

# Republic of the Philippines Supreme Court

Manila

# **EN BANC**

INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, INC., Petitioner. G.R. No. 209271

- versus -

**GREENPEACE SOUTHEAST** ASIA (PHILIPPINES), MAGSASAKA AT SIYENTIPIKO SA PAGPAPAUNLAD NG AGRIKULTURA (MASIPAG), **REP. TEODORO CASIÑO,** DR. BEN MALAYANG III, DR. ANGELINA GALANG, LEONARDO AVILA III, CATHERINE UNTALAN, ATTY. MARIA PAZ LUNA, JUANITO MODINA, DAGOHOY **MAGAWAY, DR. ROMEO QUIJANO, DR. WENCESLAO** KIAT, JR., ATTY. H. HARRY **ROQUE, JR., FORMER SEN. ORLANDO MERCADO, NOEL** CABANGON, MAYOR EDWARD S. HAGEDORN and EDWIN MARTHINE LOPEZ,

Respondents.

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# CROP LIFE PHILIPPINES, INC., Petitioner-in-Intervention.

ENVIRONMENTAL MANAGEMENT BUREAU of the Department of Environment and Natural Resources, BUREAU OF PLANT INDUSTRY and FERTILIZER AND PESTICIDE AUTHORITY of the Department of Agriculture,

Petitioners,

- versus -

**COURT OF APPEALS, GREENPEACE SOUTHEAST** ASIA (PHILIPPINES), MAGSASAKA AT SIYENTIPIKO SA PAGPAPAUNLAD NG AGRIKULTURA (MASIPAG), **REP. TEODORO CASIÑO,** DR. BEN MALAYANG III, DR. ANGELINA GALANG, LEONARDO AVILA III, CATHERINE UNTALAN, ATTY. MARIA PAZ LUNA, JUANITO MODINA, DAGOHOY **MAGAWAY, DR. ROMEO QUIJANO, DR. WENCESLAO** KIAT, JR., ATTY. H. HARRY **ROQUE, JR., FORMER SEN. ORLANDO MERCADO, NOEL** CABANGON, MAYOR EDWARD **S. HAGEDORN and EDWIN** MARTHINE LOPEZ, Respondents.

Respondents.

# CROP LIFE PHILIPPINES, INC., Petitioner- in-Intervention.

X----X

UNIVERSITY OF THE PHILIPPINES LOS BAÑOS FOUNDATION, INC., Petitioner,

G.R. No. 209301

- versus -

**GREENPEACE SOUTHEAST** ASIA (PHILIPPINES), MAGSASAKA AT SIYENTIPIKO SA PAGPAPAUNLAD NG AGRIKULTURA (MASIPAG), **REP. TEODORO CASINO,** DR. BEN MALAYANG III, DR. ANGELINA GALANG, LEONARDO AVILA III, CATHERINE UNTALAN, ATTY. MARIA PAZ LUNA, JUANITO MODINA, DAGOHOY MAGAWAY, DR. ROMEO **QUIJANO, DR. WENCESLAO** KIAT, JR., ATTY. HARRY R. **ROQUE, JR., FORMER SEN. ORLANDO MERCADO, NOEL** CABANGON, MAYOR EDWARD S. HAGEDORN and EDWIN MARTHINE LOPEZ, Respondents.

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# UNIVERSITY OF THE PHILIPPINES,

Petitioner,

G.R. No. 209430

Present:

- versus -

GREENPEACE SOUTHEAST ASIA (PHILIPPINES), MAGSASAKA AT SIYENTIPIKO SA PAGPAPAUNLAD NG AGRIKULTURA (MASIPAG), REP. TEODORO CASIÑO, DR. BEN MALAYANG III, DR. ANGELINA GALANG, LEONARDO AVILA III, CATHERINE UNTALAN, ATTY. MARIA PAZ LUNA, JUANITO MODINA, DAGOHOY

No Part.

\*\* On official leave.

SERENO, *C.J.*, CARPIO,<sup>\*</sup> VELASCO, JR., LEONARDO-DE CASTRO, BRION,<sup>\*\*</sup> PERALTA, BERSAMIN, DEL CASTILLO, VILLARAMA, JR., PEREZ, MENDOZA, REYES, PERLAS-BERNABE, LEONEN, and JARDELEZA,<sup>\*</sup> JJ. MAGAWAY, DR. ROMEO QUIJANO, DR. WENCESLAO KIAT, ATTY. HARRY R. ROQUE, JR., FORMER SEN. ORLANDO MERCADO, NOEL CABANGON, MAYOR EDWARD S. HAGEDORN and EDWIN MARTHINE LOPEZ, Respondents.

Promulgated:

December 8, 2015 Alkintonpan-france

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# DECISION

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#### VILLARAMA, JR., J.:

The consolidated petitions before Us seek the reversal of the Decision<sup>1</sup> dated May 17, 2013 and Resolution<sup>2</sup> dated September 20, 2013 of the Court of Appeals (CA) in CA-G.R. SP No. 00013 which permanently enjoined the conduct of field trials for genetically modified eggplant.

#### **The Parties**

Respondent Greenpeace Southeast Asia (Philippines) is the Philippine branch of Greenpeace Southeast Asia, a regional office of Greenpeace International registered in Thailand.<sup>3</sup> Greenpeace is a non-governmental environmental organization which operates in over 40 countries and with an international coordinating body in Amsterdam, Netherlands. It is well known for independent direct actions in the global campaign to preserve the environment and promote peace.

Petitioner International Service for the Acquisition of Agri-Biotech Applications, Inc. (ISAAA) is an international non-profit organization founded in 1990 "to facilitate the acquisition and transfer of agricultural biotechnology applications from the industrial countries, for the benefit of resource-poor farmers in the developing world" and ultimately "to alleviate hunger and poverty in the developing countries." Partly funded by the United States Agency for International Development (USAID), ISAAA promotes the use of agricultural biotechnology, such as genetically modified organisms (GMOs).<sup>4</sup>

Respondent Magsasaka at Siyentipiko sa Pagpapaunlad ng Agrikultura (MASIPAG) is a coalition of local farmers, scientists and NGOs working

Rollo (G.R. No. 209271), pp. 135-159. Penned by Associate Justice Isaias P. Dicdican with Associate Justices Myra V. Garcia-Fernandez and Nina G. Antonio-Valenzuela concurring.
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<sup>&</sup>lt;sup>2</sup> Id. at 161-174.

<sup>&</sup>lt;sup>3</sup> CA *rollo* (Vol. VI), Annex "O" of Biotech Petition.

<sup>&</sup>lt;sup>4</sup> <http://www.isaaa.org/inbrief//default.asp> (visited last November 7, 2014).

towards "the sustainable use and management of biodiversity through farmers' control of genetic and biological resources, agricultural production, and associated knowledge."

The University of the Philippines Los Baños (UPLB) is an autonomous constituent of the University of the Philippines (UP), originally established as the UP College of Agriculture. It is the center of biotechnology education and research in Southeast Asia and home to at least four international research and extension centers. Petitioner UPLB Foundation, Inc. (UPLBFI) is a private corporation organized "to be an instrument for institutionalizing a rational system of utilizing UPLB expertise and other assets for generating additional revenues and other resources needed by [UPLB]". Its main purpose is to assist UPLB in "expanding and optimally utilizing its human, financial, and material resources towards a focused thrust in agriculture, biotechnology, engineering and environmental sciences and related academic programs and activities." A memorandum of agreement between UPLBFI and UPLB allows the former to use available facilities for its activities and the latter to designate from among its staff such personnel needed by projects.<sup>5</sup>

Petitioner University of the Philippines (UP) is an institution of higher learning founded in 1908. Under its new charter, Republic Act 9500,<sup>6</sup> approved on April 29, 2008 by President Gloria Macapagal-Arroyo, UP was declared as the national university tasked "to perform its unique and distinctive leadership in higher education and development." Among others, UP was mandated to "serve as a research university in various fields of expertise and specialization by conducting basic and applied research and development, and promoting research in various colleges and universities, and contributing to the dissemination and application of knowledge."<sup>7</sup>

The other individual respondents are Filipino scientists, professors, public officials and ordinary citizens invoking their constitutionally guaranteed right to health and balanced ecology, and suing on their behalf and on behalf of future generations of Filipinos.

# **Factual Background**

Biotechnology is a multi-disciplinary field which may be defined as "any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses."<sup>8</sup> Its many applications include agricultural production, livestock, industrial chemicals and pharmaceuticals.

<sup>&</sup>lt;sup>5</sup> UPLBFI, "History" <<u>http://uplbfi.org/?page\_id=231/</u>> (visited last November 7, 2014).

<sup>&</sup>lt;sup>6</sup> "AN ACT TO STRENGTHEN THE UNIVERSITY OF THE PHILIPPINES AS THE NATIONAL UNIVERSITY."

 $<sup>^{7}</sup>$  RA 9500, Sec. 3(c).

<sup>&</sup>lt;sup>8</sup> Susan R. Barnum, <u>Biotechnology: An Introduction</u> by 1 (1998).

In 1979, President Ferdinand Marcos approved and provided funding for the establishment of the National Institute for Applied Microbiology and Biotechnology (BIOTECH) at UPLB. It is the premier national research and development (R & D) institution applying traditional and modern biotechnologies in innovating products, processes, testing and analytical services for agriculture, health, energy, industry and development.<sup>9</sup>

In 1990, President Corazon C. Aquino signed Executive Order (EO) No. 430 creating the National Committee on Biosafety of the Philippines (NCBP). NCBP was tasked, among others, to "identify and evaluate potential hazards involved in initiating genetic engineering experiments or the introduction of new species and genetically engineered organisms and recommend measures to minimize risks" and to "formulate and review national policies and guidelines on biosafety, such as the safe conduct of work on genetic engineering, pests and their genetic materials for the protection of public health, environment and personnel and supervise the implementation thereof."

In 1991, NCBP formulated the Philippine Biosafety Guidelines, which governs the regulation of the importation or introduction, movement and field release of potentially hazardous biological materials in the Philippines. The guidelines also describe the required physical and biological containment and safety procedures in handling biological materials. This was followed in 1998 by the "*Guidelines on Planned Release of Genetically Manipulated Organisms (GMOs) and Potentially Harmful Exotic Species* (PHES)."<sup>10</sup>

On December 29, 1993, the Convention on Biological Diversity (CBD) came into force. This multilateral treaty recognized that "modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health." Its main objectives, as spelled out in Article 1, are the "conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources."

In January 2000, an agreement was reached on the Cartagena Protocol on Biosafety (Cartagena Protocol), a supplemental to the CBD. The Cartagena Protocol aims "to contribute to ensuring an adequate level of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements."

On May 24, 2000, the Philippines signed the Cartagena Protocol,

<sup>&</sup>lt;sup>9</sup> University of the Philippines Los Baños National Institute of Molecular Biology and Biotechnology, "About Us" <<u>http://biotech.uplb.edu.ph/index.php/en/about-us</u>> (visited last November 7, 2014).

<sup>&</sup>lt;sup>10</sup> The Center for Media and Democracy, "GMOs in the Philippines" <<u>http://www.sourcewatch.org/index.php/GMOs in the Philippines</u>>. (visited last November 7, 2014).

which came into force on September 11, 2003. On August 14, 2006, the Philippine Senate adopted Senate Resolution No. 92 or the "Resolution Concurring in the Ratification of the Cartagena Protocol on Biosafety (CPB) to the UN Convention on Biological Diversity."

On July 16, 2001, President Gloria Macapagal-Arroyo issued a policy statement reiterating the government policy of promoting the safe and responsible use of modern biotechnology and its products as one of several means to achieve and sustain food security, equitable access to health services, sustainable and safe environment and industry development.<sup>11</sup>

In April 2002, the Department of Agriculture (DA) issued DA-Administrative Order (AO) No. 08 providing rules and regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology.

DAO-08-2002 covers the importation or release into the environment of: (1) any plant which has been altered or produced through the use of modern biotechnology if the donor organism, host organism, or vector or vector agent belongs to the genera or taxa classified by the Bureau of Plant Industry (BPI) as meeting the definition of plant pest or is a medium for the introduction of noxious weeds; or (2) any plant or plant product altered through the use of modern biotechnology which may pose significant risks to human health and the environment based on available scientific and technical information.

The country's biosafety regulatory system was further strengthened with the issuance of EO No. 514 (EO 514) on March 17, 2006, "*Establishing the National Biosafety Framework (NBF), Prescribing Guidelines for its Implementation, and Strengthening the NCBP.*" The NBF shall apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making decisions concerning the research, development, handling and use, transboundary movement, release into the environment and management of regulated articles.<sup>12</sup>

EO 514 expressly provides that, unless amended by the issuing departments or agencies, DAO 08-2002, the NCBP Guidelines on the Contained Use of Genetically Modified Organisms, except for provisions on potentially harmful exotic species which were repealed, and all issuances of the Bureau of Food and Drugs Authority (FDA) on products of modern biotechnology, shall continue to be in force and effect.<sup>13</sup>

On September 24, 2010, a Memorandum of Undertaking<sup>14</sup> (MOU) was executed between UPLBFI, ISAAA and UP Mindanao Foundation, Inc.

<sup>&</sup>lt;sup>11</sup> Id. (See also CA *rollo*, pp. 882-884).

<sup>&</sup>lt;sup>12</sup> EO 514, Sec. 2.1.

 <sup>&</sup>lt;sup>13</sup> Id., Sec. 8.
<sup>14</sup> CA *rollo* (Vol. I), pp. 82-84.

(UPMFI), in pursuance of a collaborative research and development project on eggplants that are resistant to the fruit and shoot borer. Other partner agencies involved in the project were UPLB through its Institute of Plant Breeding, Maharastra Hybrid Seed Company (MAHYCO) of India, Cornell University and the Agricultural Biotechnology Support Project II (ABSPII) of USAID.

As indicated in the Field Trial Proposal<sup>15</sup> submitted by the implementing institution (UPLB), the pest-resistant crop subject of the field trial was described as a "bioengineered eggplant." The crystal toxin genes from the soil bacterium *Bacillus thuringiensis (Bt)* were incorporated into the eggplant (*talong*) genome to produce the protein Cry1Ac which is toxic to the target insect pests. Cry1Ac protein is said to be highly specific to *lepidopteran larvae* such as the fruit and shoot borer (FSB), the most destructive insect pest of eggplant.

Under the regulatory supervision of NCBP, a contained experiment was started in 2007 and officially completed on March 3, 2009. The NCBP thus issued a Certificate of Completion of Contained Experiment stating that "During the conduct of the experiment, all the biosafety measures have been complied with and no untoward incident has occurred."<sup>16</sup>

BPI issued Biosafety Permits<sup>17</sup> to UPLB on March 16, 2010 and June 28, 2010. Thereafter, field testing of *Bt talong* commenced on various dates in the following approved trial sites: Kabacan, North Cotabato; Sta. Maria, Pangasinan; Pili, Camarines Sur; Bago Oshiro, Davao City; and Bay, Laguna.

On April 26, 2012, Greenpeace, MASIPAG and individual respondents (Greenpeace, et al.) filed a petition for writ of kalikasan and writ of continuing mandamus with prayer for the issuance of a Temporary Environmental Protection Order (TEPO). They alleged that the Bt talong field trials violate their constitutional right to health and a balanced ecology considering that (1) the required environmental compliance certificate under Presidential Decree (PD) No. 1151 was not secured prior to the project implementation; (2) as a regulated article under DAO 08-2002, Bt talong is presumed harmful to human health and the environment, and there is no independent, peer-reviewed study on the safety of Bt talong for human consumption and the environment; (3) a study conducted by Professor Gilles-Eric Seralini showed adverse effects on rats who were fed Bt corn, while local scientists also attested to the harmful effects of GMOs to human and animal health; (4) Bt crops can be directly toxic to non-target species as highlighted by a research conducted in the US which demonstrated that pollen from Bt maize was toxic to the Monarch butterfly; (5) data from the use of Bt Cry1Ab maize indicate that beneficial insects have increased

<sup>&</sup>lt;sup>15</sup> Id. at 85-86.

<sup>&</sup>lt;sup>16</sup> CA *rollo* (Vol. II), pp. 885-886.

<sup>&</sup>lt;sup>17</sup> Id. at 1058-1064.

mortality when fed on larvae of a maize pest, the corn borer, which had been fed on Bt, and hence non-target beneficial species that may feed on eggplant could be similarly affected; (6) data from China show that the use of Bt crops (Bt cotton) can exacerbate populations of other secondary pests; (7) the built-in pesticides of Bt crops will lead to Bt resistant pests, thus increasing the use of pesticides contrary to the claims by GMO manufacturers; and (8) the 200 meters perimeter pollen trap area in the field testing area set by BPI is not sufficient to stop contamination of nearby non-Bt eggplants because pollinators such as honeybees can fly as far as four kilometers and an eggplant is 48% insect-pollinated. The full acceptance by the project proponents of the findings in the MAHYCO Dossier was strongly assailed on the ground that these do not precisely and adequately assess the numerous hazards posed by Bt talong and its field trial.

Greenpeace, et al. further claimed that the *Bt talong* field test project did not comply with the required public consultation under Sections 26 & 27 of the Local Government Code. A random survey by Greenpeace on July 21, 2011 revealed that ten households living in the area immediately around the Bt talong experimental farm in Bay, Laguna expressed lack of knowledge about the field testing in their locality. The Sangguniang Barangay of Pangasugan in Baybay, Leyte complained about the lack of information on the nature and uncertainties of the Bt talong field testing in their barangay. The Davao City Government likewise opposed the project due to lack of transparency and public consultation. It ordered the uprooting of *Bt* eggplants at the trial site and disposed them strictly in accordance with protocols relayed by the BPI through Ms. Merle Palacpac. Such action highlighted the city government's policy on "sustainable and safe practices." On the other hand, the Sangguniang Bayan of Sta. Barbara, Iloilo passed a resolution suspending the field testing due to the following: lack of public consultation; absence of adequate study to determine the effect of *Bt talong* field testing on friendly insects; absence of risk assessment on the potential impacts of genetically modified (GM) crops on human health and the environment; and the possibility of cross-pollination of Bt eggplants with native species or variety of eggplants, and serious threat to human health if these products were sold to the market.

Greenpeace, et al. argued that this case calls for the application of the precautionary principle, the *Bt talong* field testing being a classic environmental case where scientific evidence as to the health, environmental and socio-economic safety is insufficient or uncertain and preliminary scientific evaluation indicates reasonable grounds for concern that there are potentially dangerous effects on human health and the environment.

The following reliefs are thus prayed for:

a. Upon the filing [of this petition], a Temporary Environment Protection Order should be issued: (i) enjoining public respondents BPI and FPA of the DA from processing for field testing, and registering as herbicidal product, *Bt talong* in the Philippines; (ii) stopping all pending

field testing of *Bt talong* anywhere in the Philippines; and (*iii*) ordering the uprooting of planted *Bt talong* for field trials as their very presence pose significant and irreparable risks to human health and the environment.

b. Upon the filing [of this petition], issue a writ of continuing mandamus commanding:

(*i*) Respondents to submit to and undergo the process of environmental impact statement system under the Environmental Management Bureau;

(*ii*) Respondents to submit independent, comprehensive, and rigid risk assessment, field tests report, regulatory compliance reports and supporting documents, and other material particulars of the *Bt talong* field trial;

*(iii)* Respondents to submit all its issued certifications on public information, public consultation, public participation, and consent of the local government units in the barangays, municipalities, and provinces affected by the field testing of *Bt talong*;

(*iv*) Respondent regulator, in coordination with relevant government agencies and in consultation with stakeholders, to submit an acceptable draft of an amendment of the National Bio-Safety Framework of the Philippines, and DA Administrative Order No. 08, defining or incorporating an independent, transparent, and comprehensive scientific and socio-economic risk assessment, public information, consultation, and participation, and providing for their effective implementation, in accord with international safety standards; and,

(v) Respondent BPI of the DA, in coordination with relevant government agencies, to conduct balanced nationwide public information on the nature of *Bt talong* and *Bt talong* field trial, and a survey of social acceptability of the same.

c. Upon filing [of this petition], issue a writ of *kalikasan* commanding Respondents to file their respective returns and explain why they should not be judicially sanctioned for violating or threatening to violate or allowing the violation of the above-enumerated laws, principles, and international principle and standards, or committing acts, which would result into an environmental damage of such magnitude as to prejudice the life, health, or property of petitioners in particular and of the Filipino people in general.

d. After hearing and judicial determination, to cancel all *Bt talong* field experiments that are found to be violating the abovementioned laws, principles, and international standards; and recommend to Congress curative legislations to effectuate such order.<sup>18</sup>

On May 2, 2012, the Court issued the writ of *kalikasan* against ISAAA, Environmental Management Bureau (EMB)/BPI/Fertilizer and Pesticide Authority (FPA) and UPLB,<sup>18-a</sup> ordering them to make a verified return within a non-extendible period of ten (10) days, as provided in Sec. 8,



<sup>&</sup>lt;sup>18</sup> CA *rollo* (Vol. I), pp. 67-69.

<sup>&</sup>lt;sup>18-a</sup> Id. at 400.

# Rule 7 of the Rules of Procedure for Environmental Cases.<sup>19</sup>

ISAAA, EMB/BPI/FPA, UPLBFI and UPMFI filed their respective verified returns. They all argued that the issuance of writ of *kalikasan* is not proper because in the implementation of the *Bt talong* project, all environmental laws were complied with, including public consultations in the affected communities, to ensure that the people's right to a balanced and healthful ecology was protected and respected. They also asserted that the *Bt talong* project is not covered by the Philippine Environmental Impact Statement (PEIS) Law and that *Bt talong* field trials will not significantly affect the quality of the environment nor pose a hazard to human health. ISAAA contended that the NBF amply safeguards the environment policies and goals promoted by the PEIS Law. On its part, UPLBFI asserted that there is a "plethora of scientific works and literature, peer-reviewed, on the safety of *Bt talong* for human consumption."<sup>20</sup> UPLB, which filed an Answer<sup>21</sup> to the petition before the CA, adopted said position of UPLBFI.

ISAAA argued that the allegations regarding the safety of *Bt talong* as food are irrelevant in the field trial stage as none of the eggplants will be consumed by humans or animals, and all materials that will not be used for analyses will be chopped, boiled and buried following the Biosafety Permit requirements. It cited a 50-year history of safe use and consumption of agricultural products sprayed with commercial *Bt* microbial pesticides and a 14-year history of safe consumption of food and feed derived from *Bt* crops. Also mentioned is the almost 2 million hectares of land in the Philippines which have been planted with *Bt* corn since 2003, and the absence of documented significant and negative impact to the environment and human health. The statements given by scientists and experts in support of the allegations of Greenpeace, et al. on the safety of *Bt* corn was also addressed by citing the contrary findings in other studies which have been per-

On the procedural aspect, ISAAA sought the dismissal of the petition for writ of *kalikasan* for non-observance of the rule on hierarchy of courts and the allegations therein being mere assertions and baseless conclusions of law. EMB, BPI and FPA questioned the legal standing of Greenpeace, et al. in filing the petition for writ of *kalikasan* as they do not stand to suffer any direct injury as a result of the *Bt talong* field tests. They likewise prayed for the denial of the petition for continuing mandamus for failure to state a cause of action and for utter lack of merit.

UPMFI also questioned the legal standing of Greenpeace, et al. for failing to allege that they have been prejudiced or damaged, or their

<sup>&</sup>lt;sup>19</sup> A.M. No. 09-6-8-SC (2010).

<sup>&</sup>lt;sup>20</sup> CA *rollo* (Vol. III), p. 2026.

<sup>&</sup>lt;sup>21</sup> Id. at 2120-2123. UPLB was not served with the writ of *kalikasan* issued by this Court nor furnished with copy of the petition of Greenpeace, et al. Its Answer, adopting the arguments and allegations in the verified return filed by UPLBFI, was filed in the CA. See CA Resolution dated August 17, 2012, id. at 2117-2119.

constitutional rights to health and a balanced ecology were violated or threatened to be violated by the conduct of Bt talong field trials. Insofar as the field trials in Davao City, the actual field trials at Bago Oshiro started on November 25, 2010 but the plants were uprooted by Davao City officials on December 17-18, 2010. There were no further field trials conducted and hence no violation of constitutional rights of persons or damage to the environment, with respect to Davao City, occurred which will justify the issuance of a writ of kalikasan. UPMFI emphasized that under the MOU, its responsibility was only to handle the funds for the project in their trial site. It pointed out that in the Field Trial Proposal, Public Information Sheet, Biosafety Permit for Field Testing, and Terminal Report (Davao City Government) by respondent Leonardo R. Avila III, nowhere does UPMFI appear either as project proponent, partner or implementing arm. Since UPMFI, which is separate and distinct from UP, undertook only the fund management of *Bt talong* field test project the duration of which expired on July 1, 2011, it had nothing to do with any field trials conducted in other parts of the country.

Finally, it is argued that the precautionary principle is not applicable considering that the field testing is only a part of a continuing study being done to ensure that the field trials have no significant and negative impact on the environment. There is thus no resulting environmental damage of such magnitude as to prejudice the life, health, property of inhabitants in two or more cities or provinces. Moreover, the issues raised by Greenpeace, et al. largely involve technical matters which pertain to the special competence of BPI whose determination thereon is entitled to great respect and even finality.

By Resolution dated July 10, 2012, the Court referred this case to the CA for acceptance of the return of the writ and for hearing, reception of evidence and rendition of judgment.<sup>22</sup>

# **CA Proceedings and Judgment**

At the preliminary conference held on September 12, 2012, the parties submitted the following procedural issues: (1) whether or not Greenpeace, et al. have legal standing to file the petition for writ of *kalikasan*; (2) whether or not said petition had been rendered moot and academic by the alleged termination of the *Bt talong* field testing; and (3) whether or not the case presented a justiciable controversy.

Under Resolution<sup>23</sup> dated October 12, 2012, the CA resolved that: (1) Greenpeace, et al. possess the requisite legal standing to file the petition for writ of *kalikasan*; (2) assuming *arguendo* that the field trials have already been terminated, the case is not yet moot since it is capable of repetition yet evading

<sup>&</sup>lt;sup>22</sup> Id. at 2100.

<sup>&</sup>lt;sup>23</sup> 1d. at 2312-2324.

review; and (3) the alleged non-compliance with environmental and local government laws present justiciable controversies for resolution by the court.

The CA then proceeded to hear the merits of the case, adopting the "hot-tub" method wherein the expert witnesses of both parties testify at the same time. Greenpeace, et al. presented the following as expert witnesses: Dr. Ben Malayang III (Dr. Malayang), Dr. Charito Medina (Dr. Medina), and Dr. Tushar Chakraborty (Dr. Chakraborty). On the opposing side were the expert witnesses in the persons of Dr. Reynaldo Ebora (Dr. Ebora), Dr. Saturnina Halos (Dr. Halos), Dr. Flerida Cariño (Dr. Cariño), and Dr. Peter Davies (Dr. Davies). Other witnesses who testified were: Atty. Carmelo Segui (Atty. Segui), Ms. Merle Palacpac (Ms. Palacpac), Mr. Mario Navasero (Mr. Navasero) and Dr. Randy Hautea (Dr. Hautea).

On November 20, 2012, Biotechnology Coalition of the Philippines, Inc. (BCPI) filed an Urgent Motion for Leave to Intervene as Respondent."<sup>24</sup> It claimed to have a legal interest in the subject matter of the case as a broadbased coalition of advocates for the advancement of modern biotechnology in the Philippines.

In its Resolution<sup>25</sup> dated January 16, 2013, the CA denied BCPI's motion for intervention stating that the latter had no direct and specific interest in the conduct of *Bt talong* field trials.

On May 17, 2013, the CA rendered a Decision in favor of Greenpeace, et al., as follows:

WHEREFORE, in view of the foregoing premises, judgment is hereby rendered by us GRANTING the petition filed in this case. The respondents are DIRECTED to:

(a) Permanently cease and desist from further conducting *bt talong* field trials; and

(b) Protect, preserve, rehabilitate and restore the environment in accordance with the foregoing judgment of this Court.

No costs.

# SO ORDERED.<sup>26</sup>

The CA found that existing regulations issued by the DA and the Department of Science and Technology (DOST) are insufficient to guarantee the safety of the environment and health of the people. Concurring with Dr. Malayang's view that the government must exercise precaution "under the realm of public policy" and beyond scientific debate, the appellate court noted the possible irreversible effects of the field trials and the introduction

<sup>&</sup>lt;sup>24</sup> CA rollo (Vol. IV), pp. 2450-2460.

<sup>&</sup>lt;sup>25</sup> Id. at 2864-2871.

<sup>&</sup>lt;sup>26</sup> *Rollo* (G.R. No. 209271), Vol. 1, pp. 157-158.

of *Bt talong* to the market.

After scrutinizing the parties' arguments and evidence, the CA concluded that the precautionary principle set forth in Section 1, Rule 20 of the <u>Rules of Procedure for Environmental Cases</u><sup>27</sup> finds relevance in the present controversy. Stressing the fact that the "over-all safety guarantee of the *bt talong*" remains unknown, the appellate court cited the testimony of Dr. Cariño who admitted that the product is not yet safe for consumption because a safety assessment is still to be done. Again, the Decision quoted from Dr. Malayang who testified that the question of *Bt talong*'s safety demands maximum precaution and utmost prudence, bearing in mind the country's rich biodiversity. Amid the uncertainties surrounding the *Bt talong*, the CA thus upheld the primacy of the people's constitutional right to health and a balanced ecology.

Denying the motions for reconsideration filed by ISAAA, EMB/BPI/FPA, UPLB and UPLBFI, the CA in its Resolution dated September 20, 2013 rejected the argument of UPLB that the appellate court's ruling violated UPLB's constitutional right to academic freedom. The appellate court pointed out that the writ of *kalikasan* originally issued by this Court did not stop research on *Bt talong* but only the particular procedure adopted in doing field trials and only at this time when there is yet no law in the form of a congressional enactment for ensuring its safety and levels of acceptable risks when introduced into the open environment. Since the writ stops the field trials of *Bt talong* as a procedure but does not stop *Bt talong* research, there is no assault on academic freedom.

The CA then justified its ruling by expounding on the theory that introducing a genetically modified plant into our ecosystem is an "ecologically imbalancing act." Thus:

We suppose that it is of universal and general knowledge that an ecosystem is a universe of biotic (living) and non-biotic things interacting as a living community in a particular space and time. In the ecosystem are found specific and particular biotic and non-biotic entities which depend on each other for the biotic entities to survive and maintain life. A critical element for biotic entities to maintain life would be that their populations are in a proper and natural proportion to others so that, in the given limits of available non-biotic entities in the ecosystem, no one population overwhelms another. In the case of the Philippines, it is considered as one of the richest countries in terms of biodiversity. It has so many plants and animals. It also has many kinds of other living things than many countries We do not fully know how all these living things or in the world. creatures interact among themselves. But, for sure, there is a perfect and sound balance of our biodiversity as created or brought about by God out of His infinite and absolute wisdom. In other words, every living creature has been in existence or has come into being for a purpose. So,

<sup>&</sup>lt;sup>27</sup> SECTION 1. Applicability. – When there is lack of full scientific certainty in establishing a causal link between human activity and environmental effect, the court shall apply the precautionary principle in resolving the case before it.

The constitutional right of the people to a balanced and healthful ecology shall be given the benefit of the doubt.

we humans are not supposed to tamper with any one element in this swirl of interrelationships among living things in our ecosystem. Now, introducing a genetically modified plant in our intricate world of plants by humans certainly appears to be an ecologically imbalancing act. The damage that it will cause may be irreparable and irreversible.

At this point, it is significant to note that during the hearing conducted by this Court on November 20, 2012 wherein the testimonies of seven experts were given, Dr. Peter J. Davies (Ph.D in Plant [Physiology]), Dr. Tuskar Chakraborty (Ph.D in Biochemistry and Molecular Biology), Dr. Charito Medina (Ph.D in Environmental Biology), Dr. Reginaldo Ebora (Ph.D in Entomology), Dr. Flerida Cariño (Ph. D in Insecticide Toxicology), Dr. Ben Malayang (Ph.D in Wildland Resource Science) and Dr. Saturnina Halos (Ph.D in Genetics) were in unison in admitting that *bt talong* is an altered plant. x x x

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Thus, it is evident and clear that bt talong is a technology involving the deliberate alteration of an otherwise natural state of affairs. It is designed and intended to alter natural feed-feeder relationships of the eggplant. It is a deliberate genetic reconstruction of the eggplant to alter its natural order which is meant to eliminate one feeder (the borer) in order to give undue advantage to another feeder (the humans). The genetic transformation is one designed to make bt talong toxic to its pests (the targeted organisms). In effect, bt talong kills its targeted organisms. Consequently, the testing or introduction of bt talong into the Philippines, by its nature and intent, is a grave and present danger to (and an assault on) the Filipinos' constitutional right to a balanced ecology because, in any book and by any yardstick, it is an ecologically imbalancing event or phenomenon. It is a willful and deliberate tampering of a naturally ordained feed-feeder relationship in our environment. It destroys the balance of our biodiversity. Because it violates the conjunct right of our people to a balanced ecology, the whole constitutional right of our people (as legally and logically construed) is violated.

Of course, the bt talong's threat to the human health of the Filipinos as of now remains uncertain. This is because while, on one hand, no Filipinos has ever eaten it yet, and so, there is no factual evidence of it actually causing acute or chronic harm to any or a number of ostensibly identifiable perms, on the other hand, there is correspondingly no factual evidence either of it not causing harm to anyone. However, in a study published on September 20, 2012 in "Food and Chemical Toxicology", a team of scientists led by Professor Gilles-Eric Seralini from the University of Caen and backed by the France-based Committee of Independent Research and Information on Genetic Engineering came up with a finding that rats fed with Roundup-tolerant genetically modified corn for two years developed cancers, tumors and multiple organ damage. The seven expert witnesses who testified in this Court in the hearing conducted on November 20, 2012 were duly confronted with this finding and they were not able to convincingly rebut it. That is why we, in deciding this case, applied the precautionary principle in granting the petition filed in the case at bench.

Prescinding from the foregoing premises, therefore, because one conjunct right in the whole Constitutional guarantee is factually and is

undoubtedly at risk, and the other still factually uncertain, the entire constitutional right of the Filipino people to a balanced and healthful ecology is at risk. Hence, the issuance of the writ of kalikasan and the continuing writ of mandamus is justified and warranted.<sup>28</sup> (Additional emphasis supplied.)

## Petitioners' Arguments

G.R. No. 209271

ISAAA advances the following arguments in support of its petition:

Ι

THE COURT OF APPEALS GRAVELY ERRED IN REFUSING TO DISMISS THE *PETITION FOR WRIT OF CONTINUING MANDAMUS AND WRIT OF KALIKASAN* CONSIDERING THAT THE SAME IS ALREADY MOOT AND ACADEMIC.

Π

THE COURT OF APPEALS GRAVELY ERRED IN REFUSING TO DISMISS THE *PETITION FOR WRIT OF CONTINUING MANDAMUS AND WRIT OF KALIKASAN* CONSIDERING THAT THE SAME RAISES POLITICAL QUESTIONS.

- IN SEEKING TO COMPEL THE REGULATORY AGENCIES A. "TO SUBMIT AN ACCEPTABLE DRAFT OF THE AMENDMENT OF THE NATIONAL **BIO-SAFETY** FRAMEWORK OF THE PHILIPPINES. AND DA ADMINISTRATIVE ORDER NO. 08," AND IN PRAYING THAT THE COURT OF APPEALS "RECOMMEND TO CONGRESS CURATIVE LEGISLATIONS," RESPONDENTS SEEK TO REVIEW THE WISDOM OF THE PHILIPPINE REGULATORY SYSTEM FOR GMOS, WHICH THE COURT OF APPEALS IS WITHOUT JURISDICTION TO DO SO.
- B. WORSE, THE COURT OF APPEALS EVEN HELD THAT THERE ARE NO LAWS GOVERNING THE STUDY, INTRODUCTION AND USE OF GMOS IN THE PHILIPPINES AND COMPLETELY DISREGARDED E.O. NO. 514 AND DA-AO 08-2002.

III

THE COURT OF APPEALS GRAVELY ERRED IN REFUSING TO DISMISS THE *PETITION FOR WRIT OF CONTINUING MANDAMUS AND WRIT OF KALIKASAN* CONSIDERING THAT RESPONDENTS FAILED TO EXHAUST ADMINISTRATIVE REMEDIES.

IV

THE COURT OF APPEALS GRAVELY ERRED IN REFUSING TO DISMISS THE PETITION FOR WRIT OF CONTINUING MANDAMUS

<sup>&</sup>lt;sup>28</sup> *Rollo* (G.R. No. 209271), Vol. I, pp. 168-170.

AND WRIT OF KALIKASAN CONSIDERING THAT PRIMARY JURISDICTION OVER THE SAME LIES WITH THE REGULATORY AGENCIES.

#### V

THE COURT OF APPEALS EXHIBITED BIAS AND PARTIALITY AND PREJUDGED THE INSTANT CASE WHEN IT RENDERED THE ASSAILED *DECISION* DATED 17 MAY 2013 AND *RESOLUTION* DATED 20 SEPTEMBER 2013.

#### VI

THE COURT OF APPEALS GRAVELY ERRED IN GRANTING THE WRIT OF KALIKASAN IN FAVOR OF RESPONDENTS.

- A. THE EVIDENCE ON RECORD SHOWS THAT THE PROJECT PROPONENTS OF THE *BT TALONG FIELD TRIALS* COMPLIED WITH ALL ENVIRONMENTAL LAWS, RULES AND REGULATIONS IN ORDER TO ENSURE THAT THE PEOPLE'S RIGHT TO A BALANCED AND HEALTHFUL ECOLOGY ARE PROTECTED AND RESPECTED.
- B. THE EVIDENCE ON RECORD SHOWS THAT THE *BT TALONG* FIELD TRIALS DO NOT CAUSE ENVIRONMENTAL DAMAGE AND DO NOT PREJUDICE THE LIFE, HEALTH AND PROPERTY OF INHABITANTS OF TWO OR MORE PROVINCES OR CITIES.
- C. THE COURT OF APPEALS GRAVELY ERRED IN APPLYING THE PRECAUTIONARY PRINCIPLE IN THIS CASE DESPITE THE FACT THAT RESPONDENTS FAILED TO PRESENT AN IOTA OF EVIDENCE TO PROVE THEIR CLAIM.

#### VII

THE COURT OF APPEALS GRAVELY ERRED IN GRANTING A WRIT OF CONTINUING MANDAMUS AGAINST PETITIONER ISAAA.

#### VIII

THE COURT OF APPEALS' *DECISION* DATED 17 MAY 2013 AND *RESOLUTION* DATED 20 SEPTEMBER 2013 IS AN AFFRONT TO ACADEMIC FREEDOM AND SCIENTIFIC PROGRESS.<sup>29</sup>

#### GR. No. 209276

Petitioners EMB, BPI and FPA, represented by the Office of the Solicitor General (OSG) assails the CA Decision granting the petition for writ of *kalikasan* and writ of continuing mandamus despite the failure of Greenpeace, et al. (respondents) to prove the requisites for their issuance.

<sup>&</sup>lt;sup>29</sup> Id. at 35-37.

Petitioners contend that while respondents presented purported studies that supposedly show signs of toxicity in genetically engineered eggplant and other crops, these studies are insubstantial as they were not published in peer-reviewed scientific journals. Respondents thus failed to present evidence to prove their claim that the *Bt talong* field trials violated environmental laws and rules.

As to the application of the precautionary principle, petitioners asserted that its application in this case is misplaced. The paper by Prof. Seralini which was relied upon by the CA, was not formally offered in evidence. In volunteering the said article to the parties, petitioners lament that the CA manifested its bias towards respondents' position and did not even consider the testimony of Dr. Davies who stated that "Seralini's work has been refuted by International committees of scientists"<sup>30</sup> as shown by published articles critical of Seralini's work.

Petitioners aver that there was no damage to human health since no *Bt talong* will be ingested by any human being during the field trial stage. Besides, if the results of said testing are adverse, petitioners will not allow the release of *Bt talong* to the environment, in line with the guidelines set by EO 514. The CA thus misappreciated the regulatory process as approval for field testing does not automatically mean approval for propagation of the same product. And even assuming that the field trials may indeed cause adverse environmental or health effects, the requirement of unlawful act or omission on the part of petitioners or any of the proponents, was still absent. Respondents clearly failed to prove there was any unlawful deviation from the provisions of DAO 08-2002. The BPI's factual finding on the basis of risk assessment on the *Bt talong* project should thus be accorded respect, if not finality by the courts.

Petitioners likewise fault the CA in giving such ambiguous and general directive for them to protect, preserve, rehabilitate and restore the environment, lacking in specifics which only indicates that there was really nothing to preserve, rehabilitate or restore as there was nothing damaged or adversely affected in the first place. As to the supposed inadequacy and ineffectiveness of existing regulations, these are all political questions and policy issues best left to the discretion of the policy-makers, the Legislative and Executive branches of government. Petitioners add that the CA treads on judicial legislation when it recommended the re-examination of country's existing laws and regulations governing studies and research on GMOs.

# G.R. No. 209301

Petitioner UPLBFI argues that respondents failed to adduce the quantum of evidence necessary to prove actual or imminent injury to them or the environment as to render the controversy ripe for judicial

<sup>&</sup>lt;sup>30</sup> Id. at 81.

determination. It points out that nowhere in the testimonies during the "hottub" presentation of expert witnesses did the witnesses for respondents claim actual or imminent injury to them or to the environment as a result of the *Bt talong* field tests, as they spoke only of injury in the speculative, imagined kind without any factual basis. Further, the petition for writ of *kalikasan* has been mooted by the termination of the field trials as of August 10, 2012.

Finding the CA decision as a judgment *not* based on fact, UPLBFI maintains that by reason of the nature, character, scale, duration, design, processes undertaken, risk assessments and strategies employed, results heretofore recorded, scientific literature, the safeguards and other precautionary measures undertaken and applied, the *Bt talong* field tests did not or could not have violated the right of respondents to a balanced and healthful ecology. The appellate court apparently misapprehended the nature, character, design of the field trials as one for "consumption" rather than for "field testing" as defined in DAO 08-2002, the sole purpose of which is for the "efficacy" of the eggplant variety's resistance to the FSB.

Against the respondents' bare allegations, UPLBFI submits the following "specific facts borne by competent evidence on record" (admitted exhibits)<sup>31</sup>:

- 118. Since the technology's inception 50 years ago, studies have shown that genetically modified crops, including *Bt talong*, significantly reduce the use of pesticides by farmers in growing eggplants, lessening pesticide poisoning to humans.
- 119. Pesticide use globally has decreased in the last [14-15] years owing to the use of insect-resistant genetically modified crops. Moreover, that insect-resistant genetically modified crops significantly reduce the use of pesticides in growing plants thus lessening pesticide poisoning in humans, reducing pesticide load in the environment and encouraging more biodiversity in farms.
- 120. Global warming is likewise reduced as more crops can be grown.
- 121. Transgenic Bacillus thuringensis (Bt) cotton has had a major impact on the Australian cotton industry by largely controlling Lepidopteran pests. To date, it had no significant impact on the invertebrate community studied.
- 122. Feeding on Cry1Ac contaminated non-target herbivores does not harm predatory heteropterans and, therefore, cultivation of Bt cotton may provide an opportunity for conservation of these predators in cotton ecosystems by reducing insecticide use.
- 123. The Bt protein in Bt corn only affects target insects and that Bt corn pollens do not negatively affect monarch butterflies.
- 124. The field trials will not cause "contamination" as feared by the petitioners because flight distance of the pollinators is a deterrent to cross pollination. Studies reveal that there can be no cross

<sup>&</sup>lt;sup>31</sup> *Rollo* (G.R. No. 209301), pp. 48-50, 53-55.

pollination more than a fifty (50) meter distance.

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135. There is a 50 year history of safe use and consumption of agricultural products sprayed with commercial Bt microbial pesticides and a 14 year history of safe consumption of food and feed derived from Bt crops.

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- 140. In separate reviews by the European Food Safety Agency (EFSA) and the Food Standards Australia and New Zealand (FSANZ), the "work" of one Prof. Seralini relied upon by [respondents] was dismissed as "scientifically flawed", thus providing no plausible basis to the proposition that Bt talong is dangerous to public health.
- 141. In a learned treatise by James Clive entitled "Global Status of Commercialized Biotech/GM Crops: 2011," the Philippines was cited to be the first country in the ASEAN region to implement a regulatory system for transgenic crops (which includes DAO 08-[2]002). Accordingly, the said regulatory system has also served as a model for other countries in the region and other developing countries outside of Asia.

On the precautionary principle, UPLBFI contends that the CA misapplied it in this case. The testimonial and documentary evidence of respondents, taken together, do not amount to "scientifically plausible" evidence of threats of serious and irreversible damage to the environment. In fact, since BPI started regulating GM crops in 2002, they have monitored 171 field trials all over the Philippines and said agency has not observed any adverse environmental effect caused by said field trials. Plainly, respondents failed to show proof of "specific facts" of environmental damage of the magnitude contemplated under the <u>Rules of Procedure for Environmental</u> <u>Cases</u> as to warrant sanctions over the *Bt talong* field trials.

Lastly, UPLBFI avers that the *Bt talong* field trial was an exercise of the constitutional liberty of scientists and other academicians of UP, of which they have been deprived without due process of law. Stressing that a possibility is not a fact, UPLBFI deplores the CA decision's pronouncement of their guilt despite the preponderance of evidence on the environmental safety of the field trials, as evident from its declaration that "the over-all safety guarantee of *Bt talong* remains to be still unknown." It thus asks if in the meantime, petitioners must bear the judicial stigma of being cast as violators of the right of the people to a balanced and healthful ecology for an injury or damage *unsubstantiated* by evidence of scientific plausibility.

## G.R. No. 209430

Petitioner UP reiterates UPLBFI's argument that the *Bt talong* field testing was conducted in the exercise of UPLB's academic freedom, which is a *constitutional right*. In this case, there is nothing based on evidence on

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record or overwhelming public welfare concern, such as the right of the people to a balanced and healthful ecology, which would warrant restraint on UPLB's exercise of academic freedom. Considering that UPLB complied with all laws, rules and regulations regarding the application and conduct of field testing of GM eggplant, and was performing such field tests within the prescribed limits of DAO 08-2002, and there being no harm to the environment or prejudice that will be caused to the life, health or property of inhabitants in two or more cities or provinces, to restrain it from performing the said field testing is unjustified.

Petitioner likewise objects to the CA's application of the precautionary principle in this case, in violation of the standards set by the <u>Rules of</u> <u>Procedure for Environmental Cases</u>. It points out that the *Bt* eggplants are not yet intended to be introduced into the Philippine ecosystem nor to the local market for human consumption.

Cited were the testimonies of two expert witnesses presented before the CA: Dr. Navasero who is an entomologist and expert in integrated pest management and insect taxonomy, and Dr. Davies, a member of the faculty of the Department of Plant Biology and Horticulture at Cornell University for 43 years and served as a senior science advisor in agricultural technology to the United States Department of State. Both had testified that based on generally accepted and scientific methodology, the field trial of *Bt* crops do not cause damage to the environment or human health.

Petitioner assails the CA in relying instead on the conjectural statements of Dr. Malayang. It asserts that the CA could not support its Decision and Resolution on the pure conjectures and imagination of one witness. Basic is the rule that a decision must be supported by evidence on record.

## **Respondents' Consolidated Comment**

Respondents aver that *Bt talong* became the subject of public protest in our country precisely because of the serious safety concerns on the impact of *Bt talong* toxin on human and animal health and the environment through *field trial contamination*. They point out that the inherent and potential risks and adverse effects of GM crops are recognized in the Cartagena Protocol and our biosafety regulations (EO 514 and DAO 08-2002). Contamination may occur through pollination, ingestion by insects and other animals, water and soil run off, human error, mechanical accident and even by stealing was inevitable in growing *Bt talong* in an open environment for field trial. Such contamination may manifest even after many years and in places very far away from the trial sites.

Contrary to petitioners' claim that they did not violate any law or regulation, or unlawful omission, respondents assert that, in the face of scientific uncertainties on the safety and effects of *Bt talong*, petitioners

omitted their crucial duties to conduct environmental impact assessment (EIA); evaluate health impacts; get the free, prior and informed consent of the people in the host communities; and provide remedial and liability processes in the approval of the biosafety permit and conduct of the field trials in its five sites located in five provinces. These omissions have put the people and the environment at serious and irreversible risks.

Respondents cite the numerous studies contained in "Adverse Impacts of Transgenic Crops/Foods: A Compilation of Scientific References with Abstracts" printed by Coalition for a GMO-Free India; a study on Bt corn in the Philippines, "Socio-economic Impacts of Genetically Modified Corn in the Philippines" published by MASIPAG in 2013; and the published report of the investigation conducted by Greenpeace, "White Corn in the Philippines: Contaminated with Genetically Modified Corn Varieties" which revealed positive results for samples purchased from different stores in Sultan Kudarat, Mindanao, indicating that they were contaminated with GM corn varieties, specifically the herbicide tolerant and Bt insect resistant genes from Monsanto, the world's largest biotech company based in the US.

To demonstrate the health hazards posed by *Bt* crops, respondents cite the following sources: the studies of Drs. L. Moreno-Fierros, N. Garcia, R. Gutierrez, R. Lopez-Revilla, and RI Vazquez-Padron, all from the Universidad Nacional Autonoma de Mexico; the conclusion made by Prof. Eric-Gilles Seralini of the University of Caen, France, who is also the president of the Scientific Council of the Committee for Independent Research and Information on Genetic Engineering (CRIIGEN), in his review, commissioned by Greenpeace, of Mahyco's data submitted in support of the application to grow and market *Bt* eggplant in India; and the medical interpretations of Prof. Seralini's findings by Filipino doctors Dr. Romeo Quijano of the University of the Philippines-Philippine General Hospital and Dr. Wency Kiat, Jr. of St. Luke's Medical Center (Joint Affidavit).

According to respondents, the above findings and interpretations on serious health risks are strengthened by the findings of a review of the safety claims in the MAHYCO Dossier authored by Prof. David A. Andow of the University of Minnesota, an expert in environmental assessment in crop science. The review was made upon the request in 2010 of His Honorable Shri Jairam Ramesh of the Ministry of Environment and Forests of India, where MAHYCO is based. MAHYCO is the corporate creator and patent owner of the *Bt* gene inserted in *Bt talong*.

The conclusions of health hazards from the above studies were summarized<sup>32</sup> by respondents, as follows:

Studies/interpretation by	Conclusion/interpretation	
Drs. L. Moreno-Fierros, N. Garcia, R. Gutierrez, R.	For <i>Bt</i> modified crops (like <i>Bt</i> talong), there is concern over its potential	

<sup>32</sup> *Rollo* (G.R. No. 209271), Vol. IX, pp. 4111-4112. Citations omitted.

Lopez-Revilla, and RI Vazquez-Padron	allergenicity. Cry1Ac (the gene inserted in <i>Bt</i> talong) protoxin is a potent immunogen (triggers immune response); the protoxin is immunogenic by both the intraperitoneal (injected) and intragastric (ingested) route; the immune response to the protoxin is both systemic and mucosal; and Cry1Ac protoxin binds to surface proteins in the mouse small intestine. These suggest that <b>extreme caution is required</b> in the use of Cry1Ac in food crops.
Prof. Eric-Gilles Seralini	His key findings showed statistical significant differences between group of animals fed GM and non-GM eggplant that raise food safety concerns and warrant further investigation.
Dr. Romeo Quijano & Dr. Wency Kiat, Jr.	Interpreting Prof. Seralini's findings, the altered condition of rats symptomatically indicate hazards for human health.
Prof. David A. Andow	The MAHYCO dossier is inadequate to support the needed environmental risk assessment; MAHYCO's food safety assessment does not comply with international standards; and that MAHYCO relied on dubious scientific assumptions and disregarded real environmental threats.

As to environmental effects, respondents said these include the potential for living modified organisms, such as *Bt talong* tested in the field or released into the environment, to contaminate non-GM traditional varieties and other wild eggplant relatives and turn them into novel pests, outcompete and replace their wild relatives, increase dependence on pesticides, or spread their introduced genes to weedy relatives, potentially creating superweeds, and kill beneficial insects.

Respondents then gave the following tabulated summary<sup>33</sup> of *field trial contamination cases* drawn from various news reports and some scientific literature submitted to the court:

What happened	Impact	How did it occur
traces of three varieties of unapproved genetically	eventually agreed to a \$750m US dollar	Field trials were conducted between the mid-1990s and early 2000s. The US Department of Agriculture
Bayer Crop Science were found in US rice exports	claims with about 11,000	(USDA) reported these field trials were the likely

<sup>&</sup>lt;sup>33</sup> Id. at 4112-4115. Citations omitted.

worldwide.	The total costs to the rice industry are likely to have been over \$1bn worldwide.	contamination between the modified rice and conventional varietics. However, it was unable to conclude [if it] was caused by gene flow (cross pollination) or mechanical mixing.
In 2009, unauthorised GElinseed (also known as 'flax') produced by a public research institution was discovered in food in several EU countries, having been imported from Canada.	Canada lost exports to its main European market worth hundreds of millions of dollars and non-GElinseed farmers have faced huge costs and market losses.	In the late 1980s a public research institution, the Crop Development Centre in Saskatoon, Saskat- chewan, developed a GElinseed variety FP96— believed to be the origin of the contamination.
During 2004, the Thai government found that papaya samples from 85 farms were genetically modified. The contamination continued into 2006 and it is likely that the GE contamination reached the food chain.	Exports of papaya to Europe have been hit because of fears that contamination could have spread. The Thai government said it was taking action to destroy the contaminated trees.	GEpapaya is not grown commercially in Thailand, so it was clear that the contamination originated from the government station experimentally breeding GE papaya trees. Tests that showed that one third of papaya orchards tested in the eastern province of Rayong and the north-eastern provinces of Mahasarakham, Chaiyaphum and Kalasinhad GE- contaminated papaya seeds in July 2005. The owners said that a research station gave them the seeds.
In the US in 2002, seeds from a GEmaize pharma- crop containing a pig vaccine grew independently among normal soybean crops.	Prodigene, the company responsible, was fined \$3m for tainting half a million bushels of soya bean with a trial vaccine used to prevent stomach upsets in piglets. Prodigene agreed to pay a fine of \$250,000 and to repay the government for the cost of incinerating the soya bean that had been contaminated with genetically altered corn.	Seeds from the GEmaize crop sprouted voluntarily in the following season.
In 2005, Greenpeace discovered that GE rice seeds had been illegally sold in Hubei, China. Then, in 2006, GE rice event Bt63 was found in baby food sold in Beijing, Guangzhou and Hong Kong. In late 2006, GErice Bt63 was found to be contaminating exports	The European Commission adopted emergency measures (on 15 August 2008) to require compulsory certification for the imports of Chinese rice products that could contain the unauthorised GE rice Bt63. The Chinese government	The source of the contamination appears to have been the result of illegal planting of GEseeds. Seed companies in China found to have sold GErice hybrid seed to farmers operated directly under the university developing GM rice. It has been reported that the key scientist sat on

in Austria, France, the UK and Germany. In 2007 it was again found in EU imports to Cyprus, Germany, Greece, Italy and Sweden.	took several measures to try to stop the contamination, which included punishing seed companies, confiscating GEseed, destroying GErice grown in the field and tightening control over the food chain.	the board of one GEseed company.
In 2005, the European Commission announced that illegal Bt10 GEmaize produced by GEseed company Syngenta had entered the European food chain. The GEmaize Bt10 contains a marker gene that codes for the widely- used antibiotic ampicillin, while the Bt11 does not. According to the international Codex Alimentarius Guideline for Conduct of Food Safety Assessment of Foods Derived from Recombinant- DNA:Plants: 'Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods' because it increases the risk of antibiotic resistance in the population.	The European Commission blocked US grain import unless they could be guaranteed free of Bt10. The USDA fined Syngenta \$375,000. There are no figures for the wider costs.	The contamination arose because Syngenta's quality control procedures did not differentiate between Bt10 and its sister commercial line, Bt11. As a result, the experimental and substantially different Bt10 line was mistakenly used in breeding. The error was detected four years later when one of the seed companies developing Bt11 varieties adopted more sophisticated analytical techniques.

Refuting the claim of petitioners that contamination is nil or minimal because the scale of *Bt talong* field trial is isolated, restricted and that "each experiment per site per season consists of a maximum net area planted to *Bt* eggplant of between 480 sq. meters to 1,080 sq. meters,"<sup>34</sup> respondents emphasize that as shown by the above, contamination knows no size and boundaries in an open environment.

With regard to the required geographical coverage of environmental damage for the issuance of writ of *kalikasan*, respondents assert that while the *Bt talong* field trials were conducted in only five provinces, the environmental damage prejudicial to health extends beyond the health of the present generation of inhabitants in those provinces.

On petitioners' insistence in demanding that those who allege injury must prove injury, respondents said that biosafety evidence could not be readily contained in a *corpus delicti* to be presented in court. Indeed, the

<sup>&</sup>lt;sup>34</sup> *Rollo* (G.R. No. 209271), Vol. IX, p. 4115.

inherent and potential risks and adverse effects brought by GMOs are not like dead bodies or wounds that are immediately and physically identifiable to an eyewitness and which are resulting from a common crime. Precisely, this is why the Cartagena Protocol's foundation is on the precautionary principle and development of sound science and its links, to social and human rights law through its elements of public awareness, public participation and public right to know. This is also why the case was brought under the <u>Rules of Procedure for Environmental Cases</u> and not under ordinary or other rules, on the grounds of violation of the rights of the Filipino people to health, to a balanced and healthful ecology, to information on matters of national concern, and to participation. The said <u>Rules</u> specifically provides that the appreciation of evidence in a case like this must be guided by the precautionary principle.

As to the non-exhaustion of administrative remedies being raised by petitioners as ground to dismiss the present petition, respondents said that nowhere in the 22 sections of DAO 08-2002 that one can find a remedy to appeal the decision of the DA issuing the field testing permit. What is only provided for is a mechanism for applicants of a permit, not stakeholders like farmers, traders and consumers to appeal a decision by the BPI-DA in case of denial of their application for field testing. Moreover, DAO 08-2002 is silent on appeal after the issuance of the biosafety permit.

Finally, on the propriety of the writ of continuing mandamus, respondents argue that EO 514 explicitly states that the application of biosafety regulations shall be made in accordance with *existing laws* and the guidelines therein provided. Hence, aside from risk assessment requirement of the biosafety regulations, pursuant to the PEISS law and Sections 12 and 13 of the <u>Philippine Fisheries Code of 1998</u>, an environmental impact statement (EIS) is required and an environmental compliance certificate (ECC) is necessary before such *Bt* crop field trials can be conducted.

# **Petitioners' Replies**

#### G.R. No. 209271

ISAAA contends that the Precautionary Principle and the <u>Rules of</u> <u>Procedure for Environmental Cases</u> do not empower courts to adjudicate a controversy that is moot and academic. It points out that respondents failed to satisfy all the requirements of the exception to the rule on actual controversies. The Biosafety Permit is valid for only two years, while the purported stages in the commercialization, propagation and registration of *Bt talong* still cannot confer jurisdiction on the CA to decide a moot and academic case.

As to the propriety of the writ of continuing mandamus, ISAAA maintains that public petitioners do not have "mandatory" and "ministerial"

duty to re-examine and reform the biosafety regulatory system, and to propose curative legislation. The law (EO 514) cited by respondents does not impose such duty on public petitioners. As for the Cartagena Protocol, it laid down a procedure for the evaluation of the Protocol itself, not of the Philippine biosafety regulatory system. ISAAA stresses that the CA is without jurisdiction to review the soundness and wisdom of existing laws, policy and regulations. Indeed, the questions posed by the respondents are political questions, which must be resolved by the executive and legislative departments in deference to separation of powers.

On the availability of administrative remedies, ISAAA asserts that respondents are mistaken in saying that these are limited to appeals. The concerned public may invoke Section 8 (G) of DAO 08-2002 which grants them the right to submit their written comments on the BPI regarding the field testing permits, or Section 8 (P) for the revocation and cancellation of a field testing permit. Respondents' failure to resort to the internal mechanisms provided in DAO 08-2002 violates the rule on exhaustion of administrative remedies, which warrants the dismissal of respondents' petition.

ISAAA points out that under Section 7 of DAO 08-2002, the BPI is the approving authority for field testing permits, while under Title IV, Chapter 4, Section 19 of the <u>Administrative Code of 1987</u>, the DA through the BPI, is responsible for the production of improved planting materials and protection of agricultural crops from pests and diseases. In bypassing the administrative remedies available, respondents not only failed to exhaust a less costly and speedier remedy, it also deprived the parties of an opportunity to be heard by the BPI which has primary jurisdiction and knowledgeable on the issues they sought to raise.

Rejecting the scientific data presented by the respondents, petitioners found Annex "A" of the Consolidated Comment as irrelevant because it was not formally offered in evidence and are hearsay. Majority of those records contain incomplete information and none of them pertain to the *Bt talong*. Respondents likewise presented two misleading scientific studies which have already been discredited: the 2013 study by B.P. Mezzomo, et al. and the study by Prof. Seralini in 2012. Petitioner notes that both articles have been withdrawn from publication.

ISAAA further describes Annex "A" as a mere compilation of records of flawed studies with only 126 usable records out of the 338 records. In contrast, petitioner cites the work of Nicolia, A., A. Manzo, F. Veronesi, and D. Rosellini, entitled "An overview of the last 10 years of genetically engineered crop safety research." The authors evaluated 1,783 scientific records of GE crop safety research papers, reviews, relevant opinions and scientific reports from 2002-2012. Their findings concluded that "the scientific research conducted so far has not detected any significant hazards directly connected with the use of GE crops." In the article "Impacts of GM *crops on biodiversity*," in which scientific findings concluded that "[o]verall, x x x currently commercialized GM crops have reduced the impacts of agriculture on biodiversity, through enhanced adoption of conservation tillage practices, reduction of insecticide use and use of more environmentally benign herbicides and increasing yields to alleviate pressure to convert additional land into agricultural use."

Debunking the supposed inherent risks and potential dangers of GMOs, petitioner cites EUR 24473 – A decade of EU-funded GMO research (2001-2010), concluded from more than 130 research projects, covering a period of 25 years of research, and involving more than 500 independent research groups, that "biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies." Another article cited is "Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review" which states that scientific findings show that GM crops do not suggest any health hazard, and are nutritionally equivalent to their non-GM counterparts and can be safely used in food and feed.

Addressing the studies relied upon by respondents on the alleged adverse environmental effects of GM crops, petitioner cites the article "Ecological Impacts of Genetically Modified Crops: Ten Years of Field Research and Commercial Cultivation" which concluded that "[T]he data available so far provide no scientific evidence that the cultivation of the presently commercialized GM crops has caused environmental harm." A related article, "A Meta-Analysis of Effects of Bt Cotton and Maize on Nontarget Invertebrates," states that scientific findings show that non-target insects are more abundant in GM crop fields like Bt cotton and Bt maize fields than in non-GM crops that are sprayed with insecticides.

The two tables/summaries of studies submitted by respondents are likewise rejected by ISAAA, which presented the following comments and criticisms on each of the paper/article cited, thus:

With respect to the study made by L. Moreno-Fierros, *et al.*, the same should be rejected considering that this was not formally offered as evidence by respondents. Hence, the same may not be considered by the Honorable Court. (Section 34, Rule 132 of the Rules of Court; *Heirs of Pedro Pasag v. Spouses Parocha, supra*)

Further, the study is irrelevant and immaterial. The Cry1Ac protein used in the study was from engineered *E.coli* and may have been contaminated by endotoxin. The Cry1Ac used in the study was **not** from *Bt talong*. Hence, respondents' attempt to extrapolate the interpretation and conclusion of this study to *Bt talong* is grossly erroneous and calculated to mislead and deceive the Honorable Court.

Moreover, in a review by Bruce D. Hammond and Michael S. Koch of the said study by L. Moreno-Fierros, *et al.*, which was published in an article entitled *A Review of the Food Safety of Bt Crops*, the authors reported that Adel-Patient, *et al.* tried and failed to reproduce the results

obtained by the study made by L. Moreno-Fierros, *et al.* The reason is because of endotoxin contamination in the preparation of the Cry1Ac protein. Further, when purified Cry protein was injected to mice through intra-gastric administration, there was no impact on the immune response of the mice.

In addition, the biological relevance of the study made by L. Moreno-Fierros, *et al.* to assessing potential health risks from human consumption of foods derived from Bt crops can be questioned because the doses tested in mice is irrelevant to human dietary exposure, i.e., the doses given were "far in excess of potential human intakes".

With respect to the interpretation made by Prof. Eric-Gilles Seralini, the same is not entitled to any weight and consideration because his sworn statement was not admitted in evidence by the Court of Appeals.

Further, Seralini's findings are seriously flawed. Food safety experts explained the differences observed by Seralini's statistical analysis as examples of <u>random biological variation</u> that occurs when many measurements are made on test animals, and which have no biological significance. Hence, there are no food safety concerns. Further, petitioner ISAAA presented in evidence the findings of regulatory bodies, particularly the EFSA and the FSANZ, to controvert Seralini's findings. The EFSA and the FSANZ rejected Seralini's findings because the same were based on <u>**questionable statistical procedure**</u> employed in maize in 2007.

In addition, it must be pointed out that the Indian regulatory authority, GEAC, has <u>not</u> revised its earlier decision approving the safety of Bt eggplant notwithstanding the findings of Seralini's assessment. In effect, Seralini's findings and interpretation were rejected by the Indian regulatory agency.

With respect to the interpretation made by Drs. Romeo Quijano and Wency Kiat, the same is not entitled to any weight and consideration because the Court of Appeals did not admit their sworn statement. Further, Drs. Romeo Quijano and Wency Kiat sought to interpret a seriously flawed study, making their sworn statements equally flawed.

In an attempt to mislead the Honorable Court, respondents tried to pass off the review of Prof. David A. Andow as the work of the National Academy of Sciences of the USA. Such claim is grossly misleading. In truth, as Prof. David A. Andow indicated in the preface, the <u>report was</u> <u>produced upon the request of Aruna Rodriguez, a known anti-GM</u> <u>campaigner</u>.

Further, Prof. David A. Andow's review did not point to any negative impact to the environment of Mahyco's *Bt brinjal* (Indian name for *Bt talong*) during the entire period of conduct of field trials all over the country. He concluded, however, that the dossier is inadequate for ERA. This is perplexing considering this is the same gene that has been used in *Bt* cotton since 1996. Scores of environmental and food safety risk assessment studies have been conducted and there is wealth of information and experience on its safety. Various meta-analyses indicate that delaying the use of this already effective *Bt brinjal* for managing this devastating pest only ensures the continued use of frequent insecticide sprays with

proven harm to human and animal health and the environment and loss of potential income of resource-poor small farmers.

Notwithstanding the conclusions of Prof. David A. Andow, to date, it is worth repeating that the Indian regulatory body, GEAC, has not revised its earlier decision approving the safety of *Bt* eggplant based on the recommendation of two expert committees which found the Mahyco regulatory dossier compliant to the ERA stipulated by the Indian regulatory body. In effect, like Seralini, Andow's findings and interpretation were also rejected by the Indian regulatory agency.<sup>35</sup>

Petitioner reiterates that the PEIS law does not apply to field testing of *Bt talong* and the rigid requirements under Section 8 of DAO 08-2002 already takes into consideration any and all significant risks not only to the environment but also to human health. The requirements under Sections 26 and 27 of the Local Government Code are also inapplicable because the field testing is not among the six environmentally sensitive activities mentioned therein; the public consultations and prior local government unit (LGU) approval, were nevertheless complied with. Moreover, the field testing is an exercise of academic freedom protected by the Constitution, the possibility of *Bt talong*'s commercialization in the future is but incidental to, and fruit of the experiment.

As to the "commissioned studies" on Bt corn in the Philippines, petitioner asserts that these are inadmissible, hearsay and unreliable. These were not formally offered in evidence; self-serving as it was conducted by respondents Greenpeace and MASIPAG themselves; the persons who prepared the same were not presented in court to identify and testify on its findings; and the methods used in the investigation and research were not scientific. Said studies failed to establish any correlation between Bt corn and the purported environmental and health problems.

#### G.R. No. 209276

EMB, BPI and FPA joined in objecting to Annex "A" of respondents' consolidated comment, for the same reasons given by ISAAA. They noted that the affidavit of Prof. Seralini, and the joint affidavit of Dr. Kiat and Dr. Quijano were denied admission by the CA. Given the failure of the respondents to present scientific evidence to prove the claim of environmental and health damages, respondents are not entitled to the writ of *kalikasan*.

Public petitioners reiterate that in issuing the Biosafety Permits to UPLB, they made sure that the latter complied with all the requirements under DAO 08-2002, including the conduct of risk assessment. The applications for field testing of *Bt talong* thus underwent the following procedures:

<sup>&</sup>lt;sup>35</sup> Id., Vol. XI, pp. 5715-5717.

Having completed the contained experiment on the *Bt talong*, UPLB filed with BPI several applications for issuance of Biosafety Permits to conduct multi-locational field testing of *Bt talong*. Even before the proponent submitted its application, petitioner BPI conducted a consultative meeting with the proponent to enlighten the latter about the requirements set out by DAAO No. 8.

Thereafter, petitioner BPI evaluated UPLB's applications *vis-à-vis* the requirements of Section 8 of DA AO No. 8 and found them to be sufficient in form and substance, *to wit*:

*First.* The applications were in the proper format and contained all of the relevant information as required in Section 8 (A) (1) of DA AO No. 08.

Second. The applications were accompanied by a (i) Certification from the NCBP that the regulated article has undergone satisfactory testing under contained conditions in the Philippines, (ii) technical dossier consisting of scientific literature and other scientific materials relied upon by the applicant showing that *Bt talong* will not pose any significant risks to human health and the environment, and (iii) copy of the proposed PIS for Field Testing as prescribed by Section 8 (A) (2) of DA AO No. 08; and

*Third.* The applications contained the Endorsement of proposal for field testing, duly approved by the majority of all the members of the respective Institutional Biosafety Committees (**IBC**), including at least one community representative, as required by Section 8 (E) of DA AO No. 08.

a. Under Sections 1 (L) and 8 (D) of DA AO No. 08, the IBC is responsible for the initial evaluation of the risk assessment and risk management strategies of the applicant for field testing using the NCBP guidelines. The IBC shall determine if the data obtained under contained conditions provide sufficient basis to authorize the field testing of the regulated article. In making the determination, the IBC shall ensure that field testing does not pose any significant risks to human health and the environment. The IBC may, in its discretion, require the proponent to perform additional experiments under contained conditions before acting on the field testing proposal. The IBC shall either endorse the field testing proposal to the BPI or reject it for failing the scientific risk assessment.

b. Relatedly, UPLB had previously complied with Section 1 (L) of DA AO No. 08 which requires an applicant for field testing to establish an IBC in preparation for the field testing of a regulated article and whose membership has been approved by the BPI. Section 1 (L) of DA AO No. 08, requires that the <u>IBC</u> shall be composed of at least five (5) members, three (3) of whom shall be designated as "scientist-members" who shall possess scientific and technological knowledge and expertise sufficient to enable them to evaluate and monitor properly any work of the applicant relating to the field testing of a regulated article, and the other members are designated as "community representatives" who are in a position to represent the interest of the communities where the field testing is to be conducted.

Before approving the intended multi-locations [field] trials, petitioner BPI, pursuant to Section 8 (F) of DA AO No. 08, forwarded the complete documents to three (3) independent Scientific Technical Review Panel (STRP) members. Pending receipt of the risk assessment reports of the three STRP members, petitioner BPI conducted its own risk assessment.

Thereafter, on separate occasions, petitioner BPI received the final risk assessment reports of the three STRP members recommending the grant of Biosafety Permits to UPLB after a thorough risk assessment and evaluation of UPLB's application for field trial of *Bt talong*.

Meanwhile, petitioner BPI received from UPLB proofs of posting of the **PISs** for Field Testing in each concerned barangays and city/municipal halls of the localities having jurisdiction over its proposed field trial sites.

In addition to the posting of the **PISs** for Field Testing, petitioner BPI conducted consultative meetings and public seminars in order to provide public information and in order to give an opportunity to the public to raise their questions and/or concerns regarding the *Bt talong* field trials.<sup>36</sup>

Petitioners maintain that Sections 26 and 27 of the Local Government Code are inapplicable to the *Bt talong* field testing considering that its subject matter is not mass production for human consumption. The project entails only the planting of *Bt* eggplants and cultivation in a controlled environment; indeed, the conduct of a field trial is not a guarantee that the *Bt talong* will be commercialized and allowed for cultivation in the Philippines.

On the non-exhaustion of administrative remedies by the respondents, petitioners note that during the period of public consultation under DAO 08-2002, it is BPI which processes written comments on the application for field testing of a regulated article, and has the authority to approve or disapprove the application. Also, under Section 8 (P), BPI may revoke a biosafety permit issued on the ground of, among others, receipt of new information that the field testing poses significant risks to human health and the environment. Petitioners assert they were never remiss in the performance of their mandated functions, as shown by their immediate action with respect to the defective certification of posting of PIS in Kabacan, North Cotabato. Upon receiving the letter-complaint on January 24, 2012, BPI readily ordered their re-posting. The same incident occurred in Davao City, where BPI refused to lift the suspension of biosafety permits until "rectification of the conditions for public consultation is carried out."

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<sup>&</sup>lt;sup>36</sup> Id. at 5835-5837.

To underscore respondents' blatant disregard of the administrative process, petitioners refer to documented instances when respondents took the law in their own hands. Greenpeace barged into one of the *Bt talong* field trial sites at Bgy. Paciano Rizal, Bay, Laguna, forcibly entered the entrance gate through the use of a bolt cutter, and then proceeded to uproot the experimental crops without permission from BPI or the project proponents. Petitioners submit that the non-observance of the doctrine of exhaustion of administrative remedies results in lack of cause of action, one of the grounds under the <u>Rules of Court</u> justifying the dismissal of a complaint.

#### **Petitions-in-Intervention**

# Crop Life Philippines, Inc. (Crop Life)

Crop Life is an association of companies which belongs to a global (Crop Life International) as well as regional (Crop Life Asia) networks of member-companies representing the plant science industry. It aims to "help improve the productivity of Filipino farmers and contribute to Philippine food security in a sustainable way." It supports "innovation, research and development in agriculture through the use of biology, chemistry, biotechnology, plant breeding, other techniques and disciplines."

On procedural grounds, Crop Life assails the CA in rendering judgment in violation of petitioners' right to due process because it was prevented from cross-examining the respondents' expert witnesses and conducting re-direct examination of petitioners' own witnesses, and being an evidently partial and prejudiced court. It said the petition for writ of *kalikasan* should have been dismissed outright as it effectively asks the Court to engage in "judicial legislation" to "cure" what respondents feel is an inadequate regulatory framework for field testing of GMOs in the Philippines. Respondents also violated the doctrine of exhaustion of administrative remedies, and their petition is barred by estoppel and laches.

Crop Life concurs with the petitioners in arguing that respondents failed to specifically allege and prove the particular environmental damage resulting from the *Bt talong* field testing. It cites the scientific evidence on record and the internationally accepted scientific standards on GMOs and GMO field testing, and considering the experience of various countries engaged in testing GMOs, telling us that GMO field testing will not damage the environment nor harm human health and more likely bring about beneficial improvements.

Crop Life likewise assails the application of the Precautionary Principle by the CA which erroneously equated field testing of *Bt talong* with *Bt talong* itself; failed to recognize that in this case, there was no particular environmental damage identified, much less proven; relied upon the article of Prof. Seralini that was retracted by the scientific journal which published it; there is no scientific uncertainty on the adverse effects of GMOs to environment and human health; and did not consider respondents' failure to prove the insufficiency of the regulatory framework under DAO 08-2002.

On policy grounds, Crop Life argues that requiring all organisms/plants to be considered absolutely safe before any field testing may be allowed, would result in permanently placing the Philippines in the shadows of more developed nations (whose economies rest on emerging markets importing products from them). It points out that the testing of *Bt* talong specifically addresses defined problems such as the need to curb the misuse of chemical pesticides.

# Biotechnology Coalition of the Philippines (BCP)

BCP is a non-stock, non-profit membership association, a broad-based multi-sectoral coalition of advocates of modern biotechnology in the Philippines.

Reversal of the CA ruling is sought on the following grounds:

#### I.

THE COURT OF APPEALS ERRED IN TAKING COGNIZANCE OF THE *KALIKASAN* PETITION IN THE ABSENCE OF ANY JUSTICIABLE CONTROVERSY.

II.

EXISTING LEGISLATION AND ADMINISTRATIVE REGULATIONS ALREADY INCORPORATE THE PRECAUTIONARY PRINCIPLE AS A GUIDING PRINCIPLE IN RELATION TO GMOS.

III.

THE CA DECISION AND THE CA RESOLUTION IMPROPERLY APPLIED THE PRECAUTIONARY PRINCIPLE.

#### IV.

THE COURT OF APPEALS' ERRONEOUS APPLICATION OF THE PRECAUTIONARY PRINCIPLE, IF SUSTAINED, WOULD PRODUCE A DANGEROUS PRECEDENT THAT IS ANTI-PROGRESS, ANTI-TECHNOLOGY AND, ULTIMATELY, DETRIMENTAL TO THE FILIPINO PEOPLE.<sup>37</sup>

BCP argued that in the guise of taking on a supposed justiciable controversy, despite the *Bt talong* field trials having been terminated, the CA entertained a prohibited collateral attack on the sufficiency of DAO 08-2002. Though not invalidating the issuance, which the CA knew was highly improper, it nonetheless granted the petition for writ of *kalikasan* on the theory that "mere biosafety regulations" were insufficient to guarantee the

<sup>&</sup>lt;sup>37</sup> *Rollo* (G.R. No. 209271), Vol. V, pp. 2386-2387.

safety of the environment and the health of the people.

Also reiterated were those grounds for dismissal already raised by the petitioners: failure to exhaust administrative remedies and finality of findings of administrative agencies.

BCP further asserts that the application of a *stringent* "risk assessment" process to regulated articles prior to any release in the environment for field testing mandated by AO No. 8 sufficiently complies with the rationale behind the development of the precautionary principle. By implementing the stringent provisions of DAO 08-2002, in conjunction with the standards set by EO 514 and the NBF, the government preemptively intervenes and takes precautionary measures prior to the release of any potentially harmful substance or article into the environment. Thus, any potential damage to the environment is prevented or negated. Moreover, international instruments ratified and formally adopted by the Philippines (CBD and the Cartagena Protocol) provide additional support in the proper application of the precautionary principle in relation to GMOs and the environment.

On the "misapplication" by the CA of the precautionary principle, BCP explains that the basic premise for its application is the existence of threat of harm or damage to the environment, which must be backed by a reasonable scientific basis and not based on mere hypothetical allegation, before the burden of proof is shifted to the public respondents in a petition for writ of *kalikasan*. Here, the CA relied heavily on its observation that "... field trials of *bt* talong could not be declared...as safe to human health and to ecology, with full scientific certainty, being an alteration of an otherwise natural state of affairs in our ecology" and "introducing a genetically modified plant in our intricate world of plants by humans certainly appears to be an ecologically imbalancing act," among others. BCP finds that this pronouncement of the CA constitutes an indictment not only against *Bt talong* but against all GMOs as well. The appellate court's opinion is thus highly speculative, sweeping and laced with obvious bias.

There being no credible showing in the record that the conduct of *Bt* talong field trials entails real threats and that these threats pertain to serious and irreversible damage to the environment, BCP maintains that the precautionary principle finds no application in this case. While Rule 20 of the <u>Rules of Procedure for Environmental Cases</u> states that "[w]hen there is a lack of full scientific certainty in establishing a causal link between human activity and environmental effect, the court shall apply the precautionary principle in resolving the case before it," the CA failed to note that the element of lack of full scientific certainty pertains merely to the causal link between human activity and environmental effect, and not the existence or risk of environmental effect.

BCP laments that sustaining the CA's line of reasoning would produce

a chilling effect against technological advancements, especially those in agriculture. Affirming the CA decision thus sets a dangerous precedent where any and all human activity may be enjoined based on unfounded fears of possible damage to health or the environment.

# Issues

From the foregoing submissions, the Court is presented with the following issues for resolution:

- 1. Legal standing of respondents;
- 2. Mootness;
- 3. Violation of the doctrines of primary jurisdiction and exhaustion of administrative remedies;
- 4. Application of the law on environmental impact statement/assessment on projects involving the introduction and propagation of GMOs in the country;
- 5. Evidence of damage or threat of damage to human health and the environment in two or more provinces, as a result of the *Bt talong* field trials;
- 6. Neglect or unlawful omission committed by the public respondents in connection with the processing and evaluation of the applications for *Bt talong* field testing; and
- 7. Application of the Precautionary Principle.

# The Court's Ruling

# Legal Standing

*Locus standi* is "a right of appearance in a court of justice on a given question."<sup>38</sup> It refers particularly to "a party's personal and substantial interest in a case where he has sustained or will sustain direct injury as a result" of the act being challenged, and "calls for more than just a generalized grievance."<sup>39</sup>

However, the rule on standing is a matter of procedure which can be relaxed for non-traditional plaintiffs like ordinary citizens, taxpayers, and legislators when the public interest so requires, such as when the matter is of transcendental importance, of overreaching significance to society, or of paramount public interest.<sup>40</sup> The Court thus had invariably adopted a liberal

 <sup>&</sup>lt;sup>38</sup> Bayan Muna v. Romulo, G.R. No. 159618, February 1, 2011, 641 SCRA 244, 254, citing David v. Macapagal-Arroyo, 522 Phil. 705, 755 (2006).
<sup>39</sup> With Strategies (2005).

<sup>&</sup>lt;sup>39</sup> Id., citing Jumamil v. Cafe, 507 Phil. 455, 465 (2005).

<sup>&</sup>lt;sup>40</sup> Social Justice Society (SJS) v. Dangerous Drugs Board, et al., 591 Phil. 393, 404 (2008); Tatad v.
policy on standing to allow ordinary citizens and civic organizations to prosecute actions before this Court questioning the constitutionality or validity of laws, acts, rulings or orders of various government agencies or instrumentalities.<sup>41</sup>

*Oposa v. Factoran, Jr.*<sup>42</sup> signaled an even more liberalized policy on *locus standi* in public suits. In said case, we recognized the "public right" of citizens to "a balanced and healthful ecology which, for the first time in our nation's constitutional history, is solemnly incorporated in the fundamental law." We held that such right need not be written in the Constitution for it is assumed, like other civil and political rights guaranteed in the Bill of Rights, to exist from the inception of mankind and it is an issue of transcendental importance with intergenerational implications. Such right carries with it the correlative duty to refrain from impairing the environment.

Since the *Oposa ruling*, ordinary citizens not only have legal standing to sue for the enforcement of environmental rights, they can do so in representation of their own and future generations. Thus:

Petitioners minors assert that they represent their generation as well as generations yet unborn. We find no difficulty in ruling that they can, for themselves, for others of their generation and for the succeeding generations, file a class suit. Their personality to sue in behalf of the succeeding generations can only be based on the concept of intergenerational responsibility insofar as the right to a balanced and healthful ecology is concerned. Such a right, as hereinafter expounded, considers the "rhythm and harmony of nature." Nature means the created world in its entirety. Such rhythm and harmony indispensably include, inter alia, the judicious disposition, utilization, management, renewal and conservation of the country's forest, mineral, land, waters, fisheries, wildlife, off-shore areas and other natural resources to the end that their exploration, development and utilization be equitably accessible to the present as well as future generations. Needless to say, every generation has a responsibility to the next to preserve that rhythm and harmony for the full enjoyment of a balanced and healthful ecology. Put a little differently, the minors' assertion of their right to a sound environment constitutes, at the same time, the performance of their obligation to ensure the protection of that right for the generations to come.<sup>43</sup> (Emphasis supplied.)

The liberalized rule on standing is now enshrined in the <u>Rules of</u> <u>Procedure for Environmental Cases</u> which allows the filing of a citizen suit in environmental cases.<sup>44</sup> The provision on citizen suits in the Rules "collapses the traditional rule on personal and direct interest, on the principle

<sup>44</sup> Rule 2, Sec. 5 reads in part:

Secretary of the Department of Energy, 346 Phil. 321 (1997); and De Guia v. COMELEC, G.R. No. 104712, May 6, 1992, 208 SCRA 420, 422.

<sup>&</sup>lt;sup>41</sup> Kilosbayan Incorporated v. Guingona, Jr., G.R. No. 113375, May 5, 1994, 232 SCRA 110, 137.

<sup>&</sup>lt;sup>42</sup> G.R. No. 101083, July 30, 1993, 224 SCRA 792, 804-805.

<sup>&</sup>lt;sup>43</sup> Id. at 802-803.

SEC. 5. Citizen suit. – Any Filipino citizen in representation of others, including minors or generations yet unborn, may file an action to enforce rights or obligations under environmental laws. x x

that humans are stewards of nature," and aims to "further encourage the protection of the environment."<sup>45</sup>

There is therefore no dispute on the standing of respondents to file before this Court their petition for writ of *kalikasan* and writ of continuing mandamus.

# Mootness

It is argued that this case has been mooted by the termination of all field trials on August 10, 2012. In fact, the validity of all Biosafety permits issued to UPLB expired in June 2012.

An action is considered 'moot' when it no longer presents a justiciable controversy because the issues involved have become academic or dead, or when the matter in dispute has already been resolved and hence, one is not entitled to judicial intervention unless the issue is likely to be raised again between the parties.<sup>46</sup> Time and again, courts have refrained from even expressing an opinion in a case where the issues have become moot and academic, there being no more justiciable controversy to speak of, so that a determination thereof would be of no practical use or value.<sup>47</sup>

Nonetheless, courts will decide cases, otherwise moot and academic if: *first*, there is a grave violation of the Constitution; *second*, the exceptional character of the situation and the paramount public interest is involved; *third*, when the constitutional issue raised requires formulation of controlling principles to guide the bench, the bar and the public; and *fourth*, the case is capable of repetition yet evading review."<sup>48</sup> We find that the presence of the second and fourth exceptions justified the CA in not dismissing the case despite the termination of *Bt talong* field trials.

While it may be that the project proponents of *Bt talong* have terminated the subject field trials, it is not certain if they have actually completed the field trial stage for the purpose of data gathering. At any rate, it is on record that the proponents expect to proceed to the next phase of the project, the preparation for commercial propagation of the *Bt* eggplants. Biosafety permits will still be issued by the BPI for *Bt talong* or other GM crops. Hence, not only does this case fall under the "capable of repetition yet evading review" exception to the mootness principle, the human and environmental health hazards posed by the introduction of a genetically modified plant, a very popular staple vegetable among Filipinos, is an issue of paramount public interest.

<sup>&</sup>lt;sup>45</sup> See Annotation on A.M. 09-6-8-SC.

<sup>&</sup>lt;sup>46</sup> Santiago v. Court of Appeals, 348 Phil. 792, 800 (1998).

<sup>&</sup>lt;sup>47</sup> Barbieto v. Court of Appeals, G.R. No. 184645, October 30, 2009, 604 SCRA 825, 840.

<sup>&</sup>lt;sup>48</sup> Office of the Deputy Ombudsman for Luzon v. Francisco, Sr., G.R. No. 172553, December 14, 2011, 662 SCRA 439, 449, citing David v. Macapagal-Arroyo, supra note 38, at 754.

# Primary Jurisdiction and Exhaustion of Administrative Remedies

In *Republic v. Lacap*,<sup>49</sup> the Court explained the related doctrines of primary jurisdiction and exhaustion of administrative remedies, as follows:

The general rule is that before a party may seek the intervention of the court, he should first avail of all the means afforded him by administrative processes. The issues which administrative agencies are authorized to decide should not be summarily taken from them and submitted to a court without first giving such administrative agency the opportunity to dispose of the same after due deliberation.

Corollary to the doctrine of exhaustion of administrative remedies is the doctrine of primary jurisdiction; that is, courts cannot or will not determine a controversy involving a question which is within the jurisdiction of the administrative tribunal prior to the resolution of that question by the administrative tribunal, where the question demands the exercise of sound administrative discretion requiring the special knowledge, experience and services of the administrative tribunal to determine technical and intricate matters of fact.

Nonetheless, the doctrine of exhaustion of administrative remedies and the corollary doctrine of primary jurisdiction, which are based on sound public policy and practical considerations, are not inflexible rules. There are many accepted exceptions, such as: (a) where there is estoppel on the part of the party invoking the doctrine; (b) where the challenged administrative act is patently illegal, amounting to lack of jurisdiction; (c) where there is unreasonable delay or official inaction that will irretrievably prejudice the complainant; (d) where the amount involved is relatively small so as to make the rule impractical and oppressive; (e) where the question involved is purely legal and will ultimately have to be decided by the courts of justice; (f) where judicial intervention is urgent; (g) when its application may cause great and irreparable damage; (h) where the controverted acts violate due process; (i) when the issue of non-exhaustion of administrative remedies has been rendered moot; (j) when there is no other plain, speedy and adequate remedy; (k) when strong public interest is involved; and, (1) in quo warranto proceedings. x x x (Emphasis supplied)

Under DAO 08-2002, the public is invited to submit written comments for evaluation by BPI after public information sheets have been posted (Section 7[G]). Section 7(P) also provides for revocation of field testing permit on certain grounds, to wit:

- P. <u>Revocation of Permit to Field Test</u>. A *Permit to Field Test* may be revoked for any of the following grounds:
  - 1. Provision of false information in the Application to Field Test;
  - 2. Violation of SPS or biosafety rules and regulations or of any conditions specified in the permit;

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<sup>&</sup>lt;sup>49</sup> 546 Phil. 87, 96-98 (2007).

- 3. Failure to allow the inspection of the field testing site;
- 4. Receipt by BPI of new information that the field testing of the regulated article poses significant risks to human health and the environment;
- 5. Whether the regulated article was imported, misdeclaration of shipment; or
- 6. Such other grounds as BPI may deem reasonable to prevent significant risks to human health and the environment.

Respondents sought relief under the <u>Rules of Procedure for</u> <u>Environmental Cases</u>, claiming serious health and environmental adverse effects of the *Bt talong* field trials due to "inherent risks" associated with genetically modified crops and herbicides. They sought the immediate issuance of a TEPO to enjoin the processing for field testing and registering *Bt talong* as herbicidal product in the Philippines, stopping all pending field trials of *Bt talong* in the field trial sites.

In addition to the TEPO and writ of *kalikasan*, respondents also sought the issuance of a writ of continuing mandamus commanding the respondents to: (1) comply with the requirement of environmental impact statement; (2) submit comprehensive risk assessments, field test reports, regulatory compliance reports and other material documents on *Bt talong* including issued certifications on public consultation with LGUs; (3) work with other agencies to submit a draft amendment to biosafety regulations; and (4) BPI, in coordination with relevant government agencies, conduct balanced nationwide public information on the nature of *Bt talong* field trial, and a survey of its social acceptability.

Clearly, the provisions of DAO 08-2002 do not provide a speedy, or adequate remedy for the respondents "to determine the questions of unique national and local importance raised here that pertain to laws and rules for environmental protection, thus [they were] justified in coming to this Court."<sup>50</sup> We take judicial notice of the fact that genetically modified food is an intensely debated global issue, and despite the entry of GMO crops (*Bt* corn) into the Philippines in the last decade, it is only now that such controversy involving alleged damage or threat to human health and the environment from GMOs has reached the courts.

# **Genetic Engineering**

Genetic manipulation has long been practiced by conventional breeders of plant or animal to fulfill specific purposes. The basic strategy employed is to use the sexual mechanism to reorganize the genomes of two

<sup>&</sup>lt;sup>50</sup> See Boracay Foundation, Inc. v. Province of Aklan, G.R. No. 196870, June 26, 2012, 674 SCRA 555, 608.

individuals in a new genetic matrix, and select for individuals in the progeny with the desirable combination of the parental characteristics. Hybridization is the conventional way of creating variation. In animals, mating is effected by introducing the desired sperm donor to the female at the right time. In plants, pollen grains from the desired source are deposited on the stigma of a receptive female plant. Pollination or mating is followed by fertilization and subsequently development into an embryo. The effect of this action is the reorganization of the genomes of two parents into a new genetic matrix to create new individuals expressing traits from both parents. The ease of crossing of mating varies from one species to another. However, conventional breeding technologies are limited by their long duration, need for sexual compatibility, low selection efficiency, and restricted gene pool.<sup>51</sup>

Recombinant DNA (*rDNA*) technology, often referred to as *genetic* engineering, allows scientists to transfer genes from one organism to any other, circumventing the sexual process. For example, a gene from a bacterium can be transferred to corn. Consequently, DNA technology allowed scientists to treat all living things as belonging to one giant breeding pool. Unlike other natural genome rearrangements phenomena, *rDNA* introduces alien DNA sequences into the genome. Even though crossing of two sexually compatible individuals produces recombinant progeny, the term recombinant DNA is restricted to the product of the union of DNA segments of different biological origins. The product of recombinant DNA manipulation is called a *transgenic organism*. *rDNA* is the core technology of biotechnology.<sup>52</sup>

The organism that is created through genetic engineering is called a genetically modified organism (GMO). Since the production of the first GMOs in the 1970s, genes have been transferred between animal species, between plant species, and from animal species to plant species. Some genes can make an animal or plant grow faster or larger, or both. A gene produced by flounder (anti-freeze) was transplanted into salmon so that salmon can be farmed in colder climates. Many species of fish are genetically engineered to speed growth, to alter flesh quality, and to increase cold and disease resistance. In farm animals such as cattle, genes can be inserted to reduce the amount of fat in meat, to increase milk production, and to increase superior cheese-making proteins in milk. Biotechnology has also modified plants to produce its own pesticide, resist common diseases or to tolerate weed-killing herbicide sprays.<sup>53</sup>

Despite these promising innovations, there has been a great deal of controversy over bioengineered foods. Some scientists believe genetic engineering dangerously tampers with the most fundamental natural components of life; that genetic engineering is scientifically unsound; and

 <sup>&</sup>lt;sup>51</sup> George Acquaah, Understanding Biotechnology: an integrated and cyber-based approach, (Pearson Education, Inc., 2004) at 62, 64, 69 and 70.
 <sup>52</sup> Id. et 72

<sup>&</sup>lt;sup>52</sup> Id. at 72.

<sup>&</sup>lt;sup>53</sup> Nancy Harris, *Genetically Engineered Foods*, (Greenhaven Press, 2004) at 5-6.

that when scientists transfer genes into a new organism, the results could be unexpected and dangerous. But no long-term studies have been done to determine what effects GMO foods might have on human health.<sup>54</sup>

# **Genetically Modified Foods**

The term GM food refers to crop plants created for human or animal consumption using the latest molecular biology techniques. These plants are modified in the laboratory to enhance desired traits such as increased resistance to herbicides or improved nutritional content.<sup>55</sup> Genetic modification of plants occurs in several stages:

- 1. An organism that has the desired characteristic is identified and the specific gene producing this characteristic is located and the DNA is cut off.
- 2. The gene is then attached to a carrier in order to introduce the gene into the cells of the plant to be modified. Mostly plasmid (piece of bacterial DNA) acts as a carrier.
- 3. Along with the gene and carrier a 'promoter' is also added to ensure that the gene works adequately when it is introduced into the plant.
- 4. The gene of interest together with carrier and promoter is then inserted into bacterium, and is allowed to reproduce to create many copies of the gene which are then transferred into the plant being modified.
- 5. The plants are examined to ensure that they have the desired physical characteristic conferred by the new gene.
- 6. The genetically modified plants are bred with conventional plants of the same variety to produce seed for further testing and possibly for future commercial use. The entire process from the initial gene selection to commercial production can take up to ten years or more.<sup>56</sup>

# Benefits of GM Foods

The application of biotechnology in agricultural production promises to overcome the major constraints being faced in farming such as insect pest infestation and diseases which lead to substantial yield losses. Pest-resistant crops could substantially improve yields in developing countries where pest damage is rampant and reduce the use of chemical pesticides. Crop plants which have been genetically engineered to withstand the application of powerful herbicides<sup>57</sup> using genes from soil bacteria eliminates the timeconsuming and not cost-effective physical removal of weeds by tilling. The

<sup>&</sup>lt;sup>54</sup> Id. at 7.

<sup>&</sup>lt;sup>55</sup> Sheweta Barak, Deepak Mudgil and B.S. Khatkar, "Genetically modified food: benefits, safety aspects and concerns" Asian Journal of Food and Agro-Industry <<u>www.ajofai.info/Abstact/Genetically%2food%20benefits,%20safety%20aspects%2concerns.pdf</u>> (visited last November 7, 2014).

<sup>&</sup>lt;sup>56</sup> Id. at 550.

<sup>&</sup>lt;sup>57</sup> Herbicide is defined as "a poisonous substance used to destroy unwanted plants." (Compact Oxford English Dictionary 473 [3<sup>rd</sup> ed. 2005]).

herbicides to which the GM crops are tolerant are "broad spectrum" weedkillers, which means they can be sprayed over the entire field, killing all plants apart from the GM crop. Herbicide-tolerant crops include transgenes providing tolerance to the herbicides (*glyphosate* or *glufosinate ammonium*). These herbicides kill nearly all kinds of plants except those that have the tolerance gene. Another important benefit is that this class of herbicides breaks down quickly in the soil, eliminating residue carryover problems and reducing adverse environmental impacts.<sup>58</sup>

Some plants are genetically engineered to withstand cold climates such as GM strawberries or soybeans, expressing the anti-freeze gene of arctic flounder, to protect themselves against the damaging effects of the frost; and GM tobacco and potato with anti-freeze gene from cold water fish. Crops could also be genetically modified to produce micronutrients vital to the human diet such as the "golden rice" genetically modified to produce beta-carotene, which can solve Vitamin A deficiency and prevent night blindness in pre-school children. Other efforts to enhance nutritional content of plants include the genetic modification of canola to enhance Vitamin E content or better balance fatty acids, cereals for specific starch or protein, rice for increased iron to reduce anemia, and plant oils to adjust cholesterol levels. There are also food crops engineered to produce edible vaccines against infectious diseases that would make vaccination more readily available to children around the world. For example, transgenic bananas containing inactivated viruses protecting against common developing world diseases such as cholera, hepatitis B and diarrhea, have been produced. These vaccines will be much easier to ship, store and administer than traditional injectable vaccines.<sup>59</sup>

Overall, biotechnology is perceived as having the potential to either help or hinder reconciling of the often opposing goals of meeting the human demand for food, nutrition, fiber, timber, and other natural resources. Biotech crops could put more food on the table per unit of land and water used in agriculture, thus resulting in decreased land and water diverted to human uses. Increasing crop yields and reducing the amount of cultivated land necessary would also reduce the area subject to soil erosion from agricultural practices, which in turn would limit associated environmental effects on water bodies and aquatic species and would reduce loss of carbon sinks and stores into the atmosphere.<sup>60</sup>

# Adverse Health Effects of GMOs

Along with the much heralded benefits of GM crops to human health and environment, there emerged controversial issues concerning GM foods.

<sup>&</sup>lt;sup>58</sup> Supra note 55, at 551-552.

<sup>&</sup>lt;sup>59</sup> Id. at 552-553.

<sup>&</sup>lt;sup>60</sup> Indur M. Goklany, "Applying the Precautionary Principle to Genetically Modified Crops" *Policy Study Number 157* (2000): 4-5, 8 and 10. Print.

In 1999, it was found that genetically engineered foods can have negative health effects. Based on scientific studies, these foods can unleash new pathogens, contain allergens and toxins, and increase the risk of cancer, herbicide exposure, and harm to fetuses and infants.<sup>61</sup> Independent studies conducted went as far to conclude that GM food and feed are "inherently hazardous to health."<sup>62</sup>

A widely reported case is that of the Brazil nut gene expressed in soybean in order to increase the methionine content for animal feed. The protein was subsequently shown to be an allergen and the product was never marketed. Genetically modified foods can introduce novel proteins into the food supply from organisms that are never consumed as foods, which may pose a health risk. This may elicit potentially harmful immunological responses, including allergic hypersensitivity.<sup>63</sup>

A feeding experiment conducted by Dr. Arpad Pusztai also demonstrated that potatoes genetically altered to produce lectins, natural insecticides, to protect them against aphids, damaged the animals' gut, other organs, and immune system. Dr. Pusztai found that "the damage originated not from the transgene and its expressed product but from the damage caused by the insertion of the transgene, probably due to insertional mutagenesis."<sup>64</sup> If confirmed, Pusztai's conclusions will reinforce concerns that gene insertion itself may create new toxins; it will also implicate the toxin commonly used in other genetically engineered crops – the *Bt* toxin which, Pusztai says, is also a lectin.<sup>65</sup>

The use of antibiotic resistance marker (*arm*) gene, inserted into a plant or microbe, that helps determine if the foreign gene has successfully spliced into the host organism, is another cause of grave concern among scientists. These *arm* genes might unexpectedly recombine with disease-causing bacteria or microbes in the environment or in the guts of animals or humans who eat GM food, thus contributing to the growing public health danger of antibiotic-resistance of infections that cannot be cured with traditional antibiotics (*e.g.*, new strains of salmonella, e-coli, campylobacter and enterococci).<sup>66</sup> However, recent advances in genetic engineering indicate that use of such selection markers is likely to diminish with the anticipated development of alternative types of marker genes.<sup>67</sup>

<sup>&</sup>lt;sup>61</sup> Roberto Verzola, "Genetically Engineered Foods Have Health Risks" supra note 53, at 38-42.

 <sup>&</sup>lt;sup>62</sup> Mae-Wan Ho, "Ban GMOs Now," Lecture by at conference on Traditional Seeds Our National Treasure and Heritage – Traditional and Organic Agriculture. Bewelder, Warsaw, Poland, April 6, 2008. <<u>http://www.i-sis.org.uk/Ban GMOs Now.php.</u>> (visited last December 4, 2014)
 <sup>63</sup> Anticip Delati "Detational Anticip Delation of the Market Action of the Market Actio

<sup>&</sup>lt;sup>3</sup> Anita Bakshi, "Potential Adverse Health Effects of Genetically Modified Crops" Journal of Toxicology and Environmental Health B (2003) <<u>http://globalseminarhealth.wdfiles.com/local-</u><u>files.nutrition/Bakshi.pdf</u>> (visited last December 4, 2014).

<sup>&</sup>lt;sup>64</sup> Ken Roseboro, ed. "Arpad Pusztai and the Risks of Genetic Engineering" *The Organic and Non-GMO Report* (June 2009) <<u>http://www.organicconsumers.org/articles/article\_18101.cfm</u>>. (visited last December 6, 2014).

<sup>&</sup>lt;sup>65</sup> Verzola, supra note 61, at 40.

<sup>&</sup>lt;sup>66</sup> Barak, Mudgil and Khatkar, supra note 55, at 555.

<sup>&</sup>lt;sup>67</sup> Bakshi, supra note 63, at 217; Barak, Mudgil and Khatkar, id.

Increased cancer risk is another critical issue in the consumption of GM foods. A growth hormone genetically modified to stimulate milk production in cows was found to elevate levels of IGF-1 (insulin-like Growth Factor-1, identical versions of which occurs in cows and humans) in cow's milk by 80%. IGF-1 is reported to be a key factor in prostate cancer, breast cancer and lung cancer.<sup>68</sup> Dr. Samuel Epstein of the University of Illinois warned of the danger of high levels of IGF-1 contained in milk cows injected with synthetic bovine growth hormone (*r*BGH), which could be a potential risk factor for breast and gastrointestinal cancers.<sup>69</sup>

Glyphosate, the active ingredient in Monsanto's Roundup® herbicide, has been found to worsen modern diseases. A report published in the journal *Entropy* argues that glyphosate residues, found in most commonly consumed foods in the Western diet courtesy of genetically engineered sugar, corn, soy and wheat, "enhance the damaging effects of other food-borne chemical residues and toxins in the environment to disrupt normal body functions and induce disease." Another research demonstrated a connection between increased use of Roundup with rising autism rates in the US.<sup>70</sup>

# Adverse Effects of GMOs to the Environment

Genetically modified crops affect the environment in many ways such as contaminating non-GMO plants, creating super weeds and super pests, harming non-target species, changing soil microbial and biochemical properties, and threatening biodiversity.

There are two primary types of technology so far deployed: insect resistance (*Bt*) and herbicide tolerance (HT). Both have drastic modes of action to kill the target species at high efficiency. *Bt* crops contain a toxin lethal to certain insects, and *Bt* sprays have been used by organic farmers as a last option to deal with certain pests like the corn borer. It is feared that genetically modified *Bt* crops will speed up resistance to *Bt*, thereby rendering the organic spray ineffective.<sup>71</sup> Lab and field tests also indicate that common plant pests such as cotton bollworms, living under constant pressure from GE crops, will soon evolve into "superpests" completely immune to *Bt* sprays and other environmentally sustainable biopesticides.<sup>72</sup> In the case of HT, the technology involves the combined use of a chemical herbicide and a GM plant. The herbicide is generally a broad spectrum herbicide (commonly glyphosate or glufosinate) which kills weeds while leaving the crop plant alive as it is genetically engineered to be resistant to the herbicide. The herbicide acts to inhibit an essential enzyme that is found

<sup>&</sup>lt;sup>68</sup> Verzola, supra note 61, at 40.

<sup>&</sup>lt;sup>69</sup> Hans R. Larsen, "Milk and the Cancer Connection" *International Health News* (April 1998) <<u>http://www.notmilk.com/drlarsen.html</u>>. (visited last December 6, 2014).

<sup>&</sup>lt;sup>70</sup> Mercola, Monsanto's Roundup Herbicide May Be Most Important Factor In Development of Autism and Other Chronic Diseases, <<u>http://articles.mercola.com/sites/articles/archive/2013/06/09/monsantoroundup-herbicide.aspx</u>>. (visited last December 6, 2014).

<sup>&</sup>lt;sup>71</sup> Ben Lilliston, "Genetically Modified Organisms are Contaminating Organic Crops," reproduced with permission in <u>Genetically Engineered Foods</u>, supra note 53, at 55.

<sup>&</sup>lt;sup>72</sup> Barak, Mudgil and Khatkar, supra note 55, at 555.

in all plants and as a result is able to eliminate all weeds whereas most conventional herbicides are selective in their action and target a limited number of weeds. Concern has been raised regarding over-reliance on use of one or two herbicides in increased amounts over time which leads to the emergence of herbicide resistant weeds. Also, the transfer of an herbicide-resistance gene into a weed can convert it into a superweed. Pests and weeds will emerge that are pesticide or herbicide resistant, which means that stronger, more toxic chemicals will be needed to get rid of the pests.<sup>73</sup>

It is a well-accepted fact that genetically engineered plants can move beyond the field sites and cross with wild relatives.<sup>74</sup> It is by nature a design of plants to cross pollinate to spread genes further afield. Maize, oil seed rape, sugar beet, barley, among others, are wind and insect pollinated, allowing pollen to travel large distances. In GM crop fields, pollen drift and insect pollination create obvious problems for nearby non-GM or organic crops.<sup>75</sup> GM maize could cross-pollinate neighboring non-GM or organic maize crops. Maize pollen can travel at least 500-700 meters and still be viable and distances of several kilometers have even been reported.<sup>76</sup> But many experiments showed varying results and actual cross-pollinations were observed in Mexico up to 200 meters only, while in Oklahoma it was 500 meters. In crop species that are outcrossers, many environmental factors influence the maximum pollination distance such as the size of pollen grains, the humidity in the air, and the wind speed.<sup>77</sup> Brinjal is usually selfpollinated, but the extent of cross-pollination has been reported as high as 48% and hence it is classified as cross-pollinated crop. The cone-like formation of anthers favors self-pollination; but since the stigma ultimately projects beyond the anthers, there is an ample opportunity for crosspollination. The rates of natural cross-pollination may vary depending on genotype, location, and insect activity. The extent of outcrossing has been reported from 3 to 7% in China and from 0 to 8.2% (with a mean of 2.7%) at Asian Vegetable Research Development Centre; however the Indian researchers have reported 2 to 48% outcrossing in *brinjal* varieties in India. Outcrossing primarily takes place with the help of insects.<sup>78</sup>

The StarLink incident is also a widely reported GM fiasco. In June 2000, Starlink, a genetically modified yellow corn which contains the pesticide Bt in every cell, was found in white corn tortilla chips in Florida, USA. Starlink had been approved for animal feed but not for human consumption due to concerns about dangerous allergic reactions. The

<sup>73</sup> Id.

<sup>&</sup>lt;sup>74</sup> Andreas Bauer-Panskus, Sylvia Hamberger and Christoph Then, "Transgene escape - Global atlas of uncontrolled spread of genetically engineered plants" *Test Biotech* <<u>https://www.testbiotech.org/sites/default/files/Testbiotech\_Transgene\_Escape.pdf</u> >. (visited last December 6, 2014).

 <sup>&</sup>lt;sup>75</sup> "Contamination of Crops" <<u>http://www.gmeducation.org/environment/p149075-contamination-of-crops.html</u>>. (visited last December 7, 2014).
 <sup>76</sup> White December 7, 2014).

<sup>&</sup>lt;sup>76</sup> Gene Watch UK, Fact Sheet No. 3 (Forage Maize), *UK Farm Scale Trials with GM Crops-2000*, <<u>http://www.genewatch.org/pub-537624</u>>. (visited last December 7, 2014).

<sup>&</sup>lt;sup>77</sup> "*Transgenic Crops: an Introduction and Resource Guide*" <a href="http://cls.casa.colostate.edu/transgeniccrops/croptocrop.html">http://cls.casa.colostate.edu/transgeniccrops/croptocrop.html</a>>.

<sup>&</sup>lt;sup>78</sup> "Biology of Brinjal," <<u>http://dbtbiosafety.nic.in/guidelines/brinjal.pdf</u>>.

Starlink incident is often cited to illustrate how difficult it is to keep genetically modified crops from spreading.<sup>79</sup>

This gene flow to wild species is particularly alarming to environmentalists. The wild species from which our agricultural plants originate are an important genetic resource for further plant breeding if, for example, there is a requirement for improved resistance to climate change or plant pests. Future plant breeding could be jeopardized if transgenes spread into these resources. Similarly, agriculture in the centers of origin could be permanently damaged if transgenes spread into regional landraces.<sup>80</sup> Invasive species can replace a single species or a whole range of species, and they can also change the conditions within ecological systems. Crossing can cause losses in the genetic information of the original species, a reduction in genetic diversity and an ongoing incremental change of genetic identity in the original plants. It is hard to predict which species will become invasive.<sup>81</sup> Indeed, GM crops could threaten the centers of crop biodiversity or outgrow a local flora to the detriment of native species.<sup>82</sup>

Bt gene in genetically modified crops might be toxic to non-target organisms that consume it. When Bt corn sheds its pollen, these are cast into the wind, dusting nearby plants and trees. Concern has been expressed about the potential toxicity of the Bt toxin in corn pollen to the monarch butterfly because initial laboratory studies showed increased mortality in larvae. However, in another study it was believed that it is unlikely that a significant risk to those butterflies exists.<sup>83</sup>

On the effect of transgene crops on soil, one study investigated CrylAc and CpTI proteins and their effects on microbial properties and enzyme activities. Results showed that there was persistence of said proteins in soil under 4-year consecutive cultivation of transgenic cottons. Soil microbial biomass carbon, microbial activities, and soil enzyme activities (except urease and phosphodiesterase) significantly decreased in soil under transgenic cottons.<sup>84</sup>

In another review, it was stated that the direct effects of the plant that has been modified is of the most concern since the introduction of transgenic

<sup>&</sup>lt;sup>79</sup> Lilliston, supra note 71, at 54.

<sup>&</sup>lt;sup>o</sup> Testbiotech Report, supra note 74, at 7.

A landrace is defined as "a dynamic population(s) of a cultivated plant that has historical origin, distinct identity and lacks formal crop improvement, as well as often being genetically diverse, locally adapted and associated with traditional farming systems." Tania Carolina Camacho Villa, Nigel Maxted, Maria Scholten and Brian Ford-Lloyd, "Defining and Identifying crop landraces," *Characterization and Utilitzation Plant Genetic Resources: Characterization and Utilization* Vol. 3, Issue 3 (December 2005) <<u>http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=689208</u>>.

<sup>&</sup>lt;sup>81</sup> Id. at 39.

<sup>&</sup>lt;sup>82</sup> <<u>http://onlinelibrary.wiley.com/doi/10.1046/j.0960-7412.2002.001607.x/full</u>>.

<sup>&</sup>lt;sup>83</sup> Barak, Mudgil and Khatkar, supra note 55, at 555-556.

<sup>&</sup>lt;sup>84</sup> Z.H. Chen, L.J. Chen, Y.L. Zhang, Z.J. Wu, "Microbial properties, enzyme activities and the persistence of exogenous proteins in soil under consecutive cultivation of transgenic cottons (Gossypium hirsutum L.)" *PLANT SOIL ENVIRON.*, 57, 2011 (2): 67-74 <<u>www.agriculturejournals.cz/publicFiles/35214.pdf</u>>. (visited last December 6, 2014).

## Decision

proteins for pest and disease resistance can involve the production of chemical substances that are potentially toxic to non-target soil organisms, including mycorrhizal fungi and soil microfauna that are involved in organic matter decomposition. Experimental studies have shown that the transgenic proteins *Bt* crystal toxin and T4 lysozyme, though used to prevent insect damage to the above ground plant parts, are not only present in root exudates but that they maintain biological activity after entering the soil.<sup>85</sup>

As to the herbicide glyphosate, recent studies revealed its negative effects on the soil, which include compaction and resultant runoff, the killing of beneficial microbes and bacteria, and the exhaustion of necessary minerals and nutrients that plants require. It was found that glyphosate "locks up" manganese and other minerals in the soil so that they can't be utilized by the plants that need them, and that it is toxic to rhizobia, the bacterium that fixes nitrogen in the soil. There is likewise evidence showing that glyphosates can make their way to groundwater supplies.<sup>86</sup> In a study which tested the effects of the herbicide Roundup on six species of larval amphibians from North America, it was demonstrated that when we "use realistic exposure times and the frequently occurring stress of predators found in natural ecologic communities, one of our most widely applied herbicides (Roundup) has the potential to kill many species of amphibians." At the same time, the study noted that Monsanto Corporation has recently released "an additional formulation of glyphosate (Roundup Biactive), which contains a different (but unspecified) surfactant that is reported to be less toxic."87

# Evidence of Damage or Threat of Damage to Human Health and the Environment

Both petitioners and respondents submitted documentary evidence consisting of reports of scientific studies and articles in support of their respective positions on the benefits and risks of GM plants.

Further, the parties presented their respective expert witnesses who testified on the allegations raised in the petition concerning damage or threat of damage to human health and the environment resulting from the conduct of *Bt talong* field trials in the Philippines. The CA conducted "hot tubbing," the colloquial term for concurrent expert evidence, a method used for giving

of.

<sup>&</sup>lt;sup>85</sup> Biao Liu, Qing Zeng, Fengming Yan, Haigen Xu, and Chongren Xu, *Review: Effects of Transgenic Plants on Soil Microorganisms*" <<u>http://link.springer.com/article/10.1007/s11104-004-1610-8#page-2</u>>. (visited last December 6, 2014).

 <sup>&</sup>lt;sup>2/2</sup> (Visited last December 0, 2017).
 E. Vinje, "Is Monsanto's Roundup Killing Our Soil?," *Planet Natural* <a href="http://www.planetnatural.com/roundup-killing-soil/">http://www.planetnatural.com/roundup-killing-soil/</a>. (visited last December 6, 2014) See also Stephanie Strom, "Misgivings About How a Weed Killer Affects the Soil" *The New York Times* (September 19, 2013) <<u>http://www.nytimes.com/2013/09/20/business/misgivings-about-how-a-weed-killer-affects-the-soil.html?pagewanted=all&\_r=0> (visited last December 6, 2014).
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 <sup>&</sup>lt;sup>87</sup> R.A. Relyea, "The Lethal Impacts of Roundup and Predatory Stress on Six Species of North American Tadpoles," *Archives of Environmental Contamination and Toxicology* v. 48, n.3, (April 1, 2005).
 <a href="http://www.mindfully.org/Pesticide/2005/Roundup-Tadpoles-Relyea1apr05.htm">http://www.mindfully.org/Pesticide/2005/Roundup-Tadpoles-Relyea1apr05.htm</a> (visited last December 6, 2014).

evidence in civil cases in Australia. In a "hot tub" hearing, the judge can hear all the experts discussing the same issue at the same time to explain each of their points in a discussion with a professional colleague. The objective is to achieve greater efficiency and expedition, by reduced emphasis on cross-examination and increased emphasis on professional dialogue, and swifter identification of the critical areas of disagreement between the experts.<sup>88</sup>

On November 20, 2012, the parties' expert witnesses testified in a hot tub hearing before the chairman and members of the CA's Special Thirteenth Division. Dr. Chakraborty, Dr. Medina and Dr. Malayang were presented by the petitioners while Dr. Davies, Dr. Halos, Dr. Ebora and Dr. Cariño appeared for the respondents.

The following are summaries of the expert witnesses' judicial affidavits:

## For Petitioners

**DR. DAVIES**, Professor of Plant Physiology at Cornell University, Jefferson Science Fellow serving as senior science advisor on agricultural biotechnology in the US Department of State, and editor for plant physiology for McGraw-Hill Encyclopedia of Science and Technology.

In his review of agricultural biotechnology around the world, he has not encountered any verifiable report of a field trial of any GM crop that caused damage to the environment and to human health. This involves more than 25,000 field trials in 20 years with crops such as Bt eggplant, Btcotton, Bt corn, and others. The same applies to the commercial cultivation of Bt crops, which have been grown in ever increasing quantities worldwide for 16 years and now comprise the majority of the world acreage of maize and cotton.

A recent European Union (EU) report which concludes that more than 130 EU research projects covering a period of more than 25 years of research involving more than 500 independent research groups, show that consuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from conventional crops. The World Health Organization (WHO), American Medical Association, US National Academy of Sciences, European Food Safety Authority (EFSA) all have come to the same conclusion.

GMOs have been proven safe as conventionally-bred crops in animal studies. A small number of poorly done studies purportedly claiming negative effects, *should be viewed with great caution and have been highly criticized for their veracity by the overwhelming majority of highly respected scientists*. Many hundreds of studies show no harmful effects. To date, not a single rigorous study of GM foods in animals has revealed any adverse effect; not a single case of allergy, illness, cancer, or death have been shown to be associated with foods derived from GM crops, despite the fact that they have been consumed by Americans for 16 years.

<sup>&</sup>lt;sup>88</sup> Mr. Neil J. Young QC, "Expert Witnesses: On the stand or in the hot tub – how, when and why? Formulating the Question for Opinion and Cross-Examining the Experts" Commercial Court Seminar, Quezon City, October 27, 2010.

Recent studies indicate that Bt crops enhance the ecological diversity in the areas surrounding those where Bt crops are grown. Over a period of 13 years, cultivation of Bt cotton in China results in an increase in insect diversity and abundance and a decrease in crop damaging insects not only in Bt crop fields but also in surrounding non-Bt fields.

GM crops deliver significant yield increases, result in less exposure to pesticides, improve food security worldwide, protect against devastating crop losses and famine, improve nutrition, and some GM crop techniques help combat climate change.<sup>89</sup>

**DR. HALOS**, Ph.D. in Genetics, University of California Berkeley, B.S. Agriculture, Major in Agronomy (Plant Breeding), UPLB, and served as Instructor, Associate Professor, Chief Science Research Specialist, Research Director at UPLB, UP Diliman, De La Salle University, Forest Research Institute now Ecosystems Research and Development Bureau of DENR and the Biotechnology Coalition of the Philippines.

From her research, she gathered that the protein product of the Bt gene CrylAc in Bt cotton that is also in Bt eggplant has been found safe by many food and environmental safety regulatory agencies such as those in Australia, New Zealand, USA, Canada, Brazil, China, India, Mexico, Argentina, South Africa, Japan and EU.

Since 2002, BPI has granted 95 biosafety permits for field trials. Of these 70 field trial permits were for Bt corn, cotton and eggplant. No adverse effect of any of these Bt crop field trials have been reported. No report of adverse effects of Bt crop field trial exists. All claims of adverse health and environmental effects of Bt crops has not been scientifically validated. The yearly expansion of GM crop areas in both the developing and industrialized countries is an attestation of the preference of farmers and the economic benefits that accrue to them.

GM crops have positive environmental impact. Currently commercialized GM crops have reduced the adverse impacts of agriculture on biodiversity. The use of *Bt* crops has significantly reduced the use of pesticides, and also increased farmer incomes.<sup>90</sup>

**DR. EBORA**, Ph. D. in Entomology, Michigan State University; B.S. Agriculture and M.S. Entomology (Insect Pathology/Microbial Control), UPLB; Post-graduate trainings in microbiology and biotechnology, Osaka University, Japan, and Intellectual Property Management and Technology Transfer, ISAAA AmeriCenter, Cornell University, USA. Director, and Research Associate Professor, National Institute of Molecular Biology and Biotechnology (BIOTECH), UPLB; Philippine Coordinator of the Program for Biosafety Systems; former Executive Director, Philippine Council for Industry, Energy and Emerging Technology Research and Development, DOST; former Chair, Biosafety Committee, DOST; and was a Member of the Institutional Biosafety Committees of UPLB and International Rice Research Institute (IRRI); and was extensively involved in the isolation, bioassay or efficacy testing and development of *Bt* as microbial insecticides for the control of Asian corn borer and mosquito larvae at BIOTECH.

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<sup>&</sup>lt;sup>89</sup> CA *rollo* (Vol. V), pp. 3482-3488.

<sup>&</sup>lt;sup>90</sup> CA *rollo* (Vol. III), pp. 1834-1836.

The contained field trial experiments, among others, were designed to address concerns on cross-pollination or horizontal gene transfer, pollination distances, harm to beneficial organisms, and development of insect resistance. To prevent cross-pollination, an isolation distance of 200 meters from other areas where eggplants are grown or wild relatives are present, was observed, and with five (5) rows of non-transgenic eggplants that serve as pollen trap plants. As to the flight distance of honeybees reaching 4 kilometers, what was not mentioned is the viability of pollen after it was shed and travelled at a certain distance. Numerous literatures have shown that isolation distances much less than 200 meters is sufficient to prevent cross-pollination. Two studies are cited: Sekara and Bieniasz (2008) noted that cross-pollination at a distance of 50 meters was nonexistent; and the Asian Vegetable Research and Development Center (AVRDC) indicated that eggplants produce perfect flowers which may be cross-pollinated but self-pollination is more common, the extent of natural crossing depends upon insect activity and this can be avoided by isolating each variety by 20 meters or with another tall flowering plant. The isolation distance imposed by DA-BPI is 10x the recommended isolation distance; the 200 meters distance was found sufficient for pure seed production in India (the same recommendation by Chen [2001] of AVRDC foundation for seed production purity standards); field studies in 2 locations in India have shown that at a distance beyond 30 meters no more outcrossing could be detected. Taking all these data into account, the 48% outcrossing being raised by petitioners is most likely for adjacent plants and therefore not a valid argument for the on-going field trials.

The *Bt* talong will not directly affect beneficial organisms like pollinators, predators and parasites of insect pests because it is toxic only to caterpillars or insects belonging to Order Lepidoptera (butterfly and moths). The selective toxicity of *Bt* protein in *Bt* talong is partly due to the fact that the gut physiology of these insects is very different from caterpillars, and not all caterpillars are affected by it. There is a significant number of literature on *Bt* protein's selectivity and specificity.

As to the development of insect resistance, this is not possible during the multi-location field trials for Bt talong because of low selection pressure and limited exposure of the insect pest to Bt talong. Insect resistance is not unique to GM crops as it is a commonly observed biological reaction of insect pests to control measures like insecticides. In the event Bt talong is approved for commercialization and will be widely used by farmers, this concern could be addressed by insect resistance management (IRM); an IRM strategy should be required prior to the commercial release of Bt talong.

There is no compelling reason to stop the field trials; on the contrary they should be allowed to proceed so that scientists and researchers will be able to generate valuable data and information which will be helpful in making informed decisions regarding the usefulness of the technology.<sup>91</sup>

## For Respondents

**DR. MALAYANG III,** Ph.D. in Wildland Resource Science, University of California at Berkeley; M.A. Philosophy, M.A. International Affairs (Southeast Asia Studies major in Economics), Ohio University; AB Philosophy, UP Diliman; former Undersecretary of Environment and

<sup>&</sup>lt;sup>91</sup> Id. at 1940-1944.

Natural Resources; served as Environmental Science representative in the National Biosafety Committee of the Philippines and participated in the drafting of the Philippines Biosafety Framework; and student, lecturer and advocate of biodiversity, food security, biosafety and environmental policy.

He is concerned with how GMOs are being introduced for commercialscale use (as against being used for academic research) in the Philippines on the following grounds: (a) how they might contaminate the indigenous genetic resources of the country; (b) how they may cause an imbalance of predator-prey relationships in ecosystems, so that certain species might dominate ecological niches and erode their biodiversity and ecological stability; (c) how they may erode the ability of farmers to control their genetic resources to sustain their cropping systems; and (d) how much are present biosafety protocols able to safeguard the long-term ecological and economic interests of the Philippines as a particularly biodiversity-rich country and which is, therefore, highly sensitive to genetic pollution; to the extent that its biodiversity is its long-term equity to advances in biotechnology, the most robust measures must be taken so that such resources will not be lost.

Being a highly biodiversity-rich country, biosafety measures in the Philippines must be adopted using a 3-stage approach: Stage 1 - Develop criteria for biosafety measures; meaning, first, adopt a set of standards for determining the level of robustness of biosafety measures and protocols that would be acceptable in the particular case of the Philippines; include required scoping and internal and external validity requirements of impact and safety assessments; Stage 2 - Using the criteria produced in Stage 1, develop biosafety measures and protocols to be adopted in the Philippines; and Stage 3 - Apply the protocol with the highest rigor.

Biosafety must be a public affair involving a broad spectrum of the Filipino state rather than its considerations being restricted only to specific professionals and sectors in the country; biosafety must be based on an enactment of Congress and open to challenge and adjudication against international laws; provisions must be made to make it a crime against humanity to recklessly erode and weaken genetic resources of our people.<sup>92</sup>

**DR. MEDINA,** Ph. D. in Environmental Biology, University of Guelph, Canada; M.S. (Insect and Plant Ecology) and B.S. Agriculture, UPLB; National Coordinator of MASIPAG; served as resource person in more than a hundred trainings and seminars, both local and abroad; served as member in international agricultural assessment sponsored by Food and Agriculture Organization (FAO), United Nations Environment Program (UNEP), WHO, and the World Bank; worked on a project for development of resistance to corn borer in 1981 at the Institute of Plant Breeding in UPLB, and served as researcher and later Associate Professor of Environmental Management of the UP Open University.

Based on her studies and extensive experience, the Bt talong field testing poses the following risks or hazards: (a) While natural Bt sprays used in organic farming have little effect on non-target organisms because the bacterial 'pro-toxin' is in an inactive state and only becomes toxic when processed and reduced in the gut of certain (targeted) species of insect

<sup>&</sup>lt;sup>92</sup> CA *rollo* (Vol. I), pp. 164-165.

larvae, in contrast, Bt plants contain an artificial, truncated Bt gene and less processing is required to generate the toxin because the toxin is already in its active form. It is therefore less selective, and may harm nontarget insects that do not have the enzymes to process the pro-toxin, as well as the pests for which it is intended; (b) Bt proteins from natural Bt sprays degrade relatively quickly in the field as a result of ultraviolet light and lose most toxic activity within several days to two weeks after application. In Bt crops, however, the Bt toxin is produced by the internal system of the plants thus non-degradable by mere exposure to sunlight and generated throughout the entire lifespan of the plant; (c) Bt talong can also affect the environment by harming important or beneficial insects directly or indirectly. Genetically engineered Bt eggplant, like other Bt crops, could be harmful to non-target organisms if they consume the toxin directly in pollen or plant debris. This could cause harm to ecosystems by reducing the numbers of important species, or reducing the numbers of beneficial organisms that would naturally help control the pest species; (c) The evolution of resistance to Bt crops is a real risk and is treated as such in ecological science throughout the world. If enough individuals become resistant then the pest control fails; the pest becomes abundant and affects crop yield. Granting the pest control practice is successful, it may also simply swap one pest for another, a phenomenon known as secondary pest outbreak. Several studies have shown that other pest insects are filling the void left by the absence of the one (or very few) insect pests that Bt crops target, and this is now the problem with Bt maize.

Eggplant is 48% insect pollinated thereby any field release or field testing of genetically modified *Bt* talong will eventually lead to contamination of non-genetically modified eggplant varieties. Insects, particularly honeybees, can fly as far as 4 kilometers and therefore the 200 meters perimeter pollen trap area in the confined field testing set by BPI is not sufficient. And once contamination occurs, genetic cleanup of eggplant or any other plant is impossible. Moreover, intra-specific gene flow from *Bt* talong to other varieties and populations of eggplants should be examined, as cultivated eggplant (*Solanum melongena*) can cross breed with feral populations of *S. melongena*, and it is possible that cultivated varieties can revert to wild phenotypes. Additionally, there is likely to be natural crossing between *Bt* talong and wild relatives. Hybridization with perhaps as many as 29 wild relative species needs to be evaluated.

In 2010, the Minister of Environment and Forests of the Government of India, in his decision for moratorium of *Bt Brinjal*, listed potential contamination of eggplant varieties as one of the reasons why the release of *Bt Brinjal* was not allowed. Dr. Andow of the University of Minnesota also published an 84-pages report on the Environmental Risk Assessment of *Bt Brinjal*, and among his conclusions is that several environmental risks were not considered and nearly all the risk assessment done were inadequate. He concluded that until the risks were understood or managed, there seems to be little reason to approve *Bt Brinjal* release.<sup>93</sup>

**DR. CHAKRABORTY,** Ph.D., M.S. Biochemistry, B.S. (Honors in Chemistry), Calcutta University; Molecular Biologist, presently Principal Scientist and Head of the Gene Regulation Laboratory in the Council of Scientific and Industrial Research – Indian Institute of Chemical Biology (CSIR-IICB); Member, Governing Body and Executive Committee of the

<sup>&</sup>lt;sup>93</sup> Id. at 329-332.

state council of Biotechnology, Government of West Bengal and Chairman of the Biotechnology group of the state council of Science and Technology, Government of West Bengal; Visiting Professor of the National Institute of Science, Technology and Development (CSIR-NISTAD); citizen of India and resident of Kolkata, India.

GMO is a classic example of "paradoxes of consequences", where human actions have unintended consequences, which are in direct opposition to what was intended. The difference in controlled laboratory condition and standards, and real life open field level micro and macro-environment pushes the advantage towards the target and non-target living system, with time. The pest resistance to Bt toxin and development of herbicide tolerance (HT) in weeds is just a matter of time. The decade long experience in Bt and Ht genes amply proves this point. If we ignore this now – we are manufacturing a global environmental disaster - which will be a crime against humanity. There is no way to recall these GMO from the environment.

Even the short term benefits of GM agriculture are not scale neutral, or location-independent. It will help the monopoly agribusiness and the expenses of monopolistic competition or cooperative organic farming. Hot climate and rich biodiversity is detrimental towards the effectiveness of *Bt* constructs, and helpful towards unintended gene flow. Moreover, the genetic manipulation is no way fail safe or exact. Shotgun techniques are being adapted, aided by focused laboratory based screen of traits – rather than the host or the full natural product. The GM labeling is avoided to cover up this major fault.

The tendency to avoid the available risk assessment, and test is very clear in the GM agribusiness. Before going ahead with spread of this technology, even in a batter form, the foremost task is to establish rigorous test and assessment procedures. There are excellent available tools of preteomics, transcriptomics, and metabolomics for detailed compositional analysis in our hand to do this. Please ask, why they are not being employed? In fact, there is not a single centre to test GM products on behalf of the corporate GM Agribusiness house. Thus, low level, long term toxicity of GM foods are yet to be tested. I believe the time has come to establish a standardization facility to carry out such test facility in any country before giving permission to GM trial or cultivation.<sup>94</sup>

The relevant portions of the "hot-tub" hearing held on November 20, 2012, are herein reproduced:

Dr. Cariño:

x x x This is to clarify something with the *BT Talong* and the *BT Talong* has its substance. It is not supposed to be consumed at the moment still under field trial, so it is not supposed to be eaten at the moment. It has not been released for food nor for feed and so in the context of a confined field test, it has supposed to have it out in the field in a very controlled manner and any produce that comes out from that area is supposed to be destroyed or kept from further safety and analysis only.

<sup>&</sup>lt;sup>94</sup> Id. at 2444-2445.

### Chairperson:

So, actually, there is no full scientific certainty that it does not cause any harm pertaining to health?

## Dr. Cariño:

BT Talong per se, has not been fully [e]valuated yet that is why it is undergoing trials. If reporting of the BT toxin in BT Talong is CrylAc, there are numerous studies that had been actually published on relative safety of CrylAc protein and it is actually considered as an additional protein and the various reviews can be seen in the OECD Digest of risk assessments on CrylAc protein. Alternatively, if you are looking at the possibility of harm coming from the introduced protein as yet, we have not done a full blown assessment of it as of the moment. But we look at the protein sequence and with a comparison of its sequence with other sequences in the data basis to see if it is similar to this amino acid sequence of other known toxins and, so far, I have actually ... in my affidavit, I have actually seen personally that it is not closely related to any of the known toxins that are found into its system.

Chairperson:

So, in effect, we can not really say that *BT Talong* is perfectly safe for human consumption?

Dr. Cariño:

Right now it is not meant to be consumed by human at this point. Let me just clarify one point. When any GM material is supposed to be introduced for food and for feed and before it is actually utilized for life skill production, it goes through several steps. The first step is actually the "lab", laboratory work and it is actually tested in this clean-houses, rolled-out confined limited field test and then it goes to butyl abyss of field tests where it is like generating more and more informations. We are still early on in this pathway, so we are only in the confined field test and, at the moment, the thing is that it is still being tested. The focus is on its efficacy after doing a preliminary assessment of the possible pathological and ecological effect, and that is the pathway that has been recommended by so many academics as well as scientific institutions as well. And, that has been a tract followed by almost all the genetically modified crops that is being introduced in the market today, but at the moment BT Talong is not yet a commodity. It is not yet being evaluated as a commodity.

Chairperson:

So, no one in this country has yet eaten this *BT Talong*?

Dr. Cariño:

No, it has not been eaten, as far as I know. Even in India it has not been consumed by human beings because it has not been introduced as a commodity.

### Chairperson:

But what is the ultimate purpose of growing BT Talong? It is not

for human consumption, of course?

Dr. Cariño:

If it passes the safety assessments. That there is always a peak condition that, if it would not to be evaluated in a step of the way much like to evaluate any new product that is coming into the market evaluation, goes on a step-by-step and at least day-to-day basis.

Dr. Davies:

Your Honor, may I interject, may I suggest with your permission? I would just like to make a little bit of explanation.

Chairperson:

Proceed.

Dr. Davies:

I would like to address "BT" as a compound which is distinct from a plain in "Talong". First of all, I think of the name BT toxin is very fortunate. It is really a protein. A protein is an essential constituent of life. It is an essential constituent of our food. In the human body, and in the body of other animals, this protein is under the same as any other protein in food. It has no effect on the human body. This has been shown for many, many years, knowing BT Talong but BT has been a constituent of "maize" in commercial production for 16 years.

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Dr. Davies:

x x x So it has been in corn for 16 years after substantial trials. It has been consumed by Americans in corn products and by any other people who in[g]est American maize corn products x x x. There is not a single case of illness or toxicity or allergenicity that can be or that has been associated with this protein and, therefore, any food containing this protein has been declared by authorities in all the countries that was mentioned by my colleagues, including the European Union and the United States x x x to be as safe as any food derived from the same plant species not containing this gene. I hope that explains a little bit about what it is.

Chairperson:

Are you aware of a study, Dr. Davies, released on September 20 of this year, saying that Monsanto's genetically modified corn is linked to cancer?

Dr. Davies:

Yes. Are you referring, your Honor, to a publication by a French Scientist named Gilles-Eric Seralini? I think this is one of the publications by Seralini's group. Dr. Seralini's work has been refuted by International committees of scientists...

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## Dr. Chakraborty:

Your Honor, may I butt in? It is wrong that proteins can not be toxins. Think about the snake venoms. They are poisons, so whether it is protein or not that is not the question. So proteins obviously venoms and proteins and enzymes and they are poisons so protein can be a poison so that is now the point at all to be considered. The second thing is, yeah, low level toxins long term in[g]estion of this *BT* toxin in human or in any other animal have not been tested. So that is true so we do not know direct consumption of this, because notice have been turned down, that is the objective fact. The third point is about the "American Corn", and if I can give you such anecdotes, "American GM Corn" are not labelled, how do you know that? What is its effect? What is its toxicity? And, obviously, there are more than a hundred of papers showing and published in very good journals. I can give many references which have shown the detrimental effect of *BT* Toxin.

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Chairperson:

But before having this BT *talong* scheduled and allowed for field testing, is it not proper that it should be first determined whether this food product is really safe for eating or not?

Dr. Cariño:

There is an initial assessment that is generally done and according to the Codex Alimentarius of the WHO, the thing that you do at this early stage of development is to compare the sequence of the protein that is being introduced with published sequence of allergens, as well as toxicants and toxins. So that has been done. Then you have to look for instability under heat conditions because there is seldom do we heat grow eggplants, so is it stable under heating. Is it stable in the presence of digestive juices? And, if the answer is "yes", there is at least fair certainty, a fair assurance that it is likely to be safe but then you start thinking of what other component not present in the product, does this. For example, any product that we consume today has something that is bad for you, otherwise, you will not see it right now. Otherwise all the different herbivores will be eating it up, right? It will be extinct if it does not have anything to protect itself and, so, the thing is one, to quantify how much of that has changed when you lead the genetic modification. So "Talong" has been known to have Solanine and glycoalkaloids whose level we'll have to quantify. We have not done that yet. They have not submitted the data for that and this as secondary metabolize whose relative concentration will change depending on the environment to which you actually place the system.

## Dr. Chakraborty:

x x x In india, we have a very bad experience x x x in location field trial with the *BT* Cotton. You known that *BT* Cotton was introduced in India through the back door black market entry. During the field trial, some of those seeds were taken out and given to the farmers for commercial cultivation to black market. Monsanto goes well, Monsanto's *BT* Cotton, like Monsanto, did

not sue now apparently sue the company and they compelled the government that farmers wanted those things and there was high...how they pressurized the government. Now, in case of BT cotton is one thing, but BT Eggplant is completely a different thing. That is why [the] Supreme Court in India has taken a very strong stand and, now, the parliamentary committee in India. The Supreme Court has also taken steps stand with the field trial. The first thing in field trial we had to see that whether there is a definite need of this kind of intervention, because the eggplant is a very common vegetable in this part of the world. There are so many hundreds of varieties here, these are the origins of these varieties of this kind of vegetable. It is cheap. It is available everyday. So why you go on changing if there is no crisis in cultivating the eggplants at present. Therefore, when you give it to this patented seeds technology, its prices will increase, lot of restrictions had to be deal. So, who will consume this high price eggplant. Many will be exported, that was why the proponents are looking into it. But, basically, that is the thing that in case of BT Brinjal, neighbor partisan is being given. There is a moratorium in India from the Supreme Court and from the government side on field trial of BT Brinjal. Now, if x x x the BT Eggplant is being taken to the Philippines, we guess, to get in as a bypass, and who will guarantee that it will not go to the farmers?

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Justice Antonio-Valenzuela:

And, I was wondering in the conduct of the tests, the field testing x x what would be the effect of the planting....of the existence of the genetically modified organism, for example, on insects, on the soil, on the air? And then I was thinking, does this have this particular protein that result[s] due to the genetic modification? Is it...how is it expelled, for example how does it go into the environment? Or, on the other hand, how does it go inside and out of human system so that does it disintegrate or is it just there forever? I am very curious, sir. You have to educate me.

Dr. Davies:

x x x Okay, the DNA is in every cell of the eggplant and, so, a very small amount to protein produced by each cell will be this *BT* protein. It does not get into the environment in general. A very small amount might be in the pollen or in the leaves that fall to the ground but it has been shown to be broken down in the soil by organisms so it will not exist in the environment. The only way that it is going to get into animals or insects is if they eat the fruit and this is what an insect that the "*talong*" fruit and shoot borer will be trying to. But, if it eats it, it reacts with its intestine so that they become toxic to the caterpillar but this is very specific to the digestive system of the caterpillar. It does not affect bees. It does not affect animals. It does not affect humans.

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Dr. Davies:

At the scientific level, it gets changed by alkalinity of the insect

gut and reacts with specific receptors of the cells of the walls of the insect gut. But, this is very specific to the gut of these insects namely the "Lepidoptera" and some "coleoptera" which are the butterflies and the beetles but it will only affect if they try to eat the plant. Now, you are asking us if what is the effect on the environment. x x x I would like to cite x x x a recent paper published in the journal "Nature" x x x the most prestigious scientific journal in the world. x x x published in "Nature" in June this year and this is the result of a study of "insects" in BT Cotton fields in China in 17 locations for 14 years of a long period study. And these scientists revolt that they show a marked increase in the abundance of three types of generalist arthropod predators (ladywings, lacewings and spiders) and a decrease in abundance of aphid pests associated with widespread adoption of Bt cotton. And they are referring to China and they conclude that such crops, x x x BT crops, can promote beneficial control services in agricultural landscapes. And, it also showed that these effects extend beyond the field. So, essentially  $x \times x$  they found that there were more insects than in conventionally grown cotton and the insect diversity was greater surrounded than being detrimental to an agriculture ecosystem such BT cotton falls beneficial.

Dr. Chakraborty:

May I interject, your Honor. Now he is citing one paper they are. But in "*Nature*," there was another news article, "Battlefield". One stream ecologist in United States itself, in a university, she has studied the effect of growing *BT* Corn in the field and what is the effect on the stream ecology, the west water, what is happening to other insects, insects in which it is getting that *BT* toxin will not go. Yes, she has found that *stream ecology*...

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Dr. Chakraborty:

Why was it published in "*Nature*" when that stream ecologist from Loyola University Chicago in Illinois published that paper, published that article in PNAS or *Proceedings of the National Academy of Sciences*, a prestigious journal? Now, they have to desert her. She was abused, so her file was taken out. So people started e-mailing, threatening her. So "*Nature*" has to publish that. How dirty the field has become so they entitled it "Battelfield." If anybody produces any evidence that *BT* Toxin or GM Technology is doing any harm to the environment then it will be battered by the entire English lobby so there is worst the situation. But National Academy of Sciences in United States has taken a strong decision and, in last year, there were six publications that published where strong evidences are being produced about the environmental and ecological damage cause[d] by this technology. So, that is the case.

### Dr. Davies:

Can I respond to that, your Honors?

Dr. Malayang:

I think Filipinos should be able to talk also here.

Chairperson:

Can we give a chance to Dr. Malayang?

Dr. Malayang:

x x x My concern is on the process and participants in vetting the safety of GM crops, not necessarily the intricacies of the science involved in genetic modification per se which, I think our international friends, would like to focus on. x x x

<u>One</u>, I am concerned with the fallibility of technology.  $x \times x$  even if it is much founded on or produced from the most robust sciences, a technology could fail to be as useful as it was intended or its use lead to an [un]intended harm to humans and the environment. This is so because science, by nature, as many scientists will agree, is very probabilistic rather than absolutist. Many cases of common knowledge illustrate this point. May I just refer, for the Court's notice for, First, the Nuclear Power Plants in Japan  $x \times x$ . The best science and the best technology did not necessarily translate to absolute safety.

<u>Second example</u>, the Union Carbide Plant in Bhopal, India. It was among the most advanced production ton at its time, yet, we know what happened.  $x \propto x$  Union Carbide's [hurry] to set up a plant to take advantage of a large pesticide market in India to help the country's farmers led to a massive and deadly safety failure.

<u>The Third example</u> is the green revolution.  $x \times x$  involves, however, the wide [use] of synthetic chemicals for fertilizer and pesticides that were [at] the time hailed as wonder technologies. Many scientists in the world at that time argued for their wider use but they later turned out to harm people, soils and water. They prove good then bad, so bad that scientists today are using their ill effects as justification for adopting alternative technologies to get us out of the synthetic chemical regime in agriculture.

<u>And finally</u>, the most common example would be the unintended effects of medicine. x x x Medicines are technologies intended to do good but, with even the best science and the vetting processes using rigid safety and risk assessment methods, they still could cause side effects entirely undesired and many of which can cause chronic or acute threats to human life. This includes the use of "DDT" that was used to control lice among soldiers after the II World War which, after all, proved to be very bad.

x x x I am also concerned with the fragility, fragility of the Philippine environment as the place and context, the particular place and context of the introduction of *BT* crops like *BT talong*. x x x the Philippines is among the world's biologically rich countries. x x x So, many of our insects are not even fully known. We do not know how they all behave to influence the transfer of genetic materials from plants to other plants. We do not fully know what we do not know about the intricate interactions between plants and between insects and other living things that define the universe of our healthful and balanced ecology. The universe of our healthful and balanced ecology certainly go beyond specific crops. I am concerned that, absent a full as against partial understanding of the intricate web of genetic flows and interactions

among plants, animals and other living things in our wet and tropical ecosystems, it will require extraordinary care to tamper with any one element of this swirl of interrelationships. This is notwithstanding the seeming preponderance of evidence of safety in other countries and environment that are certainly not the same as ours. x x x we must be extra careful because the effects might be irreversible. Introducing a genetically modified plant x x x could cause a string of changes across many plants that, like the green revolution or in the case of medicine and the two other cases cited above, could turn out and only to be realized much later to be harmful to humans and the environment more than they were intended to be useful. x x x let us ensure that we adopt in the country a biosafety vetting protocol that is: (1) sensitive to our high biodiversity this is a particular condition in the Philippines; and (2) tested for error levels that are acceptable to or which can be tolerated by our people. My affidavit states a three-stage approach to this. x x x the tests that we will be doing is a test process acceptable to all as well rather than merely concocted or designed by just a few people x x x must be a product of wider citizens' participation and reflect both scientific and traditional knowledge and cultural sensitivity of our people. It is in the NBF after all, x x x introducing BT Talong in the Philippines must be decided on the grounds of both science and public policy and public policy, in this case, must involve full public disclosure and participation in accepting both the potential gains and possible pains of BT Talong. The stakes, both positive and negative, are so high that I believe BT Talong would require more public scrutiny and wider democratic decision making beyond the [realm] of science. x x x for the sake of our country and our rich biodiversity x x x prudence requires that maximum efforts be exerted to ensure its safety beyond the parameters of science and into the sphere of public policy. For to fail in doing so what might be highly anticipated to be beneficial may in some twist of failure or precaution and prudence and failure for due diligence to establish the safety of Bt Talong beyond reasonable doubt, the BT Talong may turn out to be harmful after all. This we certainly do not want to do. I submit these views to the Court.

### XXXX

Dr. Davies:

x x x another thing I would like to point out to the Court is, if you come into a market in the Philippines and you see nice Talong, it has probably been treated with various insecticides. So, there has been insecticide spray on your tips in your crops which are going to be harm on your farmers, your farmer's children, the insect populations and also dangerous to the consumers as well. By contrast, Bt Talong, if it is adopted, the BT has been shown to be beneficial to the insects and the environment and also has been shown not to be toxic in food. Therefore, we are changing a highly toxic chemical application for a much more benign modern technique that is beneficial to the environment and beneficial to the consumers. That is my comment with the views just made by my Filipino colleagues, your Honors.

## Dr. Malayang:

x x X You know, in ecology and, I am sure you are aware of this, an expansion of anyone population or a reduction of that population it would still be both not beneficial to the healthful and balanced ecological health of the ecosystem. So to say that because the population of insects are exploded and the diversity of insects exploded as a result of this particular intervention is not necessarily good. That is my first point. The second one, you mentioned x x x the "talong" is laden with pesticide. The same pesticide were advised by scientists from the USAID before for us to use in this country because this is how to expand our production of food. This was part of the green revolution, the systemic use of pesticides and fertilizer. Now, of course, they were misused, I can guarantee that but, again, if that be the case, in the case of pesticide why can it not be in the case of BT that it can also be misused? x x x we are talking here not of the science or of the technology but on the policy aspect of the adoption of the technology. As I said, I am talking about the bakery not of a baked-bread.

## Dr. Saturnina Halos:

Well, the use of pesticide in the eggplant, right now, is very much abused.  $x \ x \ x$  In terms of the use of *Bt Talong*, then, that kind of misuse is not going to happen  $x \ x \ x$ . Now, in the Philippines, we have a very strict highly monitored field testing and I think Dr. Malayang knows about that because he was one of those who prepared the guidelines for the field testing. So that is not going to happen, it is a very strict regulatory system. We are known for that, actually, and...

#### хххх

Dr. Saturnina Halos:

No, no. It does not happen because we have a risk management plan  $x \times x$ .

#### хххх

Dr. Halos:

x x x As far as do we know what is happening after we have given approval, yes, we are monitoring. We are monitoring as far as BT*corn* is concerned. We are monitoring, continuously monitoring, not only for the beneficial insects but also the effects that is continuing, we are also continuing to monitor the weeds, weed population. In weed we decide to spray...

# Dr. Malayang:

And why is this, ma'am, why are we monitoring? Because they could be harmful?

### Dr. Halos:

No we have to know what is happening.

### Dr. Malayang:

Yes, why? Because if you are sure that they are safe, if you are sure that they are safe, why monitor?

Dr. Halos:

Well, we are going to give you the data for that because you keep on asking, you know, you asked for a long term and we are going to give you that complete data.

хххх

### Dr. Medina:

I would like to raise several issues because I feel they are misleading sometimes. Dr. Davies mentioned that the BT protein is a protein, therefore, it is safe. Are you sure that all proteins are safe, Dr. Davies? Are you aware of anti-nutrients and allergens and other kinds of protein x x x it is a misleading generalization. Secondly, I would like to say also that, when you say that BT crops is beneficial to insect population but, how about humans? But, let me tell and inform the Honorable Justices also that, in agriculture, there can be, the pests are there to reduce the yield. There are also diseases so, that this Bt is only controlling one kind of pest and, in my monitoring of BT corn as an example to this 2 years after the commercialization in 2003, at first planting in 2003, the corn is attacked by about a dozen insect pests and six major diseases. The Bt corn was attacked a "stem rot", a fungal disease. And, in this case in eggplant, there are many fungal diseases, "phomopsis" x x x So in that case it is not field safe that you will not be using pesticide anymore with BT eggplant. When you use the BTeggplant, assuming that there is no more insect pests x x x There are many other methods of control and, therefore, do not assume that you do not use pesticide therefore, BT is the only solution. That is also a risky and wrong generalization or statement. x x x Dr. Halos x x x says that field tests are safe. I intend to disagree with that. Safe to what? Especially to contamination. If I may use this picture of the field testing of the Bt eggplant x x x it was encircled with cyclone wire with a diameter of something like approximately 10 cm. by 7 cm. hole. While bees that can pollinate that, the size is about 1 cm. in length and .5 cm. in diameter of the insect. The bees and, in that case, they can easily get in and get out and when they settle into the flowers and snip nectars and the fall of the pollen then they can bring out the pollen to contaminate outside that. In fact, even assuming that the fence is very small in size of the mess, the holes, still the insects can fly above that fence because the fence is only about 5 feet in height. So, in that case it is not safe. Some arguments say that "well the pollen will be dead" but, according to this technical manual of the Training Workshop On Data Collection for Researchers And Collaborators of Multi-Location Trials of Fruit and Shoot Borers Resistant Eggplant, that is the Bt Eggplant produced by the Institute of Plant Breeding in UPLB who is one of the main researchers the datas, here say according to "Rasco", cited by Dr. Narciso, is that the pollen can live 8 to 10 days pollen by ability at 20 to 22 degrees centigrade, with a relative humidity of 50 to 55. x x x Meaning to say, that pollen can survive. This can fly as fast as something like 60 kilometers per hours so it just take may be 3 minutes and it can

travel 4 kilometers and 4 kilometers is the effective flying distance of a bee in their normal foraging.

Dr. Medina:

x x x There is no data on the contamination so how come they argue, how can they conclude that it is safe when they have not monitored any potential pollen flow by insect mitigated or insect mediated flow pollen? So, in that case, the conclusion or the statement is really beyond what their data may be is if their data is about safety.

хххх

Dr. Ebora:

**X X X X** 

x x x I hope that we will be able to look at the experimental design and you will see that all the things are properly addressed, our risk assessment was done step by step. x x x I beg to disagree with my friend Dr. Medina because it is becoming ... we are confusing 2 things. We are not referring to contained trial. We are referring to confined field trial and in the design of this particular experiment, you have your BT eggplant, your non-BT eggplant so that you can compare the performance with the 2 crops. And, on design, you have 5 rows of plant BT eggplants that will serve as a pollen trap. When we say pollen trap is that it just open the pollen from the transgenic. It is going to be trapped by those plants, 5 rows, and then, after that, you have a space of 200 meters surrounding the field which is the isolation distance. That means no eggplant should be present in that particular distance because that is the isolation distance that is found to be safe.  $x \ x \ x$  we know that Bt protein is very specific x x x effective only against caterpillar x x x if they are eaten by other organism, they are not affected because it is very specific. The gut of the larva is very alkaline while the gut of other insects is likely acidic and, in that case, it does not have any harmful effect. x x x So another thing is we are saying that it seems to be ridiculous that you are saying that honeybee is going to fly from the fence and the size were even indicated. I would like to indicate that, that is not the purpose of the fence. It is not to contain the insects. It is to prevent vandalism which is quite, unfortunately, being done by other groups who are against the technology. x x x We should be able to have our own space, our own time, considering the given regulation. Follow them. But our experimentation not be destroyed because it is only then that we will be able to get the valuable data that is needed for an informed decision. Without that we will not be able to proceed and I hope we can discuss this based on the merits of the field trial, not from any other concern because the writ of kalikasan is about the effect of field trial in the environment.

Dr. Medina:

Mr. Justice, can I give this immediate counteract to the one statement of Dr. [Ebora]? He said that the "*Cry1Ac*" is specific to caterpillars and, in fact, only some kinds of caterpillar, some species, if you can read by chemical and by physical research

communications this is Volume 271, pages 54-58, authored by Vasquez Pardonnet, published in 2000, publication under letter (b), "CrylAc protoxin" binds to the mucosal surface of the mouse" small intestine. Small intestine ay mammal po iyan so, meaning, it is a proxy animal for safety [testing] to humans because we are also mammals so, the mice are usually the mammals 12 years ago, the data has been already there that there is binding site, therefore it is not only specific to insects but also to mammals. x x x he is saying that, by working on the natural BT is the same as the transformed BT it is not true because the natural BT has 1155 "base pairs" of nucleic acids. And the transformed GM Crop contains a fragment of that BT gene which is only half of that. And the mechanism, by the way,  $x \times x$  the natural toxin is broken into smaller pieces inside the intestine of the insects because it is alkaline in terms of its system "ph" and for humans acidic. So it does not work. But, because the transformed BT is already half, almost half of the normal or natural[ly] occurring BT protein, it is already activated and, in that case, that is the reason why there is a test and immediate effect to non-insect, meaning, to mammal, so that is the explanation of scientist doing studies on that aspect.

#### хххх

## Dr. Chakraborty:

The scientists have 3 problems: One, the sparks, we have a tunnel vision; the second, fear vision; x x x I will give some example. Yes, BT toxin, was it really good biological control agent? But it is a completely different gene when you produce it into an edible plant inside genetically. So, these are 2 different things. What will happen? We are scared that the efficacy, the use of BT toxin as a spray, as biological control agent, will be vanished because now there will be resistance against those in BT toxin. x x x resistance is coming very quickly, just like antibiotic resistance. x x x The second thing, I have asked many plant biologists this simple question, simple honest question. Do you know any plant that can kill a bee or a moth? No! There is no way, why? Because those are the "pollinators". Plant never kills a bee or a moth that goes against nature. x x x So, nature, for thousands of years, farmers help select or adopt edible non-toxic plants. And, now, with the high science we are converting them, non-toxic edible plant into a toxic plant. So not only toxic for the human, for the root microorganisms. x x x Those eggplants are not only for humans to consume. So human effect, we do not know but what will be the effect? Who will mind the effect? Is it the animal which goes through it? x x x in India, x x x farmers x x x while growing BT cotton x x x the leaves and other they use to attract animals to eat. x x x they found suddenly one thing that the BT cotton plants are not touched by those buffalos, those cows, those [boars], but they can distinguish which is BT and non-BT. x x x and when their animals started dying in some cases, they always blame, it is this animal which has eaten that BT? x x x these are [going] against Only few edible seed plants are there and we are nature. converting one safest plant into a poisonous and toxic plant and what is the effect on the root microorganisms on the degrading animals and other? We do not know. That hard thing is the tunnel vision, the confined field trial. x x x why implement this confined

field trial? Is this safe? Why do they have to do this x x x these things do good for a normal hybrid that is something but for the gene concept we cannot follow the same separation rules, same rules? So those are used, those separation distincts, those parameters are used not for the gene. So, which is the safe field trial protocol for the gene plants? We do not know. So there goes against [the] writ of kalikasan.

хххх

Justice Antonio-Valenzuela:

How much is the increase in crop yield? x x x

Dr. Halos:

 $x \ge x$  The average increase yield is about 24% and that is for corn. And this data is actually taken by our own Filipino scientists, Dr. Lluroge and Dr. Gonzales.

хххх

Dr. Malayang:

x x x my question is for Ma'am Nina. I have not been up to date lately on the production of corn so, you mean to say that corn production in the country has gone up and, because of that, you are saying that 24% and the income of farmers had gone up as well? Do you mean to say that the price of corn had also gone up as a result of the increase in the volume of corn production in the Philippines?

Dr. Halos:

Well, the price is dictated by the market.

Dr.Malayang:

That is precisely the point.

Dr. Halos:

Yes.

Dr. Malayang:

x x x I am just bringing, hopefully to the attention of the Court, that, when you talk of a technology such as GM Corn or GM Talong affecting market there is also not only the regulatory but economic regime that is attendant to it that makes adjustments. So it may not be harmful to humans because we will not come out when we eat it but it might be harmful to the economy of a particular agricultural crop. x x x

 $\mathbf{x} \mathbf{x} \mathbf{x} \mathbf{x}$ 

Dr. Ebora:

x x x there are a lot of local studies being conducted now by entomologists from [UPLB] and those are independent studies. And, precisely, this is to determine the effect on natural enemies and the different insects x x x and some of those are already available.  $x \times x$  you will be able to protect the environment only if you know how to have a proper information in making the decision. So, again, I am saying that, in field trial, you will be generating a lot of information that you will be able to use in making a wise decision and informed decision.

 $x \ x \ x$  I would like to correct the impression lodged by the statement of Dr. Chakraborty regarding butterflies and moths. Because they are not affected by *BT* because they are adult insects. The only one that is affected are actually the larva, not even the pupa. So, we would like that to be clear because it might create confusion.

The other thing in resistance.  $x \ x \ x$  even conventionally bred plant [loses] resistance after sometime and that is the reason why we have a continuous breeding program. So, it is a natural mechanism by an organism as mode of ad[a]potation.  $x \ x \ x$  are you telling us that we are going to stop our breeding work because, anyway, they are going to develop resistance. I think it is a wrong message x x x.

The other thing is in terms of the study cited by Dr. Medina regarding the "binding." In toxicology, you can have the effect if you have, for example, the insects, you have a receptor. The toxin will bind into the receptor. Toxin has to fall and then the toxin has re-insert into the membrane. If you eliminate one of those steps you do not have any toxicity. So, that means binding by itself will not be toxicity. It is a wrong impression that, since you have binding, there will be toxicity. – It is simply wrong because, the actuality that it should bind, it should fall then, it should insert, and it is a very common x x x. To say that binding is equivalent to toxicity is simply not true.

The other one is natural *BT* toxin and activated toxin. When you were saying protoxin, protoxin is basically the entire crystal protein. If it is already inside the gut of the insect it has to be clipped by the *purchase* coming from the gut and you have it activated and you have the toxin. So what you have in plant is already the toxin since *the anther and the toxin, and the toxin in microorganisms, the anther which are already clipped by a purchase are the same.* So, to say that they are different is actually wrong. You are comparing protoxin and toxin.

x x x regarding the protein. x x x do you know a lot of proteins of another characteristics and that is why you have to characterize them and you have to separate the protein that are causing problem and protein that are not causing problem. That is why you have allergen and, as explained by Dr. Cariño, you have to check the sequence. x x x

Dr. Chakraborty:

x x x the field trial wanted to basically go to the protocol. This is the efficacy, the efficiency of the production not that much into the safety. You have to look into it carefully that how much will get this efficacy, not the safety to that extent x x x. Second point x x xthere is this already mentioned that European Union there is no

consensus. x x x they have published and submitted the systemic list of genetically modified crop need for new approach in risk assessment. So that is what is needed. There is another article, how does scientific risk assessment of GM crop fit within wider risk analysis. x x x This is genetic engineering. The production process is very precise in selecting the inserted gene but not in its enhancement. x x x they are never looking into it. The second thing, they do not look into that from the laboratory condition to what is the real life situation. They do not take that into account x x x so this assessment protocol has to be modified or changed. x x x in the IAASTD or International Assessment of Agricultural Knowledge, Science and Technology for Development. There is a supreme body, so many nations, so many experts, scientists x x x. Only sustainable agricultural practice and that is the only alternative. This GM technology is not going to help them x x x In my country also, when the BT toxin evaluation was there, everybody was telling that this is pro-poor, this is scale neutral so, everybody will be benefitted by that. So, we started questioning. x x x "What are the actual economic analysis indeed? Just show me". Then, they come up with an answer. Scale neutral means that even small farmers initially wanted BT cotton and big farmers also wanted BT cotton. They are partisans. It is not the economic benefit because, economically, it is not going to be beneficial so it is very much scale dependent its benefit. So, only the big farmers, large farmers and x x x the vegetable field you never can give separation. Chances you never can give refuge. The 1/5 of the land given for growing pests so that you cannot do. So it cannot help technology. They have developed this technology for partisan large scale farming to completely automated for BT technology where no label will be there. But the failed experiments, the contracts whose patent will be over within 2-3 years, they are testing them in our country. So that is the bottom line.

## хххх

Chairperson:

Let us put, probably, a close to this hot tub proceeding now.

The issue that the Court is really interested to resolve is whether or not the conduct of the field trial of BT Talong by the respondents has violated or has threatened to violate the right of the people to a balanced and healthful ecology. Is there absolute certainty that it has not so violated such right. Because that is the requirement for applying or not applying the precautionary principle. x x x

Dr. Cariño:

Yes. The answer to that is we have not violated, you know, the right of the people...

Chairperson:

But there is no absolute certainty?

Dr. Cariño:

Well, quite certain, your Honor, because we have placed all the necessary measures and they did not show us, you know, *there is no evidence of harm* that has been shown to this Court. There is no evidence at all.

Chairperson:

That is your opinion.<sup>95</sup>

As shown by the foregoing, the hot tub hearing has not yielded any consensus on the points of contention between the expert witnesses, *i.e.*, the safety of *Bt talong* to humans and the environment. Evidently, their opinions are based on contrasting findings in hundreds of scientific studies conducted from the time *Bt* technology was deployed in crop farming. These divergent views of local scientists reflect the continuing international debate on GMOs and the varying degrees of acceptance of GM technology by states especially the developed countries (USA, EU, Japan, China, Australia, etc.).

Before proceeding to the current state of global GMO research, we briefly address the strong objection of petitioners to the CA's reliance on the research conducted by Prof. Seralini, the French scientist whose study was published in September 2012 in *Food and Chemical Toxicology*, which was criticized as a "controversial feeding study." Seralini studied rats consuming Monsanto's Roundup Ready treated corn for two years (using the same kind of rats prone to tumors used by Monsanto in obtaining original approval for its product and the same methodologies, but did it for 2 years which is longer than the 90-day experiment period done by Monsanto). The rats formed massive cancerous tumors. All three test groups of rats, with 10 rats in each group, died more frequently, suffered from liver problems, and had a pronounced number of tumors specifically with grotesque mammary and testicular tumors.<sup>96</sup>

Seralini's findings created an uproar and the study was expunged from the publication in November 2013 even though the Editor-in-Chief found no evidence of fraud or intentional misrepresentation of the data. Seralini stood by his work and further conducted similar laboratory experiments. Critics faulted the experimental method, saying the number of rats studied was too small and their diet was skewed when compared with their natural food intake. But over 300 scientists condemned the retraction, they said that the retraction lacked scientific integrity and requested to reinstate the study. Last June 2014, Seralini's controversial study was republished and has passed a third peer review arranged by the journal that is republishing the study, Environmental Sciences Europe. The republished version contains extra material addressing criticisms of the original publication and the raw data underlying the study's findings, and accompanied by a separate commentary by Prof. Seralini's team describing the lobbying efforts of GMO crop supporters to force the editor of the Food and Chemical

<sup>&</sup>lt;sup>95</sup> TSN, November 20, 2012, pp. 34-117; CA *rollo* (Vol. V), pp. 4511-4594.

Plotner, Becky, "Retracted Scientific Study On GMO Rats REPUBLISHED!!!!," Nourishing Plot <<u>http://nourishingplot.com/2014/06/24/retracted-scientific-study-on-gmo-rats-republished/</u>> (visited last December 6, 2014); Plotner, Becky, "GMO Rat Study Forcibly Retracted," Nourishing Plot <<u>http://nourishingplot.com/2014/01/05/gmo-rat-study-forcibly-retracted/</u> > (visited last December 6, 2014).

*Toxicology* to retract the original publication.<sup>97</sup>

The aforesaid incident serves to underscore the crucial role of scientists in providing relevant information for effective regulation of GMOs. There can be no argument that "[s]ince scientific advice plays a key role in GMO regulations, scientists have a responsibility to address and communicate uncertainty to policy makers and the public."<sup>98</sup>

# GMOs: The Global Debate

The uncertainties generated by conflicting scientific findings or limited research is not diminished by extensive use at present of GM technology in agriculture. The global area of GM crops has reached over 175 million hectares in 2013, more than a hundredfold increase from 1.7 million hectares in 1996.<sup>99</sup> However, the worldwide debate on safety issues involving GM foods continues.

It has been pointed out that the crux of the controversy surrounding GMOs lies in the very nature of the technology itself. The process of combining inter-species genes, which is called recombinant DNA technology, does not have the checks and balances that are imposed by nature in traditional breeding. Because of this there is a risk *of genetic instability*. This means that no one can make any accurate predictions about the long-term effects of GMOs on human beings and the environment. Extensive testing in this regard is either very expensive or impractical, and there is still a great deal about the process that scientists do not understand.<sup>100</sup>

The basic concepts for the safety assessment of foods derived from GMOs have been developed in close collaboration under the auspices of the Organization for Economic Co-operation and Development (OECD) and the United Nations' World Health Organization (WHO) and Food and Agricultural Organization (FAO). The OECD's group of experts on biosafety recommended conducting the safety assessment of a GM food on case-by-case basis through comparison to an existing food with a long history of safe use. Thus, the concept of *substantial equivalence* was developed that is widely used by national and international agencies, including the US Food and Drug Administration (FDA), the WHO, OECD and the FAO.<sup>101</sup>

<sup>&</sup>lt;sup>97</sup> Id.; "Republication of the Seralini study: Science speaks for itself," <<u>http://www.gmoseralini.org/republication-seralini-study-science-speaks/</u>> (visited last December 6, 2014).

<sup>&</sup>lt;sup>98</sup> Anne Ingeborg Myrh and Terje Traavik, "The Precautionary Principle: Scientific Uncertainty and Omitted Research in the Context of GMO Use and Release," <<u>https://www.cbd.int/doc/articles/2008/A-00637.pdf</u>> (visited last December 6, 2014).

<sup>&</sup>lt;sup>99</sup> James Clive, 2013. Global Status of Commercialized Biotech GM Crops: 2013. ISAAA Brief No. 46. ISAAA: Ithaca, NY.

<sup>&</sup>lt;sup>100</sup> Sonal Panse, "The Advantages & Disadvantages of Genetically Modified Food: Both Sides of the Debate," <<u>http://www.brighthub.com/science/genetics/articles/23358.aspx</u>> (visited last December 6, 2014).

 <sup>&</sup>lt;sup>101</sup> Harry A. Kuiper, Gijs A. Kleter, Hub P.J.M. Noteborn and Esther J. Kok, "Assessment of the Food Safety Issues Related to Genetically Modified Foods,

"Substantial equivalence embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety (*i.e.*, the food or food component can be concluded to be as safe as the conventional food or food component)."<sup>102</sup> The safety assessment of a genetically modified food is directed by the results of a comparison between the genetically modified food and its conventional counterpart. It follows a stepwise process aided by a series of structured questions. Factors taken into account in the safety assessment include:

- identity;
- source;
- composition;
- effects of processing/cooking;
- transformation process;
- the recombinant DNA (e.g. stability of insertion, potential for gene transfer);
- protein expression product of the novel DNA:
  - effects on function;
  - potential toxicity;
  - potential allergenicity;
- possible secondary effects from gene expression or the disruption of the host DNA or metabolic pathways, including composition of critical macro, micro-nutrients, anti-nutrients, endogenous toxicants, allergens, and physiologically active substances; and,
- potential intake and dietary impact of the introduction of the genetically modified food.<sup>103</sup>

The above factors are particularly pertinent to the assessment of foods derived from genetically modified plants.<sup>104</sup> However, the concept of substantial equivalence as the starting point of risk assessment was criticized for being "unscientific and arbitrary" and "intentionally vague and ill-defined to be as flexible, malleable, and open to interpretation as possible." It is likewise argued that "comparisons are designed to conceal significant changes resulting from genetic modifications," "the principle is weak and misleading even when it does not apply, effectively giving producers carte blanche", and that there is insufficiency of background information for assessing substantial equivalence. A paper presented at a WHO workshop pointed out that the main difficulty associated with the biosafety assessment of transgenic crops is the unpredictable nature of transformation. This unpredictability raises the concern that transgenic plants will behave in an inconsistent manner when grown commercially.<sup>105</sup>

<sup>&</sup>lt;<u>http://www.data.forestry.oregonstate.edu/orb/BiotechClass/2004%20materials/5A-FOOD%20REG/Plant%20Journal%202001.pdf</u>>.

<sup>&</sup>lt;sup>2</sup> Joint FAO/WHO Biotechnology and Food Safety Report, 1996, p. 4.

<sup>&</sup>lt;sup>103</sup> World Health Organization (WHO), "Safety Aspects of Genetically Modified Foods of Plant Origin," <<u>http://www.fao.org/fileadmin/templates/agns/pdf/topics/ec\_june2000\_en.pdf</u>> (visited last December 6, 2014).

<sup>&</sup>lt;sup>104</sup> Id. at 5.

<sup>&</sup>lt;sup>105</sup> Mae-Wan Ho and Ricarda A. Steinbrecher, "Fatal Flaws in Food Safety Assessment: Critique of The Joint FAO/WHO Biotechnology and Food Safety Report," Accessed at

The method of testing GM foods was further described as inadequate, as currently the testing procedures consist almost exclusively of specific chemical and biochemical analytical procedures designed to quantitate a specific nutrient or a specific toxin or allergen. It was noted that in actual practice, the investigator compares only selected characteristics of the genetically engineered food to those of its non-genetically engineered counterpart. These testing schemes are viewed as completely incapable of detecting unsuspected or unanticipated health risks that are generated by the process of genetic engineering itself. Hence, clinical tests are recommended because only such tests have the broad specificity and relevance to human physiology needed to detect the wide range of allergens and toxins that might result from unexpected side-effects of the genetic engineering process.<sup>106</sup>

In another review article, it was pointed out that since a genetic modification is aimed at introducing new traits into organisms, the result will always be a different composition of genes and proteins. The most reasonable interpretation therefore is that a food derived from a GMO is considered substantially equivalent to its traditional counterpart if the genetic modification has not resulted in intended or unintended alterations in the composition of relevant nutrients and inherent toxicants of the organism, and that the new genes and proteins have no adverse impact on the dietary value of the food and do not therefore pose any harm to the consumer or the environment. It was thus concluded that establishing substantial equivalence is not a safety assessment in itself, but is a pragmatic tool to analyze the safety of a new food, and hence in the testing of new foods, the latest scientific methods have to be used. All conceivable efforts to protect consumers from health risks should thus be made, and at the same time, consumers should be adequately informed about the real extent of risks and hazards.<sup>107</sup>

The GMO global debate has so intensified that each side has accused the other camp of mounting "paid advocacy" and criticizing studies adverse to their respective positions as flawed or unscientific. Both the agri-business industry, and groups opposed to GMOs including the organic farming industry, had utilized enormous resources and funds for lobbying and media campaigns locally and internationally.

What appears to be highlighted in the promotion of GM crop production is the marked reduction in the use of harmful chemical pesticides.<sup>108</sup> The resulting increase in crop yields grown on relatively small parcels of land is also regarded as a solution to the problem of feeding a fast

<sup>&</sup>lt;<u>http://www.psrast.org/fao96.htm</u>> (visited last December 6, 2014).

John Fagan, Ph.D., "The Failings of the Principle of Substantial Equivalence in Regulating Transgenic Foods," <<u>http://www.psrast.org/jfsbqsht.htm</u>> (visited last December 6, 2014).
 <sup>107</sup> Martin Martin Construct of California Construction Foods, "The Construction of California Construction o

 <sup>&</sup>lt;sup>107</sup> Marianna Schauzu, "The Concept of Substantial Equivalence in Safety Assessment of Foods Derived From Genetically Modified Organisms" AgBiotech Net (April 2000)
 <a href="http://www.bfr.bund.de/cm/349/schauzu.pdf">http://www.bfr.bund.de/cm/349/schauzu.pdf</a>
 (visited last December 6, 2014.)

R.H. Phipps and J.R. Park, "Environmental Benefits of Genetically Modified Crops: Global and European Perspectives on their Ability to Reduce Pesticide Use," *Journal of Animal and Feed Sciences* (January 31, 2002), <<u>http:///cib.org.br/wp-content/uploads/2011/10/estudos.cientificos\_ambiental\_32.pdf</u>> (visited last December 6, 2014).
growing world population. Proponents of GM biotechnology insist that GM foods are safe to humans and the environment based on scientific studies. On the other hand, anti-GM activists disseminate adverse results of recent studies confirming the health and environmental hazards of genetically engineered crop farming. Also, some countries have maintained a firm stance against genetically engineered crops or GM foods, such as France and Austria. Over the years, however, accumulated evidence of the dangers of GMOs, as well as unrealized socio-economic benefits, has been increasingly recognized by the scientific community.

That GE farming increases crop yield has been debunked by new studies proving the contrary. In the article, "GM Crops Do Not Increase Yield Potential," the Institute for Responsible Technology cited reports from actual field studies in different countries revealing downward figures for Bt crops, as summarized below:

- *Bt* corn took longer to reach maturity and produced up to 12% lower yields than non-GM counterparts.
- Evidence for the "yield drag" of Roundup Ready soybeans has been known for over a decade with the disruptive effect of the GM transformation process accounting for approximately half the drop in yield.
- Based on a comprehensive evaluation of yield since the introduction of commercial GM crops, the International Assessment of Agricultural Knowledge, Science and Technology (IAASTD) noted that GM crop yields were "highly variable" and in some cases, "yields declined".
- The Union of Concerned Scientists' 2009 report *Failure to Yield*, based on published peer-reviewed studies conducted by academic scientists using adequate controls, concluded that genetically engineered herbicide tolerant soybeans and herbicide-tolerant corn has not increased yields while insect-resistant corn has only marginally improved yields. Traditional breeding outperforms genetic engineering hands down.
- In developing countries, crop failure can have severe consequences as illustrated in India, where a large number of cotton farmers, unable to pay back high interest loans, have committed suicide. Several investigations have implicated the unreliable performance of *Bt* cotton as a major contributor.
- *Bt* cotton was overrun by pests in Indonesia and China. In South Africa, farmers faced pest problems and no increase in yield. The 100,000 hectares planted in 1998 dropped 80% to 22,500 by 2002. As of 2004, 85% of the original *Bt* cotton farmers had given up while those remaining had to be subsidized by the government. Similarly in the US, *Bt* cotton yields are not necessarily consistent or more profitable.<sup>109</sup>

GM technology is thus seen as a failure in terms of addressing food security; rather, it supports corporate control and impedes common persons'

<sup>&</sup>lt;sup>109</sup> <<u>http://responsibletechnology.org/docs/gm-crops-do-not-increase-yields.pdf</u>>.

access to adequate food. The root cause of hunger is not a lack of food, GM critics say, but a lack of access to food. The poor lack money to buy food and lack of land on which to grow it. It is essential to follow sustainable traditional farming practices that keeps food production in the hands of small-scale farmers, thereby reducing corporate control.<sup>110</sup>

As regards the existing uncertainties of potential *long-term* effects of the release into the environment of GMOs, the BEETLE (Biological and Ecological Evaluation towards Long-term Effects) study of 2009,<sup>111</sup> made for the European Commission, analyzed more than 700 scientific publications from all over the world about GMOs and their potential effects on environment including biodiversity, and received contributions to online surveys from 100 to 167 invited environmental experts. This study declared the following uncertainties:

- increased fitness of GM plants;
- outbreeding depression after hybridization with wild relatives;
- outcrossing between related species and the fate of a transferred GM trait;
- altered flower phenology;
- altered fecundity, increasing seed (gene) flow;
- increased frequency of horizontal gene flow;
- resistance development of pests;
- effects on non-target organisms;
- effects on non-target organisms due to altered nutritional composition of the GM plant;
- effects on non-target organisms due to accumulation of toxic compounds;
- effects on rhizosphere microbiota;
- effects on symbiotic non-target organisms;
- changes in soil functions caused by GM traits;
- effects on biological control;
- altered use of agrochemicals;
- indirect changes in susceptibility of crops against pathogens;
- adverse effects on agro-biodiversity;
- indirect effects in fertilizer use;
- potential changes in landscape structure;
- increased production of greenhouse gases;
- increased mineral nutrient erosion and fertilizer leaching;
- altered chemical attributes of soil fraction;
- emerging of stacked events;
- the necessity of regional differentiation of risk assessments.<sup>112</sup>

A critical observation was made on the argument that there is not enough evidence to reject the hypothesis that GMO and GM food is safe.

<sup>&</sup>lt;sup>110</sup> Human Rights Advocates, "Promoting Right to Food Through Food Sovereignty," <<u>http://www.humanrightsadvocates.org/wp-content/uploads/2014/03/HRC-25-Promoting-Right-to-Food-Through-Food-Sovereignty.pdf</u>> (visited last December 6, 2014).

<sup>&</sup>lt;sup>111</sup> <<u>http://ec.europa.eu/food/food/biotechnology/reports\_studies/docs/lt\_effects\_report\_en.pdf</u>>.

 <sup>&</sup>lt;sup>112</sup> Prof. Dr. Ludwig Krämer, "Genetically Modified Living Organisms and the Precautionary Principle,"
<a href="https://www.testbiotech.org/sites/default/files/GMO%20and%20precaution.pdf">https://www.testbiotech.org/sites/default/files/GMO%20and%20precaution.pdf</a> (visited last December 7, 2014).

Decision

The fact emphasized was that experiments designed to clarify potential adverse effects on health or the environment are nearly absent in peer-reviewed journals. Scientific uncertainty, omitted research areas, and lack of basic knowledge crucial to risk assessments have become apparent. The present uncertainty warrants further research and it has been demonstrated that there is a risk of bias relying on hypotheses that dominate mainstream science. There is therefore a need for independent research that is without prejudice and unbiased by economic and professional interests.<sup>113</sup> In another article it was noted that the clinical trials carried out to ensure that negative externalities do not affect humans and the environment are conducted by the same private firms that created the products, raising conflict of interest concerns.<sup>114</sup>

While existing literature on health effects of GM foods indicates that they are generally safe, and similar conclusions have been drawn by government agencies and scientific organizations such as FAO/WHO and Society of Toxicology, a growing number of independent scientists have spoken strongly against such generalizations from limited research mostly sponsored by biotech companies.

In 1999, the Open Letter from World Scientists to All Governments signed by 815 scientists from 82 countries expressed that they are extremely concerned about the hazards of GMOs to biodiversity, food safety, human and animal health, and demanded a moratorium on environmental releases in accordance with the precautionary principle. They are opposed to GM crops that will intensify corporate monopoly, exacerbate inequality and prevent the essential shift to sustainable agriculture that can provide food security and health around the world, and called a ban on patents of life forms and living processes which threaten food security, sanction biopiracy of indigenous knowledge and genetic resources and violate basic human rights and dignity.<sup>115</sup>

On May 10, 2003, dozens of prominent scientists from various disciplines banded together as an Independent Science Panel on GM at a public conference in London. On June 15, 2003, they released a Final Report<sup>116</sup> as their contribution to the National GM Debate in UK. In a summary<sup>117</sup> of the final report, these scientists declared the following:

<sup>&</sup>lt;sup>113</sup> Ingeborg and Traavik, supra note 98, at 73, 80-81.

<sup>&</sup>lt;sup>114</sup> Marcelo Gortari, "GMOs, Risk and the Precautionary Principle," *Public Policy & Governance Review* (July 11, 2013) <<u>http://ppgreview.ca/2013/07/11/gmos-risk-and-the-precautionary-principle/</u>> (visited last December 7, 2014).

<sup>&</sup>lt;sup>115</sup> "Open Letter from World Scientists to All Government Concerning Genetically Modified Organisms (GMOs)," <<u>http://www.i-sis.org.uk/list.php</u>> (visited last December 7, 2014).

<sup>&</sup>lt;sup>116</sup> International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), "Agriculture at a Crossroads," <a href="http://www.unep.org/dewa/agassessment/reports/IAASTD/EN/Agriculture%20at%20a%20Crossroads\_">http://www.unep.org/dewa/agassessment/reports/IAASTD/EN/Agriculture%20at%20a%20Crossroads\_</a> Global%20Report%20(English) pdf2 (visited last December 7, 2014)

Global%20Report%20(English).pdf> (visited last December 7, 2014). "The Case for a GM-Free Sustainable World – A Summary," <<u>http://www.i-sis.org.uk/ispr-summary.php</u>> (visited last December 7, 2014.).

The Case for a GM-Free Sustainable World – A Summary

## Why GM-Free?

## 1. GM crops failed to deliver promised benefits

- No increase in yields or significant reduction in herbicide and pesticide use
- United States lost an estimated \$12 billion over GM crops amid worldwide rejection
- Massive crop failures of up to 100% reported in India
- High risk future for agbiotech: "Monsanto could be another disaster waiting to happen for investors"

### 2. GM crops posing escalating problems on the farm

- Transgenic lines unstable: "most cases of transgene inactivation never reach the literature"
- Triple herbicide-tolerant volunteers and weeds emerged in North America
- Glyphosate-tolerant weeds plague GM cotton and soya fields, atrazine back in use
- Bt biopesticide traits threatening to create superweeds and btresistant pests

### 3. Extensive transgenic contamination unavoidable

- Extensive transgenic contamination found in maize landraces in remote regions of Mexico
- 32 out of 33 commercial seed stocks found contaminated in Canada
- Pollen remains airborne for hours, and a 35 mile per hour wind speed is unexceptional
- There can be no co-existence of GM and non-GM crops

## 4. GM crops not safe

- GM crops have not been proven safe: regulation was fatally flawed from the start
- The principle of 'substantial equivalence', vague and ill defined, gave companies complete licence in claiming GM products 'substantially equivalent' to non-GM, and hence 'safe'

### 5. GM food raises serious safety concerns

- Despite the paucity of credible studies, existing findings raise serious safety concerns
- 'Growth-factor-like' effects in the stomach and small intestine of young rats were attributed to the transgenic process or the transgenic construct, *and may hence be general to all GM food*

## 6. Dangerous gene products are incorporated into food crops

- Bt proteins, incorporated into 25% of all GM crops worldwide, are harmful to many non-target insects, and some are potent immunogens and allergens for humans and other mammals
- Food crops are increasingly used to produce pharmaceuticals and drugs, including cytokines known to suppress the immune system, or linked to dementia, neurotoxicity and mood and cognitive side effects; vaccines and viral sequences such as the 'spike' protein gene of the pig coronavirus, in the same family as the SARS virus linked to the current epidemic; and glycoprotein gene gp120 of the AIDS virus that could interfere with the immune system and recombine with viruses and bacteria to generate new and unpredictable pathogens.

#### 7. Terminator crops spread male sterility

• Crops engineered with 'suicide' genes for male sterility, promoted as a means of preventing the spread of transgenes, actually spread both male sterility and herbicide tolerance traits *via pollen*.

## 8. Broad-spectrum herbicides highly toxic to humans and other species

- Glufosinate ammonium and glyphosate, used with herbicide tolerant GM crops that currently account for 75% of all GM crops worldwide, are both systemic metabolic poisons
- Glufosinate ammonium is linked to neurological, respiratory, gastrointestinal and haematological toxicities, and birth defects in humans and mammals; also toxic to butterflies and a number of beneficial insects, to larvae of clams and oysters, *Daphnia* and some freshwater fish, especially the rainbow trout; it inhibits beneficial soil bacteria and fungi, especially those that fix nitrogen.
- Glyphosate is the most frequent cause of complaints and poisoning in the UK, and disturbances to many body functions have been reported after exposures at normal use levels; glyphosate exposure nearly doubled the risk of late spontaneous abortion, and children born to users of glyphosate had elevated neurobehavioral defects; glyphosate retards development of the foetal skeleton in laboratory rats, inhibits the synthesis of steroids, and is genotoxic in mammals, fish and frogs; field dose exposure of earthworms caused at least 50 percent mortality and significant intestinal damage among surviving worms; Roundup (Monsanto's formulation of glyphosate) caused cell division dysfunction that may be linked to human cancers.

#### 9. Genetic engineering creates super-viruses

- The most insidious dangers of genetic engineering are inherent to the process; it greatly enhances the scope and probability of horizontal gene transfer and recombination, the main route to creating viruses and bacteria that cause disease epidemics.
- Newer techniques, such as DNA shuffling, allow geneticists to create in a matter of minutes in the laboratory millions of

recombinant viruses that have never existed in billions of years of evolution

• Disease-causing viruses and bacteria and their genetic material are the predominant materials and tools of genetic engineering, as much as for the intentional creation of bio-weapons.

## 10. Transgenic DNA in food taken up by bacteria in human gut

• Transgenic DNA from plants has been taken up by bacteria both in the soil and in the gut of human volunteers; antibiotic resistance marker genes can spread from transgenic food to pathogenic bacteria, making infections very difficult to treat.

## 11. Transgenic DNA and cancer

- Transgenic DNA known to survive digestion in the gut and to jump into the genome of mammalian cells, raising the possibility for triggering cancer
- Feeding GM products such as maize to animals may carry risks, not just for the animals but also for human beings consuming the animal products

## 12. CaMV 35S promoter increases horizontal gene transfer

 Evidence suggests that transgenic constructs with the CaMV 35S promoter could be especially unstable and prone to horizontal gene transfer and recombination, with all the attendant hazards: gene mutations due to random insertion, cancer, re-activation of dormant viruses and generation of new viruses.

# 13. A history of misrepresentation and suppression of scientific evidence

• There has been a history of misrepresentation and suppression of scientific evidence, especially on horizontal gene transfer. Key experiments failed to be performed, or were performed badly and then misrepresented. Many experiments were not followed up, including investigations on whether the CaMV 35S promoter is responsible for the 'growth-factor-like' effects observed in young rats fed GM potatoes.

GM crops have failed to deliver the promised benefits and are posing escalating problems on the farm. Transgenic contamination is now widely acknowledged to be unavoidable, and hence there can be no co-existence of GM and non-GM agriculture. Most important of all, GM crops have not been proven safe. On the contrary, sufficient evidence has emerged to raise serious safety concerns, that if ignored could result in irreversible damage to health and the environment. GM crops should therefore be firmly rejected now.

The ISP further concluded that "[s]ustainable agricultural practices have proven beneficial in all aspects relevant to health and the environment. In addition, they bring food security and social and cultural well being to local communities everywhere. There is an urgent need for a comprehensive global shift to all forms of sustainable agriculture."<sup>118</sup>

In 2008, a Global Report<sup>119</sup> was released by the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), a three-year international collaborative effort (2005-2007) developed out of a consultative process involving 900 participants and 110 countries from all over the world. This global initiative assessed agricultural knowledge, science and technology (AKST) in relation to meeting development and sustainability goals of (1) reducing hunger and poverty; (2) improving nutrition, health and rural livelihoods; and (3) facilitating social and environmental sustainability. The report concluded that a radical transformation of the world's food and farming systems especially the policies and institutions that affect them - is necessary if we are to overcome converging economic and environmental crises and feed the world sustainably. It also warned that technologies such as high-yielding crop varieties, agrochemicals and mechanization have primarily benefited the better-resourced groups in society and transnational corporations, rather than the most vulnerable ones. In general, the IAASTD found little evidence to support a conclusion that modern biotechnologies are well suited to meeting the needs of small-scale and subsistence farmers, particularly under the increasingly unpredictable environmental and economic conditions that they face.<sup>120</sup>

More recently, in 2013, the European Network of Scientists for Social and Environmental Responsibility (ENSSER), an international group of more than 90 scientists, academics and physicians, released a statement that there is no scientific consensus on the safety of GM foods and crops.<sup>121</sup> The statement<sup>122</sup> is herein reproduced:

#### 10/21/13

#### Statement: No scientific consensus on GMO safety

As scientists, physicians, academics, and experts from disciplines relevant to the scientific, legal, social and safety assessment aspects of genetically modified organisms (GMOs), we strongly reject claims by GM seed developers and some scientists, commentators, and journalists that there is a "scientific consensus" on GMO safety and that the debate on this topic is "over".

We feel compelled to issue this statement because the claimed consensus on GMO safety does not exist. The claim that it does exist is misleading

<sup>&</sup>lt;sup>118</sup> Id.

<sup>&</sup>lt;sup>119</sup> Supra note 116.

<sup>&</sup>lt;sup>120</sup> International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), "Biotechnology and Sustainable Development," <<u>www.biosafety-info.net/file\_dir/4542994024ca566872c339.pdf</u>> (visited last December 7, 2014).

 <sup>&</sup>lt;sup>121</sup> "No scientific consensus on safety of genetically modified organisms," <<u>http://phys.org/news/2013-10-scientific-consensus-safety-genetically.html</u>> (visited last December 7, 2014).
<sup>122</sup> The scientific consensus of the sc

<sup>&</sup>lt;sup>22</sup> European Network of Scientists for Social and Environmental Responsibility, "Statement: No scientific consensus on GMO safety," <<u>http://www.ensser.org/increasing-public-information/no-scientific-consensus-on-gmo-safety/</u>> (visited last December 7, 2014).

and misrepresents the currently available scientific evidence and the broad diversity of opinion among scientists on this issue. Moreover, the claim encourages a climate of complacency that could lead to a lack of regulatory and scientific rigour and appropriate caution, potentially endangering the health of humans, animals, and the environment.

Science and society do not proceed on the basis of a constructed consensus, as current knowledge is always open to well-founded challenge and disagreement. We endorse the need for further independent scientific inquiry and informed public discussion on GM product safety and urge GM proponents to do the same.

Some of our objections to the claim of scientific consensus are listed below.

#### 1. There is no consensus on GM food safety

Regarding the safety of GM crops and foods for human and animal health, a comprehensive review of animal feeding studies of GM crops found "An equilibrium in the number [of] research groups suggesting, on the basis of their studies, that a number of varieties of GM products (mainly maize and soybeans) are as safe and nutritious as the respective conventional non-GM plant, and those raising still serious concerns". The review also found that most studies concluding that GM foods were as safe and nutritious as those obtained by conventional breeding were "performed by biotechnology companies or associates, which are also responsible [for] commercializing these GM plants".

A separate review of animal feeding studies that is often cited as showing that GM foods are safe included studies that found significant differences in the GM-fed animals. While the review authors dismissed these findings as not biologically significant, the interpretation of these differences is the subject of continuing scientific debate and no consensus exists on the topic.

Rigorous studies investigating the safety of GM crops and foods would normally involve animal feeding studies in which one group of animals is fed GM food and another group is fed an equivalent non-GM diet. Independent studies of this type are rare, but when such studies have been performed, some have revealed toxic effects or signs of toxicity in the GM-fed animals. The concerns raised by these studies have not been followed up by targeted research that could confirm or refute the initial findings.

The lack of scientific consensus on the safety of GM foods and crops is underlined by the recent research calls of the European Union and the French government to investigate the long-term health impacts of GM food consumption in the light of uncertainties raised by animal feeding studies. These official calls imply recognition of the inadequacy of the relevant existing scientific research protocols. They call into question the claim that existing research can be deemed conclusive and the scientific debate on biosafety closed.

## 2. There are no epidemiological studies investigating potential effects of GM food consumption on human health

It is often claimed that "trillions of GM meals" have been eaten in the US with no ill effects. However, no epidemiological studies in human

populations have been carried out to establish whether there are any health effects associated with GM food consumption. As GM foods are not labelled in North America, a major producer and consumer of GM crops, it is scientifically impossible to trace, let alone study, patterns of consumption and their impacts. Therefore, claims that GM foods are safe for human health based on the experience of North American populations have no scientific basis.

## 3. Claims that scientific and governmental bodies endorse GMO safety are exaggerated or inaccurate

Claims that there is a consensus among scientific and governmental bodies that GM foods are safe, or that they are no more risky than non-GM foods, are false.

For instance, an expert panel of the Royal Society of Canada issued a report that was highly critical of the regulatory system for GM foods and crops in that country. The report declared that it is "scientifically unjustifiable" to presume that GM foods are safe without rigorous scientific testing and that the "default prediction" for every GM food should be that the introduction of a new gene will cause "unanticipated changes" in the expression of other genes, the pattern of proteins produced, and/or metabolic activities. Possible outcomes of these changes identified in the report included the presence of new or unexpected allergens.

A report by the British Medical Association concluded that with regard to the long-term effects of GM foods on human health and the environment, "many unanswered questions remain" and that "safety concerns cannot, as yet, be dismissed completely on the basis of information currently available". The report called for more research, especially on potential impacts on human health and the environment.

Moreover, the positions taken by other organizations have frequently been highly qualified, acknowledging data gaps and potential risks, as well as potential benefits, of GM technology. For example, a statement by the American Medical Association's Council on Science and Public Health acknowledged "a small potential for adverse events ... due mainly to horizontal gene transfer, allergenicity, and toxicity" and recommended that the current voluntary notification procedure practised in the US prior to market release of GM crops be made mandatory. It should be noted that even a "small potential for adverse events" may turn out to be significant, given the widespread exposure of human and animal populations to GM crops.

A statement by the board of directors of the American Association for the Advancement of Science (AAAS) affirming the safety of GM crops and opposing labelling cannot be assumed to represent the view of AAAS members as a whole and was challenged in an open letter by a group of 21 scientists, including many long-standing members of the AAAS. This episode underlined the lack of consensus among scientists about GMO safety.

## 4. EU research project does not provide reliable evidence of GM food safety

An EU research project has been cited internationally as providing evidence for GM crop and food safety. However, the report based on this project, "A Decade of EU-Funded GMO Research", presents no data that could provide such evidence, from long-term feeding studies in animals.

Indeed, the project was not designed to test the safety of any single GM food, but to focus on "the development of safety assessment approaches". Only five published animal feeding studies are referenced in the SAFOTEST section of the report, which is dedicated to GM food safety. None of these studies tested a commercialised GM food; none tested the GM food for long-term effects beyond the subchronic period of 90 days; all found differences in the GM-fed animals, which in some cases were statistically significant; and none concluded on the safety of the GM food tested, let alone on the safety of GM foods in general. Therefore the EU research project provides no evidence for sweeping claims about the safety of any single GM food or of GM crops in general.

### 5. List of several hundred studies does not show GM food safety

A frequently cited claim published on an Internet website that several hundred studies "document the general safety and nutritional wholesomeness of GM foods and feeds" is misleading. Examination of the studies listed reveals that many do not provide evidence of GM food safety and, in fact, some provide evidence of a lack of safety. For example:

- Many of the studies are not toxicological animal feeding studies of the type that can provide useful information about health effects of GM food consumption. The list includes animal production studies that examine parameters of interest to the food and agriculture industry, such as milk yield and weight gain; studies on environmental effects of GM crops; and analytical studies of the composition or genetic makeup of the crop.
- Among the animal feeding studies and reviews of such studies in the list, a substantial number found toxic effects and signs of toxicity in GM-fed animals compared with controls. Concerns raised by these studies have not been satisfactorily addressed and the claim that the body of research shows a consensus over the safety of GM crops and foods is false and irresponsible.
- Many of the studies were conducted over short periods compared with the animal's total lifespan and cannot detect long-term health effects.

We conclude that these studies, taken as a whole, are misrepresented on the Internet website as they do not "document the general safety and nutritional wholesomeness of GM foods and feeds". Rather, some of the studies give serious cause for concern and should be followed up by more detailed investigations over an extended period of time.

#### 6. There is no consensus on the environmental risks of GM crops

Environmental risks posed by GM crops include the effects of Bt insecticidal crops on non-target organisms and effects of the herbicides used in tandem with herbicide-tolerant GM crops.

As with GM food safety, no scientific consensus exists regarding the environmental risks of GM crops. A review of environmental risk assessment approaches for GM crops identified shortcomings in the procedures used and found "no consensus" globally on the methodologies that should be applied, let alone on standardized testing procedures.

Some reviews of the published data on Bt crops have found that they can have adverse effects on non-target and beneficial organisms – effects that are widely neglected in regulatory assessments and by some scientific commentators. Resistance to Bt toxins has emerged in target pests, and problems with secondary (non-target) pests have been noted, for example, in Bt cotton in China.

Herbicide-tolerant GM crops have proved equally controversial. Some reviews and individual studies have associated them with increased herbicide use, the rapid spread of herbicide-resistant weeds, and adverse health effects in human and animal populations exposed to Roundup, the herbicide used on the majority of GM crops.

As with GM food safety, disagreement among scientists on the environmental risks of GM crops may be correlated with funding sources. A peer-reviewed survey of the views of 62 life scientists on the environmental risks of GM crops found that funding and disciplinary training had a significant effect on attitudes. Scientists with industry funding and/or those trained in molecular biology were very likely to have a positive attitude to GM crops and to hold that they do not represent any unique risks, while publicly-funded scientists working independently of GM crop developer companies and/or those trained in ecology were more likely to hold a "moderately negative" attitude to GM crop safety and to emphasize the uncertainty and ignorance involved. The review authors concluded, "The strong effects of training and funding might justify certain institutional changes concerning how we organize science and how we make public decisions when new technologies are to be evaluated."

## 7. International agreements show widespread recognition of risks posed by GM foods and crops

The Cartagena Protocol on Biosafety was negotiated over many years and implemented in 2003. The Cartagena Protocol is an international agreement ratified by 166 governments worldwide that seeks to protect biological diversity from the risks posed by GM technology. It embodies the Precautionary Principle in that it allows signatory states to take precautionary measures to protect themselves against threats of damage from GM crops and foods, even in case of a lack of scientific certainty.

Another international body, the UN's Codex Alimentarius, worked with scientific experts for seven years to develop international guidelines for the assessment of GM foods and crops, because of concerns about the risks they pose. These guidelines were adopted by the Codex Alimentarius Commission, of which over 160 nations are members, including major GM crop producers such as the United States.

The Cartagena Protocol and Codex share a precautionary approach to GM crops and foods, in that they agree that genetic engineering differs from conventional breeding and that safety assessments should be required before GM organisms are used in food or released into the environment.

These agreements would never have been negotiated, and the implementation processes elaborating how such safety assessments should be conducted would not currently be happening, without widespread

international recognition of the risks posed by GM crops and foods and the unresolved state of existing scientific understanding.

Concerns about risks are well-founded, as has been demonstrated by studies on some GM crops and foods that have shown adverse effects on animal health and non-target organisms, indicated above. Many of these studies have, in fact, fed into the negotiation and/or implementation processes of the Cartagena Protocol and Codex. We support the application of the Precautionary Principle with regard to the release and transboundary movement of GM crops and foods.

#### Conclusion

In the scope of this document, we can only highlight a few examples to illustrate that the totality of scientific research outcomes in the field of GM crop safety is nuanced, complex, often contradictory or inconclusive, confounded by researchers' choices, assumptions, and funding sources, and in general, has raised more questions than it has currently answered.

Whether to continue and expand the introduction of GM crops and foods into the human food and animal feed supply, and whether the identified risks are acceptable or not, are decisions that involve socioeconomic considerations beyond the scope of a narrow scientific debate and the currently unresolved biosafety research agendas. These decisions must therefore involve the broader society. They should, however, be supported by strong scientific evidence on the long-term safety of GM crops and foods for human and animal health and the environment, obtained in a manner that is honest, ethical, rigorous, independent, transparent, and sufficiently diversified to compensate for bias.

Decisions on the future of our food and agriculture should not be based on misleading and misrepresentative claims that a "scientific consensus" exists on GMO safety.<sup>123</sup>

One of the most serious concerns raised against GM crops is that expressed by one of our political analysts now serving in Congress, *viz*:

x x x patented GMO seeds concentrate power in the hands of a few biotech corporations and marginalize small farmers. As the statement x x x of the 81 members of the World Future Council put it, "While profitable to the few companies producing them, GMO seeds reinforce a model of farming that undermines sustainability of cash-poor farmers, who make up most of the world's hungry. GMO seeds continue far-mers' dependency on purchased seed and chemical inputs. The most dramatic impact of such dependency is in India, where 270,000 farmers, many trapped in debt for buying seeds and chemicals, committed suicide between 1995 and 2012."<sup>124</sup>

In sum, current scientific research indicates that the biotech industry has not sufficiently addressed the uncertainties over the safety of GM foods and crops.

<sup>&</sup>lt;sup>123</sup> Citations omitted.

<sup>&</sup>lt;sup>124</sup> Walden Bello, "GMO Wars: The Global Battlefield," Foreign Policy in Focus and TheNation.com (October 28, 2013), <<u>http://fpif.org/gmo-wars-global-battlefield/</u>> (visited last December 9, 2014).

## **Bt Brinjal Controversy in India**

*Brinjal* (eggplant) is a major crop and a popular component of food diet in India, an important ingredient in Ayurvedic medicine, and is of special value for the treatment of diabetes and liver problems. The attempted commercial propagation of *Bt brinjal* spawned intense debate and suffered obstacles due to sustained opposition from local scientists, academicians and non-government organizations in India.

As in the case of the Philippines, proponents of *Bt brinjal* in India, believed to be the origin of eggplant's diversity, said that if the new technology is adopted, decrease in the use of insecticides, substantial increase in crop yields and greater food availability, can be expected. But opponents argued, alongside food safety concerns, that there is a potential for toxic effects on populations of non-target invertebrates, and potential replacement of traditional landraces as farmers may move towards cultivation of a restricted number of GE forms. In addition to these issues, there was the additional concern raised over the transfer of *Bt* transgenes to non-GE *brinjal* or its wild relatives, and the consequences for plant biodiversity.<sup>125</sup>

Writ petitions were lodged before the Supreme Court of India to stop the release into the environment of *Bt brinjal (Aruna Rodrigues and Ors, etc. vs. Union of India).* The Court formed a Technical Evaluation Committee (TEC) composed of experts nominated by the parties to undertake a comprehensive evaluation of the feasibility of allowing the open field trials of *Bt brinjal* and submit a final report, and in the event the TEC is unable to submit said final report, it was directed instead to submit an interim report within the period set by the Court on the following issue: *Whether there should or should not be any ban, partial or otherwise, upon conducting of open field tests of the GMOs? In the event open field trials are permitted, what protocol should be followed and conditions, if any, that may be imposed by the Court for implementation of open field trials.*" The Court also directed that the TEC would be free to review report or studies authored by national and international scientists if it was necessary.

In its Interim Report dated October 17, 2012, the TEC recommended that, in view of its findings, all field trials should be stopped until certain conditions have been met. A Final Report<sup>126</sup> was eventually submitted to the Court which noted weaknesses in the conditions imposed by the regulatory agencies for conduct of field trials, as follows: 1) post-release monitoring, an important aspect of environmental and health safety (if the GE crop is consumed as food) is not given adequate attention; 2) the importance of need and socio-economic impact assessment of GM products as one of the criteria that should be applied in the evaluation at an early

<sup>&</sup>lt;sup>125</sup> Dr. John Samuels, "Genetically engineered Bt brinjal and the implications for plant biodiversity – revisited," <a href="http://www.greenpeace.org/seaasia/ph/PageFiles/415937/GE-Bt-brinjal-revisited.pdf">http://www.greenpeace.org/seaasia/ph/PageFiles/415937/GE-Bt-brinjal-revisited.pdf</a> (visited last December 9, 2014).

<sup>&</sup>lt;sup>126</sup> "CONFIDENTIAL: Final Report of the Technical Expert Committee (TEC)," <<u>http://www.greenpeace.org/india/Global/india/report/2013/TEC-report.pdf</u>> (visited last December 9, 2014).

stage; and 3) need for additional tests not currently done such as long-term feeding studies for assessment of chronic and intergeneration toxicity in small animals, genomewide expression analysis in the toxicity studies to screen for possible unintended effects on host physiology. It was recommended that a moratorium on field trials of herbicide tolerant crops until the issue had been examined by an independent committee, and also noted that said technology may not be suitable in the Indian socio-economic context due to possible impact of extensive use of broad spectrum herbicides on the environmental biodiversity and smaller average farm size. Examination of the safety dossier of Bt brinjal indicated certain concerns on the data, which had not been addressed in the course of regulatory testing leading to approval due to lack of full-time qualified personnel for the purpose. Overall, it was found that the quality of information in several of the applications is far below what would be expected and required for rigorous evaluation by a regulatory body and is unlikely to meet international regulatory guidelines.

On the mechanism of Cry1A proteins, the TEC cited studies showing that it is possible under certain conditions for Cry1A protein to kill insects that lack the cadherin receptor. Also, while it is generally believed that Cry toxins do not exert an effect on vertebrates as vertebrates lack the receptor for Cry toxins, two studies (one in mice and the other in cows) have provided evidence that Cry proteins can bind to mammalian intestinal epithelial cells. The report also discussed the emergence of resistance in insect pests, health and food safety of *Bt* transgenics, and herbicide tolerant crops and their effect on biodiversity and the environment. Specific recommendations were made to address the foregoing issues and the report concluded that:

The release of a GM crop into its area of origin or diversity has far greater ramifications and potential for negative impact than for other species. To justify this, there needs to be extraordinarily compelling reasons and only when other choices are not available. GM crops that offer incremental advantages or solutions to specific and limited problems are not sufficient reasons to justify such release. The TEC did not find any such compelling reasons under the present conditions. The fact is that unlike the situation in 1960s there is no desperate shortage of food and in fact India is in a reasonably secure position. The TEC therefore recommends that release of GM crops for which India is a centre of origin or diversity should not be allowed.<sup>127</sup>

In 2010, responding to large-scale opposition to Bt brinjal's introduction in India, former environment minister Jairam Ramesh placed an indefinite moratorium on its further field testing. This was done after discussions with scientists, both pro and anti-GM crops, activists and farmers across the country.

<sup>&</sup>lt;sup>127</sup> Id. at 81-82.

## GMO Field Trials in the Philippines

As earlier mentioned, the conduct of field trials for GE plants and crops in our country is governed primarily by DAO 08-2002 and implemented by the DA through the BPI. Petitioners EMB, BPI and FPA all maintain there was no unlawful deviation from its provisions and that respondents so far failed to present evidence to prove their claim that *Bt* talong field trials violated environmental laws and rules.

Within the DA-BPI, it is the Scientific and Technical Review Panel (STRP) which, as an advisory body, was tasked to "evaluate the potential risks of the proposed activity to human health and the environment based on available scientific and technical information." Under DA Special Order 241 and 384 (2002) the STRP membership was expanded to include "an independent pool of experts...tapped by the [BPI] to evaluate the potential risks of the proposed release of GMOs for field testing, propagation, food, feed to human health and the environment based on available scientific and technical information."

DAO 08-2002 supplements the existing guidelines on the importation and release into the environment of products of modern biotechnology by institutionalizing existing operational arrangements between DA-BPI and the NCBP. Effective July 2003, applications for field test are received and processed by DA-BPI, but the approval process for projects on contained use remains under the supervision of NCBP. A mandatory risk assessment of GM plant and plant products is required prior to importation or release into the environment. Experiments must first be conducted under contained conditions, then the products are tested in field trials the product is reviewed for commercial release. Risk assessment is done according to the principles provided for by the Cartagena Protocol on Biosafety. Risk assessment is science-based, carried out on a case by case manner, targets a specific crop and its transformation event, adopts the concept of substantial equivalence in identifying risk, allows review, and provides that the absence of scientific information or consensus should not be interpreted to indicate the absence or presence and level of risk.<sup>128</sup>

Greenpeace, however, claims there is actually only a committee of three to five members which conducts the risk assessment, and is aided by an informal group, the DA's Biotech Advisory Team (BAT), of representatives from government biotech regulatory agencies: BPI, BAI, FPA, DENR, DOH and DOST. It also assails the government regulatory agencies for their refusal to open to scrutiny the names and qualifications of those incharge of regulation and risk assessment, and for allowing the entry and use of *all* GMO applications requested by multinational companies.<sup>129</sup>

<sup>&</sup>lt;sup>128</sup> The National Biosafety Framework FOR the Philippines. Department of Environment and Natural Resources-Protected Areas and Wildlife Bureau 2004. Quezon City, Philippines.

<sup>&</sup>lt;sup>129</sup> Greenpeace, "Ties that bind: regulatory capture in the country's GMO approval process" <<u>http://www.greenpeace.org/seasia/ph/Global/seasia/report/2007/10/ties-that-bind-regulatory-cap.pdf</u>> (visited last December 7, 2014).

It must be stressed that DAO 08-2002 and related DA orders are not the only legal bases for regulating field trials of GM plants and plant products. EO 514<sup>130</sup> establishing the National Biosafety Framework (NBF) clearly provides that the NBF shall "apply to the development, adoption and implementation of all biosafety policies, measures and guidelines and in making biosafety decisions concerning the research, development, handling and use, transboundary movement, *release into the environment* and management of regulated articles.<sup>131</sup> The objective of the NBF is to "[e]nhance the decision-making system on the application of products of modern biotechnology to make it more efficient, predictable, effective, balanced, culturally appropriate, ethical, transparent and participatory".<sup>132</sup> Thus, "the socio-economic, ethical, and cultural benefit and risks of modern biotechnology to the Philippines and its citizens, and in particular on small farmers, indigenous peoples, women, small and medium enterprises and the domestic scientific community, shall be taken into account in implementing the NBF."<sup>133</sup> The NBF also mandates that decisions shall be arrived at in a transparent and participatory manner, recognizing that biosafety issues are best handled with the participation of all relevant stakeholders and organizations who shall have appropriate access to information and the opportunity to participate responsibly and in an accountable manner in biosafety decision-making process.<sup>134</sup>

Most important, the NBF requires the use of precaution, as provided in Section 2.6 which reads:

2.6 Using Precaution. – In accordance with Principle 15 of the Rio Declaration of 1992 and the relevant provisions of the Cartagena Protocol on Biosafety, in particular Articles 1, 10 (par. 6) and 11 (par. 8), the precautionary approach shall guide biosafety decisions. The principles and elements of this approach are hereby implemented through the decision-making system in the NBF;

The NBF contains general principles and minimum guidelines that the concerned agencies are expected to follow and which their respective rules and regulations must conform with. In cases of conflict in applying the principles, the principle of protecting public interest and welfare shall always prevail, and no provision of the NBF shall be construed as to limit the legal authority and mandate of heads of departments and agencies to consider the national interest and public welfare in making biosafety decisions.<sup>135</sup>

As to the conduct of risk assessment to identify and evaluate the risks to human health and the environment, these shall be guided by the following:

<sup>&</sup>lt;sup>130</sup> Approved on March 17, 2006.

<sup>&</sup>lt;sup>131</sup> EO 514, Sec. 2.1.

<sup>&</sup>lt;sup>132</sup> Id., Sec. 2.2.2.

<sup>&</sup>lt;sup>133</sup> NBF, Sec. 2.5.

<sup>&</sup>lt;sup>134</sup> Id., Sec. 2.7.

<sup>&</sup>lt;sup>135</sup> Id. 2.13.

5.2.1 **Principles of Risk Assessment.** – The following principles shall be followed when performing a RA to determine whether a regulated article poses significant risks to human health and the environment:

- 5.2.1.1 The RA shall be carried out in a scientifically sound and transparent manner based on available scientific and technical information. The expert advice of and guidelines developed by, relevant international organizations, including intergovernmental bodies, and regulatory authorities of countries with significant experience in the regulatory supervision of the regulated article shall be taken into account in the conduct of risk assessment;
- 5.2.1.2 Lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;
- 5.2.1.3 The identified characteristics of a regulated article and its use which have the potential to pose significant risks to human health and the environment shall be compared to those presented by the non-modified organism from which it is derived and its use under the same conditions;
- 5.2.1.4 The RA shall be carried out case-by-case and on the basis of transformation event. The required information may vary in nature and level of detail from case to case depending on the regulated article concerned, its intended use and the receiving environment; and,
- 5.2.1.5 If new information on the regulated article and its effects on human health and the environment becomes available, and such information is relevant and significant, the RA shall be readdressed to determine whether the risk has changed or whether there is a need to amend the risk management strategies accordingly.

5.2.2 **Risk Assessment Guidelines.** – The conduct of RA by concerned departments and agencies shall be in accordance with the policies and standards on RA issued by the NCBP. Annex III of the Cartagena Protocol shall also guide RA. As appropriate, such department and agencies may issue their own respective administrative issuances establishing the appropriate RA under their particular jurisdictions.

5.3 Role of Environmental Impact Assessment. – The application of the EIA System to biosafety decisions shall be determined by concerned departments and agencies subject to the requirements of law and the standards set by the NCBP. Where applicable and under the coordination of the NCBP, concerned departments and agencies shall issue joint guidelines on the matter. (Emphasis supplied)

Considering the above minimum requirements under the most comprehensive national biosafety regulation to date, compliance by the petitioners with DAO 08-2002 is not sufficient. Notably, Section 7 of the NBF mandates a more transparent, meaningful and participatory public consultation on the conduct of field trials beyond the posting and publication of notices and information sheets, consultations with some residents and government officials, and submission of written comments, provided in DAO 08-2002.

#### SECTION 7. PUBLIC PARTICIPATION

The concerned government departments and agencies, in developing and adopting biosafety policies, guidelines and measures and in making biosafety decisions, shall promote, facilitate, and conduct public awareness, education, meaningful, responsible and accountable participation. They shall incorporate into their respective administrative issuances and processes best practices and mechanisms on public participation in accordance with the following guidelines:

7.1 Scope of Public Participation. – Public participation shall apply to all stages of the biosafety decision-making process from the time the application is received. For applications on biotechnology activities related to research and development, limited primarily for contained use, notice of the filing of such application with the NCBP shall be sufficient, unless the NCBP deems that public interest and welfare requires otherwise.

7.2 Minimum Requirements of Public Participation. – In conducting public participation processes, the following minimum requirements shall be followed:

7.2.1 Notice to all concerned stakeholders, in a language understood by them and through media to which they have access. Such notice must be adequate, timely, and effective and posted prominently in public places in the areas affected, and in the case of commercial releases, in the national print media; in all cases, such notices must be posted electronically in the internet;

7.2.2 Adequate and reasonable time frames for public participation procedures. Such procedures should allow relevant stakeholders to understand and analyze the benefits and risks, consult with independent experts, and make timely interventions. Concerned departments and agencies shall include in their appropriate rules and regulations specific time frames for their respective public participation processes, including setting a minimum time frame as may be appropriate;

7.2.3 Public consultations, as a way to secure wide input into the decisions that are to be made. These could include formal hearings in certain cases, or solicitation of public comments, particularly where there is public controversy about the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before the application is acted upon. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages when public consultations, and the circumstances when formal hearings will be required, including guidelines to ensure orderly proceedings. The **networks of agricultural and fisheries councils, indigenous peoples and community-based organizations in affected areas shall be utilized**;

7.2.4 Written submissions. Procedures for public participation shall include mechanisms that allow public participation in writing or through public hearings, as appropriate, and which allow the submission of any positions, comments, information, analyses or opinions. Concerned departments and agencies shall include in their appropriate rules and regulations the stages when and the process to be followed for submitting written comments; and,

7.2.5 Consideration of public concerns in the decision-making phase following consultation and submission of written comments. Public concerns as reflected through the procedures for public participation shall be considered in making the decision. The public shall be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision, upon request.

We find that petitioners simply adhered to the procedures laid down by DAO 08-2002 and no real effort was made to operationalize the principles of the NBF in the conduct of field testing of *Bt talong*. The failure of DAO 08-2002 to accommodate the NBF means that the Department of Agriculture lacks mechanisms to mandate applicants to comply with international biosafety protocols. Greenpeace's claim that BPI had approved nearly all of the applications for GMO field trials is confirmed by the data posted on their website. For these reasons, the DAO 08-2002 should be declared invalid.

Significantly, while petitioners repeatedly argued that the subject field trials are not covered by the EIS law, EO 514 clearly mandates that concerned departments and agencies, most particularly petitioners DENR-EMB, BPI and FPA, make a determination whether the EIS system should apply to the release of GMOs into the environment and issue joint guidelines on the matter.

The Philippine EIS System (PEISS) is concerned primarily with assessing the direct and indirect impacts of a project on the biophysical and human environment and ensuring that these impacts are addressed by appropriate environmental protection and enhancement measures. It "aids proponents in incorporating environmental considerations in planning their projects as well as in determining the environment's impact on their project." There are six stages in the regular EIA process. The proponent initiates the first three stages while the EMB takes the lead in the last three stages. Public participation is enlisted in most stages.<sup>136</sup>

Even without the issuance of EO 514, GMO field testing should have at least been considered for EIA under existing regulations of petitioner EMB on new and emerging technologies, to wit:

g) Group V (Unclassified Projects): These are the projects not listed in any of the groups, e.g. **projects using new** 

<sup>&</sup>lt;sup>136</sup> "The Role of Government Agencies in the Philippine Environmental Impact System: Under the Revised Procedural Manual," <<u>http://www.emb.gov.ph/portal/Portals/21/EIA/EIA%20FOLDER/For%20National%20Government%</u> <u>20Agencies.pdf</u>> (visited last December 9, 2014).

**processes/technologies with uncertain impacts.** This is an interim category – unclassified projects will eventually be classified into their appropriate groups after EMB evaluation.<sup>137</sup> (Emphasis supplied)

All government agencies as well as private corporations, firms and entities who intend to undertake activities or projects which will affect the *quality of the environment* are required to prepare a detailed Environmental Impact Statement (EIS) prior to undertaking such development activity.<sup>138</sup> An environmentally critical project (ECP) is considered by the EMB as "likely to have significant adverse impact that may be sensitive, irreversible and diverse" and which "include activities that have significant environmental consequences."<sup>139</sup> In this context, and given the overwhelming scientific attention worldwide on the potential hazards of GMOs to human health and the environment, their release into the environment through field testing would definitely fall under the category of ECP.

During the hearing at the CA, Atty. Segui of the EMB was evasive in answering questions on whether his office undertook the necessary evaluation on the possible environmental impact of *Bt talong* field trials subject of this case and the release of GMOs into the environment in general. While he initially cited lack of budget and competence as reasons for their inaction, he later said that an amendment of the law should be made since projects involving GMOs are not covered by Proclamation No.  $2146^{140}$ . Pertinent portions of his testimony before the CA are herein quoted:

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ATTY. SORIANO:

Let us go back Mr. Witness to your answer in Question No. 5 regarding the list under the PEISS law. Granting Mr. Witness that a certain project or undertaking is not classified as environmentally critical project, how would you know that the BT talong field testing is not located in an environmentally critical area this time?

## ATTY. ACANTILADO:

Objection Your Honor, argumentative.

#### HON. J. DICDICAN:

Witness may answer.

ATTY. SEGUI:

As far as my recollection can serve me, in a reading of the Petition itself, somewhere along the Petition, petitioners never alleged that

 <sup>&</sup>lt;sup>137</sup> Section 7.g, Revised Procedural Manual for DAO 2003-30 on the Overview of the Philippine EISS (PEISS).
<sup>138</sup> PA 2550 (Philippine Eichering Code) Sec. 12

<sup>&</sup>lt;sup>138</sup> RA 8550 (Philippine Fisheries Code), Sec. 12.

<sup>&</sup>lt;sup>139</sup> Overview of the Environmental Impact Assessment Process, 25 September 2013. Accessed at <<u>https://www.doe.gov.ph/microsites/ipo%20web/linked%20files/2013/MEIF2013/03\_DENR\_Procedures.pdf</u>>.

<sup>&</sup>lt;sup>140</sup> Proclaiming Certain Areas and Types of Projects as Environmentally Critical and Within the Scope of the Environmental Impact Statement System Established Under Presidential Decree No. 1586. Issued December 14, 1981.

the project, the subject matter rather of this instant petition, is within an environmentally critical project.

#### ATTY. SORIANO:

Your Honor the Witness did not answer the question.

HON. J. DICDICAN:

Please answer the question.

#### ATTY. SEGUI:

Personally I have conferred with our personnel from the Environmental Impact Assessment Division and they intimated to me that the locations of the project, rather of this subject matter of the instant petition, not within any declared environmentally critical area.

HON. J. BARRIOS:

In other words, you are aware of the area where the BT Talong experiments are being conducted. Is that the premise?

ATTY. SEGUI:

Judging from previous discussions we had . . . judging from the Petition, and showing it to the as I said personnel from Environmental Impact Division at our office, as I said they intimated to me that it's not within declared environmentally critical area.

#### HON. J. BARRIOS:

That being the case, you did not act further? [You] did not make any further evaluation, on whether the activity has an environmental impact? Is that the correct premise?

#### ATTY. SEGUI:

Well Your Honors I may be the Chief of the Legal Division of the EMB, I handle more of the legal aspects of the Bureau's affairs. But when it comes to highly technical matters, I have to rely on our technical people especially on environmentally impact assessment matters.

#### ATTY. SORIANO:

I will just ask him another question Your Honors. So did the Department of Agriculture Mr. Witness coordinate with your Office with regard the field testing of BT Talong?

#### ATTY. SEGUI:

I'm sorry Your Honors I am not privy to that personally.

#### ATTY. SORIANO:

Mr. Witness, the question is did the Department of Agriculture coordinate with your Office with regard the field testing of BT Talong as required under the law?

#### ATTY. SORIANO:

Already answered your Honor, objection.

#### HON. J. DICDICAN:

The witness in effect said he does not know, he's not in a position to answer.

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#### ATTY. SORIANO:

Did the EMB Mr. Witness perform such evaluation in the case of BT Talong field testing?

#### ATTY. ACANTILADO:

Your Honor that is speculative, the witness has just answered a while ago that the EMB has not yet received any project with respect to that Your Honor. So the witness would not be in a position to answer that Your Honors.

#### HON. J. DICDICAN:

Lay the basis first.

#### ATTY. SORIANO:

The earlier answer Your Honor of the witness is in general terms. My second question, my follow-up question is specifically Your Honor the BT talong field testing.

#### ATTY. SEGUI:

Well from where I sit Your Honors, it would appear that it could be categorized as unclassified...

HON. J. VALENZUELA:

Unclassified?

#### ATTY. SEGUI:

As the section will initially provide. But there must be prior ... may I continue to harp on that Your Honors. There must be prior ... let's say conditions ... there must be prior evaluation and assessment just the same by the EMB.

#### HON. J. VALENZUELA:

Prior to what Mr. Witness?

#### ATTY. SEGUI:

We will categorize it as unclassified but there must be ... (interrupted)

### HON. J. VALENZUELA:

So initially you call it unclassified and then you say prior to...

ATTY. SEGUI:

I'm sorry Your Honors, may I reform.

#### HON. J. VALENZUELA:

Yes please.

#### ATTY. SEGUI:

Initially they will be considered/categorized as unclassified but there will be hopefully a subsequent evaluation or assessment of the matter to see if we also have the resources and expertise if it can be finally unclassified. I should say should fall within the fairview of the system, the EIA system. In other words, it's in a sort of how do you say that it's in a state of limbo. So it's unclassified, that's the most we can do in the meantime.

HON. J. VALENZUELA:

And Mr. Witness you also said that the agency the EMB is without the capability to evaluate the projects such as this one in particular?

Yes, Your Honors as of now.

HON. J. VALENZUELA:

So therefore, when you say initially it's unclassified and then you're saying afterwards the EMB needs evaluation but then you're saying the EMB is without any capability to evaluate then what happens?

ATTY. SEGUI:

Well Your Honors, I did not draft the regulation myself. As the Chief of the Legal of the EMB that's how we interpret it. But the truth of the matter is with all pragmatism we don't have the resources as of now and expertise to do just that.

HON. J. BARRIOS:

So in other words you admit that the EMB is without any competence to make a categorical or initial examination of this uncategorized activity, is that what you mean?

ATTY. SEGUI:

It would appear, yes.

HON. J. BARRIOS:

What do you think would prompt your office to make such initial examination?

ATTY. SEGUI:

ATTY. SEGUI:

Well executive fee at the usual dictates . . . the Secretary of the DENR probably even by request of the parties concerned.

HON. J. BARRIOS:

So that means you are waiting for a request? Are you not? Proactive in this activity in performing your obligations and duties?

ATTY. SEGUI:

Well Your Honors, the national budget if I may ... I attend budget hearings myself. The budget for the environment is hardly ... the ratio is ... if we want to protect indeed the environment as we profess, with all due respect if Congress speaks otherwise.

HON. J. BARRIOS:

May I interrupt, can we go into specifics. From what I have read so far, under No. 2 of your Judicial Affidavit, [you] are saying that the EMB is tasked in advising the DENR on matters related to environmental management, conservation and pollution control, right?

ATTY. SEGUI:

Yes.

HON. J. BARRIOS:

Thereafter you stated that you are tasked mainly with PD 1586 which refers to Environmental Critical Areas of Projects and more specifically focused on Proclamation No. 2146. With respect to this BT Talong, you mentioned that this is at first is uncategorized, it's not within?

ATTY. SEGUI:

It's not within Proclamation 2146 Your Honor.

HON. J. BARRIOS:

But you did mention that under the rules and regulations, even in an uncategorized activity, pertaining to the environment, your Office has the mandate and then you later say that your Office is without competence, do I follow your line of standing?

ATTY. SEGUI:

Yes, precisely it will be categorized as per section 7 as unclassified because it doesn't fall as of now within Proclamation 2146.

HON. J. BARRIOS:

Yes, but under the implementing rules your Office has the mandate to act on other unclassified activities and you answered that your Office has no competence. ATTY. SEGUI:

Proclamation 2146 executed by then Pres. Marcos, the IRR pointed to was executed by I believe the Secretary of DENR. We need an amendment of 2146.<sup>141</sup> (Emphasis supplied)

The foregoing stance of the EMB's Chief of the Legal Division is an indication of the DENR-EMB's lack of serious attention to their mandate under the law in the implementation of the NBF, as provided in the following sections of EO 514:

#### 4.9 Mandate of the Department of Environment and Natural Resources.

- As the primary government agency responsible for the conservation, management, development and proper use of the country's environment and natural resources, the Department of Environment and Natural Resources (DENR) shall ensure that environmental assessments are done and impacts identified in biosafety decisions. It shall also take the lead in evaluating and monitoring regulated articles intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources.

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#### 4.12 Focal Point and Competent National Authorities.

4.12.1 For purposes of Article 19 of the Cartagena Protocol on Biosafety, the national focal point responsible for liaison with the Secretariat shall be the Department of Foreign Affairs. The competent national authorities, responsible for performing the administrative functions required by the Protocol, shall be, depending on the particular genetically modified organisms in question, the following:

#### хххх

4.12.1.4 The Department of Environment and Natural Resources, for biosafety decisions covered by the Protocol that concern regulated organisms intended for bioremediation, the improvement of forest genetic resources, and wildlife genetic resources, and applications of modern biotechnology with potential impact on the conservation and sustainable use of biodiversity. (Emphasis supplied)

On the supposed absence of budget mentioned by Atty. Segui, EO 514 itself directed the concerned agencies to ensure that there will be funding for the implementation of the NBF as it was intended to be a multi-disciplinary effort involving the different government departments and agencies.

SEC. 6. *Funding.* – The DOST, DENR, DA, and DOH shall allocate funds from their present budgets to implement the NBF, including support to the operations of the NCBP and its Secretariat. Starting 2006 and thereafter, the funding requirements shall be included in the General Appropriations Bill submitted by each of said departments to Congress.

<sup>&</sup>lt;sup>141</sup> TSN, February 7, 2013, pp. 13-16, 18-20.

These concerned departments shall enter into agreement on the sharing of financial and technical resources to support the NCBP and its Secretariat.

All told, petitioners government agencies clearly failed to fulfil their mandates in the implementation of the NBF.

## Application of the Precautionary Principle

The precautionary principle originated in Germany in the 1960s, expressing the normative idea that governments are obligated to "foresee and forestall" harm to the environment. In the following decades, the precautionary principle has served as the normative guideline for policymaking by many national governments.<sup>142</sup> The Rio Declaration on Environment and Development, the outcome of the 1992 United Nations Conference on Environment and Development held in Rio de Janeiro, defines the rights of the people to be involved in the development of their economies, and the responsibilities of human beings to safeguard the common environment. It states that the long term economic progress is only ensured if it is linked with the protection of the environment.<sup>143</sup> For the first time, the precautionary approach was codified under Principle 15, which reads:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Principle 15 codified for the first time at the global level the precautionary approach, which indicates that lack of scientific certainty is no reason to postpone action to avoid potentially serious or irreversible harm to the environment. It has been incorporated in various international legal instruments.<sup>144</sup> The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, finalized and adopted in Montreal on January 29, 2000, establishes an international regime primarily aimed at regulating trade in GMOs intended for release into the environment, in accordance with Principle 15 of the Rio Declaration on Environment and Development. The Protocol thus provides:

Article

#### 10

#### **DECISION PROCEDURE**

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<sup>&</sup>lt;sup>142</sup> "GMOs, Risks and the Precautionary Principle" by Marcelo Gortari, supra note 114.

<sup>&</sup>lt;sup>143</sup> Principles 1, 2, 3 and 4. <<u>http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163</u> > (visited last December 7, 2014).

The Global Development Resource Center, "The Rio Declaration: Principle 15 – The Precautionary Approach," <<u>http://www.gdrc.org/u-gov/precaution-7.html</u>> (visited last December 9, 2014).

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

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#### Article

#### 11

## PROCEDURE FOR LIVING MODIFIED ORGANISMS

#### INTENDED FOR DIRECT USE AS FOOD OR FEED,

### **OR FOR PROCESSING**

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

#### Annex III

#### RISK ASSESSMENT

General principles

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4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

The precautionary principle applies when the following conditions are met<sup>145</sup>:

- there exist considerable scientific uncertainties;
- there exist scenarios (or models) of possible harm that are scientifically reasonable (that is based on some scientifically plausible reasoning);
- uncertainties cannot be reduced in the short term without at the same time increasing ignorance of other relevant factors by higher levels of abstraction and idealization;
- the potential harm is sufficiently serious or even irreversible for present or future generations or otherwise morally unacceptable;

and

<sup>&</sup>lt;sup>145</sup> "The Precautionary Principle," World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). March 2005. <<u>http://unesdoc.unesco.org/images/0013/001395/139578e.pdf</u>>.

• there is a need to act now, since effective counteraction later will be made significantly more difficult or costly at any later time.

The Rules likewise incorporated the principle in Part V, Rule 20, which states:

#### PRECAUTIONARY PRINCIPLE

SEC. 1. *Applicability*. – When there is a lack of full scientific certainty in establishing a causal link between human activity and environmental effect, the court shall apply the precautionary principle in resolving the case before it.

The constitutional right of the people to a balanced and healthful ecology shall be given the benefit of the doubt.

SEC. 2. Standards for application. – In applying the precautionary principle, the following factors, among others, may be considered: (1) threats to human life or health; (2) inequity to present or future generations; or (3) prejudice to the environment without legal consideration of the environmental rights of those affected.

Under this <u>Rule</u>, the precautionary principle finds direct application in the evaluation of evidence in cases before the courts. The precautionary principle bridges the gap in cases where scientific certainty in factual findings cannot be achieved. By applying the precautionary principle, the court may construe a set of facts as warranting either judicial action or inaction, with the goal of preserving and protecting the environment. This may be further evinced from the second paragraph where bias is created in favor of the constitutional right of the people to a balanced and healthful ecology. In effect, the precautionary principle shifts the burden of evidence of harm away from those likely to suffer harm and onto those desiring to change the status quo. An application of the precautionary principle to the rules on evidence will enable courts to tackle future environmental problems before ironclad scientific consensus emerges.<sup>146</sup>

For purposes of evidence, the precautionary principle should be treated as a principle of last resort, where application of the regular Rules of Evidence would cause in an inequitable result for the environmental plaintiff — (a) settings in which the risks of harm are uncertain; (b) settings in which harm might be irreversible and what is lost is irreplaceable; and (c) settings in which the harm that might result would be serious. When these features — uncertainty, the possibility of irreversible harm, and the possibility of serious harm — coincide, the case for the precautionary principle is strongest. When in doubt, cases must be resolved in favor of the constitutional right to a balanced and healthful ecology. Parenthetically,

<sup>&</sup>lt;sup>146</sup> ANNOTATION TO THE RULES OF PROCEDURE FOR ENVIRONMENTAL CASES.

judicial adjudication is one of the strongest fora in which the precautionary principle may find applicability.<sup>147</sup>

Assessing the evidence on record, as well as the current state of GMO research worldwide, the Court finds all the three conditions present in this case – uncertainty, the possibility of irreversible harm and the possibility of serious harm.

Eggplants (*talong*) are a staple vegetable in the country and grown by small-scale farmers, majority of whom are poor and marginalized. While the goal of increasing crop yields to raise farm incomes is laudable, independent scientific studies revealed uncertainties due to unfulfilled economic benefits from *Bt* crops and plants, adverse effects on the environment associated with use of GE technology in agriculture, and serious health hazards from consumption of GM foods. For a biodiversityrich country like the Philippines, the natural and unforeseen consequences of contamination and genetic pollution would be disastrous and irreversible.

Alongside the aforesaid uncertainties, the non-implementation of the NBF in the crucial stages of risk assessment and public consultation, including the determination of the applicability of the EIS requirements to GMO field testing, are compelling reasons for the application of the precautionary principle. There exists a preponderance of evidence that the release of GMOs into the environment threatens to damage our ecosystems and not just the field trial sites, and eventually the health of our people once the Bt eggplants are consumed as food. Adopting the precautionary approach, the Court rules that the principles of the NBF need to be operationalized first by the coordinated actions of the concerned departments and agencies before allowing the release into the environment of genetically modified eggplant. The more prudent course is to immediately enjoin the Bt talong field trials and approval for its propagation or commercialization until the said government offices shall have performed their respective mandates to implement the NBF.

We have found the experience of India in the *Bt brinjal* field trials -for which an indefinite moratorium was recommended by a Supreme Courtappointed committee till the government fixes regulatory and safety aspects -- as relevant because majority of Filipino farmers are also small-scale farmers. Further, the precautionary approach entailed inputs from all stakeholders, including the marginalized farmers, not just the scientific community. This proceeds from the realization that acceptance of uncertainty is not only a scientific issue, but is related to public policy and involves an ethical dimension.<sup>148</sup> For scientific research alone will not resolve all the problems, but participation of different stakeholders from

<sup>&</sup>lt;sup>147</sup> Id.

<sup>&</sup>lt;sup>148</sup> Ingeborg Myhr and Traavik, supra note 98.

scientists to industry, NGOs, farmers and the public will provide a needed variety of perspective foci, and knowledge.<sup>149</sup>

Finally, while the drafters of the NBF saw the need for a law to specifically address the concern for biosafety arising from the use of modern biotechnology, which is deemed necessary to provide more permanent rules, institutions, and funding to adequately deal with this challenge,<sup>150</sup> the matter is within the exclusive prerogative of the legislative branch.

WHEREFORE, the petitions are DENIED. The Decision dated May 17, 2013 of the Court of Appeals in CA-G.R. SP No. 00013 is hereby MODIFIED, as follows:

1. The conduct of the assailed field testing for *Bt talong* is hereby **PERMANENTLY ENJOINED**;

2. Department of Agriculture Administrative Order No. 08, series of 2002 is declared NULL AND VOID; and

3. Consequently, any application for contained use, field testing, propagation and commercialization, and importation of genetically modified organisms is **TEMPORARILY ENJOINED** until a new administrative order is promulgated in accordance with law.

No pronouncement as to costs.

SO ORDERED.

VILLARAMA, JR. Associate Justice

WE CONCUR:

manun **MARIA LOURDES P. A. SERENO Chief Justice** 

<sup>&</sup>lt;sup>149</sup> Anne Ingeborg-Myhr and Terje Traavik, "Genetically Modified (GM) Crops: Precautionary Science and Conflicts of Interests" <<u>http://www.pages.drexel.edu/~ls39/peer\_review/Myhr.pdf</u>> (visited last December 9, 2014).

 <sup>&</sup>lt;sup>150</sup> Department of Environment and Natural Resources – Protected Areas and Wildlife Bureau, "The National Biosafety Framework for the Philippines," <a href="http://www.unep.org/biosafety/files/PHNBFrep.pdf">http://www.unep.org/biosafety/files/PHNBFrep.pdf</a>> (visited last December 9, 2014).

Ko lin ANTONIO T. CARPÍO

Associate Justice

Pls. see Concurring PRESBITERO J. VELASCÓ, JR. Associate Justice

Lionasto de Costio LEONARDO-DE CASTRO TERESITA J. LEON **Associate Justice** 

(On official leave) ARTURO D. BRION Associate Justice

DIOSDADO M. PERALTA Associate Justice

in

MARIANO C. DEL CASTILLO Associate Justice

ssociate Justice

**JOSE** GAL **YEREZ** ssociate Justice

JOSE C MENDOZA RAL Associate Justice

BIENVENIDO L. REYES Associate Justice

Se sparate concurs

**ESTELA M** BERNABE Associate Justice

MARVIC M.V.F. LEONEN Associate Justice

(No Part) FRANCIS H. JARDELEZA Associate Justice

## CERTIFICATION

Pursuant to Section 13, Article VIII of the <u>1987 Constitution</u>, it is hereby certified that the conclusions in the above Decision had been reached in consultation before the case was assigned to the writer of the opinion of the Court.

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MARIA LOURDES P. A. SERENO Chief Justice