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Substantial Equivalence

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Synonyms

Equivalence of GM and non-GM foods

Introduction

The expression "substantial equivalence" stands for a key concept introduced to evaluate the risks and the means of production and consumption of novel foods. In particular, the concept has famously been employed to evaluate the risks for human health of consuming genetically modified (GM) foods, that is, of genetically modified organisms raised for human consumption as well as foods that contain these organisms as ingredients (cfr. Andrée 2007; Gupta 2013; Shahin 2007). In a nutshell, that the GM food is substantially equivalent to its non-GM ("natural"; see entry on "▶ Metaphysics of Natural Food") counterpart is an important reason to regard the GM food as safe to be consumed.

For instance, if a variety of GM corn is substantially equivalent to the non-GM corn variety from which it was engineered, then the GM corn is likely to be considered as safe to be consumed as the non-GM counterpart. Derivatively, and more generally, the *doctrine of substantial equivalence* holds that, from the perspective of human health, GM foods are as safe to be consumed as their non-GM counterparts.

The doctrine has been endorsed by a number of agencies worldwide, starting with the United States Department of Agriculture and the United States Food and Drug Administration; other notable endorsements include the Canadian Food Inspection Agency, the Food and Agriculture Organization of the United Nations, the World Health Organization, and the Organization for Economic Co-operation and Development. Although the doctrine owes its name and makes reference to two eminently metaphysical concepts, namely, substance and identity, metaphysicians devoted little or no attention to the underpinnings of the doctrine.

The Doctrine of Substantial Equivalence

GM foods constitute a particularly interesting category of *novel foods*. Their novelty, indeed, stems from their different genetic makeup. As the modification of a genome takes place in a laboratory and is thus the product of human intellectual ability and artifice, the resulting novel organism is oftentimes awarded a patent, in recognition of its intellectual specificity. Questions arise, however, regarding the potential threats to human health of the novel food. For instance, it is unclear whether the novel genome will alter the production of the nutrients provided by the food, such as proteins, amino acids, or carbohydrates. It is also unclear whether the novel food will contain vitamins, minerals, potential toxicants (e.g., solanine in potatoes, erucic acid and glucosinolates in canola), and allergenic proteins. Thus, before introducing a novel food into a marketplace, competent food safety agencies need to assess the food's risks to human health. It is at this stage that the doctrine of substantial equivalence finds employment.

To regard a GM food as substantially equivalent to its counterpart, a number of properties of the novel food are examined. If the properties are found to be fundamentally identical to the corresponding properties of the non-GM counterpart, then the food is regarded as safe, from a nutritional point of view. The GM food and its non-GM counterpart are "equivalent," hence, because they are *identical in some key nutritional properties*. They are "substantially" equivalent, instead, because not all of the foods' properties are taken as relevant to justify the equivalence claim: only those properties that are fundamental from a nutritional point of view are salient to determine the matter.

Disagreement has risen among the international scientific community on which properties shall constitute the basis of comparison between a given GM food and its non-GM counterpart. Typically, the fact that the GM food and its non-GM counterpart have different genomes – fact that is crucial to award a patent to the inventor of the GM food – will be deemed as irrelevant from the point of view of human nutrition and health. Thus, in light of the doctrine of substantial equivalence, it is possible that a GM food is considered a novelty within a country's patent office, but standard within that country's food safety agency.

Upon presenting the doctrine, it is important to clarify its scope. Ascertaining the substantial equivalence of a GM food with respect to its non-GM counterpart is only one part of the process of evaluating whether and how to produce a GM organism and to introduce it in the marketplace. Following the EU regulations circa the production and marketing of GM organisms (see entry on "▶ EU Regulatory Conflicts over GM Food"; "▶ GMO Food Labeling"), we may divide up the evaluation of a GM organism in four categories.

Substantial equivalence contributes in different manners to the evaluation of a food in each of the four categories.

(i) *Biosafety*. Substantial equivalence pertains primarily to the assessment of the *biosafety* of the GM organism. In particular, it concerns the safety of consumers, as opposed to – for instance – the safety of biodiversity within an area of production. The appeal to substantial equivalence has thus served to argue that GM foods raise no distinct threat to human health because they do not deliver novel nutritional constituents to the organism.

(ii) *Labeling*. Substantial equivalence influences also the practices of food labeling. If a GM food is substantially equivalent to its

non-GM counterpart, from a nutritional standpoint there is no reason why the two sorts of foods should be distinctly labeled.

(iii) *Traceability*. The doctrine of substantial equivalence has arguably jeopardized the possibility of tracing the effects of GM foods on human health. Countries that have endorsed the doctrine, and where GM foods are not distinctly labeled, have rendered impossible for consumers to study whether the emergence of certain allergies (e.g., food allergies and intolerances) and diseases has been influenced by the consumption of GM foods.

(iv) *Freedom of choice*. By blurring the distinction between GM organisms and their non-GM counterparts, the doctrine of substantial equivalence has weakened the freedom of producers and consumers to choose what sort of product they wish to, respectively, eat or deliver to the market.

Substantial equivalence has an underlying role also in the 2003–2006 debate within the World Trade Organization on the measures that are necessary to protect human, animal, or plant life or health. The debate eventually led to the so-called SPS Agreement – the Agreement on the Application of the Sanitary and Phytosanitary Measures (see the entry on "▶ The 2003–2006 WTO GMO Dispute: Implications for the SPS Agreement"). If GM organisms are deemed as substantially equivalent to their non-GM counterparts, then countries that buy into the SPS Agreement have no reasons pertaining to the safety of human nutrition for impeding production of GM organisms or for distinctly labeling GM foods.

Empirical Evidence Against the Doctrine

The doctrine of substantial equivalence is of dubious scientific rigor. In their seminal 1999 article on the topic, Millstone, Brunner, and Mayer remarked that:

> The concept of substantial equivalence has never been properly defined; the degree of difference between a natural food and its GM alternative before its 'substance' ceases to be acceptably 'equivalent' is not defined anywhere, nor has an exact definition been agreed by legislators. It is exactly this vagueness which makes the concept useful to industry but unacceptable to the consumer. Moreover, the reliance by policymakers on the concept of substantial equivalence acts as a barrier to further research into the possible risks of eating GM foods. (Millstone et al. 1999a, p. 525; cfr. also Millstone et al. 1999b for a sequel)

After nearly 20 years, a good deal of empirical and theoretical evidence against substantial equivalence has been amassed. From a more practical point of view, a first criticism concerns the looseness of the concept of substantial equivalence. Little has been done to tighten it. Rather than being treated on a par with novel chemical compounds such as food additives, pesticides, and pharmaceuticals, GM foods were regarded as safe once a few basic data on their biochemical properties had been provided.

Specific data have recently been collated to show important nutritional differences between GM foods and their non-GM counterparts. In a study of the variation of nutritional values among three sorts of soybeans on the market – GM, non-GM conventionally farmed, and non-GM organically farmed – researchers were able to discriminate "all the individual soy samples . . . into their respective agricultural practice background" (Bøhn et al. 2014, p. 14). Other strategies for the analysis of transgenic foods suggest that, contrary to the prevalent view held so far, even from a nutritional standpoint, non-negligible differences exist between GM foods and their non-GM counterparts (cfr. Valdés et al. 2013). The equivalence, that is, was apparent in that the wrong cluster of properties had been selected. But, there is more to the story, which relates to broader theoretical presuppositions within the doctrine of substantial equivalence.

Theoretical Evidence Against the Doctrine

The doctrine of substantial equivalence employs, in an unorthodox fashion, a conceptual tool of Aristotelian descent – the theory of substance. In Aristotelian philosophy, the identity of a substance

is defined on the basis of some essential properties, which are selected among a larger cluster of properties, including both essential and accidental ones. Thus, for instance, a human is essentially a rational animal, while accidentally it may be tall or short, sitting or standing, and bold or hairy.

The doctrine of substantial equivalence, however, seems to adopt a double-standard approach to a given food that is questionable. In order for a food to count as both novel (at a patent office) and standard (at a food safety agency), one of the two following views has to be held. Either what is presented to the two offices is not the same entity or, if it's the same entity, one of the two agencies (or both) overlooks some of the food's essential properties. Call the first the *miracle view* (it multiplies entities), while the second the *deflationary view*. Both of them face considerable difficulties.

The deflationary view is suitable to those that take a deflationary attitude regarding governmental procedures of sorting and labeling. This is an attitude that weakens the ontological presumptions of such procedures. For instance, suppose a governmental agency registers a citizen as a Caucasian male. The deflationist will hold that such a classification says little with respect to the real racial profile and sexuality of the citizen. Analogously, suppose a food safety agency claims that a GM food is substantially equivalent to its non-GM counterpart. The deflationist will regard such a claim as saying little real with respect to what the food is. While "Caucasian male" and "substantially equivalent" may partially capture the real identity of a person or a food, their role is to serve a specific practical purpose for a government and its citizens.

The deflationary attitude has two significant drawbacks. First, it promotes a form of skepticism towards food labels. The skepticism runs against those who take food labels seriously. Second, in the debate over the palatability of the doctrine substantial equivalence, the deflationist leaves open a worrisome possibility: that the double standard applied by the patent office and the food safety agency is motivated by practical purposes, which run against the purposes of the citizens, who demand that the label be as close to describing the real food as possible.

The shortcomings of the miracle view, on the other hand, are more obvious: it is in striking contradiction with ordinary talk. The miracle view can be savaged only by suggesting that the judgments of the patent office is not on the *food*, but rather on a specific DNA sequence, while the judgment of the food safety agency pertains to the food and not to the DNA sequence. While such an analysis may be accurately describing extant practices, at once it points out the lack of a comprehensive and systematic treatment of regulations pertaining to GM foods (cfr. Andrée 2007).

The theoretical tenability of the doctrine of substantial equivalence has been criticized from another significant angle. The claim, in this case, is that the doctrine leaves no room for certain qualitative considerations of the food that are of importance to consumers. As Sylvie Pouteau writes in a classic paper:

> The misuse of equivalence points to the fact that food quality cannot be restricted to mere substance and that food acts on human beings not only at the level of nutrition but also through their relationship to environment and society. Besides chemical, toxicological, and immunological issues, ethical issues should also be addressed. Beyond substantial equivalence, "qualitative equivalence" and "ethical equivalence" are to be found as ethical counterparts. (Pouteau 2000, p. 276)

According to Pouteau, the doctrine of substantial equivalence should be replaced by a doctrine of *ethical equivalence* (cfr. Pouteau 2000, 2002; Madsen et al. 2002). What matters to citizens and consumers is that GM foods and their non-GM counterparts are equivalent from an ethical standpoint. Judgments of ethical equivalence will be based not solely on the biochemical properties of the foods, but on additional properties of the foods that are ethically relevant. Pouteau's position has been rounded off by studies that point out the importance of familiarity, risk, and method of production in assessing the equivalence of GM foods and their non-GM counterparts (cfr. Siipi and Launis 2009; Meghani 2009; Gupta 2013).

The suggestion, ultimately, is that governmental agencies should base their respective guidelines regarding the production and marketing of GM foods not simply upon some (disputable) biochemical properties of the foods, but also

upon relevant ethical properties. Through appropriate labeling requirements, consumers should be consented to make an informed choice about their diet: a choice that allows tracing back potential sources of allergies, intolerances, and diseases and a choice that reflects the consumer's ethical commitment to a tradition, to a system of production, and to a specific risk-taking conduct.

Summary

According to the doctrine of substantial equivalence, from the perspective of human health, GM foods are as safe to be consumed as their non-GM counterparts. While a number of governmental agencies and institutions worldwide have endorsed the doctrine, important criticisms have been raised against it. After rehearsing the key tenets of the doctrine, the entry surveys its major practical and theoretical shortcomings. From a practical point of view, not only is "substantial equivalence" loosely understood in national and international regulations, but some recent studies point out to some nutritional differences between GM foods and their non-GM counterparts too. The theoretical shortcomings of the doctrine, then, rest on its problematic use of some classic metaphysical concepts (i.e., substance and identity) as well as on its lack of consideration for ethical properties that are of importance to consumers, such as risk, familiarity, tradition, and method of production.

Cross-References

- EU Regulatory Conflicts over GM Food
- GMO Food Labeling
- Metaphysics of Natural Food
- The 2003–2006 WTO GMO Dispute: Implications for the SPS Agreement

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Sustainability and Animal Agriculture

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Synonyms

Animal production; Animal welfare; Environment; Food safety; Public health; Sustainability