

peaked. At last week's meeting in Kiev, Ukrainian health officials presented to experts and aid organizations a plan to vaccinate or complete the vaccination of the entire population of 52 million by the end of this year. Earlier this year, the other ex-Soviet republics approved an outbreak containment plan drawn up by WHO and UNICEF, involving rapid diagnosis and treatment of cases and their contacts, and mass vaccination campaigns.

But for most of these countries, the plan could be sunk by a desperate shortage of vaccine, particularly of the adult variety known as Td. There is also a dearth of antitoxin, a horse serum containing anti-*C. diphtheriae* antibodies that can prevent the cardiac and neural damage that kills between 3% and 10% of patients. The only production plants in the region are on Russian soil. Narkevich and Yashinsky say that because these plants can only supply Russia's own needs, the Russian government banned export of the vaccine and antitoxin after the breakup of the Soviet Union, leaving its neighbors to rely on international donors. Dittmann reckons that about 500 million doses of vaccine will be needed over the next 2 years at a cost of more than \$50 million and at least 200,000 vials of antitoxin costing about \$1 million—although prices are rising rapidly as world demand outstrips supply. Colette Roure, EPI

adviser to WHO's European office, says funds are desperately needed.*

Heading west. Before the lifting of the Iron Curtain, such an outbreak would almost certainly have been contained within the Soviet Union. No longer. A few cases have cropped up in close neighbors such as Poland, Finland, and Norway. Further west, Germany has reported six cases, and in the last few months two Russian-born American citizens returned home to give the United States its first taste of the Russian epidemic.

WHO's Galazka believes some industrialized countries may have the ingredients for an epidemic. Some have certainly let childhood immunization slip in recent years: In the United States, for example, only 44% of children were fully vaccinated in 1991–92, according to CDC estimates. More disturbing, says the CDC's Iain Hardy, is the large proportion of adults—between 30% and 60%, he reckons—whose immunity has fallen to low levels in many countries, including the United States, Canada, and Australia. In Europe, the proportion of unprotected adults ranges from as low as 20% in Finland and Denmark to 53% in Poland.

WHO has advised all European countries

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to ensure that at least 95% of children are immunized by 2 years of age and that they receive a booster on starting and another on leaving school. Most countries have begun implementing these measures, says Roure. States close to the Russian epidemic are taking special measures: Finland, for example, has already vaccinated 80% of its adult population, and Poland has immunized all adolescents aged 19 and all officials policing its eastern border.

In the United States, Hardy believes the risk of infection spreading from a few isolated cases "is real but not worrying: We have a fairly aggressive management approach to contact tracing, surveillance, diagnosis ... and rapid hospitalization of cases." But state public health authorities and physicians throughout the country "should be made more aware of this disease. Most American doctors have not seen a single case of diphtheria and could easily fail to diagnose it or could misdiagnose it."

Meanwhile, back in Russia, officials are understandably anxious to get the diphtheria epidemic out of the way so they can get on with the other problems of daily life, such as cholera, dysentery, tuberculosis, AIDS, and even malaria.

—John Maurice

John Maurice is a science writer in Challex, France.

BIOTECHNOLOGY

European Parliament Axes Patent Policy

After 6 years in the drafting, a European Union (EU) directive seeking to set common standards of patent protection for biotechnological inventions was thrown out last week by the European Parliament in Brussels. The directive would have set ground rules for the patentability of genes, cells, and other biological material derived from humans, animals, and plants. Its demise means that the biotech industry will have to stick with existing legislation—which was not designed to deal with the complex issues of living inventions—and build up precedents on a case-by-case basis. It could also result in a patchwork of different regulations in different European countries.

The ethics of patenting biological organisms has long been controversial in Europe, and the Directive on the Legal Protection of Biotechnological Inventions had a stormy ride through Europe's legislative corridors. Indeed, at one point last year, the Parliament and the Council of Ministers were so deeply divided over the text and subsequent amendments that a conciliation procedure established by the 1992 Maastricht Treaty had to be invoked for the first time. But even that wasn't enough: Unexpected opposition from many new members of the Euro-

pean Parliament (MEPs) elected last year killed the directive by 240 votes to 188, with 23 abstentions.

The vote was hailed as a victory by environmentalists and animal-rights groups, who opposed the basic premise of the directive,

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—Nick Scott-Ram

that life is patentable. But genetics researchers are disappointed. They fear that without guidelines specifically designed to address genetic engineering inventions, the existing practice of patent offices may give commercial companies too much control over genetic data, thereby restricting research. The biotech industry, surprisingly, isn't hitting the panic button: It feels that in its final form the directive was too ambiguous and would

have achieved few of its original aims.

The biotech industry provided the initial impetus for the directive. It wanted to ensure that European patent regulations were generally in line with those of the United States and Japan, which have tended to be less restrictive in deciding what kinds of living inventions can be patented. Currently, applications in Europe can be filed with a national patent office for protection in that country only, or with the European Patent Office (EPO) in Munich, Germany, for protection in the 17 countries that signed the 1973 European Patent Convention (EPC). Each nation has been treating biotech patents slightly differently, and the EPO has been interpreting the EPC on a case-by-case basis. If the directive had been passed, all EU member states would have had to write its provisions into their patent laws.

It took more than 5 years of negotiations before the European Parliament and the Council of Ministers agreed on a draft text in December 1993. This was modified in February 1994 to address the biotech community's concern that the directive would have been more restrictive than the EPC. Then last May, MEPs requested several amendments, one of which—aiming to clarify exactly the instances in which a human body part can be patented—required conciliation proceed-

ings that were only concluded on 23 January.

By the time the directive was put to the vote last week, however, a clutch of new MEPs were in place following elections last year. They hadn't been exposed to years of lobbying from the biotech industry, and homed in on issues that hadn't been sticking points in earlier drafts of the directive. In particular, some of the new parliamentarians opposed the directive because it would not have explicitly banned human germline gene therapy, which introduces permanent, inheritable traits into genes. And, in a surprise move, the European socialist group resolved to vote against the directive, one of their members saying that patents on living things would inhibit research in the field.

Biotech industrialists seem untroubled by the defeat. Ron James, managing director of PPL Therapeutics in Edinburgh, U.K., which has patent applications pending in the United States and Europe on transgenic sheep that produce drugs in their milk, believes the final directive would have been

little improvement on the EPC. "Clarity wouldn't have occurred. ... Many of the clauses were open to different interpretations." And industry leaders are now adopting a wait-and-see attitude. "We'll see what comes out of EPO case law, and I think industry's happy to abide by that," says Nick Scott-Ram, chair of the intellectual-property advisory committee of the U.K. Bio-Industry Association.

Biotech companies are encouraged because since they first began pushing for the directive, the EPO has granted one patent for a transgenic animal: Harvard University's "oncomouse." And Christian Gugerell, a director of the EPO, predicts further applications on transgenic animals "in the pipeline ... will be granted," including James' sheep, because they satisfy the necessary criteria of novelty, inventiveness, and utility.

Researchers are more worried. The directive made a clear distinction in the case of DNA between a "discovery," which is not patentable, and an "invention," which is.

Thus a strand of complementary DNA, for example, with no other defined use than "expected" applications such as a probe or primer, would have been declared unpatentable. Without the directive, that distinction remains untested. Cells, complete genes, or proteins would not have been patentable under the directive unless they were part of an invention—which corresponds to the situation that exists under the EPC.

Green Party MEPs and various lobby groups such as Greenpeace and animal-rights organizations will continue to try to stop the patenting of animals by challenging individual cases. The British Union for the Abolition of Vivisection, for example, is challenging the oncomouse patent in a case to be heard at the EPO in November. In the absence of the directive, the outcome of such cases will provide the basis for European biotech patent law.

—Claire O'Brien

Claire O'Brien is a science writer in Cambridge, U.K.

CANADIAN R&D

Science Budget Takes 15% Whack

TORONTO—The Canadian government last week unveiled a draconian budget that will slash research spending by roughly 15% in the next 3 years. The cuts—the first significant across-the-board reductions to Canadian science in more than a decade—are part of a campaign to shrink government and reduce a budget deficit that, in proportion to its economy, exceeds that of the United States. The government also made it clear that it will step up pressure on research agencies and institutions to show the economic value of the work they are funding.

"We will be putting government activities on a commercial basis wherever that is practical and productive," said Finance Minister Paul Martin last week in presenting the government's budget to the House of Commons. "In the future, our science and tech-

nology efforts will be concentrated more strategically on activities that foster innovation, rapid commercialization, and value-added production."

Approval of the government's budget for the 1995–96 fiscal year starting 1 April is a foregone conclusion, given the ruling Liberal Party's parliamentary majority. It will wipe out a scheduled 1.5% increase in the budgets of all three university granting councils—the Natural Sciences and Engineering Research Council, the Social Sciences and Humanities Research Council, and the Medical Research Council. Instead, they will see their funding drop by 12% to 13% over the next 3 years (see table).

Even harder hit is the Canadian Space Agency (CSA). Its base budget will drop by 15% in the next 3 years, with spending increasingly directed toward private-sector partnerships and joint ventures in Earth observation, space science, and technology. One third of the cut will come out of work on the sophisticated robotic arm that is Canada's main contribution to the international space station; the remainder will come from reductions in the agency's infrastructure. Daniel Goldin, head of the U.S.

National Aeronautics and Space Administration, told *Science* that CSA chief Mac Evans last week assured him the reductions should not affect Canada's participation in the space station effort.

The National Research Council (NRC), a network of government laboratories, will have to trim spending by 17% by 1997–98, including a \$30 million cut in the coming year. "I'm disappointed. We've certainly taken a hit," says NRC President Arthur Carty. "With limited resources you just can't afford to spread yourself too thin."

While the impact of the new budget on specific programs remains unclear, the cuts have focused attention on the way Canada funds science. Current total R&D expenditures of \$4.1 billion are spread across 18 departments, and a recent report by the auditor-general called the distribution "more incidental than the result of a well-formulated strategy." In response, the government launched a review of federal spending on science and technology that is expected to be finished in June, and Bill Milliken, a spokesperson for Industry Canada, says the exercise has benefited from the fact that "a shortage of funds tends to focus things."

As bad as the cuts are for science, the government's new budget is even worse news for other sectors. The \$116 billion budget includes spending cuts of \$9.2 billion over 2 years, as well as the elimination of 45,000 civil service jobs, about 15% of the government payroll.

—Douglas Powell

Douglas Powell is a graduate student at the University of Guelph.

RESEARCH CUTS IN SELECTED R&D AGENCIES (millions of Canadian dollars)

Organization	Current budget	Proposed for '97–98	% change
Canadian Space Agency	174*	148	–15%
Nat'l Research Council	449	372	–17%
Natural Sci. & Engin. Res. Coun.	494	428	–13%
Soc. Sci. & Humanities Res. Coun.	101	89	–12%
Medical Research Council	266	235	–12%
Agriculture Ministry	269	239	–11%

*Base programs; excludes Radarsat
One Canadian dollar = \$0.71 U.S.

SOURCE: CANADIAN GOVERNMENT MINISTRIES