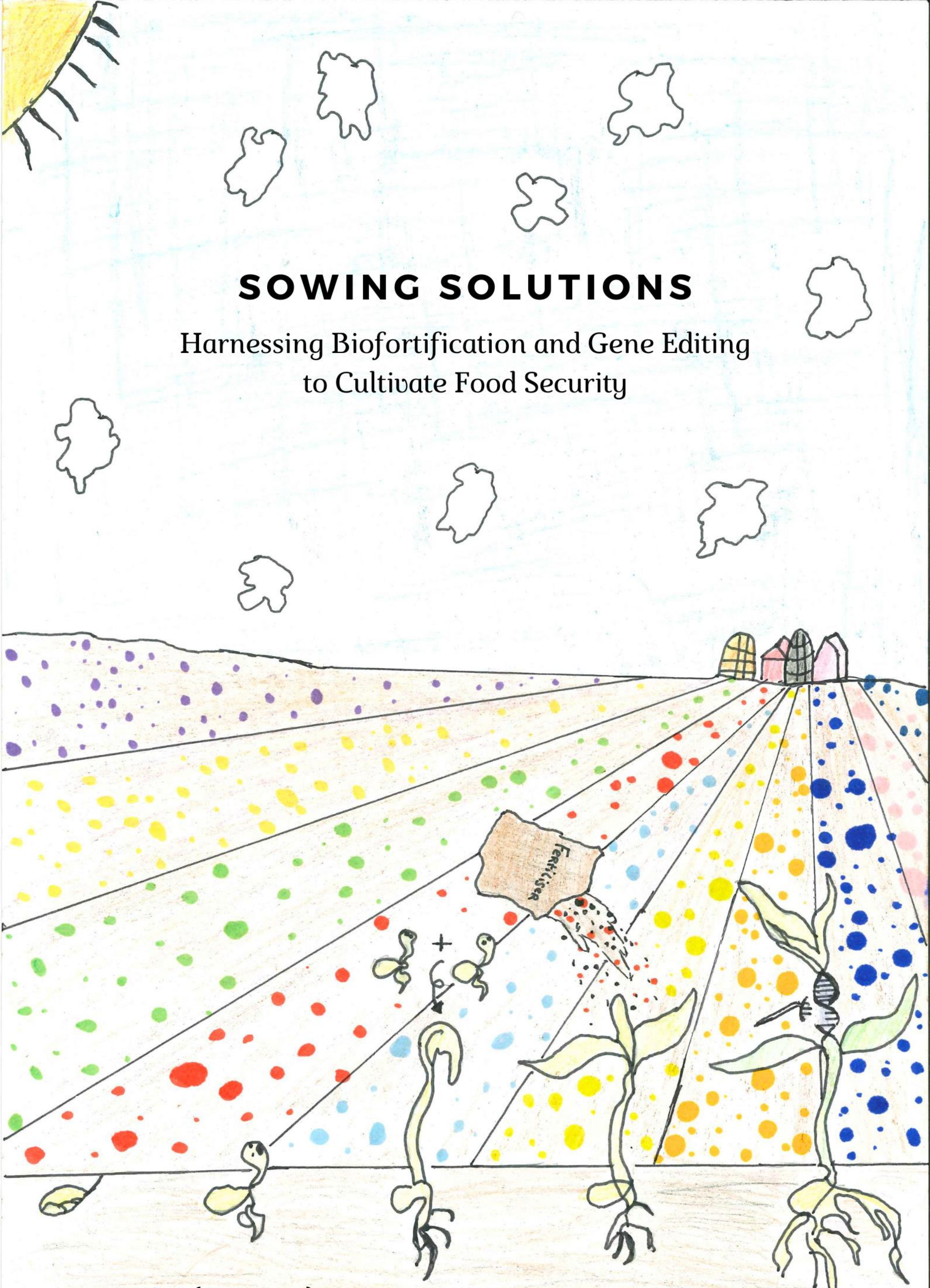
SOWING SOLUTIONS

Harnessing Biofortification and Gene Editing to Cultivate Food Security



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Sowing Solutions

Harnessing Biofortification and Gene Editing to Cultivate Food Security

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A Research

Submitted to the Law Chair Group

Wageningen University & Research

In Partial Fulfilment of the Requirements

for the master's degree in Food Safety Law and Regulatory Affairs

May 2024

Disclaimer: I hereby declare that this dissertation is my own original work and has not been submitted before to any institution for assessment purposes.

Acknowledgements

I want to express my deep appreciation to my supervisor, Dr. Radha Jethu, for her assistance, interest in the subject, and constant readiness to answer all my questions. Her advice and enthusiasm in developing this thesis, and her extensive knowledge and skills provided strong groundwork for my thesis.

I would also like to thank my family and friends. Their willingness to participate in conversations on the subject, to give advice, their enthusiasm about the topic, and them helping me relax during my breaks were essential in keeping my health and concentration intact during this experience.

Finally, I want to show my sincere gratitude to all the specialists who generously committed their time to have discussions with me. Their significant experience and deep understanding greatly contributed to the results of this study. Their comments helped increase my understanding and offered multiple viewpoints on topics like food security, biofortification, and GMOs. This resulted in a giving me a more comprehensive understanding of these intricate topics.

This thesis could not have been completed without the assistance, encouragement, and input of all these individuals, and I am sincerely thankful for their support and direction.

Abstract

By 2030, over 670 million people worldwide will still face hunger, with 37 million in the EU unable to afford a quality meal every other day. Hidden hunger, caused by a lack of essential micronutrients, affects one in three people globally and is the most common form of malnutrition. The Green Revolution, while increasing agricultural output, worsened hidden hunger by limiting access to diverse fruits and vegetables and focusing on staple crops. The right to food, a fundamental human right, ensures regular access to culturally appropriate food for a dignified life. Food security goes beyond averting hunger and includes access to safe and nutritious food that meets dietary needs and preferences. Rebalancing the current inefficient food system is necessary for sustainable and environmentally friendly food systems. The discourse on hunger and malnutrition highlights the importance of addressing hidden hunger, improving food quality, and promoting access to culturally appropriate and sufficient food for all individuals.

Biofortification offers hope in addressing malnutrition and micronutrient deficiencies. However, the lack of coherent legislation, particularly in new genomic techniques, transgenic biofortification, and GMOs, poses challenges. This thesis aims to analyse the relevance of biofortification in combating hidden hunger, considering alternative methods and gene alterations within the regulatory landscape.

This interdisciplinary thesis used a mixed-method design using primary and secondary research, including literary research and four semi-structured expert interviews.

Food security is a multifaceted issue requiring access to quality and culturally relevant food. Advocates have pushed for food security and sustainable farming practices. Due to consumer acceptance and GMO debates, challenges arise in nutrient fortification and biofortification. Robust regulatory approaches are essential for addressing food security and ethical concerns. The success of biofortification relies on regulatory support and flexible policies, with the need for harmonised global standards to promote innovation and sustainability.

Biofortification and gene editing are crucial for improving food security by enhancing nutrition, sustainability, and resilience. Biofortification targets malnutrition by enriching crops with essential nutrients, benefiting vulnerable communities. Gene editing enhances crop resilience, productivity, and nutritional value amidst climate change. However, regulations for these technologies are complex globally and, in the EU, with varying approaches to gene editing. The study explored the need for harmonisation in regulatory standards to support global food security. Interviews with experts highlighted factors influencing consumer acceptance and equity challenges.

This thesis has a small sample size with only four expert interviews, allowing for in-depth exploration of viewpoints but potentially limiting the diversity of perspectives. However, the experts from various relevant fields provide insight into current attitudes without being fully representative. Semi-structured interviews provide rich qualitative data but may introduce bias. Interviewer influence and reliance on literature could limit the exploration of new perspectives. Video interviews, due to logistical issues, may impact rapport and data quality compared to in-person. Biases in transcription and analysis highlight the need for cautious interpretation of findings to ensure clarity and objectivity.

Future research should focus on closing knowledge gaps, exploring long-term impacts, and promoting transparent regulations for sustainable food systems. Policymakers must balance innovation with precaution while addressing ethical considerations for equitable access and sustainability.

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List of abbreviations

AIA	Advanced Informed Agreements
CAC	Codex Alimentarius Commission
CAP	Common Agricultural Policy
Cartagena Protocol	Cartagena Protocol on Biosafety under the Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Center for Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Center
CRISPR/Cas9	Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR-Associated protein 9
DAL	Disability-Adjusted Life Years
EFSA	European Food Safety Authority
ERA	Environmental Risk Assessment
EU	European Union
FAO	Food and Agriculture Organisation
FFI	Forever Food Initiative
GAIN	Global Alliance for Improved Nutrition
GATT	General Agreement on Tariffs and Trade
GMO	Genetically Modified Object
ICCIDD	International Coordinating Committee on Iodine Deficiency Disorders
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social, and Cultural Rights
IFAD	International Fund for Agricultural Development
IFPRI	International Food Policy Research Institute
IRRI	International Rice Research Institute
IZINCG	International Zinc Nutrition Consultative Group
LMO	Living Modified Organism
MEA	Multilateral Environmental Agreement
NAFTA	North Atlantic Free Trade Agreement
NGT	New Genomic Technique
OECD	The Organization for Economic Cooperation and Development
SDG	Sustainable Development Goal
SDN	Site-Directed Nucleases
SPS Agreement	Application of Sanitary and Phytosanitary Measures Agreement
SUN	Scaling Up Nutrition
TBT Agreement	Technical Barriers to Trade Agreement
UDHR	Universal Declaration of Human Rights
UNICEF	United Nations Children's Fund
WFP	World Food Programme
WHO	World Health Organisation
WTO	World Trade Organisation

1. Introduction

1.1 Context

In the shadow of progress, a sombre reality persists by 2030, nearly 670 million people will still face hunger and in the European Union (EU) over 37 million people cannot afford a quality meal every other day (European Commission, n.d.-a; FAO, n.d.). However, hunger characterised by an insufficient energy intake to live a normal life is only the tip of the iceberg; beneath lies the spectre of hidden hunger. Hidden hunger is characterised by a diet lacking essential micronutrients for optimal mental and physical health (Ritchie et al., 2023; Sharma et al., 2017). Additionally, with one in three people globally suffering from one or more micronutrient deficiencies, it is the most prevalent form of malnutrition (Hefferon, 2023; Van Der Straeten et al., 2017).

The Green Revolution offered a ray of hope by increasing agricultural output. However, the Green Revolution only exacerbated hidden hunger by limiting access to a diverse range of fruits and vegetables essential for a healthy diet and instead focusing solely on staple crops (Hefferon, 2015). Moreover, non-staple crops became more expensive and less available, which again only increased the problem of hidden hunger (Van Der Straeten et al., 2017). Consequently, the resulting dependence on calorie-dense staple crops like maize, rice, and wheat has not adequately solved the hunger problem and only helped reduce quantitative malnutrition without reducing qualitative malnutrition or hidden hunger (Sharma et al., 2017; Van Der Straeten et al., 2017). Thus, the Green Revolution, while increasing food quantity, failed to improve its quality (Sharma et al., 2017).

Central to the discourse on hunger and malnutrition lies the right to food, enshrined in the Universal Declaration of Human Rights (UDHR), and further elaborated in the International Covenant on Economic, Social, and Cultural Rights (ICESCR) (FAO, n.d.). However, the right to food is not just a moral or policy concern; it is a fundamental human right, encompassing the Right to Adequate Food, that entails having regular access to culturally appropriate food to ensure a dignified life (FAO, n.d.; Ramcharan, 2021). Food must be sufficient, accessible, and available to benefit everyone. This right imposes obligations on states to respect, protect, and fulfil individuals' access to culturally appropriate and sufficient food, in both a facilitating and providing manner, but does not in itself include the right to food security (Oguamanam, 2015; Ramcharan, 2021).

But as Dannenberg et al. (2024) point out, food security involves more than just averting hunger. In the words of the World Food Summit 1996, "Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life" (FAO, 2006). This includes not only maintaining a healthy diet but also adhering to cultural standards and personal ethical ideals. Moreover, according to Amicarelli & Bux (2020), it is impossible to discuss sustainable food systems without first rebalancing the current inefficient food system to something fair, healthy, and environmentally friendly.

Amidst this backdrop, biofortification appears as a ray of hope, promoted by organisations like HarvestPlus, part of the Consultative Group on International Agricultural Research (CGIAR) (HarvestPlus, n.d.; Meinke et al., 2023). However, the amount of clear and harmonised legislation on biofortification, especially on biofortification through new genomic techniques, trans- and cisgenic biofortification and Genetically Modified Objects (GMOs) is limited and often vague.

This thesis will start with an introduction that provides a short background information on the Green Revolution, malnutrition, micronutrient deficiencies, the right to food, food security, sustainability, and biofortification. A more in-depth analysis of these topics is given in the theoretical framework, chapter two. After this, the aim and relevance, research questions and objectives, methodology and the structure of this thesis will be discussed.

1.2 Problem statement and relevance

1.2.1 Aim and Relevance

The relevance of this thesis is based on the need for nutrient-rich food to combat micronutrient deficiencies while keeping in mind the sustainability goals. The European Commission adopted the proposal for a regulation on New Genomic Techniques (NGTs) as part of the proposals for legislative frameworks to support the Farm to Fork Strategy (European Commission, n.d.-b).

This thesis aims to fill the research gap on the regulatory issues and ambiguity between different regions, countries and organisations regarding biofortification through not biologically induced genetic changes. To do so, this thesis will investigate the relevance of biofortification as a strategy to combat hidden hunger, potential alternatives, and methods of biofortification with a focus on gene alterations and the relevant regulatory landscape. To this end, the thesis will look at policy tools, communication documents, reports of organisations active in the field and United Nations publications.

Overall, this thesis will highlight the importance and need for attaining sustainable food security and clear legal frameworks to support biofortification efforts.

1.2.2 Research questions and research objectives

This thesis aims to describe the existing legislative body on biofortification and gene editing and establish its role in food security. To achieve this, the following research question and sub-questions have been established.

1.2.2.1 Main research question

What is the role of biofortification and gene editing in enhancing food security, and how are these technologies currently regulated and governed in policy frameworks on the International and EU level?

1.2.2.2 Sub-questions

1. What theoretical foundations support the role of biofortification in improving food security, and how do these foundations inform policy development and implementation?

2. How does biofortification compare to alternative food-based strategies such as dietary diversification, fortification, supplementation and more, regarding consumer acceptance, sustainability, and socioeconomic and environmental implications, and what policy implications arise from these comparisons?

3. How do variations in existing regulatory standards for nutrient-enriched biofortified foods across countries intersect with international regulatory bodies, initiatives like the EU's Green Deal, and existing trade agreements, in the context of enhancing food security through biofortification and gene editing?

4. Given the complexities of regulatory standards and trade agreements, how can harmonisation strategies ensure global consistency while facilitating the adoption and diffusion of biofortified agriculture?

1.3 Methodology

This interdisciplinary thesis uses a mixed-method design, including literary and empirical research, e.g. interviews.

1.3.1 Literature research

Drawing primarily from secondary legal sources like law journal articles, policy documents, communications, and guidance documents and primary law sources like international regulations, Trade agreements, EU Directives and Regulations (Highline College, n.d.). The non-legal disciplines used are human nutrition and environmental approaches.

Moreover, non-legal sources, such as scientific journal articles, scientific opinions and reviews, and grey literature, were included in this thesis to explain theories, provide evidence and context for the nutritional information, and support and analyse the application and suitability of various approaches to combat micronutrient deficiencies (Simon Fraser University, n.d.).
The answers to the thesis's (sub) research questions are obtained using legal and non-legal sources

and interviews. The articles are obtained from sites like Scopus, Westlaw, and PubMed. EUR-Lex is used to obtain EU communications, regulations, and directives.

1.3.2 Interviews

The interviews were conducted through qualitative semi-structured interviews. The interview guide can be found in Appendix 1. The interviews were conducted through online video calls via Microsoft Teams, which lasted between 50 and 90 minutes, depending on the person interviewed. The semi-structured nature of these interviews makes them a meaningful addition to this research as they contain both preset open-ended questions and leave the possibility for unplanned follow-up questions (Adams, 2015; Jamshed, 2014). These questions asked during the interviews are based on legal and non-legal sources. There were 17 preset questions, but depending on the interviewee and their answers, some were passed over or added. The complete interviews can be read in Appendix 2. A total of 4 interviews were conducted for this thesis.

1.3.3 Limitations

This thesis was written between January and July 2024. As this is a qualitative thesis it is prone to subjectivity and researcher biases. To limit these effects, findings will be compared to previous findings and conclusions drawn from the same or similar research. As the field of law, regulatory affairs, and nutrition knowledge is ever-changing and the body of literature is only increasing, not everything can be included. Therefore, it is imperative to identify the period discussed, limited to literature made publicly available before April 15th, 2024. This, combined with the potential subjectivity of personal interpretation, the risk of research bias, low validity, and the exact people approached for the interviews could negatively affect the replicability of this thesis.

For this thesis, interviews were conducted, both people who are against biofortification and those in favour were approached. However, finding multiple interviewees who are knowledgeable and willing to talk about it proved challenging. Additionally, interviews carry the risk of the interviewees giving socially desirable answers.

1.4 Conceptual framework model

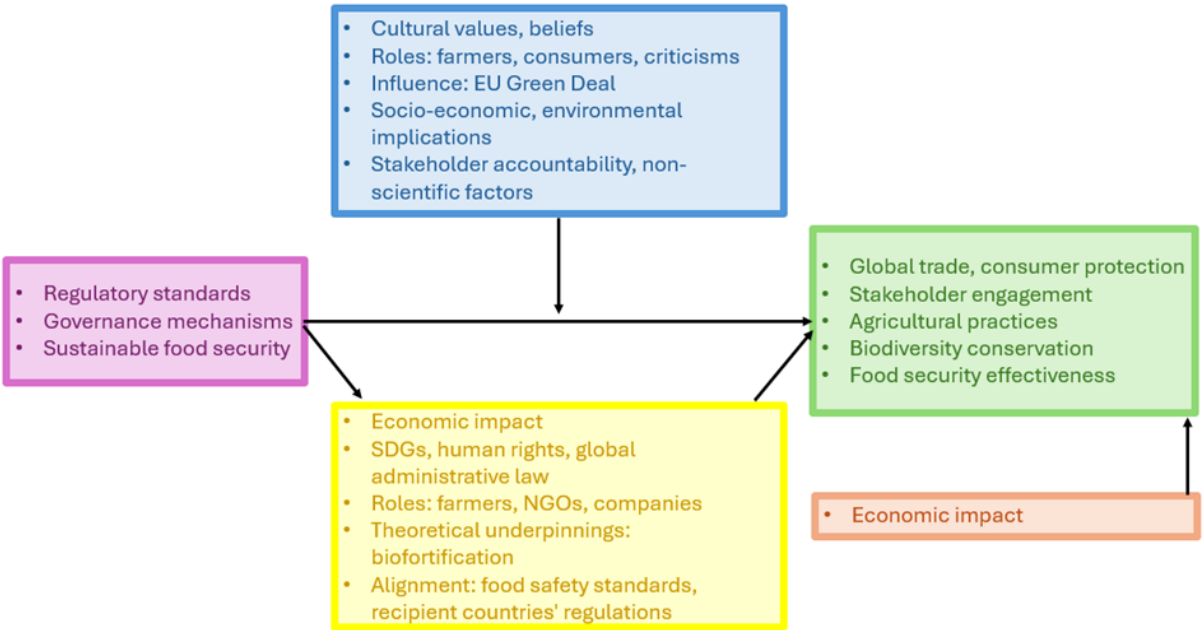

Figure 1: The purple box of the conceptual framework indicates the independent variables, the blue box the moderating variables, the yellow box the mediating variables, the green box the dependent variables and the orange box the control variables.

1.5 Chapter structure

This thesis is divided into seven chapters. The first chapter consists of the introduction, the second chapter is the theoretical framework, the third chapter covers food security, the fourth chapter covers policy and regulation, the fifth chapter contains the methodology and results of the field research, the sixth chapter consists of the discussion and the seventh and closing chapter consists of the conclusion.

The first chapter, “Introduction”, provides an overview of the background information necessary to understand the thesis’s research, main aims, and objectives. The research questions and overall methodology are also illustrated here. The second chapter provides the theoretical framework, expanding on the information given in the introduction to an academic level by looking into theories.

The third and fourth chapters introduce the subjects of GMO and biofortification regulation and policy and food security, respectively. The third chapter, called “Food Security”, introduces the available knowledge on food security including food acceptability and food waste, but also the diverse ways and programmes to achieve this and their respective advantages and disadvantages such as (bio)fortification, and its variations, supplementation, and dietary diversification. This chapter also illustrates the effect of climate change on food security, GMO biodiversity and the Common Agricultural Policy (CAP). The fourth chapter, called “Policy and Regulation” introduces the existing body of policy and regulation around the world and through the chapter more focus is put on the EU, it also includes topics like harmonisation, and the commercialisation of gene-edited crops, the precautionary principle and substantial equivalence. It starts with the global regulatory landscape and then concentrates on the USA as an example of a product-based approach, and then the process-based approach of the EU is explained. Chapter five describes the methodology and results of the conducted field research. Finally, this thesis will end with chapters six and seven. In chapter six, called “Discussion”, the considerations arising from the overall analysis in the context of the thesis questions and the literature study will be explained and interpreted, and the potential consequences will be examined. This will then support the conclusion and recommendations given in chapter seven.

2. Theoretical framework

2.0 Chapter Introduction

This chapter provides the theoretical framework, expanding on the information given in the introduction and sets out the first part of the sub-question of what theoretical foundations support the role of biofortification in improving food security, and how these foundations inform policy development and implementation. First, the Green Revolution is explained, followed by the right to food. Then, the consequences of malnutrition are explained, followed by the costs of malnutrition. After that, the pillars of food security are explained. Then, the background of biofortification will be given, followed by the link from the previous topics to policy. This chapter will end with a chapter conclusion.

2.1 Green Revolution

Between the 1960s and 1970s doctor Norman Borlaug, father of the Green Revolution, developed dwarf and semi-dwarf varieties of wheat and rice that are high-yielding, short-stature, disease-resistant, and, as a result, highly sensitive to fertilisers, which caused productivity to increase remarkably at a lower cost (Devi & Aglawe, 2021; Hu et al., 2022; Permyakova & Deineko, 2024). The introduction of F1 maize hybrids further contributed to the Green Revolution (J. Singh et al., 2016). Like wheat, the crop productivity of rice has also increased by 140% since the start of the Green Revolution (Devi & Aglawe, 2021).

The need to increase food production in the Global South both in terms of land use and yields per acre, aligns with a Green Revolution model of agricultural development, reflecting one of the most prominent global policy narratives (Vercillo et al., 2023). The innovations rapidly found application on large and small farms, particularly in Asia, where they were introduced in India in 1965 (Paarlberg et al., 2024). Within five years, wheat and rice production nearly doubled (Paarlberg et al., 2024). However, the spread of the seeds of these crops to Southeast Asia and Latin America sparked controversy, while adoption in Africa remained limited due to factors like limited access to irrigation and fertilisers and the lesser dominance of wheat and rice as staple crops (Paarlberg et al., 2024).

By the 1980s, the primary objective changed to adjusting global food production to meet growing demand by addressing obstacles such as pests and diseases (Malézieux et al., 2023). The breeding efforts during the Green Revolution laid the foundation for the emergence of GMOs in plant sciences (Malézieux et al., 2023).

Since the beginning of the Green Revolution, several improvements in crop enhancement have been made, surpassing conventional breeding in both efficiency and time saved through collaborative efforts between international agricultural research centres and national programmes (Devi & Aglawe, 2021; Malézieux et al., 2023). Currently, the goals of the Green Revolution are primarily achieved through subsidising private sector actors (Vercillo et al., 2023). These new achievements have led to a decreased impact of the advancements made during the earlier phase of the Green Revolution, it also brought along new environmental problems, but the successes and adoption have varied across regions (Malézieux et al., 2023; J. Singh et al., 2016). One of these new accomplishments is marker-assisted selection, which helps the introduction of numerous agronomically essential traits, including quality and resistance to (a)biotic stressors in staple food crops like maize, rice, and wheat (Devi & Aglawe, 2021). These traits are important to meet global demands while guaranteeing environmental protection (J. Singh et al., 2016). Conversely, Malézieux et al. (2023) identify a negative correlation between grain weight, yield, and nutritional quality resulting in many staple crops producing grains deficient in micronutrients. This is exemplified by a decreased concentration of essential nutrients like zinc and iron in grains, despite yields doubling in many regions since the 1960s (Malézieux et al., 2023). Additionally, since its inception, the approaches taken for the Green Revolution have also led to challenges like environmental degradation and concerns, which according to Vercillo et al. (2023) calls for a more holistic and sustainable approach to agricultural development.

2.2 Right to Food

The UDHR, adopted in 1948, asserts everyone's right to an adequate standard of living, including food, clothing, and housing (Bokhary, 2022). While some view the UDHR as aspirational, it has profound implications, leading to the creation of the International Bill of Rights, comprising the UDHR and the International Covenant on Civil and Political Rights (ICCPR) and ICESCR (Bokhary, 2022). These treaties establish binding treaty obligations on their Parties, emphasising the fundamental nature of ensuring an adequate standard of living for all individuals (Bokhary, 2022).

While the UDHR recognises the right to food, criticism has been levelled at its perceived lack of enforceability, rendering it an empty manifesto (Pulle, 2012). Nevertheless, several international organisations and agreements, like the ICESCR and Sustainable Development Goal (SDG) 2 of the United Nations, 'Zero Hunger', reinforce the global commitment to ending hunger and promoting sustainable agriculture, emphasising the importance of physical and economic access to nutritious food and ensuring access to adequate food for all (Chattopadhyay et al., 2021; FAO & WHO, 2020; Gonzalez, 2014).

In response to the pressing issue of global malnutrition and micronutrient deficiencies outlined in the UN's Sustainable Development Goal 2, Jiang et al. (2021) emphasise the need for swift action. They suggest a multi-faceted approach involving: gathering comprehensive data on the prevalence of vitamin deficiencies across different populations, particularly focusing on those affected by related disorders; identifying specific vitamin deficiencies contributing to these conditions to guide targeted interventions; and implementing interventions such as vitamin supplementation and educational campaigns promoting dietary diversity and biofortification to improve overall vitamin status. This approach aims to combat malnutrition and promote better health outcomes worldwide effectively (Jiang et al., 2021).

2.3 Consequences of Malnutrition

Deficiencies in one or more micronutrients pose a global concern, it is a leading cause of diseases and immune system disorders, and negatively affect physical and mental development in adolescents and children and learning capacity (Koç & Karayiğit, 2022; Sharma et al., 2017). In developing countries, women, and children under five are especially vulnerable to hidden hunger, which is characterised by insufficient intake of essential micronutrients (Gupta et al., 2022). However, micronutrient deficiencies primarily affect women and children, micronutrient deficiencies also impact adult men and women's productivity (Sharma et al., 2017). Iron and vitamin A deficiencies rank among the top 15 causes of the global burden of disease, contributing to around a million child deaths annually and are especially prevalent in low- and middle-income countries, primarily due to inadequate consumption of nutrient-dense foods and nutrient losses from poor diets and illnesses (Olson et al., 2021). Undernutrition is a factor in over one-third of deaths in children under five globally (Hefferon, 2015; Olson et al., 2021). Limited access to nutrient-rich foods, coupled with diets reliant on staple crops, exacerbates deficiencies in vitamins A, iron, and zinc (Gupta et al., 2022; Mishra et al., 2022). They, together with iodine and folate, are the most common micronutrient deficiencies worldwide (Woods et al., 2020). The first 1000 days from pregnancy to two years of age are crucial for a child's development, deficiencies during this period can lead to severe consequences such as blindness, deficiency diseases, and even death (Mishra et al., 2022; Olson et al., 2021). Additionally, micronutrient deficiencies can result in a range of health issues from stunting, which affects one in four children due to undernutrition, to anaemia and impaired physical activity, night blindness and child morbidity and mortality posing significant challenges to socioeconomic development (Gilligan et al., 2020; Hefferon, 2015; Nayak et al., 2022; Van Der Straeten et al., 2017). They function as a significant barrier to socioeconomic development, particularly in developing nations, with long-term consequences on mental development, thus maintaining a cycle of underdevelopment (Van Der Straeten et al., 2017).

2.4 Costs of Malnutrition

Hess et al. (2021) state that estimating the worldwide burden of disease caused by micronutrient deficiencies is an ongoing effort that requires the use of novel data sources and processing methods as they become available. Disability-Adjusted Life Years (DALY) and the incidence of micronutrient deficiencies are still high even if the burden of micronutrient deficiencies has been declining since 1990 (Han et al., 2022). Estimating the worldwide burden of illness associated with micronutrient deficiencies is currently hampered by the low availability of data on the micronutrient status from reflection surveys. Owing to the restricted data accessibility, approximations are employed to estimate the values. However, this is likely going to lead to an underestimate of the actual extent of deficits and the ensuing effects on world health (Hess et al., 2021).

Although attempts have been made to measure micronutrient deficiencies worldwide, these attempts have been hindered by inadequate intake and population-level status data (Olson et al., 2021).

2.5 Pillars of Food Security

Though the interpretation of international human rights has led to the idea of food security, this does not align entirely with the way international trade addresses food security (Tania & Mapulanga-Hulston, 2016). Tania and Mapulanga-Hulston (2016) argue that there is an infringement of human rights if agricultural trade policies harm food security as this affects their right to food. The ICESCR recognises the right to adequate food. As a consequence, the measures to achieve the right to food include using technical and scientific knowledge to their fullest extent while spreading awareness of the principles of nutrition, and structuring or changing agricultural systems to achieve optimal development and utilisation of natural resources (*International Covenant on Economic, Social and Cultural Rights*, n.d.).

Tyczewska et al. (2023) and the FAO (2006) identified six factors that together constitute the framework of food security: access, agency, availability, stability, sustainability, and utilisation. According to Dronamraju (2008), increasing food distribution and consumption is important, and increasing agricultural productivity should also be a priority, especially considering the vital role agriculture plays in ensuring livelihood security. The six factors of the framework of food security are elaborated in the chapter Food Security.

Figure 2: Pillars of Food Security & Nutrition (FAO, 2006; Tyczewska et al., 2023)

2.6 Biofortification

Gene editing involves making targeted changes in the DNA of an organism (Muir, 2014). This process is used to create GMOs, with CRISPR/Cas9 being a common tool for gene editing (Muir, 2014). While there are other methods for producing GMOs, gene editing allows for precise alterations in the genome of an organism for various purposes (Muir, 2014).

The CGIAR outlined five Impact Areas in their Strategy the goal of One CGIAR including nutrition, health, and food security; poverty reduction, livelihoods, and jobs; gender equality, youth, and social inclusion; climate adaptation and greenhouse gas reduction; and environmental health and biodiversity (Meinke et al., 2023). Their research efforts are further outlined in three Action Areas, separating systems transformation, resilient agrifood systems and genetic innovations (Meinke et al., 2023).

Typically targeting crops like cassava, maize, potato, rice, and wheat, biofortification addresses deficiencies commonly found in these staple foods (Van Der Straeten et al., 2017). Most biofortification efforts focus on the same three micronutrients: vitamin A, zinc, and iron (HarvestPlus, n.d.; Nayak et al., 2022). Traditionally, breeding and occasionally modification have been the primary methods of biofortification (Sharma et al., 2017).

A biofortified crop has to meet certain requirements to be successful: it must be profitable and high-yielding for the farmer; it must also be acceptable to farmers and consumers in the intended areas, each age and gender group must consume a certain amount of the staple crop each day; the nutrients must be bioavailable and not lost after harvest (Sharma et al., 2017). Biofortification can be achieved in several ways, this thesis will describe the three most used and well-established:

agronomic biofortification, biofortification through conventional breeding and the use of biotechnology to achieve biofortification (Hefferon, 2015).

The benefits and limitations of the different biofortification strategies will be further expounded in the chapter Food Security.

2.7 Link towards Policy

As regulations on biofortification are missing or lacking, the Codex Alimentarius Commission (CAC) considered several topics: the bioavailability of nutrients, consumer perception, quality consideration and safety. More organisations improve crops' nutrition composition to lower the number of people with micronutrient deficiencies. Among these organisations are the CGIAR, CIAT, CIMMYT, FAO, FFI, GAIN, ICCIDD, IFPRI, IRRI, IZINCG, UNICEF, WFP, and WHO (S. Thakur et al., 2023; V. Thakur et al., 2022).
According to S. Thakur et al. (2023), the food legal systems that have followed food fortification with the greatest degree of success are the FDA in the United States and the EU food rules. However, EU regulatory frameworks do not fully cover the entirety of biofortification.

According to Mampuys (2023), the discussion around new plant breeding techniques, like gene editing, reveals a process of delegation in which questions regarding their legal and scientific classification are raised. The social acceptance of GMOs differs per country; unlike many other environmental issues, it is not divided into the global north and south (Laxman & Ansari, 2023a). Instead, many developed countries have significantly differing policies and regulations on GMOs (Laxman & Ansari, 2023a). According to Laxman & Ansari (2023a), there are disparities between developing countries in terms of how cautiously they are accepting GM crops. While many developing nations remain neutral towards this fast-advancing plant technology, others remain adamantly opposed (Laxman & Ansari, 2023a). Permyakova & Deineko (2024) stated that the unclear social perception of GMOs is caused by the differences in the difficulty of registering a GMO, in some countries this difficulty is significant and in others, it is completely impossible. Moreover, these regulations come with an inflated cost and lengthy procedure (Garg et al., 2018). Another drawback is that several countries have implemented various regulatory frameworks to approve and commercialise these transgenic crops (Garg et al., 2018).

According to Bouis & Saltzman (2017), biofortification must go beyond organisations like HarvestPlus to be able to reach one billion people by 2030. Policymakers need to prioritise the contribution of agriculture to better health (Bouis & Saltzman, 2017). Target country-specific factors include the prevalence of specific micronutrient deficiencies, the population or populations most affected, dietary compositions, infrastructure availability, capacities for food processing and production systems, national regulation, and governmental leadership, all of which influence the optimal fortification strategy (Olson et al., 2021). To this end, national and multinational governments must incorporate biofortification into the nutrition agenda (Bouis & Saltzman, 2017). One of the biggest threats to biofortification programmes is the absence of national and international standards (V. Thakur et al., 2022). Breeding partners in the public and private sectors need to integrate the biofortified trait into all their product lines (Bouis & Saltzman, 2017). Some even call for the requirement of certain actions to educate producers and consumers about the advantages of biofortified crops (V. Thakur et al., 2022). Biofortification will not become the standard operating procedure or the goal of reaching one billion people until there is cross-value chain collaboration (Bouis & Saltzman, 2017).

Though transgenic plants have ushered in a new era for plant cultivation and agriculture, the technology spread has slowed considerably and, in some cases, even stopped due to public opinion and concerns about GMOs (Permyakova & Deineko, 2024).

International trade links significantly influence policy choices in the developing world, especially concerning GMOs (Falkner & Gupta, 2009). Despite the initial development of transgenic crop varieties using recombinant DNA methods in the 1990s, their uptake was not widespread (Paarlberg et al., 2024).

2.8 Conclusion theoretical framework

In this chapter, the theoretical framework is given to provide the necessary background and introductory information to understand the information needed to answer the main research question. It also shows the relevance of the subsequent chapters where the topics are described in more detail and specifically applied to the main research question. The next, third, chapter, Food Security, further elaborates on topics relevant to this subject.

3. Food Security

3.0 Chapter Introduction

This chapter sets out to answer the first two sub-questions: 'What theoretical foundations support the role of biofortification in improving food security, and how do these foundations inform policy development and implementation?', and 'How does biofortification compare to alternative strategies such as dietary diversification, fortification, supplementation and more, in terms of consumer acceptance, sustainability, and socioeconomic and environmental implications, and what policy implications arise from these comparisons?'

Traditionally, a combination of fortification, supplementation, and dietary diversity is used to improve nutrition status. This chapter focuses on the different food-based strategies, and their respective advantages and disadvantages. GMOs are discussed under biotechnological as this is one of the biotechnological approaches to biofortification.

3.1 Theoretical foundation of biofortification

As already mentioned in Chapter 2, the definition of food security has evolved and changed over the past 50 years, including the introduction of the six commonly cited pillars of food security: food availability, access, utilisation, and stability, which have been important in shaping policy.

Figure 3: Pillars of Food Security & Nutrition (FAO, 2006; Tyczewska et al., 2023)

The brief explanation is as follows:
(1) Food availability entails the availability of enough culturally acceptable food of appropriate quality, free from harmful substances in stores, food outlets, imports, and primary production (D'Auria et, 2023; Tyczewska et al., 2023). This includes the costs, quality, selection of food, location of stores, and traditional meals and food aid.
(2) Food access refers to having the financial and physical means to buy nutritious food; Availability and access aspects can both be included in food stability (D'Auria et, 2023; Tyczewska et al., 2023).
(3) Food utilisation refers to the nutritional value of food, feeding practices, dietary diversity, and having the skills to use and prepare food ingredients properly and proportionately (D'Auria et, 2023; Tyczewska et al., 2023). It also refers to the social acceptability of food (Batt, 2024).

(4) Stability refers to the stability of the three previous components over an extended period. In the case of recurring events, such as seasonal food insecurity, or abrupt shocks, such as an economic, health, war, or climatic catastrophe, the capacity to provide food security is referred to as stability (D'Auria et, 2023; Tyczewska et al., 2023).
(5) Agency refers to the ability of people and groups to decide on issues about their local food system. When all households have the financial and material means to purchase enough, qualitative, varying food to guarantee a nutritious diet for all household members, including vulnerable people and groups, food access is ensured (D'Auria et, 2023; Tyczewska et al., 2023). The ability of people and groups to exert some degree of control over their circumstances – to choose what they eat, produce, and how that food is produced, processed, and distributed – as well as to take an active role in the governance processes that influence food systems is referred to as agency (D'Auria et, 2023; Tyczewska et al., 2023).
(6) Sustainability involves not only securing global food access for the current generation but also advocating for eco-friendly approaches to minimise ecological and carbon footprints (D'Auria et, 2023; Tyczewska et al., 2023). It encompasses food system practices that support the lasting regeneration of natural, social, and economic systems (D'Auria et, 2023; Tyczewska et al., 2023). This ensures the fulfilment of present generations' food requirements without jeopardising those of future generations (D'Auria et, 2023; Tyczewska et al., 2023). To achieve a state of nutritional well-being when all physiological demands are satisfied, food utilisation depends on knowledge and comprehension of an appropriate diet (D'Auria et, 2023; Tyczewska et al., 2023). It considers social settings, cultural factors, health care, clean water, sanitation, and cooking, storing, and preparing skills (D'Auria et, 2023; Tyczewska et al., 2023).
Furthermore, D'Auria et al. (2023) identified three additional factors contributing to food sustainability: economic, environmental, and social. These factors can be applied to food safety; responsible food consumption; and a decrease in food waste. Enacting sustainable development involves balancing the environment and pursuing a high standard of living to deviate from the current pattern of development (D'Auria et al., 2023).

The long-term sustainability of food security systems depends on ecological variables, regardless of the guarantee of physical and economic access to food (Dronamraju, 2008). Malézieux et al. (2023) suggest a holistic strategy that acknowledges the interconnectedness of inputs, processes, infrastructures, actors, institutions, and other elements of the food system.
Malézieux et al. (2023) define food systems as encompassing various elements such as individuals, infrastructure, procedures, resources, dissemination, surroundings, etc., along with tasks linked to food cultivation, refining, distribution, cooking, and consumption, and their resulting impacts on society and the environment.

The differences between food security and food insecurity are outlined by Silvee & Wu (2023), who highlight that food security includes both the intake of safe and nutritious food as well as the availability, cost, and accessibility of enough food. Nevertheless, even if food is easily accessible, cheap, and abundant, the presence of unsafe and nutritionally deficient food may still result in food insecurity (Silvee & Wu, 2023). This contrast emphasises two separate factors of food security: the adequacy of food availability and the quality and safety of food (Silvee & Wu, 2023).

3.2 Comparison of biofortification, dietary diversification, fortification, supplementation

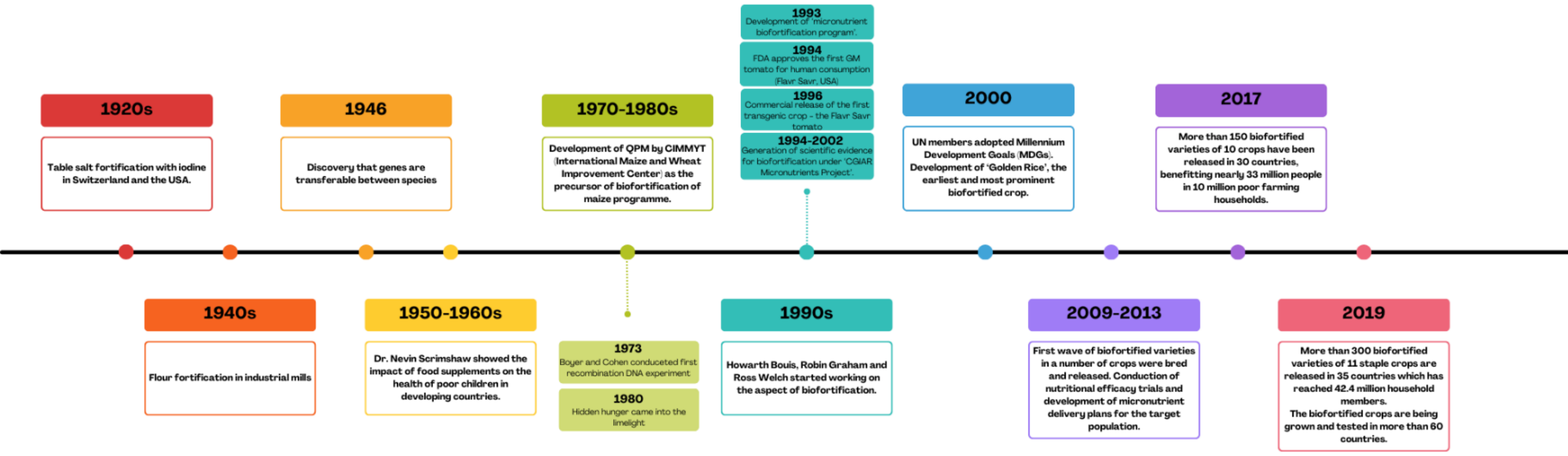

Figure 4: Timeline of GMOs and Biofortification (Abdul Aziz et al., 2022; Ghouri et al., 2022; Kumar et al., 2022)

The FAO and WHO have proposed and used various food-based strategies to combat hidden hunger, like biofortification, dietary diversification, supplementation, and fortification (Nayak et al., 2022; Sharma et al., 2017; Vishwakarma et al., 2022). While these approaches have shown promise, they have each encountered limitations primarily caused by economic, social, and technical challenges (Sharma et al., 2017). The bioavailability of an ingested micronutrient is also important as this determines the amount of micronutrients taken up in the body from the ingested food (Hefferon, 2015). Bioavailability refers to the amount of a nutrient that an individual can absorb and use, and it can be affected both positively and negatively by other nutrients and chemical compounds (J. Singh, 2016). It can also be affected by processing and cooking methods. Furthermore, traditional methods of cooking have been proven best to improve the bioavailability of nutrients such as iron (Yadav et al., 2020). Moreover, Granato et al. (2023) mention the need for functional foods that have a potentially beneficial effect on human health when consumed regularly in certain amounts, for sustainable food consumption and production, but also for human health and the prevention of illnesses.

In the context of the SDGs, Scown & Nicholas (2020) note that the CAP currently aligns with SDGs 1 and 2, and is most relevant for 2, 6, 12, 13 and 15. Nevertheless, as indicated by Bayramoglu et al. (2023), the EU's focus on meeting nutrition goals emphasises the importance of moving towards sustainable food systems. This becomes even more apparent once the fact that European, and more generally Western[1], diets frequently differ from national dietary guidelines is considered, necessitating dietary changes for health and sustainability purposes, like the SDGs (Abdul Aziz et al., 2022; Bayramoglu et al., 2023).

Even though nutrition policies focus on improving national health outcomes, their impact extends to global concerns like climate change mitigation thereby blurring the distinction between private and public goods (Bayramoglu et al., 2023). In this situation, the EU, as a global key player, has the responsibility to ensure its policies support global resilience, like food security, without worsening

[1] The Western diet consists of consuming large amounts of processed foods, refined grains, red and processed meat, sugary drinks, sweets, fried foods, conventional animal products, high-fat dairy, and products high in fructose (Clemente-Suárez et al., 2023).

environmental damage elsewhere (Poppe, 2023). Advancements in agricultural biotechnology make it possible to increase crop yields, improve nutrition, and reduce environmental impacts (Abdul Aziz et al., 2022). Gene editing tools like Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR-Associated protein 9 (CRISPR/Cas9) have the potential to significantly contribute to improving worldwide food security and sustainability (Abdul Aziz et al., 2022).

However, the CAP has inadvertently disrupted local markets in developing countries by introducing high tariff rates and export subsidies in sectors like bioenergy, trade, and development aid (Pânzaru et al., 2023). These actions have resulted in affordable agricultural imports, weakening the competitiveness of local producers and exacerbating food insecurity in regions like West Africa, the Middle East, India, and the Caribbean (Pânzaru et al., 2023).

Considering these challenges, sustainable food systems necessitate a comprehensive approach that considers both domestic and global concerns, ensuring alignment between agricultural policies and broader development goals (Poppe, 2023). The focus of the EU's efforts to improve global food security should be on supporting food supply chains in developing countries rather than harming their markets with goods that come at the cost of environmental health and biodiversity (Poppe, 2023).

3.2.1 Biofortification

Biofortification, a process aimed at increasing the bioavailability and quantity of essential micronutrients in plants, offers a sustainable solution to malnutrition by directly adding essential nutrients in the field or the plants, thereby enhancing the nutritional content of staple crops and combining various techniques to address global micronutrient deficiencies (Gilligan et al., 2020; Koç & Karayiğit, 2022; Monika et al., 2023; Nayak et al., 2022; Sharma et al., 2017).
Using contemporary biotechnology techniques, biofortification aims to purposefully raise the amounts of essential micronutrients such as vitamins and minerals in food crops (Vishwakarma et al., 2022). Agronomic techniques apply micronutrient-rich fertilisers directly to crops, transgenic biofortification employs gene insertion for targeted delivery, and conventional practices crossbreed staple crops with nutrient-rich varieties (Vishwakarma et al., 2022).

Biofortification's targeted approach contrasts with the approach taken with dietary diversification, which advocates for consuming a variety of foods to ensure a spectrum of micronutrient intake (Malézieux et al., 2023). Gilligan et al. (2020) found that for biofortification to be effective as a public health intervention, a significant portion of families must transition from traditional low-nutrient staple crops to biofortified nutrient-dense crops. Crop trait improvement is speeding up as new breeding techniques, such as gene editing, are becoming more widely accepted (Lassoued et al., 2021). These modern technologies present a chance to enhance food security and tackle societal issues not solved by traditional breeding and the first generation of GMOs (Lassoued et al., 2021). Furthermore, Kumar et al. (2022) discuss specific actions in the biofortification of crops like beans, pearl millet, rice, wheat, orange-fleshed sweet potato, cassava, and maize to address deficiencies in iron, zinc, and vitamin A. These initiatives underscore the intricate approach required to effectively tackle hunger. Incorporating biofortified foods into the diet requires promoting widespread adoption of the novel crop varieties, which in many poor, rural African and Asian communities where people have limited access to markets, is difficult (Gilligan et al., 2020).

3.2.1.1 Methods of Biofortification

Conventional breeding

Conventional breeding through mutagenesis is the oldest form of biofortification going back to 300 BC, this is called domestication historically focused on crop resistance and yields without considering nutritional values (Permyakova & Deineko, 2024; V. Thakur et al., 2022; Yadav et al., 2020). This results in conventionally bred fortified crops being more accepted than transgenic crops (Marques et al., 2021).

This technique has the benefit of being cost-effective and eco-friendly (Marques et al., 2021; Nayak et al., 2022). It is also easy and convenient (V. Thakur et al., 2022). Compared to some agronomic techniques, this approach to biofortification is more sustainable as it does not rely on increasing the amount of synthetic compounds used in agroecosystems (Marques et al., 2021). Still, it is also costly, labour-intensive, time-consuming, and relies on both the plant variation and the environment, including soil content, for successful biofortification (Lassoued et al., 2021; Marques et al., 2021). The success of this technique is dependent on genetic variations and supply for the aimed traits, as such there is a need to identify which cultivars should be used to improve the nutritional status (V. Thakur et al., 2022; Yadav et al., 2020).

However, as mentioned by Girish et al. (2021), undesirable genes can be transferred with helpful genes while the progeny's DNA is randomly rearranged from two mixed parent genomes and some genes also might be absent in the offspring. These issues can be resolved by plant breeders by repeatedly backcrossing to the parent (Dhaliwal et al., 2022). Conventional breeding can cause unintended effects that can potentially be dangerous (Girish et al., 2021; Permyakova & Deineko, 2024). Additionally, crossing to distant relatives may overcome limitations like insufficient genetic variability for micronutrients in the plant gene pool and the time needed to generate cultivars with desired traits, but breeding for specific traits using conventional means can be unrealistic (Garg et al., 2018; V. Thakur et al., 2022). According to Nayak et al. (2022), some researchers discovered a negative correlation between zinc content and grain production and that biofortification through conventional breeding and biotechnology had an impact on grain yields.

Agronomic

Agronomic biofortification is widely used to enhance micronutrient concentrations in the edible portion of plants through the application of fertilisers, either directly absorbed from the soil or through soilless cultivation systems (Mishra et al., 2022; V. Thakur et al., 2022). An example of agronomic biofortification is selenium biofortification in wheat, which has shown promise globally (Mishra et al., 2022). Similar successes have been observed in crops like soybeans, chickpeas, field peas, and beans fortified with zinc and selenium using various techniques (Mishra et al., 2022). Moreover, Nayak et al. (2022) show zinc fertilisation in cereals increased the zinc concentration in the grains and increased the yield, suggesting agronomic biofortification as a quick and complementary solution to other biofortification methods.

While this technique temporarily increases the nutritional value of crops by physically applying different nutrients, including potassium, phosphorus, and nitrogen, its success can be unpredictable, particularly given variations in mineral transport and accumulation in plants and soil compositions across regions (V. Thakur et al., 2022; Yadav et al., 2020). Despite these challenges, agronomic biofortification remains an efficient technique to address micronutrient deficiencies in crop plants (Monika et al., 2023).

Improving soil conditions, especially chemical composition, has gained significant attention globally due to the scarcity of ideal soil for plant development. As agricultural operations have increased, different methods for adding soil fertilisers have been applied more often and are effective (Dhaliwal et al., 2022). Agronomic biofortification, involving both organic and inorganic fertilisers, has the benefit of being simple and time-efficient and the limitations of being costly, labour-intensive, unsustainable, and reliant on both the within-species variation and environment for successful biofortification (Hefferon, 2015; Marques et al., 2021). Where organic fertilisers offer a higher bioavailability than inorganic fertilisers (Mishra et al., 2022). Despite its benefits, the method demands constant input. It faces challenges, such as decreased bioavailability from anti-nutrient compounds and environmental impacts from fertiliser residues, leading to reduced biodiversity (Garg et al., 2018; Marques et al., 2021; V. Thakur et al., 2022; Yadav et al., 2020).

Biofertilisers, another form of agronomic biofortification, have the benefits of being simple, eco-friendly, and timely (Marques et al., 2021). However, they are also costly and depend on environmental conditions for efficacy (Marques et al., 2021).

Agronomic biofortification provides a solution for crop nutrient deficiency issues and is an efficient technique and supplemental way to reduce different micronutrient deficiencies in crop plants (Monika et al., 2023). However, it only works with certain minerals and plant species, including crop genotype and phenotype, and requires careful consideration of methods and cost economies to benefit impoverished populations (Garg et al., 2018; Marques et al., 2021; Mishra et al., 2022).

Biotechnological

DNA determines the characteristics of an organism, if the DNA is changed the characteristics can also be changed (Dutta, 2017). Genetic modification is the process of adding desired traits to or deleting unwanted traits from an organism's genetic profile by introducing DNA segments from the same, cisgenesis, other, transgenesis, species (Dutta, 2017). Compared to traditional breeding methods, GM technology offers a more precise and efficient means of modifying the genetic composition of crops (Girish et al., 2021). Organisms with modified DNA exhibit unique features from those with unmodified DNA, and GM technology facilitates the simultaneous addition of multiple traits without extensive crossbreeding (Dutta, 2017; Girish et al., 2021). Furthermore, the transfer of genetic material in GM crops is specifically focused and reduced, lowering the chances of unwanted traits being transferred alongside the desired ones and expediting the progress of crops with enhanced traits (Girish et al., 2021; Sharma et al., 2017).

Normally, GM crops do not contain any inserted foreign DNA, as this is only the case with transgenic genetic modification, many scientists think that they may be compared to mutation breeding (Devi & Aglawe, 2021). The basis for all breeding methods, conventional, mutation, new breeding techniques, GM, and gene editing, is a genetic variation of the initial genotype (Devi & Aglawe, 2021). Even though there are multiple ways of manipulating plant genes, like conventional breeding, cell fusion techniques, and mutagenesis, only organisms obtained using recombinant nucleic acid techniques can technically be called GMOs (Dutta, 2017; UN. Secretary-General, 2023). This can be further divided into cisgenic and transgenic GMOs. Cisgenic organisms are the result of using genetic material from a species that can naturally reproduce with its host or from the same species, and transgenic organisms are created when genetic material from one species is incorporated into the host (Dutta, 2017). The newly changed genetic material then starts expressing itself, leading to the desired trait being present in the GMO (Dutta, 2017).

To treat micronutrient deficiencies, transgenic biofortification—a common strategy among many crop types—involves directly adding genetic material into the plant genome (V. Thakur et al., 2022). Transgenic plant research has reduced the quantity of pesticides and herbicides used in agriculture, altered intensive farming practices, and improved yield, input efficiency, and resistance to biotic and abiotic stressors (Permyakova & Deineko, 2024; Shew et al., 2018; UN. Secretary-General, 2023). Additionally, little to no extra environmental pressure is needed to achieve these gains (Shew et al., 2018). Moreover, the limitation of restricted genetic variation among plants is overcome (Garg et al., 2018). Transgenesis makes it possible to add genes from other organisms, like animals, bacteria, plants, viruses and more, to be incorporated into the plant and facilitates mutagenesis and gene silencing induction (Jiang et al., 2021; Permyakova & Deineko, 2024).

In addressing global food security, GM crops offer higher yields, improved nutritional value, and reduced environmental impact through decreased pesticide usage (Sharma et al., 2017). According to the UN Secretary-General's (2023) report on agricultural technology for sustainable development, gene editing has the potential to enhance nutritional status, food security, and environmental sustainability. Nonetheless, concerns around safety such as potential harm to non-target organisms and biodiversity loss necessitate comprehensive risk assessment, evaluation, and regulation (Sharma et al., 2017). One of the big limitations of transgenic crops is their acceptance, for it to help with global food security, farmers and the community must adopt biofortified crops in large enough quantities to enhance the community's overall nutritional health (Garg et al., 2018; Sharma et al., 2017). Furthermore, even though it is established that agricultural biotechnologies, like gene editing, have the potential to boost food and agricultural production systems' productivity, their application is uncommon in developing countries due to regulatory frameworks, funding constraints, access restrictions, and intellectual property right laws (UN. Secretary-General, 2023). However, acceptance by environmentalists, farmers, the public, and governing bodies has been a contentious subject from the inception of GM technology-derived crops (Devi & Aglawe, 2021). Without the implementation of technology-derived crops, it is impossible to achieve food security in vulnerable communities around the world (Devi & Aglawe, 2021). Therefore, it is important to look at the policies that exist on GMOs.

National and international support is crucial for the spread of biofortified crop types, as large-scale production systems bear the majority of the expenses (Malézieux et al., 2023). As stated by Malézieux et al. (2023), regulatory restrictions and varying food preparation methods are hindering the widespread adoption of biofortified crops.

3.2.1.2 Advantages of Biofortification

Various initiatives have played a significant role in the success of biofortification, which has demonstrated great promise in enhancing the nutritional value of crops. For example, the cost-benefit ratio analysis of biofortified cassava with provitamin A trait demonstrates promising results, suggesting a nearly twofold increase in effectiveness compared to oral vitamin delivery interventions (Sharma et al., 2017). While GM crops have not been widely adopted, agricultural innovations like GM crops have quickly become popular in modern farming practices in the last twenty years (Girish et al., 2021; Sharma et al., 2017). GM crops offer numerous benefits, including increased food production efficiency, customer satisfaction, and health advantages through dietary supplementation, contributing significantly to global, sustainable, agriculture (Girish et al., 2021).

The biofortification programme's success is due to multiple key factors, such as the collaboration of HarvestPlus, CIP, and various CGIAR centres, in addition to more than 500 global partners, including governments, research institutions, NGOs, and farmers (Mishra et al., 2022). Furthermore, investment in biofortification has shown significant potential returns, as indicated by cost-effectiveness analyses. According to Monika et al. (2023), the 1993 World Bank report stated that public health measures that cost less than 150 USD per DALY are extremely cost-effective. Additionally, they reported how, even when using pessimistic estimates, the biofortification of rice has a positive impact of less than 20 USD per DALY (Monika et al., 2023).

Crop biofortification has the benefit of ensuring regular access of rural and poor populations to nutrient-dense food in appropriate amounts without causing changes in their diets (Sharma et al., 2017). The initial investment for crop biofortification is high, but the recurring expenses are minimal, and the germlines can be moved across borders (Mishra et al., 2022; Sharma et al., 2017).

Biofortified crops are highly sustainable as the crops will continue to grow and be consumed, even if government focus and international financing on micronutrient concerns diminish (Sharma et al., 2017). According to Monika et al. (2023), HarvestPlus reports that approximately 9.7 million farming families grow biofortified crops in Latin America, Africa, and Asia, showing a 14% increase from 2019. These crops are now being eaten and providing benefits to more than forty-eight million household members (Monika et al., 2023).

3.2.1.3 Disadvantages of Biofortification

The obstacles that biofortified crops, particularly those developed through biotechnology, encounter include expensive production costs, meeting regulatory requirements, and securing public acceptance throughout their creation and utilisation phases (Mishra et al., 2022). Issues related to ownership and intellectual property rights are often brought up by transgenic technologies, requiring thorough monitoring (Mishra et al., 2022). For biofortification initiatives to succeed, both farmers and consumers must be open to accepting alterations in the appearance and taste of crops, as illustrated by the example of golden rice (Mishra et al., 2022). Attempts to narrow the divide between the biotechnology industry and public acceptance focus on emphasising the importance of communication between policymakers and the public, increasing the body of studies on product risks, ensuring transparent regulatory procedures, encouraging authentic community engagement, and educating the public on genetic engineering and gene cloning to enhance local comprehension (Hafeez et al., 2023). Notably, one of the key differences between plant breeding using non-targeted mutagenesis and NGT plants is that the number of mutations is usually lower in the latter (Koller & Cieslak, 2023). Additionally, the European Food Safety Authority (EFSA) also suggest off-target modifications in targeted mutagenesis are fewer and similar in type to those in conventional breeding (European Commission, 2023). And they stress the significance of determining whether foreign DNA is present in the finished product (Koller & Cieslak, 2023).

Conversely, when compared to conventionally bred crops, the genomic regions and context and their frequency may vary due to the technological features of NGTs (Koller & Cieslak, 2023). Non-target mutations, like targeted mutations in NGT, follow a non-random pattern, which may result in unexpected consequences in off-target regions (Koller & Cieslak, 2023). While both natural and GM foods can present health hazards, it is essential to conduct in-depth research on potential risks and effectively communicate with the public to establish trust, the EFSA has confirmed that NGTs are more precise, controllable, and predictable than conventional methods and their precision is continually increasing with technological progress (European Commission, 2023; Hafeez et al., 2023). The EFSA acknowledges that there may be fewer mutation frequencies in NGT plants when compared to conventional breeding techniques, but they also note that there are research gaps concerning unforeseen consequences (European Commission, 2023; Koller & Cieslak, 2023). According to Koller & Cieslak (2023), whole genome sequencing and comparisons to a crop's wild type can be applied to find the non-target mutations caused by NGTs. In the case of wild-type comparisons, they can also be compared to the genetic changes that would occur through conventional breeding, but no one method can reliably identify every kind of significant gene alteration that CRISPR/Cas9 can produce (Koller & Cieslak, 2023). This is especially true due to the near identity in genetic information between non-transgenic NGTs and classical improvement techniques, analytical methods may not distinguish between food cultures obtained by different techniques (Bello et al., 2024).

Scientific organisations, such as the German Federal Agency of Nature Conservation and TestBiotech, disagree, arguing that NGTs pose new and specific risks to the environment and human health compared to previous genetic engineering methods (European Commission, 2023). They question the precision, controllability, and predictability of NGTs and suggest that NGTs can induce genomic changes beyond those achievable by conventional breeding (European Commission, 2023). Following that, the European Commission (2023) reported that in comparison with traditional breeding or well-established genomic procedures, EFSA and other scientific agencies decided that there are no additional dangers directly associated with the genetic change created via targeted mutagenesis and cisgenesis. Therefore, the EFSA suggests that, on a case-by-case basis, fewer data may be needed for risk assessments of plants produced through targeted mutagenesis and cisgenesis, emphasising the importance of flexibility in data requirements (European Commission, 2023). However, the focus of the EFSA's methodology is on the frequency and kinds of mutations, without considering the precise locations that NGT processes target, the resultant gene combinations, or any potential unwanted gene products (Koller & Cieslak, 2023). As a result, Koller & Cieslak (2023) state that the possible negative impacts on human health, the environment, and agricultural productivity may be missed by the EFSA in its risk assessments.

Finding a balance between updating agriculture and maintaining traditional farming practices is essential for enhancing the effectiveness of biofortification to tackle these challenges (Monika et al., 2023). Despite being cost-effective and requiring a lot of effort, the agricultural technique faces challenges like mineral movement, alterations in soil composition, and the complexities of improving nutrient absorption in plant edible parts (Monika et al., 2023). Similarly, conventional breeding encounters difficulties such as limited genetic variation, availability, and lengthy processes (Gocht et al., 2021; Monika et al., 2023). One disadvantage of gene editing techniques is their reliance on seeds, especially in small farming operations, which can lead to concerns about sustainability due to the continual need for patented seeds and restricted farmer independence (Malézieux et al., 2023). Malézieux et al. (2023) emphasise that inadequate knowledge about transgenic crops may result in hazards like toxicity, allergies, and genetic risks, posing potential threats to food security as downsides of gene editing.

Moreover, there are concerns that biofortification strategies may inadvertently prioritise certain nutrients and fail to address underlying issues of inequality and poverty (Malézieux et al., 2023). Thus, promoting diversity and sustainability in biofortification strategies is essential to ensure neglected species, rich in micronutrients and adapted to local conditions, are not overlooked (Malézieux et al., 2023). This emphasises the necessity of an inclusive strategy that considers wider socioeconomic variables in addition to technological feasibility. This is also advised by Sharma et al. (2017), who states that biofortification should not be seen as the only effective technique to combat hidden hunger; instead, an approach that incorporates education, financial security, and social equality is needed to completely eradicate hidden hunger.

Biofortification is still in its early phases, necessitating significant financial resources and continued (Sharma et al., 2017). Garg et al. (2018) conducted a comparative analysis of transgenic varieties and traditional biofortified crops, indicating that, while transgenic varieties receive more attention, conventional breeding-based efforts had greater success rates for release. The concept of biofortification raises worries about biodiversity loss. Poor farmers who retain seed rather than purchase it risk losing some of the nutritional advantages of a biofortified crop (Sharma et al., 2017).

Methods such as agronomic techniques, biofertilisation, conventional plant breeding, and optimal fertiliser applications are widely recognised as effective biofortification strategies worldwide (Koç & Karayiğit, 2022). Despite the obstacles, biofortified foods offer a hopeful solution for tackling nutritional deficiencies, sometimes matching, or even exceeding the nutritional value of traditional foods (Sharma et al., 2017). Cereals have seen the most significant biofortification efforts among the three techniques, while vegetables and legumes have been targeted relatively equally by agronomy, conventional breeding, and transgenic-based approaches (Garg et al., 2018).

3.2.2 Dietary diversification

Nair et al. (2016) show the importance of acquiring micronutrients from a variety of food sources to adequately fulfil nutrient requirements. They believe that getting all micronutrients from just one or two types of food is not possible and stress the importance of consuming a variety of foods and food groups regularly to achieve nutritional sufficiency (Nair et al., 2016).

Including a variety of micronutrient-rich foods in the diet through traditional food preservation and processing methods can improve nutrient intake and overall nutritional status, according to Vishwakarma et al. (2022). Research shows a significant link between variety in diet and getting enough nutrients, especially in low- and middle-income countries, where diets mainly consist of starchy foods, causing them to be deficient in essential nutrients (Millonzi, 2008). According to the WHO & FAO (2006), dietary diversification calls for the development of initiatives that increase access to – and consumption of a variety of foods high in micronutrients, such as fruits, vegetables, and animal products, in sufficient amounts, particularly for those who are predisposed to or at risk of micronutrient deficiencies. To improve the absorption of the few available micronutrient sources, the sufficient intake of oils and fats in impoverished populations must also be ensured (WHO & FAO, 2006).

Furthermore, according to Millonzi (2008) increased dietary diversity is associated with a reduced risk of micronutrient deficiencies and undernourishment, regardless of economic environment. Nevertheless, the relationship between the variety of foods in one's diet and health outcomes like weight and non-communicable diseases is complex and influenced by different circumstances, although there is proof that a diverse diet may help prevent health issues (Millonzi, 2008).

Meanwhile, Malézieux et al. (2023), emphasise the significance of agrobiodiversity on farms in enhancing food variety, boosting agricultural production, and offering extra sources of income for farmers. In addition, Malézieux et al. (2023) advocate for global initiatives that promote eating a variety of foods to increase the production and intake of nutrient-rich foods. Efforts such as these encourage healthier eating habits and decrease the environmental impacts of food production. Malézieux et al. (2023) emphasise the considerable influence of international trade on the structure of food systems, affecting the accessibility and dietary habits of different food items worldwide.

3.2.2.1 Advantages

According to Nair et al. (2016), the primary advantages of dietary diversification are that it is a long-term sustainable strategy, it emphasises food groups and food synergy, it improves the quality of diets and ensures improved micronutrient intake by entire households, it targets multiple micronutrients, it uses a holistic approach towards understanding how foods interact with the human biological system, it has relatively low antagonistic interactions, it is culturally acceptable, economically feasible and promotes biodiversity and employment. Moreover, unlike other approaches that have the disadvantage of only targeting the known factors of micronutrient deficiencies, dietary diversification can also address the unknown and more food components than just micronutrients at the same time (Nair et al., 2016; WHO & FAO, 2006).

3.2.2.2 Disadvantages

Vishwakarma et al. (2022) and Nair et al. (2016) show the multifaceted challenges associated with the adoption of dietary diversification including a lack of data, quantifiable endpoints, slow returns, and affordability problems. Vishwakarma et al. (2022) caution that the efficacy of dietary diversification depends on factors like the amount of time different micronutrient-rich foods are available at home, the purchasing power of households, and how easy it is for them to embrace dietary behaviour adjustments.

In many impoverished areas, dietary diversity is not feasible, despite its long-term effectiveness in addressing hidden hunger (Sharma et al., 2017). With the FAO's Food Price Index rising 40% in 2022, there has been a renewed focus on GMO crop replacements, regulations, and public opinion because of the increased cost of food globally (Laxman & Ansari, 2023a). While some, like Dronamraju (2008), advocate for dietary diversity, citing vitamin-A-rich foods like sweet potatoes, leafy greens and fruits as solutions to deficiencies, others argue that such diets are not financially achievable for many impoverished individuals, similar to the historical statement “Let them eat cake!”. It was probably propaganda meant to incite resistance to the monarchy rather than something Marie Antoinette actually said (Cunningham, 2023).

Despite these challenges Nair et al. (2016) state that, once implemented effectively, dietary diversification is a sustainable strategy for simultaneously addressing multiple micronutrient deficiencies. However, according to Nair et al. (2016) and WHO & FAO (2006), dietary diversification presents significant disadvantages, including the need for long-term practice for impact, the requirement for an enabling environment and nutrition education, challenges in ensuring adherence, the complexity of biological pathways, data accuracy issues, the necessity for behavioural change, and cost considerations, among others.

3.2.2.3 Link biodiversity and dietary diversity

The environmental effects of GM crops are subject to debate, primarily due to concerns about their impact on non-target species (Tsatsakis et al., 2017). Chemicals used with GM crops present environmental challenges, affecting both the ecosystem and native plants (Tsatsakis et al., 2017). Additionally, GM crops can be toxic to beneficial species like beetles, bees, and butterflies, raising further environmental concerns (Tsatsakis et al., 2017). The introduction of GM crops poses challenges to biodiversity, concentrating breeding efforts on a smaller group of commercial varieties (Ahmad et al., 2021). Dannenberg et al. (2024) emphasise the need to distinguish between an ecosystem's natural biodiversity; wild animals and plants, wild crops, and its agrobiodiversity.

Studies show mixed results on the impact of GM crops on biodiversity, with some indicating a decrease in genetic diversity in certain regions (Ahmad et al., 2021). Aside from the conventional dichotomy, there is an increasing number of ecosystems, particularly in cities (Dannenberg et al., 2024). Agrobiodiversity, resulting from interactions among genetic resources, environment, and agroecosystems, is important in improving land management and rural living standards (Henke & Vaquero-Piñeiro, 2023). However, GM crops can also enhance biodiversity by introducing novel traits and bringing underutilised germplasm into cultivation (Ahmad et al., 2021). When asked if there are risks associated with the unintended consequences of biofortification, such as biodiversity loss or environmental impacts.
According to Leogrande et al. (2022), the Farm to Fork Strategy considers biodiversity´s requirement for agricultural strategies to make European agriculture more resilient to climate change. The EU biodiversity strategy for 2030 aims to address environmental dimensions, including soil biodiversity, and encourages a transition to fully sustainable agricultural practices (Heuser & Itey, 2022). One of the primary objectives of the EU Green Deal is to increase biodiversity, and the agriculture sector is expected to make greater commitments to biodiversity protection and socioeconomic sustainability (Henke & Vaquero-Piñeiro, 2023). As Ahmad et al. (2021) point out, that biodiversity is crucial for agricultural productivity and resilience to climate change, but it faces challenges with the introduction of GM crops.

According to the FAO: Nutrition and Consumer Protection Division (2009), biodiversity is essential in guaranteeing dietary diversity as there can be both interspecies and intraspecies differences in the nutrient composition of crops. As a result, the difference between micronutrient deficiency and adequacy may be determined by the type of crop consumed (FAO: Nutrition and Consumer Protection Division, 2009). Since we do not yet know how dietary assessments systematically include food biodiversity, there has been increased research recently on the assessment of local biodiversity in consumption studies (Medeiros et al., 2022). Plant breeders can evaluate genetic materials to improve crop cultivars' nutritional values by using the acquired data on nutrient content (FAO: Nutrition and Consumer Protection Division, 2009).

Fanzo (2019) found that though there are no certain links between the availability of diverse crops on a farm and a diverse diet, a positive association is shown. A more micronutrient-rich diet can be achieved through promoting biodiversity in diets (Baldermann et al., 2016). Especially because Fanzo (2019) show demonstrated a significant correlation between the number of foods purchased and sold at nearby markets and the diversity of household diets. It is believed that the diversity of agricultural biodiversity will impact the dietary diversity of populations who rely on traditional farming methods by offering them a broader range of food options (Fanzo, 2019). This pattern is not always seen; in the case of highly biodiverse landscapes in Benin and Kenya, the diverse crop availability did not translate to mothers and children; the populations most vulnerable to micronutrient deficiencies (Fanzo, 2019). Researching this methodologically is challenging because of the restricted funding, the presence of biodiversity hotspots in underdeveloped nations with limited resources for scientific funding, and the shortage of trained scientific experts to conduct organised studies effectively (Medeiros et al., 2022). As a solution, Medeiros et al. (2022) suggest that international research agencies could allocate additional resources to Global South scholars focusing on the food biodiversity agenda.

3.2.3 Fortification

Fortification dates to the early 1920s, with the voluntary fortification of table salt with iodine in Switzerland and the USA being among the earliest instances (Fischer et al., 2023; Mishra et al., 2022; Yadav et al., 2020). Food fortification involves adding micronutrients to processed foods. Throughout history, essential micronutrients have been added to foods such as butter, margarine, sugar, cereals, and milk to address deficiencies (Mishra et al., 2022; Yadav et al., 2020). This method frequently leads to rapid alterations in a community's micronutrient status with minimal expenses in numerous instances (WHO & FAO, 2006). Food fortification with micronutrients is an effective method for decreasing micronutrient deficiency and increasing dietary variety as a component of a food-based strategy when the existing food supply and restricted access fail to deliver appropriate quantities of the relevant elements in the diet (Olson et al., 2021; WHO & FAO, 2006; Woods et al., 2020). In such circumstances, food fortification strengthens and supports current nutrition improvement efforts and should be considered as part of a larger, integrated approach to avoid micronutrient deficiencies, therefore complementing other measures to enhance micronutrient status (WHO & FAO, 2006).

However, the implementation of food fortification can be subject to regulatory challenges, as demonstrated in Chapter 4.3.1. Despite scepticism, by 2016 approximately 61 countries were fortifying wheat flour with folic acid, highlighting its widespread adoption (Mishra et al., 2022).

3.2.3.1 Advantages

Yadav et al. (2020) identified the main advantages of fortification: it is one of the most cost-effective interventions and the techniques are well-established. Moreover, it does not require people to change their dietary behaviour; individuals are not required to comply; and multiple micronutrients can be provided in adequate amounts constantly and simultaneously (Yadav et al., 2020). Food fortifications are sustainable for a long time because they are easily integrated into the current food production and distribution system (Yadav et al., 2020). Given the benefits, food fortification can be a highly economical public health measure (WHO & FAO, 2006). Moreover, Hefferon (2015) and Olson et al. (2021) found that mandatory fortification is more effective than voluntary fortification in impacting populations.

3.2.3.2 Disadvantages

The practice of industrial fortification, aside from the success seen with iodised salt, has had limited success, primarily due to challenges in accessibility for impoverished communities and the necessity of central processing facilities (Komarnytsky et al., 2022; Sharma et al., 2017). Additionally, fortifying foods with synthetic forms of specific micronutrients may inadvertently mask other micronutrient deficiencies (Komarnytsky et al., 2022).

Despite its benefits, food fortification is hindered by various limitations despite its evident potential (Yadav et al., 2020). Although fortified foods can help with nutritional deficiencies, they are not a replacement for a varied diet that offers essential nutrients for good health (Yadav et al., 2020). Moreover, while the classic fortification of staple foods such as salt has helped reduce deficiencies in micronutrients, demonstrating the efficacy of biofortified foods is difficult due to several factors in the populations being studied, as mentioned by Hotz & McClafferty (2007) and Yadav et al. (2020).

Difficulties in reaching fortified foods continue for low-income individuals because of financial limitations, leading to an increased chance of micronutrient deficiencies (Yadav et al., 2020). Furthermore, the challenges to effective food fortification include technological complexities such as the stability of fortified products, nutrient interactions, and consumer acceptance (Yadav et al., 2020). To achieve the potential benefits of food fortification, they need to be consumed in adequate amounts (WHO & FAO, 2006). Issues such as changes in colour, flavour, and loss of nutrients further complicate food fortification (WHO & FAO, 2006; Yadav et al., 2020). Although cost-effective, the introduction of food fortification could face obstacles due to high expenses, as well as lingering uncertainties regarding absorption, bioavailability, and potential toxicity (Yadav et al., 2020).

3.3 Consumer Acceptance

House et al., p. (2023, p. 13) define cultural acceptability as follows: “Cultural appropriateness is the qualification of particular foods as appropriate to eat, in a particular manner, in a particular context. It is a relational phenomenon, arising through interaction between the embodied, enculturated dispositions of the eater(s) themselves and the socio-material context of consumption (including socially shared standards of normal or suitable conduct, available foodstuffs, and other social actors).”. Spök et al. (2022) mention three different dimensions of social acceptance: market acceptance, socio-political acceptance, and community acceptance.

The adoption of sustainable food consumption practices is dependent on cultural appropriateness, and acceptability (hereafter cultural acceptability or acceptance), since it cannot be merely enforced (House et al., 2023). This is also enshrined in the FAO definition of sustainable diets, which adds sociocultural and economic aspects like cultural acceptability, to the notion of sustainability in addition to nutrition and the environment (Lairon, 2012).

House et al. (2023) present two main perspectives on cultural acceptability in combination with a shift to sustainable diets; the first perspective revolves around providing substitutes for conventional foods to not disrupt established food practices, this perspective places the responsibility of maintaining cultural acceptability during dietary shifts on actors in the supply chain and supply chain governance. In this perspective, cookies with enriched flour are given as an example of a food item that does not violate established food norms as this tastes quite like their conventional counterparts and the main reference is the established diet (House et al., 2023). The second perspective describes cultural acceptability as dynamic and negotiated progress, this perspective includes several themes: cultural acceptability as alignment of food practices with people's preferences; cultural acceptability shaped by eating contexts; and cultural acceptability shaped by the context of food acquisition and preparation (House et al., 2023).

Multiple studies have investigated the acceptance of biofortified crops by consumers, providing insights into their reception among various demographics and regions (Bechoff et al., 2018). Prior studies have demonstrated that the acceptance of GM crops does not necessarily mean that consumers or others in the food industry would be willing to adopt them in a social or commercial context (Spök et al., 2022). A study in Brazil investigated how people's willingness to pay for GM biofortified yellow cassava could be influenced by their awareness of the product being GM, which could impact their acceptance of it compared to conventionally bred cassava (Bechoff et al., 2018).

Bechoff et al. (2018) also demonstrated that yellow biofortified maize types were better received than white maize by preschoolers in South Africa, however, this changed with older children and adults, potentially due to the adverse connotations of the yellow colour. Conversely, in Mozambique, orange biofortified maize was well accepted, while adult consumers showed higher acceptance of yellow cassava cultivars compared to local white varieties (Bechoff et al., 2018). The focus of Gilligan et al. (2020) on the relative health advantages of orange-fleshed sweet potatoes in GM crop adoption generated a gender difference in the research, indicating that while men and women probably decided together to adopt orange-fleshed sweet potatoes, women could have been crucial in the process. These results highlight the significance of recognising differences in consumer perceptions of biofortified crops based on region and demographics.

Furthermore, Bechoff et al. (2018) found that biofortified crops are generally well-received by both rural and urban communities in terms of sensory evaluation, regardless of how they are prepared. Visible traits of crops, like the colours, do not seem to be significant barriers on their own, with the possible exception of yellow maize due to the perceived inferiority and association with poverty (Bechoff et al., 2018).

Consumers have generally expressed a lower level of acceptance for GM crops and foods because they are sceptical about the risks and benefits associated with these products (Ofori et al., 2022). For example, Spök et al. (2022) argue the following preference order, based on willingness to pay studies performed in Italy and Denmark: organic, cis- or transgenic with environmental benefits, conventionally bred, cisgenic, and finally transgenic crops. Concerns have been raised about the human health implications, environmental impacts, toxicity, and allergenicity of GM crops, leading to their rejection based on unverified grounds, even though scientific reports have shown that GM crops are safe to consume (Ofori et al., 2022). Therefore, it may be necessary to create adequate informational programs to highlight the importance of biofortified GM plants and quell misconceptions about GM crops (Ofori et al., 2022). Busch et al. (2022) show that people opposed to the use of gene editing believe it should be illegal disregarding any potential advantages. As of 2019, just 27% of people were concerned about GM food or drink components, which is lower than 63% in 2005 (Caradus, 2023). According to Shew et al. (2018) and Caradus (2023), the more favourable perception of gene editing is compared to other, older, GM technologies, especially in the EU.

The successful implementation of biofortification programmes depends on the acceptance of biofortified crops by farmers and consumers (Ofori et al., 2022). But consumers are frequently caught between ambiguous lines of caution when it comes to GMOs, strong public opposition to GMOs and consumer education are mentioned as major influences of the talks that ultimately led to the adoption of the Cartagena Protocol on Biosafety under the Biological Diversity (Cartagena Protocol) (Millonzi, 2008). Globally, GM crops are governed by different regulations that have significant effects on their commercialisation and adoption (Ofori et al., 2022). Regulations and legislations governing GM crops should be adjusted, especially in developing countries, to be less rigorous and more cost-effective to promote their adoption especially since the emergence of new breeding techniques raises questions about the regulatory landscape and the future of GM crops (Ofori et al., 2022).

3.4 Conclusion Food Security

This chapter answers two sub-questions. The first investigates the theoretical foundations supporting the role of biofortification in improving food security and how foundations inform policy development and implementation.

The theoretical underpinnings of biofortification improving food security are rooted in a comprehensive understanding of the complexities within food systems. These foundations draw from various perspectives on food security, climate change effects, and biodiversity. Additionally, historical perspectives highlight the evolution of food security concepts and interpretations, from a focus on food production during the Green Revolution, to a broader understanding that includes nutritional quality and safety.

The second sub-question investigates how biofortification compares to alternative food-based strategies such as dietary diversification, fortification, supplementation and more, in terms of consumer acceptance, sustainability, and socioeconomic and environmental implications, and what policy implications arise from these comparisons.

Comparing biofortification to alternative strategies like dietary diversification, fortification, and supplementation across consumer acceptance, sustainability, and socioeconomic and environmental implications provides valuable insights for policymaking and program development:

The consumer acceptance of supplements may vary based on factors such as ease of use, perceived health benefits, and affordability. Trust in the efficacy and safety of supplements, along with clear labelling and guidance, can influence consumer behaviour.

Biofortification integrates nutrient enhancement into staple crops, reducing reliance on other interventions like supplementation or fortification, and promoting agricultural biodiversity. Moreover, according to some, it can support smallholder farmers and it can contribute to environmental sustainability by reducing chemical inputs. Sustainable sourcing of supplements and consideration of environmental impacts are necessary for long-term viability.

The next chapter will delve deeper into the role of policy and regulation in shaping the landscape of food fortification and nutrition interventions.

4. Policy and Regulation

4.0 Chapter Introduction

This chapter sets out to answer the final two sub-questions: ‘How do variations in existing regulatory standards for nutrient-enriched biofortified foods across countries intersect with international regulatory bodies, initiatives like the EU's Green Deal, and existing trade agreements, in the context of enhancing food security through biofortification and gene editing?’, and ‘How can harmonisation strategies ensure global consistency while facilitating the adoption and diffusion of biofortified agriculture, considering the complexities of regulatory standards and trade agreements?’.

4.1 Global

The first transgenic crop to be commercially released was the Flavr-Savr tomato, which marked the introduction of GMOs into regulation in 1996 (Caradus, 2023; Ghouri et al., 2022; Lassoued et al., 2021). The commercial release and increased use of biotechnology in plant breeding have led governments worldwide to adapt, or entirely remodel, their regulatory regimes to embrace or overlook the advantages of innovative technologies (Lassoued et al., 2021). Global GM crop acreage expanded from 1.7 to 190.4 million hectares between 1996 and 2019 (Spök et al., 2022).

GMOs are governed by several interrelated legal frameworks, and debates over the efficacy and consistency of these frameworks are common. At the top of this hierarchy is the WTO Agreement, which governs multilateral trade agreements such as the General Agreement on Tariffs and Trade (GATT), the Application of Sanitary and Phytosanitary Measures Agreement (SPS Agreement), and the Technical Barriers to Trade Agreement (TBT Agreement) (Laxman & Ansari, 2023a). GMOs are governed by two key international legal instruments (Haseeb Ansari & Kamal Nik Mahmod, 2008):

1. the Cartagena Protocol
2. the WTO’s SPS Agreement

The primary goal of the SPS Agreement is to prevent unnecessary obstructions of international trade and in the case of GMOs, GMOs, and their products to protect human, plant and animal life and health (Haseeb Ansari & Kamal Nik Mahmod, 2008).

The Cartagena Protocol prioritises human health and environmental protection from living-modified organisms (LMOs) and monitors global biodiversity by outlining detailed criteria for the safe handling and transportation of GM crops across countries (Haseeb Ansari & Kamal Nik Mahmod, 2008; R. B. Singh et al., 2022). Notably, Article 3.2 incentivises WTO Members to align their national sanitary and phytosanitary standards with those established by the CAC (Gerstetter & Maier, 2005). Compliance with CAC standards is presumed to satisfy WTO regulations, promote international harmonisation, facilitate trade, and ensure food safety and health standards are upheld. Similarly, the Cartagena Protocol mandates, under Article 10.6, Advanced Informed Agreements (AIA) for the cross-border movement of LMOs, providing importing countries with the necessary information for conducting risk assessments and making informed decisions (UNEP, n.d.). Following Article 16, the measures adopted by the importing country should only go as far as to protect against the identified risk (Haseeb Ansari & Kamal Nik Mahmod, 2008). Risks should be assessed following Article 15 of the Cartagena Protocol (Falkner & Gupta, 2009).

With this, the Cartagena Protocol is like the provisions of the SPS Agreement, where there should be no more stringent measures than deemed necessary based on risk assessment (Haseeb Ansari &

Kamal Nik Mahmod, 2008). It does not, however, fully comply with the SPS Agreement. Despite similarities, some have noted that the Protocol goes against the Agreement.

The Cartagena Protocol was written to protect biodiversity and the environment, which makes it not a trade barrier (Haseeb Ansari & Kamal Nik Mahmod, 2008). The Cartagena Protocol gives more flexibility in limiting the trade of GMOs by not imposing a deadline for reviewing precautionary measures compared to the WTO-SPS Agreement and guides national economies (Caradus, 2023; Falkner & Gupta, 2009). Additionally, Article 2.4 of the Cartagena Protocol affirms the right of Parties to enact measures more protective of biological diversity, provided they align with the Protocol's objectives and provisions (Union, 2003).

Furthermore, Article 11.6 outlines procedures for developing country Parties to make decisions on the import of LMOs, emphasising risk assessment and timely decision-making (Union, 2003).

Moreover, the Cartagena Protocol, aimed at reconciling GMO import and export discrepancies, remains inconclusive, sparking ongoing debates about its efficacy and implementation challenges (Falkner, 2000; Lim Tung, 2014). Despite addressing critical issues such as its scope and liability, it faces resistance from major GMO exporters like the USA due to its alignment with EU regulations (Falkner & Gupta, 2009). This lack of consensus hampers global efforts to establish a unified approach to GMO regulation and management. Additionally, concerns about harmonising national biosafety regulations and risk assessment standards persist (Lim Tung, 2014). Meanwhile, the Nagoya-Kuala Lumpur Supplementary Protocol addresses liability for environmental harm resulting from transboundary movements advocating for response measures by operators (Laxman & Ansari, 2023b). As of July 21, 2022, the Supplementary Protocol has been ratified, accepted, authorised, or acceded to by fifty-one parties (Laxman & Ansari, 2023b). However, concerns persist regarding harmonising of national biosafety regulations, risk assessment standards, and socioeconomic considerations (Lim Tung, 2014). The Protocol's risk assessment clauses include language that, while not clear, might be interpreted as including a precautionary measure in the procedure (Gerstetter & Maier, 2005).

The Cartagena Protocol has been ratified by one hundred and seventy countries, but the United States, Canada, Australia, and Argentina—all significant exporters of GM crops—did not sign the agreement (Haseeb Ansari & Kamal Nik Mahmod, 2008). Instead, they, together with Argentina, Brazil, the Dominican Republic, Guatemala, Honduras, Paraguay, and Uruguay signed an international statement on the application of precision biotechnology under the SPS Agreement to avoid trade barriers for products derived from gene editing (Schiemann et al., 2021). The Russian Federation has also not signed the agreement (Ghouri et al., 2022). In the US, Japan, Chile, Brazil, Australia, Israel, and Argentina SDN1 GM organisms are considered non-GMOs (Gocht et al., 2021; Hafeez et al., 2023). Because of the high degree of resemblance of the gene-edited crops, these countries subject them to the same regulations as traditional crops (Schiemann et al., 2021).

The distinction between a GMO and a non-GMO in certain countries is determined by the definition of an LMO in the Cartagena Protocol, as described in Article 3g (Gocht et al., 2021). According to this definition, certain gene-edited crops like foods produced through SDN1 events are not subject to GMO regulation (Spök et al., 2022). These organisms are considered similar to those developed through conventional breeding methods as no new genetic material is added to the gene, making them exempt from the protocol definition for LMOs (Gocht et al., 2021).

The regulation of GM crops worldwide encompasses various approaches, with regulations typically categorised as process-based and product-based (Agarwal & Singh, 2021; Devi & Aglawe, 2021; Hafeez et al., 2023). Process-based labelling is the regulation of GM crops where the technique applied separates the GM crops from the non-GM crops (Devi & Aglawe, 2021; Hafeez et al., 2023). This is based on the idea that potential risks are also influenced by the procedure used to produce GM crops and is outlined by international bodies like the FAO and treaties such as the Cartagena Protocol, this method evaluates potential risks associated with the production process itself, assuming that genetic modification is indicated by deviations from natural gene transfer (Agarwal & Singh, 2021; Devi & Aglawe, 2021; Hafeez et al., 2023). This applies to the EU, the United Kingdom, Brazil, India, China, Pakistan, South Africa, and New Zealand (Ghouri et al., 2022). Similar to Japan and New Zealand; Norway, Switzerland, and the EU have implemented stricter regulations, resulting in a slow or limited cultivation and commercialisation of GM crops in the food industry (Spök et al., 2022). Product-based regulation is the regulation of crops where the focus is on the characteristics of the final product instead of on the process used to achieve the desired product (Devi & Aglawe, 2021; Hafeez et al., 2023). The idea behind this is that no health risk is associated with the process (Hafeez et al., 2023). Therefore, the danger is limited to the finished product and does not depend on the GM method (Hafeez et al., 2023). This is done in the United States, Argentina, and Canada (Ghouri et al., 2022).

According to Hafeez et al. (2023), the product-based regulatory approach is superior as it complies with the free trade agreements of the WTO and loosens the constraints on controlling GM crops. Additional criteria for GM crop labelling, such as mandatory versus voluntary labelling and threshold levels, are more about labelling for the consumer and less about labelling for regulation (Jha et al., 2021). However, Ghouri et al. (2022) state that the regulations in the EU primarily favour the production of GM crops, whereas the regulations in the United States oppose the development of GMOs.

Furthermore, ongoing debates surrounding the categorisation and regulation of GMOs, with differing viewpoints between regions such as the EU and the USA (Lim Tung, 2014). Critics argue that the Cartagena Protocol's regulatory process is overly burdensome and may hinder legitimate technological advancements (Miller & Conko, 2000). Similarly, concerns have been raised that a global regulatory regime for biotechnology could exacerbate habitat loss and biodiversity decline, suggesting a need for greater focus on habitat conservation efforts (Adler, 2005). However, Caradus (2023) argues that regulations are essential for protecting society, the environment, and the economy, though the specific form and management are under scrutiny. The Director-General of the IFPRI warns against condemning agricultural biotechnology without considering the risks of not addressing hunger, malnutrition, and child mortality (Caradus, 2023). Ultimately, there is a need to find a balance between regulation and freedom to operate to ensure the benefits of new technologies are realised (Caradus, 2023).

Moreover, implementing CAC standards in trade-sensitive domains compels WTO countries to adhere to these norms to avoid legal disputes, even without scientific rationale for nation-specific, trade-restrictive food safety measures (Maier, 2012). Despite CAC standards not being binding and directly incorporated into the WTO legal framework, compliance with these standards is presumed to align with WTO legislation under Article 3.2 of the SPS Agreement (Gerstetter & Maier, 2005). This provision essentially encourages WTO Members to justify SPS measures based on international norms, incentivising adherence to global standards while reinforcing the principle of rewarding compliance over penalising non-compliance (Gerstetter & Maier, 2005).

Precautionary principle and substantial equivalence

In the General Food Law, Regulation (EC) No 178/2002, Article 3, paragraphs 9 and 10 define risk and hazard as "*a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard" with hazard meaning "a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect*" (European Parliament & Council of the European Union, 2002).

The precautionary principle allows countries to take certain regulatory measures as long as they are based on risk assessments that meet certain criteria (Haseeb Ansari & Kamal Nik Mahmod, 2008). Though contested the precautionary principle has been reaffirmed and operationalised in international decision-making, such as in the Cartagena Protocol, where States should prioritise caution in the absence of scientific certainty, potentially restricting GMO imports (Dronamraju, 2008). The method by which a country, organisation, or individual assesses the probability of particular risks in line with the precautionary principle is known as the precautionary approach (Caradus, 2023). For instance, the Cartagena Protocol views the precautionary approach as a basic principle for utilising GMOs rather than adopting the term precautionary principle (Caradus, 2023).

The interpretation of the precautionary principle, like the definition of risk, remains a topic of discussion and as a result, there is not one precautionary principle (Caradus, 2023). This can even be seen in literature; for example, R. B. Singh et al. (2022) describe it in the context of GMOs as ensuring that new GM items are not made available to consumers unless there is direct proof of safety or a lack of conflicting safety assessments among analysts, differing somewhat from other interpretations.

While not explicitly recognised as a legal principle, the precautionary principle influences discussions and policymaking globally, structuring debates and influencing risk regulation agendas (Gerstetter & Maier, 2005). Its role in legal interpretation has been debated with the WTO's Appellate Body acknowledging its importance but not granting it overriding status as the principle can help justify existing non-tariff barriers to trade (Gerstetter & Maier, 2005).

The relationship between the precautionary principle and international law, particularly within the WTO framework, has been subject to criticism. While some argue for its integration into regulations, others caution against its misuse as a barrier to trade (Gerstetter & Maier, 2005). Despite a lack of evidence linking the widespread adoption of GM plants globally to substantial or irreversible harm, the precautionary principle has had a major influence on the usage of these plants in nations such as the EU and New Zealand (Caradus, 2023). Nevertheless, the precautionary principle underscores the need for careful consideration of potential consequences, especially in contexts such as unwarranted health and environmental risks integrating legal regimes and scientific projects to ensure informed decision-making (Gerstetter & Maier, 2005; Sourgens, 2021).

Meanwhile, the concept of substantial equivalence, which underpins the principle stating that GM plant varieties do not present fundamentally different risks compared to conventionally bred varieties, embodies the notion that existing organisms utilised in food production can serve as a benchmark for evaluating the safety of modified or new food components for human consumption (Falkner & Gupta, 2009; OECD, 1993). This concept was first mentioned in the 1993 report of The Organization for Economic Cooperation and Development (OECD) 'Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles' (OECD, 1993). Despite its limitations, substantial equivalence remains ingrained in modern regulatory methods within the biotechnology food regime, guiding policies, and evaluations of biotechnological food products (Petetin, 2017). Additionally, the ISAAA (n.d.) notes that substantial equivalence cannot replace safety evaluation and that it is important to pick the right comparators, the degree of exposure, and the intended use(s) (OECD, 1993).

The interaction between the precautionary principle, which Mitra-Ganguli et al. (2022) and Caradus (2023) describes as a “better safe than sorry” approach to addressing the uncertainties surrounding biotech foods, and substantial equivalence is evident in recent regulatory regimes, emphasising the importance of both concepts in shaping policies and regulations concerning biotechnological food products. These regimes underscore the fundamental role of substantial equivalence in the regulation and evaluation of biotechnological food products Mitra-Ganguli et al. (2022).

Furthermore, Winter (2016) criticises the narrow scope of the required risk assessment within the SPS Agreement, advocating for a more comprehensive approach that considers wider environmental evaluations. This difference generates a logical gap, as broad environmental risk assessments cannot always be accurately appraised in terms of seriousness and likelihood of damage (Winter, 2016). Winter (2016) recommends widening the area of risk assessment or allowing for risk substantiation based on generic environmental assessments and risk weighting (Winter, 2016). Furthermore, Winter (2016) questions the TBT Agreement's validity and argues against a violation of the GATT under Article III.4, claiming that cultivation limits do not help foreign goods over domestic ones.

Crops acquired through gene editing are regulated differently per region. In Canada, the EU, New Zealand, and South Africa gene-edited crops are regulated the same as GMOs (Vora et al., 2023). However, according to Hafeez et al. (2023), India should also be added to the list of countries that consider GM organisms created using CRISPR/Cas9 technology GMOs, together with the EU and New Zealand. The UK and China, they have simplified GMO regulations (Vora et al., 2023). Gene-edited crops in Argentina, Brazil, Chile, Colombia, India, Israel, Japan, Kenya, Nigeria, Paraguay, the Philippines, and Russia are not subject to GMO regulations (Vora et al., 2023). However, they must be officially approved by regulatory agencies before being introduced to the market (Vora et al., 2023).

4.2 USA

In the United States of America, GMO labelling approaches and regulations have sparked debates and discussions over the years. The USA has historically emphasised scientific and industry self-regulation in biotechnology (Falkner & Gupta, 2009).

Up to three different agencies under the Coordinated Framework for the Regulation of Biotechnology: United States Department of Agriculture, Animal and Plant Health Inspection Services; the Food and Drug Administration; and the Environmental Protection Agency, may be involved in the regulatory framework for gene-edited crops, their GMO-specific laws and regulations have not been consistently applied to gene-edited food and crops (Spök et al., 2022; Vora et al., 2023). The regulatory framework established in 1986 promoted a product-based risk regulation approach, focusing on substantial equivalence between GM and conventionally bred varieties (Falkner & Gupta, 2009). Consequently, numerous GM crops have been assessed, planted, and introduced to the market in the USA (Falkner & Gupta, 2009). The USA, as does Canada, uses the product-based GM labelling approach and, to this end, uses substantial equivalence (Falkner & Gupta, 2009; Gocht et al., 2021; Jha et al., 2021). As such, plants derived from CRISPR/Cas9 or other gene editing methods are considered non-GMO (Devi & Aglawe, 2021; Vora et al., 2023). If they do not contain foreign DNA and could have been achieved through traditional breeding methods (Spök et al., 2022; Vora et al., 2023).

At the moment, GMO labelling is not mandatory in the USA (Jha et al., 2021). However, developers are obligated to ensure that goods put on the market are safe for use and consumption, with gene-edited crops not subject to pre-market regulatory examination under certain conditions (Vora et al., 2023).

Mandatory labelling of food that contains GM products easily becomes inconsistent and difficult as it requires mentioning the GM product on the packaging (R. B. Singh et al., 2022). For example, there has been debate over whether products containing modified protein or transgenic DNA should require special labelling. However, some GM products do not contain these elements, prompting discussion on whether they still warrant special labelling (R. B. Singh et al., 2022). Conversely, concerns over the implementation of obligatory GMO labelling have led to increased interest from American consumers (Jha et al., 2021). According to R. B. Singh et al. (2022), many consumers claim they obtain information on GMOs via the media, the internet, and other news sources. Consumers in the USA have more positive opinions on GM plants and food than EU consumers, leading to a faster adoption of GM crops, and expanded acreage in the past 15 years due to a lower regulatory burden (Spök et al., 2022). These sources may give less solid information than professionals who can supply more credible and science-based material (R. B. Singh et al., 2022). However, consumer attention to GMO labelling in the United States remains low despite increasing pressure for obligatory labelling like EU norms (R. B. Singh et al., 2022). This is exacerbated by the fact that 70-80% of all processed food consumed in the USA contains GM products (Jha et al., 2021). This can, in part, be attributed, to the introduction of herbicide-tolerant soybeans and insect-resistant yellow maize seeds which have been widely adopted by USA farmers due to their effectiveness and cost-efficiency in weed and insect management (Paarlberg et al., 2024). The optional GMO labelling policy now in place under the USA Food and Drug Administration is supported by 63% of Americans and has been influenced by the mandatory labelling laws adopted in some states (Jha et al., 2021).

Despite ongoing discussions, back in March 2016, the US Senate denied a bill to negate the obligatory labelling of GMOs at the state or local level in the US, indicating an ongoing debate (Jha et al., 2021). If GMO labelling becomes required, as it is in the EU, Japan, and New Zealand, the US food business could face significant challenges, potentially leading to the removal of GMO-containing products from shelves due to consumer aversion (Jha et al., 2021). Additionally, the transition to non-GMO ingredients, which are typically more expensive, could result in higher food prices for consumers (Jha et al., 2021).

4.3 EU

The precautionary principle plays a vital role in EU law; however, like in international law, its precise definition remains unclear within the TFEU (Leonelli, 2021). According to Anyshchenko & Yarnold (2021), Article 191(2) of the TFEU and Article 7 of Regulation (EC) No 178/2002 include the precautionary principle. Though in the TFEU the precautionary principle refers to environmental protection and sustainable development, the scope changed to a general principle of EU law by the CJEU (Anyshchenko & Yarnold, 2021). Nonetheless, several references in EU risk regulation emphasise the importance of keeping a high level of public health and environmental protection and when determining the framework for GMO authorisation, the precautionary principle should always be considered (Anyshchenko & Yarnold, 2021; Leonelli, 2021). While Article 7.1 of the General Food Law, (EC) No 178/2002, defines the precautionary principle, a more comprehensive description is provided in the Commission Communication on the Precautionary Principle, COM_2000_0001_FIN, (Leonelli, 2021). This Communication reiterates that the precautionary principle applies when insufficient scientific information indicates potential dangers inconsistent with the chosen level of protection and emphasises the political nature of determining acceptable risk levels for society (Leonelli, 2021).

Aligned with this principle, the CJEU has affirmed that adopting protective measures under the precautionary principle does not necessitate proof of zero risk, recognising the inherent limitations of scientific certainty (Guida, 2021). What differentiates a legal protective measure from illegitimate protectionism is, among other things, the former's ability to scientifically address a verifiable risk (Gerstetter & Maier, 2005).

According to Ghouri et al. (2022), the processed-based legislation of the EU depends on the safety of GM products for people, animals, and the environment; freedom of choice, including the protection of consumers' and producers’ rights and the labelling and traceability of GM products; and the free movement of GM products within the EU market.

The 1997 Novel Foods Regulation is based on substantial equivalence, and the idea alone is deleted in the 2015 Novel Foods Regulation, the Food and Feed Regulation and the Traceability Regulation Mitra-Ganguli et al. (2022). As a result, the EU food system is undermined and the establishment of truly precautionary regulatory regimes is prevented (Petetin, 2017). To address these concerns, proactive measures are necessary, including establishing pre-market approval processes, and implementing comprehensive labelling, segregation, and traceability requirements, all while evolving scientific assessments and regulatory frameworks alongside advancements in modern agricultural food biotechnologies (Petetin, 2017).

However, on the topic of genetic modification, the EFSA published guidance documents concerning conducting Environmental Risk Assessment (ERA) as per Directive 2001/18 and Regulation 1829/2003 (Tsatsakis et al., 2017). According to Tsatsakis et al. (2017), the ERA uses, among other principles, the principle of comparative safety assessments, which they compare to the principle of substantial equivalence which is also used for risk assessment in the USA.

In the EU, highly precautionary regulations on GMOs have hindered their widespread adoption in farm fields (Paarlberg et al., 2024). According to the EU’s definition, a GM organism is “in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.”(EUR-Lex, n.d.).

The EU signed the Cartagena Protocol on May 24, 2000, and ratified it on August 27, 2002, which resulted in a streamlined version of the GMO definition (Ghouri et al., 2022). These regulations, characterised by mandatory labelling of foods containing 0.9% GMOs, reflect the EU’s stringent stance against GMOs (Gocht et al., 2021; Jha et al., 2021). European countries have individual rules and regulatory agencies for GMOs, overseen by the EC and EFSA, both working together to frame regulations (Gocht et al., 2021; Jha et al., 2021). This could also be because GMOs have traditionally been regulated differently from the beginning (Gocht et al., 2021). Before their public introduction, GMOs in any European country require permission at the country level through the EC, subject to rules and objection evaluations (Jha et al., 2021).

Historically, most European countries adopted a ‘light-touch’ approach to GMO regulation until the late 1980s (Falkner & Gupta, 2009). As a result of anti-GMO activists, NGOs, and civil societies, field trial disruptions, retailer boycotts and fear-mongering media headlines, which some call misleading, the development of GM crops has been complicated (Kafle, 2023; Spök et al., 2022). An example of this is the EU, where gene-edited crops are now categorised as GMOs (Devi & Aglawe, 2021). While NGOs can exert influence on aspects of the political agenda, they rarely ever directly influence the content of the agenda-setting process, which is mostly decided by states and other stakeholders (Millonzi, 2008). A tangible example of this is that eight NGOs worked together to make the regulations around new breeding techniques stricter (Devi & Aglawe, 2021). Conversely, Devi & Aglawe (2021) mention how in other countries like Canada gene-edited crops belong to the group of non-GM plants that exhibit novel characteristics.

However, rising concerns led the EU to adopt a more precautionary approach, institutionalising biosafety regulation in 1990 with directives emphasising risk assessment under conditions of scientific uncertainty (Falkner & Gupta, 2009; Ghouri et al., 2022). The EU legislation for GMOs was revised between 2000 and 2003 and because of this revision made more stringent (Ghouri et al., 2022). The influence of the anti-GMO movement in the EU extends beyond its borders, impacting regulatory decision-making in other countries (Devi & Aglawe, 2021). Many European countries have chosen an "opt-out strategy" for growing GM crops, influenced by the potential loss of European markets (Devi & Aglawe, 2021).

4.3.1 Fortification

Regulation (EU) No 1925/2006 governs the addition of the retinoid form of vitamin A, selenium, copper, and zinc to food within the EU if they do not exceed the specified maximum amount (van der Meer & Schebesta, 2020). National authorities can restrict the marketing of micronutrient-enriched foods in cases of scientific uncertainty, though importers only need to submit the relevant available information to the authorities for their safety assessment (van der Meer & Schebesta, 2020).

As such, implementing food fortification can be subject to regulatory challenges, as demonstrated by a case study on the pre-market authorisation of fortified foods in France (Berends & Carreño, 2005). In this case, France invoked Article 30 of the TEC, and Article 36 of the TFEU, to restrict the marketing of foodstuffs fortified with nutrients, because, as the French authorities argued that there was no identified nutritional need for these fortified products, thus justifying their restriction (Berends & Carreño, 2005). Nevertheless, the CJEU determined that France's pre-approval process impeded the unrestricted movement of goods and was deficient in transparency and ease of access (Berends & Carreño, 2005). The Court stressed the importance of national rules being in proportion to protect public health, backed by proven scientific data (Berends & Carreño, 2005). Since then, Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to food have been accepted in the EU to govern supplementation, however the maximum amounts as referred to in Article 6 of the latter regulation, were not submitted before January 19 2009 which makes this regulation difficult to apply (Vettorazzi et al., 2020).

The case also emphasised the significance of showing genuine safety concerns grounded on current information to validate restrictions on fortified products (Berends & Carreño, 2005). Although France's prohibition of specific energy drinks was maintained because of the presence of caffeine and additives that could pose health risks, the Court stressed the importance of having strong scientific proof to back up these actions (Berends & Carreño, 2005).

4.3.2 Biofortification

4.3.2.1 Agronomic

Agronomic biofortification is regulated under Regulation (EU) 2019/1009 as this describes the use of fertilisers, the limits of micronutrients in the fertilisers and the contaminant limits (European Parliament & Council of the European Union, 2023).

The implications of the Farm to Fork Strategy on biofortification are limited, but they do exist as one of the main targets of the Strategy is the reduction of fertiliser use by 20% (Leogrande et al., 2022). This would at least in part hinder agronomic biofortification as this makes use of fertilisers to achieve a higher nutrient content in crops. However, another Farm to Fork Strategy target is to reduce nutrient losses by at least 50%, which could very well be achieved through various methods of biofortification, but considering the fertilisation targets, maybe conventional breeding and biotechnological approaches would be recommended (Leogrande et al., 2022).

4.3.2.2 Biotechnological

4.3.2.2.1 GMOs

The internal market is defined in Article 4 of the TEU and is further described in Article 26 of the TEU, which is mentioned in Article 114 of the TFEU (The Member States, 2012). According to Szajkowska (2011) and The Member States (2012), Article 114(4) of the TFEU permits countries to establish specific exceptions in place of the customary harmonised standards, provided that they can show the exceptions are needed to protect human health and/or the environment through risk assessment (Szajkowska, 2011; The Member States, 2012). As a result of the protection of the internal market and opposition to national protectionism, the only way to support national food safety regulations is through science (Szajkowska, 2011).

Member states have adopted precautionary measures in different manners, such as applying safeguard clauses, exceptions from harmonisation measures, or emergency measures, especially in regulating GMOs (Guida, 2021). This can respectively be seen in the Monsanto Italy (C-236/01) and France Monsanto (C-58/10 to C-68/10), the Austrian case (C-439/05 P and C-454/05), and finally the France Monsanto (C-58/10 to C-68/10) and Fidenato cases (C-111/16) (Guida, 2021). Anyshchenko & Yarnold (2021) identify more cases that defined the precautionary principle in the EU; cases C-132/03, T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, T-141/00, and T-392/02.

However, applying the precautionary principle faces challenges, notably in reconciling divergent scientific views and assessing risks (Guida, 2021). Despite efforts to broaden the notion of risk assessment, uncertainties persist, reflecting a "weak" expression of the precautionary principle (Guida, 2021). Moreover, Member States can refuse the import of GMOs under the safeguard clause mentioned in Article 23 of Directive 2001/18/EC, with the exceptions in Article 12 stating to which GMOs this does not apply. Although chemical and radiation mutagenesis methods are exempt from the Directive, the CJEU decided that genome editing could not be exempted because it was developed after the GMO legislation was implemented (Vora et al., 2023). Mampuys (2023) identified three more EU legal documents regulating GM crops: Regulation (EC) 1829/2003, Regulation (EC) No 1830/2003 and Directive (EU) 2015/412.

The ever-changing nature of law regulatory affairs can be seen here as Mampuys (2023) identified different legal instruments than Hafeez et al. (2023) who use a reference from 2018 and as a result, refer only to Regulation (EC) 258/97, which is no longer in force, and Directive 2001/18/EC.

EU Courts frequently follow the scientific advice of EU scientific institutions, like the EFSA, where national and EU scientific viewpoints differ (Szajkowska, 2011). The identification of the danger, the characterisation of the hazard, and the evaluation of exposure to the hazard and the characterisation of the risk are the foundation of European risk assessments. With the EFSA forming the basis of an EU policy, it might seem difficult for countries to go against the EU, however, countries can also use the EFSA’s risk assessment to justify stricter national regulations (Szajkowska, 2011).

4.3.2.2.2 NGTs

The ambiguity and inadequacy of current regulatory frameworks are highlighted in the debate over categorising products acquired through new plant breeding techniques as GMOs (Gocht et al., 2021; Mampuys, 2023). In the EU, the classification of mutagenised crops as GMOs was confirmed by a 2018 CJEU ruling, subjecting them to strict regulations and labelling requirements (Gocht et al., 2021). Resulting of this decision, any characteristics that come from SDN1 will result in a GMO, but traits that come from natural or induced random mutagenesis are not subject to this regulation (Gocht et al., 2021).

Following the decision by the CJEU on the GMO status of mutagenised crops, a study commissioned by the Council and conducted by the EC found that certain NGTs are not adequately covered by EU legislation. The study also emphasised the potential of NGTs in transitioning towards a more sustainable agri-food system as outlined in the European Green Deal, Farm to Fork, and biodiversity strategies (Gocht et al., 2021; Spök et al., 2022). They also concluded that

"*In certain cases, it would be difficult to identify or trace the presence of NGT products not authorised in the EU and to prove in court that it did not result from naturally occurring mutations. Trade disruptions may occur, with economic losses and a lack of access to resources outside the EU…*" (Secretary-General of the European Commission, 2021, p. 59).

Recognising the need for a more flexible approach, the EC proposed a new legal framework that would loosen EU regulations on gene-edited crops and other products derived from NGT (Vora et al., 2023). This proposal introduces a classification system for NGT plants, dividing them into two categories, 'category 1 NGT plants' and 'category 2 NGT plants', based on the type and number of modifications, with different regulatory requirements for each as the current EU regulatory framework struggles to differentiate between products of classical techniques and NGTs, placing the EU food biotechnology industry at a disadvantage (Bello et al., 2024; EUR-Lex, 2024; Vora et al., 2023). Thereby acknowledging the necessity for a more inclusive and transparent decision-making process (Mampuys, 2023). Additionally, the EFSA emphasises the necessity of evaluating the dangers related to inadvertent genetic alterations by NGTs and acknowledges research gaps concerning unforeseen consequences, yet critics argue that this approach may miss potential negative impacts on human health, the environment, and agricultural productivity (Koller & Cieslak, 2023).

Certain researchers in Europe argue that the "innovation principle" is a better alternative than the precautionary approach on a case-by-case basis to allow for the use of gene-edited products while still addressing risks effectively (Caradus, 2023; Spök et al., 2022). Bello et al. (2024) suggest an adapted regulatory framework for NGTs could align with EU policy ambitions and benefit consumers and industry. The innovation principle focuses on evaluating the full impact of innovation to ensure that the methods and regulations chosen support innovation rather than impede it (Caradus, 2023). Moreover, because of the disadvantages stated in Chapter 3.2.5.1.3.2, especially those regarding the difficulties with distinguishing non-transgenic NGTs and classical breeding techniques, the current GMO regulatory framework is not fit for purpose and is prone to noncompliance, especially from imports benefiting from more lenient regulations (Bello et al., 2024).

Bello et al. (2024) emphasise that adopting non-transgenic NGTs could enhance the European food industry's ability to achieve the ambitious goals set by the Green Deal and Farm to Fork policies. However, the current process-based GM regulatory framework poses challenges, lacking adaptability to modern technologies and potentially impeding innovation (Bello et al., 2024).

Caradus (2023) and Bello et al. (2024) propose revising the regulatory framework to ensure it is adaptable to emerging technologies and market demands, aligning with pragmatic regulatory approaches seen in other regions to prevent noncompliance and promote innovation, additionally, they propose avoiding process-based regulatory system as this results in an overly precautionary approach for delivery of GM crops and forages (Bello et al., 2024; Caradus, 2023). As a step towards a product-centric approach, Bello et al. (2024) advocate exempting microorganisms obtained by non-transgenic NGTs from the obligations of the EU GM regulatory framework for deliberate release, like conventional mutagenesis methods.

4.4 Harmonisation

Since the mid-1990s, a lot has changed in the field of molecular biology, like the possibilities of RNAi, cisgenesis, marker-assisted selection, and transgenesis, causing the current legislation to be no longer fit for purpose (Caradus, 2023; Ghouri et al., 2022). Regulatory efforts aim to ensure human safety, environmental production, fraud prevention, and address public concerns (Caradus, 2023). However, one of the primary obstacles to the success of gene editing technologies lies in their regulation, particularly the question of whether to regulate them (Ghouri et al., 2022).

For gene-edited crops to become commercially viable, regulatory environments must be deregulated and harmonised internationally, with implications for small-scale farmers and consumers (Vora et al., 2023). Divergent regulatory standards have created a global divide in international biotechnology (Falkner & Gupta, 2009). Debates surrounding regulatory restrictions and consumer attitudes towards GMO trade have raised questions about the efficacy of international authorities such as the WTO and standard-setting bodies like the CAC and the Cartagena Protocol (Laxman & Ansari, 2023a).

Gerstetter & Maier (2005) and Maier (2012) demonstrate how policies not supported by a risk assessment or globally harmonised food standards, such as those defined by the CAC, and set up by the FAO and WHO, can be contested through the WTO dispute settlement process. Transatlantic disagreements over the application of the precautionary principle, such as the hormone dispute between the USA and EU, and the regulation of GM foods underscore the challenges of global influences in regulatory affairs (Maier, 2012).

According to Lassoued et al. (2021) and Ghouri et al. (2022), experts surveyed, regardless of their background and region, agree on the need to enhance regulatory procedures to better integrate socioeconomic factors with scientific standards, which has only been exacerbated with the rise of gene editing technologies and gene-edited crops. Addressing the conflict between Indigenous customs and global scientific knowledge is crucial for addressing global standardisation and the equal distribution of biotechnological advancements in agriculture (Caradus, 2023; Lassoued et al., 2021).

Ghouri et al. (2022) propose an adaptable and flexible regulation that maintains safety measures while accommodating modifications and addressing various challenges. Key components of regulation include mandatory pre-market approval, safety standards, transparency, public participation, expert scientific advice, independent agency decisions, post-approval activities, and enforcement authority (Caradus, 2023). Changing regulatory processes may hinder the pursuit of change due to lengthy procedures (Caradus, 2023). Harmonisation of GM regulations globally, or within regions, could be preferable (Caradus, 2023).

International trade plays a significant role in shaping food systems, emphasising the importance of promoting healthier diets and environmental sustainability (Malézieux et al., 2023).

Ten years ago, in 2014, in Rome at the Second International Conference on Nutrition, high-level government representatives from various countries highlighted the role of biofortification in national strategies to combat malnutrition by 2025 (Bouis & Saltzman, 2017). More than 20 countries, including Bangladesh, Malawi, Nigeria, Pakistan, Uganda, Colombia, Panama, Rwanda, and Zambia, have integrated biofortified crops into their national agriculture and nutrition plans, facilitated by regional and global initiatives like the African Union's Comprehensive Africa Agriculture Development Program and the Scaling Up Nutrition (SUN) Movement (Bouis & Saltzman, 2017). However, to reach the goal of reaching one billion people by 2030, biofortification efforts must extend beyond HarvestPlus, requiring higher prioritisation from policymakers, inclusion in nutrition agendas, and mainstreaming by breeding partners and food processors across the value chain (Bouis & Saltzman, 2017). To address uncertainties, contradictions, and conflicts, several agencies, governments, and NGOs propose using current regulatory frameworks for gene editing events (Ghouri et al., 2022).

4.5 Commercialisation

The development and commercialisation of bioproducts using gene editing tools enabled them to move from the lab to the field; however, the adoption of these technology-driven crops from the lab to the farmer's field is hampered by policy-making and regulatory framework challenges (Devi & Aglawe, 2021; Hafeez et al., 2023; Hemalatha et al., 2023).

The extended approval times, which Hafeez et al. (2023) estimated to be seven years in the EU and five years in the US, pose challenges for smaller biotechnology companies and public institutions, limiting their ability to enter the market. As getting GM varieties to market is both time-consuming and expensive, there has been a need to create new quicker and cheaper techniques to execute DNA sequence-specific alterations to improve crop performance in the face of environmental shifts caused by climate change (Lassoued et al., 2021). A slow, burdensome, and stringent regulatory system inevitably results in a loss of international competitive advantage in the development and use of GM crops, as well as a significant risk to food security and biodiversity, as more land is required to feed a growing global population (Caradus, 2023). Especially because policy interventions and regulatory frameworks play a crucial role in shaping innovation in agricultural biotechnology, legal mechanisms are both the regulators and facilitators of scientific progress (Lassoued et al., 2021; K. K. Singh, 2021). This division between the two key research and growing regions exacerbates the already challenging world of asynchronous use of novel biotech crops, with knock-on effects on global trade (Lassoued et al., 2021). However, concerns regarding the equal distribution of benefits, monopolistic practices of large biotechnology companies, and labelling issues driven by consumer preferences and lobbying interests remain (K. K. Singh, 2021). The decision by the CJEU to subject organisms created using modern mutagenesis techniques to EU GMO law has led EU-based businesses to focus on markets outside the EU often to countries that use a product-based system, which exists in most of the countries in North-, Middle-, and South-America (Lassoued et al., 2021; Vora et al., 2023). Additionally, emerging GM production companies have gravitated towards developing countries like India as these do not, yet, have established regulations, market conditions, public perceptions, and socioeconomic factors that complicate the success of GM products (Agarwal & Singh, 2021).

Addressing these multifaceted challenges necessitates policy measurements such as subsidies, robust monitoring systems, and strategies to mitigate insect refuge problems (Agarwal & Singh, 2021; Hafeez et al., 2023). Against this background, countries must navigate a variety of challenges and considerations in formulating robust policy frameworks for GM crop adoption and commercialisation (Agarwal & Singh, 2021).

Consumer acceptance remains a significant challenge for transgenic crops, with issues such as changes in colour and taste affecting their popularity (Monika et al., 2023). Despite research efforts in developing countries on a wider range of crops and traits relevant to food security, acceptance by the masses remains uncertain (Dronamraju, 2008; Monika et al., 2023). Developing countries have been researching a broader range of crops and traits, indicating a potential shift towards more diverse GMOs relevant to food security (Dronamraju, 2008).

4.6 Conclusion Policy and Regulation

This chapter gives an answer to the two remaining sub-questions. ***The first one investigates how variations in existing regulatory standards for nutrient-enriched biofortified foods across countries***

intersect with international regulatory bodies, initiatives like the EU's Green Deal, and existing trade agreements, in the context of enhancing food security through biofortification and gene editing.

Variations in regulatory standards for biofortified foods intersect with international regulatory bodies, initiatives like the EU's Green Deal, and existing trade agreements in complex ways. Harmonising these standards while promoting the adoption of biofortification and gene editing technologies is essential for enhancing food security and ensuring access to nutritious foods worldwide.

The second sub-question investigates how harmonisation strategies can ensure global consistency while facilitating the adoption and diffusion of biofortified agriculture, considering the complexities of regulatory standards and trade agreements.

Harmonisation strategies offer a multifaceted approach to promoting global consistency in regulatory standards for biofortified agriculture. By promoting standardisation, collaboration, alignment with international agreements, capacity building, stakeholder engagement, and flexibility, harmonisation facilitates the adoption and diffusion of biofortified crops, contributing to enhanced food security, nutrition, and sustainability on a global scale.

5. Methodology and Results

5.1 Research Design and Interviewees

Besides drawing from literature to answer the research questions, semi-structured interviews with four experts in the field of biofortification and food security were conducted. The interviews were designed to first establish a background of the definitions discussed, such as biofortification, GMOs, and food security since these can significantly impact other questions asked.

5.1.1 Interview Method

The interviews for this research were conducted using a semi-structured interview approach (Adams, 2015). This method aims to collect in-depth insights based on the interviewees' expertise and viewpoint on the asked topic. Here, the semi-structured interviews were used to obtain knowledge from professionals in the fields of biofortification, GMOs, and food security.

Table 1 shows the people approached for an interview, their role within their organisation, and whether they replied to the message, ignored it or were unavailable. In the e-mail, a description was given of the thesis topic, the definitions used for this thesis were also given and, in the attachments, the questions that were going to be asked were given. This allowed for a more conversational interview and exchange of viewpoints, resulting in a more thorough understanding of the potential future role of biofortification in food security and micronutrient deficiencies.

To stay on topic during the interviews, an outline of planned themes was created along with leading questions, which can be found in Appendix 1. These questions were reviewed and revised before the interviews took place to ensure their relevance and objectivity. Adjustments were made during the interview based on each interviewee's role within their respective organisation and their expertise, the specific questions asked can be found in Appendix 2. Interviewees were sent the questions and background information to better prepare for the interviews and to allow for a focused exploration of the topic. Although these questions are open-ended in nature, they are specifically directed towards important viewpoints and insights on biofortification and food security as well as any knowledge gaps identified by the literature research. Afterwards, the interviews took place through video conferencing. The interviews began by establishing the background and role of the interviewee within their organisation before diving into the remaining questions. The interviews were recorded and then transcribed. After the transcription was finished, the results were sent to the interviewee to ensure clarity, objectivity, correctness and understanding of the interview. It also allowed interviewees to give additional remarks.

Table 1: Overview of people approached for interviews.

Person	***Interviewee ID Code***	***Role and Organisation***	***Reply***
Alexandra Nikolakopoulou		Head of unit Farm to Fork Strategy |DG SANTE	No reply
Andres Acre		Publications and communications | GRAIN	Referred me to Susan Nakacwa
Gijs van den Berg		Policy Officer International Cooperation and Biodiversity | Ministry of Infrastructure and Water Management	No reply
Hannah Sievers		Policy Officer | DG SANTE	No reply
Helene Schmutzler		Policy Coordinator | IFOAM Organics Europe	No reply
Janne Balk		Head of Department for Biochemistry and Metabolism | John Innes Centre	No reply
Martina Ciccarello		Legal/Policy Officer at European Commission | DG SANTE UNIT A.2 - Inter-institutional relations	Referred me to Paschalia Koufokotsiou
Saskia Osendarp		Visiting Associate Professor Nutrition and Health in Low- and Middle-Income Countries | Wageningen University & Research	No reply
Silvia Schmidt		Policy Manager | IFOAM Organics Europe	Referred me to Helene Schmutzler
Teresa Penfield		Programme Manager | John Innes Centre	Replied, no interview due to field of work
Niels Louwaars	I01	Director | Plantum	Interviewed
Irene Santoro	I02	Research Intern | ATNI	Interviewed
Diane Bosch	I03	Senior food and nutrition security advisor | Wageningen Centre of Development Innovation	Interviewed
Susan Nakacwa	I04	Programme staffer | GRAIN	Interviewed

5.2 Results

It is essential to select the appropriate data analysis methods to ensure the validity and reliability of interpreting the collected data for the research. A thematic analysis was used to examine the potential of biofortification in ensuring food security and identify related concerns, the themes to which the research question and interview question relate, can be seen in Table 2. Experts' quotes were used in this study, an overview of the interviewed experts can be found in Table 1, and the full transcriptions of the interviews can be found in Appendix 2.

Thematic Analysis of the Interviews

Table 2: Overview of themes with the relevant interview question and research question.

Themes	Interview question	Research question
GMOs	How would you define GMOs?	1, 2, 3
	In your opinion, do you think GMOs differ from conventionally bred crops?	2
	Are there any emerging ethical considerations or debates concerning the use of genetic modification and biotechnology in biofortification efforts?	2
Biofortification	How would you define biofortification?	1
	Would you say that you are in favour of biofortification?	1, 2
	What, in your view, are the main advantages and limitations of biofortification compared to other approaches for tackling malnutrition and enhancing food security?	2
	How do you foresee biofortification aligning with broader sustainable development goals?	2, 3
	What potential conflicts exist between promoting biofortification and adhering to established food safety and nutritional labelling standards?	3, 4
	Are there risks associated with the unintended consequences of biofortification, such as biodiversity loss or environmental impacts?	2
	Are there any emerging ethical considerations or debates concerning the use of genetic modification and biotechnology in biofortification efforts?	2
Food Security	What does food security mean to you?	1
	(How) do you think food security can be achieved?	2, 3
Consumer Acceptance	What strategies do you think could enhance consumer acceptance and trust in biofortified crops, especially in regions with a limited understanding of biotechnology?	2, 3
Policy and Regulation	How do government policies and regulatory frameworks influence the adoption and safety of biofortified crops?	3, 4
	Looking ahead, what do you believe are the priority areas for policy development and regulatory reform to further integrate biofortification into sustainable food systems and nutrition strategies?	3, 4
	What potential conflicts exist between promoting biofortification and adhering to established food safety and nutritional labelling standards?	3, 4
Commercialisation	In your view, what are the key regulatory challenges associated with the commercialisation and deployment of biofortified crops, both within the European Union and internationally?	3, 4

GMOs

The exploration of GMOs revealed a variety of perspectives among the interviewees, reflecting the complexity of this controversial topic. While some interviewees offered technical definitions, others delved into deeper ethical considerations, highlighting the moral dilemmas inherent in GMOs. When asked about the difference between GMOs and conventionally bred, GMOs were described as organisms whose genetic material/DNA was modified in a way that would not be possible naturally, indicating that human intervention makes the difference between GMO and non-GMO (*Interviewees I01 & I02*). The unnaturalness and unpredictability of GMOs as disadvantages compared to conventional breeding can be a reason for some to disregard GMOs as a potential way to achieve biofortification (*Interviewee I03*). Whereas these are like the official definition of GMOs, some defined it the same as biofortification:

"Tinkering with food using technology, or using scientific methods that go against the norm, or what we know." – I04

Ethical debates surrounding GMOs emerged as a central theme, with interviewees expressing concerns about corporate interests overshadowing societal welfare. Additionally, the fact that people profit from biofortified crops can cause a barrier for people in low-income households (*Interviewees I02, I03 & I04*). A balance between profitable biofortification efforts and ensuring they are available to all consumer groups *Interviewees I02 & I03*). Indicating a potential trade-off between making food for all kinds of consumers, which can be unhealthy, and the availability of unprocessed crops, which is why there is a need for regulation to ensure availability for every consumer.

The interviewees underscored the need for transparency, equitable access, and comprehensive regulatory frameworks to effectively address these ethical challenges.

Biofortification

The second theme of the interviews focuses on biofortification. The discourse on biofortification unveiled a spectrum of perspectives, ranging from enthusiastic endorsements to cautious scepticism. While the potential of biofortification to address nutritional deficiencies, disparities emerged regarding its alignment with GMOs (*Interviewees I01, I02 & I03*). Reservations about GMOs to achieve biofortification, highlighting divergent views within the community were also expressed (*Interviewee I03*). As mentioned in the GMO part of the interview results, one interviewee compared it to GMOs, with the added notion that they do differ as the science behind them is not the same (*Interviewee I04*). However, according to them, they both aim to achieve the same goal, increasing food security.

Biofortification offers several advantages, including catering to the specific nutritional needs of vulnerable populations and enhancing nutrient stability, which contributes to sustainable agriculture. However, challenges like environmental impact and regulatory hurdles persist. While biofortification is instrumental in achieving food security and combating malnutrition, it cannot single-handedly address broader issues like poverty and dietary diversity.

"Biofortification is not solving the underlying problem, but just an important effect." –I01

Though the micronutrient levels in biofortified crops are important, the question of how to effectively measure and regulate them remains. Concerns about potential toxicity from excessive consumption of biofortified crops may be overstated, particularly in regions with prevalent micronutrient deficiencies (*Interviewee I03*). However, they stress the importance of justifying biofortification efforts and addressing any safety concerns transparently. They also mention hesitance about introducing micronutrients in currently available staple crops and instead suggest producing biofortified crops as substitutes. Additionally, concerns about the limited scope of micronutrients targeted through biofortification efforts have been raised.

When asked about the environmental and biological consequences of biofortification, the interviewees gave diverging answers. Interviewee I01 argued that introducing biofortified varieties is not fundamentally different from introducing disease-resistant varieties. However, others emphasise the importance of considering biodiversity risks associated with biodiversity as we cannot be entirely sure of the outcome (*Interviewees I02 & I03*). Interviewee I03 mentioned the need to enhance biodiversity and ensure environmental safety when implementing biofortification initiatives.

Ethical debates surrounding biofortification centre on affordability, access, and transparency, with biofortification remaining a key component in addressing broader SDGs, particularly SDG 2 related to ending hunger, promoting sustainable agriculture, and achieving food security and economic prosperity for small-scale farmers. Biofortification can contribute to viable agricultural production while enhancing nutritional outcomes.

Biofortification can be seen as a technological solution multifaceted challenge of malnutrition, hunger, and food access. Particularly in terms of advancing technological solutions to the problems hindering the achievement of the SDGs. However, Interviewee I04 gave an example from personal experience where a specific local banana, the Nakitembe, was used to develop the Super banana. The developers did not consult the Baganda when the genetic material was taken, but now there is a patent on the variety, and the Baganda can no longer freely use it.

Food Security

The interviewees offered diverse perspectives on what food security means to them; in most cases, food security was described as food of sufficient quantity and quality for all. The four main components of food security, namely food availability, access, utilisation, and stability, were mentioned with the addition that the diet achieved would have to be healthy and sustainable to achieve food security, acknowledging variations in policy definitions that may focus more narrowly on staple foods (*Interviewees I02 & I03*).

Conversely, the difference between food security and food sovereignty was discussed by interviewee I04 (personal communication, April 2024). They argue that food sovereignty encompasses broader cultural, social, and individual aspects beyond mere access to food. Food sovereignty recognises diverse cultural practices, respects individuals' identities, and acknowledges the role of farmers in preserving traditional foods and seed varieties.

When asked if food security can be achieved, some interviewees were more positive than others. While interviewees I01 and I04 did not explicitly state scepticism towards the possibility of achieving food security, or sovereignty, the remaining interviewees expressed more scepticism.
For ways to achieve food security, interviewees I01, I02, and I03 all expressed addressing the underlying, multifaceted causes of food insecurity: culture, economics, geopolitical factors, food waste, consumer decision-making, dietary preferences, and sustainability concerns; a holistic approach is recommended.
However, interviewee I04 advocates for food sovereignty as an alternative approach to achieving food security. They emphasise the importance of recognising and empowering farmers, preserving traditional agricultural practices, and resisting industrial agriculture. They highlight grassroots efforts to reclaim control over food production and decision-making processes, underscoring the role of communities and organisations in promoting smallholder farming and protecting indigenous seeds.

Consumer Acceptance

Strategies to enhance consumer acceptance of biofortified crops emerged as a critical focus of discussion, with interviewees highlighting the importance of education, the availability of information, community engagement, and transparent communication. The interviewees emphasised the need for tailored approaches that resonate with diverse cultural contexts, underscoring the pivotal role of trust-building and information dissemination in fostering acceptance and adoption.

Policy and Regulation

Government policies and regulatory frameworks significantly influence the adoption and safety of biofortified crops. Adoption processes may be relatively straightforward in regions like the USA and Brazil, but challenges arise in the EU due to consumer attitudes and regulatory complexities. Harmonising legislation is considered challenging, requiring efforts to address consumer mistrust through education and stakeholder engagement, particularly with farmers.
Defining biofortified crops through regulatory standards ensures they offer substantial nutritional benefits. Taste testing and consumer education are essential for adoption, alongside considerations for reducing cooking time, especially in regions where women bear the bulk of household cooking responsibilities. Regarding safety, existing safety measures are advocated to apply to biofortified crops without necessitating additional regulations.

Conversely, interviewee I04 explicitly stated being against harmonisation and international, free, trade agreements as disrespecting national identities and farmers' rights:

"[…] the journey of colonialism ends up in free trade agreements." – I04

Looking ahead, priority areas for policy development and regulatory reform to integrate biofortification into sustainable food systems and nutrition strategies include investing in research for robust safety assessments and stakeholder engagement, particularly with local communities. It is essential to include biofortification in relevant policies, such as agriculture and marketing regulations, with dedicated sections addressing concerns raised by stakeholders. Policies should ensure adequate monitoring systems to assess micronutrient content and regulate breeding techniques to maintain safety and nutritional quality. Additionally, economic aspects need safeguarding to ensure benefits for both producers and consumers.

"… it needs to be regulated because it needs to be made sure that it is available for all consumer groups." – I03

Commercialisation

The key regulatory challenges associated with commercialising and deploying biofortified crops, both within the EU and internationally, include addressing consumer mistrust and educating stakeholders to build support for regulatory frameworks. Harmonising legislation across regions is challenging but crucial for ensuring consistent standards. It is essential to regulate commercialisation to ensure accessibility to all consumer groups, particularly low-income households, without compromising food security or promoting highly processed foods. Striking a balance between commercial interests and public health goals requires careful regulation to prevent the depletion of raw crop availability and maintain the nutritional integrity of biofortified products. Additionally, addressing cultural preferences and perceptions, such as crop colour biases, is important for consumer acceptance and adoption of biofortified crops.

6. Discussion

6.1 Interpretation

Results

Food Security

Taking into consideration the 6 pillars of food security (see Chapter 3) the multifaceted nature of food security encompasses not only access to food but also its quality, sustainability, and cultural significance (Fanzo, 2019; *Interviewee I04*). While some interviewees express optimism about achieving food security through holistic approaches that address underlying causes such as culture, economics, and sustainability (*Interviewees I01, I02 & I03*), others advocate for food sovereignty as an alternative paradigm (*Interviewee I04*). Food sovereignty emphasises the empowerment of farmers, preservation of traditional agricultural practices, and resistance to industrial agriculture (*Interviewee I04*). Food sovereignty, as explained by Interviewee I04 with the definition of food security given by the (FAO, 2006) and Tyczewska et al. (2023).

Addressing food security demands a comprehensive approach considering various interventions like biofortification, dietary diversification, fortification, and supplementation (Fanzo, 2019; Olson et al., 2021).

Fortification, with its historical roots dating back to the early 1920s, has emerged as a cost-effective intervention for combatting nutrient deficiencies (Fischer et al., 2023). By adding essential nutrients to processed foods, fortification has successfully altered the micronutrient status in communities with minimal expenses (Mishra et al., 2022). However, challenges persist, including limited accessibility for impoverished communities and the potential masking of other deficiencies due to the use of added micronutrients (Komarnytsky et al., 2022). Although fortified foods can help with nutritional deficiencies, they do not replace a varied diet that offers essential nutrients for good health (Yadav et al., 2020; *Interviewee I01*). Moreover, while the classic fortification of staple foods such as salt has helped reduce deficiencies in micronutrients, demonstrating the efficacy of biofortified foods is difficult due to several factors in the populations being studied, as mentioned by Hotz & McClafferty (2007) and Yadav et al. (2020).

In contrast to fortification, biofortification offers a promising solution by integrating nutrient improvement into staple crops, thereby reducing reliance on external interventions like supplementation or fortification (Yadav et al., 2020). While it offers advantages such as catering to specific nutritional needs and enhancing nutrient stability, challenges like environmental impact and regulatory hurdles continue (Fanzo, 2019; Ofori et al., 2022). Consumer acceptance remains a critical factor. This can be enhanced by including tailored approaches that resonate with diverse cultural contexts and build trust through information distribution (Bechoff et al., 2018; *Interviewees I02, I03 & I04*).

Literature, desk research, and interviewees, field research, reveal varying perceptions based on factors like regional demographics and visible traits of crops (Bechoff et al., 2018; Fanzo, 2019). While biofortified crops generally fare well in sensory testing, concerns about GMOs and scepticism about risks and benefits can influence consumer acceptance (Ofori et al., 2022). GMOs have emerged as a central theme in the discourse on biofortification. While some interviewees view GMOs as a viable means of achieving biofortification, others express reservations about their unnaturalness and unpredictability (*Interviewees I01, I02 & I03*). Ethical debates surrounding GMOs highlight concerns about corporate interests, equitable access, and regulatory transparency. These discussions underscore the need for comprehensive regulatory frameworks and transparent communication to address ethical challenges effectively (Fanzo, 2019; *Interviewee I04*).

Furthermore, the success of interventions like biofortification depends not only on consumer acceptance but also on regulatory frameworks and policy support. Regulatory challenges, as demonstrated in the widespread adoption of wheat flour fortification with folic acid, underscore the need for flexible and adaptive regulations to facilitate the implementation of nutrition interventions (Mishra et al., 2022).

Policy and Regulation

NGTs have emerged as promising tools for enhancing agricultural productivity, sustainability, and food security (Ofori et al., 2022). However, the regulatory landscape surrounding NGTs is complex and full of challenges that must be addressed for NGTs to realise their full potential (Caradus, 2023; Ofori et al., 2022). A few of the relevant to regulating GMOs cases were discussed in this thesis: the Monsanto Italy (C-236/01) and France Monsanto (C-58/10 to C-68/10), the Austrian case (C-439/05 P and C-454/05), and finally the France Monsanto (C-58/10 to C-68/10) and Fidenato cases (C-111/16) (Guida, 2021). The cases discussed relevant to defining the precautionary principle in the EU are: 132/03, T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, T-141/00, and T-392/02 (Anyshchenko & Yarnold, 2021).

In response to the challenges posed by current regulatory frameworks, policymakers and stakeholders have proposed various policy responses (Caradus, 2023). The debate over categorising products acquired through NGTs as GMOs highlights the ambiguity and shortcomings of current regulatory frameworks (Ofori et al., 2022). In the EU, a 2018 ruling classified mutagenized crops as GMOs, subjecting them to stringent regulations (Ofori et al., 2022). Efforts to address this include the European Commission's proposal of a new legal framework that would loosen regulations on gene-edited crops and NGT-derived products (Caradus, 2023). This framework introduces a classification system for NGT plants, to address the current regulatory framework's shortcomings and promote innovation in the EU food biotechnology industry.

The debate over NGTs also raises questions about the balance between precaution and innovation in regulatory decision-making (Caradus, 2023). Some researchers advocate adopting the "innovation principle" as an alternative to the precautionary approach, arguing that it allows for using gene-edited products while effectively addressing risks on a case-by-case basis (Caradus, 2023). Interviewee I01 emphasised the need for a nuanced approach, advocating for a balance between precaution and innovation in regulatory decision-making. Interviewee I04 highlighted the importance of recognising and empowering farmers in shaping regulatory policies, aligning with the principles of food sovereignty.

Harmonisation of regulatory standards for NGTs ensures global consistency and facilitates their adoption and diffusion (Ofori et al., 2022). Divergent regulatory standards have created a global divide in international biotechnology, raising questions about the efficacy of international authorities and standard-setting bodies (Fanzo, 2019; Ofori et al., 2022). Challenges in regions like the EU include consumer attitudes and regulatory complexities (Caradus, 2023). Harmonisation strategies offer a multifaceted approach to promoting global consistency in regulatory standards for biofortified agriculture, contributing to enhanced food security, nutrition, and sustainability on a global scale (Ofori et al., 2022).

Alternative explanations

Alternative explanations for the effectiveness of food security interventions include differences in the quality of implementation, accessibility of interventions to target populations, and socio-cultural barriers to adoption.

Differences in results in consumer acceptance of biofortified crops include variations in trust levels towards biotechnological innovations, cultural attitudes towards GMOs, and competing priorities in

household food choices.
Alternative explanations for regulatory challenges include differences in regulatory capacity, alignment with international standards, and the influence of public opinion on policy decisions.
Variations in ecosystem dynamics, long-term effects of agricultural practices, and regional variations in environmental sensitivity can lead to differences in environmental impact results.
Alternative explanations for the ethical considerations identified in this thesis include debates over food sovereignty, corporate influence on agricultural practices, and the rights of farmers and consumers in decision-making processes.
History, institutional capacities, and power dynamics may influence policy responses to challenges in biofortification and GMO regulation. Alternative explanations include political will variations, industry stakeholders' lobbying efforts, and competing agendas within government agencies.

6.2 Implications

The results of this research are consistent with the resources that have been reviewed. One of the main differences is the apparent scepticism during the interviews about whether food security can be achieved. Furthermore, on the same topic of food security, the importance of transparency and communication with the target population and including was underscored more than is often applied in food interventions. The interviewees stressed the importance of focusing on what the target population needs, wants and what is realistic and include various stakeholders.

Another difference is that the results of this research are more in favour of biofortification through gene editing compared to previous research, which often favoured conventional breeding techniques.

These results provide valuable insights and guidance for various stakeholders involved in addressing food security and malnutrition challenges. Policymakers can use these findings to develop more effective strategies and regulations, while researchers can identify areas for further investigation and innovation. Understanding consumer perceptions and preferences regarding biofortified crops can also benefit farmers and food producers.

Integrated policies are essential for addressing food security comprehensively. They require a balance between innovation and safety in biofortification technologies within regulatory frameworks. Tailored communication strategies are pivotal in enhancing consumer acceptance of biofortified crops.

Furthermore, research investments are crucial for developing biofortified crops and fortified foods, while supporting food sovereignty initiatives strengthens local food systems. International collaboration remains vital for sharing best practices and harmonising regulations.

6.3 Limitations

This qualitative research, written between January and June 2024, acknowledges the inherent subjectivity and researcher biases due to its qualitative nature. To mitigate these, findings are contextualised through comparisons with prior research. The scope, limited to literature publicly available before April 15th, 2024, in the changing fields of law, regulatory affairs, and nutrition, is acknowledged. Despite efforts to mitigate bias and subjectivity, factors like personal interpretation, limited validity, and challenges in securing knowledgeable interviewees pose risks to replicability.

Interviews conducted for this thesis, targeting both proponents and opponents of biofortification, encountered difficulty in sourcing knowledgeable participants. Moreover, the risk of socially desirable responses in interviews is acknowledged. And an attempt to mitigate this through advice given by (George, 2023).

Two approaches to the legislation and characterisation of GMOs and gene-edited crops are discussed: the process-based approach taken in, among other countries, the EU and the product-based approach taken in several countries, and also in the USA. The EU and the USA are highlighted in this thesis as examples for the others, however, there could be differences between countries using similar approaches. This choice was made as the USA and EU both have a significant impact, and the legislation and regulatory frameworks can be easily found. Previous research made similar comparisons.

Potentially missed variables in this thesis could include factors such as geographic location, cultural differences, and socioeconomic disparities, which may influence perceptions and experiences related to biofortification, GMOs, and food security. Additionally, the perspectives of stakeholders such as farmers, policymakers, and community members may provide valuable insights that were not captured in the interviews with experts alone. Furthermore, the impact of specific biofortified crops or interventions on local agricultural systems and food environments could represent important variables that were not fully explored. Other missed variables may include technological advancements, market dynamics, and policy changes that could shape the future landscape of biofortification and food security.

7. Conclusion

7.1 Main research question

The main research question in this thesis investigates the role of biofortification and gene editing in enhancing food security and how these technologies are currently regulated and governed in policy frameworks on the International and EU levels.

Biofortification and gene editing play a complex role in improving food security through enhancing nutrition, sustainability, and resilience. Biofortification addresses malnutrition and dietary deficiencies by enhancing crops with essential nutrients, especially benefiting vulnerable communities. Gene editing techniques contribute to food security by enhancing crop resilience, productivity, and nutritional value, ensuring stable food supplies amid climate change and environmental stressors.

The regulation and governance of these technologies at the international and EU levels are complex and evolving. Internationally, organisations like the CAC offer guidelines for food safety and food quality. However, the regulation of gene editing lacks a global agreement, resulting in varied approaches worldwide.

Biofortification and gene editing face strict regulatory frameworks in the EU, especially within the context of the EU's Green Deal and sustainability policies. Legal rulings have classified gene-edited crops as GMOs, sparking ongoing debates and efforts to revise these regulations for a more balanced framework that promotes innovation while maintaining safety and sustainability.

Differences in regulatory standards for biofortified foods across countries intersect with global initiatives and trade agreements, highlighting the importance of harmonisation to support global consistency and improve food security globally. Harmonisation strategies include standardisation, cooperation, stakeholder engagement, and flexibility, supporting the adoption and spread of biofortified crops worldwide.

In conclusion, the regulation and governance of biofortification and gene editing technologies are influenced by scientific, ethical, and socioeconomic factors, with ongoing debates and policy developments shaping their implementation and impact on food security at the international and EU levels. Efforts toward harmonisation and balanced regulatory frameworks are essential to maximise the benefits of these technologies while ensuring safety, sustainability, and equitable access to nutritious foods.

7.2 Reflection on the Research Questions

This thesis used a combined approach of a literature review and semi-structured interviews, which allowed for a comprehensive exploration of topics related to biofortification, gene editing, and food security. A deeper understanding of the complex issues and factors influencing food security was gained by integrating theoretical foundations with insights from experts in the field.

The research sub-questions guiding this thesis were:

1. What theoretical foundations support the role of biofortification in improving food security, and how do these foundations inform policy development and implementation?
2. How does biofortification compare to alternative food-based strategies such as dietary diversification, fortification, supplementation and more, regarding consumer acceptance,

sustainability, and socioeconomic and environmental implications, and what policy implications arise from these comparisons?
3. How do variations in existing regulatory standards for nutrient-enriched biofortified foods across countries intersect with international regulatory bodies, initiatives like the EU's Green Deal, and existing trade agreements, in the context of enhancing food security through biofortification and gene editing?
4. Given the complexities of regulatory standards and trade agreements, how can harmonisation strategies ensure global consistency while facilitating the adoption and diffusion of biofortified agriculture?

The semi-structured interviews provided valuable insights and perspectives from experts in biofortification, GMOs, and food security. These insights complemented the existing literature and offered nuanced viewpoints on policy frameworks, regulatory challenges, and potential implications of biofortification and gene editing technologies.
The combined approach ensured the relevance and applicability of the findings to the main research question. By tailoring interview questions to key themes and objectives, information directly relevant to understanding the role of biofortification and gene editing in enhancing food security, as well as the current regulatory landscape, was obtained.

While exploring the regulatory frameworks for biofortification and gene editing technologies, unexpected insights emerged regarding the nuanced differences in policy approaches between regions and countries. This raised questions about the potential implications of these differences on international trade, agricultural innovation, and food security.
Through expert interviews, unexpected insights were gained into the complex dynamics of consumer acceptance of biofortified crops and gene-edited foods. This raised questions about the role of communication strategies, cultural factors, and trust-building in shaping consumer perceptions and behaviours towards these technologies.
Discussions on the environmental impact of biofortification and gene editing technologies raised new questions about the interventions' long-term sustainability and ecological implications. This highlighted the need for further research into the broader environmental consequences beyond immediate nutritional benefits.
Unexpected insights emerged regarding the equity and access issues related to biofortification interventions. This raised questions about ensuring that vulnerable populations, particularly in low-income countries, have equitable access to biofortified crops and benefit from their nutritional advantages.

7.3 Emphasise your contribution

The research presented in this thesis is expected to contribute to a deeper understanding of the complexities surrounding food security, biofortification, and GMOs. By synthesising findings from literature reviews, empirical studies, and interviews, this study aims to provide insights that can inform policy, practice, and future research in these areas.
Practitioners in fields such as agriculture, nutrition, and public health can benefit from the findings of this research by gaining a deeper understanding of the advantages and challenges associated with biofortification and GMOs. Practical implications include adopting tailored approaches to enhance consumer acceptance, promoting sustainable agricultural practices, and developing innovative solutions to address malnutrition and food insecurity.

The research provided a detailed analysis of the policy frameworks governing biofortification and gene editing technologies at the international and EU levels. This included insights into the

complexities of regulatory standards, trade agreements, and governance structures, shedding light on the challenges and opportunities for advancing food security through these technologies.
The research uncovered nuanced insights into the factors influencing consumer acceptance of biofortified crops and gene-edited foods through interviews with experts. This included considerations such as cultural attitudes, trust in regulatory processes, and perceptions of risk and benefit, contributing to a deeper understanding of the social dynamics surrounding these technologies.
The research highlighted the environmental implications of biofortification interventions, including potential impacts on biodiversity, soil health, and ecosystem resilience. By examining these aspects, the research expanded our understanding of the broader sustainability implications of biofortification beyond immediate nutritional benefits.
Through discussions with experts, the research identified equity and access challenges related to biofortification interventions, particularly in low-income countries. This included issues such as affordability, distribution systems, and farmer empowerment, adding new insights into the social justice dimensions of biofortification efforts.

Overall, the research contributes new knowledge by deepening understanding of the multifaceted issues surrounding biofortification, gene editing, and food security and by uncovering novel insights into policy, consumer behaviour, environmental sustainability, and social equity aspects related to these technologies. Ultimately, the long-term goal of this research is to contribute to the development of sustainable, equitable, and nutrition-sensitive food systems that promote food security and improve nutrition outcomes for all populations, particularly vulnerable and marginalised groups. By advancing knowledge and informing policy and practice in this area, this research seeks to contribute to achieving global goals related to food security, health, and sustainable development.

7.4 Limitations of Research Methods

The limitations of this thesis include the small sample size of interviews, as only four experts were interviewed. While this small number allowed for in-depth explorations of each participant's viewpoints, it may have limited the diversity of perspectives and insights gathered, thereby constraining the comprehensiveness of the study's findings. Various experts from different fields relevant to the subject of this thesis were approached, as can be seen in Table 1. The variety in specialisations of the experts ultimately interviewed provides insight into the current attitudes and opinions in the field without necessarily being representative for all.

Moreover, while facilitating rich qualitative data collection, the use of semi-structured interviews introduces the risk of bias or subjectivity. The interviewer's interpretation and interactions with the interviewees could influence their response, potentially skewing the data. Additionally, the reliance on literature to inform research questions and interview design may have constrained the exploration of novel or emerging perspectives, potentially overlooking valuable insights. Furthermore, the use of video conferencing for interviews, though necessary due to logistical constraints, may have affected the depth of rapport and engagement between the interviewer and interviewees compared to face-to-face interactions, possibly impacting the quality of data obtained. Lastly, despite efforts to ensure clarity and objectivity in the transcription and analysis process, inherent biases or misinterpretations may persist, underscoring the need for cautious interpretations of the findings.

7.5 Recommendations

Future research in biofortification, GMOs, and food security should prioritise addressing existing knowledge gaps and exploring emerging issues. Key areas for further investigation include assessing the long-term environmental and health impacts of biofortification, evaluating the efficacy of different regulatory approaches, and fostering the development of innovative technologies to enhance food security and nutrition outcomes.

While this study employs a mixed-methods approach to examine various aspects of food security, biofortification, and GMOs, future research can benefit from additional methodological innovations. These could include longitudinal studies, randomised controlled trials, or research methods emphasising participation.

Recommendations for policymakers include the development of comprehensive regulatory frameworks that balance innovation with precaution, harmonisation of standards across regions, and efforts to promote transparency and consumer trust in biotechnological innovations.

Analysing policy and regulatory frameworks surrounding biofortification and GMOs highlights the need for more flexible and adaptive regulations. Such regulations should facilitate the implementation of nutrition interventions while upholding safety and transparency standards.

The implications of this research extend to both global and local contexts, emphasising the need to consider regional disparities in consumer preferences, regulatory frameworks, and agricultural practices. Future studies should delve into how interventions can be tailored to diverse cultural, economic, and environmental contexts to optimise their efficacy.

Future research and policy development should continue to address ethical considerations related to GMOs and biofortification, such as equitable access, transparency, and environmental sustainability. Efforts to engage stakeholders in transparent and inclusive decision-making processes are essential for promoting ethical practices in agricultural biotechnology.

The ethical debates surrounding GMOs highlight concerns about corporate interests, equitable access, and regulatory transparency. These discussions underscore the need for comprehensive regulatory frameworks and transparent communication to address ethical challenges effectively.

Furthermore, the success of interventions like biofortification depends not only on consumer acceptance but also on regulatory frameworks and policy support. Regulatory challenges, as demonstrated in the widespread adoption of wheat flour fortification with folic acid, underscore the need for flexible and adaptive regulations to facilitate the implementation of nutrition interventions.

Comparing biofortification with alternative strategies such as dietary diversification, fortification, and supplementation provides valuable insights for policymakers. While each strategy has its merits, a nuanced understanding of its advantages, disadvantages, and implications for consumer acceptance is essential for informed decision-making.
Addressing malnutrition requires a multifaceted approach considering the complex interplay between interventions, consumer perceptions, regulatory frameworks, and socioeconomic factors. By leveraging the strengths of various strategies while addressing their limitations, policymakers can develop holistic solutions that contribute to improved food security and nutrition outcomes on a global scale.

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Appendices

Appendix 1

Can you please introduce yourself (name, job, etc)?

Could you describe your current role and responsibilities?

How would you define GMOs?

How would you define biofortification?

How does your work intersect with GMOs and biofortification?

What does food security mean to you?

Can you please provide a brief overview of your background and expertise in the field of GMOs and GMOs/biofortification?

What, in your view, are the main advantages and limitations of biofortification compared to other approaches for tackling malnutrition and enhancing food security?

How do you foresee biofortification aligning with broader sustainable development goals?

In your view, what are the key regulatory challenges associated with the commercialisation and deployment of biofortified crops, both within the European Union and internationally?

How do government policies and regulatory frameworks influence the adoption and health safety of biofortified crops?

What potential conflicts do you think exist between promoting biofortification and adhering to established food safety and nutritional labelling standards?

What strategies do you think could enhance consumer acceptance and trust in biofortified crops, especially in regions with a limited understanding of biotechnology?

Are there risks associated with the unintended consequences of biofortification, such as biodiversity loss or environmental impacts?

Are there any (emerging) ethical considerations or debates concerning the use of genetic modification and biotechnology in biofortification efforts?

Looking ahead, what do you believe are the priority areas for policy development and regulatory reform to further integrate biofortification into sustainable food systems and nutrition strategies?

Is there something I did not ask but you feel is relevant to my thesis?

Appendix 2

Interviewee 1

Can you please introduce yourself and could you describe your current role and responsibilities?

Niels Louwaars, I am the Director of Plantum, the sector association for seeds and young plants.

How would you define GMOs?

By using the official definition: an organism in which the DNA, the genetic code, has been altered by humans.

In your opinion, do you think GMOs differ from conventionally bred crops? If so, how?

Some GMOs, like transgenics and category 2 NGTs in the EU discussions are substantially different in that they would not logically emerge in nature (even though even that can be discussed). Most GMOs are non-regulated GMOs like products of mutation breeding (and also category 1 NGTs) and are not substantially different from products of nature or conventional breeding.

Would that also include conventional breeding as this also alters DNA?

No, not in that official definition as conventional breeding simply rearranges existing DNA. It does include mutation breeding where human intervention (irradiation/chemical) induces changes – however, the same changes could occur through natural mutation, but the human factor is determining here. The products of such genetic modification are explicitly NOT regulated in Europe (no safety assessment, no labelling requirement). It means that we are consuming GMOs of this non-regulated category every day (including organic products).

How would you define biofortification?

Enriching products with positive dietary substances through breeding (in the widest sense)

Would you say that you are in favour of biofortification?

Why not, primarily for undernourished people in the global South who depend on one or two foodstuffs like rice? Enrichment of vitamins, micronutrients or even amino acids that are harmless if consumed too much is also ok.

One of the main foci of biofortification efforts is vitamin A, as this is one of the most occurring micronutrient deficiencies and is known to be toxic in high quantities. What are your opinions on that?

I fully agree! It has to be assessed whether such risk of over-consumption is real, for example in golden rice or orange potatoes. How many kilos of such products do you have to eat to get in the danger zone?

So, yes, I think there is a difference, and when such possibilities occur in certain enrichments, such analysis needs to be done before introduction in my view.

How does your work intersect with GMOs and biofortification?

It could intersect, some biofortified crops like orange sweet potato are products of conventional breeding; golden rice is GMO. In Europe, biofortification is not a breeder's main goal, particularly because claiming the health of the new product is very restricted in Europe. If enrichment goes too far you could run into problems with very costly novel food regulations.

What does food security mean to you?

Having sufficient quantity and quality food for all.

And how do you think it can be achieved?

Primarily through stopping wars, and increasing the availability of food, including the reduction of food waste. And finally doing away with poverty.

Can you please provide a brief overview of your background and expertise in the field of GMOs and GMOs/biofortification?

Policy debates – currently those on NGTs.

Could you elaborate on that, please?

Currently, all discussions about the GMO legislation are about whether and which NGTs could be considered non-regulated (like mutants), fully regulated like transgenics or something in between. The EU Commission has created two categories, Category One with minimal regulations and Category Two with full GMO regulation. However, the debate in the European Parliament now focuses not so much on safety, but on patentability (who will be able to use the technology when it is deregulated). Our position as seed sector is that we want deregulation of technologies (category 1), and we do not want patents on plants (plant traits) to affect plant breeders and farmers. These are two very important discussions for us.

What, in your view, are the main advantages and limitations of biofortification compared to other approaches for tackling malnutrition and enhancing food security?

I see biofortification as useful when it answers specific needs, for example in food for geriatrics or patients in hospitals and indeed for the poor who cannot afford a healthy diet. In that last case, biofortification is an unfortunate strategy since a diverse diet is much better, but the poor cannot afford vegetables et cetera. However, biofortification is preferred as opposed to food additives because it is, one, economically more sustainable, pills or additives in processed food are a recurrent cost – biofortification represents a one-time high research cost – if all works well –, it reaches the very poor and remote populations potentially better than pills, and additives, like iodine in salt in Europe, work only for people who buy such foods – in our case notably bread – which does not reach subsistence populations.

How do you foresee biofortification aligning with broader sustainable development goals?
Unfortunately, biofortification will remain a relevant health strategy.

Why would you say that is unfortunate?

Diversity of the diet is a much better strategy, but that is poverty-related and difficult to solve. Biofortification is not solving the underlying problem, but just an important effect.

In your view, what are the key regulatory challenges associated with the commercialisation and deployment of biofortified crops, both within the European Union and internationally?

In this order: Novel Food Regulation, Health Claims regulations, GMO legislation, and food culture. Many tribes in the South reject golden rice and orange sweet potatoes because of the colour, according to them ‘good rice is white and non-white rice is dirty or rotten’.

How do government policies and regulatory frameworks influence the adoption and safety of biofortified crops?

Food law is not my speciality so I cannot answer this.

What strategies do you think could enhance consumer acceptance and trust in biofortified crops, especially in regions with a limited understanding of biotechnology?

People do not need to know about biotechnology if the food they get is healthy.

What do you think about the transparency or people's right to know?

Yeah – that is a bit of a rough statement, I admit. There are so many biotechnologies that are more or less complex. I do not want to know how all components of my car work as long as the car type has passed all security aspects. I do not need to know all the processing steps in the production of a Mars bar – the remark was in that category. If, however, there are people who want to know – then transparency needs to be provided though.

Are there risks associated with the unintended consequences of biofortification, such as biodiversity loss or environmental impacts?

No, it is not different whether you introduce a new variety that is resistant to a disease or a new variety that is biofortified.

Are there any emerging ethical considerations or debates concerning the use of genetic modification and biotechnology in biofortification efforts?

Specifically, on biofortification? The main ethical debate, in relation to HarvestPlus of the CGIAR, was that it would be unethical NOT to use it for the poor. A counterargument in the Golden Rice discussion in the Philippines was that it was promoted not for the poor, but to force an easier GMO legislation, if you consider that an ethical thing.

Looking ahead, what do you believe are the priority areas for policy development and regulatory reform to further integrate biofortification into sustainable food systems and nutrition strategies?

That is different in different parts of the world.

Interviewee 2

Could you please introduce yourself? So, your name and your job, or what you are doing now?

My name is Irene, right now I am finishing my internship at Access to Nutrition Initiative. My internship started in December, and it was initially planned until May, but we decided to finish it one month earlier, in April, and then starting next month I will be hired by ATNI. So, my internship role was research intern and my position from next month will be researcher. So basically, I do not know if you are familiar with Access to Nutrition Initiative, but it is a not-for-profit organisation that employs approximately 25 people. I think maybe a little less than 25 people and some of these employees are researchers.

So, we basically assess companies; the main food and beverage producers globally and we check their compliance with international guidelines, and we hold them accountable for the health of their portfolio and their marketing practices, or the workforce nutrition. Also, how they fortify their products for example, is I think interesting for you.

And as my background, I am also doing a master's in food law and regulatory affairs. And before that, I did a bachelor's in food technology in Wageningen, but I have actually, so I am actually 30 years old and before I studied Communication and Marketing, so something unrelated, then I worked for a few years and went back to university.

So, what are your current responsibilities or what is going to be your responsibility within/at ATNI?

I think within ATNI there are two main roles, let's say. One is a researcher, and the other one is partnership management, which can be seen as a sort of programme manager or project manager. So, the partnership manager manages the relations with the companies or the project budget and planning and then the researchers like me, we really delve into the documentation like into the company policies for example. Or we do a nutritional product profiling. We basically assess all the information they provide or the information that is available in the public domain and then out of that information that we analyse, we usually give them a score and these scores are then published in a report and the two main reports that ATNI publish are the global index which will be published at the end of this year. There we assess the companies globally for the beverage manufacturers and then there is also another index that has actually just been published and that is the breast milk substitute and complementary food index. And there we basically do the same, but instead of focusing on global companies, global food and manufacture and beverage manufacturers, we focus on companies producing breast milk substitutes or infant formula and complementary food products which are products targeted at children 6 to 36 months of age.

So now I am going to ask you for some definitions or how you would define some concepts. First, how would you define GMOs, so genetically modified objects?

The definition that I have in mind based on my previous course, like let's say, let's start by saying that I am not an expert like the. Yeah, the GMOs, you know, my knowledge of GMOs before was just limited to whatever news like the general public could read online or like a media. And then last month, we had a course which you probably had as well, which is National Food Safety Law in a comparative perspective, I think that is the new name. I think before it was just a national food safety comparison in the US and China. Now they do a sort of comparison between different countries, US, Brazil, European Union, Portugal, the Netherlands, yeah. So, GMOs were one of the topics they analysed from a comparative perspective between the EU, Brazil, and the USA. So, there I had the chance to learn a little more about that and that the definition they were giving was that it is an organism whose genetic material has been modified in a way that will not be possible naturally. And that involves DNA techniques, basically.

I think that is the official definition.

I remember that the professor in that course, he highlighted the fact that even though you know the EU has pretty conservative legislation in that respect the US is more open, and Brazil also is a little like more open than the EU. The definition of GMOs, the obviously the differing legislation, but they all have those two elements that the, you know, the genetic material has been modified in a way that would not occur neutral and the second element is that genetic technique has been used to do that.

So now some other terms, how would you define biofortification?

So, by wait, because if I look there, it is because I read your questions before, and I took some notes of things that I want to remember to say. You asked me for biofortification. Yeah, so it is basically enhancing right, the nutritional content of crops through basically, if I understood correctly, it is through genetic modification, but also normal regular plant breeding.

Would you say that you are in favour of biofortification or not?

I would say I am, yes. So, I think that probably a few years ago, I would have said no. Because I was lacking the tools to understand what that implies, and I think there is a lot of mistrust in general in Europe. So as a European consumer and citizen, I think without really any knowledge about that and about food technology in general, I think I would have said no.

Now after [the] Bachelor Food Technology and a master's in food law and Regulatory Affairs, I would say that I am in favour, especially for those areas of the world where, you know, biofortification may solve certain, you know, nutrition problems. Such as low-income countries. You know, where maybe certain types of crops represent really a staple [crop]. I think that could be a solution to provide you know the necessary nutrients for certain categories [of people], and we think about children or women.

You are working with fortification, or at least fortification, being relevant in your job… are GMOs and/or biofortification also relevant?

So, it is relevant, there is a team who is, and they are working specifically on a fortification project in Africa, so they recently went to Kenya and Tanzania. I think to meet with some local experts. But I do not have a lot of information about that project because I have not been involved at all and it is mainly two or three people. This is also something pretty new for ATNI. And both of them are on holiday now so I could not really get more information from them, but I know that there is this project focused on the fortification of certain products in Africa. So that is how you know the topic is relevant for ATNI at the moment.

Also, maybe it is also interesting to know that right now we are assessing, you know, the information provided by the company for the global index and that includes a lot of aspects such as product reformulation. And within product, the product reformulation category, we are also asking companies about their policy on product fortification and evidence that they are fortifying staples in the markets they operate.

So, for example, we are asking them, you know, we are checking that they are explicitly committing to not fortifying any unhealthy food products you know. And then which staples they are fortifying and how does that fit within certain regulatory requirements, you know, certain governments may have some programmes for fortification of certain. Yeah, maybe flour or salt. So, are these companies following those guidelines, are they mandatory or are they voluntary?

So, another basic question, what does food security mean to you?

Yeah. So, for me, it is mainly it is ensuring access to healthy food, nutritious food, and safe food. I remember when I was thinking about these, I wrote. I think there were four main things for me that are part of the definition of food security. One is, you know, food availability. So, making sure that there is enough food. Food access. So, you know, making sure the households actually have access to the food. Food utilisation and by that I mean not only having the resources and capabilities you know, to know what to do with that food that [have] access to, but also that your health status allows you to use that food and then, the stability, the access and the availability of need to be constant.

Do you think if, and if so how, food security can be achieved?

I wish I could say yes, but I yeah. I think it is so much of a complex topic that I think it really involves so many aspects. It really needs a food system approach, right? And it is not only about food, but it is also about geopolitics, you know, like the stability of certain areas. Yeah, there are so many variables that affect food security. That I would say it is very difficult to achieve at the moment. I think there is also sustainability. Now you know in the same place, which maybe until a few years ago was not really considered. I think that is also like important environment also plays a big you know role in this right now. So yeah, I think achieving it is very difficult and I think it really requires efforts from all actors and from all points of view. I think it is really a problem that requires a change in the whole system. So not just specific to food, but also politics, economics, supply chains, the environment, everything really.

I agree, I think it is very difficult.

But I also think sorry, I just, I just remembered. Yeah. No, I always think that for example, innovation and technology are one of the tools that we may be able to leverage, you know, to think that alone is enough to solve like food crisis is worldwide and to ensure food safe food security. But I do think that Innovation and technology can play an important role in that.

That blends in nicely with the next question I am going to ask. What in your view are the main advantages and limitations or disadvantages of biofortification, compared to other approaches to tackling malnutrition?

So, I think that one of the main advantages is probably [the] availability of crops. And then the, you know, the nutrients that derive from the fortification of those crops, for example. I think one other advantage, but this is rather a doubt or a question that I have than a fact, but just because I know that there is also the issue of whenever we fortify products. So, we have a normal crop, and we fortify it during production. I think one of the questions is also how much of the nutrients eventually end up in the plate of the person. So how stable is the nutrient after we added it during production and processing? How much is it affected by the way people use it in their household? And I am thinking, I am hoping that biofortification would maybe help solve that question.

If we manage to get a crop that has certain characteristics as we like it, hopefully, those characteristics are also more stable, and we make sure the health benefit has the effect that we want and is not really lost. You know, in between the processing and the consumption phase, let's say. Then it could be a long-term solution, instead of relying on companies to voluntarily fortify their products, so that all the nutrients necessary for certain people and certain categories of consumers are met. I think there should be a more global approach and a more constant approach to solving these problems. And I think using biofortification, especially if backed by the government, could be a long-term solution to the problem.

And then you also asked me about the limitations, yeah, I think the limitations are probably yeah, environmental factors. How is biofortification going to affect the environment, the environment and you know, like the soil, and other types of crops? Also, I think mistrust in general from people I think that would be a limitation. Is there a lot of backlash against that? And also, I think regulatory issues surrounding the, you know, the use of biofortification I think it would not be easy for sure to have you know a country adopting that and regulating that. And yeah, there are a lot of regulatory I think aspects that you can think about, yeah.

So how do you see it aligning with the broader sustainable development goals, specifically sustainable development goal two, Zero Hunger?

Yeah, I think it does align right in. Yeah, in light of what we have discussed so far, in light of biofortification being a possible technological solution to malnutrition, hunger, and food access. So, I do see it as I see it, a technique, a technological solution to the problems that now do not allow us to reach the [sustainable development] goals.

You mentioned earlier, the regulatory challenges, so the commercialisation and deployment. Do you think those are both in the European Union and internationally because you mentioned the comparative course?

Mm-hmm, no, I think it would be, especially in the European Union and less in other countries. So yeah, I think you know, the US and Brazil for example, those are the countries we had a look at, I think it would not be a problem there to adopt biofortification and to you know, implement the legislation, allowing it probably already there, but in the EU, yeah, in the EU I would think that is, you know, it would be much more difficult. And I think we will see. I think the big problem in the EU is probably consumer's attitude towards them. I mean, when we talk about the European Union, we obviously talk about like a higher income area, so they might not be that needed in these, countries. But if we talk about South or Latin America or Asia or Africa then I think there might be much, much more relevant. And I am not sure about the legislation there, how easy it would be to have them, to have legislation passed regulating that. I do not know if it exists already if it is possible.

So, the negative, like the regulatory issues for commercialisation is also just the regulatory issues in general in the European Union's also internationally. How do you think they can be improved, and do they need improvement or not or?

It is a difficult question, let me see if I had taken notes about that, but I do not think so.

I think the only, not the only but one of the ways that I can think of is really harmonising legislation. But I think this is, I would say challenging if not impossible. I think that to really improve the regulatory framework of this, you first would have to work on consumer mistrust by providing education, I think that would be the only way and maybe work more with stakeholders. So, in this specific case, it would be farmers. So not only [with] consumers but also farmers and really work with them to understand, you know, where the concerns come from and really address all the concerns so that legislation can then be passed. I think it is really challenging. I do not have any other ideas on how that could be tackled.

What potential conflicts exist between promoting biofortification and adhering to established food safety and nutritional labelling standards, do you think? Or do you think it is not a concern?

No, I think it is a concern and I think for example, there would have to be specific labelling standards for that. I think consumer information is especially important in the European Union, for example, but I think it also got more important in other countries such as the US recently. So, I think that could be one of the tools to also address consumer mistrust. So obviously legislation has to be modified to ensure that.

And for the established food safety and see if I think specifically of the European Union, I think you would need a really robust risk assessment from the EFSA. That could also, you know, help address consumer mistrust. So, I think I think it would be mainly these two like a really robust risk assessment on the one hand and then clear information to consumers through education, but also like very clear labelling. And those would hopefully help increase the acceptance of biofortified products.

That also ties into the next question. Do you think, you mentioned the labelling and the information sharing, and addressing the mistrust… do you think there are more ways to enhance consumer acceptance, because these were specifically for the EU? For other regions, maybe as well?

I think in other regions, I think it would be, I think also their consumer education I think would be important. But also maybe, and I am thinking of more rural communities, maybe as it could be in Africa, for example. I think that local participation there would be really important so that you do not, you know, because there is probably very likely you are trying to intervene in a setting that is very traditional so you do not want to disrupt that tradition, the heritage, traditional knowledge and skills that those communities have. So I think if you do not want to do that, but at the same time you want to introduce biofortified crops, then I think you really need to work with the communities and make sure that the traditional skills are carried on, but that they are also, you know trained and the new biofortified products are introduced. And then there is also the need for, you know, like a scientific approach. You know what would be the consequences of introducing, you know biofortified crops in a territory where you know traditional crops are farmed. I think in general, again, it would be engage with consumers, but also engage with local communities, you know. And maybe, you know, look for customised solutions so that it is not that we are biofortifying crops and it is going to be the same crop for everyone, but really understand, you know what the community's

needs are and what is their traditional, what is the traditional heritage and how can the crop fit within that tradition?

So, way before you mentioned the potential risks or at least some concerns of biodiversity loss and the environmental impacts of GMOs. Do you also think these are maybe relevant for biofortification, or do you think there are maybe other risks involved?

I think there is. Oh, I think that probably the main risk is biodiversity loss, I guess. But again, yeah, I am not really an expert in that. I would also think we do not know, obviously long-term consequences, both on human health and the environment and animal health as well. I mean, even though you know we are, I do not think we can be 100% sure about long-term effects. And then, yeah, but I think biodiversity loss would maybe be the main risk associated with that.

I would not worry about health risks or health effects. We are obviously always left with the doubt about long-term risk effects, but I think that that is a minor risk. I think the main risk would be biodiversity.

So, continuing with the maybe negative part. Do you think there are any emerging ethical considerations or debates concerning the use of GMOs and biotechnology in bio-fortification efforts?

Yeah. I think that like [an] ethical consideration would relate a little to what we just talked about so access you know. To buy biofortified crops by local communities, their involvement, how would you distribute the wealth you know, created by, like, who would really profit from the introduction of fortified crops? Yeah, I think [those] would be I think the main concerns would be really like, yeah, ethical consideration around, you know. Local communities' involvement and well distribution.

Looking ahead, what do you believe are the priority areas for policy development and regulatory reform to further integrate biofortification into sustainable food systems and nutrition strategies?

I think, yeah. So, for policy development and regulatory reform, I think they should invest in research. And that would allow [for] a more robust safety assessment. And then, what else? Also, stakeholder engagement. Like we just said, especially local communities. Yeah, I would say for me those are the two main foci. So, stakeholder engagement on the one hand and then investing in research to build a more robust risk assessment.

Interviewee 3

Can you please introduce yourself? So, your name, job et cetera.

Yes. Hi. I am Diane Bosch, and I am a senior food and nutrition security advisor at Wageningen Centre of Development Innovation, which is a Wageningen Research Institute of Wageningen University and Research. And I have been working now with Wageningen for close to 11 years.

That is a very long time!

Yes.

Could you please describe your current role and responsibilities within the research institute?

Yes! Our roles are always changing within the thing. So, at the moment, I am busy with food systems for healthy and sustainable diets. It is just sustainable and healthy diets in general to integrate that, nutrition centre of agriculture activities, in projects and training. And next to that, I am also part of the educational side of the work that we are doing and also functioning in an inter-organisational little group of social sciences, ethical and strategic thinking on education.

What else do I do? Yes, that is it. And I am also, running a course on food systems for healthy diets, together with the Department of Human Nutrition and Health, once a year.

And then all the regular stuff that you do within the organisation.

So, to get more into the GMOs and the topic of my thesis, how would you define GMOs?

So, I am not really very updated with the last sciences, but genetically modified, in crops especially. And I do not regard biofortification as part of it. So, for me, those are two different lines of dealing with crops, for micronutrients of course.

So how would you say, because you mentioned GMOs are genetically modified crops, does that differ from conventional breeding?

I think with biofortification, the breeding there is much more on the natural side, although it is focused, you are picking out exactly which traits you want. So, it is a much longer process, and maybe a little bit up to chance because you put something together and hope something comes out of it. And then you pick that one and you continue breeding with that.

And genetically modified crops are more like, we go sit in a laboratory and we say: “OK, this is what we want, and this is what we put in.”, so it is more targeted.

And so, for me those are two different things because for biofortification you normally also work with crops or breeds that are already available and with genetic modification you can actually fiddle around with it as you like, and of course, there are limitations with it.
And I think the major issue with the GMO is that you do not really know what comes out of it, while with breeding, you have maybe a better expectation out of it. Although it continues to be a test and trial, but in the long run you know what the impact is on the environment. While I think with GMO there were a lot of problems with that part of the process. So, it is a little bit more unexpected what you get out of it in my opinion, but I have never completely delved in.

You mentioned it a little bit already, but how would you define biofortification?

Biofortification is breeding for, in this case from a food and nutrition security point of view for better, better micronutrient traits, and sometimes protein traits. So macro- and micronutrient traits.

And that is using existing varieties in the world.

Would you say that you are in favour of biofortification?

Yes, I would especially when it can function as a substitute of currently used staple and pulses crops. I am a bit hesitant to say that they should be added to the staples crops that we already have, as currently too much focus is given to the production of staples. If we can improve the quality, increase [the] micronutrients, of staple crops and produce [them] as substitutes that would be for me an ideal situation.

However, these biofortified crops should have a high acceptability among the population who should consume them. So, I would suggest that consumers, but also other stakeholders are high engaged right from the start in the breeding process, increasing the likelihood that they will be accepted.

So how does your work intersect with GMOs and/or biofortification?

At the moment, not so much. But in my previous professional life, I worked for Helen Keller International and there we worked with a big group of people on the evidence of biofortification of orange-fleshed sweet potato. So, I sort of got involved with the implementation of the project, but also with the research and the breeding parts.

From that aspect, I have been following it and I have been following what happens in HarvestPlus, which is one of the I think lead agencies that is doing a lot of breeding for better macro- and micronutrient traits.

And I also read quite a bit of work that Elise Talsma does with her trials on yellow cassava. And it is really coming out of the practice that I had and now I am sort of following it and sometimes I am getting this kind of reports or theses underneath that I am involved with that is working on the acceptability of this kind of crops because that in the end that is very important that it is acceptable for the population that we are growing it for.

So, the orange-fleshed sweet potato and the cassava are examples of breeding for better micronutrient content and availability. But there is also the case of Golden Rice, which is probably one of the most or more famous examples [of biofortified crops]. That is one that is made with GMOs, or genetic altering within the genes of the crops. What do you think about Golden Rice?

Yeah, actually last year I was in the Micronutrient forum, and they presented the yellow rice crop. And when I was a student at Wageningen, I did my thesis research in the Philippines and there, they already were talking about Golden Rice. And I visited, I think the International Rice Institute there.

I did not completely get that Golden Rice was genetically altered. So, I listened to the story, and I think it is very good. And in principle, I do not really have a problem with the GMO, but it is really about acceptability by the consumers and by the countries, that is the problem, and that is also what I said that a lot of, yeah, farmers or national policymakers do not know what is going on. But I think for the yellow rice that is the golden rice, the case is much better documented and proven that it does not go haywire when you put it in nature and it is causing uncontrolled interactions with nature that you do not know what is going on with it. But I think in principle that it is good to have these kinds of products developed and grown and if it is acceptable by the nationals and the national government and the consumers, of course, you can make beautiful things, but people do not want to eat it then it sort of missed the point. And I think that is very important that we sometimes very much overlook. From a breeding point of view like they are very, very enthusiastic. But yeah, how is it really acceptable and sustainable over the long run?

So, to go back to one more basic question, what does food security mean to you?

So, food security for me means, and I can give you the definitions, but basically, food security for me needs to end up in a healthy and sustainable diet.

We have a really generic definition for it, but basically food security should lead to the consumption of a sustainable, healthy diet specifically for the contracts, according to the food-based dietary guidelines that countries might have or might not have. But that is basically maybe an ideal situation, but that is what for me is food security, although I know that food security in many policies is translated in the availability of cereals, crop cereals, or starchy products because that is what people want to have a full belly in. If an Asian cannot eat three times a day, rice, for instance, or an African, in some parts of Africa, does not have a cassava or maize meal, then they have not eaten.

And it still prolongs that idea, still continues.

Do you think that also adds to the micronutrient deficiency problems because, in the Green Revolution, the focus was mainly on increasing the starch content, which according to some research led to the lesser micronutrient content?

I have not thought about that that way. Yeah, they could. I do think that policies, and especially you also see that here in Europe with the subsidies and the targeting of one of the main staples of the meal. Yeah, you could say that has led to lesser attention to other crops. Also, because food security principles were implemented from that point of view. And yeah, that might have been contributed. It would be an interesting research question, but I cannot say that it is evidence-based.

(How) do you think food security can be achieved?

Honestly, I think it is a nice concept, but I do not think it is achievable.

I have always asked questions, because I do quite a bit of training with professionals, from especially sub-Saharan Africa and Asia, and I always ask them the question when we deal with the concept of food security “Do you feel food secure here in the Netherlands?”. And then I am happy to see them go: “yeah”, “yeah”, “yeah”, “yeah”, “yeah, “yeah”. And then lately they say no, and then I ask, “Why not?” and then it is often the cultural aspects that they cannot find the culture. So, I think it is very difficult.

And I do think that we could have situations where people have 24-hour availability of food, but the question is if it is healthy food. Yeah, that would be ideal, that we would have all the food options available. And secure, sustainably secure. But I do not think we will. So, you really need to consider, what you mean with food security if you do it really specifically according to the definition. Then, because I also think when we are getting more overweight and obese, that also means food insecurity, but on a different kind of scale. So, I think, because for me food security is not only the provisioning of food and all the concepts there, but also how consumers are able to make those choices. Because in the end, it is the consumer that makes the choices. So I think maybe on the national level, yes, looking at all the elements, but maybe on the individual level, I think that there will always be a tension between a completely healthy diet and a desire desired diet because we all have our emotions and mental state that make us make different choices than the healthy ones.

Would you then say that for food security on the individual level, education is also necessary to be able to achieve it fully?

I am not saying education, but I think there needs to be a certain knowledge base within people and you can achieve that through education or other things. But I do think there needs to be a certain knowledge base available and mental space.

For another project, we did some interviews with stakeholders working with people at the bottom of the pyramids in the Netherlands, and we do have them. And you see mental space is very important to have that reflection next to your knowledge base. I think that would be two important elements for individuals to actually choose to be food secure.

What, in your view, are the main advantages and limitations or disadvantages of biofortification compared to compared to other methods of tackling malnutrition or micronutrient deficiency in enhancing food security? So, because there are various strategies, you also have normal fortification or supplementation or dietary diversification.

That is a very interesting question. When I started out as a professional in this field, I was told [that] to get micronutrient status up with people, you need a sort of threefold approach. You need your supplementation, your fortification, and your dietary diversification, including biofortification. And I think that still holds true. For me, that is still very important, because I do not think either one of those strategies will tackle the problems we are dealing with today, so I do think biofortification is very important.

I also see at our university we do not do a lot of work with that, I might be wrong, but I do not see a lot of work around that because I think we always talk about healthy, sustainable, healthy diets and then all the micronutrients. The majority [of micronutrients] should be coming out of the diet and I do not think with the number of certain fruits and vegetables that we are eating and the advised amount, I do not think we will manage that really in the near future. So, I think the more we can get natural products in the diet that have more micronutrients in different things. And that is not only on starchy staples, and I know we often target the starchy staples because of the amount in which they are eaten, but I do think everything has its time and place and I do not think we will reach food security, a food secure world, without biofortification.

And yeah, and of course vitamin A is already still a problem, although I think sort of the problem, the mortality issues are becoming less with vitamin A deficiency because we are more aware of it and we have better programmes in place, but it remains a concern. So, I think biofortification definitely has its role to play. And maybe from a sustainable and economic point of view, biofortification might be a better long-term and more viable solution than supplementation and fortification as these also have their problems, not on a large scale but especially when you are not buying industrialised products but more from your own production.

So, for sustainability, there are of course the Sustainable Development Goals and part of that is "Zero Hunger", goal 2. Do you think biofortification aligns with the broader sustainable development goals or not or partly?

Yes, SDG two has different aspects within zero hunger, it is not only ending all forms of malnutrition, and we are focussing mainly on that work on this part, but I also feel like there is an agricultural production, viable production, and farmers need to earn a liveable income. So, there is also an economic aspect of farming.

I do think it aligns with that because it would give an opportunity for more income for farmers. I do think it will help smaller-scale farmers if they are able to produce these products for household consumption, it will help with ending all forms of malnutrition, and of course especially micronutrients. But we also know that if we have a more diverse diet energy and protein intake is increased, not sure if the evidence still shows that, but I know that in the past, we mentioned that, and I have not deep-dived into that lately, but I do think that if you eat more diverse that you also get a, in general, better diet. So, it also affects your energy intake and other micronutrients. So, I do think it fits very well with that SDG from both ending all its forms of malnutrition, but also the production and the economic side for farmers that they should have a liveable income from farming or agriculture. So, I do think it fits quite well actually.

So, to the commercialisation and use of biofortified crops, what do you think are the main key regulatory challenges associated with the commercialisation and the use of biofortified crops?

That is a big question. I think the consumer needs to be aware if they buy biofortified crops, that it is a biofortified crop. It still needs to be a decision consumers make.

The commercialisation, what we often do with these kinds of biofortified crops, or at least in the past, and I am not sure if HarvestPlus is still doing that, but we thought, OK you make a crop with better micronutrient features so you should also earn more money from it. But that is also then a barrier for low-income households that they will not have access to, and I think I liked the example of the Golden Rice that they said we are now able to offer it at the same price and inputs as the normal regular white rice varieties. And that will make it much more accessible, also for lower-income households.

Yes, commercialisation is good, but I do think it needs to be regulated. Because if you commercialise it, there is always a larger profit attached to it and I think that is really a discussion and a balance that we look at now. Also, a lot of these kinds of things are about what agriculture is, of course, an income-generating activity, but we also want to make it have an impact on food security and then, consequently, on healthy and sustainable diets.

Commercialisation is good for a certain amount of time, but I think as long as we can make products available for all consumer groups and also in a form that is still acceptable. [But] I was talking to another NGO the other day that was working with the food technology people from Wageningen and they were making a kind of burger from beans, a bean burger in a low- or middle-income country, and I was like "Why are you doing that, it is a country that eats beans, so why not promote eating beans?". And of course, beans, if you do it traditionally, you harvest beans, you dry them and then you have to soak the beans and then you can cook them. That is quite a lengthy process. I mean why do we eat sandwiches because of time and in the end, it all came around because of saving time. And that was also their answer "We want to have a product for all kinds of consumers". But this is then also the commercialisation of a product, and I think what a trade-off here could be is that you are using so much of a crop to make it into a, often highly processed, food, that contains a lot of salt and maybe sugar. It takes away quite a bit of the crop, for that product that might have a chance that the raw product, which would be a good product to eat and to cook, becomes less available because you transform it into a commercial product that might have a bit of a bigger profit but is not per se always healthier. Just look at all that is happening with plant-based foods, which are highly processed and often very salty.

So, I think that it is good to do commercialisation, but it needs to be regulated because it needs to be made sure that it is available for all consumer groups.

So, for the regulation, how do you think they influence the safety and adoption of biofortified foods?

I think the regulation should also talk about when you can say it is a biofortified crop. I think it needs to be a certain amount of the enhanced micronutrient in it, so that you are not saying I have a biofortified crop, but it is hardly giving you any additional profit, but you still pay for it. So that is one of the regulations I would install.

Adoption rates have a lot to do with taste testing. I think we need to do more and more taste testing, consumer adoption, good role models, and how people can use it. What I think, if we are talking about biofortified crops, is that we really also need to look at how far biofortified crops could reduce cooking time because we still have a very high, although we are here in Europe, where women have so much support and appliances to reduce cooking time and a lot of yeah roles are also changing at the household level. But a lot of women in sub-Saharan Africa and Asia are still the ones that need to do the cooking and sometimes still spend 2 hours cooking a lunch with all the other chores. So, it is women's workload that I think also needs to be considered. So, if you have a biofortified crop that is healthy, and tasteful, that is something consumers would like to eat and will make a choice to eat. And then also looks at a reduction of cooking load in households that would be very great.

In the safety issue. I am not really sure. Yeah, I am not really sure what kind of safety issues there are, but I do think that there needs to be the same for then for all the other crops. I am not sure that there should be extra safety measures. I do think that safety measures for pesticides and these kinds of things should be in place also for biofortified crops. I do not see any from my perspective at this moment, not much different, but it should adhere to all these rules and regulations.

Some have expressed their concern about making the levels of vitamin A higher in crops because too high levels could be harmful.

Oh from that perspective, the amount… Yeah, I do not think with vitamin A [that is a concern], because in the end it is pro-vitamin A and it still has to be converted by the body to vitamin A and the absorption and bioavailability are very important, but also what they eat with it. And I know that for fortification, you always take the level that is safe for the consumers with the lowest needs. I am not sure at the moment, but I think the levels are sort of that it is safe for children to either they do not overeat it and then and that is sufficient then to help.

I do think that is a good point to think about the levels of micronutrients in crops, but how are you going to measure that? And I think that is again as I said at the beginning, I would like to see what kind of varieties are really suitable for consumption that you will get sufficient micronutrients, but at the same time, you can also say OK, these varieties have a likelihood to if they are eaten in a huge amount [to be toxic], but you need to eat a lot of vitamin A to have a toxicity level. So, I am not really sure how I think it is good to think about it, but I do not think at this moment it should be a concern [causing people] not to do biofortification. Because I would rather be concerned about the fortification of products because I mean how much vitamin C are we eating throughout all the products? Because vitamin C is also often used as a conservative, and so we are eating a lot of vitamin C, but you never hear anybody about it. So yeah, it is good to think about it and have justification underneath what you are doing that you have sort of thought about, that I do not think you should do it, but at the moment for the countries that we are targeting, I do not think as long as their children are still getting high doses of vitamin A capsules twice a year. Then in those kinds of countries, I do not think that the vitamin A level or the pro-vitamin levels of biofortification should be a huge concern, although I do think you need to address it and justify it.

So, you previously also mentioned the consumer acceptance or the acceptability of crops, how do you think this could be improved, especially in regions where there is limited understanding of biotechnology?

Yeah, I think there are different ways to do it. I think that maybe they are not always the most cost-effective ones, but I think having a lot of taste testing done by consumers that they can taste it and you can do either a specific study on that or with groups of people.
I also know that a lot of these new crops, new crops, are often being presented at agricultural fairs all over. Sometimes a role model could be helpful if you find a role model that is promoting the product. I do think you need to think about how to present the product. So, a good communication strategy behind it could be helpful and then making sure that people hear about it as many points as possible. So also look at trustworthy institutes, like women are going to health centres and they are often seen as a trustworthy source. Not sure that that is always the case, but anyway, so if they hear it there, and if they hear it in other areas, you might increase consumer acceptance. But it is a lengthy process and I think if a crop is very close to a traditional crop that they already used to eat, and I think I read a thesis of the acceptance of iron-rich beans in Rwanda, in certain areas, and they actually did use the same kind of traditional beans that was there and just improved it and it turned out in that study, I am not sure how true it is, that the biofortified bean was more liked because it was easier to cook and softer to cook.

So, it is not only about consumer acceptance but also consumer use and if you can merge the two it is a good micronutrient-rich product and it is easier to cook, and of course, it also needs to taste good. For instance, what we saw in the orange-fleshed sweet potato project is that they did a lot of taste testing, and it turned out that adults preferred a more high dry matter potato. But for the children and softer, sweeter variety was more accepted. So, these are very important issues to take [into account] and I am not sure that we at this moment in time take enough focus on consumer acceptance in all this work.

I have a question about that because for example there have been a few studies on the colour of maize in certain African countries where it turned out that they did not want to eat the enriched/yellow maize because of its associations. How would you say that could be helped because it was a very ingrained problem in people and the children did not have it, but the minute they started getting older they did also have those negative associations?

No, that is a very good point and I think that is throughout the world. And I have been teaching the last few days quite a bit and we were deep diving into a healthy diet and exploring the Lancet diet. And the Lancet diet has only whole grains now.

Try to get whole Asian countries to go from white rice to brown rice, let alone yellow rice. I mean that is such a huge challenge and I think that is the same for us and white bread and brown bread.

You need to have a lot of patience, and again, I do think that it should be a multiple approach. I do not think there is 1 magic bullet to get consumers to accept these kinds of changes in colour because colour does matter. You know if I buy bananas, for instance, I do not buy the brown bananas. And, you know, these kinds of things. So, it does really matter.

I do think, I am not sure if there are any studies [proving this], but I do think that the acceptance of different crops and the sort of venturing out beyond your normal traditional diet is probably higher in consumers with a higher knowledge base about healthy and healthy foods. And that does not mean that they have to have a higher level of education, but they need a higher knowledge base. And that is all really what I want to specify in the differences.

It is very difficult to change habits, and it took us also ages and ages to change that. I am not really sure if there is one big [solution], but I think it is a multiple approach with different strategies and I think it really depends on which country you are [in] what kind of strategies are effective.

I have a few more questions. About biodiversity loss, because there is the Cartagena Protocol on Biodiversity. Do you think there are risks associated with the unintentional consequences of biofortification like biodiversity loss or environmental impacts et cetera?

You always have to think about it. That is also maybe why I like biofortification more than GMO because biofortification uses breeding, uses existing varieties, although for instance for the orange-fleshed sweet potato. The variety was, in that context, not really existing in Africa, if I am hopefully I am not wrong, but they have got the varieties from the United States and started breeding for that. So that is sort of increasing biodiversity, but it is always a risk, and it is good to think about it.

But if you use really locally available varieties and you add a variety that is drought resistant, these kinds of traits are often bred in as well. So not only biofortification, but also the drought resistance and it is adding on to variety that is already existing with better traits. I think you will increase biodiversity, but there is always a risk if you are only going to do this commercially that you have that your commercial endeavours could actually negatively affect the biodiversity because you only use the ground and the land for these kinds of productions. And we also see it a lot in neglected crops that we say, OK we want to bring them back because it is good for health, but also for the planet, for biodiversity.

So, it is always good to. But I am not sure if with biofortified crops the principles are still the same as with using local varieties to breed local varieties with other varieties better and also across countries it would be acceptable for that ecosystem. There are a lot of things to think about and that is also climate resistant or climate-adapted, whatever you want to call it. Then I think it will only increase biodiversity, but you always have to disregard the varieties that have a lot of viruses and stuff, so you also have to safeguard safety environmental safety in that and that you do not put crops on the crops on the fields that are attracting and possibly infecting other crops with viruses and whatever else they can have.

There is one example of the tomatoes. There was one point in history where there was the tomato genetic diversity of tomatoes. They decreased it by 95% so only 5% of biodiversity that was there once before is now available in tomatoes because of selective breeding, which is very fascinating to me.

Yeah. And I think the same thing happened with banana trees, there is one variety and then there was a couple of years ago a big virus that killed a lot of them. There was very little diversity in banana trees. But I think it is also for coconut trees. There were there along the coast of Africa, there was an infection that killed a lot of coconut trees.

I think it is very interesting because that also leads to less food security. After all, you have less food available.

Yeah, it is always in the trade-off. Yeah. trade-offs. Synergies are the trade-offs. What are the trade-offs if you do A? And I think you always have to think about what is more, what is the most important. And I think whatever we are doing, biofortification should not completely eradicate one other variety, but the variety should be standing hand in hand. As long as the gene pool remains healthy.

Do you think or are there emerging ethical considerations concerning the use of biofortification or debates?

I am not really sure because we do not have a lot of discussions at the moment in our field area or field because we do not do a lot with biofortification.

I am not really sure that there will be an increased number of ethical concerns. I do think there are ethical concerns that have not been discussed. That is, I think more what the issue is. But I think what is very important when we talk about biofortification is that the ethical concern is like the golden rice that it requires the same kind of inputs and pesticide management skills, which preferably should be natural and as little as possible as any other crop. And I think that we have not discussed that quite well because I do think that biofortified crops sometimes, I am not sure, but should have and similar kind of or maybe lower, need of inputs and fertiliser and pesticides. And I think that aspect is often not very much discussed, and it is not that it was not there ever, but it is it was never put on the forefront. So, I think in each step of the value chain from production to on the plate, you need to really consider what kind of ethical issues you have to consider. We tend to introduce new crops that have a high dependency on fertilisers, and you really need to consider that if that is something that you want to do in biofortified crops. And that is why breeding is so important and I am not sure how that works out with GMO produce crops. I know that in a lot of animals, when you have a higher breed, if you have a higher breed available, you need more. You need better and more inputs and also and the inputs in biofortified crops are land use and water and fertilisers, and I think you need to consider that very much. It is nice to make an improved crop, but you also have to look at sustainability and health issues, not only for people but also for the planet. And cross-contamination that might happen.

Some articles are, besides crop contamination, also mentioning the effects of crops on insects. (how) do you think that is important?

Of course, that is important. I mean, we are killing off the bee population in the world, so our pollination becomes more and more problem. I do think that is important because the insects all have a function. Although we do not like some of them very much, or at least not when they are coming to our house. But I mean, I do not have a problem with mosquitoes and flies as they are food sources for spiders and other insects. You know, that is the circle of life.

But I do think, I actually have not thought about it, but I do think it would be good to also consider what is the impact not only on the soil health and the other crops but overall, the animal part as well. Because the other thing is, what do we do with the rest of production? There are always things left over and who is going to eat that? And how is that affecting the soil and also the animals, but also the insects? It is just as important of course, some of the insects that attack crops you want to have very reduced; I think the world can do without a locust, a locust epidemic. I am not sure what the impact on the environment would be if we do not have those. So, I think it is dual. So, first of all, it should not kill certain amounts of insects, but it should also not promote plagues of insects. So, it is always the dual. So, I think all the elements in the environment should add to soil health. It should not contaminate other crops.

What kind of competition is there in the fields of crops? That is not my area of expertise, but I can imagine that. Maize needs a lot of water, so it is very important that when you do biofortified crops. If we have a say in it, that it fits in the ecological system where it is being introduced or being replaced – we should not go to replacement, we should add to it rather than replace –, because sometimes it is just a matter of balance, but it is also not really my area of expertise.

Looking ahead, what do you believe are the priority areas for policy development and regulatory reform to further integrate biofortification in sustainable food systems and/or nutrition strategies?

I have really no idea if they have been included in policy development. Yeah, I am just thinking about what they normally say in policies. So, I do think they need to be mentioned in policies so that is that. But then I think they need a separate chapter with all these concerns that we talked about. We do, we often do policies, and I am not really sure. They should be included in the agriculture policies; they should be included in policies about – I am not really sure how you call these policies – about marketing regulations. And I think policies need to be reviewed, to see if they are included and if they give the sort of the same with GMOs, I think it is about how consumers regard this as a safe food, not per se, as a healthy food. But I think often it is about the safety of foods so that pesticides et cetera and things are regulated and I also think there need to be good monitoring systems in policies to actually monitor the, in this case, micronutrient content of these kinds of products because before you know it they are not using the right breeding techniques and then the micronutrients are going down or maybe too high up. And that that might help. Yeah. I think from that perspective, I think you also need to have these kinds of regulations in place and policy reforms to sort of guarantee safety for the general population, for your environment, and also for the people that grow it, so that the economic aspects need to also be safeguarded.

Interviewee 4

Could you please introduce yourself, so your name, job etc?

My name is Susan Nakacswa and I work with GRAIN, I am one of the two programme staffers for Africa, I am based in Kampala Uganda.

Could you please describe your current role within GRAIN and your responsibilities?

My responsibilities are not in a specific area. I do research, I write, and I also represent the organisation whenever need arises. I also support requests from partners and friends of GRAIN on finding information supporting their advocacy and just generally giving them enough information to do their advocacy. But we are mainly a research and writing organisation, so that is where our strength lies for most of us in the organisation.

How would you define GMOs or genetically modified objects?

So, I am going to try and define it in the same way that we define biofortification, tinkering with food using technology, or using scientific methods that go against the norm, or what we know.

So how do you think conventional breeding, for example, the high-yield short varieties, compares to GMOs and biofortification?

Yeah, biofortification and GMOs are totally different things. Maybe we could say that the end goal is the same that they want to increase food security or something along those lines. But the science behind GMOs and the science behind biofortification is slightly different.

I wrote it down as a question, I think I know the answer, but just to ask… would you say that you are in favour of biofortification and GMOs?

So, you might have seen already the organisation that I come from, and no, I am not in favour of and have not been and will not be, both as a person who works for GRAIN and as an individual who comes from the African continent. I do not favour any of them at all personally and also professionally.

So how does your work with GRAIN intersect with GMOs and biofortification? And I read some of the articles GRAIN published

Our stand as an organisation is that biofortification and GMOs and just the whole idea of tinkering with food systems does not solve any problems. It brings more problems actually. For example, a lot of the arguments around all of these interventions is because we are not food secure, that we are missing some nutrients in our food. Yeah, that is sort of like the argument that is put on the table, but our argument as an organisation is that we have a whole lot of smallholder farmers who are feeding the world but doing it on very, very little support and also very little land. So based on that, I think that biofortification, GMO and any kind of system or technology that tinkers with the production of food the way we know it, is not a solution and cannot be a solution. The solution to food security is diversity. In fact, we call it food sovereignty. That intersection with all of that is that there are age-old farming practices that are mainly practised by smallholder farmers which greatly contribute to a food system that is sustainably and healthily grown.

What does food security mean to you?

It is interesting. So as an individual food security is not what I would argue for and I will try and explain this to you using myself as an individual, I am an African but also, I am an Ugandan and I am a

Muganda who was born and raised in the central part of Uganda. The Muganda that I am is critical because it informs my culture, well-being and interaction with food and people.

So, for me, I do not talk about food security because food security essentially would mean that even if you are in a police cell and you had a meal, then you are food secure. This does not mean that you are food sovereign. Food sovereignty encompasses everything about ourselves; It respects and recognises our cultures. It recognises every single aspect of my life. What I define as food is not what a person from the next district to Kampala defines as food. There is diversity in food sovereignty. My type of food is something called matooke. It is a certain variety of banana that we steam/cook as food. And if you go further north in Uganda, you find some people eat millet. In different parts of Uganda, different cultures have their food. Food sovereignty recognises all of that. It recognises people's cultures, it recognises the individual, it recognises the important role that farmers play in planting, selection and storage of food and seed. So, food sovereignty is much broader and much more respectful of every person's existence and role. Food is more than just food, there are some cultural celebrations and activities that are attached to food or seed. There are foods you do not eat when you are planning to be a mother. There are foods you eat only when you are breastfeeding, and all of those have cultural aspects. If you are going to marry a woman, there is food you do not take to a function because that would not be suitable. So, all of that respect that we have for our cultures and the foods that we plant for particular cultural practises, all of that we take into consideration when we talk about food sovereignty.

How do you think that could be achieved?

Food sovereignty? That is what we are doing right now. That is what organisations like GRAIN and all the other partners that we are working with are fighting for, that recognition of the farmer. Because what the industrial agricultural system does, is that they take the farmer out of the decision-making process on saving seeds, on seasons of planting, seasons of harvesting and the market. So, when we start talking about all of these things as organisations that work in the food sovereignty movement and the agaricology movement, that is, that is what we are aiming for. So, this is how food sovereignty can be built again. The recognition of the different levels and sectors in society that have been taken out of the decision-making process that is one way. Doing the research, telling the stories organically and beautifully as they are all of this. Because one of the things that is happening is that they remove farmer stories from the narrative. You do not hear about farmers anymore. You do not hear seeds, the protection of seeds, the age-old practises. All of those fall away in a system that pushes for a commercialisation of the agricultural system. So, what we are talking about are the organic stories and the organic, authentic lived experiences of farmers, of grassroots communities and trying to encourage them to rebuild. We are saying no to industrial agriculture and that is another way also, because the industrial, the plantation agriculture that we know and see, at the end of the day, undermines food sovereignty. We are starting to recognise the farmers and our research is very intentional on telling stories about those who have been affected and also bringing out joint practices. For example, our research titled “Land grabs at gunpoint,” which we did on land grabbing and commercial agriculture in one part of Uganda realistically tells the story about the impact of land grabs on food sovereignty, the human rights violations and our research titled “The real seed producers,” explores different ways of saving, storage and selection of seeds across different countries on the continent. It also recognises, among other things, the different roles that communities play in protecting and securing indigenous seeds. We do not own the solutions, the communities and the grassroots do, and we support the processes of grassroot communities. We empower women to be able to tell their own stories and to own their decisions and we support different organisations who have come out and said we need to be able to understand what this policy means. We need to say no. Campaigns like “say no to UPOV”, are also doing exactly that. Putting building blocks around revitalising the story around smallholder farming. Smallholder farmers feed the world.

I asked the question a bit differently when I wrote it down, but how do you because there is a problem with malnutrition, especially like qualitative malnutrition, so micronutrient deficiencies, that is pretty well documented as well. How do you think that can be best tackled a lot of people are proposing biofortification as a solution, but that does not seem like a solution to you or GRAIN. How do you see that then being tackled or helped?

I think in the reports that I shared with you, you also see that biofortification mainly focuses on three nutrients, zinc, iron, and vitamin A. Biofortification only deals with those three and that is why biofortification cannot be a solution to malnutrition. The solution is diversification. That is diversifying the gardens and therefore diversifying what is on the plate. So, I will give you an example and I touched on it a bit earlier, the nutrition decisions in our home are made by a woman. And she makes those decisions based on what she knows she has in her store. Smallholder farming is normally done by women. And when they do smallholder farming, normally they do mixed cropping and other sustainable farming methods. She will have her food garden and then there will be cash crops and food crops. Yeah. When we are growing up. So, you knew that the cash crops garden was purely a man's garden. The food crops part was for the family. So, one of the things that industrial agriculture or any other farming system, that removes that, fails to recognise is that that removes women from that value chain and removes children from that value chain as well. That effect is felt on the plate later on because she is not making decisions on what to plant. She is not making decisions on what to save, and therefore she is not making decisions on what to harvest and what to keep. And therefore, the nutrition decision is taken away from her. So, the solution to nutritional deficiencies is not in biofortifying, rather, the solution is in ensuring that all the farmers are supported financially, and in policy. Also to be left to own and till their land.

What I am trying to say is that biofortification is not a solution for micro- or macronutrient deficiency. The solution lies in the diversification of foods, both on the plate and in the garden. And if smallholder farmers can be supported to do that, then a lot of problems that are related to nutrition deficits would be solved.

You mentioned the millet porridge, a lot of times, at least in the Netherlands these are fortified with, for example, fibres or vitamins or minerals which could also help micronutrient deficiencies. What are your views on that kind of micronutrient addition to diets?

Well, like I said earlier, I do not come from the school of thought that says that. And I know that that the additions are happening, and I am not naive to the fact that also happening on the African continent, the fortification, the biofortification, all of that is happening now. But what we are coming out to say is that this is not a solution because it is not sustainable. When, like I said, there are age-old practices and there is Indigenous knowledge that we know that addresses certain problems around micro- and macronutrient deficiencies. We do not have to go into biofortification, we can reach out to that knowledge using methods that our fathers, our forefathers and our ancestors have used. And what we are saying when we argue under the agroecology movement is that let’s support farmers who are sustainably growing food. Let’s support food systems that we know, and address problems like that. So, for example, you are talking about the porridge that is fortified to be able to address certain deficiencies and I am also sharing that we have millet porridge here which women take, and it is not fortified. It is not gene-edited. It is porridge that we have taken over many years and we know that millet porridge is good. It is not the normal white maize meal that you know. It is another kind of millet. It is millet which we grind and then make porridge and food out of. There is research out now to the effect that it is good for pregnant women, lactating mothers, women, children, and everyone in the home since it is rich in iron, even our mothers and our forefathers knew it. When you are pregnant, the first thing they will give you is that porridge will be like you keep taking that porridge in the morning and when you go through breastfeeding, they will give you that porridge as well. They take it because it is good in iron, it is good in calcium and even when you feed the baby with it, you will see the baby will be very nice and heavy and well-looked after and all of that, and the skin would be great. And even for women, it is good to rebuild your digestive system and all of that. So, what we are saying is that there are solutions like that which you do not need to go into a laboratory to figure out if a child is deficient. Or because iron deficiencies mean also that you do not have enough blood in your system. So, the vegetables, we have so many vegetables, black nightshades, spider grass. All of those things we have all of those things that are good for fibre, but also good for restoring blood in someone who has lost, who has lost a lot of blood. Interestingly so you know guava. So, for example, the leaves of guavas, our parents have used them for generations. And we have also come and said using them for restoring blood in one's system. Things like mango leaves, and avocado leaves, all of these solutions from the ground. But Big Pharma, big industry agricultural systems are telling us no, you cannot take that, you need to go and take tablets. And we say no, we could take those tablets, but we also have solutions here. Do not say no to them [our solutions].

So that balance to be able to recognise that we also have our Indigenous knowledge and indigenous solutions that can be used to address some of the problems without any future impacts on our health, and I think that is where we are going.

Do you think that it is possible to integrate Indigenous or traditional knowledge with scientific knowledge? And would it maybe change your opinion on biofortification? For example, if it is more focused on for example local crops or more indigenous crops and not only on the three kinds of vitamins or minerals, do you think that would change it maybe?

I personally do not agree with biofortification. So, there is nothing that is going to tell me that biofortification is a solution to anything, simply because even after years where it has been tried and tested, it has still failed. 30 years of golden rice and we are still having the same conversation. But Golden Rice has not addressed what it set out to do. So currently, the story of biofortification is a non-starter. I do not know if I could believe like because there are really no results that we can look at and say, OK, biofortification worked in this country or biofortification is helpful in this country. No, we have not had it. Maybe if there was another better narrative or different narrative around it, maybe we could hear a different. But now I have not heard of a biofortification success story anywhere. Maybe. I doubt it.

I mean there are examples, I think, of the introduction of biofortification being successful in countries. Not necessarily the GMO kinds, but for the orange or yellow casava and the orange-fleshed sweet potato and then also maize has had success stories. Golden Rice is one of the more difficult examples because it is a really big regulatory thing. So, my question is, because you said you do not believe in biofortification, it sounds maybe like it is more of a principal thing. If that is not the case you can also say that, but can I ask why?

I do not believe in biofortification as a solution to food sovereignty. I do not believe in biofortification as a solution to food security. Yeah. Some will say there is success around the orange-fleshed sweet potato. We do have it here. There's a huge uptake of it as well in Tanzania because I think there was a release of that in a few African countries say in Uganda, it is in Tanzania, I think it is in Zambia as well and some country more northern, I think it is Senegal in West Africa. But like I said, and I will say it again, we have a very diverse food system so once in a while you will eat the orange-fleshed sweet potato, but it cannot be the entirety of one's diet. So, there is no way that someone can prove that someone ate orange-fleshed sweet potato for three years and got their vitamin A replenished. I do not know about that. It can work maybe, but to prove it beyond reasonable doubt. Yeah, the science is not there. There has been success in producing it, but I do not know if the results do tell a story of success. So, I do not believe and trust that the solution to any kind of food insufficiency lies in biofortification. I believe it lies in diversification. There might be success stories of having released this in the gardens of different people, but I cannot honestly say that because they have released them in the gardens. People are consuming them to the level they need to consume them to deal with nutritional deficiencies. If, for example, have you eaten sweet potatoes?

Yes, I have

Like on a daily basis for like a week without changing your diet or anything else?

No, I have not

It is not possible. It is not possible. It is not possible.

I mean, it may be if you really want to, but you would not do it automatically I think

You already kind of mentioned it, but I do want to ask it specifically to check the answer to the question; do you think biofortification would maybe be an ethical or biological/biodiversity issue or problem?

I would not be the best person to talk about the environmental [concerns] although they have said that there are [environmental concerns]. But with regard to ethical concerns. Definitely, there are ethical concerns. I will give you an example and this is coming from me as a Muganda. Like I said, all of these arguments are purely academic, but there is also the fact that we come from these communities. For example: the banana that they are using to make, what is it called, the Super banana? Which is the same sort of thinking around the Golden Rice, that super banana, the variety, the particular variety? Because it is not every variety that they are using, the particular variety that they are using to make the Super banana. Is very dear to us, the Baganda, in our opinion, it makes the best food. It makes the softest food. And there are certain cultural ceremonies that we do using these bananas. There was never an interest or question such as "What do the Baganda feel about us tinkering with this banana?". It was just a matter of picking up a few scientists and taking them to someplace in the world. I think it was Australia and doing all this research, doing the testing, you know, it is very interesting because they carry the banana, which is going to be eaten by us, the Ugandans, and they take it to Australia, they do their research. Then they take it to the US for clinical tests and trials, and then they bring it back for commercialisation. And then there is a rush to change the legislation around this so they can quickly commercialise the banana. Yeah. So, we only come in at the tail end of all of this to commercialise the banana. No consultation, no clear information, no transparency whatsoever. But there are certain important aspects of this food that you are tinkering with that we were not consulted on. And I think it is general. There is no consultation, there is no agreement, it is just the decision on "Oh this banana will do wonders, let's use these bananas.". The assumption is that every single person in Uganda eats bananas. Not every single person in Uganda eats those bananas. So, you are not addressing any nutritional deficiencies because you are also talking about just a section of Ugandans, the Baganda who define matooke as food. And then there is the generalisation, the assumption that all Ugandans like, enjoy and eat Matooke all the time! Same story with the orange-fleshed sweet potato. There were no consultations or conversations with the people that were purportedly being assisted in their deficiencies. Even information about the super banana is not accessible or available to the people in a language that they understand. Even for us, we are doing advocacy on this banana. We get this information on this banana from people outside of Uganda. Yet it is supposed to be changing our lives. So the fact that there is no transparency, the fact that it is not considering our cultures, our beliefs and our systems, the fact that we are not having conversations about this very clearly explaining what this means to us, is clear enough to show that there is some form of disrespect that is going on and I think it would go for every single person there, are generalisations, there are assumptions, there is a lack of transparency. There are no conversations on it, or this will work, but you dump it there and you are not even giving information. It is still a laboratory somewhere here in Uganda, we have not seen it, but we know it is there. But they are trying to switch legislation so that they can commercialise it, not to distribute it to people, to commercialise it, to make money.

So how are you addressing deficiencies when you are commercialising the food? You are saying you are supposed to be dealing with deficiencies? If it is good enough, tell us about it. Give it out to people and let's see the uptake and what it means if they eat it.

So, for transparency, because it means something different to different people. For some, it means the transparency and labelling or where it comes from and to others it means, in the case of biofortification, the laboratories and research behind it. Which parts do you find most important, or are they all important or something else?

All of those. So, all of those different aspects of transparency. The research is not available to ordinary Ugandans. The biggest and most existing research around the Super banana I will give that as an example because it is directly in our backyards. Is very scientific and online. And you have to buy the journals.

That is not very available.

Yes. When they brought their samples back to Uganda they took them, the cells, to Kawanda research station, they never gave them to Ugandans. If they have given them to Ugandans, they have not told them that this is what it is. So, they are just planting them.

And because one of the things we have done we have been asking for within the Ugandan civil society sector for a long time is transparency in developing certain pieces of legislation around GMOs, gene editing and every kind of scientific research that is tinkering with our food. And you asked about labelling, and we have been very clear. And that is one of the reasons why the GMO bill in Uganda did not pass because there was no clarity and there was no labelling. There was no transparency, and the Ugandans were like, no, you need to be transparent enough to label, and to tell us the effects and to talk about patents and all of these are conversations that need to be had. If you are not transparent enough, you will not be able to hear these things. So, for example, when we go to the Super banana, the Super banana is patented to someone. So, if it is patented to someone, it means it is not ours. The material that made the Super banana is ours. You did not consult us when you were picking up that material to take it and started doing what you are doing. But you have come back with a variety that now you need to sell to us, and we cannot plant it anyhow. Yet before we could plant our bananas anyhow. So, the variety that they use, which is called Nakitembe, is a variety that we know is ours. We gave you the genetic material to start your journey. But now it is registered to someone, and we need permission to use it and they do not have to label it so where is the ethics in that? And when you bring it back to our country, you bring back our food to our country, but we have to buy it. But when you were taking [it], you did not buy [it]. Now you are bringing [it] back and we have to buy [it]. So, this is where the story around ethics becomes really tricky and very interesting. And I think for every single person who is doing the journey of the GMOs, the journey of genetic engineering, all those sciences. I think what they fail to recognise is the uptake of their technologies by the ordinary citizen because, at the end of the day, this is who they are producing for. But the ordinary citizens are telling you, you did not tell us what is in this. And then it is “You do not need to know. You do not need to.” I do not need to know. But you are telling me to correct my deficiencies in something. How is that even possible? If it is going to correct any deficiencies, then tell me what is in it. And give me all the information that is there. Let's sit down at the table and have a conversation. Me, as the person who is going to take your product and you as the producer of that product. And let's talk about it. What did you do? How did you do it? Where did you go? In my language? Because those conversations are not happening in local languages, they are happening in English.

So, do you think the transparency part and the clear communication are the priority areas for policy development and regulatory reform around biofortification?

They are they are they are not. They are not the priority areas, but they are definitely important areas to consider looking into.

What would you then say are the priority areas?

It is a lot depending – by the way, the whole conversation around legislation and policymaking is also very specific – in context, so every country will have its unique requests. And what it wants to prioritise when it is legislating and that is why both as an organisation and also as an individual, I always say it is problematic to legislate in uniform.

I cannot talk for legislation of people beyond Uganda because I am also interested in ensuring that we recognise the context, our unique problems in Uganda are not the problems in Kenya or Tanzania. So, for example, that is why we are against UPOV. Because UPOV standardises legislation. We are against seed harmonisation because that also aims to standardise legislation. The biotech rules at the African Union level the East African Community seed harmonisation processes, all of these are very dangerous areas to go into when we are talking about farmers' rights. So as organisations that are in the agroecology movement, we are talking about farmer-managed seed systems and farmers’ rights. We cannot talk about standardised legislation. We are talking about and requesting explanations that make sense to people. We talked about understanding our context, we are a community of smallholder farmers and because we are a community of smallholder farmers, we need to legislate with that in mind in our agricultural systems.

So it is one of many and I think we need to be able to understand instead of lumping the African continent into one and saying we need to legislate from our continent, we are saying no, look at the uniqueness of every country, the smallholder farming situation in that country, the systems, the soils, the lands, the, the farming systems that we that grow, political zones. All of those need to make sense because we are not planting the same fruits. If we start talking about making uniform and standard rules, that sometimes miss the point, that becomes problematic.

For international trade, a lot of regulations are harmonised, or at least to some extent, there are international agreements. Do you think these are possible if there is also separate legislation per country or even smaller or bigger [regions]?

Like which international agreements are you talking about?

There is, for example, the Cartagena Protocol, including LMOs, and we also have the WTO which is also more standardised. Not necessarily for every country but there are certain agreements within

those protocols/agreements/regulations. Do you think that is possible, because for international trade there has to be some kind of mutual understanding usually… how would that work then?

So, we have clearly come out and said no to any international trade agreements. They are not good for any sort of national processes. I think one of the things that was pushing for Brexit was that we need to get out of these international systems because of nationalism. So, one of the reasons for Brexit was around, OK, we are losing our national identity and therefore we need to hold on to our national identity. And I think from my reading, that was one of the reasons why Brexit happened. And then we, as African countries have come out and said no to Economic Partnership Agreements and we are very clear about that. Cotonou, post-Cotonou [Agreement], we have said no to all of that, and I think that is why, 20 years after it had started, it still failed to come out because it is basically liberalisation. I think free trade agreements just pushed the whole liberalisation agenda even bigger. And I think it is part of the World Trade Organisation. Again, when you start tracing the World Trade Organisation, it is the reason why UPOV came about. And why the World Intellectual Property Organisations have gained credence because of those international standardisation and trade agreements, I mean World Trade Organisation says you can now go and do your own legislation at the national level and make it possible and then free trade agreements come and tell you, no you cannot. You have to liberalise. So, you have to deal with the formation of – I mean us saying no to the EPA, the Economic Partnership Agreement – has brought us now what we have – which we are battling within the African continent – I think and it is termed as the as a mega trade deal. Which is a mega free trade deal which is the African Continental Free Trade Area. And again, we have come out and said no to the African continent free trade area. We stand by that because it is basically liberalisation. And if you trace the journey of colonialism, the journey of colonialism ends up in free trade agreements. So, our argument as number one, an organisation and number two as many people on the continent who are part of the movement, is that free trade agreements, including our very own African Continental Free Trade Area, is just a section of that. What that means is liberalisation. It means disrespecting farmers' rights because they are protecting plant breeders' rights. And our argument is that farmers' rights need to take centre stage, but the African Continental Free Trade Area is doing exactly that, diminishing, and taking away all those rights because they are pushing for agribusiness, plant breeders' rights, standardisation, and the harmonisation of seed systems. They are pushing for intellectual property regimes on the continent, which is very difficult, they are pushing for biotech harmonisation.

The African Continental Free Trade Area is pushing for special economic processing zones, which have been reported to have huge labour rights abuses in different parts of the world. So basically, any free trade agreement, anywhere in the world, is pushing for liberalisation and privatisation and not helping any country.