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National Capacity Elements Required to Ensure the Safety of Genetically Modified Organisms and Genetically Modified Foods

(Prepared by Consumers International)

Introduction

Consumers International has surveyed its 250 member organisations regarding their top priorities among food safety issues, and the most important concern, by far, among these consumer organisations world-wide, is genetically modified (GM) foods. Governments around the world also are grappling with whether to accept imports of GM foods and/or to allow the release of genetically-modified organisms (GMOs--plants, animals including fish, and micro-organisms) into their environments.

In CI's view, governments must assure themselves and consumers that GMOs and GM foods derived from them are safe, for health and the environment, under the specific conditions of use in the specific country, before allowing those organisms and foods to be commercially deployed or offered for sale within their borders. Countries facing import or approval decisions need sufficient capacity in the areas of adequate regulations, agencies, and technical facilities such as laboratories, personnel and budget in order to make informed choices in this regard. To facilitate and focus capacity-building efforts related to GM foods, CI offers this CRD, based on its own expertise and the experiences of its members in many ongoing national debates over GM foods, which enumerates the various capacities we believe all governments require in order to make sound policy decisions on this topic.

Needed Capacities

Capacities governments should have in place to effectively ensure the safety of GM foods and GMOs include the following elements:

1. Regulatory capacity. Countries need laws/regulations that would require:

- **Environmental assessment** of GMOs prior to commercialization. The environmental regulations should be consistent with the all provisions of the Biosafety Protocol. They should require testing in a range of environments within the country where the GMO is to be released. Environmental testing data on GMOs from other countries should not be accepted in lieu of testing from the local environments where the GMOs will be released.
- **Human safety evaluation** of GM foods prior to commercialization. The safety testing regulations should mandate the full range of tests and data as suggested by the safety assessment documents developed by the Codex Ad-Hoc Task Force on Foods Derived From Biotechnology (e.g. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, and Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms), adopted last year by the Codex Alimentarius Commission.

- **Safety standards** based on a sound risk analysis, which should require positive approval of GM foods/GMOs by a competent authority before they may be sold or commercially deployed in the country.
- **A monitoring and surveillance system for food-borne illness** capable of detecting any unexpected adverse health effects that may be associated with consumption of GM foods.
- **Postcommercialization testing and monitoring** to detect any environmental effects of released GMOs. Post-market monitoring is crucial as many environmental effects (intermittent, low-magnitude, accumulative) of transgenic organisms may be undetectable during pre-commercialization field trials, due to the small size and number of the field trials, or may be detectable only after large areas are sown to transgenic crops. Systematic monitoring of the spatial distribution of GMOs (especially plants) should be required.
- **Postcommercialization testing and monitoring** to facilitate traceback and recall of any GM food that leads to an adverse health effect, either expected or unexpected.
- **Mandatory labelling** of GM foods to allow informed consumer choice about the food they eat and to facilitate traceback and recall in the event that a GM food leads to an unexpected adverse health effect.
- **Traceback requirements** that include gene sequence information that can be used to identify each transformation event in commercialized crops, evidence of molecular stability of genetic modifications over many generations, and mandatory record-keeping documenting distribution of GM seeds, harvested crops, and foods.
- **Stakeholder input** (especially civil society organizations such as consumer groups, environmental groups, farmer and peasant organizations, etc.) into the approval or decision-making process, with meaningful impacts on approval decisions.
- **Strict liability provisions** that hold industry or other developers of GM technologies responsible for economic or biological damage caused by release of GMOs into the environment, and for any adverse human health effects caused by consumption of GM foods, that they developed and marketed.

2. Human and institutional capacity to reliably implement and enforce the laws and regulations outlined in Section 1, including:

- **Health and medical scientists** to evaluate food safety of GM foods--toxicologists, nutritionists, molecular biologists, statisticians, etc.
- **Environmental scientists** to evaluate potential environmental impacts of GMOs at the pre-commercialization stage--ecologists, botanists, zoologists, entomologists, soil scientists, agronomists, microbiologists, molecular biologists, statisticians, etc.
- **Technicians and data analysts** to monitor and test for post-commercialization environmental impacts. This may include disciplines listed above, plus trained observers—technical staff in agricultural and natural areas management, who are frequently in the field and could be enlisted to detect environmental effects.
- **Enforcement staff/inspectors and technicians** who can monitor compliance with any conditions associated with commercialization of GMOs, such as requirements for buffer zones (refuges), or segregation of harvested grains. Government employees should monitor growers to ensure that such requirements are carried out.
- **Medical scientists and support personnel** to detect any unexpected adverse health effects that may result from consumption of GM foods--doctors, epidemiologists, lab technicians, data analysts and statisticians, nurses, etc.
- **Laboratories** to perform the pre-market safety testing and post-market testing in support of monitoring, such as tests for the presence of transgenic DNA or foreign proteins. This includes

adequate equipment and laboratory staff to carry out needed tests on a timely basis. Clusters of developing countries may elect to build common, shared sub-regional laboratory facilities. Such multi-national enterprises need to have adequate capacity and management systems to meet all the anticipated needs of each national partner, in a timely manner.

- **Testing facilities and programs**, for instance in port cities, to monitor imported foods for GM content, on arrival in the country, before dispersal into markets.
- **Simple, reliable test methods**, such as quick tests for the presence of transgenic DNA or protein, suitable for use in the field, for example to detect contamination of non-GM crops/foods with GM traits at the farm or factory, without having to wait days or weeks for laboratory results.
- **Personnel to monitor labelling** and test products, to ensure that label requirements for foods containing GM ingredients are properly met and foods are accurately labelled. Such testing could also be done on organic and other supposedly GM-free foods to see if there is any contamination with GM ingredients
- **Training programs and faculty.** Human capacity building requires training scientists and inspectors to perform risk assessments and other studies on the environmental and human safety aspects of GM foods and GMOs, and to carry out myriad tasks in enforcing and implementing laws and regulations.

3. Budgetary capacity.

Sufficient funds must be provided to carry out all of the activities listed in Section 1 and Section 2. These costs can be substantial, especially for countries that currently lack, or have only some elements of, the needed legislation, institutional framework, scientific facilities, and trained workforce.

Conclusions and Recommendations

Any country that needs to assess GM foods for consumption by their population and/or to approve GMOs for release into their environment, must have sufficient capacity in a wide number of areas—legislation, institutions, technical facilities, human resources, and the budget—to meet all the enumerated needs. Many countries, and particularly developing countries, currently lack the needed capacity and may also lack the financial resources to develop the proper capacity. CI believes that national governments are in the best position to judge their own readiness to evaluate GM foods and GMOs. We further believe that governments that do not feel capable at present of ensuring themselves and their citizens that such foods and GMOs are safe, in their own national context, are fully justified if they decide not to accept the risks (i.e. to exclude GM foods/GMOs from their national food supply). Given that many developing countries also face other serious food safety and food security problems, governments must assess the relative priority of putting limited resources into building capacity to assess GM foods. Many countries may legitimately have higher priorities for the use of whatever resources they have.

Consumers International therefore ***recommends***:

1. That national governments in developing countries, international agencies and developed countries working to build capacity, and other interested parties, consider all of the various parts of capacity to regulate GM foods and GMOs listed here as essential elements, when seeking to build capacity for this task;
2. That the principle of national self-determination be respected, and that countries that currently do not have the capacity to effectively regulate GM foods/GMOs, and that may also have other serious national food safety capacity-building needs, not be subjected to trade challenges and other forms of international pressure that would tend to distort their national allocation of scarce food-safety resources toward preparedness to accept GM imports. Such pressures serve neither the goal of international harmony nor the interests of consumers in the affected countries.