THIS WEEK

Room for growth

The European Commission's plans to allow individual countries a veto on the farming of genetically modified crops, although a compromise, should enable the technology to move forward.

When the two camps on either side of a vitriolic debate unite against you, you are probably doing something right — or something horribly wrong. When it comes to acrimonious arguments over genetically modified (GM) crops in Europe, it is hard to be sure, but a move last week by the European Commission does seem to suggest the former.

Last week's political compromise, which should see individual countries able to ban the cultivation of GM crops, even if the crops have been approved at a pan-European Union (EU) level, was attacked by both industry and environmental groups. But some scientists involved in developing and testing the crops were cautiously optimistic that years of rancour have at last yielded to a sensible conclusion.

For years, many European crop researchers have despaired over the hostility to growing GM crops in the region. Although other parts of the world — notably, North America — have sown the seeds and reaped the rewards, the EU has dug itself into an ever deeper hole. Last week's agreement can certainly been seen from two perspectives. National bans that go against the best available evidence about the threat posed by the crops are unfortunate. But, armed with such powers, anti-GM countries should have less incentive to block EU-wide approvals in the first place (see *Nature* http://doi.org/xmq; 2014).

In principle, the EU has a perfectly sensible system for approving new GM crops across the continent. Their safety is assessed by the European Food Standards Agency, which draws up a report for the European Commission. The commission produces a decision that can be discussed by member states, which must then make a final decision by majority. If the member states cannot agree, the final decision is made by the commission. This should take months, not years.

Even those only casually familiar with the EU will see the 'but' coming here. Faced with opposition to GM organisms from member states such as France, and the staunch support of other countries such as the United Kingdom, the commission has sat on approvals, leaving crops and the companies that developed them to languish in a Brussels limbo for years. Companies such as Monsanto have abandoned the EU entirely as far as GM crops are concerned. Research has undoubtedly suffered.

On 3 December, representatives from EU member states and the European Parliament came to a compromise deal. They plan to pass legislation that will allow individual countries to ban crops — something that has been done in the past, but which is a legal grey area. If this agreement clears certain political hurdles, and with nations having the right to stop the use of GM crops in their fields, subject to various provisions, it is to be hoped that the wheels will begin to turn again on the approval process.

Naturally, not everyone is pleased by compromise. Industry groups want a single, uncomplicated market in which to sell their products. Growing and selling GM crops in a fragmented EU will give them a headache. Their opponents in the GM fight are also displeased. The spokesman for the European Parliament's Green grouping said that the agreement could turn into a "Trojan horse", and "could undermine the hand of those wanting to say 'no' to GMOs". The Greenpeace EU Unit said the draft agreement would leave countries that do ban GM organisms open to legal challenges from industry.

Nature has long supported the principle of using GM technology to improve crops (see *Nature* **497,** 5–6; 2013). But it must be acknowledged that a significant proportion of the EU population simply does not want them, for whatever reason. As this journal has also argued, evidence-based policy-making does not always have to side with what the science 'says' is true. It seems correct that countries should have the right to make decisions on this issue that are not based solely on evidence of safety or harm, just as they do on, say, recreational-drug use.

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If the EU's politicians can shepherd last week's agreement into law, at least there will be a way forward. Europe has some highly talented scientists in this field, and they have seen it become increasingly isolated. New technologies are opening up huge opportunities in the genetic engineering of crops, and Europe has already been left behind. But last week's agreement at least shows a willingness to try to catch up. That politicians are willing to compromise on this issue, rather than ignore it, deserves recognition from all sides. ■

Ethical overkill

Institutions should take a unified look at protections for research on human subjects.

The most important resource needed to conduct research on humans, it is said, is not brainpower or money: it is trust. In the United States, as elsewhere, hundreds of institutions and thousands of investigators work to protect that trust by carefully evaluating proposals for clinical trials and other research that uses human subjects.

Each US institution hosting such a study typically conducts its own ethical review of the proposal. The review process serves many functions: it is an expression of the responsibility that these investigators feel towards protecting their local community, an opportunity to tweak protocols to adapt to the community's specific needs, and a protection against potential lawsuits resulting from a flawed research protocol.

Sadly, evidence suggests that much of this effort is misplaced. A 2010 survey of 45 institutions reviewing the same protocol found that local scrutiny resulted in no substantial changes (B. Ravina *et al. Ann.*

Neurol. **67,** 258–260; 2010). Instead, most alterations simply inserted standardized institutional language — unrelated to the proposed study — to the informed-consent document signed by research participants before they enter a trial. The total cost of all that review: more than US$100,000.

On 3 December, the US National Institutes of Health (NIH) announced a draft policy intended to reduce that redundancy. Open for comment until 29 January, the proposal would require NIH-funded trials that are conducted at more than one site to be approved by a single institutional review board (IRB), which must be willing to shoulder responsibility for all of the sites. The intention is to speed up the approval process for trials that are conducted at multiple facilities. At present, each site may take a crack at reviewing a protocol, often delaying the start of a trial and introducing potential inconsistencies in study protocols and consent forms at different sites.

The NIH's move is the latest in a string of efforts by US regulators to change this institutional practice. In 2006, the US Food and Drug Administration released guidance for clinical trials conducted at multiple sites. In it, the agency stated that this ethical review need not take place at every institution. Instead, each trial could designate an institution to conduct a central review for all participating sites. Four years later, the US Office of Human Research Protections wrote a letter stating its support for that guidance. Despite these assurances, however, it has been difficult to change entrenched institutional practices that have been solidified for more than 40 years.

The NIH's proposal does not prohibit any participating site from conducting its own review, but clearly frowns on the practice — and explicitly pushes the cost of a duplicate review onto the institution.

Inertia is difficult to overcome, particularly at large institutions and with such a valuable resource at stake. Much of this stubbornness is due to an understandable desire by investigators to protect their patients and community. Some local IRB members feel that abdicating their review of research protocols is a violation of their responsibility to that community, and worry that standards will slip if they do not personally review the study.

"There is no evidence that multiple ethics reviews enhance protections for human subjects."

As the NIH has said, there is no evidence that multiple ethics reviews enhance protections for human subjects. Centralized review may seem to save time and money, but there is no clear evidence that it protects study subjects any better. Still, the NIH's move to encourage central review is the right one, given the available evidence.

Regulations that favoured local IRB reviews were developed in an era when studies were typically done at a single site. This is no longer the case. As therapies become more tailored to individual genetics, and diseases are subdivided into rarer subtypes, more sites are needed to enrol enough patients to evaluate an intervention.

Around the world, DNA sequencing labs are generating reams of genetic data that could hold the clues to the next medical revolution. Finding those clues quickly and ethically will require studies that combine data from across the globe. Investigators are clamouring for unified informed-consent documents that will allow them to compile genetic information into databases without creating a legal thicket of differing privacy protections. The NIH's move is an important step in that direction, but there is much farther to go. ■

Protect and serve

Nations must keep expanding conservation efforts to avoid a biodiversity crisis.

There are 22,413 species deemed at risk of extinction by the International Union for Conservation of Nature (IUCN). If some ambitious person tried to read out their names — without any breaks for food or water — it would take at least half a day. But that would be just the start. The IUCN has assessed the status of only 76,199 of the 1.7 million species of animals, plants, fungi and protists on Earth that have been described by scientists. And some suggest that at least five times more species still wait to be discovered. Many of these are also threatened, and it would take months to read out all of their names. (Except that they do not, of course, have names.)

There remain vast gaps in knowledge about the planet's biodiversity — and the precarious state of life. Every day, animals and plants go extinct. Nobody knows exactly how many, but estimates range from 500 to 36,000 extinctions per year. A News Feature on page 158 draws together some of the best studies of biodiversity and tries to make such vast numbers fathomable.

Before human populations swelled to the point at which we could denude whole forests and wipe out entire animal populations, extinction rates were at least ten times lower. And the future does not look any brighter. Climate change and the spread of invasive species (often facilitated by humans) will drive extinction rates only higher.

The pace of extinction is leading towards a crisis. If all currently threatened species were to go extinct in a few centuries and that rate continued, the die-offs would soon reach the level of a mass extinction — the kind of biological catastrophe that ended the reign of the dinosaurs and that has happened only five times in Earth's history. The sixth mass extinction could come in a couple of centuries or a few millennia, but it lies somewhere in the future if nations keep to their present course.

There are some hopeful signs. Countries are rapidly expanding the areas they shield from destructive human activities. The United Nations Environment Programme (UNEP) announced last month that countries have set aside 6.1 million square kilometres of ocean and land habitat since 2010, which increases the total protected areas to 15.4% of Earth's land and 3.4% of its oceans. According to UNEP, countries are on track to meet a 2020 goal established under the Convention on Biological Diversity to protect 17% of land areas, although reaching the 10% target for coastal and marine regions will require further efforts. The total areas set aside now equal the size of Africa.

But these efforts are not enough. Many protected zones are 'paper parks', where hunting, fishing and habitat destruction continue apace because of lax enforcement. And most parks established so far do not protect the most crucial areas — the ones full of threatened species and habitats. Nations are also investing much less on protection than they were 15 years ago, after adjustments are made for inflation.

In the face of this uncertainty about biodiversity, what should the world do? UNEP estimates that it would take US$76 billion each year to establish and manage a set of expanded parks that protect important habitats for all wildlife groups. That figure is just as unfathomable as the number of species on the planet. But consider that a blockbuster video game can sell $500 million in copies in a single day. According to UNEP, the economic benefits of protected areas far outweigh their costs, which could be met through a mixture of conventional sources and innovative funding mechanisms, such as green taxes and payments for the services that ecosystems provide.

As part of this protection effort, nations also need to devote more resources to taking stock of life. The IUCN has set a 2020 goal of assessing 160,000 species, roughly double the current number, which it calculates would cost $60 million and cover a good representation of most major taxonomic groups and ecosystems. The job of counting and evaluating is not the most exciting science. But it is one of the most fundamental and important tasks that humans can do — to take a measure of life and protect what remains before it disappears. ■

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