DISCUSSION POINTS: ANSWER KEY

DP 1: A National Focal Point in Thailand receives a request from a local non-government organization to provide information on what transgenic potato varieties are currently being cultivated in the United States. How can she use the BCH to assist the caller?

The US is not a Party to the Protocol, therefore they are not legally obliged to provide information to the BCH. However, the US is voluntarily providing information about decisions it has taken in accordance with Article 11 (LMO-FFPs).

The BCH can provide information about transgenic potatoes that have been approved for commercial release in the U.S. It currently does not include information as to what potato (or any other crop) varieties are actually being cultivated. Some governments may provide this information in the "other relevant information" field of registered decisions, but it is not mandatory to report it.

However, in this case, the US Government website, which can be reached via the BCH, provides a link to a non-governmental website that provides information on the commercial status of certain products of agricultural biotechnology: http://usbiotechreg.nbii.gov/database_pub.asp.

In addition, Biosafety Information Resource Centre in the BCH provides, as well as the US Government website in this case, links to an industry site that includes this information (www.biotradestatus.com)

DP 2: The Competent National Authority in Brazil receives a request for a list of all companies in neighbouring Paraguay that use cornstarch derived from transgenic maize in their processed food products. What relevant information can the BCH provide?

Cornstarch is not a living modified organism and therefore information about cornstarch derived from transgenic maize will not be found on the BCH.

However, the Competent National Authority could use the BCH to get contact information for relevant focal points, the Competent National Authority/ies in Paraguay, and any national or international databases that may be able to assist them in finding this information.

DP 3: The BCH Focal Point for Cameroon is called with a request for the contact details of laboratories that do eco-toxicity studies for LMOs. What assistance can they provide through the BCH?

The BCH does not contain this type of information. However, the Focal Point could suggest that the caller search the Roster of Experts database of the BCH to identify scientists that may be able to provide this type of information.

DP 4: The Competent National Authority of Slovenia receives a request from its customs office indicating that a shipment of cloned pigs has arrived from Belgium. The customs officer wants to know if they can accept the shipment under the requirements of the Biosafety Protocol.

The Protocol applies to living modified organisms as described by Article 3(g) of the Protocol. Since the cloned animals do not necessarily possess a novel combination of genetic material (i.e. they should be a replica of the animal from which the original cells were taken), Protocol provisions do not apply and there is no information in the BCH regarding the transboundary movement of cloned organisms. In this case, the CNA would look to its national legislation to make a decision.

If the cloned pigs were also genetically modified, then the relevant provisions of the Protocol would apply.

DP 5: A German biotechnology corporation plans to ship genetically modified bacteria to a colleague in India for use in a certified laboratory. The company wants to obtain from the BCH a copy of a previous Advanced Informed Agreement (AIA) assessment that was applied to such a shipment.

The AIA procedure only applies to LMOs that are to be intentionally introduced into the environment of the party of import (see Article 7.1). It does not apply in instances of contained use (Article 3b and Article 6.2) and therefore would not be registered with the BCH under the AIA provisions.

However, governments may still subject any LMO to risk assessment prior to taking a decision and set standards for contained use. Information on relevant legislation and risk assessments would be found in the BCH by searching for "national laws and regulations" under the "contained use" subject area, and any relevant risk assessments (registered in accordance with Article 20.3(c)). (Note that legislation that covers all aspects of the Protocol will also be retrieved and will have to be examined to determine its applicability.)

DP 6: A Swiss pharmaceutical company wants to ship a genetically modified live vaccine for hepatitis B to its sister company in Ethiopia. A representative from the Ethiopian company asks its BCH Focal Point if the shipment can be accepted or if further procedures apply.

Transboundary movement of living modified organisms that are pharmaceuticals for humans is addressed primarily by the World Health Organization (WHO) regulations. The Protocol does not apply if pharmaceuticals for humans are addressed by other agreements or organization (Article 5) and the company representative should be advised to follow up with relevant pharmaceutical legislation. (In rare cases where pharmaceuticals for human use are not addressed by relevant international agreements or organizations, Protocol provisions apply.)

However, governments may choose to subject all LMOs to risk assessment prior to making decisions on import and therefore the company representative should contact the Ethiopian Competent National Authority(ies) to confirm if local provisions apply, and they could also search for "national laws and regulations" under the "pharmaceuticals" subject area in the BCH. (Note that legislation that covers all aspects of the Protocol will also be retrieved and will have to be examined to determine its applicability.)

DP 7: A French company is shipping, by rail, LMOs to Belarus intended for direct release into the environment. The train will pass through Poland en route to Belarus. The Polish government wants to apply the AIA procedure for assessment purposes.

LMOs that are "in transit" – i.e. LMOs that are moving or passing through or across the territory of a party to the Protocol – are exempt from the AIA procedure (Article 6.1). Poland may, however, apply its own regulatory regime upon the shipment while it is within its borders and therefore the French company should search for "national laws and regulations" under

the “transit and contained use” subject area. (Note that legislation that covers all aspects of the Protocol will also be retrieved and will have to be examined to determine its applicability.)

DP 8: A researcher in Malta advises their Competent National Authority that a genetically modified vaccine for pigs they have been testing at in field trials may have infected some birds that have flown to Italy. What should the Competent National Authority do?

The Maltese authorities should take appropriate measure to notify the affected (or potentially affected) countries, the BCH, and any relevant international organizations as soon as it learns of the situation. The appropriate point(s) of contact are available in the National Focal Points section of the BCH. To minimise adverse effects, the countries should consult to enable them to determine the appropriate responses and initiate necessary action, including emergency measures.
