ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD) [7 OCTOBER 2003] [SUBMISSION: ENGLISH]

Recommendations by the third meeting of the ICCP requesting action from relevant organizations

I would first like to congratulate you and your colleagues in the Secretariat for all your hard work, which culminated in the Cartagena Biosafety Protocol entering into force on 11 September 2003. This has been no small achievement. I am told that, as of today, 62 States and the European Commission have ratified the Protocol and this is clearly a strong basis for a successful first meeting of the Conference of the Parties serving as the meeting of the Parties, which will be held in Malaysia, February 2004.

I would also like to emphasize that the cooperation between our respective organizations, which is covered by our Memorandum of Cooperation of 23 January 2002, has been a valuable experience for us at OECD. The lessons we have learned, especially through the implementation of interoperability between our databases, has benefited a wide range of our activities.

I would like now to turn to your letter of 6 June 2003, which addresses the Recommendations by the third meeting of the ICCP requesting action from relevant organizations. Specifically, I would like to bring you up to date with progress on those topics referred to in the attachment to your letter under *Item 4.1.3: Information Sharing*.

One of the key topics is that of the Unique Identifier. The OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants (developed under the auspices of our Working Group for Harmonization in Biotechnology) was published in March 2002. Since that time, national authorities have been working with the developers of products to assign unique identifiers for those products which have already been approved and for which records exist in OECD's product database.

This process has accelerated in recent weeks and we are now at the point where 80 unique identifiers have been assigned. These cover the majority of plant products in our product database and, as far as we know, most of the LMO products which have received commercial approval around the world. It is my understanding that unique identifiers are also being assigned for products not yet approved and under consideration by certain authorities. As a result, we now have clear evidence that the "guidance" can be (and is being) implemented widely in practice. I am convinced that this "guidance" for a unique identifier could make an important contribution to the implementation of the Protocol.

By the way, as products in our database have been assigned unique identifiers, information on each product together with the unique identifier, has been made available (through interoperability) to the component of the Biosafety Clearing-House which addresses Article 11 decisions.

At the same time, there remain several plant products which have not yet had unique identifiers assigned. In these cases, there does not appear to be an issue with the "guidance", but rather, there appears to be a question as to what exactly is considered to constitute a commercial application or (within the context of Article 11 of the Protocol) a "final decision". The OECD Secretariat, together with the Working Group, is currently clarifying the situation with respect to these products, and I believe that the findings, which will be considered by the next meeting of our Working Group in November, will be of interest to you. At the same time, the Working Group will be considering whether and how the "guidance" might be extended to products of microbial and animal origin, which are not yet covered.

In any event, we are now in a position to establish interoperability with the registry of unique identifiers of the Biosafety Clearing-House, which will clarify those which have been assigned to date. We expect that this will be established within a very short period.

As regards interoperability between our product database and the component of the Biosafety Clearing-House addressing Article 11 decisions, I believe that this has worked well. So far, we have forwarded information on 38 products which have been the subject of national decisions. This number will increase in the near future, given the recent progress made in assigning unique identifiers.

A number of our member countries have indicated their intention to take direct responsibility for their information on national decisions in the future, and to become directly interoperable with the Biosafety Clearing-House via their national nodes. In the OECD Secretariat, we believe that our role is to facilitate this transition as efficiently as possible, while maintaining (and where possible improving) the current information that is found in the Biosafety Clearing-House. We expect that this transition will be undertaken in an orderly and coordinated way. This will also be an important topic of discussion at the meeting of our Working Group in November.

I have already alluded several times to the role of our Working Group for Harmonization in Biotechnology in managing the issues which are the subject of our collaboration. The 14th meeting of the Working Group will be held from 24 to 26 November. Because of the nature of the issues to be addressed within the context of our collaboration, I believe that it will be important for the Secretariat to attend this meeting of the Working Group, as it has on previous occasions. If necessary, I suggest that we find an opportunity immediately following the November meeting, to discuss between the two Secretariats, whether we need to take any additional actions in advance of the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

As regards our existing Memorandum of Cooperation, it is my understanding that it is still valid in the current situation and need not be revisited in the immediate future. I assume that you will inform us when you feel that the status of the Biosafety Clearing-House has changed as the Memorandum only covers the pilot phase of the Biosafety Clearing-House. At the same time, I recognize that we will need to revisit the Memorandum following the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

Finally, I would like to take this opportunity to raise an issue which has not been addressed (at least directly) in our Memorandum of Cooperation, though it is related to information exchange. I refer to the OECD Consensus Documents which have been published under the auspices of our Working Group. The subject of most of these documents has been either crop plants (such as maize, soybean, rapeseed, etc,) or traits relevant to LMOs (such as herbicide tolerance, virus resistance, etc.).

These documents contain information which OECD countries have agreed is important in risk/safety assessment. They contain, for example, references to the "centre of origin and diversity" of the crop in question. Our product database is making increasing reference to these documents and because of interoperability, such references might also appear in the Biosafety Clearing-House. Because these documents contain information which could become of increasing relevance to the implementation of the Protocol, I feel it is important to draw to your attention an upcoming workshop (hosted by Canada, Mexico and the United States) which will be held in Washington DC, from 21 to 24 October. One of the main objectives of the Workshop is to ensure the increased utility and applicability of Consensus Documents and to ensure their effective development. As always, the Secretariat of the Convention is welcome to attend. In any case, I will make the report of the Workshop available to you.

I have covered a number of issues in this letter and I recognize that you may have questions of clarification or might wish to have a follow-up discussion. If that is the case, please do not hesitate to contact me. In the meantime, I would like to offer you my best wishes as you move forward with the preparations for the first meeting of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. I have every confidence that this will be a successful meeting.