teorema
Vol. XL/1, 2021, pp. 199-213
ISNN 0210-1602
[BIBLID 0210-1602 (2021) 40:1; pp. 199-213

Health Claim Regulation and Public Health: Individual Choice or Libertarian Paternalism?

Oliver Todt and José Luis Luján

RESUMEN

En este trabajo presentamos una interpretación de las controversias actuales relacionadas con la regulación de las declaraciones de salud. Estas son afirmaciones validadas científicamente respecto de los efectos positivos sobre la salud humana de un determinado alimento. Nuestro análisis identifica un debate subyacente a dichas controversias (incluidas las metodológicas) y que está relacionado con quién debe ser el actor más relevante en las decisiones: los consumidores o (por lo menos parcialmente) los reguladores. Interpretamos este debate como una contraposición entre una postura coherente con el paternalismo libertario y otra con la elección individual basada en la "buena ciencia".

PALABRAS CLAVE: *sustanciación científica, requisitos evidenciales, declaraciones de salud, paternalismo libertario.*

ABSTRACT

We present an interpretation of the current debate 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 who takes the decisions about consumption of foods with health claims: 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 analyze the debate in the field of health claim regulation about alternative regulatory approaches, as well as their implications for public health, consumer choice and standards of proof. We show that there are several aspects to this controversy that on our interpretation

can be reduced to a single issue: who takes the decisions about the consumption of foods with health claims, exclusively the consumer, or partially the regulators? In the first case, it is individual consumers who take the decisions, while regulators limit themselves to providing consumers with scientific information which is considered certain beyond any reasonable doubt. In the second case, regulators intervene in consumer decisions, by appropriately adjusting the standards of proof, with the aim of boosting consumption of foods with health claims to the benefit of public health.

Health claims are statements (usually found on food labels) which indicate health benefits that a particular food or ingredient might confer upon its consumers. These benefits are not the standard nutritional benefits associated with a food, but rather any additional beneficial effects that enhance human health. An example is a food or ingredient whose consumption contributes to preventing (or lowering the likelihood of being affected by) cardiovascular disease. Health claims potentially are an important tool for improving public health, given that the aggregate effects of a significant percentage of the population choosing to consume foods identified by such claims could help combat widespread societal health problems, like diabetes or overweight.

Given that health claims confer an additional commercial value on a food item, they are usually subject to regulation. In this paper we focus on the European regulation for health claims. In the European Union (EU), health claims are regulated by a common regulatory framework [European Parliament and Council (2006)]. All such claims must obtain premarketing authorization on the basis of a scientific assessment which establishes their efficacy. These assessments are carried out by the European food 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)].

For authorizing a proposed health claim European regulators require the establishment of a causal relationship between intake of the food in question and the desired positive health outcome. The requirement for causality, which implies the use of randomized controlled trials (RCTs, clinical trials) for generating the decision-relevant data, is at the heart of the controversy that has ensued [Luján and Todt (2020)]. Critics of EFSA's current regulatory approach argue that the establishment of causal relationships is too demanding a standard in nutrition, and that RCTs are not necessarily appropriate for generating scientific data on health claims.

This controversy, as we will see, has important implications for public health.

Our analysis reveals a tension in health claim regulation between two conflicting objectives, which cannot be easily reconciled: on the one hand, improvement of the individual consumer's health, and, on the other, improvement of public health. In the first case, regulators assist individual consumers in efficiently and effectively enhancing their health, even though this means that collectively no or only moderate effects ensue (no significant improvement in public health). In the second case, regulators – in privileging the improvement of public health – sanction that a few consumers of foods with health claims, at least on certain occasions, are misled, waste money and do not improve their health.

In this paper we first offer an analysis of the debates about EU health claim regulation. We then assess the implications of these (primarily regulatory and methodological) debates for individual consumer choice, as well as for public health. We recur to the concept of libertarian paternalism in order to analyze potential justifications for alternative approaches to health claim regulation. On our interpretation, there are two opposing stances: one the one hand, a stance which is compatible with libertarian paternalism; and on the other, a stance focused on individual choice on the basis of "sound science".

II. Debating Health Claims and Public Health

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

EFSA and its critics disagree on several important issues, the latter of which underlie the entire methodological and regulatory controversy. Fundamental to the debate are conflicting views about the minimization of different types of statistical error [Todt and Luján (2017a)]. The European regulators aim at reducing false positives, while their critics argue for the need for minimizing false negatives. This debate about statistical error is a fairly standard regulatory controversy [Reiss (2015)].

EFSA's declared aim is to ensure that consumers are provided with information that is as certain as scientifically and technically possible. In

other words, the aim is to protect consumers from erroneous or false health claims [European Parliament and Council (2006)]. EFSA attempts to achieve this by reducing false positives, i.e., minimizing the likelihood of ineffective claims receiving regulatory approval. This approach is nevertheless constrained by the fact that it is scientifically and technically difficult to establish, with a high degree of certainty, the effectiveness of many health claims (see below). As a result, EFSA approves relatively few claims. Thus, in the EU there are proportionally fewer authorized health claims on the market than in, for instance, Japan (where the concept of health claims originated) or the United States [Verhagen and van Loveren (2016)].

In contrast, EFSA's critics argue that it is fundamental to provide consumers with a wide selection of authorized claims, not only to increase consumption of foods with health claims, but also to achieve aggregate benefits for public health [Richardson (2012)]. According to the critics, EFSA's regulatory approach results in few positive effects for public health. This is why they argue for an alternative approach, based on a reduction in false negatives. The latter is a minimization of the number of effective claims that are denied regulatory authorization due to a lack of data establishing their effectiveness [Heaney (2008)]. This approach, 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 on the European market than today. Their reliability, however, would likely be somewhat lower than under EFSA's current approach. The critics' principal argument is that, overall, public health is better served by lowering the evidence requirements, as compared to EFSA's approach, because of the concomitant boost to consumption, which augments desirable 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 in at least two different ways: 1) by wasting money on a food product that does not deliver the claimed benefits, and 2) by relying on a food that does not provide the health benefits that the consumer is counting on (e.g., desired health improvements, like a reduction in blood pressure, or long-term maintenance of overall health, as in keeping a chronic disease under control).

Tightly related to the debate about the minimization of alternative statistical errors is the controversy about the level of proof required for authorizing health claims. Due to their objective of only authorizing

claims whose efficacy has been proven "beyond any reasonable doubt", EFSA regulators require the establishment of a causal relationship between intake of a particular ingredient or food (to which the claim under study applies) and the desired outcome (positive health effect) [EFSA (2016), EFSA (2017)]. From a methodological point of view, the only scientific methodology available for establishing (statistical) causality is the randomized controlled trial. In regulatory practice EFSA therefore requires data from RCTs that show the efficacy of a health claim. Without establishment of causality the claim does not obtain authorization [EFSA (2016)]. The only exception to this rule are claims on ingredients that are considered essential for the functioning of the human body. EFSA recognizes that in this case there are serious difficulties in designing and executing meaningful RCTs [Valtueña Martínez and Siani (2017)].

EFSA regards data from other, non-RCT 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 alternative of qualified health claims (tentative authorizations of claims based on incomplete but promising data [Boer and Bast (2015)]), the only way of obtaining authorization is by establishing causality on the basis of RCT data.

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 pharmaceuticals testing) [Blumberg *et al.* (2010), Richardson (2012)]. The most significant differences between foods and pharmaceuticals are: a) the multifunctional nature, as well as functional complexity of nutrients; b) the difficulties in designing control groups for nutrition RCTs, due to the impossibility of depriving subjects of nutrients; c) challenges in correctly carrying out nutrition RCTs, for instance, when controlling subjects' background diet; and d) the long-term and usually very subtle nature of nutrient effects.

A related controversy concerns the tension between the type of scientific method employed, and individual study quality. Which is more important, the quality of each particular study (with independence of the methodology used for data generation), or always recurring to the "most capable" scientific methods? EFSA considers that each type of scientific method inherently provides a certain level of proof; thus, the (in principle) best method, i.e., RCTs, always delivers the best data. Accordingly, 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 pursue 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 provide data of inherently less quality and relevance [EFSA (2017)]. The critics question the assumption that particular scientific methodologies, with independence of individual study quality, provide data of a certain "inherent level of quality" [Richardson (2012)]. To the contrary, they argue that in regulatory decisions an epidemiological or mechanistic study of very high study quality (well designed, executed and analyzed) should be given priority over an RCT of dubious quality (or which is constrained by the inherent limitations of nutrition RCTs). The critics also reject EFSA's (2017) argument that epidemiological (or mechanistic) studies do not allow for establishing causality between intake and outcome, pointing to the possibility for causal interpretation of very high-quality observational data [Howick, Glasziou and Aronson (2009)].

Another tightly related debate concerns plausibility. An RCT shows that a particular (statistical) relationship between intake and outcome exists [Cartwright (2010), Hill (1965)]. It does, however, not explain *why* this relationship holds (even if it establishes the relationship with a very high degree of reliability, at least in the case of well-designed and executed clinical trials). For EFSA plausibility is mostly irrelevant; what matters is establishing if a particular ingredient is efficient or not [Valtueña Martínez and Siani (2017)]. The latter is, on the regulators' interpretation, the key issue for a consumer who wants to improve his or her health.

EFSA's critics, though, argue that the "why" or "how" question is relevant [Heaney (2008)]. And that regulatory decisions should take into account plausible explanations as to why a particular relationship between intake and outcome holds. They argue that it does not suffice to simply consider the RCT a "black box", which establishes causal relationships without explaining why. This point is directly related to the controversy about single ingredients. EFSA (2016) limits regulatory authorization to claims on single and well-characterized foods or ingredients (like copper) that produce a single and well-characterized outcome. In contrast, it rejects health claims related to multiple effects and complex interactions, because the latter cannot easily be studied with an RCT. EFSA's requirement has led to the rejection of health claims on, for instance, honey [Boer, Vos and Bast (2014)].

The critics, however, consider that what matters most for public health are precisely these complex, long-term and multiple positive ef-

fects derived from foods with health claims. Such complex effects could help in fighting chronic diseases, preventing illnesses like cancer, as well as contributing to long-term (spanning decades) and sustained maintenance of bodily functions [Gregori and Gafare (2012)]. As we have seen above, RCTs are in practice unsuited for studying complex effects. The latter can, however, be analyzed by mechanistic and epidemiological studies (which address the how or why questions). This is why EFSA's critics argue that in order to provide consumers with claims on foods with multiple positive endpoints, 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 analyzed in the previous section allow us to identify two alternative regulatory approaches:

- Under the first (EFSA's) approach, regulators limit authorizations to claims for which a causal relationship between intake and outcome has been established by an RCT, even if this makes obtaining an authorization much more difficult. Regulators privilege data from the "best scientific methodologies", while minimizing the role of expert appraisal of the specific circumstances of each individual case.
- Under the second (the critic's) approach, regulators take into account likely or desired population-level effects in their choice of scientific methodology for generating decision-relevant data, as well as in their decisions on authorization. Their principal aim is the minimization of false negatives, even if this implies that a (possibly small but certainly not irrelevant) percentage of approved claims will be ineffective.

The tension between these two regulatory approaches has direct implications for the consumer of foods identified by authorized health claims [Luján and Todt (2018)]. Let us consider each approach in turn.

Under the first approach, all foods that carry an authorized claim are (within the epistemic limits of the RCT methodology) guaranteed to provide the claimed positive health effects. Regulators have minimized the percentage of false positives as much as scientifically and technically feasible. Consumers can be confident not to be misled, and to obtain the

advertised benefits. It is up to each individual consumer to choose among the various foods with authorized claims, or to choose not to consume any of them. Positive collective (public health) effects, if any, are the result of the sum of all those individual consumer decisions. The regulatory authorities, though, do not actively further such aggregate outcomes. In other words, population-level effects are a (welcome but never sought-for) side-effect, or a "secondary impact".

Regulatory intervention in this case is limited to authorizing claims only if there is practically no doubt as to their efficacy. Decision-relevant data are restricted to data on causal relationships (in practice, RCT data). Other types of data, like mechanistic data (even from high-quality studies), are not considered decisive. Authorizations proceed in semi-automatic fashion: as long as statistical causality between intake and outcome has in effect been established, the claim obtains authorization (as long as it fulfills further criteria that apply to all claims, like being well characterized, etc.).

Under the second approach, there are more food products with authorized claims on the market, even though the reliability of any individual claim is lower than under the first approach. Regulators do not limit decision-relevant data to RCT data. Rather, they take into consideration data from all kinds of sources (including epidemiological and mechanistic studies), as long as individual studies are of sufficient quality. Under this second approach, the regulators' overarching aim, as we have already seen, is the minimization of false negatives. From a public health perspective, this aim consists in providing consumers with more choice, i.e., making available the largest number possible of approved, reasonably effective claims. The relevant criterion for authorizing a claim is the existence of sufficient indications as to its efficacy (but, crucially, without requiring the establishment of causal relationships).

The main difference between the two approaches is that in the second case regulators' choices are (at least partially) influenced by *non-epistemic aims*. Their principal non-epistemic aim under the second approach consists in increasing consumer uptake of approved health claims. We could interpret this as an explicit "non-epistemic intervention" in the regulatory process: regulators rely on case-by-case expert judgment in authorizing claims, according to varying data sets (different methods, multiple sources, etc.), on the basis of individual study quality. Underlying this approach is the assumption that more choice leads to increased consumption (without undermining trust), due to: a) a wider choice of foods with claims on the market, which appeal to more consumer; b) more

competition that leads to lower prices; as well as c) a higher number of claimed positive health effects, which boosts demand [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 rather passive. EFSA's critics, in contrast, argue for a more active approach, under 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 is reminiscent of 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 the two approaches be justified? On our interpretation, EFSA's regulatory approach can be justified by a very straightforward argument in favor of a "sound science approach": whenever decisions are based on the best scientific data obtained from the best scientific methodologies, such decisions ought to be considered as objectively validated, and do not require any further justification. Consumers, driven by their individual interests, will consume foods with health claims in order to maximize personal advantage (improving their health, while spending as little money as possible, and without being misled). That under this approach population-level effects are likely to be small, given the more limited supply of foods with claims, is considered irrelevant.

The second approach, from a philosophical point of view, is more complex. Here, after all, we are faced with an argument for a regulatory intervention that implies bringing harm (at least from an economic point of view) to a certain number of individual consumers, in order to obtain population-level benefits. How could such a stance be justified? The concept of libertarian paternalism [Thaler and Sunstein (2003)] provides a possible defense for this approach. Thaler and Sunstein's central argument flows from the cognitive limitations (cognitive biases, computational limitations, use of heuristics, etc.) that humans are subject to. Libertarian paternalism argues that individual rationality is constrained by these cognitive limitations, making people take decisions which are not necessarily 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 individuals' well-being by correcting for these cognitive limitations.

Libertarian paternalism argues that, under the conditions given above, intervention by public authorities aimed at inducing changes in individual preferences is justified, because such preferences usually are not stable, and may depend on the way in which the pertinent information is presented. Thus, following Thaler and Sunstein (2009), altering consumer preferences is acceptable under the condition that individual consumers retain the right to act, if they wished so, against the course of action promoted by the public authorities.

Let us illustrate the concept of libertarian paternalism with an example discussed by the authors themselves [Thaler and Sunstein (2003)]. Imagine a typical self-service cafeteria. Customers select food items at a series of food counters or stalls, before continuing to the check-out. The different food options for customers to choose from can be presented in a number of ways. One possibility is to display 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, for example, by placing the healthy food options where they are more easily accessible and clearly in view of customers (similar to well-known examples from supermarket shelves in which items are presented at eye height in order to promote products). To the contrary, less healthy options could be placed in less visible locations so that customers would have to actively search them out.

The cafeteria provides an example of trying to influence consumer behavior without recourse to more heavy-handed intervention, like changes to pricing. In fact, Sunstein and Thaler argue against comprehensive modifications in economic incentives. Rather, what makes people prefer certain choices is what the authors call the situations' "choice architecture" [Thaler and Sunstein (2009)].

The authors argue that in one way or another there always are prior decisions on rules, methods and standards that create a structure or framework (a "choice architecture") for the situation or process that interests us. In our cafeteria example, this is the placement of food items. The important point is that there *always* is such a framework. Running a cafeteria necessarily requires choices on placement and presentation of the food on offer. Sunstein and Thaler argue that given that this framework is always present and therefore *always* influences peoples' choices, the best solution is to consciously design a choice architecture which aims at enhancing individuals' well-being. In our example, this means

presenting food in such a way as to try to influence customers to choose the healthier options.

The example shows that outcomes (here, customers consuming more or less healthy cafeteria food) can be influenced by the prior selection of rules, standards or methods. In our case, rules on how to display the different food choices. Many customers are likely to choose their food among the healthier options, simply because they are more easily accessible or visible. Those customers who, to the contrary, 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 sum, a conscious selection of standards, rules and methods could nudge individuals to make choices which are "good for them", while at the same time enhance the well-being of the entire population (as individual benefits add up). This is achieved without imposing certain choices by way of obligations, taxes, or the like.

In our second approach to regulating health claims, the one argued for by EFSA's critics, Thaler and Sunstein's conditions are met. Lowering the evidence requirements for approving claims results in a likely increase in the consumption of foods with claims. This augments population-level effects. In other words, it implies an improvement in the "average consumer's" health. At the same time, coercion is absent: consumers retain the option of choosing not to consume any of the foods identified by health claims. Thus, 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.

Under a libertarian paternalist approach to health claim regulation, public authorities aim at subtly 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", at least from the regulators' standpoint, 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 EFSA's approach consumers obtain guarantees from the public authorities that their choices are protected against deceit, because foods with approved claims are certified to be effective.

In sum, while EFSA's current decision making approach can be defended on the basis of sound science, libertarian paternalism offers a justification for the alternative approach. We do not intend to argue here for any of the two approaches. Yet, our analysis shows that both are val-

id. The crucial question is this: does giving consumers a wider choice of foods with authorized (even though somewhat less reliable) health claims has a significant impact on consumption, i.e., does it lead to an improvement in public health? Sunstein and Thaler (2003) argue that regulators should always opt for the alternative that is better at improving general well-being, in this case, public health. Currently there is, however, no empirical evidence that would allow us to decide which of the two alternative approaches to health claim regulation is preferable in practice.

V. Conclusions

We interpret the debates related to European health claim regulation, as far as their effects on public health and the consumer are concerned, as debates about who takes the decisions about consumption of foods with claims:

1) Solely the 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 are considered "scientifically proven beyond reasonable doubt". At the same time, regulators restrict authorization to "proven" claims, even if this means that only a few claims obtain authorization [Verhagen and van Loveren (2016)].
2) Partially the regulators. Here the regulators set up a choice architecture that nudges consumers to act in a way that is most likely to maximize the expected positive population-level effects (improvement in public health) from the consumption of foods with health claims (even if this means that a certain, albeit low percentage of consumers will be misled).

In the first case, decisions are exclusively in the hands of the consumer. For an individual consumer who decides to consume a food with an authorized health claim, this has the advantage that he or she can be (almost 100%) sure that the claim is effective. In other words, under this approach consumers won't waste money, and will obtain the desired health benefits from the food in question. On the one hand, consumers obtain the advantages of "scientifically proven" authorized claims. On the other, they pay a price in that the number of foods with claims to choose from is limited (meaning fewer opportunities for improving their health). However,

since consumers can trust the available claims, their level of overall trust in health claims and their regulation is likely to be high.

In the second case, decisions are (implicitly) shared between the regulators and the final consumer. The regulators take into account population-level effects during the regulatory process. Consequently, they apply less stringent evidence requirements for authorization in order to increase the number of approved claims on the market. Claims obtain authorization if there are sufficient scientific data that allow to conclude that the claim is most likely effective, even though a causal relationship between intake and outcome has not been (or cannot be) established.

Under this second 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 consumers will purchase and consume products that despite their authorized claims are ineffective. These consumers will waste their money, and (unknowingly) not improve their health.

The fact that consumers cannot always rely on approved claims might, under this second scenario, dent trust in health claims and their regulation, at least in the long run. It has to be remembered, though, 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 the impossibility of establishing a causal relationship as a result of the complexity, long-term action, and/or subtlety of the effect). On balance, under this second scenario, not only is there a likely advantage for public health, but also for many (but – crucially – not all) individual consumers.

Lowering the evidence requirements could conceivably lead to contradictory outcomes: on the one hand, a possible denting of trust in health claims resulting in lower consumption, on the other, a wider selection of claims on the market leading to increased consumption. This shows the crucial importance of expert intervention. Decisions on which of the two regulatory approaches to pursue will need to be informed by expert knowledge, as well as empirical information on actual regulatory outcomes. This is inevitable because both approaches imply trade-offs.

In sum, the methodological and regulatory controversies in health claim regulation may conceal a very different debate, about who ought to be involved in decision making about consuming foods with health claims. This underlying debate 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, methodological choice requires (expert-based) decisions on balancing the quality of the data on the basis of which health claims are authorized, and the ultimate effects of regulation for all of society.

Department of Philosophy
University of the Balearic Islands (UIB)
Ed. Ramon Llull
Crta. de Valldemossa, km 7.5
07071 Palma, Spain
E-mails: Oliver.Todt@uib.es; JL.Lujan@uib.es

ACKNOWLEDGEMENTS

This work was supported by the European Commission's European Regional Development Fund (ERDF-FEDER)/ Spanish Ministry for Science and Innovation – State Research Agency (AEI) under Grant no. FFI2017-83543-P ('Estándares de prueba y elecciones metodológicas en la fundamentación científica de las declaraciones de salud').

REFERENCES

BLUMBERG, J., HEANEY, R., HUNCHAREK, M., SCHOLL, T., STAMPFER, M., VIETH, R., WEAVER, C., and ZEISEL, S. (2010), 'Evidence-based Criteria in the Nutritional Context'; *Nutrition Reviews*, vol. 68, pp. 478-484.

BOER, A. DE, VOS, E., and BAST, A. (2014), 'Implementation of the Nutrition and Health Claim Regulation – The Case of Antioxidants'; *Regulatory Toxicology and Pharmacology*, vol. 68, pp. 475-487.

BOER, A. DE, and BAST, A. (2015), 'International Legislation on Nutrition and Health Claims'; *Food Policy*, vol. 55, pp. 61-70.

CARTWRIGHT, N. (2010), 'What are Randomised Controlled Trials Good for?'; *Philosophical Studies*, vol. 147, pp. 59-70.

CRANOR, C. (2017), *Tragic Failures;* New York, Oxford University Press.

EUROPEAN COMMISSION (2008), 'Commission Regulation (EC) No 353/2008 of 18 April 2008 Establishing Implementation Rules for Applications for Authorization of Health Claims as Provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council', *Official Journal* L.109, pp. 11-16.

EFSA (2016), 'General Guidance for Stakeholders on Health Claim Applications'; *EFSA Journal* 14(1):4367, pp. 1-38.

— (2017), 'Scientific and Technical Guidance for the Preparation and Presentation of a Health Claim Application', *EFSA Journal* 15(1):4680, pp. 1-31.

EUROPEAN PARLIAMENT AND COUNCIL (2006), 'Regulation (EC) 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims Made on Foods'; *Official Journal of the European Union* L.404, pp. 9-25.

GREGORI, D., and GAFARE, C. (2012), 'Multifunctional Food: Medical Evidence and Methodological Notes on Substantiating Health Claims?'; *International Journal of Food Sciences and Nutrition*, vol. 63(S1), pp. 29-36.

GUTHRIE, J., MANCINO, L., and LIN, C. (2015), 'Nudging Consumers toward Better Food Choices: Policy Approaches to Changing Food Consumption Behaviors', *Psychology & Marketing*, vol. 32, pp. 501-511.

HEANEY, R. (2008), 'Nutrients, Endpoints, and the Problem of Proof'; *The Journal of Nutrition*, vol. 138, pp. 1591-1595.

HILL, A. (1965), 'The Environment and Disease: Association or Causation?'; *Proceedings of the Royal Society of Medicine*, vol. 58, pp. 295-300.

HOWICK, J., GLASZIOU, P., and ARONSON, J. (2009), 'The Evolution of Evidence Hierarchies: What can Bradford Hill's 'Guidelines for Causation' Contribute?'; *Journal of the Royal Society of Medicine*, vol. 102, pp. 186-194.

LUJÁN, J.L., and TODT, O. (2018), 'The Dilemmas of Science for Policy: Scientific Evidence and the Consequences of Regulatory Options in Risk and Benefit Assessment'; *EMBO Reports*, vol. 19, pp. 194-196.

— (2020), 'Standards of Evidence and Causality in Regulatory Science: Risk and Benefit Assessment'; *Studies in History and Philosophy of Science Part A*, vol. 80, pp. 82-89.

REISS, J. (2015), *Causation, Evidence, and Inference*; New York, Routledge.

RICHARDSON, D. (2012), 'Preparing Dossiers: Strength of the Evidence and Problems of Proof'; *Proceedings of the Nutrition Society*, vol. 71, pp. 127-140.

SHRADER-FRECHETTE, K. (2004), 'Using Metascience to Improve Dose-Response Curves in Biology: Better Policy Through Better Science'; *Philosophy of Science*, vol. 71, pp. 1026–1037.

SUNSTEIN, C., and THALER, R. (2003); 'Libertarian Paternalism is Not an Oxymoron', *University of Chicago Law Review*, vol. 70, pp. 1159-202.

THALER, R., and SUNSTEIN, C. (2003); 'Libertarian Paternalism', *The American Economic Review*, vol. 93, pp. 175-79.

— (2009), *Nudge: Improving Decisions About Health, Wealth and Happiness*; *2d edition*, New York, Penguin Books.

TODT, O., and LUJÁN, J.L. (2017a), 'The Role of Epistemic Policies in Regulatory Science: Scientific Substantiation of Health Claims in the European Union'; *Journal of Risk Research*, vol. 20, pp. 551-565.

— (2017b), 'Health Claims and Methodological Controversy in Nutrition Science'; *Risk Analysis*, vol. 37, pp. 958-968.

VALTUEÑA MARTÍNEZ, S., and SIANI, A. (2017), 'Health Claims Made on Food in the EU: The Edge Between Scientific Knowledge and Regulatory Requirements'; *Trends in Food Science & Technology*, vol. 69, pp. 315-323.

VERHAGEN, H., and VAN LOVEREN, H. (2016), 'Status of Nutrition and Health Claims in Europe by Mid-2015'; *Trends in Food Science & Technology*; vol. 56, pp. 39-45.

WANDALL, B. (2004), 'Values in Science and Risk Assessment'; *Toxicology Letters*, vol. 152, pp. 265-272.