Health claim regulation for public health: individual choice or libertarian paternalism?

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ABSTRACT

We present an interpretation of the debate that is currently ongoing in the field of health claim regulation with respect to public health and standards of proof. Health claims are scientifically validated statements regarding the health benefits that a food may confer upon its consumers. We argue that the methodological debates in health claim regulation conceal a very different debate, related to the locus of decision making: individual consumers or (at least partially) regulators. Our analysis reveals two opposing stances: one which on our interpretation is compatible with libertarian paternalism, and the other focused on individual choice on the basis of "sound science".

KEYWORDS: S*cientific substantiation, evidence requirements, health claims, libertarian paternalism.*

I. Introduction

In this paper we want to present an interpretation of the debate that is currently ongoing in the field of health claim regulation with respect to the implications which alternative regulatory approaches have for public health, consumer choice, and standards of proof. We will show that there are several, apparently only loosely related aspects of this controversy that on our interpretation can be reduced to a single issue: where does the locus of decision making related to consumption of foods with health claims ultimately lie? In other words, who will take the decisions: the individual consumer, on the basis of information provided by the regulators that is considered to be certain beyond any reasonable doubt? Or the regulatory authorities, who would decide which level of standard of proof (certainty) is appropriate in each case, taking into account the non-epistemic effects of their decision on the entire population, particularly for public health?

This issue reveals a tension between two conflicting objectives in the regulation of health claims: on the one hand, the improvement of health of individual consumers, and, on the other, the improvement of public health. The principal issue is this: is it more important for each individual consumer to efficiently and effectively improve their health, even if that means that collectively no important effect will ensue (meaning no relevant improvement in public health)? Or, alternatively, is it preferable to privilege the improvement of public health, even though this means that a few consumers, at least on certain occasions, will be misled, waste money and not improve their health?

Health claims are statements that can be found on food labels, and which indicate benefits for health that a particular food might confer upon its consumers. Benefits in this context do not refer to the standard nutritional benefits of a food or ingredient, but rather to additional effects that improve human health. An example is a food whose consumption contributes to preventing (or lowering the likelihood of developing) cardiovascular disease. Health claims could constitute an important tool for improving public health, given that the aggregate effects of many consumers

choosing to consume foods identified by such claims could help to combat widespread societal health problems, like diabetes or overweight.

Given that health claims confer an additional commercial value on a labeled food item, they are usually subject to regulation. We will focus here on the European regulation. In the European Union (EU), health claims are regulated by a common regulatory framework [European Parliament and Council (2006)]. In order to be displayed on a food product, such claims must have previously been authorized on the basis of scientific assessments as to their efficacy. These assessments are conducted by the relevant European regulator, the European Food Safety Authority (EFSA). EFSA evaluates the scientific data presented by applicants from the food industry, in order to decide if a proposed claim warrants regulatory approval or not [EFSA (2016), EFSA (2017)].

As we will show, European regulators aim at establishing causality between intake of a particular food and the desired positive outcome for health, in order to proceed with authorization of a proposed health claim. This requirement for causality, which implies the use of randomized controlled trials (RCTs, clinical trials) for the generation of the data used as input for decision making, is at the heart of the controversies that have ensued [Luján and Todt (2020)]. Critics of EFSA's current regulatory approach argue that the establishment of causal relationships is too demanding a standard, while RCTs are not necessarily appropriate for generating scientific data on health claims. This controversy, as we will see, has important implications for public health.

In this paper we will first offer an analysis of some of the counterpoised arguments involved in the debates about EU health claim regulation. In the discussion, we will assess the implications that those (primarily regulatory and methodological) debates have for individual consumer choice, as well as for public health. We will recur to the concept of libertarian paternalism to understand possible justifications for alternative ways of regulating health claims. On our analysis, there are two opposing stances: one the one hand, a stance which on our interpretation is compatible with libertarian paternalism; and on the other, a stance focused on

individual choice on the basis of "sound science" (and which –from the point of view of the regulators– could be interpreted as a more passive type of paternalism).

II. Debates about health claims, and their effects on public health

There are several debates related to health claims and their regulation that, as we will show, are interrelated. We focus our analysis on the particular controversy that has arisen in Europe between, on the one hand, the European regulator (EFSA) and, on the other, part of the relevant scientific community (mostly scientists in the field of nutrition sciences) [Blumberg *et al.* (2010), Todt and Luján (2017b)].

In the following we present some of the principal counterpoints between EU regulators and their critics, which underlie most of the methodological and regulatory debates.

Fundamental to the entire controversy are conflicting views about the need for minimizing different kinds of statistical errors [Todt and Luján (2017a)]. The European regulators aim at reducing false positives, while their critics argue for the need for minimizing false negatives. Seen from this particular vantage point, this debate can be understood as a fairly standard regulatory controversy [Reiss (2015)].

In the case of EFSA, the declared aim is to ensure that consumers will be provided with information that is as certain as scientifically and technically possible. In other words, the aim is to make sure consumers are not misled by erroneous or false health claims [European Parliament and Council (2006)]. Reducing false positives, i.e., minimizing the likelihood of ineffective claims receiving regulatory approval, serves this aim. The limiting factor for this approach is that it is scientifically and technically difficult to establish, with a high degree of certainty, the effectiveness of most health claims (see below), leading to fewer claims obtaining authorization. In fact, in the EU there are proportionally a lot fewer authorized health claims on the market than in, for instance, Japan (the place where health claims originated) or the United States [Verhagen and van Loveren (2016)].

In contrast, EFSA's critics argue that it is more important to provide consumers with a wide choice of authorized claims, in order to increase consumption of foods identified by health claims, and ultimately, multiply the aggregate benefits for public health [Richardson (2012)]. The problem with EFSA's approach, from the critics' point of view, is that it results in few claims reaching the market for consumers to choose from, implying fewer, if any, positive aggregate effects for public health. That is why they argue for an alternative approach: trying to minimize the number of effective claims that are denied regulatory authorization due to lack of data establishing their effectiveness, i.e., reducing false negatives [Heaney (2008)]. This, however, automatically implies an increase in false positives (which the critics accept as an inevitable corollary).

Under this alternative approach to health claim regulation, there would be more approved claims available than today, but their level of reliability would be somewhat lower than under EFSA's current approach. The critics' central argument is that, overall, public health is better served by somewhat lowering the evidence requirements, as compared to EFSA's approach, because of the concomitant boost to consumption, which increases population-level effects. This argument obviously applies to the *average* consumer only. Due to the unavoidable increase in false positives, any *particular* consumer could be misled or deceived at any time in two different ways: 1) by wasting money on a product that does not provide the claimed additional benefits, and 2) by relying on a product that does not provide the individual benefits that the consumer is counting on, be those benefits specific desired health improvements (like maintaining correct blood pressure), or long-term maintenance of overall health (as in keeping a chronic disease under control).

Tightly related to this debate about the minimization of statistical error is the controversy about the level of proof that is required for proceeding with authorization of a particular health claim. In order to fulfill their objective of only authorizing claims whose efficacy has been proven "beyond any reasonable doubt", EFSA regulators require the establishment of causality between intake of a particular ingredient or food (to which the claim under study applies), and the desired outcome

(positive effect for health) [EFSA (2016), EFSA (2017)]. From a methodological point of view, the only scientific methodology available for establishing causality (at least of a statistical kind) is the randomized controlled trial (RCT, clinical study). EFSA in regulatory practice therefore requires data from RCTs that show the efficacy of the claim on the basis of a causal relationship. Without the establishment of causality the claim does not obtain authorization [EFSA (2016)]. The only exception that EFSA contemplates are claims on ingredients that are considered essential for the functioning of the human body, and for which EFSA accepts that RCTs are very difficult, if not impossible to design and execute [Valtueña Martínez and Siani (2017)].

What this means is that EFSA considers data from other scientific methodologies (particularly epidemiological and mechanistic studies), even if of high study quality, as insufficient for authorization of a health claim [EFSA (2017)]. Absent in Europe the possibility of qualified claims (tentative authorizations of claims based on incomplete but promising data, Boer and Bast (2015)), the only way of obtaining authorization is to establish causality by way of an RCT.

However, as EFSA's critics point out, for a number of reasons RCTs are much more difficult to apply to foods than to pharmaceuticals (the latter of which constitute the baseline for practically all RCTs, due to the central role that clinical trials play in pharmaceutical testing) [Blumberg *et al.* (2010), Richardson (2012)]. Among the most relevant differences between foods and pharmaceuticals are: a) the multifunctional nature and functional complexity of nutrients; b) the difficulties in designing control groups for nutrition RCTs, due to the impossibility of depriving subjects of nutrients; c) problems in correctly carrying out nutrition RCTs, for instance, when controlling subjects' background diet; and d) the long-term and usually very subtle effects of nutrients.

Another important controversy concerns the question if regulation-relevant data should always be generated by the "best possible" scientific methodologies, or if individual study quality (with independence of the particular method used for generating the data) is more important. EFSA considers that different scientific

methods inherently provide a certain level of proof, meaning that recurring to the (in principle) best method (RCTs) will always deliver the best data. Therefore, the European regulators have devised a hierarchy of methods [European Commission (2008)] in order to assess the data presented by applicants from the food industry who desire authorization of a health claim. This hierarchy places human intervention studies (particularly RCTs) at the top, while assigning observational and mechanistic studies to lower categories, implying that the latter inherently provide data of less quality and relevance [EFSA (2017)]. The critics tend to reject the idea of particular scientific methodologies providing data of a particular "inherent level of quality", without fully taking into account individual study quality [Richardson (2012)]. In other words, they argue that an epidemiological or mechanistic study of very high study quality (well designed, executed and analyzed) should be given priority in regulatory decisions, as compared to a RCT of dubious quality (or which is inherently limited by the problems related to nutrition RCTs identified above). The critics also reject EFSA's (2017) point that epidemiological (or mechanistic) studies could never establish causality between intake and outcome, pointing to the possible causal interpretation of very high quality observational data [Howick, Glasziou and Aronson (2009)].

Another tightly related debate concerns plausibility. From the point of view of the kind of proof provided, it is well known [Cartwright (2010), Hill (1965)] that an RCT can only show that a particular (statistical) relationship between intake and outcome exists. An RCT cannot explain *why* this relationship holds (even if it can establish the existence of this relationship with a very high degree of reliability, at least in cases of well designed and executed clinical trials). For EFSA this point is mostly irrelevant, given that high quality RCT data will simply establish if a particular ingredient is efficient or not [Valtueña Martínez and Siani (2017)]. Which is the only issue that on the regulators' interpretation counts for an individual consumer who wants to improve his or her health.

The critics, though, argue that the "why" or "how" question is relevant [Heaney (2008)]. And that regulatory decisions should take into account plausible explanations

of why a particular relationship between intake and outcome exists in the first place. They argue that the "black box" of an RCT (establishment of causality without explaining why) is insufficient. This point is directly related to the controversy about single ingredients. EFSA (2016) limits regulatory authorization to claims on single, individualized and well-characterized ingredients or foods which produce a single, well-characterized outcome (like copper). In contrast, it rejects health claims related to multiple effects, complex interactions, etc., particularly because the latter cannot easily be captured by RCTs. This requirement has led to the rejection of health claims on, e.g., honey [Boer, Vos and Bast (2014)].

The critics consider that it is precisely those complex, long-term and multiple positive outcomes which potentially constitute the main contribution of health claims to public health. Because in order to fight chronic diseases, prevent complex illnesses like cancer, or contribute to long-term (meaning, spanning decades) and sustained maintenance and improvement of bodily functions, most of the contributions of foods with health claims will come from such complex effects [Gregori and Gafare (2012)]. RCTs, in practice, do not allow for the analysis of such effects, as we have seen above. In contrast, mechanistic studies (which address the how or why questions) and epidemiological studies do. On this view, in order to provide consumers with claims on foods with multiple endpoints, arising from complex interactions (particularly with the entire food matrix), RCT data will necessarily have to be complemented by data from non-RCT sources [Richardson (2012)].

III. NON-EPISTEMIC AIMS, AND DECISION MAKING

The debates that we have identified above raise questions as to how the regulators ought to proceed:

- Is it appropriate for regulators to systematically privilege data from the "best scientific methodologies", while minimizing the role of expert appraisal of each individual case and its specific circumstances? In other words, to issue authorizations

only for claims whose efficacy has been shown from RCT data by establishment of a causal relationship between intake and outcome, even if that makes obtainment of authorization much more difficult?

• Or, alternatively, is it legitimate for regulators to take into account likely or desired population-level effects in their choices of scientific methodologies for generating decision-relevant data, as well as in the decisions to authorize claims? And is this minimization of false negatives appropriate, even if it means that a (possibly small but certainly not irrelevant) percentage of all approved claims will be ineffective?

The opposition of those two stances has a direct implication for the consumer of products identified by authorized health claims [Luján and Todt (2018)].

In the first case, all foods with authorized claims would be (almost, i.e., within the epistemic limits of the RCT methodology) certain to provide the claimed effects. Regulators would have reduced the percentage of false positives as much as scientifically and technically possible. Consumers could be sure not to be misled, and to spend their money on products that are guaranteed to provide the advertised health benefits. And it would be entirely up to each consumer to choose among the various foods with authorized claims, or to choose not to consume any of them. Any collective, i.e. public health, effects would result from the sum of all those individual decisions, but without any intent on the part of the regulatory authorities to further such outcomes. In other words, any population-level effects would always be a (welcome but never sought-for) side-effect, or a “secondary impact”.

Regulatory intervention in this case would be limited to allowing on the market only those claims about whose efficacy there is practically no doubt. The latter would be established from data on causal relationships (in practice, RCT data), while excluding other types of data (even if the quality of individual studies, for instance, mechanistic studies, were high). Authorizations could proceed in semi-automatic fashion: as long as statistical causality between intake and outcome has in effect been established, the claim can be authorized (if it fulfills further criteria that apply to all claims, like being well characterized, etc.).

In the second case, there would be more products with authorized claims on the market, even though the reliability of any individual claims would be less than in the first case. Regulators would not limit the decision-relevant data to data from RCTs only. Rather, they would consider data from all kinds of sources (epidemiological studies, mechanistic analysis, etc.), as long as the quality of each individual study was judged to be sufficient. In this case, the overarching aim of the regulators, as we have already seen, would be to minimize false negatives. From a public health perspective, the regulators' ultimate aim would be to give consumers more choice, i.e., make available the largest number of approved claims possible, as long as there were reasonable indications as to their efficacy (but, crucially, without requiring causality).

From the perspective of decision making, the main difference is that in this second case regulators' choices are (at least partially) influenced by *non-epistemic aims*. We could interpret this as an explicit "non-epistemic intervention" during the regulatory process: regulators rely on case-by-case expert judgment for authorizing claims, according to varying data sets (different methods, different sources, etc.) on the basis of the perceived quality of individual studies, with the (non-epistemic) aim of increasing the number of approved and reasonably effective claims at the disposal of the consumer. The regulators' overall aim is to increase consumer uptake of health claims, based on the supposition that wider choice increases consumption (without undermining trust), due to: a) a wider choice of types of foods with claims on the market to appeal to more people; b) an increase in competition that leads to lower prices; as well as c) a higher number of claimed positive health effects, which again widens the appeals for consumers [Guthrie, Mancino and Lin (2015)].

IV. Sound science vs libertarian paternalism

We could interpret EFSA's current approach to health claim regulation, at least as far as population-level (public health) effects are concerned, as a rather passive approach. It contrasts with a more active approach, as defended by EFSA's critics, in

which decisions for authorization are explicitly influenced, on a case-by-case basis, by the aim of minimizing false negatives. This latter, more interventionist stance echoes debates from risk assessment about the need for regulators to take into account the non-epistemic effects of their methodological choices [Cranor (2017), Shrader-Frechette (2004), Wandall (2004)].

How could each of those two stances be justified? In the case of EFSA's regulatory approach, its justification –on our interpretation– is a classical, very straight-forward defense of a "sound science approach": whenever decisions are based on the best scientific data obtained from the best methodologies, then such decisions can be considered as objectively validated, and do not need any further justification. Consumers, driven by their personal, individual interests, will consume foods with claims in order to maximize advantages for themselves (improving their personal health, while spending as little money as possible, and without being misled). The implication that, given the more limited supply of foods with claims, population level effects are likely to be small does not have any importance for regulators.

The second case, from a philosophical point of view, is more complex. Here, after all, there is an argument for a regulatory intervention that in the end means bringing harm (from an economic point of view, at least) to a certain number of individual consumers, in order to obtain population-level benefits. How could such a stance be justified? One possible defense, among others, for such an approach might come from the concept of libertarian paternalism [Thaler and Sunstein (2003)]. Its central argument flows from the cognitive limitations of human beings (cognitive biases, computational limitations, use of heuristics, etc.). Libertarian paternalism argues that individuals' rationality is limited due to such cognitive limitations, implying that many of their decisions might not be in their own best interest. Sunstein and Thaler (2003) conclude that there are situations under which paternalism is justified, as long as it is aimed at fostering the well-being of individuals. In other words, as long as policy makers' decisions matched the kind of decisions that individuals would take if they were not bound by their cognitive limitations.

Libertarian paternalism argues that, under the above-mentioned conditions, intervention by public authorities aimed at inducing changes in individuals' preferences are justified, in part, because such preferences usually are not stable, and even may depend simply on the way in which the pertinent information is presented. Thus, following Thaler and Sunstein (2009), trying to alter consumer preferences in order to improve individuals' well-being could be justified as long as individual consumers retain the capacity, if they wished so, to act against the course of action promoted by the public authorities.

We can illustrate the idea of libertarian paternalism with an example taken from the authors themselves [Thaler and Sunstein (2003)]. Imagine a typical self-service cafeteria in which people line up and pass in front of a series of food counters, shelves or stalls, from which they select food items which they then place on their tray, before continuing to the check-out. The different food options that people can choose from could be arranged in a number of varying ways. One possibility is to physically arrange, and present items in such a way as to try to nudge people to prefer, among all the food on offer, the healthier options. This could be achieved by placing, for example, the healthy options on more easily accessible shelves and clearly in view of people who are standing in line at the cafeteria (similar to well-known examples of arranging items in supermarket shelves in order to promote particular products). Less healthy options, on the other hand, could be placed in such a way that they are less easy to find.

This would be a fairly easy manner of trying to influence consumer behavior, without recourse to more heavy-handed intervention, like for instance changes in pricing. In fact, Sunstein and Thaler consider that nudging consumers to prefer certain choices should mostly exclude changes in economic incentives. Rather, what makes people prefer certain choices is what the authors call the "choice architecture" [Thaler and Sunstein (2009)] of the situation.

This is a crucial aspect of the authors' idea: in one way or the other, there always will be a number of previous decisions on rules, method and standards that will create a framework (a "choice architecture") of the situation or process that interests us. In

our example, that is the arrangement of the food in the cafeteria. The important point is that there *always* will be such a framework. There is no way of operating a cafeteria without making choices on placement and presentation of the food items on offer. Sunstein and Thaler argue that given that this framework, product of all the prior decisions, will always be present and therefore will *always* influence peoples' choices, the best way to go about this is to create a choice architecture which tries to enhance peoples' well-being. In our cafeteria, since food has to placed and presented anyways, why not do so in such a way as to try to influence customers to choose the healthier options?

The example shows how outcomes (here, people tending to consume more or less health cafeteria food) could be influenced by the prior selection of certain rules (standards, methods, etc.). In this case, those are rules on how to arrange the different food choices. Many consumers will likely choose their food among the healthier options, simply because these are more easily accessible or visible. Those consumers who, to the contrary, would prefer any of the less healthy options can still do so. They just might have to make a little extra effort in searching out those alternatives. In this sense, a conscious selection of standards, rules and methods could nudge consumers into directions which are "good for them", while at the same time tending to increase the well-being of the population at large (due to the adding up of individual benefits gained by the majority of consumers), without imposing certain choices by way of obligations, taxes, etc.

In our second regulatory alternative to health claim regulation, the one argued for by EFSA's critics, Thaler and Sunstein's conditions are met. Lowering the evidence requirements for approving claims implies a likely increase in the consumption of foods with claims, automatically multiplying population-level effects; in other words, improving the health of the "average consumer". But, at the same time, coercion is absent: any individual consumer retains the option of deciding not to consume any of the foods identified by health claims. In sum, libertarian paternalism could justify this second, more interventionist regulatory approach

because, despite harming a few individual consumers in a limited number of instances, it aims at improving the overall health of all consumers.

A libertarian paternalist approach to health claim regulation implies that public authorities –even if in a fairly subtle way– aim at conditioning consumers' preferences in order to change their behavior for the benefit of public health, by offering them more choice (more foods with approved claims). EFSA's current "sound science approach" to regulation, at least from the standpoint of the regulators, could also be interpreted as a kind of paternalism: a "passive paternalism" focused on the individual consumer who wants to improve his or her health. Under this latter approach, consumers obtain guarantees from the public authorities that their choices are protected against deceit: foods with approved claims are certified to be effective.

In sum, while EFSA's current decision making in claim authorization can be defended on the basis of sound science, our discussion of libertarian paternalism shows that the alternative stance could also be justified. While we do not intend to argue here for any of the two stances, our analysis shows that both are defensible. The crucial question is if giving consumers a wider choice of foods with authorized (even though somewhat less reliable) health claims has a relevant impact on consumption or not, i.e., if it results in an improvement of public health or not. Sunstein and Thaler (2003) argue that regulators should, among the alternatives, always opt for the one regulatory approach which is better at improving general well-being, in this case, public health. Currently, however, there are no data that would allow to decide which of the two alternatives of health claim regulation is preferable in practice.

V. CONCLUSIONS

On our interpretation, the debates related to health claim regulation in Europe, at least as far as their effects on public health and the consumer are concerned, can be understood as debates about where the locus for decision making ultimately lies:

1) exclusively with the individual consumer. Here the regulators do not take account of any population-level effects. Rather, they limit themselves to providing individual consumers with information about the efficacy of claims that can be considered "scientifically proven beyond reasonable doubt", while at the same time limiting authorization of claims precisely to those "proven" ones; even if that means that only a few claims obtain authorization [Verhagen and van Loveren (2016)]; or alternatively

2) partially with the regulators who prepare the terrain for consumers to act in a way that is most likely to maximize the expected positive population-level effects (improvement of public health), due to the consumption of products with health claims (even if that means that a certain, albeit low percentage of consumers will be misled).

In the first case, the locus of decision making lies exclusively with the individual consumer. From the vantage point of individual consumers this is highly advantageous, because if they decide to purchase and consume a food with an authorized health claim, they can be (almost 100%) sure that the claim is effective; in other words, that they won't waste money, and that they will obtain the desired health benefit from the food in question. The individual consumer here obtains the advantages of "scientifically proven" authorized claims for her or himself, even though he or she pays a price in that the number of claims to choose from is limited (meaning limited opportunities for improving their health by eating foods officially approved as beneficial for health). But since consumers can trust those claims that are available, their level of overall trust in health claims and their regulation is likely to be high.

In the second case, the locus of decision making can be understood to be divided between the regulators and the final consumer. The regulators do take into account the population-level effects during the regulatory process, and consequently apply less stringent evidence requirements for authorization in order to increase the number of approved claims on the market. The relevant authorization criterion is that there are sufficient scientific data to indicate that the claim is most likely effective, even

though causality between intake and outcome has not (or, even worse, cannot) be established. The decision to consume foods with claims still lies with individual consumers, but given the highly increased consumption (as compared to case 1), the aggregate effects are much more important.

Under this latter scenario the "average consumer" of health claims will most likely gain (as compared to the first scenario), despite some individual consumers being misled: a certain number of individual consumer will at some point purchase and consume a product whose (authorized) claim is ineffective, thereby wasting their money, and (unknowingly) not improving their health (if we suppose that consumers trust all authorized claims). And this would of course happen with full knowledge and participation of the regulators, in the name of the "greater good" of maximizing the aggregate, population-level health effects.

The fact that consumers cannot always rely on approved claims might, in the long run, dent trust in health claims and their regulation. It has to be pointed out, however, that due to the lower percentage of false negatives under this second scenario there are (potentially many) consumers who will consume foods with authorized *effective* claims which under the first scenario would never have obtained authorization (because of it being impossible to establish causality as a result of the complexity, long-term action, and/or subtlety of the effect). So, on balance, under this second scenario, not only is there a likely advantage for public health, but also for many (but –crucially– not all) consumers.

The possibility, however, that lower evidence requirements could lead to different, conceivably even contradictory outcomes (on the one hand, a possible denting of trust resulting in less consumption, on the other, more effective claims on the market resulting in increased consumption) shows the crucial importance of expert intervention. The decisions on which of the regulatory strategies to pursue will need to be informed by expert knowledge, as well as empirical information on actual regulatory outcomes, precisely because it implies trade-offs and involves causal pathways which might produce opposing effects. In this second approach, there certainly is no semi-automated decision-making as in EFSA's current approach.

In sum, the methodological and regulatory debates in health claim regulation may conceal a very different debate, related to the locus of decision making. Recognizing this underlying and implicit debate may help to resolve the methodological and regulatory debates. Because it shows that the choice of scientific methodology for generating regulation-relevant data may not be as simple as selecting "the one best scientific method available". Rather, it may necessitate (expert-based) decisions on balancing the quality of the data on the basis of which health claims are authorized, and the ultimate effects for society at large (in this case, public health).

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