The Cartagena protocol and GMOs

To the editor:

More than 100 countries have ratified the Cartagena Protocol on Biosafety. Identification of genetically modified organisms (GMOs) in the shipping documentation was one of the main contentious issues addressed by the 1st Meeting of the Parties (MOP1) to the Protocol, which took place in Kuala Lumpur in February 2004. As raised in a commentary by De Greef in the July issue (*Nat. Biotechnol.* **21**, 811–812, 2004) and in two related news stories[1,2], the decision seems to have raised concerns among the research community and agriculture trade associations. As I had the privilege to chair the Working Group that specifically discussed identification, I would like to try to provide some clarifications.

The identification requirements specified in the Cartagena Protocol in paragraph 2 of Article 18 set out what information needs to be provided in the documentation accompanying trans-boundary movements of GMOs. This information does not pertain to the labeling of shipments of GMOs in the sense of putting markings or description of contents of shipments on packages or containers. The information conveyed through documentation accompanying the shipment is intended to help authorities, as well as relevant operators in the transit or importing states, to identify what shipment is passing through or coming into their territories so that they are able to undertake appropriate action in handling the shipment. It is therefore appropriate to appreciate, from the outset, the distinction between labeling (in the conventional meaning of the word) on the one hand, and identification through accompanying documentation as required in the Protocol, on the other. It is also important to emphasize that the information contained in the accompanying documentation is not intended to be used as a basis for risk assessment by the authorities of the importing country. For such purposes, the Protocol foresees more detailed notification provisions.

The documentation requirements set out by the Cartagena protocol vary according to GMO's intended use. Those destined for contained use or intended for intentional introduction into the environment should be clearly identified as such in the accompanying documentation. In the latter case, additional information is also required specifying the identity and the relevant traits and characteristics of the GMO(s). On the other hand, the content of the documentation accompanying shipments of GMOs intended for direct use as food or feed or for processing—in other words agricultural commodities—was not fully resolved during the protocol's negotiation. For the time being, such shipments shall be identified as 'may contain' GMOs. However, this should be seen as a temporary measure because the Protocol requires that a decision on the detailed documentation requirements for such transgenic organisms, including specification of identity and any unique identification system, be taken within two years after entry into force (that is, before September 2005).

There were several achievements at MOP1, six months after the Protocol entered into force. Sets of practical recommendations based on available practices were adopted to facilitate implementation of the documentation requirements. For example, in order to avoid unnecessary administrative burden, it was decided to integrate the protocol's documentation requirements into commercial invoice or other relevant existing documentation systems, such as the Shippers Declaration of Dangerous Goods for Pathogenic Micro-organisms. Moreover, templates were provided as examples for documentation that shall accompany GMOs for contained use or for intentional introduction in the environment. Those templates will help users, including scientists, to fulfil their obligations.

Another important achievement was the recognition that, when available, the Organisation for Economic Cooperation and Development's (OECD; Paris) unique identifier for transgenic plants could be used to cover information requirements in the documentation. The OECD unique identifier is based on the transformation event and works as a key to access additional relevant information on the transgenic crop. All the crop varieties derived from one transformation event will share the same unique identifier. Developers have attributed the OECD unique identifier to almost all transgenic crops approved for commercialization so far. Using the OECD unique identifier, information on those transgenic crops is already accessible through the Biosafety Clearing House, the information exchange platform of the Cartagena Protocol (http://bch.biodiv.org/).

MOP1 also decided that any GMO shipment should detail common and scientific names of the GMO and information on the transformation event(s) used in its creation. However, this requirement is designed to be as flexible, depending on the intended use of the GMO. For example, for GMOs intended for food or feed, governments are 'urged' to require exporters, for the time being, to include such information in accompanying documentation or the reference to the unique identifier. At this stage, parties to the protocol and other governments are strongly encouraged that this information be made available with each shipment. This reflects the actual practice in some countries that have ratified the protocol,

where a simple statement such as 'may contain' in the shipment documentation without any reference to the identity of the GMO is insufficient. It does not preclude any final decision on this specific issue that will have to be taken at the next meeting of the parties to the protocol (MOP2). Along the same line, information on transformation event and risk class should not be provided with all samples shipped for research. For GMOs destined for contained use (which includes most research activities), such additional information would be provided only when appropriate, and, in some cases, would be limited to the availability of the information itself (e.g., risk classes apply only to pathogenic microorganisms).

The implementation of the Cartagena Protocol is a process that will build upon practical experience gained by governments and stakeholders. This is especially relevant for documentation requirements. Indeed, all users, in particular scientists and agricultural commodities operators, will be urged to report either to their national focal point for the Cartagena Protocol or to the Secretariat of the Convention on Biological Diversity on their practical experiences with the use of the tools developed by the MOP1, such as templates or the unique identification system. Such feedback will help guide future decision making.

Last but not least, as DeGreef recently emphasized in these columns, the scientific community will certainly gain from a stronger participation in the program of work of the Cartagena Protocol. This will ensure that their legitimate concerns are fully taken on board.

1. Cyranoski, D. *Nature* **428**, 6 (2004).
2. Cyranoski, D. *Nat. Biotechnol.* **22**, 372 (2004).

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Ethics, industry and 'animal farm'

To the editor:

The use of animal imagery ('porcine,' 'lapdog,' 'swill' and 'show dog') in Leigh Turner's commentary 'Bioethic$ Inc" in the August issue (*Nat. Biotechnol.* **22**, 947–948, 2004) adds a level of rhetoric that demeans the importance of the subject matter. More serious than the rhetoric, Turner makes a factual error by citing the Centre de recherche en droit public (CRDP) at the University of Montreal as a recipient of funding from corporate sponsors.

Corporate monies are not, and never have been, used as a source of funding for academic research at the CRDP. We accept corporate funding in only two situations. The first is for international conferences where such funds are earmarked for the high travel costs associated with bringing speakers to CRDP from around the world, including developing countries. The second is for the creation, maintenance and dissemination of HUMGEN, a free website which consists of a database of socio-ethical and legal policies and laws on human genetics.

HUMGEN (http://www.humgen.umontreal.ca/) provides access to policy documents (professional guidelines, ethical codes and legislation) related to human genetics, which are produced by governmental and nongovernmental organizations, including industry, professional associations and advocacy groups from over 30 countries. This site provides public-policy makers, scientists, legislators, corporations, ethics committee, mass media and citizens interested in ethical and socio-legal issues, free access to policy statements related to human genetics. It fosters informed decisions and increases sensitivity to the ideas and positions of other cultures.

This publicly accessible educational website is not marketed by the CRDP or the corporate sector, who figure in its list of sponsors. It is funded by a mixture of private, public and governmental agencies. There are no strings attached from any of our sponsors.

Being a publicly funded, educational and research institution, the CRDP created this website as a way of giving back to the community and making available its own research tool to everyone in French, English and in Spanish in 2005, funding permitting.

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