

Review

Global political, economic, social and technological issues on transgenic crops

Kazuo N. Watanabe^{1*}, Yoshiko Sassa², Eiko Suda¹, Chia-Hsin Chen¹, Masakazu Inaba¹, Akira Kikuchi¹

¹ Graduate School of Life and Environmental Sciences, University of Tsukuba, Tsukuba, Ibaraki 305-8572, Japan;

² Life and Bio-Plaza 21, 3-5-3 Kayaba-cho, Nihonbashi, Chuo-ku, Tokyo, 103-0025, Japan

* E-mail: nabechan@gene.tsukuba.ac.jp Tel: +81-29-853-4663 Fax: +81-29-853-7723

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Abstract Current issues on transgenic crops were discussed with respect to political (including legal and regulatory issues), economic, social and technological factors. Present concern on the transgenic crops was examined particularly on these components by focusing the biosafety issues and public perception. Japanese controversy on the GM crops was raised as specific cases for assessments and critiques. Regional collaboration on the uses of GM crops was also indicated in the close future needs for the sustainable uses of products from plant genetic engineering.

Key words: Coexistence, ELSI, PEST, public perception, risk-benefit analysis, transgenic crops.

Global status of Research and Development (R&D) of the transgenic crops

Genetically modified (GM) crops are beneficial

Commercial production and uses of transgenic crops are uprising and more than 15 countries produce the crops in quantity and the total areas of the production have been becoming larger yearly (James 2004). The total area of the GM crop production is more than 80 million hectares globally in 2004, consisting mainly of soybean, maize, canola and cotton.

These products are not only for domestic uses, but also as exports for food, feed and processing (FFP) purposes, and quantity comes into Japan as commercial trade commodity. Besides uses as FFP, those GM varieties could also be planted in Japan: three soybean, ten maize, ten canola and one papaya cultivars are regarded as approved for growing in field under given conditions in Japan (http://www.bch.biodic.go.jp/lmo_nosaku_list_1.html), and more are being approved for field testing such as rice genetics lines with biotic-stress tolerance conferring defensin, meanwhile concerned civilian groups do not agree on the field testing (<http://gm.ine.seesaa.net/>).

Plant and agriculture scientists should clearly recognize that transgenic crops are one of many approaches in enhancing the agriculture production and

environmental sustainability with consideration of human health (Chrispeels and Sadava 2003; Watanabe and Komamine 2000). While the effects of transgenes may benefit growers more than consumers with the present transgenic cultivars, further values shall be also pointed out on the beneficial environmental significance and food safety issues furnished by the uses of these commercial transgenic varieties (Halford 2003). The major merits are: 1) Herbicide tolerance decreases overall field-cultivation which could be a cause of soil erosion and also reduces the uses of various herbicides; 2) Bt-based insect tolerance also reduces the application doses and types of insecticides with an appropriate insect-resistance management (Bates et al. 2005); 3) Reduction of incidence could be achieved on the mycotoxin produced by the insect damages to the crops such on maize with the uses of Bt-based insect tolerant varieties; and 4) Overall cost-cuts in production also profit the consumers by lower prices in the FFP (Qaim and Zilberman 2003). More of the benefits could be pointed out with the new generations of GM products, however, appropriate public access of the information and intermediation is important to receive positive perception.

As for experimental field testing, many countries including modest developed countries have been conducting experiments (<http://www.cropcomposition>).

Abbreviations: ELSI: ethical, legal and social implications, FFP: food, feed and processing, IPR: intellectual property right, LMO: Living Modified Organisms, PEST: political (including legal and regulatory issues), economic, social and technological, R&D: research and Development, S&T: science and technology.

This article can be found at <http://www.jspcmb.jp/>

org/, http://www.oecd.org/topic/0,2686,en_2649_34385_1_1_1_1_37401,00.html), and many cases have been reported as generally regarded as safe on the environmental biosafety (Refer to the proceedings, <http://www.isbr.info/>; See the journal, <http://www.edpsciences.org/journal/index.cfm?edpsname=ebr>). It is interpreted that many modest-developed countries such as Argentina, Brazil, Mexico and South Africa have more experiences in field assessments than what Japan has (Cohen 2005, <http://www.bch.biodic.go.jp/english/lmo.html>). European countries also have implementation of many field-testing cases of the transgenic crops: 1) UK had experienced the farm scale evaluations (FSEs) with the involvement of local farmers and diverse sectors (<http://www.defra.gov.uk/environment/gm/index.htm>); 2) France and Italy have more field-testing experiences in numbers of cases than in Japan in spite of strong perception on the commercialization in these countries; and 3) Spain and Romania have cases in commercial production of Bt-corn and herbicide tolerant soybean, respectively (James 2004). However, the application strategy and systems should be well examined upon the locations of the uses of GM crops especially the areas sympatric to wild relative species and traditionally-important landraces (Anman et al. 2003; Den Nijs et al. 2004; NRC 2002). Overall it is acceptable to say that GM crops are globally received and positively used (Watanabe 2005a).

Japan is far behind from the international races in agricultural biotechnology

Since the 1980's, Japan has been always the loser in taking the leadership in R&D and business development in agricultural biotechnology (Watanabe and Komamine 2004). In spite of a huge investment made by public and private sectors in 1980's to the end of 1990's, no fruitful commercialization with a decent cash return had taken places domestically in Japan. Many factors could be indicated: i) weakness of decision-making at the senior administration of corresponding organizations; ii) dwindling gut-minds and challenging spirits of scientists and overall human resources; iii) lack of strategic approach from R&D to commercialization particularly unorganized intellectual property right (IPR) strategy; iv) poor responsibility and accountability particularly in public funded research; v) poor public communication approaches and consequent negative sentiment (Watanabe 2003; Watanabe et al. 2004a, c); and vi) regulations unfavored for R&D in spite of government policy to support overall biotechnology. It seems that no major venture capitols are actively funding the Japanese plant biotechnology compared with the other areas in biotechnology (<http://www.jba.or.jp/bv/>, <http://biotech.nikkeibp.co.jp/venture/db/index.jsp>). On the other hand, patience may be needed by such investors as in general

agricultural biotechnology area is slow in R&D and consequently in corporate growth. Also the Japanese government need considering its overall trade and food security policy in association with supporting R&D capacity in agricultural biotechnology by recognizing the uprising production and field testing of GM crops in many developing countries which export FFP to Japan (Watanabe 2005b).

However, it is not totally hopeless yet: there is policy update on general support on biotechnology as the national priority area on Science and Technology (S&T) which was originally proposed in December, 2002 (<http://www8.cao.go.jp/cstp/index.html>), and subsequent and ultimate reorientation by the governmental funding agencies such as Research Institute of Innovative Technologies for the Earth (RITE) (<http://www.rite.or.jp/English/E-home-frame.html>) and New Energy and Industrial Technology Development Organization (NEDO) (<http://www.nedo.go.jp/english/index.html>) under supervision of Ministry of Economy, Trade and Industry (METI) (<http://www.meti.go.jp/english/index.html>). Ministry of Agriculture, Forestry and Fishery (MAFF) constantly keeps efforts to support the crops genome research emphasizing rice and the applications (<http://www.nias.affrc.go.jp/project/inegenome/>) and its subsidiary National Institute of Agrobiological Sciences (NIAS) also promotes GM crops (<http://www.nias.affrc.go.jp/gmo.html>). These may drive to the developmental outcome associated with the Kyoto Protocol on environmental biotechnology including transgenic applications and at a long term it could go to overall agricultural biotechnology involving GM crops as revival. Also as happening in US and Europeans (Lee and Dibner 2005), major private sector at plant biotechnology could make restructuring by redefining and limiting their business context and partners.

Introduction to assessments of diverse factors

PEST indicates Political (including legal and regulatory issues), Economic, Social and Technological, and these are often used in the factors for business development in science and technology venture (Friedman 2004). Scientific justification often overtake the implementation of R&D in academic circles, however, PEST components are even essential in planning and soliciting the research grant including consideration on how to appeal to the policy markers and to show the accountability to various stakeholders (Arntzen et al. 2003). The below, some assessments and comments on PEST factors were made.

Political factors: International law negotiation, regulation and compliances in liabilities

Political and Legal aspects on biosafety

International fora actively discuss the movement and uses of Living modified organisms (LMOs) for R&D and commercialization (Figure 1). While more than 120 nations participate in the Cartagena protocol on Biosafety (<http://www.biodiv.org/biosafety/default.aspx>) as of September, 2005, it is cardinal to make rapid progress in understanding the subject in many developing countries (Bail *et al.* 2002; Pythoud 2004; Watanabe *et al.* 2004b). United Nations Environmental Programme—Global Environmental Facility (UNEP-GEF, <http://www.unep.ch/biosafety/>) makes efforts in the national biosafety framework project with majority of developing countries, but the synergy efforts with the international organizations specialized in the biotechnology and biosafety are under valued and under-utilized. Such organizations are, for example: The International Center for Genetic Engineering and Biotechnology (ICGEB, <http://www.icgeb.org/>) under United Nations Industrial Development Organization (UNIDO, <http://www.unido.org/>), Consultative Group on International Agricultural Research (CGIAR, <http://www.cgiar.org/>) which is strongly associated with Food and Agriculture Organization of UN (FAO), particularly, International Biosafety Service (IBS) of International Food Policy Research Institute (IFPRI, <http://www.ifpri.org/>), (Formerly managed at International Service for National Agriculture Research, which merged into IFPRI). These organizations have quite strong relationships with the developing countries needing the supports for the capacity building and also have a long-term assistance for well-identified partners in developing countries and other stakeholders (Watanabe *et al.* 2004b).

There have been a lot of challenges under the Cartagena Protocol on Biosafety on the implementation: since the period of negotiation for the agreement of the Protocol, there have been non-scientific debates on the scientific contents of the Protocol (Watanabe 1999a, b). Yet it seems that scientific understanding is needed at present to be promoted among participating parties to make common sense. The Article 18 of the protocol which associates with the transport, documentation, handling etc, would be of the typical one to look in as it also associates with the contained uses including research purposes in confined conditions, while the protocol main issues are on the deliberate releases of LMOs to the environments. General concepts in risk assessment and risk management should be references for individual LMO evaluations, and the consequent information should be promptly deposited to Biosafety-Clearing House Mechanism (BCH, <http://www.biodiv.org/biosafety/bch.aspx>).

<http://www.biodiv.org/biosafety/bch.aspx>).

Based on globally common knowledge and the understanding of the Cartagena Protocol on Biosafety, further details could be discussed on the liability issues, to make clear and comprehensive standards to make smooth transboundary movement of the LMOs. But liability issues could be discussed case by case based on the commercial examples or incidence if it take place, otherwise, imaginary set up of the rules could not be implemented. Also further needs are to make the synergy efforts among the international rules associated with the LMOs as shown in Figure 1. Indeed, the trade aspects are much stronger in international negotiations and even the Biosafety Protocol contains elements on LMO-FFPs which is more suitable agenda at World Trade Organization (WTO, <http://www.wto.org/>).

Evolving regulations for sustainable development

Biosafety regulation is based on precautionary approach as its principles (Bail *et al.* 2002; Pythoud 2004). R&D and commercialization should be separated into different entities to facilitate the understanding on the LMOs, while careful approaches shall be taken into the commercialization at the basis of each product (Evenson and Santeniello 2004). Deregulation shall be considered on the R&D with relevant accumulation of environmental biosafety assessments at each nation, and indeed European countries are making consideration on many entities for R&D and also on commercial products such as maize to be deregulated. On the other hand, options are always available in enforcing the regulation if needed upon the consequence of the monitoring of specific LMOs as a consequence of a risk management scheme. There shall be flexible decision-making on the LMO testings: it may go deregulated and may need re-examination in regulation at individual LMO events. However, with the precautionary approach, it could be unilateral from careful evaluation to deregulation if a LMO investigated to be environmentally safe or could be sustainable and useful.

Case studies on liability compliances under the biosafety regulation, have been made at examples in public research and private sector business (Evenson and Santeniello 2004; Smyth *et al.* 2004). The liability issues take place more in the private business rather than at a R&D phase. However, yet it seems that there are confusion on mixing up the R&D materials with the immediate commercial products, and this deters the real understanding on the R&D of LMOs such in the debates in Japan.

A co-existence law could be the option to make presence of GM crops and non-GM ones together. These were taken places in Denmark, Germany, Italy and The Netherlands in 2004. Yet the law needs further elaboration so far, but it is a good movement from the

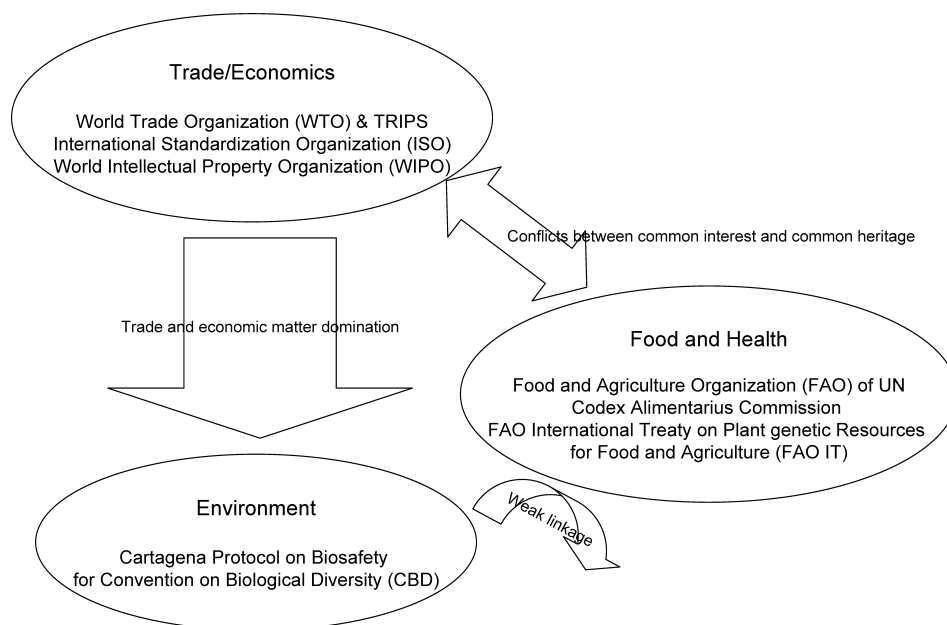


Figure 1. General view on International organizations & laws and their roles associated with Living Modified Organisms (LMOs) (Modified from Watanabe 2005c).

total rejection to positive consideration of balancing rights of all stakeholders. Representation may be given by the one from Denmark (Boelt 2004). The feature of such a law is: 1) license system on growing LMO crops, 2) compliance on the isolation of distance which is scientifically evaluated and agreed, and 3) liability on the apparent damage given by the occurrence of hybridization and/or mixing the GM crops with non-GM crops.

Intellectual property rights

Intellectual property right (IPR) issues are important in any S&T area and it should be positively taken for the fair and equitable direction. However, IPRs are taken as pro-patent strategies by multinational enterprises, especially the ones based in North America. Misinterpretation is often taken by public that patented technology and products on biotechnology are dominated only by few major companies, and end-users are obliged to pay for the high prices. Any innovation needs incentive, and the protection of the invention is essential to make fair competition in R&D and industrialization. The scope of patents or IPR protection is further concern of various stakeholders, and discussed at the WTO discussions on trade-related aspects intellectual properties (TRIPS, http://www.wto.org/english/tratop_e/trips_e/trips_e.htm) and World Intellectual property organization (WIPO, <http://www.wipo.int/portal/index.html.en>), particularly. There are debates among nations and different sectors whether life or living organisms to be immediate subject for the IPR protection. These aspects also shall be explained besides the safety issues

on the LMOs as ethical and social implication aspects.

It is not totally true that protected technology and products are inaccessible or expensive to get permission to uses. There are coordinating agencies for granting uses, cross-licensing and integration of the IPs at public and private sectors. Also the philanthropic view of the plant biotechnology transfer including the IPR donation has been discussed since long time ago (Altman and Watanabe 1995, Watanabe and Pehu 1997). On the other hand, it may be more reasonable to enhance the understanding of IPRs by taking an alternative option on the incentive payback to the IPRs donor(s) rather than a full give-away of IPRs (Sinebo and Watanabe 2005).

Economic and trade matters

Global food security is concerns of many nations and also at the United Nations (Rosegrant and Cline 2003). Against the dwindling natural resources, crop variety-based enhancement of the productivity with the consideration of sustainability is one of strong options to take at present (Chrispeels and Sadava 2003). Commodity GM crop trade is ordinary economic agenda at WTO now. Learning from the economic impact of the Green Revolution by crop varieties (Evenson and Gollin 2003), we should not deny the possibility of contribution of GM crops as the new generation of achievement to facilitate the food production to alleviate the concerns on the food security and further enhancement of cash-acquirement for the end-users such as subsistent farmers in developing countries. Indeed, socio-economic factors have been considered in many field testings to the local

communities, and positive examples are also coming out (Qaim and Zilberman 2003; Wolfenbarger and Pfifer 2000). Further attention may be needed on holistic view and monitoring on the local community changes by the introduction of new cultivars and agriculture system.

Social issues: Overview of public perception on GM crops in Japan

Public perception is one to consider in adoption of S&T, and it is very important for overall agricultural biotechnology. Japan has been a good example in negative sentiment on crop genetic engineering and the products thereof: i) consumers express unsafe feeling; ii) non-governmental organizations influence the local prefecture governments to double-regulate excessively the GM crops; and iii) concerned groups sue governmental organizations to stop R&D, etc. (Watanabe *et al.* 2004a, c).

Inaba *et al.* (2005) overviewed and made an integrative assessment on a series of public surveys on GM crops conducted since at the middle of 1990's to the date by compiling original survey data obtained by Imai and Watanabe (1998), Inaba and Macer (2004) and Macer and Ng (2000). The 'public' perception has been increasing on GM crops in Japan, and the concern has been focusing into particular aspects. Environmental risk and food safety are both important issues for 'public', particularly cropping of transgenic plants has dual concerns: direct influence on food uses and crop co-mingled with non-transgenic ones.

High 'public' perception over the decades were examined by Inaba *et al.* (2005). First of all, the survey methods per se alter the reaction of the audience. Sampling methods are particularly in question in many surveys whether the representation is fairly made over Japanese population thus the information in the past and present may be opinions rather from biased groups. Indeed, we may not be able to generalize as 'public' in the past survey. It may be more suitable to say concerned groups rather than real general public as demonstrated by Imai and Watanabe (1998) on specific groups. Lack of overall education is the serious issue on the Japanese country status of the food security and environmental aspects as well as basic biology knowledge. Public awareness and continuing education could in part provide relieves on the feeling toward GM crop uses and ecological concerns. The concept of Decade Education for Sustainable Development (DESD), should be well incorporated in to the GM crop and food security issues. DESD is the resolution which Japanese government had proposed at World Summit on Sustainable Development (WSSD, <http://www.johannesburgsummit.org/>) in 2002, with United Nations Educational, Scientific and Cultural Organization (UNESCO) as an implementation agency,

(http://portal.unesco.org/education/en/ev.php-URL_ID=27234&URL_DO=DO_TOPIC&URL_SECTION=201.html). However, those aspects are yet to be alleviated in educational actions: i) Lack of participatory decision making on the commercialization; ii) weak community engagement approach; and iii) piece-meal activities without integration of efforts and behind from the global standardization on education for sustainable development.

Criticism could be made on the recent sensational news by media and aggressive debates by civil groups, e.g., regarding the news on canola spilled over ports and roadsides: the gene pollution messages from NGOs are transformed information and it is cheating the Japanese public and making adverse effects to the value of the crops, our society and the human life (Inaba *et al.* 2005). Authors feel that Japan may be standing as the worst example of poor accountability of scientists and their organizations on the public communications of scientific facts besides the highly unethical reaction of aggressive concerned civil organizations.

Challenges in confinement of transgenes with new technologies

Having accumulation of information of possibility of the transgene introgression to wild relatives, it can not be generalized that there is adverse effect to the biodiversity by dissemination of GM plants to fields (NRC 2002; Stewart *et al.* 2003). It is particularly depending on the type of transgenes, crop species and wild relatives. The presence of hybrids is not a hazard in itself and does not imply inevitable ecological change (Wilkinson *et al.* 2003). Gene transfer is complex process and is dependent on many factors including environmental conditions, plant variety, insect behavior, and plant density and all of components should be considered in assessing the risk (Rieger *et al.* 2002). Some GM crops do not have negative effect in field dissemination by an appropriate cropping system, and others such as maize may have more active introgression in to the surrounding environment, and precaution and risk management are needed in balancing the risk benefit in practical uses (Watkinson *et al.* 2000; Wolfenbarger and Pfifer 2003). Product-base or case-by-case evaluation is thus, essential in GM crops. But it has been proven that there were confusion and/or also mistakes in research processes judging from many of the consequences from the sensational gene-contamination news made by civilian groups and concerned scientists. An example would be given on a questionable report on the presence of GM maize in Mexico (Quist and Chapela 2001), but there was no GM maize contaminated at all (Marris 2005). However, many concerns from public address the fear of possibility on the introgression and mix-up with non-GM

crops, and further ecological domination as super-weeds. Also there must be the precaution to the specific uses such as medicinal substance production that should be under more comprehensive regulation of the planting of LMO crops (Watanabe 2005c).

Horizontal gene transfer is another concerned issue (Halford 2003) and arguments have been made in scientific fora (See such a correspondence by Davison 2004). However, case studies have been proven the unlikely possibilities in many cases, and further examinations with long term monitoring experiments are expected in journal publications and other media releases (<http://www.edpsciences.org/journal/index.cfm?edpsname=e=ebr>).

Many biotechnological approaches with revival of old cytogenetic knowledge could have far better control of gene flow from the transgenic plants to the environments. These have been well documented and examined by several reviews in English (Dale et al. 2002; Danielle 2002; NRC 2004; Roderick and Navajas 2003) and for the Japanese readers, an introduction was given for general understanding (Watanabe 2005c).

For an example, the use of chloroplasts as transformation target would be an option on the regulation of pollen-mediated gene flow (Danielle 2002), and this could be conducted at ease now. Introduction of apomictic seed could be another alternative, however, there is no sufficient scientific knowledge and tools ready for the immediate application (Spillane et al. 2004). Importantly, no single approach would be sufficient to regulate fully the gene flow from transgenic plants (NRC 2004). Also many of technology proposed in the above reviews are yet being developmental stages while they are quite promising, and further examination, investment and scientific challenges are essential for the practical application to the biological confinement.

Application of PEST concepts and partnerships in transgenic crops in Asia

The emergence of India and China as possible developing country producers of commercial GM crop in Asia is a landmark for the global crop commodity market (Economist November 20th issue, 65, 2004; Newsweek December 20th issue, 36–38; 2004, SciDev.net News, 22 February, 2005, Website: <http://www.scidev.net/news>). The ratification of China to the Protocol will accelerate the dissemination of and trade of GM crops in the region (<http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt>). The scientists working in the area of agricultural biotechnology in these countries, are applauded for their achievement in making the potential benefits for the developing countries closer to reality. However, in the commercial release of the GM crops, countries must reflect not only on the effects to the

domestic economy and R&D but also on the regulatory concerns of the neighboring countries that have not yet introduced or harnessed the technology. In the case of China for an example, this applies mainly to those sharing borders with China particularly concerning GM rice, and it is vital that their national biosafety regulatory systems work effectively (Okusu and Watanabe 2005). We have already seen how controversies could arise from the accidental/illegal domestic and transboundary movements of seed material in other parts of the world. Considering the borderless nature of the agricultural practice, if unregulated GM seeds enter neighboring food-exporting countries, they could easily “contaminate” fields intended for GM-free, organic, or traditional agriculture. We must avoid adding yet another incident to the public’s anxiety over agricultural biotechnology. In such cases, the risks and benefits of the introduction of GM crops for small-scale farmers should be assessed relevantly in a participatory manner. Deregulation of GM crops in India and China should be accompanied by discussion and exchange of information/technology in each corresponding region. It must be ensured that effective border control systems are in place to mitigate accidental transboundary movements, and harmonize risk assessment/risk management strategies with a view to protect export-oriented agricultural products in the region. Such regional collaboration contributes to the operationalization of the biosafety regulatory system in the GM-producer countries as well as in the neighboring countries, optimizing the benefits brought upon by the coexistence of agricultural practice from both modern biotechnology and traditional means. It would also complement the various bilateral/multilateral support on the development and implementation of national biosafety frameworks, and allow such efforts to make an impact (Watanabe et al. 2004b). The issues surrounding these debutantes in the global GM market demonstrate that region-specific approaches must be taken in order to include relevant stakeholders in both the regulatory and commercialization processes of GM crops. These situations also signal that the time is ripe for these countries to begin working with the real-life implementation scenario of their biosafety regulatory frameworks.

Governance needs in agricultural biotechnology

In contrast to the international legal efforts, it is unethical that some activists and their umbrella organizations abuse and intentionally transform of the scientific facts. Recent examples are: 1) an intervention by an international NGO at a formal diplomatic meeting, the Conference of Parties to the Convention on Biological Diversity serving as the Meeting of the Parties

to the Cartagena Protocol on Biosafety (COPMOP-2) in May, 2005 on the sensational but scientifically incorrect statement on the canola spillage in Japan (<http://www.greenpeace.or.jp/press/2005/20050601.html>) and 2) information transformation of original reports by self-claiming sound-like scientific but science-fiction media such as Bio21 (<http://www.biokagaku.com/bio21/>), which is a similar name to the public-standing and fair organization, Life and BioPlaza 21 (<http://www.life-bio.or.jp/>) that has a high credential by different sectors. Our point is not to express the antisense to the presence of civilian organizations, but it is strong protest on the actions made by these organizations that they did not have appropriate ethical and sophisticated approaches. It is quite adverse effects to the flocks of innocent public and it is damaging to socio-economic values in communities. We take it that the imprecision and wrongful uses of the scientific facts are confusing and scaring to the communities. The authors also concern that the threatening and noisy voices of the activities bring down the value of the communities and rights of the public to appreciate in consideration of the absolute values of the LMOs-FFP. Enhancement of open forum discussion and opinions from the South on their sentiment and needs, should be reconsidered and indeed, dialogue exchanges between the various stakeholders are more important.

Ethics, legal and social implications (ELSI) are essential factors on any modern science and technology. But consideration to the human-minds is often behind in many modern S&T areas: attentions are weak on cultural aspects, religious respects and ethnic creeds in overall governance of the S&T. There are many components to be elaborated on policy, regulatory framework and implementation of biosafety on the genetic engineering and products thereof particularly on the transgenic crops by learning from the past. An example is given on the turmoil in information confusion and negative sentiment on GM crops such in Japan in the past. This shall suggest that the poor participatory approaches with weak ELSI components, would not reach sufficient public understanding to the R&D and commercialization of GM products. Revisit of the governance issues on the agricultural biotechnology is now essential in each nation and also at the global basis, including fair representation on all sectors.

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