have to perform the WGS themselves (or have a service lab do it for them).

> 'By using the whole genome sequencing data through the lab and AGES, I am now in a situation where I have more information and more data, and I can initiate a certain improvement circle on a different level than other sites. But at the same time, the other sites [in other countries] don't have to send in this. They also improved their system; maybe sometimes it would help, maybe sometimes it's not necessary'.[461]

Beyond this, a slight weakness with the Austrian system as it currently appears to function seems a lack of prompt and clear information between the authorities and FBOs on the legal details adopted in decrees.[462] Information is evidently conveyed by industry organisations or local food authorities to the FBOs they prioritise, in a manner creating a risk that not everyone is well updated on their current duties.[463] As knowing one's obligations is a precondition for complying with them, this could contribute to fewer submitted isolates.

5.6 Feasibility of the Austrian Approach in Norway

5.6.1 General Considerations

As pointed out above, in Austria, all *Lm* isolates collected through the FBOs' internal food safety control programmes are subjected to WGS. There is mandatory submission of all isolates to AGES. Although Austria is working to lower the costs of WGS by centralising it, the costs are considerable. The feasibility of this approach in Norway is far from assured. In Norway, FBOs are currently not even required to notify authorities about detection of *Lm* in environmental samples. Weighing the costs against the need and benefits for MT to initiate WGS—at least at any extensive scale—points to a low likelihood of similar priorities being made in Norway. Human isolates in Norway are already being routinely sequenced by FHI. Sequencing of relevant isolates originating from food and food processing environments is also standard procedure for purposes of outbreak investigations. *Routine* sampling of *all* industry isolates, however, appears neither desired nor a priority on which to spend resources. Thus, there would

[460] Austrian FBO: interview 22 June 2022.
[461] Ibid.
[462] Ibid.
[463] Ibid.

likely not be the political will for adopting an approach in Norway like the Austrian one. Norway also does not have the same background as Austria with a long-lasting focus on, and prioritisation of, such a strategy for controlling *Lm*.

To Norwegian FBOs, the idea of submitting all *Lm* isolates, including even isolates from the processing environment, appears strange, as they are accustomed to not even notifying MT upon such detections. Leaping to an approach like the Austrian one would likely be seen as drastic and a case of 'overkill'. Some of the concerns expressed by Norwegian FBOs regarding increased data collection from the authorities, have involved worries about inadequate equality and fairness in the data. At the same time, they have expressed that submission at the scale performed in Austria is unrealistically extensive. This view could be countered by suggesting that the fact that the Austrian approach is so extensive and involves all *Lm*, would make it more acceptable as a way to foster increased equality and fairness.

If the requirements to submit are perceived as excessive, and the FBOs do not feel reassured about the use of the data, there is a risk that they seek to avoid detecting the bacterium so as to not having to submit it. The Austrian FBO interviewed stated that 'if you look more, you find more, and then you send in more, and that's the other side of the coin'.[464] Those who submit more, may not necessarily have more *Lm* in their facilities, just because they detect more. FBOs who sample actively and extensively, have a higher likelihood to end up with many *Lm* strains in AGES' database. A risk then is a skewed picture in the data AGES receives, since some will submit more than others. Another risk is the effect this bias may have on the FBOs' attitudes towards seeking to detect *Lm* in their factories, and—as a consequence—towards gaining maximum information about that *Lm*.

At the same time, it should be noted that, under the Austrian system, an FBO that does not send in *Lm* might stand out as suspicious for this reason and thereby become the subject of inquiries. As AGES has control of which samples originated from each company, the AGES interviewee indicated that if a company does not send in isolates, this would be considered an indication that it is not fulfilling its obligation to submit.[465]

Nevertheless, it seems possible that some FBOs would worry about submitting too much *Lm*, or about what the authorities will then learn about their *Lm* and thereby about their facilities and processes. This may influence the acceptance of mandatory submission and the degree to which it should be anonymous.

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[464] Ibid.

[465] AGES: interview 20 July 2022.

A considerable difference between Austria and most other states—including Norway—is that Austria has a common NRL for both human and food/environmental *Lm*. The authorities and laboratories are gathered under one roof, rather than strictly separated by sectors. This allows closer cooperation and comparisons, in the spirit of One Health, to ensure an efficient and holistic consideration of *Lm* from human, food and environmental sources. In Norway, however, the interviewee from one of the NRLs (VI) did not agree with the desirability of such a solution and raised instead advantages of keeping separate the different reference laboratories' responsibilities for their different sectors (see Section 5.6.2).[466]

It is interesting to consider the current FBO concerns in Norway against the situation in Austria. FBO concerns in Austria seem to have slowly decreased over time, which triggers the question of whether such worries might also be overcome in Norway, hereunder what would be required from the Norwegian approach for a similar development to take place. It appears relevant, again, to point to the importance of factors like trust in appropriate and competent handling of the data, and the realisation of all stakeholders of their common interests in food safety and early detection.

5.6.2 The Norwegian MSIS Regulation: An Instrument for Expanded Submission Requirements?

A particularly interesting provision to consider in light of the above-described Austrian practices is § 2-4a in Norway's MSIS regulation (MSIS-forskriften).[467] The regulation has its main basis in Norway's Act pertaining to control of communicable diseases (smittevernloven)[468] and its principal remit is to lay down procedures for ongoing and systematic collection, analysis and reporting of data on the occurrence of such diseases.[469] As elaborated in the following, § 2-4a of the regulation could be applied so as to radically expand the current obligations for laboratories in Norway to submit *Lm* isolates to NRLs for testing.

The provision applies to a variety of pathogens (including *Lm*). It lays out four categories of obligations for laboratories to submit these pathogens to NRLs, with each category dealt with by separate sub-paragraphs in § 2-4a. While human pathogens are subject to the first and second sub-paragraphs, the third and fourth sub-paragraphs are relevant for the purposes of this report. The third sub-paragraph concerns samples from foodstuffs. It lays down an absolute obligation

[466] Taran Skjerdal, VI: interview 5 October 2022.

[467] Full title set out in n 56.

[468] Lov 1994-8-5-55 om vern mot smittsomme sykdommer.

[469] MSIS-forskriften § 1-3 ('MSIS skal bidra til overvåkningen av smittsomme sykdommer hos mennesker i Norge gjennom fortløpende og systematisk innsamling, analyse, tolkning og rapportering av opplysninger om forekomst av smittsomme sykdommer').

for microbiological laboratories to send pathogens they discover to the relevant NRL for foodstuffs, pursuant to specifications made by MT.[470] As pointed out earlier in the report, the relevant NRL for *Lm* found in food or feed is either VI or HI. The fourth sub-paragraph pertains to pathogens from 'other sources' ('andre kilder'). It lays down an obligation on microbiological laboratories to send such pathogens they discover to the national clinical and public health microbiology reference laboratory, which is housed at FHI.[471]

The materials that are subject to both these submission obligations encompass 'smittestoff' and 'prøvemateriale', ie, the pathogen and isolated *Lm* strains. WGS data on such pathogens are not encompassed. Moreover, the provisions refer to pathogens that 'can cause' ('kan gi') illness in humans. Thus, the obligations are not contingent on anyone actually (or being suspected of) falling ill.

An interesting question is to consider the boundary between the categories of the third sub-paragraph on the one hand and those of the fourth sub-paragraph on the other hand, particularly as there are different recipients involved. However, before delving into this question, it bears emphasis that the third sub-paragraph appears currently dormant. In practice, the provisions applied for FSA access to material or data are those of matloven, as discussed in Section 5.3 of this chapter. However, those provisions contain somewhat different possibilities for the authorities to collect data, than MSIS-forskriften § 2-4a. On its face, the latter provides an opportunity for much more comprehensive routine collection of isolates, with the potentials that entails for, eg, monitoring and tracing of *Lm* outbreaks. In this regard, it bears emphasis that § 2-4a does not contain the word 'necessary' or any equivalent qualifier (as described in Section 5.3.1, for administrative discretion); it uses the word 'shall' ('skal').

Unlike the case for matloven, which places obligations primarily on FBOs, the obligation in MSIS-forskriften § 2-4a is placed on laboratories. The latter comprise any laboratory, public or private, including in-house, research laboratories, reference laboratories, and private laboratories engaged by FBOs. However, the provision only applies in Norway, so if an FBO uses a

[470] The third sub-paragraph states: 'Mikrobiologiske laboratorier som i prøver av fôrvarer, dyr, kosmetikk eller næringsmidler, herunder drikkevann, påviser smittestoff som kan gi sykdom hos mennesker, skal sende slikt smittestoff til relevant referanselaboratorium på matområdet etter Mattilsynets nærmere angivelser. Mattilsynet kan ved mistanke om sykdomsutbrudd i befolkningen eller dersom det er nødvendig av hensyn til smitteoppsporing, angi at laboratoriet også skal sende slikt smittestoff direkte til relevant laboratorium med nasjonal referansefunksjon i medisinsk mikrobiologi'.

[471] The fourth sub-paragraph states: 'Mikrobiologiske laboratorier som i andre kilder enn prøver av human opprinnelse, fôrvarer, dyr, kosmetikk eller næringsmidler, herunder drikkevann, påviser smittestoff som kan gi sykdom hos mennesker, skal sende slikt smittestoff til relevant laboratorium med nasjonal referansefunksjon i medisinsk mikrobiologi etter dets nærmere angivelser.'

laboratory in, eg, Germany, the obligations (towards Norwegian authorities) must fall on the FBO pursuant to matloven.

Looking more closely at the third and fourth sub-paragraphs, the logic and mechanics of their interrelationship are not entirely clear; nor are they arguably entirely cogent. For example, a strict reading of the reference to 'foodstuffs' ('næringsmidler') in the third sub-paragraph would be that *Lm* from processing environments is not encompassed under the third sub-paragraph. Such *Lm* would then be left to the fourth sub-paragraph, covering 'other sources', for which the recipient is the reference laboratory at FHI. Such an interpretation may entail a rather strange distinction in how to treat samples from foodstuffs versus from food production facilities, even though the wording indicates this to be the case.

Another issue concerns when an obligation to submit arises under each sub-paragraph: does it arise only when MT (in the case of the third sub-paragraph) or the reference laboratory at FHI (in the case of the fourth sub-paragraph) has issued 'specifications' ('nærmere angivelser'), or does it arise by default? The provision has been referred to as an obligation to submit ('innsendingsplikt'),[472] which could be read as suggesting that the default ought to be submission regardless of specifications. Yet, considering that this obligation appears so far not carried out in practice, at least for *Lm*, it seems more in accordance with the understanding of the actors involved if submission becomes an obligation only when more defined specifications are made. This understanding appears also to be embraced in a circular memorandum ('rundskriv') from the Ministry of Health.[473]

Regardless, the third sub-paragraph contains on its face—and in the broadest possible application—the opportunity for MT to decide that all isolates from *Lm* positive samples from foodstuff are to be sent to the relevant NRL for food, while the fourth sub-paragraph provides for FHI to decide that all other non-human positives are to be sent to them. This entails a potential for relatively vast requirements for laboratories to submit material. Submission can be specified as a routine obligation applying for all *Lm* positive samples, should the authorities desire to do so. And this potential may be realised without further legislative processes.

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[472] Consultation letter from the Norwegian Ministry of Health and Care Services (Helse- og omsorgsdepartementet; HOD): 'Høringsnotat. Forslag til endringer i MSIS- og Tuberkuloseregisterforskriften', 30 November 2011, 18.

[473] Rundskriv from the Norwegian Ministry of Health and Care Services (Helse- og omsorgsdepartementet - HOD) I-2013-5 (replacing I-2005-14) of 26 September 2013, 2.5 (specifying (for submission from other sources) that the national clinical and public health microbiology reference laboratory 'skal *gi nærmere angivelse for innsendingen av smittestoff* eller prøvematerialer, *og* fastsette *rutiner for den praktiske innsendingsmåten*'; emphasis added).

The question then is whether this is desirable in the Norwegian context. There have been no indications that the NRLs for food actually want, or have the resources, to receive and analyse all *Lm* isolates from FBOs' internal *Lm* management programmes. Yet, the above-mentioned circular memorandum emphasises the importance of a holistic monitoring of communicable diseases at a national level, with systematic collection of data and a sufficient amount of sample material for analyses.[474] This is in accordance with how collection is carried out for human *Lm* isolates in Norway (including all human *Lm*), although not for *Lm* detected in foodstuffs or production facilities. The circular memorandum describes it as decisive that the clinical and public health microbiology reference laboratory at FHI can link pathogens detected in patients to pathogens in possible sources of infection.[475] That is essentially what the Austrian approach is considered to ensure, encompassing all *Lm* from humans, food and environment.

A significant difference between these countries (as already discussed in Section 5.6.1) is that, in Norway, there are separate reference laboratories for *Lm* from human and food origins, whereas Austria has a common NRL for all *Lm* regardless of its origin. Were Norway to ramp up its submission obligations yet also keep its current division of reference laboratory competences, it would need to rely on extensive data sharing between the two sectors. While isolates from, *inter alia*, food and animals can be shared directly with FHI when an outbreak is suspected or when it is necessary for outbreak investigations,[476] there would be a need for a special agreement that such isolates be shared in other situations. Whether increased sharing would be considered desirable among the stakeholders is not given. Furthermore, it would require a significant re-prioritisation of resources to make it functional at a scale even close to the Austrian approach.

Regards the desirability of routine sharing between sectors, or, alternatively, of keeping food and human reference laboratories separate, the interviewee from VI pointed out that under the current organisation in Norway, NRLs for food take care of their dedicated areas of responsibility, while FHI takes care of its, and that this ensures that the interests of each sector are looked after by specialised expertise dedicated to their respective fields.[477] The interviewee stated that the different reference laboratories may both focus on different data and metadata, and need to consider different aspects in dealing with the data. The separation of roles and responsibilities is thus an advantage, as it fosters the various actors' ability to best safeguard

[474] Ibid, 2.4.

[475] Ibid, 2.5.

[476] Third sub-paragraph of MSIS-forskriften §2-4a.

[477] Taran Skjerdal, VI: interview 5 October 2022.

the interests they are tasked to protect.[478] They also report to different government directorates, which impacts what data can be shared between sectors.

The importance of not sharing more data than necessary was raised, and according to the VI interviewee, this is easier to manage with sector specific databases than a common database for multiple sectors.[479] As always, what renders a bacterial genome sequence as potentially sensitive data is the existence of the associated metadata describing the source of the isolate.

In sum, although MSIS-forskriften §2-4a caters for data collection that could allow for more extensive analyses, comparisons, and monitoring of *Lm* in the food industry, such scaling up does not seem likely anytime soon. In Norway, there is not the same prioritisation of resources to perform WGS on such a massive scale as there is in Austria. Add to this that Norwegian FBOs traditionally have not even notified MT or NRLs about *Lm* findings in their processing environments or in products not sent to the market. An obligation for their laboratories to submit all, or even some, of the *Lm* isolates they detect on a routine basis, is thus a 'bridge too far', at least for now and the near future.

[478] Ibid.

[479] Ibid.

6 Food Business Operators' Access to WGS Data Held by Regulatory Authorities

6.1 Introduction

When NRLs hold isolates or sequences of *Lm* from FBOs as part of (or based on samples from) official controls or other official activities, the FBOs may wish access to these, particularly the WGS data. They may, for example, want to use it to inform their own internal food safety management programmes, or to verify the data as analysed and used by the FSA and NRLs.

Currently, Norwegian authorities appear to apply WGS primarily for tracing outbreaks. It might also be considered useful for surveillance programmes. Isolates from samples from official controls, gathered to verify compliance, are not sequenced for the purposes of the control.[480] However, isolates may be stored and sequenced at a later date, most likely as part of outbreak investigations. The NRL concerned may also ask MT for permission to sequence, eg, to gain more knowledge about the bacteria—a request that MT apparently would normally accept.[481]

This chapter explores rights to WGS data from isolates originating in FBOs' facilities, subjected to sequencing as part of official activities. It examines the extent to which FBOs may gain access to such data in various situations and for various purposes. If access to WGS data is not granted, FBOs could in certain situations be interested in accessing the isolates on which authorities have had WGS performed, and subsequently arrange for their re-sequencing to obtain the equivalent WGS data. With this in mind, this chapter also examines the extent to which FBOs may gain access to isolates originating in their facilities, held by the FSA and NRLs.

In addition to considering the position of FBOs in Norway, this chapter draws on equivalent experiences in two other states—Austria and Denmark—as points of comparison and inspiration. Industry opinions are also presented, based on interviews with multiple Norwegian FBOs.

6.2 Interests Involved

The fact that the *Lm* under discussion originates from an FBO's facilities, provides both a strong link and clear interest for that FBO in attaining access. At the same time, FSAs and NRLs that took the initiative to perform WGS and financed it also have an interest in the data. In particular, who paid for the sequencing and what conditions are linked to that assignment, can be crucial

[480] MT: e-mail 10 May 2023. Cf also n 371 regarding matloven and NOU 1996:10.

[481] MT: e-mail 29 April 2021.

for the rights involved. The purpose for which sampling and WGS was performed is also relevant.

It bears reminder that FBOs are not obliged to use WGS data to fulfil their obligations. The basic requirement is, when an FBO detects or learns of *Lm* in its food or facilities, that it takes appropriate measures to prevent the products from representing risks to consumers (eg, withdrawal/recall, investigating other foods it produces, hygiene measures, etc).[482] Monitoring of *Lm* in processing environments is currently performed using qualitative sample analyses indicating whether *Lm* is detected or not. Furthermore, the current framework providing acceptable thresholds of *Lm* detected in foods does not distinguish between various subtypes of *Lm*. Qualitative and quantitative analyses are thus adequate to comply with requirements on *Lm* levels in food products. They are therefore also adequate for FSAs to verify compliance.

An FBO may nevertheless wish to apply WGS to support and inform its food safety management programme. In this context, it may wish to gain access to any WGS data or isolates relating to their business, held by the authorities.

Access to sequence data will likely be more useful to some FBOs than others, depending, ia, on their size, number of production sites, types of food, scale of export, and their *Lm* regime. For example, sequence data is likely to be more useful to large FBOs (eg, companies with multiple factories that send foods and raw materials between them, which may make use of more extensive comparisons of isolates within their organisations). For a small business, at least under the current state of the art, the costs of utilising WGS data may be harder to justify compared to the expected utility and other benefits.

For the purpose of verifying authority assessments of its food and food production process, access to WGS data can be equally relevant for any FBO. In this context, there is a strong need for transparency, also beyond access to the actual WGS data. For example, one FBO interviewee who was involved in an outbreak investigation where WGS was applied, was asked whether it felt it had received the information desired and needed regarding WGS as a basis for MT assessments relating to their business. The reply was a clear 'no'.[483] The reasons for this specific answer may be complex and case specific. Nevertheless, it is noteworthy that the FBO was left with the perception of the FSA as not properly communicating and ensuring transparency on how the WGS data was assessed, and thus had not obtained an adequate understanding of the reasons for the authority's decisions. Such experiences will affect the FBO's perceived legal security and is not likely to improve its willingness to cooperate with the FSA. This points

[482] See eg matloven § 6(3).

[483] Interview with the FBO 19 December 2022.

to the importance of FSAs addressing how to approach FBOs in ways that foster trust and co-operation. Facilitating ready access to material in their hands, also WGS data, can play a part here. Ensuring explanations on how it is used in authority assessments, would also contribute.

Considering that FBOs may always have an interest in access to WGS data concerning *Lm* from their own food processing plants, an obvious question is whether there are any reasons why FBOs should not get access to this data. As for the NRL and FSA perspective, whether there is any interest in minimising the sharing of this data, is less clear. As a starting point, data sharing brings advantages through strengthening the FBOs' food safety control programmes, to the gain of all parties. There should furthermore be a strong interest from the side of the FSA in sharing for the purpose of ensuring transparency and engendering trust.[484] At the same time, there may be sensitivities in the data that create challenges. For instance, if an FBO receives a copy of a *Lm* sequence while also knowing that this is a close match to a clinical isolate from a patient, it could be necessary to consider potential conflicts with rules protecting personal (health) data. Furthermore, if the sequencing is financed and performed by the NRL beyond what the FSA assigns it to do, the NRL would likely wish to use the data for research. This raises the question of whether such research interests could motivate (and even justify) reluctance to sharing the sequence data with FBOs. Furthermore, there might be challenges relating to sharing of information during an ongoing outbreak, eg, if there is a risk that sharing negatively influences the investigations.

Sensitivity of the data is likely the strongest argument to potentially withhold *Lm* originating from food and food production from FBOs. WGS data contains detailed genetic information about a bacterium. In some cases, there is a potential that it indirectly reveals trade secrets or other information sensitive to an FBO's business. This could be, for example, proprietary information or details about production processes. When this is the case, caution should be exercised in providing direct access to the sequence data. This consideration, however, is not applicable if the FBO requesting the data is the same as the FBO from which the *Lm* originated, and no other FBOs' data are implicated by the request (eg, comparative analyses).

Providing the FBO with access to such WGS data can offer an opportunity for it to conduct its own analyses or consult with experts to gain a deeper understanding of the genetic characteristics of *Lm* from its own facilities. This can generate knowledge useful for *Lm* risk assessment and mitigation.

[484] See OCR (n 340) Art 11(1) which makes a 'high level of transparency' an explicit aim for the performance of official controls.

Access can furthermore, as already mentioned, support transparency and collaboration. To this should be added that Norwegian authorities generally operate under an ideal of transparency and providing access to information. This is evident from the Norwegian Freedom of Information Act ('offentleglova') which grants individuals and organisations rights to access to documents held by public sector agencies.[485] The access rights are wide and considered a crucial building block of democracy. Several exemptions allow the authorities to withhold or redact information considered confidential, commercially sensitive, or protected by data privacy laws. Nonetheless, the main rule in administrative law is access to government-held data.

The following sections are based primarily on interviews and written correspondence with the Norwegian FSA (MT) and the NRLs VI and HI during 2021-2023, with a view to gauging current practice and perceptions of rights and obligations.

6.3 The Norwegian Food Safety Authority (MT)

According to MT, WGS is performed primarily when there is an outbreak, to find the source.[486] It may also be applied in surveillance programmes.[487] MT commented that WGS can also provide information about the pathogenicity of *Lm* if the *Lm* detected is 'similar' to bacteria that have caused disease.[488] Sequencing of bacterial isolates, if performed in the context of official activities, is usually performed by the NRLs.

Samples gathered from FBOs by, or on behalf of, MT as part of official activities, are collected based on MT's authority as FSA.[489] MT considers samples it collects from FBOs to be its property, including analyses it orders and findings made from those analyses (eg, isolates).[490] MT has authority to use the material within applicable law and as necessary for the purposes of its activities.

The relationship between MT and each of the two NRLs is regulated in cooperation agreements.[491] Chapters 7 in these agreements contain provisions on rights to ownership and use, of

[485] Lov 2006-5-19-16 om rett til innsyn i dokument i offentleg verksemd.

[486] MT: e-mail 19 February 2021.

[487] Ibid.

[488] Ibid.

[489] See eg matloven §§ 13, 14.

[490] MT: e-mail 29 April 2021.

[491] VI and MT, 'Samarbeidsavtale om kunnskapsstøtte mellom Veterinærinstituttet og Mattilsynet' (22 September 2022); HI and MT, 'Samarbeidsavtale om kunnskapsstøtte mellom Havforskningsinstituttet og Mattilsynet' (27 May 2021).

sample material provided by MT and data generated by the NRLs.[492] The cooperation agreements are not identical. The agreement between MT and VI clearly states that MT owns data and analyses that VI performs on behalf of MT.[493] MT's agreement with HI makes the same statement for sample material,[494] but must likely be considered to apply also for analyses of such material that MT finance.[495] Both VI and HI have the right to use results from analyses performed for MT for research purposes, provided that the results are anonymised.[496]

In the case of HI, ownership rights to the physical sample material are transferred to HI after the final report on the work financed by MT is delivered,[497] after which decisions on further use of the material appear to be left to HI's discretion. VI is instead provided a right to 'use' sample material from MT, but no ownership rights.[498] In both cases, the rights to further use of the sample material are dependent on MT not having objected in writing.

The cooperation agreement between MT and VI furthermore explicitly provides the original owner of the sample material—eg, an FBO—a right to object to the use of the sample material for other purposes than those for which the sample was originally collected.[499] If VI wishes to perform WGS on a sample collected by MT from an FBO in an official activity context for, eg, research purposes, that constitutes a different purpose than the one for which it was collected. It is not clear how an FBO is currently provided such an opportunity to object to the further use of such samples, including whether they are actively informed of this right, whether it should be in writing, etc.

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[492] Ibid, Chapter 7.

[493] VI and MT (ibid) 5 ('Mattilsynet har eierskap til data og analyser som Veterinærinstituttet gjør på Mattilsynets vegne').

[494] HI and MT (n 491) 5 ('Når Mattilsynet har betalt Havforskningsinstituttet for å utføre en analyse, er Mattilsynet eier av prøvematerialet frem til sluttrapporten er levert').

[495] MT: e-mail 29 April 2021.

[496] VI and MT (n 491) 5 ('Veterinærinstituttet kan benytte anonymiserte data og prøvemateriale som har kommet inn via aktivitet regulert av denne avtalen for formål knyttet til vitenskapelig eller historisk forskning eller for statistiske formål, og offentliggjøre resultater derfra'); HI and MT (n 491) 4-5 ('Analyseresultatene kan brukes (anonymisert) i forskningsvirksomhet.'; 'Havforskningsinstituttet kan benytte anonymiserte data og prøvemateriale som har kommet inn via aktivitet regulert av denne avtalen i sin forskningsvirksomhet og offentliggjøre resultater derfra').

[497] HI and MT (n 491) 5 ('Da overtar Havforskningsinstituttet eierskap til de fysiske prøvene, såframt ikke skriftlig reservasjon er gitt, og hvis prøvene har en forskningsmessig verdi å langtidslagre').

[498] VI and MT (n 491) 5 ('Veterinærinstituttet [har] bruksrett til innsendt prøvemateriale dersom ikke Mattilsynet skriftlig har reservert seg mot slik bruk').

[499] VI and MT (n 491) 5 ('Dersom en prøve skal benyttes av Veterinærinstituttet til noe annet enn det den er innhentet for, vil dyre- eller virksomhetseier få mulighet til å reservere seg mot slik bruk. Dersom slik reservasjon er gitt, kan Veterinærinstituttet ikke benytte prøven til andre formål enn den er prøvetatt for').

In MT's view, those who finance the analyses, own the isolates and analysis data.[500] When analyses are performed to isolate *Lm*, those who paid for the analyses have rights to use the isolates. Although MT usually does not order WGS analyses, WGS may nevertheless be performed on isolates originating from official activities. If, for instance, an NRL (VI or HI) takes the initiative to perform WGS on isolates from a surveillance programme, MT would likely permit this, but the WGS would then not be requested nor financed by MT.[501] Ownership of and access to WGS data concerning isolates owned by MT is in this case less straight forward.

One example involving WGS and further use of isolates from samples collected by MT as part of official controls concerns 22 *Lm* isolates found during a 2021 official control campaign in salmonid slaughter facilities ('tilsynskampanje').[502] After performing qualitative and quantitative *Lm* analyses of the samples collected during the campaign on behalf of MT,[503] the NRL (HI) took the initiative to perform WGS on the collected isolates. They did this for research purposes.[504] This constitutes a use of the samples other than for the purpose for which MT had them collected. HI is allowed such further use provided that MT agrees; the data should then be anonymised and their use should be for research purposes.[505]

One may ask whether the FBOs could have objected to HI's further use of the material and if so, whether they were told that they could. This right applies for such use by VI but is not explicit in the cooperation agreement between MT and HI and thus may not apply for analyses performed by HI. Interviews with several FBOs which were controlled by MT as part of the campaign did not indicate that any explicit opportunity was provided for them to object.

In situations where FBOs are provided the opportunity to object and consider whether to do so, this might serve as an opportunity for them to improve their access to data on *Lm* from their facilities, for instance, by allowing further use (ie, not object) under a precondition of access to the resulting WGS data. Regardless, consideration should also be made as to whether FBO objection is the desired mechanism for this at all.

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[500] MT: e-mail 10 May 2023.

[501] MT: e-mail 29 April 2021. Note that MT's limited financial resources necessitate that it cannot always prioritise WGS. Although individual assessments are made for each surveillance programme, on MT's part, product sampling and analysis for presence of pathogens would usually be prioritised rather than WGS. It therefore appears likely that WGS initiatives beyond the most necessary would be taken by other actors, such as the NRLs. Cf also n 371 regarding matloven and NOU 1996:10.

[502] MT, 'Listeriatiltak i lakseslakteri. Sluttrapport etter tilsynskampanje 2021' (30 November 2021). For an English version, see CS Svanevik and others, '*Listeria monocytogenes* in salmonid slaughter facilities — Screening program for the Norwegian Food Safety Authority' (2021) *Rapport fra havforskningen* 2021-45.

[503] Ibid.

[504] HI: meeting 15 February 2022.

[505] HI and MT (n 491) 4-5.

Turning to the question of FBOs' access to results: MT's guidelines entitled 'Prøvetaking i Mattilsynet',[506] written for the performance of official controls, provide that results from sample analyses performed as part of official controls are to constitute part of the subsequently prepared official inspection report. If no report is made, MT is to provide—as far as possible—the FBO with access to the 'test results.' This is in accordance with the EU Official Controls Regulation (OCR) Article 13(2). Note, however, that this guidance and OCR Article 13 are restricted to official controls; they do not extend to other official activities such as outbreak investigations or surveillance programmes. The obligation to provide information is thus related to the aims of the control, ie, results that verify compliance.[507] For *Lm*, 'test results' in the MT guidelines would refer to qualitative and/or quantitative analyses. Sequencing and further analyses are not mentioned explicitly and likely not encompassed. MT does not require WGS analyses to be performed in connection with sampling for *Lm* during official controls,[508] and WGS does not verify compliance. Seeing also as WGS involves a significantly higher level of complexity and detail, the same access to results can likely not be presumed.

According to MT, there is currently no requirement that the laboratory needs to provide documentation beyond the relevant analysis results, which, if part of an official control based on microbiological criteria (MCR), is restricted to data obtained using the methods specifically listed in the regulation (or alternative, equivalent methods).[509] MT refers to processed material ('bearbeidet materiale'), such as bacterial isolates, as material that as a main rule is not shared (eg, with the FBO).[510] Thus, MT will normally not share isolates or their genome sequences with FBOs.[511]

MT appears to be of the opinion that FBOs do not have a right to data from samples from other official activities than official controls.[512] Both the guidelines mentioned above and OCR Article 35 are restricted to official controls. Food law does not contain provisions that explicitly provide FBOs a right to analysis data from other official activities.[513] Still, at least to the extent

[506] MT, 'Prøvetaking i Mattilsynet' (5th edn, last amended 16 December 2021), 3 ('Resultater fra tilsynsprøver skal registreres i MATS[] som del av tilhørende saksbehandling / tilsynsrapport. Dersom tilsynsrapport ikke utarbeides, skal virksomheten så langt det er mulig, få tilgang til prøveresultatene av Mattilsynet').

[507] OCR Art 13(2)(2); see also OCR Art 13(1)(c). On official controls vs. other official activities, see Section 6.8.1.

[508] MT: e-mail 10 May 2023. Cf also n 371 regarding matloven and NOU 1996:10.

[509] MT: e-mail 10 May 2023.

[510] Ibid ('Mattilsynet har nå konkludert med at utlevering av dokumentasjon i forbindelse med offentlig kontroll (dvs. resultater basert på analysemetoder angitt i regelverket) skal utgis, men at bearbeidet materiale, som isolater, i hovedregel ikke utgis').

[511] Ibid ('I hovedregel vil ikke isolater utleveres').

[512] Ibid.

[513] On the difference between official controls and other official activities, see Section 6.8.1.

that the data do not involve personal data or data regarding *Lm* from other FBOs (eg, based on comparisons made), it is not clear why FBOs could not get access to isolates or sequences of *Lm* originating from their own facilities, eg, from a surveillance programme. MT seemingly does not explain why it considers that FBOs should not be allowed to receive data also from other official activities.

Summing up, MT would usually not allow FBOs access to isolates it has collected or WGS data generated from such isolates.

6.4 National Reference Laboratories for Food and Feed (VI and HI)

Whether an FBO may receive WGS data from, for instance, *Lm* collected for a surveillance programme, had at the time of the interviews not yet become a relevant issue for VI or HI in practice, either by request through MT or directly by FBOs.[514]

When asked whether FBOs have a right to results pertaining to samples gathered from them as part of official activities, HI expressed that 'in principle there is no reason why the FBOs should not have access to data collected from them, however this would need to be formalised in collaboration with the FBO and the funding body'.[515] Both NRLs referred to MT's ownership to samples gathered by MT or by the NRLs on MT's behalf, commenting that it is to MT that the FBO would need to direct such a request: ie, that it becomes a matter between the FBO and MT (not the NRL).[516] Both NRLs also indicated that any direct request they receive, would be referred to MT.[517] The reasoning seemed to be, at least to some extent, that such sharing would have to go through the legal owners of the programme, who also are those who select the samples and finance the analyses.[518] For surveillance programmes, official controls, etc., this is MT. For WGS analyses it becomes more complicated, as the one paying for the initial qualitative or quantitative *Lm* analyses and for WGS is not necessarily one and the same.

HI explained that when it performed WGS of isolates from the previously mentioned 2021 official control campaign in salmonid slaughter facilities,[519] WGS was not part of its mandate from MT as such, but rather an activity initiated by HI, with project funds.[520] That is, HI was

[514] Taran Skjerdal, VI: interview 5 October 2022; HI: meeting 15 February 2022. Such a request was later received by one of the NRLs, as discussed in Section 6.8.7.

[515] HI: meeting 15 February 2022, cf HI: e-mail 10 October 2023.

[516] Taran Skjerdal, VI: interview 5 October 2022; HI: meeting 15 February 2022.

[517] Ibid.

[518] HI: meeting 15 February 2022, cf HI: e-mail 10 October 2023, cf Taran Skjerdal, VI: interview 5 October 2022.

[519] See MT; CS Svanevik and others (n 502).

[520] HI: meeting 15 February 2022.

given permission to perform WGS for *Lm* research. Conditions could be set out in a more specific contract between the FSA and NRL. The question may nevertheless be raised as to whether potential data sharing with FBOs must go through MT even when MT did not order the sequencing, for the reason that MT owns the sample material and the results from the initial qualitative or quantitative analyses. WGS was financed by the NRL. Furthermore, subsequent to the delivery of the final report published in November 2021,[521] the ownership of the samples would, according to the cooperation agreement between MT and HI, be transferred to HI.[522] A relevant factor may be that MT still owns the 'keys' (metadata) linking the material to the specific FBOs; HI made it clear that its purpose is research and scientific publication, for which it does not link samples to FBOs.[523] The permission for HI to use data for research purposes, is for data in anonymised form.[524]

Detection of *Lm* in samples obtained as part of official surveillance programmes (conducted by or on behalf of MT) is to be notified to the FBOs, at least if the concentration is above the legal limit. Isolates from these samples are stored by NRLs—for a shorter or longer period of time—and may be sequenced at a later date if relevant for research purposes or outbreak investigations, if agreed between MT and the NRL.[525] As discussed, however, according to the cooperation agreement between MT and VI, the FBOs should have the right to object to further use of samples taken from them, if that use is for purposes other than those for which the samples were originally collected.[526]

A remark was made by an NRL employee that the FBO is not necessarily notified if an isolate obtained from a sample taken from it in an official activity context (eg, *Lm* from a surveillance programme) is subjected to WGS.[527] Thus, the FBOs do not necessarily even know to request WGS data, if they do not know of its existence. This would significantly impede FBOs' practical ability to claim access at all.

In addition to analysing samples on behalf of MT, the NRLs may analyse *Lm* received from other actors: For example, VI offers qualitative and quantitative *Lm* analyses to FBOs as a

[521] CS Svanevik and others (n 502).

[522] HI and MT (n 497).

[523] HI: meeting 15 February 2022.

[524] HI and MT (n 496).

[525] Taran Skjerdal, VI: interview 5 October 2022; see also VI and MT (n 491) 5.

[526] HI and MT (n 499).

[527] Taran Skjerdal, VI: interview 5 October 2022. Information obligations on analyses performed exist primarily when they aim to verify compliance: see OCR Art 13.

commercial service.[528] Isolates originating from analyses performed in the context of this service are owned by the FBO, and rights (eg, to further use) rely on the private agreement between the FBO and the NRL.[529] In this regard, it is worth noting that VI states in its general terms and conditions for the use of this service, that it reserves the right to use the material also for 'other societally useful purposes' ('annen samfunnsnyttig hensikt'), unless otherwise specifically agreed.[530] The opportunity for VI to further use such material thus relies on the scope of 'other societally useful purposes', combined with the specific agreement between VI and those who submit sample material for analysis.

Summing up; at the time of the interviews (2022), neither VI nor HI had experienced an FBO requesting access to WGS data, either directly or through MT. They both considered a request would have to go through MT and that permission from MT was a prerequisite for sharing. Beyond this, FBOs' access rights seemed a matter not yet fully discussed, and thus the solution appeared not entirely given.

One of the NRLs received a request for WGS data a while after being interviewed. That case is further discussed below (Section 6.8.7). It is interesting to observe that this NRL, when confronted with a direct request from an FBO, did not refer it to MT; instead, it apparently decided internally against sharing the requested WGS data, based on the funding of the sequencing of the specific isolates in question.[531]

6.5 Approaches Elsewhere

6.5.1 Denmark

In Denmark, although there seem to be few cases of FBOs requesting WGS data, the FSA (Fødevarestyrelsen) appears to take the approach that it would share such data with an FBO who asks for it.

[528] See eg VI, '*Listeria monocytogenes*, påvisning', https://www.vetinst.no/provetaking-og-diagnostikk/prislister-og-analysetilbud/listeria-monocytogenes-pavisning.

[529] Cf the principle of freedom of contract, in Norwegian law see Kong Christian Den Femtis Norske Lov (NL) 5-1-2.

[530] VI, 'Prøvesvar og generelle vilkår', https://www.vetinst.no/provetaking-og-diagnostikk/proveresvar-og-generelle-vilkar.

[531] Interview with the FBO 19 December 2022; VI: e-mail to the FBO 15 November 2022.

Regarding submitted isolates from FBOs' own internal controls, Fødevarestyrelsen provides FBOs with the desired data, including sequence data.[532] This relies on a request by the FBO.[533]

Fødevarestyrelsen considers isolates and sequence data from official activities to be public 'property'.[534] Accordingly, FBOs are not offered such sequences and will not usually receive genetic data beyond subtyping information (the ST-type).[535] The reason why official activity isolates and sequences are considered public property, is partly due to the public funding of such activities, and partly based on the FSA's right to collect the samples.[536]

The Danish regulation that entitles the FSA to samples provides that the relevant authority, as part of control and surveillance, can take (or mandate the FBO to take) samples of foodstuff, including food at any stage in the production process, materials and objects, etc.[537] This is similar to provisions in Norway's Food Act (matloven) that FBOs upon the authority's request must provide necessary sample material or results of performed analyses,[538] and to give or send necessary information and sample material.[539]

In other words, to the extent WGS is publicly funded, one could argue in Norway on the same basis as in Denmark, that isolates originating from samples taken during official activities and WGS data are public property. This is so far also in accordance with the Norwegian FSA and NRL perceptions described above.

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[532] Fødevarestyrelsen: e-mail 9 February 2022 ('Det er forekommet, at en virksomhed har bedt om at få udleveret sekvensdata på et indsendt egenkontrol-isolat – typisk i forbindelse med opsporing af smitte i besætninger. I de tilfælde udleverer Fødevaretyrelsen [sic] naturligvis de ønskede data. Virksomhederne skal i disse tilfælde ikke betale for at få udleveret data'. (Fødevarestyrelsen offers, in addition to its role for samples from official activities, a commercial service https://foedevarestyrelsen.dk/kost-og-foedevarer/kontrol/laboratorieanalyser/foedevarestyrelsens-laboratorieydelser).

[533] Fødevarestyrelsen: e-mail 17 December 2021.

[534] Fødevarestyrelsen: e-mail 20 December 2021 ('Virksomhederne får ikke tilbudt at få udleveret sekvensen af offentligt udtagne prøver – netop fordi isolat og sekvens er offentlig "ejendom"').

[535] Fødevarestyrelsen: e-mail 17 December 2021 ('Hvis *Lm* isolatet stammer fra en offentligt udtaget prøve oplyses virksomheden om ST-typen på analyseattesten. Virksomheden får ikke udleveret selve sekventeringen').

[536] Fødevarestyrelsen: e-mail 1 February 2022 ('Offentligt genererede isolater og tilhørende sekvenser vurderes at tilhøre det offentlige dels fordi det er det offentlige, der betaler og dels som følge af formuleringen i den danske "Bekendtgørelse nr. 8 af 06/01/2022 af lov om fødevarer", § 54, Stk. 3').

[537] Bekendtgørelse af lov om fødevarer §54(3) ('Tilsynsmyndigheden kan som led i kontrol og overvågning vederlagsfrit mod kvittering udtage eller pålægge virksomheden at udtage prøver af fødevarer, herunder råvarer, halvfabrikata og færdigvarer, is, vand, damp, luft, luftarter, materialer og genstande, bekæmpelsesmidler, rengørings- og desinfektionsmidler m.v.').

[538] Matloven §13(3) ('Virksomheten skal på anmodning fra tilsynsmyndigheten vederlagsfritt avgi nødvendig prøvemateriale eller resultater av gjennomførte analyser').

[539] Matloven §14(1)(1) ('Virksomheten skal når tilsynsmyndigheten krever det, gi eller sende inn nødvendige opplysninger og prøvemateriale').

In any case, Fødevarestyrelsen commented that, although it is not routine for FBOs to be offered isolates or sequence data pertaining to samples collected in the context of official activities, Fødevarestyrelsen will usually provide these if requested by the FBO.[540] This appears to be based on the 'goodwill' of the authorities more than an actual perceived right for the FBO. Fødevarestyrelsen's approach contrasts the strategy seemingly taken by the Norwegian FSA: its main rule is to not share WGS data with FBOs requesting it,[541] even when there are no legal provisions to hinder such sharing.

6.5.2 Austria

The situation in Austria is, already as a starting point, significantly different compared to Norway and Denmark (see Section 5.5). This weakens the possible 'transfer value' of Austria's approach. Nevertheless, it is interesting to consider how FBOs are provided access to WGS data there.

It will be recalled that it is mandatory in Austria for FBOs to submit all *Lm* isolates they find through their own food safety control programmes, and that the NRL performs WGS on all of them. This makes it less relevant for FBOs to perform WGS themselves (unlike in Norway). It also gives the NRL possession of sequences of (at least in theory) all *Lm* strains detected in every FBO's facility.

Although the FBO obligation in Austria to submit is routine and applies to all isolates, it is to some extent comparable to the obligation for FBOs to provide sample material upon request in Norway and Denmark. In the latter countries, such sample material is considered the FSA's property. Also in Austria, the FSA (the Ministry of Health) is considered to formally own the material, including WGS data.[542]

Austrian FBOs are provided with WGS-based *Lm* data by the NRL upon request. According to the NRL (AGES), at the time of the interview (2022), not many companies were asking for WGS data. The few who ask, get what they wish, be this complete sets of WGS data (eg, FASTQ files) or less detailed results.[543] FBOs do not have to pay for the sequencing or analyses that AGES performs anyway; they only pay an administrative fee for the data to be extracted

[540] Fødevarestyrelsen: e-mail 1 February 2022 ('Som nævnt får virksomder [sic] ikke rutinemæssigt tilbudt isolater eller sekvenser fra offentligt udtagne prøver, men efterspørger virksomheden dette, vil fødevarestyrelsen normalt efterkomme ønsket').

[541] MT: e-mail 10 May 2023.

[542] Austrian Ministry of Health: interview 10 October 2022.

[543] AGES: interview 20 July 2022.

and sent to them, making the costs for the FBOs considerably lower than if the FBOs were to themselves fund sequencing and analyses. Whether such access is considered an actual right for the FBOs or based on the 'goodwill' of the FSA is not entirely clear. The Austrian FSA interviewee was not certain whether this was a right for the FBOs but considered that it might be. In either case, it is interesting to note that neither the FSA nor the NRL seem to find any reason to refuse FBO access.[544]

According to AGES, there are FBOs requesting and receiving complete sets of WGS data.[545] The fact that there are FBOs asking for WGS data recurringly, led the AGES interviewee to conclude that the data likely is useful to those who receive it.[546] Requesting this data, however, seems more of an exception than a trend. When asked why it may be that many FBOs do not ask for WGS data or other analysis results, the AGES interviewee expressed the impression that FBOs' general awareness and knowledge of WGS and what it can do for the companies, is currently fairly low, albeit getting better.[547] The interviewee added: 'I think many of [the FBOs] don't know exactly what we can do for them'.[548] The Austrian FBO interviewee pointed to three possible reasons for few data requests, seen from the industry perspective:

> 'One is that maybe some even don't know that that's possible and don't know what the power of this information [] can do. The other reason is possibly that some food business operators don't want to be too closely in cooperation with those with the dark side of the food control, maybe that's something. And then, in the end, you also need a certain level of knowledge to work with this data to make use of it'.[549]

The interviewed Austrian FBO uses WGS data it receives to improve the company's *Lm* management and mitigation efforts. It thought the sequences likely belong to the NRL (AGES)[550] 'because they have the know-how, they did their analysis, and they do their work with them'.[551] The FBO considered this quite acceptable, as it is 'obliged to send in these strains, which helps

[544] Note, however, that if AGES were to start making comparisons involving data from multiple FBOs, this would naturally create limitations for what the FBOs may receive.

[545] AGES: interview 20 July 2022.

[546] Ibid.

[547] Ibid.

[548] Ibid.

[549] Austrian FBO: interview 22 June 2022.

[550] In reality, to perform WGS is a decision taken by the Ministry of Health (FSA) and AGES (NRL) in cooperation. The Ministry owns the samples and has assigned AGES as NRL, also providing funding. For this reason, it may be more correct to consider the Ministry as owner.

[551] Austrian FBO: interview 22 June 2022.

a public interest, so it's fine'.[552] This FBO only requests and receives certain parameters that identify the strain; it does not request the complete set of WGS data, as that would be going more in-depth than it feels necessary.[553] However, it could receive such data if it wished.

It is particularly interesting to note that FBOs in Austria are allowed to receive sequences and WGS data regardless of whether they originate from isolates from official controls or isolates from their own food safety control programmes. When the data is submitted to the EFSA One Health WGS database, however, AGES makes a distinction between submission of sequence data from isolates from internal versus official controls. During an outbreak, either category must be shared.[554] Beyond this, sharing with the EFSA database is voluntary (on the part of the NRL).[555] AGES stated that it considers that, for such voluntary submission, they can only submit *Lm* from official controls .[556] This may reflect a difference regarding ownership or legitimate purposes based on how the authorities acquired the isolates.

6.6 Industry Perceptions and Opinions on Ownership and Rights in Norway

Among Norwegian FBOs, incertitude appears prevalent with respect to access rights. All FBOs that were asked during interviews, expressed an expectation that they would (or should) have a right to access to sequences of *Lm* originating from their facilities or products, generated by the NRLs (eg, collected as part of surveillance programmes).[557] Reflecting upon the reasons why they believed the NRLs or authorities would (or should) share this data, some FBOs stated that they otherwise (for qualitative/quantitative analyses) always receive analysis results.[558] Others remarked that, as they see it, there is little to gain from not sharing such data,[559] and that MT would have no interest in hiding the data from the FBOs, considering their common interest in ensuring safe food and thus in the FBOs learning about and improving their food safety mitigation measures wherever possible.[560]

Of those FBOs who commented on perceived ownership, most leaned towards considering WGS data to be MT's property (likely not considering NRL ownership, as NRLs often work

[552] Ibid.
[553] Ibid.
[554] G Costa and others (n 60) 6.
[555] Ibid.
[556] AGES: interview 20 July 2022.
[557] Interviews B, C, D, E, F, G, H.
[558] Interviews B, D.
[559] Interview H.
[560] Interview B.

on behalf of MT). They based this on acceptance that MT has legitimate authority to perform controls and sampling,[561] in addition to MT owning the samples.[562]

As for the FBOs' purposes for obtaining access to sequence data, reference was generally made to comparing them with other findings they make internally, and to learning what *Lm* strains exist in their facilities compared to typical kinds of *Lm* in relevant types of foods or facilities, etc. Access aimed at verifying authority analyses was not mentioned as central by any of the FBOs interviewed.

One interviewee raised the concern of whether an FBO would in practice be able to utilise WGS data, commenting that it would need some assistance in understanding the data.[563] To use and interpret the data—eg, to compare it with isolates collected and sequenced through the FBO's own food safety control measures—the FBO would likely need access to in-house bioinformaticians or assistance from a competent consultant or service partner, and this would have to be financed by the FBO. The need for specialised competence is part of the reason why rights to WGS data seem more relevant for large and medium-size FBOs than their smaller counterparts. In this regard, it is worth noting that commercial services are emerging to support Norwegian FBOs in managing their WGS data.[564]

6.7 Interim Summary

The above sections have pointed to current opinions and uncertainties about rights to WGS data from *Lm* originating from FBOs, obtained through the FSA's official controls or activities. The samples and isolates themselves belong to the FSA, based on its authority to require such material, and on its funding of the analyses. It also appears likely that any WGS data from such *Lm* belongs to whomever funded those analyses. This is usually an NRL.

The uncertainty about what applies appears greatest for FBOs' access to isolates and WGS data. This appears to be an important issue for the FBOs, particularly for their acceptance of NRLs' and authorities' whole genome sequencing of *Lm* found at their facilities. The question of FBOs' access to WGS data for use in their own food safety management programmes seems to have been little discussed among the Norwegian FSA and NRLs until relatively recently (2023), when MT stated that FBOs would, as a main rule, not get access to such data.[565]

[561] Interview E.
[562] Interview D.
[563] Interview G.
[564] Eg Eurofins.
[565] MT: e-mail 10 May 2023.

As for granting access to WGS data to facilitate FBOs' verification of FSA and NRL analyses and assessments, a provision in the OCR[566] appears relevant. That provision is therefore examined in the next section.

6.8 The Right to a Second Expert Opinion

OCR Article 35 affords FBOs the right to have documents from FSA sampling, analyses, tests or diagnoses reviewed.[567] This is termed the right to a 'second expert opinion'. As it may include WGS data and potentially isolates, the provision is worth exploring. The question to be examined here is whether it provides a way for FBOs (or, their second expert) to gain access to sequence data or isolates held by the FSA (ie, their NRLs), and if so, under what limitations.

OCR Article 35(1) is phrased as follows (emphasis added):

> '1. The competent authorities shall ensure that operators, *whose animals or goods are subject* to *sampling, analysis, test or diagnosis* in the *context of official controls*, have the right to a second expert opinion, at the operator's own expense.
>
> The right to a second expert opinion shall entitle the operator to request a *documentary review* of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.'

This right is for the FBOs to request a 'documentary review'. It applies provided that the FBO's 'animals or goods' are 'subject to sampling, analysis, test or diagnosis', and that this takes place 'in the context of official controls'.

The purpose of the right to a second expert opinion is to safeguard the FBOs' legitimate rights, 'in particular their right of appeal against measures taken […], by contributing to a sound factual basis'.[568] Application of the provision should be in accordance with this objective. FBOs that desire access to data pertaining to isolates originating from their facilities (eg, for purposes of their internal risk assessments) may thus not use data obtained under OCR Article 35 for that intended purpose.

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[566] OCR (n 340).

[567] Cf the more general requirements of Norway's Public Administration Act ('forvaltningsloven') §§ 18-18c on the rights of parties to access case documents.

[568] Commission Notice on the implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) (2022/C 467/02) 18.

Understanding the scope of this provision must first and foremost be based on the legal instrument itself. This means that 'its wording, context and objectives must all be taken into account'.[569] There does not appear to be any relevant CJEU[570] case law on OCR Article 35. A Commission Notice providing guidelines on the implementation of the OCR discusses several aspects of Article 35.[571] Such guidelines have no binding force,[572] but are occasionally considered for the interpretation of EU legislation.[573] They are taken into account in the following. Beyond this, national guidelines can provide insights on interpretations and implementation within EU member states, including specifications that are left to the discretion of each state.

6.8.1 Official Controls

OCR Article 35 is explicitly limited to activities performed 'in the context of official controls'. This significantly delimits its scope by excluding sampling and analyses performed as part of other official activities.[574]

The division between 'official controls' and 'other official activities' is laid out in OCR Article 2(1), which defines 'official controls' as 'activities performed by the competent authorities or the delegated bodies or the natural persons […] *in order to verify*' the compliance of the FBOs or that their animals or goods meet the relevant requirements.[575] In other words, official controls pertain to verification of compliance.

The Commission Notice sets out three mandatory characteristics of 'official control' activities implied by the legal definition: that its purpose is (i) 'the verification of compliance', (ii) 'by operators or by animals or goods', (iii) 'with the OCR and/or the rules referred to in Article 1(2) thereof'.[576] Furthermore, it specifies that 'all steps necessary to complete an activity should be considered part of that activity', while activities that are not in themselves part of the official

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[569] Case C-558/15, *Vieira de Azevedo and Others v CED Portugal Unipessoal, Lda and Instituto de Seguros de Portugal – Fundo de Garantia Automóvel*, judgment of 15 December 2016 (ECLI:EU:C:2016:957) para 19.

[570] Court of Justice of the European Union.

[571] Commission Notice (n 568).

[572] TFEU Art 288(i.f.) (Treaty on the Functioning of the European Union. 23.3.1957. Consolidated version. EUT 2016/C 202/01).

[573] See Opinion by Advocate General Hogan in Case C-523/18, *Engie Cartagena SL v Ministerio para la Transición Ecológica* (ECLI:EU:C:2019:769) para 43. See also Case C-329/16, *Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé*, judgment of 7 December 2017 (ECLI:EU:C:2017:947) para 33 (referring to Commission Guidelines as confirming an interpretation).

[574] Commission Notice (n 568) 18, 5.

[575] OCR Art 2(1); emphasis added.

[576] Commission Notice (n 568) 6.

control but, eg, based on their outcomes (like issuing certificates) are considered 'other official activities'.[577]

'Other official activities' include, ia, 'surveillance for the detection of animal diseases', as well as 'epidemiological surveillance and monitoring' and 'investigations of food-borne outbreaks'.[578] These activities are not aimed at verifying compliance and are thus not 'official controls' as encompassed under OCR Article 35.

FSA sampling and analysis for *Lm* in an FBO's facility may thus be an official control activity or other official activity depending on the purpose for which it is performed.[579] If it is carried out to verify whether, for example, the foodstuff produced is compliant (eg, with maximum *Lm* thresholds),[580] it qualifies as an 'official control' activity and OCR Article 35 can be invoked. If similar sampling is performed as part of outbreak investigations to identify the source of the outbreak strain and prevent further spread of the disease, it is 'other official activities'.[581] Surveillance programmes carried out to map and document the current status[582]—for example, the prevalence and distribution of *Lm* among salmon producers or in RTE products—are 'other official activities'.[583] Even when these can lead to a subsequent 'official control', the surveillance programme activities are regarded as 'other official activities'. Monitoring of food contaminants performed to verify compliance are, however, 'official controls'.[584] Note also that '[m]aking use of the results of surveillance conducted by operators' can be used for 'preparation of official controls, [but is] not in itself verification of compliance' and thus not 'official controls'.[585]

It will be recalled that WGS normally is not included in activities performed to verify compliance.

The 'official controls' limitation of OCR Article 35 excludes its application towards activities performed, ia, for outbreak investigation or for surveillance programmes to, eg, map the prevalence of bacteria.[586]

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[577] Ibid.

[578] Ibid. See also OCR Art 2(2) and Recital 25.

[579] Ibid, 7.

[580] Ibid, 9, as it involves verification of compliance with the MCR, cf OCR Art 1(2).

[581] Ibid, 8-9; see also OCR Recital 25.

[582] GFL Art 33.

[583] Commission Notice (n 568) 12.

[584] Ibid.

[585] Ibid, 8.

[586] See also MT: e-mail 10 January 2023.

6.8.2 Samples Encompassed

Within the scope of official controls, OCR Article 35 provides that the FBO's 'animals or goods' must be 'subject to sampling, analysis, test or diagnosis'. There is no explicit inclusion of situations where the FSA samples—or performs analyses on samples from—the processing environment.

The wording can, in the strict sense, be read to mean that the goods themselves must be subject to the sampling and analysis, or at least that the goods must be examined in addition to environmental samples for the latter to be encompassed. Alternatively, keeping in mind that 'official controls' are performed to verify the compliance of FBOs or of their products, and that both these objectives are ultimately aimed at ensuring safe food, it seems not unreasonable to consider sampling of the processing environment a way of testing the safety of the goods produced there.

Thus, if read in the broadest sense, there might be room for including a wider category of activities if they are ultimately aimed at examining the safety of animals or goods. Such an interpretation is likely in accordance with the provision's objective of securing a sound factual basis and rights for the FBO to test the results of the NRLs. On the other hand, it could be a stretch of the wording. If the provision was intentionally phrased to focus only on activities performed directly towards animals or goods (possibly being considered more 'pertinent' or central activities to trigger a right to a second opinion), this wider interpretation may go beyond the legislative intention.

Environmental samples may well be of minor importance for official controls in practice, at least beyond the fact that they have been collected. Samples of goods can be collected to check, eg, compliance with legal *Lm* thresholds. There is, however, no rule prohibiting presence of *Lm* in the processing environment, making such samples less central for official controls. Environmental samples are more relevant as part of other official activities such as surveillance programmes or outbreak investigations. Still, they can be collected also during official controls, eg, for control of hygiene and cleaning procedures. As already mentioned, WGS nevertheless seems an unlikely choice of analysis for the FSA in this context, as it would provide negligible or no support for assessing compliance.

Considering that environmental sampling provides little support for verifying compliance, together with the possibly intentional exclusion of such samples by listing 'animals or goods' as the objects for sampling, the need to include environmental samples under this provision appears low. Although sampling of other subject matter seems possible to fit within the provision's wording if considering the products as the ultimate aim of the activities performed (eg,

analysing samples from the processing environment with the aim of assessing the foodstuff produced), this might stretch the provision needlessly beyond its intended scope.[587] It therefore seems most appropriate to interpret the wording more narrowly, as regarding activities more directly performed towards animals and goods.

To conclude: OCR Article 35 encompasses samples, analyses, etc of animals and goods. Environmental samples are less likely to be included.

6.8.3 Documentary Review – Documents Encompassed

Another question is what data Article 35(1) provides a right to, for the performance of a 'documentary review'.[588]

The term 'document' is not defined in the Regulation but should likely be construed broadly. This is intimated by, ia, the definition used in the EU's Open Data Directive (Directive (EU) 2019/1024)[589] which defines 'document' as 'any content whatever its medium (paper or electronic form or as a sound, visual or audiovisual recording)' or as 'any part of such content' (Article 2(6)). Similarly, the Norwegian Freedom of Information Act ('offentleglova') defines a document as a logically delimited amount of information that is stored on a medium for later reading, listening, display, transmission, or similar (§ 4(1)).[590] Under this definition, 'document' is 'medium neutral', meaning that it also encompasses, ia, electronic documents consisting of text, sound or images, or a combination.[591] WGS data fulfils the description of being a limited amount of information, to be, eg, read, transferred, or used later. It is kept in datafiles that can be shared and analysed. It thus appears reasonable to consider WGS data as 'documents' also for the application of OCR Article 35(1).

The complete set of sequence data (ie, FASTQ files) can be considered part of the documentation for WGS analyses and thus a crucial part of the documentation necessary for adequate second expert assessments of the NRL's analyses, at least to the extent WGS-based analyses

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[587] The wording should not be stretched too much: see Joined Cases C-310/98 and C-406/98, *Hauptzollamt Neubrandenburg v Leszek Labis* (C-310/98) and *Sagpol SC Transport Miedzynarodowy i Spedycja* (C-406/98), judgment of 23 March 2000 (ECLI:EU:C:2000:154**)** para 46.

[588] OCR Art 35(1)(2).

[589] Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information [2020] OJ L 172 56.

[590] Offentleglova § 4(1) ('Med dokument er meint ei logisk avgrensa informasjonsmengd som er lagra på eit medium for seinare lesing, lytting, framsyning, overføring eller liknande').

[591] Graver (n 360) 321.

have been used in the FSA's assessments. Inclusion of WGS data would then also be in accordance with the objectives of OCR Article 35.

As an aside, contact with the Danish FSA (Fødevarestyrelsen) revealed that it (as of February 2022) had not yet experienced any requests from FBOs for a second expert opinion.[592] Fødevarestyrelsen nevertheless commented that, should it become relevant, analysis protocol and sequence data would be provided upon request.[593] It can be drawn from this that, at least in Denmark, WGS data is considered as being part of the 'documents' FBOs can require under their OCR Article 35 right.

It must also be remarked that WGS is currently not applied during official controls in Norway,[594] and that WGS does not, at present, provide information decisive to assess compliance. This decreases the relevance of OCR Article 35 for WGS data, as a second expert opinion will likely rarely encompass assessments of WGS.

6.8.4 Isolates

Regarding material to facilitate re-analysis, ie, sample material or bacterial isolates (biological material), which might then be further sequenced and analysed by the second expert if relevant for the second opinion, it seems an awkward stretch of the wording to include this under 'documentary review'. Any documents describing such material should, however, be encompassed.

Whether the actual isolates can be requested under Article 35 is possibly rather a question of whether they may be encompassed under the provision's second paragraph. OCR Article 35(2) gives FBOs the right to require that more sample material is gathered for the purposes of a second analysis. It provides (emphasis added):

> '2. Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall:
> (a) when taking the sample, and *if so requested* by the operator, ensure that a *sufficient quantity* is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or
> (b) where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof.'

[592] Fødevarestyrelsen: e-mail 9 February 2022.

[593] Ibid ('Vi har endnu ikke været ude for at virksomhederne har krævet en supplerende ekspert udtalelse, men skulle det blive aktuelt vil analyseprotokol og sekvensdata blive udleveret på forlangende').

[594] Cf ia MT: e-mail 10 May 2023.

Strictly speaking, the second paragraph regards ensuring collection of a sufficient quantity of sample material. It does not refer to bacteria that the NRL has isolated from sample material. Furthermore, it is a right relying on request from the FBO, who should then ask for further material to be collected *before* the sampling takes place.

It could be that access to isolates is not explicitly included due to only simpler second analyses (than, eg, WGS) having been envisaged at the time of legal drafting (eg, qualitative and quantitative). For *Lm*, for the purposes of qualitatively detecting the bacterium or quantitatively determining the amount of it, one would need sample material (as is explicitly encompassed by OCR Article 35(2)).

At the same time, to the extent that the extraction of the bacterium from the sample material itself is not disputed (eg, suspicion of cross-contamination), a copy of the isolate from the NRL would allow for re-assessment of WGS analyses. Bacteria can be grown and multiplied, so that there is no need for added test material to enable re-analysis of NRL's more in-depth analyses. Paragraph 2 is to be applied where 'relevant' and 'appropriate', and access to isolates (if the parties agree for it to be acceptable) could satisfy the objective of the provision. That would, however, require a widened interpretation, applying the second paragraph on isolates by analogy.

Access to isolates is not mentioned in the provision. For official controls, WGS is rarely relevant, and isolates may have been left out for this reason: that re-analyses were envisaged to regard qualitative and/or quantitative detection. For such review, the wording provides right to documentation (OCR Article 35(1)), as well as sufficient sample material (upon request before sampling) to perform a second analysis (OCR Article 35(2)), if relevant and possible. This points towards the conclusion that isolates likely cannot be requested under OCR Article 35.

6.8.5 Use

For material acquired under OCR Article 35 arises the question of how it may be used. In particular, FBOs may wish to exploit the data to strengthen their risk assessments and *Lm* management efforts. The question is therefore whether the FBO or the second expert—when they are first in possession of data acquired based on OCR Article 35—may store and use that data for other purposes.

The answer is fairly straight forward: the data should be used to fulfil Article 35, ie, to perform the second expert opinion, hereunder to provide a sound factual basis.[595] There is no explicit provision for further use. Use for other purposes (eg, for FBO's internal *Lm* risk management) would therefore likely rely on permission from the FSA or the proprietor of the material, beyond OCR Article 35.

With no such permission, the use is for the second expert opinion only, and data is likely expected to not be stored or used beyond what is necessary for the purposes of OCR Article 35. For the Article 35(1) right to a 'documentary review', the guidelines made by the Irish FSA specify, ia, that 'any uncontrolled copies' (such as printed or physical copies) 'will only be available to the recognized and appropriately qualified expert to examine during the documentary review and duplication of any records will not be possible'.[596] This indicates an understanding (at least in Ireland) that access to the material is limited to the time when the review is ongoing, and that the data may not be stored or used for other purposes.

Furthermore, the Irish guidelines specify that FBOs 'should note that documents held by the HSE [ie, Health Service Executive] that could contain proprietary information will remain under the control of the HSE during the documentary review'.[597] What situations they envisage for this to become relevant, are not specified. One might, however, imagine that a review involving WGS data to which some party (eg, the FSA or a NRL) consider they have ownership, could fall under this phrasing. This likely also depends on what is practically feasible to protect ownership while also ensuring the right to a documentary review. Whether the same approach would be taken in Norway, and how it should be performed in practice, has not been specified.

In either case, there seems little room for use of documents or material accessed by evocation of OCR Article 35 beyond the purpose of the second expert opinion—at least not unless any specific permission is provided for it. Using Article 35 for access to WGS data (or isolates, if possible) then appears a rather futile path if the results obtained by the NRL are not contested and the aim is rather to use that data to eg, inform the FBO's food safety management programme.

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[595] As perceived also by Mattilsynet: 'Dokumenter det gis innsyn i, i denne sammenheng, skal kun benyttes for å fremskaffe en second expert opinion. Prøvemateriale som er virksomhetens eiendom oppfatter jeg at de kan råde over' (MT: e-mail 10 January 2023).

[596] Food Safety Authority of Ireland, 'Guidance for Food Business Operators Supervised by the Health Service Executive on their Right to Second Expert Opinion', Guidance Note 39 (2022) 11.

[597] Ibid.

6.8.6 Timeframe

Whether the FBOs should be subject to a deadline for claiming their rights under OCR Article 35(1) —and, if so, what the timeframe should be—is up to each EU member state.[598] In Ireland, for instance, the national guidelines set a timeframe of seven working days for the FBO to request a documentary review.[599] No fixed timeframe appears to have been set in Norway.

Seeing as the purpose of OCR Article 35 is to provide rights in situations where the FBOs disagree regarding the results of official controls, the right to appeal decisions is likely relevant for the timeframe allocated for claiming such rights, at least in practice. In Norway, FBOs usually have three weeks to appeal an administrative decision.[600]

At the same time, in the case described in the next section, the FBO requested isolates and sequence data almost two months after the last samples had been collected by MT, and respectively seven and a half, and six weeks, after receiving decisions based on the sampling results. This was clearly beyond any deadlines to appeal the decisions.[601] Still, MT made no comment of this being an issue.

It should also be noted that when the FSA takes action, eg, to address a threat to human health, that action will not be postponed awaiting a second expert's investigations under OCR Article 35.[602]

6.8.7 Practice

The prevalence of FBO claims under OCR Article 35 in Norway is unknown. One case where it was tried, can be observed for understanding how it was dealt with at least in that one instance. Whether it is representative, is difficult to assess. It seems likely, however, that the questions discussed herein relating to OCR Article 35, had not at the time been widely considered and practiced by the Norwegian FSA.

An FBO was being investigated as a possible source of an *Lm* outbreak. MT performed official controls,[603] involving multiple aspects of the business (including hygiene, sampling, corrective

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[598] Cf Commission Notice (n 568) 20.

[599] Food Safety Authority of Ireland (n 596) 13.

[600] Forvaltningsloven § 29(1) (from the time they are informed of the decision).

[601] Ibid.

[602] See OCR Art 35(4) ('shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health').

[603] See matloven § 23.

measures, food safety, and raw materials), hereunder sampling for *Lm*. Samples collected qualify as samples taken as part of official controls. The FSA had previously collected *Lm* samples from the same FBO as part of a surveillance programme. In addition, the FBO had sent environmental samples it had collected for analysis through the NRL's commercial diagnostic service.[604] WGS was performed on isolates obtained from these various samples for the purpose of the outbreak investigation.

The FBO wished to receive copies of the sequence data generated by the NRL from isolates from those samples. Alternatively, the FBO wanted the isolates. It therefore wrote to the FSA requesting this data for the purpose of using it in connection with its internal *Lm* control efforts.[605] The FBO also made reference to OCR Article 35, hoping this might strengthen its chances of gaining access to the data or isolates.

Specifically, the FBO asked MT for the WGS data (FASTQ files) for isolates originating from its facilities,[606] which included: (i) two isolates from product samples collected as part of a surveillance programme some months earlier; (ii) isolates from a processing environment sample collected by MT as part of an official control; and (iii) isolates found in environmental samples from drains collected as part of internal controls by the FBO and qualitatively analysed by the NRL at the FBO's expense. The WGS for all these isolates appears to have been performed by the NRL as part of the outbreak investigation.

At the time, MT replied to the request, referring to OCR Article 35, and stated that it could provide the isolates (and data related to them) from samples pertaining to the FBO upon request.[607] It further stated that the FBO would then have the opportunity to have WGS performed and thereby re-test the results, and that this fulfilled the OCR obligations. MT did not make any comment on the FBO's expressed intention of using the data as part of its own *Lm* management efforts.

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[604] VI (n 528).

[605] E-mail from the FBO to MT 28 November 2022, included in MT 2022/216829-38. The FBO wrote: 'Grunnen til at jeg ønsker sekvensene er at jeg vurderer å ta i bruk helgenomsekvensering av isolater vi ev finner i vårt prøvetakingsprogram og i råvarer. Det vil være viktig for oss å kunne sammenligne ev nye funn med de isolatene som tidligere er funnet i produkt fra vår bedrift […]. Dessuten ønsker jeg å benytte meg av retten til uttalelse fra en annen sakkyndig'.

[606] E-mail from the FBO to MT 28 November 2022, included in MT 2022/216829-38.

[607] E-mail from MT to the FBO 16 December 2022, included in MT 2022/216829-38. ('Det er enighet om at det på forespørsel kan utleveres isolater (og data knyttet til dette) av prøvene til virksomheter, jf. forpliktelser gitt i kontrollforordningens artikkel 35').

Regarding access to WGS data generated by the NRL, MT referred to this as a question of principle which it needed to clarify by involving also the NRL.[608] Thus, not yet (at the time) having assessed whether the sequences could be provided to the FBO, the FBO was not given access to any sequence data. Through direct contact with the NRL, the FBO was refused access to the sequencing data.[609]

Considering the isolates requested, only one sample had produced isolates as part of official control activities. The surveillance programme only qualifies as 'other official activities' which should not be encompassed under OCR Article 35. The samples from the FBO's internal controls had been collected by the FBO, who paid for the qualitative analyses performed by the NRL. Those isolates should thus already belong to the FBO.

Note also that only the two surveillance programme isolates were from product samples (cf 'goods' in OCR Article 35(1)), while the rest of the isolates originated from the processing environment.

The sequencing of all isolates appears to have been performed in the context of the outbreak investigation, ie, for the purpose of comparison with the outbreak strain and to assess the FBO as a possible source of that strain. Such sequencing activities cannot be considered part of official controls to verify the FBO's compliance.

As OCR Article 35 pertains only to samples from official controls, it should thus be applicable to—potentially—only one of the isolates (depending on the 'goods' criterion) and no WGS data (unless MT somehow defined more of this material as pertaining to 'official controls'). However, according to the discussion in Section 6.8.4, isolates are not encompassed under OCR Article 35, making Article 35 non-applicable altogether.

The FBO was eventually, however, allowed access only to the isolates from the sample collected at its facilities during the official control, and the isolates from samples collected by the FBO itself through its own sampling efforts. Access to the isolates from the sample from the official control was granted with reference to OCR Article 35. The allowed use by the FBO was restricted accordingly: it received access to the isolates under condition that they only be used

[608] E-mail from MT to the FBO 16 December 2022, included in MT 2022/216829-38. ('Når det gjelder utlevering av data knyttet til helgenomsekvensering av produkter sendt inn av Mattilsynet, er det et prinsipielt spørsmål vi må avklare').

[609] VI: e-mail to the FBO 15 November 2022 (this was prior to the request to MT). The refusal (from VI) was related to the funding of the sequencing: It was not funded by MT, but by specific contingency funds ('beredskapsmidler') provided to VI over the state budget.

for the purpose of verifying the results that were the basis for authority decisions.[610] Access to the isolates from the samples collected by the FBO itself was granted without reference to OCR Article 35.

Despite the original reply from MT granting access to all six isolates pertaining to the FBO,[611] the FBO was in the end not granted access to the isolates from the two product samples collected as part of the surveillance programme. The reason provided was that these were not official control samples but from other official activity, for which the FBO's right to access does not apply.[612] No comment was made at this point as for whether the FBO had a right to access this material on any other basis than OCR Article 35.

How MT considered isolates encompassed under that provision, was not specified. Neither was it commented to what extent MT expected already isolated *Lm* strains to contribute to verify whether *Lm* was found in the facilities, or otherwise what aspects of MT's decisional basis it should help verify. There may also not have been agreement within MT that isolates could be encompassed under OCR Article 35.[613] A possible explanation for this may be the (at least at the time) paucity of discussions on this point within the agency. In any case, isolates are not included in the wording and would entail an expansive interpretation of the provision (see Section 6.8.4).

Six months after the original request from the FBO, MT had apparently dedicated more time to discussing these questions. MT then explained, on a general basis, that processed materials, including bacterial isolates and similar, are as a main rule not provided to the FBOs.[614]

The FBO was not allowed access to WGS data. This had apparently been assessed only according to OCR Article 35. Thus, sequences were not provided since they do not make the basis for decisions relating to the official control (as these were—what regards the *Lm* samples—only based on qualitative or quantitative results).[615] Sequences constitute data generated beyond the official control, for which reason access was denied. The sequencing data was generated as part

[610] MT 2022/216829-33 ('materiale skal kun benyttes for formålet om å verifisere resultatene som danner grunnlaget for offentlig vedtak').

[611] MT (n 607).

[612] MT: e-mail to the FBO 5 May 2023, included in 2022/216829-38, stating: 'Ok-prøver er ikke offentlig kontroll, men annen offentlig aktivitet. Derfor gjelder ikke virksomhetens rett til innsyn i data'.

[613] MT: e-mail 6 January 2023 expressing that isolates are not encompassed.

[614] MT: e-mail 10 May 2023 ('Bearbeidet materiale, som opparbeidede analyseprøver, bakterieisolater og liknende, utleveres som hovedregel ikke').

[615] MT 2022/216829-32.

of an outbreak investigation. Thus, if they were to have been granted to the FBO, it would have had to be outside the scope of OCR Article 35.

6.9 Summary and Some Considerations

This section has explored rights associated with isolates from official activities and WGS data, particularly to what extent FBOs may gain access to WGS data—or as an alternative; bacterial isolates—under various situations and for various purposes.

Different opinions and practices have been considered. FBOs express both an interest and an expectation to be granted access to such material. They primarily envisage to use it to strengthen their own *Lm* control efforts. Verification of analyses and assessments performed by the authorities is also a relevant objective. It seems likely that FBOs will, to an increasing extent, desire and request access to WGS data. The questions under discussion are thus no longer reserved for the future.

Samples collected through official activities are owned by the FSA. Any WGS data generated through official activities also appear likely owned by the NRL, although this may depended on the situation. The Norwegian FSA is reluctant to share either with the FBOs: it has decided and stated its main rule to be that 'processed materials' like isolates or sequence data will not be shared.[616] By contrast, Austrian practice and envisaged practice in Denmark points to the FSAs there generally consider it advantageous to grant access to WGS data to the FBOs, or at least they do not seem to find sufficient reasons to prevent sharing.

Regarding access for verification of analyses performed by authorities (OCR Article 35), the legal right provided to FBOs holds limitations: It does not encompass outbreak investigations or surveillance programmes but is limited to official controls aimed at verifying FBOs' compliance. In these situations, WGS is less relevant and, consequently, so is also the possibility to use this right for access to WGS data. The right to a second expert opinion, thus, appears too narrow to provide any true aid for the purposes of FBOs' access as discussed herein. Practice opens the door for possible use of this provision for access to isolates, although it is not clear from OCR Article 35 that such material should be included under the provision.

It makes most sense, and is more in accordance with its objectives, if OCR Article 35 is applied only when there is a problem or a dispute relating to an analysis result, not for the purpose of access to WGS data for use to strengthen the FBOs' *Lm* management programmes. Article 35 then becomes a slightly awkward way of attempting to circumvent legal lacunae. It is not ideal if FBOs who desire this data for internal *Lm* control purposes need to make use of a provision

[616] MT: e-mail 10 May 2023.

with a completely different objective. Ideally, they should be able to base their rights on provisions drafted more in accordance with the needs and purposes involved. Applicability of OCR Article 35, thus, does not solve the question of FBOs' rights to access for the purpose of informing their *Lm* control programmes. As we are still at the emerging stage of FBOs' interest in WGS data, it would be better to find legal address aimed at the situation at hand.

When the situation first arose (cf the request described above)[617], the Norwegian FSA and NRLs seemed to not have thoroughly discussed how do deal with such claims and, thus, were not fully prepared to meet them. After several months, they took a stand which entailed to normally share as little as possible of the data. The conclusion did not come with particularly elaborate reasons or discussions weighing interests involved, beyond that they are not legally required to share this by any existing provisions.

WGS already entails significant levels of unpredictability for the food industry. Legal predictability, although not involving the desired outcomes, is likely better than uncertainty. At the same time, transparency would be a key factor to support FBO acceptance and trust towards the authorities' practice. Refusing to grant FBOs access rather risks increasing the divide and hindering FBOs' willingness to cooperate.

Providing FBOs with access could be a way to make authority practices better accepted among FBOs, both by enhancing transparency and information sharing, and also by providing something back to the businesses, who are naturally wired to worry about how the FSA uses their data and possible detrimental consequences of that use. Sharing seems to have contributed to acceptance in Austria. Furthermore, it should be in all stakeholders' interest that the FBOs apply this data to improve their *Lm* management programmes and thereby the safety of foods on the market.

When the authorities consider whether to provide access to the materials and data discussed, it is important that they weigh both benefits and potential risks or legal constraints to sharing. The main rule could have been sharing, with an assessment case-by-case to assess possible risks and necessary limitations. It would likely also be advantageous to prepare for dialogue with FBOs making such requests, to discuss with them both their reasons for the request and implications of access to the data, to allow for more informed FSA decisions, increased transparency, and improved understanding for the FBO. That might allow for a more informed dialogue and joint efforts in addressing food safety challenges.

[617] E-mail from the FBO to MT 28 November 2022, included in MT 2022/216829-38.

In Norway, currently, there are instead several information challenges creating the opposite effect towards the FBOs. Firstly, it would be preferable if FBOs were explicitly informed about their right to object to further use of material by the NRLs (as discussed in Section 6.3). Secondly, it would contribute to FBOs' abilities to stay informed and uphold their rights, if they were informed when *Lm* isolates originating from their facilities or products were subjected to WGS, so as to be aware of what WGS data pertaining to their businesses exists. Finally, as discussed, there are arguments in favour of the FSA and NRLs considering granting access to requested data and material to the extent they can without conflicting on legal requirements (eg, legal requirements restricting data sharing).

Access would support transparency and collaboration and allow better insights for FBOs to support their effective address of food safety challenges they might experience. It can facilitate more targeted risk assessments, *Lm* measures, and control mechanisms. This should be part of the balancing when considering whether to allow FBOs access. It is important for the authorities to strike a balance between transparency, public health considerations, and protecting legitimate interests, such as privacy and commercial confidentiality, when making decisions regarding access to WGS data.

7 Conclusion

The research underlying the current report has explored certain questions for the purpose of facilitating implementation of WGS in the Norwegian food industry. The chapters point to challenges that risk becoming barriers for FBOs' uptake of WGS. Some indications of possible legal shortcomings or regulatory needs have been provided, which should invite making some adjustments, considering WGS under current law. Possibilities range from entirely new laws to providing guidelines to existing rules.

For food law to function as designed, collaboration between authorities and the FBOs is important. This is partly a consequence of how food law is designed, with the responsibility for food safety placed on the FBOs. Thus, the authorities—and regulation—need to strike a balance between posing stringent food safety standards and making them realistically achievable, for example if considering to raise the standards for safe food, or how much data the authorities should require access to. It is important to ensure that the rules function in a manner that is both effective in protecting public health and reasonable towards challenges faced by FBOs.

WGS presents both opportunities and challenges, much due to its increased potential for detailed information on bacteria. This may necessitate review and update of relevant legislation—taking into account advantages of data sharing as well as legitimate interests like data protection and confidentiality—to facilitate both sharing of WGS data and integration of it in assessments made by various stakeholders.

Relevant frameworks must likely be subject to continuous review to ensure their continued suitability toward the ever-current state of the art—both in the food industry and more generally—in WGS technological advancements, and in changing food safety challenges and knowledge. Current legislation is, to a large extent, designed to be flexible and technology neutral, both for FBOs to choose the approaches best suited to them and to accommodate technological advancements like sequencing technology. This makes it easier to address newly developed needs and perceived lacunae or unclarities through administrative regulations or guidelines to the current legislative instruments, as these can be more rapidly updated.

The previous chapters leave the impression that clarifications relating to WGS can largely be achieved under current legal instruments, without excessive hard law amendments. They could, for example, take the form of more general guidelines or specifications, based on assessments of current law towards WGS at present and in the foreseeable future. 'Harder', more binding approaches might contribute to better predictability, but perhaps not be the optimal approach in practice unless there is an obvious legal gap. Clearer guidelines were raised as a need by several

of the FBOs interviewed. It appears that they primarily wish for a clear stance from the authorities, and for some specifications. What form these take is perhaps less important to the FBOs, as long as they are provided with more clarity and predictability.

Furthermore, the stakeholder interviews pointed to the importance of building knowledge and skills, both for FBOs' use of WGS and not least for FBOs' trust in FSA assessments involving WGS data. Regarding the FSAs' competence when considering WGS data as the basis for administrative decisions, it is important that they (in addition to the NRL(s) performing WGS) have been trained in how to interpret and use WGS information in that context. This may require increased education on the topic, also locally, as FSAs often make decisions at the local level.

Thus, to cater for FBOs' implementation of WGS in Norway, guidelines on how to apply current law towards WGS could play a central role. In addition, measures such as enhancing knowledge and skills among the actors involved, appear central, also for the purposes of trust enhancement.

One should also take account of the fact that adjusting Norwegian legislation alone is not sufficient, as *Lm* travels transnationally between actors situated world-wide. Particularly for sectors where export is central—like Norwegian salmon and trout production—both legislation, guidelines and 'mentalities' need to function at the international level. Consistencies in rules pertaining, ia, to use of WGS data across borders, would be central to achieve this, aiming to promote both trade and food safety. The risk could otherwise be to stifle the market due to requirements or specifications in Norway that are inconsistent with those of other trading countries.

In general, whatever legal approaches are taken, it appears pivotal that the authorities prioritise providing information and explanations to FBOs and seek to build trust and understanding, thereby providing a beneficial environment for FBOs to maximise their food safety efforts.

Food Safety Assessments

To the FBOs, WGS data—to the extent generated—would be a natural addition to inform their risk assessments and *Lm* management efforts, to make them more accurate and allow for more targeted measures. This can take place within the current rules, at least as long as it does not cause FBOs to lower their *Lm* mitigation standards. If WGS is to be implemented through a particular regulatory instrument, industry standards or guidelines are probably better 'vehicles' for this purpose than hard law legislation, so as to cater for rapid adjustments that do not require a full legislative process. Such guidelines would likely be useful to the FBOs, both to enable more informed use of WGS and to support more harmonised application among various FBOs.

While WGS clearly holds valuable potentials for FBOs, it should be regarded that—in addition to being a risk to health—*Lm* is, to the FBOs, also financially demanding. In the end, an assessment of costs and benefits may not necessarily favour them to implement extensive WGS; it is not obvious that sequencing all *Lm* would be a benefit, neither economically (for each factory or Norway as an export country) or for health (spending money on sequencing rather than other health priorities, eg, interventions such as informing vulnerable groups about risks or combatting more serious health issues). WGS seems more likely to rather be implemented for certain selected samples or in particular situations.

FSA Access to FBOs' WGS Data and Other Material

As far as FSA access to FBOs' WGS data (or other material) is concerned, it would likely be beneficial if the authorities make available to the FBOs assessments of when they envisage it relevant to require such data, when they would not request it, and in what situations such access needs to remain highly discretionary, ad hoc or unpredictable. It is to be hoped that the authorities consider these questions thoroughly. At least some indications should be possible to make, so that FBOs know what to expect. Some FBOs appeared reluctant to apply WGS until such information is available. Ensuring that FBOs are properly informed about any guidelines, would also be important.

As for what approach to take, the Austrian approach appears unlikely to be adopted in Norway, at least for the near future. Activating the third sub-paragraph of § 2-4a of MSIS-forskriften to the full extent also seems improbable, as (at least currently) this appears to exceed the extent of isolates that the NRLs or FSA wish to receive, even if such increased data collection could enhance the surveillance of *Lm*. Activating it for certain chosen categories of samples, might then be a more likely approach. The most probable appears that routine submission of isolates or sequences will not become mandatory anytime soon, and rather that matloven §§ 13 and 14 will be applied, as is currently the case. However, it would be beneficial to provide clearer indications for how those provisions will be applied relating to WGS—in other words, assessing and conveying this issue proactively, rather than reactively. This would increase predictability for both FBOs and the FSA and reduce one apparent barrier to FBOs' uptake of WGS.

FSA access to information should rely on a balanced assessment of its legitimate need for information or data, against the FBOs' need for 'room' to operate without excessive interference if they are to apply technology beyond the minimum required.

The question may be asked as to how detrimental it would be for the FBOs if the authorities gather, systemise and use their data. It is possible to envisage functional approaches to increased

data collection, although certain factors likely need to be better in place for this to function expediently (both for FBOs to use WGS, and generally to not minimise their sampling). These include predictability (ie, a need to establish up front what applies and how rules will be practiced) and equality in the sense of assurance that increased use of WGS from the side of FBOs will not augment the risks of negative consequences for them, compared to FBOs not applying this technology.

As for the prospects of a centralised platform for WGS in Norway, data sharing between public sectors to any considerable extent beyond what takes place currently, appears unlikely in the near future, and sharing between competing FBOs even less so. Still, there might be reason to explore further how data sharing and collaboration between various stakeholders—FSAs, FBOs, researchers—could be encouraged and enhanced. There are potentially multiple positive outcomes, both in better understanding biological variations between *Lm* strains and transmission patterns, in allowing more targeted risk assessments, and in addressing foodborne outbreaks. However, account must be made both of data sharing limitations and of the concerns expressed by various stakeholders. Should FBO *Lm* data sharing become mandatory in some form, this may also lower the threshold for perceived sensibility in sharing information about *Lm*, which currently appears to be a barrier in itself.

FBO Access to Sequences Held by the Authorities

Based on the discussions in Chapter 6, it may be preferable if the authorities reconsider to what extent FBOs can and may access authority-held sequences originating from *Lm* from their facilities and products, and under what conditions and for what purposes, etc—particularly for the purposes of improving their internal *Lm* management programmes. Currently, no legislation in Norway appears to mandate sharing of such sequences in the relevant contexts. If such legislation is developed, it should outline specific conditions and procedures for WGS data sharing between the authorities and FBOs. If no regulatory measures are taken to address this, the hope would be that the FSA at least provides clearer and more accessible guidance as for when data may be shared and not, with explanations underlying its decisions. Such assessments should take into account the advantages of transparency, as well as addressing any privacy and confidentiality concerns. One should likely also consider involving the industry in such an assessment process. If FBOs are not to be given access, it is important that they understand the reasons why.

Final Remarks

The above reflections point to factors that will be central for the success of any legal approach taken to facilitate implementation of WGS. These include collaboration, building knowledge,

predictability, transparency, equality, and trust. Much can likely be achieved by authority assessments of how to apply current rules in the context of WGS, providing specifying guidelines, and ensuring that information reaches the relevant stakeholders. Of the questions discussed, the most glaring legal lacuna is likely for FBOs' access to WGS data or isolates, for which there is no explicit provision. Whether or not to share them should be subject to careful and thoroughly reasoned assessments.

Furthermore, should one decide on a more comprehensive approach to collect and use WGS data, eg, on a routine basis—although seemingly not desirable in Norway at present—new legislative provisions for this might also be preferable, the development of which could also take into account the role of sequencing technologies. The MSIS-regulation holds several limitations in this regard.

Depending on the desired direction in Norway going forwards, catering for FBOs' implementation of WGS should likely combine providing specifications or guidelines under current rules, with possible legal amendments. Whatever approach is taken, it is important to consider the involvement of various stakeholders—FBOs, relevant authorities, NRLs, scientific experts, consumer representatives—and balance the different interests involved, so as to maximise WGS implementation and benefits while minimising concerns and detrimental effects.

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Interviews

AGES: interview 20.07.2022

Austrian FBO: interview 22.06.2022

Austrian Ministry of Health: interview 10.10.2022

FBO: interview 19.12.2022

HI: meeting 15.02.2022

Norwegian FBOs: interviews with Norwegian food business operators (FBOs) have been lettered from A to I, where interview I does not make part of the interview descriptions or discussions. They were conducted between May 2021 and December 2022 (although most of them during the spring of 2022). Among these are the FBO interview also referred to as 'interview with the FBO 19 December 2022' for the purpose of anonymisation.

Taran Skjerdal, Senior researcher at VI: interview 05.10.2022.

E-mail Correspondence

All e-mails with no specified recipient were sent to and are accessible from author Christiane Hunsbedt.

AGES e-mail 22.07.2022.

HI e-mail 10.10.2023.

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