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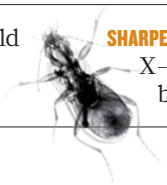

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A watchdog with bite

The world must strengthen the ability of the International Atomic Energy Agency to make independent assessments of nuclear safety.

In a recent press conference at the International Atomic Energy Agency (IAEA) in Vienna, a reporter asked a simple question. Chronicling the ongoing nuclear emergency at the Fukushima Daiichi nuclear power plant in Japan, the agency's website consistently referred to "white smoke" rising from the reactors. Why, the journalist asked, did the agency put quotations around the words white smoke?

Denis Flory, the agency's head of nuclear safety and security, said the term arose from lengthy discussions with Japan's nuclear regulator over how to translate the phrase "白い湯気のような煙" (*shiroi yuge noyouna kemuri*), the words used in official Japanese statements. "We got the answer that it meant 'white smoke', so this is why we use 'white smoke'," he said flatly.

Even by the strict standards of international organizations, the IAEA chooses its words carefully. As the globe's nuclear watchdog, it must simultaneously pronounce on a nation's nuclear programme while being careful not to accuse the country of wanting to develop weapons. Its statements are sometimes cryptic, but they are vital for upholding the delicate Nuclear Non-Proliferation Treaty, which is designed to halt the spread of nuclear weapons.

In the latest nuclear emergency in Japan, however, the IAEA's agonizing over its choice of words has not helped to allay public fears or clarify the situation at the reactors. As illustrated by its derivative use of the term 'white smoke', the agency has been reluctant to deviate even slightly from information delivered by the Japanese government. Its press conferences have been rapid-fire deliveries of temperatures, pressures and radiation readings handed to them by government sources, often with little context.

The agency has good reason to avoid annoying Japan, which is one of 35 members of the board of governors that oversees the IAEA and its budget. Because of the security role played by the organization, these nations have kept the IAEA on a short leash. In the area of nuclear safety, even the rating of a nuclear emergency is out of its hands: individual nations, not the IAEA, judge the severity of an accident.

Nuclear accidents are politically and commercially sensitive events, and it is understandable that countries do not want to cede control of their management to an international body. And nor should they: plant operators are often the best qualified to handle an emergency, and nations must take the responsibility for protecting their citizens.

Yet these nations, and the public at large, would be better served by an IAEA more able to deliver frank and independent assessments of nuclear crises as they unfold. In the aftermath of Fukushima, statements from the Japanese government were often confused. It initially rated the event as an "accident with wider consequences", and then upgraded it to a Chernobyl-scale event a month later, raising anxiety across the country. Moreover, far more severe assessments consistently came from others on the ground, notably the US Nuclear Regulatory Commission. An impartial and authoritative international voice would have been invaluable to avoid at least some of this confusion.

Next month, the IAEA will hold a conference of ministers to discuss lessons to be learned from the Fukushima accident (see page 397). The countries should give the IAEA an explicit mandate, and the necessary resources, to deliver its own safety assessments, both in times of crisis and during the normal operation of nuclear power plants. This more active role would be extremely sensitive, but the IAEA is up to the task. In its job as a nuclear watchdog, the agency already employs highly trained inspectors who regularly visit commercial power plants. The remote systems it uses to monitor nuclear materials could be extended to automatically report conditions at a plant during an emergency. Most important, the agency is politically savvy enough to avoid embarrassing its member states, unless absolutely necessary.

"The public would be better served by an IAEA more able to deliver frank and independent assessments of nuclear crises as they unfold."

In the case of Fukushima Daiichi, an IAEA acting in this way might have strengthened the Japanese position. Japan was criticized in the first days of the crisis for providing too little information on conditions at the plant. An IAEA assessment, based on independent data, could have provided backing for the Japanese decision to rapidly evacuate the surrounding population. It could have provided some reassurance to a panicked population that the government knew what it was doing.

As long as there is nuclear power, there will be the risk of a nuclear emergency. Giving the IAEA the rights and means to pursue a safety agenda cannot prevent such events, but it can reduce their likelihood and strengthen the world's response. ■

A united front

Pharmaceutical firms should come clean to tackle drug contamination.

When biotechnology company Genzyme announced the presence of a contaminating virus at its drug-manufacturing plant in Allston, Massachusetts, in 2009, patients were told not to worry. Only a small stockpile of uncontaminated drugs existed, but the company said that it would resume production within two months.

Two years and a host of manufacturing problems later, Genzyme still cannot supply enough of its treatment for Fabry's disease, a rare and potentially lethal enzyme deficiency. Genzyme's replacement-enzyme drug, Fabrazyme, which is made at the Allston plant, has been rationed since 2009 so that patients receive smaller doses than initially

recommended. And those diagnosed with the disease after rationing began are barred from receiving Fabrazyme. The restrictions understandably make patients uneasy: many see their symptoms worsening under the new dose regime, and some have started a lawsuit against the firm. In 2010, the European Medicines Agency reported that adverse events in patients with Fabry's disease had risen since the shortage, and advised doctors to prescribe the full dose again. Genzyme's stock price dived amid screams from investors, and the company agreed early this year to be acquired by Paris-based pharmaceutical company Sanofi-aventis.

The fiasco sounded alarm bells across an industry familiar with the difficulty of manufacturing biological molecules such as antibodies and enzymes for use as drugs. These 'biologics' were once the domain of speciality biotechnology firms, but are now being produced in large quantities. The number of clinical trials involving a biologic increased from 1,197 between 2000 and 2005 to almost 6,000 in the following five years. And in 2010, the drugs brought in US$40 billion in sales worldwide.

But success has its price. Unlike the manufacture of small-molecule drugs, which typically relies purely on large-scale chemical synthesis, biomanufacturing usually involves massive cultures of live cells maintained in rich, contamination-prone media. Anyone who has struggled to keep a 1-litre laboratory cell culture sterile will appreciate the challenge of doing the same for a 10,000-litre reactor. Viruses are stealthy intruders and can lie undetected in a culture for weeks, while the infected cells move down the pipeline to spread the scourge through the manufacturing facility — into those 10,000-litre reactors and through million-dollar chromatography columns.

This means that viral contamination can shut down drug production for months and cost a company millions of dollars, interrupting drug supplies and leaving patients vulnerable.

At least 17 incidences of viral contamination in biologics have been reported, but industry insiders say that many more go unreported. Rather than risk negative publicity and lawsuits, companies have largely chosen to keep the details of contamination, and even their occurrence, secret — even, at times, from government regulators. Genzyme's experience, which legally had to be made public because it caused a significant drug shortage, may have only deepened industry's fears of going public.

"Viruses are stealthy intruders and can lie undetected in a culture for weeks."

But although secrecy may make short-term business sense, it hampers industry's collective ability to learn from these catastrophes.

Down the road from Genzyme's troubled plant, researchers at the Massachusetts Institute of Technology in Cambridge are forming a consortium with industry to tackle the problem. The academic organizers hope that it will encourage greater openness and allow industry partners to divulge confidential information under the protection of non-disclosure agreements. The consortium plans to draw lessons from contamination data that could benefit the industry as a whole, and to publish answers to questions such as where viral contaminants originate and what the best way to detect and eradicate them is, or how to prevent them altogether.

These are crucial questions as interest grows in lucrative biopharmaceuticals. The answers should be able to guide research to reduce the incidence and impact of viral contamination on drug manufacturing.

At present, only six companies have signed up to participate in the study's pilot phase, and the organizers say they will eventually need at least twenty more to draw meaningful conclusions. More biotechnology companies should embrace this rare and valuable opportunity to pool resources without compromising their business interests. It could benefit patients and investors alike. ■

Seeing REDD

Plans to conserve the world's tropical forests must respect the rights of indigenous peoples.

As 'REDD' projects to protect forests in developing countries gain pace, campaigners and other groups representing indigenous peoples have warned that the plans could offer little benefit to local communities that depend on the forests for their livelihoods.

REDD — reducing emissions from deforestation and forest degradation — is touted by proponents as win–win for both conservation and poverty reduction. It is based on taking money from polluters in the developed world and channelling it to tropical nations for use in protection of carbon stocks. The agreement that covers such projects, signed at the United Nations climate meeting in Cancún, Mexico, last year, includes environmental and social safeguards that call for respect for the rights of local and indigenous peoples. But forest-dependent communities and human-rights organizations fear that these provisions offer weak and ineffective protection.

These concerns are starting to play out on the ground. A study by UK-based human-rights group the Forest Peoples Programme (FPP), which looked at nine REDD pilot projects in Cameroon, warns that forest communities there have not been adequately consulted on efforts to move on from the pilot schemes to develop national REDD plans. In addition, the national plans include no measures to protect the rights of these people — such as seeking their free, prior and informed consent to projects that may affect them — nor to ensure that they benefit.

REDD was always going to have teething problems, and there will be opportunities to address these concerns. Eyes are already on an upcoming meeting of the Forest Carbon Partnership Facility (FCPF) — a global fund administered by the World Bank to help developing nations to devise national REDD plans. At the meeting on 20–22 June in Oslo, Cameroon will present its plans, and will ask for up to US$3.6 million to start implementing them.

Will attending conservation organizations such as the WWF, which led the development of Cameroon's REDD plans, have time to note and attempt to rectify the shortcomings identified by the FPP in time for the meeting? Perhaps not, but a subsequent meeting of scientists, international organizations and donors to discuss the social sustainability of REDD will certainly have the opportunity to examine them. The Oslo REDD Exchange will take place on 23–24 June.

An important first step would be for organizations involved in funding and driving REDD projects, such as the World Bank, to take the involvement of local communities more seriously. The FCPF has yet to finalize standards and safeguards for activities it funds, for example, those governing human rights. And it remains unclear what standards REDD projects will be measured against, given that the FCPF is just one of a number of donors. Until these issues are resolved, it will be impossible to tell whether adequate precautions are in place.

Many who follow these issues closely argue that the World Bank must lead by example, and could start by bolstering its own policies on the rights of indigenous peoples. Currently, the bank requires indigenous peoples to be 'consulted' on funded projects that may affect them. Human-rights campaigners would like to see this provision strengthened so that 'consent' is required. They are hoping that this will be a key feature of a review the bank launched last month to examine its operational safeguard policies.

The REDD initiative is too important to be undermined by a reckless disregard for indigenous peoples. It is vital that key players use this year's opportunities to steer it back on course. To ensure that projects on the ground run straight, funders must set a good example. Otherwise, a major opportunity to reduce carbon emissions and improve people's livelihoods will fail before it has a chance to succeed. ■

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