

## REGULATORY SCIENCE

# Amid Europe's Food Fights, EFSA Keeps Its Eyes on the Evidence

Europe's food-safety watchdog, celebrating its 10th anniversary this month, wins praise for sticking to the science—even when Europeans prefer not to hear it

**PARMA, ITALY**—This small town of quiet squares and historic churches in northern Italy has long been associated with food; it is, after all, the home of the world-famous Parma ham and Parmigiano-Reggiano cheese, also known as Parmesan. But today, Parma plays another big role in Europe's kitchens: It hosts the European Food Safety Authority (EFSA), the agency charged with a wide variety of tasks, such as assessing the safety of genetically modified (GM) plants for 500 million Europeans, preventing *Salmonella* outbreaks, and deciding whether probiotic drinks really boost the immune system.

EFSA was founded in 2002 to help set food standards at the European level; earlier this month, 700 scientists attended its anniversary conference to help celebrate. But if European officials had hoped that Parma's calm atmosphere would rub off on EFSA, they were wrong. The agency has found itself at the center of some of the most ferocious food fights in Europe.

EFSA has angered environmental and consumer groups by ruling again and again that genetically modified organisms (GMOs) and artificial sweeteners pose no health risks—advice governments sometimes choose to ignore. It has come under fierce attack from advocacy groups and politicians for not being totally independent from industry—a charge that inquiries have found not entirely baseless. At the same time, EFSA has upset the food and supplement industry by pushing some of the most aggressive evidence-based policies in the world. Starting on 14 December, manufacturers will no longer be able to tout the health effects of thousands of their products on labels and in ads, because EFSA says they have not been proven.

Amid all of these pressures, “somehow they have managed to doggedly stick to the scientific data no matter what was happening,” says nutrition scientist Martijn Katan of Free University Amsterdam. “I think they have succeeded beyond everybody's wildest expectations.” “It can be slow going at times, but they have done very thorough, good science,” says Hans-Georg Joost, a pharmacologist at the German Institute of Human Nutrition in Potsdam.



**Home of the ham.** EFSA, headed by Catherine Geslain-Lanéelle (*inset*) since 2006, has its headquarters in Parma, Italy.

## Speak up, stand up, gang up

EFSA was established in the wake of several European food scandals in the 1990s that had rocked consumer confidence, including “mad cow disease,” or BSE. “We are a child of the BSE crisis,” says Catherine Geslain-Lanéelle, the French food-safety scientist who has headed EFSA since July 2006. E.U. leaders hoped to marshal the best scientists from across Europe to review food risks and present a strong scientific consensus to guide decision-making. “Before the BSE crisis, it was a hodgepodge of politics and science,” says Andreas Hensel, who heads the German Federal Institute for Risk Assessment. “No one was really responsible for the science on a European level.” EFSA has been a particular blessing for smaller member states that lack their own food-safety agency, he says.

But the science hasn't always won out. EFSA prepares scientific opinions for the European Commission, which then drafts decisions based on them, which are approved or rejected by the Standing Committee on

the Food Chain and Animal Health, consisting of representatives of the member states. The final decision thus rests with politicians, and their opinions vary widely. EFSA has so far approved every GMO that it has reviewed; in the Standing Committee, Luxembourg and Austria have voted against EFSA's opinion on GMOs every single time, whereas Sweden, Finland, the Czech Republic, and the Netherlands have never voted against them.

In a talk at the conference here, Anne Glover, chief scientific adviser to the European Commission, urged scientists to “speak up, stand up, and gang up” to defend the science behind EFSA's assessments. “If we do not communicate, it is as if we never did the science,” she told the audience. Countries can vote against GMOs for other reasons, Glover argued, but they cannot reject the evidence just because it's politically inconvenient.

The GMO issue flared up again in September, when a paper in *Food and Chemical Toxicology* concluded that a maize variety called NK603 and low levels of a herbicide could together cause tumors in rats. The study, by French biologist Gilles-Éric Séralini, was widely criticized by scientists for leaving out important information, using rats prone to spontaneous tumors, and looking at too few animals.

Séralini was already well-known at EFSA. In 2007, a panel at the agency looked into his claims that MON 863 maize, which EFSA had given a clean bill of health, was toxic to the liver and kidney in rats. Then, a panel roundly rejected Séralini's analysis, and this time, too, EFSA made short work of his paper. An initial assessment published on 4 October concluded that the study was “of insufficient scientific quality for safety assessments.” (An in-depth analysis was in preparation as *Science* went to press.)

EFSA critics seized on the report as a sign of double standards. Studies of similar quality had been accepted as evidence for the safety of GM food, they argued. But Elisabeth Waigmann, head of EFSA's GMO unit, says there is no comparison, as the studies on which risk assessments are based run hundreds of pages. Séralini's paper was missing too much information to be useful, she says: “We have asked Séralini for the full data, but so far we have not received anything.”

If anything, the issues will only get thornier. Most GM crops approved so far had only a single new trait, usually resis-

tance to a herbicide; in most cases, EFSA's risk analysis was based on comparing those GM crops with the non-GM version of the same variety. But GM plants now being developed often have more than one new gene. "The comparison could then lead to so many differences that need to be followed up individually, that it becomes a question whether this comparative approach is still practical," Waigmann says. EFSA will also have to review GM animals when they are ready—not just those intended for human consumption, but also GM mosquitoes set free to curb the spread of a disease. The agency is still drawing up guidelines for that task.

### Claims and conflicts

Conflicts about scientific evidence have also occurred with EFSA's biggest and most ambitious project so far. Starting next month, companies in the European Union will no longer be allowed to advertise food products with unsubstantiated promises about their effect on human health. Since 2008, EFSA panels have assessed thousands of such health claims, including cranberry juice supposedly reducing the risk of urinary tract infections and a type of chocolate that its producer says "helps children grow" (*Science*, 5 March 2010, p. 1189). Of more than 3000 claims, only some 200 were deemed sufficiently proven.

The food industry has protested vigorously. "EFSA's methodology is almost identical to that for assessing medicine. It is based on randomized controlled trials, and that is not feasible for food," says Patrick Coppens of the European Responsible Nutrition Alliance, an industry group. Such trials would be far too expensive, and the rules could stifle innovation, he warns.

Industry representatives have also pointed out that there is no clear consensus on what a health claim is. Some national authorities have hinted that they will no longer accept the term "probiotics" in marketing, for instance, because the term itself suggests a health benefit; other countries say it's just a product category. Some people have joked that German candy manufacturer Haribo may have to submit evidence to prove its slogan that "Haribo makes children happy!"

"Industry was surprised how much science was needed," says Juliane Kleiner, head of EFSA's nutrition unit. "But these are no outrageous criteria." Katan says the mass rejection of claims reflects the fact that the food industry has been unable to produce food that makes a real difference for health. By being so rigorous, EFSA has set a new standard, he



**Seeds of conflict.** Activists have taken aim at EFSA's assessments of GM crops.

says: "The FDA is doing an excellent job on the safety, but as to health claims, the world is now looking to Europe."

The process has produced new problems, however. For instance, the European Commission put EFSA's evaluation of botanical products on hold because it could lead to a paradox: Health claims of herbal foods could be dismissed on scientific grounds, but the same substances could still be sold as medicine because in many European countries, they can be marketed on so-called traditional



**Not convinced.** EFSA rejected supposed health benefits of rapeseed oil, cranberry juice, coffee, and chocolate, along with thousands of other claims.

use grounds with no need to prove efficacy. How this issue will be resolved is still unclear.

But EFSA's long-term credibility will depend not just on the rigor of its reviews, but also on the trust it enjoys from the European public—and on that front, it has fared less well. In February, a report by two campaign groups, Corporate Europe Observatory (CEO) and Earth Open Source, concluded that "[m]any EFSA panel members have ties with biotech, food, or pesticide companies." EFSA's rules allowed blatant conflicts of interest to persist, the groups said.

EFSA dismissed the report as biased and unfounded, but the criticism only increased in

May, when Diána Bánáti, chair of the management board of EFSA, had to resign effective immediately because she had accepted a position at the International Life Sciences Institute, a nonprofit science organization based in Washington, D.C., and funded among others by Coca-Cola, McDonald's, and Monsanto. Members of the European Parliament have pounded on the issue, and the Parliament temporarily deferred approval of EFSA's 2010 budget report to put pressure on the agency.

A long-delayed report by the European Court of Auditors, issued in October, showed that the accusations had some basis in fact. The report—which also looked at three other agencies—concluded that EFSA's management of conflict-of-interest situations was not adequate. It said there were either no clear criteria for assessing declarations of interest, or that they were not applied consistently.

EFSA responded that it had addressed several of the critical points in the meantime with a new independence policy adopted in December 2011—the review finished in October 2011—and that it had assessed 8000 declarations of interest in 2011 and excluded experts totally or partially from EFSA activities on 356 occasions. Nina Holland of CEO agrees that there have been some improvements, but several forms of conflict of interest are still allowed, she argues.

Geslain-Lanéelle says that dismissing everyone with any ties to industry would make it impossible to find good experts. If

someone has worked with industry, that person will not be allowed to work with EFSA on the same subject, she says. Moreover, decisions are made by panels that usually have 21 members. "Even if you had one or two experts with a conflict of interest, they would have to convince another 20 experts. And believe me, they are not easy to convince."

Still, Geslain-Lanéelle acknowledges that EFSA needs to work on building trust. But the fact that science is now center stage in the decision-making process in the E.U. is new, she says, and reason to celebrate. "Don't forget: We are only 10 years old."

—KAI KUPERSCHMIDT