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Monsanto and the Requirement for Real Risks in GM Food Regulation

By Ruby R. Fernandez

Consumer resistance to GM foods is fierce in Europe, and this is reflected in the laws regulating them.¹⁵ These regulations, for the most part, have eliminated trade in GM foods within the European Union (EU). From 1998 to 2003, no GM products were approved for sale within the EU.¹⁶ Indeed, the EU did not lift the 5-year moratorium on GM foods until after the United States, Canada, and Argentina commenced an action against it in the World Trade Organization.¹⁷ The perceived safety risks associated with GM foods have undermined their trade even as these concerns remain unfounded.¹⁸

The European Court of Justice's (ECJ) decision in the case of *Monsanto v. Presidenza del Consiglio dei Ministri*¹⁹ is significant because it illustrates a more constructive approach to GMO ("genetically modified organism"²⁰) trade than those advocated by people on opposite sides of the GMO debate. By holding that novel foods containing transgenic proteins may still be considered substantially equivalent to existing foods and emphasizing a risk assessment based on real, perceived risks instead of hypothetical risks,²¹ the Court strikes the proper balance between safety and trade concerns. The Court's decision will likely have wide-ranging implications on how novel foods will be regulated in the future. It is also likely that the decision's effects will expand to include all of GM foods, not just a subsection of it. With this decision, the Court signaled to Member States that it is prepared to overturn, if necessary, GM food regulations that are based on mere hypothetical risks to health.

Although the issues presented here apply to all organisms or products involving recombinant technology, this note will focus solely on GM foods. Part II discusses the relevant provisions of Directive 90/220 on the deliberate release of GMOs into the environment and Regulation 258/97 concerning novel foods and novel food ingredients ("Novel Foods Regulation"). Part III recounts the facts of *Monsanto*. Part IV begins with a discussion of the role of risk perception in foods and its effect on GM food regulation. It then analyzes the Court's decision, keeping in mind its impact on future GM food regulation, and how the Court's emphasis on real, perceived risks strikes the proper balance between safety and trade concerns.

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... A. *The Role of Risk Perception in Foods on GM Food Regulation*

As this article will show, GM food regulation is heavily influenced by how the public perceives risks in foods. In assessing risk, the key issue is to determine whether a product's attendant risks are judged to be acceptable.⁶⁰ Among many European consumers, the attendant risks of GM foods are simply unacceptable.⁶¹ However, this was not always the case. In 1996, Safeway and Sainsbury's, the United Kingdom's two largest supermarket chains, began selling tomato puree made from genetically engineered tomatoes.⁶² These modified tomatoes required less heat and concentration before canning, thus costing less to produce.⁶³ The clearly-labeled product flew off the shelves; by late 1997 Safeway's stores had sold 750,000 cans.⁶⁴ By July 1999, however, both Safeway and Sainsbury's had withdrawn the product, mainly because of pressure from consumer groups.⁶⁵ Public opposition against genetically engineered food became so fierce, not just in the UK but throughout Europe, that some politicians won elections by vowing to keep "Frankenfoods" at bay.⁶⁶ **Several factors contribute to the perception that the risks presented by GM foods are simply unacceptable. First, food is "high culture, if not religion" in Europe.**⁶⁷ Europeans tend to be more attached to national culinary traditions and are more likely to expect food products to be fresh and natural compared to their American counterparts.⁶⁸

...⁶⁷. Rosenthal, *supra* note 15. **One author, reflecting the views of pro-trade groups, suggests that the strong anti-GM stance in Europe is based on more than just "cultural preferences" and mistrust of food safety regulators but is instead simply based on classical trade economics. Lawrence A. Kogan, *Ducking the Truth about Europe's GMO Policy Trade Protectionism*, INT'L HERALD TRIBUNE, Nov. 27, 2004, available at http://www.iht.com/bin/print_ipub.php?file=/articles/2004/11/26/opinion/edkogan.html . See Lawrence A. Kogan, *Exporting Europe's Protectionism*, THE NATIONAL INTEREST, Oct. 1, 2004, 2004 WL 76694309, for an in-depth critique of EU's stringent GM regulations.**
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