I appreciate the opportunity to participate with colleagues in this dialogue on monitoring. A number of issues have been raised and I would like to comment on them.

1. In general, I support the views expressed by Drs Abdel-Kawy and Zughart. Elizabeth Bravo’s comments on considering the distributional aspects of any impacts from the use of LMOs cannot be emphasized too strongly. Just as the benefits are not equally shared by all, neither are the risks. Risks to vulnerable communities need to be especially monitored. For example, as in many public health policies, children may be especially sensitive and thus are closely monitored.
2. As the literature makes clear, risk assessment is always iterative, not static. One of the key consequences of monitoring is to give feedback to the RA which then may need to be modified based on these observations. This is, overall, an aspect of risk management which we cannot ignore. See my next point.
3. All environmental risk assessments involve uncertainty. Since there may be thousands of species in a receiving environment (and thousands of biological processes going on) and since we have knowledge about only a tiny proportion of these, it is not possible to assume a stance of perfect knowledge in a RA. Our stance, rather, needs to be of inquiring humility. The Precautionary Principle, twice included in the Protocol, recognizes the necessity of this sort of posture. Monitoring is thus essential to carry out precaution. Thus, I differ with the suggestion of Dr. Benedict—the risk analysis and the monitoring need to be expansive; if the argument is that this would be costly, my response is that such expenses should be internalized into the actual cost of the LMO rather than borne by government taxpayers or innocent victims.
4. As a result, I must differ with my friend Yoshikura-san when he says that monitoring should be proportional to risk. On a logical level, this may be so, but in actual experience, we often don’t really have a firm grasp of what the risk actually is, and so applying his approach is really not practical. That is why there is discussion of “unanticipated” consequences (and hence risks). Many of the proffered assessments are performed by the industry proponents (in the US, government agencies almost never do independent assessments of LMOs); these are usually highly flawed—they don’t use real world conditions, may assess isolated compounds (like the Bt chemical instead of the plant incorporating the Bt gene), the samples are too small, etc. These deviations from reality make monitoring all the more necessary. If there is a “conventional counterpart” (a concept I question, since the whole point of an LMO is that it *differs* from conventional organisms), the proponents imply that the risks are lowered; Yoshikura-san’s points 3 and 4 seem to be contradictory as to whether monitoring then should be more necessary or less.
5. Dr. Deise Maria Fontana Capalbo, says “Our position is that monitoring could not be used as a safeguard after consent for environmental release of a LMO – if it is not safe, why approve a release? If a LMO is consider safe then why to ask any monitoring? So, a guidance document could be useful to help management and/or when there is an ‘uncertainty’ for a specific risk”. Dr. Adriana Otero-Arnaiz expresses a similar view. However, “safe” is a value judgment that the assessed risk is acceptable; “safe” is not an objective term—otherwise everybody would or would not smoke cigarettes or wear seat belts without the necessity of legal compulsion, whereas individuals have different conclusions as to whether these are safe activities. An RA under the Protocol does not determine “safety;” it attempts to determine “risk.” Thus, I strongly disagree with these two statements.

As my discussion of uncertainty, above, indicates, any assessment of the risks of an LMO in a receiving environment is—at best—an approximation. With deference to the sensibilities of our Japanese colleagues, the risks of radiation exposure at Fukishima apparently did not anticipate the simultaneous striking of an earthquake and a tsunami.

I agree with Dr. Quist that appreciating the importance that unanticipated effects may have makes monitoring all the more necessary.

1. Risk Analysis comprises more than direct effects (so-called “first order”). Effects of effects (second and higher order) may be of far greater importance to human health or biodiversity. While it is imperative that such effects be included in the assessment, each step does tend to introduce greater uncertainty and hence greater need for monitoring. This would include socio-economic consequences, relevant under Art. 26.

I appreciate again this opportunity to participate.

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