The role of non-scientific data in risk analysis

Chapter 10

Impact paragraph

The main conclusion of this thesis is that the use of non-scientific information coming from traditional use in risk analysis is possible, but creates many new problems. First and foremost, it would require an amendment of current or new legislation, which would cost time in which potentially misleading claims are still to be found on the market. It would also require the implementation of a graded evidence approach in which the wording would reflect the 'strength' of the evidence. This graded evidence is expected to have an influence on consumer trust, which would impact the objective of European Union (EU) food law negatively. After all, we have learned that the provision of information on botanical products, and food products in general, goes beyond merely the *content* of the presented information. Personal and societal aspects influence the perception of the provided information. Because of this, it is of utmost important that the information provided on or along with the product is visible, clear, and unambiguous. Whilst the evaluation of botanical health claims is on hold, Dutch authorities require the use of a disclaimer along with the botanical health claim. This disclaimer must indicate that the evaluation of the evidence underlying the health claim is pending. Although this shows the effort to be transparent in the provision of information, it is questionable whether consumers understand the content and implication of this disclaimer. Additionally, the use of this mandatory disclaimer is a requirement set by the Dutch institutions, and may consequently result in unequal competition among member states which do not mandate the use of this disclaimer. Together, it is very much debatable whether the use of such a disclaimer is in line with the objectives of EU food law.

Since it is impossible to control for every factor that may influence the perception of provided information, it would be detrimental if the content itself already allows for varying interpretation just by the wording of it. This could be a result when a graded evidence approach would be used in the EU. Given that member states are implementing new rules for the botanicals now, it is of utmost importance that the evaluation of the botanical health claims is resumed, with the existing evaluation criteria. By doing so, food business operators, consumers and other stakeholders involved will finally have an answer to the current impasse.

10.1 Beyond botanicals

A secondary conclusion from this thesis is that the full risk analysis cycle should be involved when adjustments are required in one aspect of it. Previous research on botanical health claims mainly focused on risk assessment and the criteria for substantiation with traditional use evidence. This may have resulted in stake-

holders believing that such adjustments would be easy to accomplish. When considering risk management, risk communication and risk assessment together, the complexity and barriers become apparent and the conclusion on the implementation of traditional use evidence for substantiation health claims shifts.

The provision of information on health benefits of a product is voluntary. Even though the nutrition and health claims regulation only lays down the provision for providing information on the relationship between food and health, different types of voluntary information are provided on food products these days. Messages regarding sustainability, animal welfare or production circumstances are visible both on packaging and in advertisements of (food) products. Even though these messages should in general not be misleading, there is no formal EU evaluation procedure in place that evaluates the underlying evidence of such statements. Since 2021, the European Commission started the Sustainable EU food system initiative in which setting rules for sustainability labelling is one objective. If a formal evaluation procedure would be instated using the principles of risk analysis, the lessons from the thesis can aid in setting up the procedure and defining the necessary framework up front. Important aspects which would need specific attention are, for example, that the provided information to consumer is unambiguous, and the roles and responsibilities of the different actors in the evaluation procedure are clear. The data requirements which allow for clear and transparent communication of sustainability information should be determined before the implementation of a legal framework on the provision of such sustainability information. Although the initiative is still in its early phase, it does show that providing more information on food products is important, but also that centralisation of the regulation of such information is strived after. As a consequence, food business operators as well as risk managers, risk assessors and risk communicators need to deal with these existing and new legislation covering the provision of information. They would benefit from transparent rules and clear guidelines. Consumers are potentially confronted with more and potentially different information on products they intent to purchase. It is therefore of utmost importance that they understand the content information, and ideally, the underlying rules and regulations.

10.2 The role of science in law

Scientific studies have a dominant role in EU food law as they are used for showing a product's health benefits and demonstrating there are not adverse effects. By requiring human intervention trials as evidence for the substantiation of health

claims, there is as much certainty as possible with regards to the cause-and-effect relationship of food products and health benefits. Science consequently becomes an inevitable part of society: if it cannot be proven scientifically, a statement will not be authorized and consequently such statements cannot be used in the communication towards the general public. Although implemented to protect the general public, this regulatory framework also results in a limited information supply and a tremendous pressure on nutritional sciences to broaden this information supply. This may in the end also lead to scientism in society: decision making purely based on the results of scientific studies. This is also the conclusion of this thesis: within the current regulatory framework, evidence on traditional cannot play a role without major changes in the legislation. The case on botanicals does show that it sometimes becomes difficult to defend that everything should be based on scientific studies. Other information sources including studies using an *in vitro* or longitudinal research methodology may provide an indication of a beneficial health effect. These sources can now solely be used as supporting evidence within the authorisation procedure. Even though it is known that showing beneficial effects of food products in human intervention trials is difficult, it is the only way to show a cause-and-effect relationship. And since authorisation will only occur when a cause-and-effect relationship between food product and health benefit is established, the human intervention trial is the only way to go in the current regulatory framework.

In deciding upon the role of science in food law, one must find the perfect equilibrium in providing sufficient information and the certainty that the information is truthful. In the current legal framework, the scale moves towards certainty. If there is a desire to also increase the amount of information provided to consumers, the level of certainty must decrease, simply because sources beyond human intervention trials must be considered. This does however require further research into consumer understanding of information, consumer use of information and validation of scientific and non-scientific sources of information. When the ambition is to increase the provision of information, science, policy-makers and food business operators must work together to cover these topics.

10.3 Conclusion

The research presented in this thesis allowed for obtaining a broader perspective on risk analysis and the provision of information to consumers. The conclusions from this thesis firstly shed light on the underlying argumentation in the discussion on botanical health claims; and additionally allow for understanding

the complexities of risk analysis for voluntary information provision. With new societal challenges these days and a food system that may be asked to deliver sufficient, nutritious, healthy as well as sustainable food products, also other messages beyond health effects may become regulated. Risk analysis – or a more broadly defined term better suitable for its use in EU food law, for example scientific analysis - may again be implemented to assess the underlying evidence of these messages. The findings from this thesis may aid in shaping the framework for the evaluation of that information.