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Europe's Pretense and Reality for Better Governance in the case of Health Claims Regulation

Pretensiones y realidad de Europa para una Mejor Gobernanza en el caso de la Regulación de las declaraciones de propiedades saludables

Noemí Sanz Merino (*)
Departamento de Filosofía y Trabajo Social, Universitat de les Illes Balears
https://orcid.org/0000-0002-5093-3883 noemi.sanz@uib.es

Oliver Todt
Departamento de Filosofía y Trabajo Social, Universitat de les Illes Balears
https://orcid.org/0000-0001-9363-0543 oliver.todt@uib.es

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ABSTRACT

We analyze the European Commission's policy objectives of introducing a more open, more participatory and less hierarchical way of regulating science and technology, in one particular case: the European Regulation of Health Claims. This relatively recent regulatory framework, being primarily consumer-oriented and recently amended by the new European transparency regulation, provides a test case for the European institutions' aspirations of improving governance of science and technology. However, our analysis shows that these aspirations have not been fulfilled. European health claim regulation does not allow for any relevant public or consumer involvement, nor stakeholder participation in decision making. It does not offer any mechanisms for facilitating public or consumer debate with respect to the regulation's chosen aims, scientific standards, nor the trade-offs involved, particularly the regulatory outcomes that are the result of regulators' choices. Very different from the Unite States and Japanese health claim regulations, for example, the underlying epistemic and policy suppositions of the European approach tend to make attainment of most of the participatory objectives more difficult.

PALABRAS CLAVE

Ciencia para la política,
nueva gobernanza,
mejor legislación,
evaluación de beneficios,
giro participativo

RESUMEN

Analizamos los objetivos de la política de la Comisión Europea de introducir una forma más abierta, más participativa y menos jerárquica de regular la ciencia y la tecnología, en un caso particular: la Regulación Europea de las Declaraciones de Propiedades Saludables. Este marco regulatorio relativamente reciente, en principio orientado al consumidor y modificado recientemente por la nueva regulación europea de transparencia, proporciona un caso de prueba para las aspiraciones de las instituciones europeas de mejorar la gobernanza de la ciencia y la tecnología. Sin embargo, nuestro análisis muestra que estas aspiraciones no se han cumplido. La regulación europea de las declaraciones de propiedades saludables no permite ninguna participación relevante del público o de los consumidores, ni la participación de las partes interesadas en la toma de decisiones. No ofrece ningún mecanismo para facilitar el debate público o de los consumidores con respecto a los objetivos elegidos por la regulación, los estándares científicos ni los costes-beneficios involucrados, en particular las consecuencias que son el resultado de las decisiones de los reguladores.

(*) Corresponding author / Autor de correspondencia

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Al contrario que en las regulaciones de las declaraciones de propiedades saludables de los Estados Unidos y Japón, por ejemplo, los supuestos epistémicos y políticos subyacentes al enfoque europeo tienden a dificultar el logro de la mayoría de los objetivos participativos.

1. Introduction

In the last 20 years, the European Commission (EC) has made repeated attempts at introducing changes to the way in which scientific-technological processes, applications and advice are regulated. One of its most comprehensive attempts was the 'Science in Society' program that the EC espoused during the first years of this century. Most of the proposals of this, as well as related programs, were aimed at opening up regulatory decision making to a wider range of stakeholders, as well as subjecting assessments based on expert knowledge to increased public scrutiny. Presented as 'democratic' and 'open', as well as characterized by a 'new governance' (EC, 2001; 2006; 2007; 2008), their aim was to question mainstream approaches to policy making and regulation. As such, many concrete EC's regulatory initiatives were supposed to be enacted by then in accordance with what has been called the 'participatory turn' in the production and management of science and technology (Jasanoff, 2003; Lengwiler, 2008).

Although different concepts, other than 'governance', have taken center stage since then, such a participatory approach is still exerting influence on recent EC reports and legislation: the current EU Better Regulation agenda (European Parliament, Council of the European Union and European Commission, 2016), and the EU Transparency Regulation (European Parliament and Council, 2019), for instance. We may found it under the most recent report 'Futures of Science for Policy in Europe' of the Directorate-General for Research and Innovation (Sarvaranta et al. 2023). However, while there is a renewed interest in the participatory approaches through increasing research on assessing approaches of evidence-based policies, it remains unclear if the shift towards this new approach in governance was as profound as envisioned because of the lack of enough case studies on concrete regulatory implementations (Jasanoff, 2003; Lengwiler, 2008; Dehousse, 2016; Guéguen & Marissen, 2022; Sarvaranta et al. 2023).[1]

The aim of this paper is to analyze one particular European regulatory process, the regulation of health claims on foods, in order to ascertain if and to what degree any of the objectives of a new, more participatory, governance approach have been taken into account in policy making. The European Health Claim (HC) regulation was enacted in 2006, shortly after the elaboration of the European White Paper on Governance and the Science in Society program, but still rules (since it started to be applied in July 2007), without any important change, the use of health claims in food labeling and the way in which the food benefits assessment is implemented.

The HC regulation is a particularly appropriate case study. It was a new EU regulation that was designed from scratch, thus it was less likely to suffer from many of the problems related to legacy regulatory schemes, which are well established in practice and therefore difficult to change. Besides, HC regulation concerns a matter of direct interest to consumers, but, at the same time and given that it is a regulation in the field of benefit assessment, it was and it is also –for the most part– free of the public controversies that surround many EU Regulations in the area of risk assessment (e.g. those typical considered within the EU registration, evaluation, authorization and restriction of chemicals (REACH) regulation). It therefore offered, at least in theory, an opportunity for the practical application of some of the principles of a 'more open, more participatory, less top-down' governance of science and technology by the European Commission.

Our analysis, however, shows that in practice this regulatory framework neither correspond to the discourse of its time in favor of a 'new European governance of science and technology', nor to the same current one in favor of involving citizens, businesses and stakeholders for Better Regulation. Rather, we observe the opposite: the epistemic and policy suppositions that underlie the HC regulatory process, as well as the authorities' understanding of how to operationalize expert advice as basis for regulatory decision making would appear to make attainment of most of the participatory objectives more difficult; in particular, the aim of opening up regulatory decision making to social actors and stakeholders other than experts or regulators.

[1] It is also worthy to remind here the European Commission's own interest in 'Regulatory Impact Assessment', as part of the Better Regulation agenda, that is expected to work as a support for decision-makers enabling well-justified choices via ex-ante analyses of the regulatory options' impacts in order to legitimate regulatory designs (Rantala, Alasuutari & Kuorikoski 2023).

2. A *New* European Governance Of Science And Technology

Debates about objectives, uncertainties, vulnerabilities, as well as alternative outcomes are inevitable and even necessary in the formulation and operationalization of science and technology policy and regulation (Jasanoff, 1990). As 'the aim of science for policy is to produce actionable science, however, the level of control over those producing the knowledge and their responsibility for the consequences of the action is a matter of important societal dispute' (Sarvaranta et al. 2023, 3). Many of the key ideas, principles and objectives contained in the various proposals for improving regulatory governance and decision making have been under debate in many countries for decades. Since the 1980s, some of those proposals, such as different approaches to assessment or mechanisms for public deliberation on science and technology, have been adopted on certain occasions in policy making and regulation.[2]

The underlying idea of the approach that flows from the 'participatory turn' is that regulation will tend to be more effective, as well as more likely to achieve its aims if it is socially representative, transparent, as well as responsible as to its outcomes. The preferred way to achieving this aim is supposed to be the participation of, and monitoring by, non-experts. The European Commission has explicitly taken into consideration some of these ideas by way of white papers, expert groups and programs since the very beginning of this century (e.g. EC, 2001; 2006; 2007; 2008).[3] The scope of such a *new* European approach (to which in the remainder of the paper we opt for still calling the 'new governance' approach) was well beyond science and technology regulation and the 'science for policy' concern, which are the focuses of attention of this paper.

Our objective is to carry out a comparison between, on the one hand, some of the key aspirations that were part of the new governance approach and that –as expressed in those European documents– would be in accordance with the so-called participatory turn, with, on the other, the reality of the regulatory discourse, as well as regulatory decision making in our case study, the EU regulation of health claims. The focus of our analysis will thus be twofold, centering on both discursive coherence and practical enactment.

In order to focus our analysis on a few key aspects, we have selected a limited number of regulatory objectives from the first EU documents on the matter, those that characterize the 'participatory turn' in regulation (Jasanoff, 2003) and that still are part of the EU general aspirations.[4] The following selected objectives will allow us to understand if and in what ways the aspirations for a new governance of science and technology are reflected in the reality of the regulatory process of our case study.

(1) Improving the *transparency* of processes which make use of expert knowledge. The main objective here is to keep expert-based decision making from turning into black boxes. The European Commission's aspiration is to 'publish guidelines on collection and use of expert advice, so that it is clear what advice is given, where it is coming from, how it is used and what alternative views are available' (EC, 2001: 3). Shortly afterwards, the EC declared the need for opening debate 'with civil society and the wider public' on questions of governance and related issues (EC, 2008: 11). (See also: EC, 2006; 2007)
(2) Increasing *public scrutiny* of the use of expert knowledge and the decisions arrived at on the basis of expert knowledge. This includes, among other, the debate on possible alternative outcomes as a result of adopt-

[2] Particularly, for examples of 'participatory' decision making related to science and technology, see, e.g. Guston (2000), Joss & Durant (1995). In the particular case of science and technology in health-related implementations of the new governance approach within recent EC policy-making, there are a few outstanding cases, such as the *Strategy on Nutrition, Overweight and Obesity-related Health Issues* enacted in 2007. This Community Strategy, close to our case study, which functions as a European policy on the macro level, was partially designed by a participatory process, with important input provided by the *Platform on Diet, Nutrition and Physical Activity*, an EU deliberative forum that encompasses representatives of EU Member States, industry, NGOs and civil society (see more in: Greer & Vanhercke, 2010: 194).

[3] Alongside the participative turn, there have been a few related changes to the European Union's overall scientific policies. One relevant change concerns the concept of Responsible Research and Innovation (RRI). RRI has been implemented as part of the Horizon 2020 program's global values (European Commission 2013; also 2017). What this means, at least in theory, is that R&D activities are conducted in a transparent and interactive manner, while facilitating the interchange between social actors and scientists/innovators with the ultimate objective of improving the sustainability, as well as ethical and social acceptability of the innovation process and its outcomes. This is hoped to make possible an adequate societal integration of scientific-technological advances (Von Schomberg, 2014: 63). In any case, our paper focuses on the participative turn only in relation to the implementation of "science for policy". For a conceptual and political history of the RRI framework, see for instance, Woolley et al. (2024).

[4] Although we will refer here, as sources, to the first systematic European proposals on the matter, the chosen items are still present behind the main objectives of the current EU Better Regulation agenda. These are, apart from 'ensure EU policymaking is based on evidence': 'Making EU laws simpler and better, and avoiding unnecessary burdens' and 'Involving citizens, businesses and stakeholders in the decision-making process'. See on: https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation_en

ing one or the other regulatory decision. In the EC's own words, the 'EU's multi-disciplinary expert system will be opened up to greater public scrutiny and debate. This is needed to manage the challenges, risks and ethical questions thrown up by science and technology' (EC, 2001: 33). Increased public and stakeholder deliberation in policy and regulation related to innovation results in 'a shift from expert-dominated to more open deliberative science-informed institutions on ethics, risk and innovation' (EC, 2007: 11).

(3) Promoting *less hierarchical structures* of policy making, regulatory processes and regulatory decision making. The EC aims at 'following a less top-down approach and complementing the EU's policy tools more effectively with non-legislative instruments' (EC, 2001: 2). This would include more opportunities for multi-level (i.e. non-hierarchical) governance: 'there should be explicit interlinkage of different processes at different levels of governance and measures to ensure deliberation and reflection over these links as part of the processes themselves' (EC, 2006: 31).

(4) Broadening the *participation* of stakeholders and/or the general public in regulatory decision making, or in the preparatory steps for decision making. In particular, 'where scientific research is aimed at informing decision making on the regulation of technologies with potential environmental or health risks, or wider social impacts, participation offers a way to help prioritize the different dimensions of appraisal and identify important questions that might otherwise remain neglected' (EC, 2006: 19). This includes the possibility of establishing dialogues between experts and non-experts (EC 2001; 2006; 2007; 2008).

It is clear that all these issues overlap. While the chosen items can be considered critical to a fundamental change to regulatory governance, they are far from exhaustive. However, given that our objective in this paper is circumscribed to the study of a single regulatory process, we consider the four chosen objectives sufficient for our analysis.

3. Health Claim Regulation In Europe

A health claim (HC) is a statement referring to particular health benefits that a food confers upon its consumers. Examples of such benefits in question are the maintenance of correct bodily functions (e.g. correct blood pressure) or the reduction in the likelihood of the onset of a disease (e.g. cardiovascular disease) (Bagchi, 2019). Health claims are usually stated on food labels and are subject to regulation, since they confer an added value to the food item. Thus, in order to authorize a health claim, regulators usually require scientific evidence that allows to substantiate (verify) the claimed effect (Boer & Bast, 2015).

In the European Union (EU), health claims are regulated by a common EU regulation, the Nutrition and Health Claim Regulation (NHCR) (European Parliament and Council, 2006). This regulation is operationalized, since it entered into force in 2007, by the relevant regulatory body, the European Food Safety Authority (EFSA). All scientific assessments are carried out by an expert committee within EFSA, the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA Panel). The NHCR's primary objectives are to protect consumers from false claims, provide them with useful information for improving their health, facilitate innovation in the food industry, as well as contribute to the creation of a European HC market. Scientific substantiation on the basis of the 'highest possible standards'[5] is a prerequisite to authorization.

In order to achieve the objective of authorizing claims only if their effectiveness has been established with a high degree of certainty, EFSA in regulatory practice requires data from randomized controlled trials (RCTs, clinical trials)[6]. This is because RCTs, at least in principle, allow for the establishment of causal relationships between intake of a particular food or ingredient, and the desired health outcomes (López Mas & Luján, 2022). As a general rule, other scientific methodologies (like, for instance, epidemiological or mechanistic studies) are unable to establish such causal links. The regulation's focus on RCT data aims at drastically reducing false positives (Todt & Luján, 2017). In other words, EFSA authorities want to make sure that all health claims that obtain regulatory approval are truthful and not misleading. This will protect consumers

[5] Recital 23 (European Parliament and Council, 2006).

[6] This requirement by EFSA has been applicable for submissions from and before March 2021. Currently, the relevant requirements can be found in European Food Safety Authority (2021a; 2021b). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) explains in these guidelines: 'the revision concerns only the administrative part. The scientific content remains unchanged'. Before March 2021, the details on the necessary data for HC substantiation could be found in: European Food Safety Authority (2016; 2017). For more Guidences and details on this modification of HC regulation, see: https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance (accessed 20/7/2023).

against erroneous claims, while also minimizing the likelihood of market distortion (European Parliament and Council, 2006).

EFSA's assessment approach, based primarily on RCT data in humans, thus fulfills the NHCR's objective of protecting consumers from false claims. Since establishment of causality is difficult, by 2023 only about 260 health claims, out of the more than 2300 submissions received, had received EU authorization.[7] What this means, however, is that there are likely to be foods with important benefits which consumers are not aware of, because the related health claims have been unable to obtain authorization.

It is important to point out that the EU's health claim regulation has recently been amended by the European Transparency Regulation (European Parliament and Council, 2019). This change has however not affected the technical requirements (for more details, see section 4.1.1. and notes 6 and 13).

4. Eu For Better Governance?

We will now analyze some of the key features and assumptions of the NHCR with regard to each of the EC's objectives for a new governance, as outlined above. This will allow us to understand if and to what degree these policy and governance objectives might have had any influence in the drafting of the Health Claim Regulation.

4.1. Analysis

4.1.1. Increasing transparency and public scrutiny

Here we will see the level of involvement of stakeholders and/or the public in the drafting and monitoring of HC Regulation. We will also understand if its practical implementation can be considered transparent.

In a preparatory step, the EC gave a number of invited stakeholders the possibility to comment on the *Nutritional Claims and Functional Claims Discussion Paper* (Directorate General Health and Consumer Protection, 2001), drawn up in preparation for the future Health Claim Regulation. According to official data, among a total of more than 90 invited stakeholders, there were nine consumer organizations, as well as a handful of scientific institutions, European agencies and NGOs (like advertisement associations). The remainder of invited stakeholders came from the food industry. Practically all of the discussions centered on issues particularly relevant to industry, rather than consumers. As we will see, the ultimate design of EU health claim regulation, as subsequently adopted by the European institutions, for the most part does not reflect the concerns voiced by the stakeholders in this deliberative process (including those from the food industry).[8]

There was no further stakeholder or public participation nor deliberation with respect to the Regulation, until the publication of the final Common Opinion of the European Parliament and the Council (European Parliament and Council, 2005) that formed the basis of the NHCR. One of the fundamental decisions included in this Opinion was to task the European food authority, EFSA, with the scientific assessments. Following the Regulation's adoption, the EC tasked EFSA and its NDA Panel with preparing the entire regulatory process foreseen in the NHCR (European Parliament and Council, 2008).

More recently, EFSA organized a number of seminars with stakeholders from industry in order to keep collecting opinions (Valtueña & Siani, 2017). Another potential avenue for external scrutiny is the process for an ex-post assessment of the NHCR that the EC offered to a number of stakeholders in 2015. This process was very narrow, however, focusing exclusively on health claims made on plants.[9]

Therefore, we can conclude that since the enactment of the Regulation the expert system that underpins it has not been opened up to greater public scrutiny nor debate. Nor have there been any relevant changes to its regulatory objectives, or the operationalization of the assessments and authorizations of health claims. And this is still the case, even after the enactment of the 'Interinstitutional Agreement on Better Law-Making',

[7] See EU HC Register https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register (accessed 27/6/2024)

[8] Prominent among those issues were the requirements for scientific substantiation (with industry suggesting that data from all kinds of methodologies, including mechanistic data, be relevant for authorization), as well as the administrative procedure for authorization (including who would have authority for authorizing health claims, as well as suggestions by industry with respect to the implementation of a 'notification' procedure (see discussion section)). See on https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims_es (accessed 27/7/2023).

[9] See on https://ec.europa.eu/food/safety/labelling-and-nutrition/nutrition-and-health-claims_es (accessed 27/7/2023)

which explicitly considers that, not only ex-post evaluation of existing legislation, but also public and stakeholder consultation will help achieve its objectives (European Parliament, Council of the European Union, and European Commission, 2016).

As for transparency: a lot of relevant information has been available on various EC and EFSA websites and in periodic publications, particularly expert opinions, discussion papers, panel reports related to the establishment of the NHCR (including related to the monitoring of the NHCR's implementation), as well as all relevant guidelines for industry and stakeholders elaborated so far. All of EFSA's decisions on claim authorization have been publicly available in the *EFSA Journal*, giving the applicants from the food industry the possibility for appeal in case of rejection of the authorization. Furthermore, with the enactment of *Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain* (European Parliament and Council, 2019), applicable as of the 27th of March of 2021, the new 'OpenEFSA portal' also allows for public access[10] to the documents and information that are part of the life cycle of any EFSA assessment process for all HC applications (at least as long as there are no property rights conflicts). In other words, any public consultations and comments received,[11] as well as any official responses, are publicly available at least until the authorization procedure has come to a close.

In one sense we can thus consider the regulatory process as transparent, even more so since 2021, due to the implementation of EFSA's new 'transparency and stakeholders engagement' approach.[12] It is, however, not transparent in the broader sense as understood by the 'new governance' approach, as explained above.[13] That is because neither the EC nor EFSA have ever given attention in their published documentation to possible implications, impacts or alternative choices, as far as the objectives of the regulation and the operationalization of the assessments are concerned.

In sum, 'public scrutiny' and 'transparency' (according to the procedures foreseen in the 'new governance' approach) have been either absent or only partially implemented in European HC regulation. In fact, public scrutiny and deliberation would appear very difficult to conduct in the current framework of the NHCR. This point applies particularly to any possible deliberations as to the regulation's objectives and their contribution to social preferences or needs, including questions like, for instance, what kind of knowledge ought to underlie the regulatory process or what role the expert committees should have in the decision processes. However, it is issues like these which underlie, as we have seen, the ideas of a 'new governance'.

This partial lack of transparency, as well as absence of social debate with respect to regulatory objectives and the role of expert assessments in Europe, is very important to take into account, given that in health claim regulation in other parts of the world there exist well-established alternative approaches to scientific assessments and stakeholder involvement that differ from the EC's policy choices and that result in social impacts that differ from the European ones (see in Discussion).

4.1.2. Increasing bottom-up mechanisms and stakeholders participation

Here we will analyze the 3. and 4. objectives: less hierarchical structures and more participation, particularly the type of participation and stakeholder dialogue that is possible under the NHCR.

From its inception, the NHCR has foreseen the possibility for comments from applicants, stakeholders or the general public on EFSA's scientific opinions in the case of certain types of health claims (those subject to an individual authorization procedure).[14]

[10] https://open.efsa.europa.eu/ (accessed 20/7/2023)

[11] See next subsection on public participation.

[12] See for more detail on https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation (accessed 28/7/2023)

[13] It is important to point out that the proposal for the new 'Transparency Regulation' (see below), as well as its impacts on HC regulation, has not been the result of any public discussion or controversy with respect to the implementation of the NHCR, its regulatory objectives, the consideration of its possible societal consequences, nor the underlying expert assessments. In this sense, it can be considered part of the EC's commitment to more public engagement in risk communication. The Transparency Regulation shows a very restricted understanding of 'transparency' in the context of risk assessment in the food chain, namely, as restricted to the regulators' responsibility of making public the scientific, administrative, and decision-making documents related to HC assessments, as far as property and personal data rights allow (European Parliament and Council, 2019).

[14] According to Article 16(6) of the original Regulation, stakeholders and the general public may voice opinions on the authorization of the types of health claims referred to by Articles 14 (a and b) and 13(5). See examples on https://ec.europa.eu/food/food-feed-portal/screen/health-claims/claims-individual-proc (accessed 19/7/2023)

In spite of this possibility for non-binding comments, as well as the recent creation of the 'OpenEFSA portal' as EFSA's new way of public information with respect to each particular assessment process, there is no institutionalized mechanism for facilitating any kind of particular participation (or in any way less top-down interaction) of operators from the food industry (beyond their submitting proposals for health claims and appealing rejected applications). Nor do their exist any deliberative mechanisms that would facilitate an actual dialogue between experts, regulatory authorities, as well as non-experts with respect to non-scientific or technical issues of the Regulation. In practice, the NHCR basically assigns a passive role to consumers and the food industry: they are supposed to accept regulatory decisions that are 'good for them', meaning being protected from uncertain or false information (false health claims).

In any case, the EC received several uninvited letters related to the NHCR from stakeholders and the general public after the first and third series of EFSA opinions on Article 13 claims. The Directorate-General for Health & Consumers responded with 'Collective Answers', which have also been made public.[15] In response to stakeholders' concerns about the effects of the Regulation on the sector of food with health claims, these Answers have focused on the need for maintaining the current strict scientific requirements in order to achieve the Regulation's objectives. EFSA experts, in fact, have a critical and predominant role in the entire regulatory process. The European Commission itself made explicit that it defers to these experts: the scientific assessments are in the hands of EFSA's expert committees whose conclusions are not to be questioned by the Commission, nor any other authority, like for instance EU member states:

> EFSA has the responsibility for advising the Commission as to the extent of the scientific substantiation of health claims and the Regulation requires EFSA to apply a scientific assessment of the highest standard. It is not for the Commission to stipulate how the independent scientists at EFSA should assess the science to substantiate health claims (Directorate-General for Health and Consumers, 2011).

In sum, not only the assessment procedure, but –in fact– the entire regulation can be considered a top-down policy instrument that does not allow for binding participation. There is no possibility for stakeholder intervention in the mechanism for assessing health claims. Rather, the entire regulatory approach remains highly expert-based. Given the way the regulation has been designed and operationalized, it becomes clear that consumers, market operators and food innovators are understood as mere passive receptors of the benefits provided by scientific knowledge that is considered 'certain beyond any reasonable doubt', given that it previously has been assessed by the NDA Panel.

4.2. Discussion

We argue here that there are several fundamental assumptions that underlie the Nutrition and Health Claim Regulation (NHCR) that can be considered incompatible with the participatory turn, i.e., with the European approach for a 'new governance' of science and technology and also with the mentioned objectives of the current EU approach on 'Better Regulation'.

We also show that there exist alternative approaches to health claim regulation that differ from the EU's one. In doing so, we do not mean to endorse such alternative approaches. Rather, our aim here is to show that such alternatives do exist, and argue that current EU regulation is at least partially the result of fundamental regulatory *choices* which have not been, but precisely could be, the subject of public, consumer or stakeholder debate and decision-making.

4.2.1. Social, political and epistemic assumptions and decisions underlying the NHCR

As stated in the NHCR, food market operators and, even more, consumers are the targeted beneficiaries of this Regulation. However, as far as those stakeholders are concerned, the NHCR makes a number of implicit, underlying assumptions. On the one hand, the entire European HC regulatory process presupposes a certain type of consumer of foods with claims, as –homogeneously and narrowly– having specific knowledge and attitudes. It has to be taken into account that, from the standpoint of EU regulation, the 'consumer' in this context is a mere theoretical entity, namely, the 'average consumer', as established by the Council of the

[15] See on https://ec.europa.eu/food/safety/labelling_nutrition/claims/health_claims_en

European Communities (Council of the European Communities, 1984/2005). The NHCR incorporates this definition of a consumer: one 'who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors' (European Parliament and Council, 2006). This concept carries with it the implicit (and questionable) supposition that consumers in the real world will make the 'rational choice' of improving their health (by consuming foods with health claims) if presented with accurate, relevant and 'certain' information on the food labels (Sanz Merino, 2020).

On the other hand, EU regulation also presupposes a consumer with particular needs and preferences: EFSA and its NDA Panel pre-define this consumer as (almost exclusively) worried about being misled by false or erroneous health claims (Todt & Luján, 2021). A similar point can be made with respect to industry: the NHCR and EFSA interpret that the food sector's most important need, in the development of a market for health claims and related innovation, is protecting food companies from fraudulent competitors.

On the basis of such suppositions about stakeholders' preferences and needs, EFSA has since worked on the assumption that the NHCR's objectives can best be achieved by providing scientific certainty, in the sense of requiring the highest possible scientific standards (namely, clinical trials) in data generation. Thus, as we have seen above, the entire regulatory process is geared towards restricting authorization of claims to those that can be considered certain beyond any reasonable doubt.

Two further circumstances contribute to this very strict regulatory approach and give it its internal coherence: firstly, the EC's long-standing separation in food governance of risk assessment from risk management (part of the EC's response to the late 20th century EU food crises and the concomitant loss of public trust in institutions and experts (Levidow, Carr & Wield, 2005)); a separation that the EC is appealing to in health claim regulation, too, as we have already seen[16]. Secondly, the trust that the EC places in its experts, and in EFSA's particular approach to HC regulation: providing scientific certainty to consumers by way of assigning most relevance to data from RCTs in the hierarchy of evidence (EFSA, 2017; 2021b). However, bestowing such relevance onto RCTs in this context is in itself a methodological decision that is based on particular epistemic suppositions: namely, that in nutrition –as a general rule– it is feasible to generate useful RCT data on causal relationships between intake and outcome, and that such data (and the certainty that come with them) are indispensable for regulating health claims (Todt & Luján, 2017).

In sum, EFSA's decisions on scientific standards and preferred methodologies *naturally* flow from EFSA's interpretation of the principal aim of HC regulation as protecting food markets and consumers from erroneous health claims (Todt & Luján, 2021). However, while EFSA presents its approach based on the 'best science' as obvious and self-evident, this interpretation is not unanimously shared within the relevant scientific community. In fact, there is a controversy in the nutrition sciences about which scientific methods are most appropriate for assessing the health and nutritional benefits of food.[17] The European regulatory process does, however, not show any sign of recognition of the existence of this controversy, as well as its possible implications for choices of regulatory aims and scientific methods.

We can conclude that not only are the new governance's objectives of public scrutiny and wider participation not reflected in the NHCR. Even more so, neither do the EC nor EFSA consider them necessary or advantageous in HC regulation, at least as long as the scientific assessments make use of the has been stablished as the highest possible scientific standards. The predominant idea is that it is the experts who guarantee the application of the best science; thus, questioning of the experts does not carry any regulatory or social advantage. This stance is, of course, coherent with the current lack of non-expert participation or stakeholder dialogue during the assessments: any non-expert participation is useless if scientific certainty is the 'best', and only, way of protecting the market and consumers from false claims (the objective of highest social concern). This of course does nothing but reinforce the consideration of consumers and applicants as mere passive receptors of absolutely reliable information on health outcomes. In other words, the NHCR's successful

[16] See again the above-cited answer from the Directorate-General for Health and Consumers.

[17] The debate revolves around the wholesale transfer of the RCT methodology (clinical trials) from assessing pharmaceuticals to health claim assessment, without allowing for crucial differences between the two scientific fields given the differences between their objects of attention. Part of the community of nutrition scientists questions the notion that RCTs are undoubtedly the most appropriate ('best') scientific method for generating regulation-relevant data. They point to several limitations of RCTs, which –while not relevant in clinical trials in pharmacology– do have an impact on nutrition RCTs: a) in nutrition, RCTs in practice cannot effectively study long-term (lasting years or decades), multiple, as well as subtle nutrient effects; b) they do not easily allow for controlling background diets, the latter of which can be relevant for nutrient uptake; and c) designing control groups for nutrition RCTs can be very difficult or even impossible because subjects cannot be deprived of essential nutrients (Blumberg et al., 2010). See also: Biesalski et al. (2011), Gregori & Gafare (2012).

practical application, as measured by its *own* standards, is not dependent upon any of the features of the participatory turn; even more, incorporation of any such features would be considered counterproductive.

The new EU transparency regulation does not change this situation: as already stated, this regulation does nothing to further the objectives of the new governance approach, namely, being transparent in terms of making public any alternative views on science and technology regulations, possible alternative outcomes, the varying uses of expert knowledge in regulation or the mentioned nutrition scientists' and industries' controversial opinions.

In the following, we will see that, in other jurisdictions, authorities have found approaches to HC regulation that differ in fundamental ways from the European approach. Those alternative regulatory approaches are based, of course, on alternative assumptions. Assumptions that, under the 'new governance', should be the subject of public and stakeholder debate.

4.2.2. Aspects of HC governance subject to debate, and some consequences for stakeholders

The previous discussion has shown that in EU regulatory practice consumer interests other than not being misled, like informed choice or usefulness of health claims for improving consumer health (explicitly mentioned in the NHCR), are subordinated to the primary aim of minimizing false positives (as are other NHCR objectives, like fostering innovation in the European food market). Giving more relevance to these alternative objectives would have a direct impact on how to treat false positives and false negatives, which particular scientific methodologies to require for generating decision-relevant data, or how to rank scientific methods according to their relevance for data generation (see footnote 17). One important point for our discussion is that the underlying assumptions are none other than implicit or explicit *choices* made by the regulatory and assessment authorities. Some of such choices, in principle, are open to public and stakeholder debate and engagement, because they are not based on scientific facts, or not alone, but rather grounded in social, political and epistemic preferences. Even more so because these possible choices have direct effects on relevant regulatory outcomes. For instance, making obtainment of regulatory approval more difficult, as EU Regulation does, result in fewer approved claims reaching the market (and will tend to depress industry funding for health claim-related food innovation) (Khedkar, Bröring & Ciliberti, 2017; Sanz Merino, 2022).

In sum, it is uncertain or false information (false health claims) that the European regulatory process is designed to weed out, on the basis of the regulators' unquestionable preference for the 'best possible science' (establishing causal relationships between intake and outcome), as well as expert assessment. Therefore, as a result of the epistemic and social assumptions and decisions made in EU regulation, European consumers are being protected against fraud and error, but they also have both less choice of food products with approved health claims, as well as fewer options for participation in food governance. In practice, EU consumers of foods with health claims have one type of (binary) choice only: to buy or not to buy. They do not have, for instance, the possibility of assessing for themselves what 'level of certainty' (or lack thereof) they are comfortable with in order to proceed with the decision to purchase a food identified by a health claim.

An alternative regulatory approach with less stringent evidence requirements would lead to more health claims obtaining authorization, thus increasing consumer information and choice. In order to better understand such alternative regulatory outcomes, we will contrast EFSA's current regulatory choices with the choices made by HC regulators in other relevant jurisdictions. We will consider here the cases of the United States and of Japan.

In the U.S., for instance, health claims can obtain authorization on the basis of varying evidence requirements (FDA, 2003; 2009/2018). One important difference, as compared to the EU, is that in the U.S. claims may be authorized as 'Qualified Health Claims' on the basis of not (yet) fully confirmed but still credible scientific information (Domínguez-Díaz, Fernández-Ruiz & Cámara, 2020; Sanz Merino, 2022). Foods with qualified claims come with one of four possible levels of scientific backing, identified on the food item's label (FDA, 2009/2018). Overall, U.S. health claim regulation is more tolerant towards false positives, which is the inevitable trade-off for aiming at maximizing the number of approved, reasonably substantiated claims. U.S. consumers, as compared to EU consumers, have more choice but less certainty as to the quality (reliability) of each individual claim. In part, consumers assess for themselves the level of available evidence, in order to decide what 'level of certainty' (or lack thereof) they are comfortable with in order to proceed with the decision to purchase a food identified by a health claim. Therefore, consumers assume the responsibility for judging if the advertised level of scientific substantiation is good enough for them in order to trust the claim, or not.

Another important example of a different approach to health claim regulation is provided by the Japanese approach (Iwatani & Yamamoto, 2019) which currently is mostly based on industry self-regulation (Kamioka et al., 2019). Apart from foods with fully-fledged Health Claims, as well as Qualified Health Claims, with assessment criteria similar to the U.S., there is a category called 'Foods with Function Claims'. This type of health claim (that only exists in Japan) is subject to a notification system only. Companies submit information on food safety, efficacy and possible risks to the regulatory agency prior to proceeding with commercialization. All those steps are 'under food business operators' own responsibility' (CAA, 2015). The system has led to a certain liberalization of the regulatory environment, resulting in an important increase in health claims (of this latter kind) on the market (Iwatani & Yamamoto, 2019).

Therefore, as these examples of alternative approaches to health claim regulation show, it is the regulatory authorities' choices in interpreting the requirements set by regulation that drives the overall regulatory approach, as well as the final (non-epistemic) outcomes (Sanz Merino, 2021, 2022). In other words, health claims can be (and are) regulated (and even assessed) in a wide variety of manners and the decision as to which of the alternatives to prefer is a fundamental regulatory *choice*, non-scientific one. (See Table 1)

	EUROPEAN UNION	UNITED STATES	JAPAN
Regulations currently in force	*Regulation on Nutrition and Health Claims Made on Foods (2006); EU Regulation on the transparency and sustainability of the EU risk assessment in the food chain (2019)*	*Nutrition Labeling and Education Act (1990); Food and Drug Administration Modernization Act (1997); FDA Consumer Health Information for Better Nutrition Initiative (2003).*	*Nutrition Improving Law (1991); Amendment of Nutrition Improving Law (2005); Food with Function Claims System (2015)*
Explicit objectives of the regulations	To protect consumers from erroneous information. To promote food innovation.	To protect consumers and promote informed choice. To promote food innovation. To safeguard the *Fourth Amendment* (to facilitate the system) and the *First Amendment* (freedom of information).	To protect consumers, and promote informed choice and food innovation. To simplify the application and approval processes.
Regulatory Assumptions	False positives are bad for the market and for society	The acceptance of false positives maximizes information and consumer options	The acceptance of false positives maximizes production and consumer options
Basis of regulators' decision making	Trust only EFSA assessors. Listen to other opinions.	Trust governmental assessors and other experts. Trust and empower citizens.	Trust governmental assessors. Trust and empower citizens. Trust and empower food operators.
Assumptions underlying Assessment	Causal relationships (RCTs) embody highest standards	Highest standard (RCTs) / Weight of evidence	Highest standard (RCTs plus mechanistic studies) / Weight of evidence (including reviews)
Implementation of Assessment	Methodological Monism	Methodological Pluralism	Pluralism / No assessment

Table 1. Differences between objectives, assumptions and implementation of the current EU, US and Japanese Health Claim Regulations and Assessments.
Source: authors' own work

Considering the participatory turn's objectives, it would be reasonable to expect that regulators, vis-a-vis consumers, stakeholders and the public, could make of this regulation a more socially robust one in such senses as much as possible. It seemed viable in this case, since the unveiled regulatory assumptions and options are typical subjects of public scrutiny and decision-making according to the (still valid) EU's 'new governance' approach.

5. Conclusion

Our socio-epistemological analysis of the European (EU) regulatory process for health claims (HC), in light of the various elements of a 'new European governance' that we selected above (more transparency, increased

public scrutiny, less hierarchical structures, participation in decision making), shows very little influence of those objectives on the HC regulation's original design nor in its current operationalization.

Under the EU system of separating risk assessors from risk managers, the European Commission and EU Member States (as final decision makers) assume full responsibility for the health claims placed on (or excluded from) the market. But in regulatory practice, it is EFSA's expert committee that takes those decisions, given that the EC simply adopts the experts' criteria without further questioning. Furthermore, EFSA presents its interpretation of the 'best science' as obvious and not subject to debate, while there is indeed a scientific controversy about what is considered the best possible evidence in nutrition. Besides, since those decisions are considered to be based on 'certain [implying unquestionable] scientific knowledge', other stakeholders, like the consumers (whom the regulation is mainly aimed at), are left with little choice or participation beyond deciding to purchase or not one of the (relatively few) foods with authorized claims on the EU market. Therefore, we can interpret the European regulatory process for health claims as the result of a number of regulatory *choices* (even though certainly reasonable and defensible ones), which have direct consequences for the outcomes of the regulation (e.g. for consumers and industry, or even for public health) and which have not undergone any public scrutiny or debate.

However, the European regulation is different from health claim regulation in other highly important markets: the U.S. one, in which consumers have (albeit very limited) opportunity for information and making choices, and the Japanese one, in which the responsibility for substantiation is mostly in the hands of the food industry. Both the U.S. and Japanese regulations show that there do exist alternative (even though varying) approaches to regulating health claims, which seem less 'technocratic' and which, in any case, imply different outcomes.

Our overall conclusion is that the EU health claim regulation follows a top-down, expert-based model. This can be considered internally coherent, in theory and practice. However, as such, it is externally incoherent with the general aspirations that the EC have explicit in its proposal of a 'new governance' (more participatory) approach to science and technology regulation at the beginning of this century and that has been updated in some current EU initiatives (e.g. within the Best Regulation agenda). Rather, it can be considered a fairly standard science for policy approach, because it makes involvement of other stakeholders very difficult or impossible in practice given the above-mentioned epistemic and social assumptions and decisions made by the regulators and experts in charge.

According to our analysis, aspects like transparency, public scrutiny, debate and participation would have to be improved within the HC regulatory process. In particular, it seems that these participatory features can be increased with respect to alternative HC regulatory approaches, as well as possible unintended outcomes of the regulation's implementation. There would furthermore be a need for enabling less top-down mechanisms for public debate in relation to issues like, for example, the level of confidence that may be acceptable to consumers when purchasing foods identified by health claims, the availability on the market of larger numbers of foods with officially authorized claims, or the publicly available amount of officially sanctioned information.

However, in current practice, there is no possibility for stakeholders or the general public to contribute to any of these issues. Even more, many of these aspects could never be achieved with respect to HC regulation in Europe while some of the seen epistemic and non-epistemic assumptions would be still underlying it.

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