

Although in theory the moratorium could be squashed by just a ten-vote shift, the situation is not at all easy to predict. The socialist government of Greece, for example, remains quite radical on the matter and public opinion there is still very hostile toward GMOs, according to George Sakellaris of the Institute of Biological Research at the National Hellenic Research Foundation (Athens). Austria is also unlikely to budge. "On 23 May 2002, the Parliament unanimously voted in support of maintaining the moratorium, also asking to evaluate the possibility to setting up GM-free regions in the country and for a clarification of the open juridical questions in the area of liability in case of unintended releases

of GMOs. From an Austrian understanding, labeling, traceability, and liability are inseparable and GM-free regions are seen as a possible solution for the contamination problem since 1997," says Helge Torgersen of the Institute of Technology Assessment at the Austrian Academy of Sciences (Vienna). Moreover, since October 2001, Belgium and Germany are reported to have joined the anti-GMO side, supporting the moratorium until traceability and labeling measures are in place. Germany is set to hold national elections on September 22 and its new government is likely to represent an important piece of the European political jigsaw.

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## USDA poised to reconsolidate biotech regulatory units

Officials at the US Department of Agriculture (USDA; Washington, DC) are poised to reconsolidate biotechnology-related regulatory activities and programs, bringing them more or less to where they were five years ago. However, amid lingering uncertainty over recent sweeping proposals from President George Bush (*Nat. Biotechnol.* 20, 643, 2002) that, at least initially, sought to move the entire Animal and Plant Health Inspection Services (APHIS) into the wholly new Department of Homeland Security, USDA officials refused in July to comment publicly on an otherwise tame, seemingly well-grounded set of administrative proposals for regulating biotechnology outlined in a widely circulated memorandum from APHIS administrator Bobby Acord.

In that mid-June memorandum, Acord notified APHIS staff that he was establishing a new entity, called the Biotechnology Regulatory Services (BRS), within this USDA agency. A major purpose of forming BRS, he explained, is "to consolidate the loose collection of biotechnology activities ... in APHIS ... [to] bring the necessary focus to regulatory capacity building, domestic and international policy coordination and development, risk assessments, permitting, and compliance." Acord also is planning to assign Cindy Smith, an associate deputy administrator for wildlife services within the USDA, to serve as the acting deputy administrator of BRS before a search for someone to fill that post begins.

Plans call for BRS, which will be funded as a distinct entity among other APHIS units and activities, to review not only biotechnology-derived plants but also transgenic animals including insects. However, the biotechnology unit will not have regulatory oversight of vet-

erinary biologics or certain environmental services, and also will not include those APHIS employees who spend part of their time monitoring biotechnology field trials.

This consolidation is intended to benefit "both producers and consumers," according to the Acord memo. Moreover, these administrative changes are expected to help USDA officials meet a broader and more fundamental goal insofar as biotechnology is concerned: "global adoption of policies that provide for the safe use of biotechnology, while at the same time encouraging the development, acceptance, and use of the technology and its products," he notes. The change thus goes beyond the purely administrative, reflecting "the need to focus on APHIS's key role in regulating and facilitating development of this technology."

The new BRS harks back to a similar entity within APHIS, known as the Biotechnology, Biologics, and Environmental Protection (BBEP) unit, which was formed about a decade ago. However, USDA officials dismantled BBEP in 1997, figuring that so many biotechnology-derived crops were entering mainstream agriculture that it was time to assign biotechnology-related regulatory products and related policy issues "to be handled as a part of the normal business of the regulatory and scientific staffs..." However, this dispersal of biotechnology-related regulatory programs and the expertise that developed around them seems to have been premature, impairing the ability of APHIS officials to "coordinate adequate responses to biotechnology issues and challenges," Acord notes.

Indeed, that move to disband BBEP several years ago "balkanized what had been a coherent effort, and was demoralizing to the staff,"

says Val Giddings, a vice president of the Biotechnology Industry Organization (BIO; Washington, DC) and former APHIS official.

In recognizing the importance of biotechnology to agriculture, USDA Secretary Ann Veneman, Acord, and other top department officials reviewed the situation earlier this year and realized that outsiders coming to the department with biotech products to be regulated (or with other biotech-related questions) "couldn't find biotechnology ... and figured that's not right," Giddings says. "So they appointed a task force to figure out how to organize their biotechnology capabilities to best meet the challenges, and devised this system." Consolidating such regulatory expertise in BRS could also improve efforts by USDA officials to coordinate biotechnology regulatory activities with other federal agencies having overlapping jurisdiction, such as the Environmental Protection Agency (Washington, DC).

Meanwhile, no one at the USDA is saying how these administrative changes within APHIS might be affected by the more sweeping proposals President Bush put forward as part of his plan for building a new Department of Homeland Security. Other proposed shifts (such as moving all the coast guard into a new department) are running into plenty of opposition from Congress, and similar opposition or criticisms of the measures affecting APHIS also could erupt sometime soon. Although Bush implied a wholesale transfer of APHIS into that new department, his homeland security advisor Tom Ridge subsequently indicated only parts of APHIS, such as those units responsible for border inspections of imported plants and animals, that might be moved into the proposed department while leaving other functions at the USDA.

"If they cut the baby in half, it will require some carefully crafted memorandums of understanding not to disrupt [routine] activities," BIO's Giddings says. One reason this separation of duties and activities promises to be "not so easy" from an administrative standpoint is that several regulatory activities, including border inspections of plants or animals that might require quarantining, are funded in part through user fees, he points out.

Regardless of which department eventually oversees those inspections, little else will change in terms of the quality and type of review that biotechnology researchers and companies will face, Giddings adds. "The only significant change will be in the color of hat that the inspectors might wear." In terms of genetically modified seeds or plantlets, researchers will still "need the same piece of paper and will face the same inspections."

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