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Review

The need for biosafety regulation in developing countries: Benefits and controversies

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Nowadays, the rapid development of biotechnology has become a main concern for a larger part of the world. It has become one of the most promising fields which guarantee returns to businesses and offers benefits to the society. When dealing with biotechnology, the first issue that comes to mind is the safeness of the technology from tip to toe, that is, the safeness of the products of biotechnology, how they can be used on human beings and animal, and their effects on the environment. The objective of this paper is to assess the needs and adequacy of the regulation in developing countries compared to the developed countries. In order to address these concerns, governments have adopted appropriate regulations to ensure the safety of the biotechnology products, and to protect not just human but the environment universally. This paper will discuss those regulations, especially as adopted by developing countries along with their implications. It is hoped that the paper will recover the lack of the regulations in relation to developed country.

Key words: Biotechnology, biosafety, developing countries, benefits, risks and controversies.

INTRODUCTION

New technologies often offer great potentials. But, they also need to be adequately monitored in order to ensure their safeness, as well as environmentally and socially sustainability. Although, genetic engineering and genetically modified organisms (GMOs) are beneficial to the society, concerns remain over the risks they may pose to human, animal health and the environment. Moreover, there are many socio-economic considerations that need to be kept in view particularly in developing countries (Marrero, 2009). Biotechnology is the application of scientific techniques which modifies and improves the plants', animals', and microorganisms' genetic materials in order to enhance their value. On the other hand, major biotechnology concerns relate more to human health and the environment itself. It is important to differentiate between conventional biotechnology and modern biotechnology. According to Zepeda and Cohen (2006) and Abraham (2009), biosafety regulation applied only to the modern biotechnology products whereas tissue culture, marker assisted selection, breeding and mutagenesis are excluded from using the regulation. Along the way, as we think about the GMOs, realizing what the GM products would look like in reality and how the GM crops can nurture the developing world. In addition, plants resistant to pest and weed killers were among the first commercial products of genetic engineering to be proved by some researchers to verify the situation.

As we think about GMOs, several key issues need to be addressed. In this regard, research has shown that

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Abbreviations: GMOs, Genetically modified organisms; **GM,** genetically modified; **NRE,** Natural Resources and Environment; **NBB,** National Biosafety Board.

the first commercial products of genetic engineering were plants resistant to pest and weed killers. As Pechan (2005) observes, it is mainly farmers that reap the benefits. However, researchers in Europe and many other parts of the world are now developing new products designed to be of direct benefit to consumers. As has been said earlier, the acceptance and perception of consumers and the general public are highly dependent on the performance of the GM products themselves. Consumers would rather ignore the GM products if they perceived the products as more burdensome than beneficial. Indeed, a positive attitude towards biotechnology is important to the building of consumers' trust in GM products.

In developing countries, a research decision is based on local priorities, and is often a question of need, rather than choice (Pechan, 2005). Wisniewski et al. (2002) believes the main arguments of GM supporters are food security, improved food quality and extended shelf-life. These are the reasons why they believe that GM crops will benefit not only consumers and farmers, but also the environment. Nevertheless, while GM crops may hold great possibilities for food security, there are also potential negative consequences. Furthermore, not only consumer safety should be taken into account, but also their understanding of GM technology is critical and should be considered. According to Hosein and Ho (2010), it is a matter of considerable concern that access to vital information is much more difficult in developing countries than in developed countries. Thus, the use of GM technology to bolster agricultural outcomes for small-scale subsistence farmers in developing countries has both potentials and limitations (Hosein and Ho, 2010). Moreover, there are many socio-economic considerations that need to be taken into account, particularly in developing countries (Marrero, 2009).

The impact of modern biotechnology can be enormous if not properly monitored and regulated. According to some studies, there is no scientific proof that the use of biotechnology has adverse effects on human health and the environment. However, regulations are being made as a precautionary measure against whatever risks that GMOs might present to human health and the environment, and to instil confidence in the public before the GMOs are released into the environment. Although the term "biosafety" itself is always used in relation to the risks associated with the products of modern biotechnology, the release of a GMO into the environment should be of more concern.

Concerns over environmental safety arising from the release of GMOs are justified, because it is difficult to determine their long-term environmental impacts, which could be very grave (Lu, 2008). There are two broad categories of release of GMOs into the environment:

The experimental release of GMOs into the environment; that is, the introduction of GMOs into the environment for experimental purposes, also commonly known as field or clinical trials. These types of releases are mainly carried out for the purposes of study, research, demonstration and development of novel varieties. The behaviour of the GMOs in an open environment and their interactions with other organisms and the environment are studied. In legislation, these releases are referred to as Part B releases.

Release of GMOs into the environment by placing it on the market for commercial purposes; if the results of the experimental release are positive, the company may decide to place the GMOs on the market, making them available to the third parties either free of charge or for a fee. The GMOs may be placed on the market for purposes of cultivation, importation or transformation of GMOs into industrial products. In legislation, these releases are referred to as Part C releases.

CONTESTED RISKS AND BENEFITS

Although, advances in biotechnology may prove valuable, there is also a need to take the associated risks into consideration. Of course, not all products emanating from modern biotechnology carry risks. According to Pretty (2001) while there are sharp divisions over risks and benefits, genetic modification (GM) is not a single homogenous technology. Every application entails varying risks and benefits for different interested parties.

While the rapid development of biotechnology could have positive impact on developing countries, they can become the greatest hosts for agricultural activity, unless stringent actions are taken to characterize plant and animal species at the molecular level so as to assess their production potential and disease and environmental-stress resistance, and to ensure long-term conservation. As stated by Dobe and Sen (2009), the massive production of GMOs has both positive and negative consequences for the environment. Their immediate impact is visible from organisms that feed on the crops, and the broader impact can be seen in food chains produced by increases or decreases in numbers of other organisms. Whereas the combination of some GM crops with long-lasting herbicides has proven to be harmful to biodiversity, using other GM crops without those herbicides has actually led to improvement in biodiversity.

In some reason, the rapid emergences of this technology could give positive impact to developing countries. On the other hand, developing countries can be the greatest host for agricultural activity unless stringent plan and actions are taken on characterizing these plant and animal species at the molecular level to assess their production potential and disease and environmental-stress resistance or to ensure long-term conservation. As stated by Dobe and Sen (2009), "the large scale growth of GMOs has positive and negative environmental effects. Direct effects are seen on organisms that are fed

on the crops. Wider effects are manifested on food chains produced by increases or decreases in numbers of other organisms. The combination of some GM crops with long-lasting herbicides was bad for biodiversity, using other GM crops without these herbicides increased biodiversity".

Pretty (2001) further notes that soon after the development of the first GM crops, sharply conflicting views arose over their actual benefits and risks. Although some argue that GMOs are safe and indispensable to society, others insist that they carry too many risks, and are therefore not useful to society. Those who argue in support of GMOs believe that media manipulation and scaremongering are limiting useful technologies, whereas opponents contend that scientists, private companies and regulators are understating hazards for the sake of economic returns (cf. House of Lords Select Committee on the European Communities, 1998; Royal Society, 1998; British Medical Association, 1999; Nuffield Council on Bioethics, 1999; Royal Society et al., 2000). Neither view is entirely correct, for one simple reason. GMOs, as Pretty (2001) correctly observes, are not a single, homogenous technology, as each application and product brings different benefits to different stakeholders, each poses different environmental and health risks.

The first generation technologies came into commercial use in the late 1990s, and have tended to bring few distinct consumer benefits. The realization of promised benefits to farmers and the environment has only been erratic, as these technologies have tended to benefit mainly the companies producing them; herbicide tolerant soya, for example, locks the farmers into buying the herbicide produced by the company marketing the GM seed. *Bt* maize and cotton permits reduced use of insecticides, thus saving the farmers money, but companies currently recover much of the margin through increased seed costs.

The second generation technologies comprise those already developed and tested, but not commercially released, either because of uncertainties over the stability of the technology itself, or over concerns for potential environmental risks. Some of these applications will clearly bring more public and consumer benefits, and includes a range of medical applications. The third generation technologies are those that are still far from market, but generally require the better understanding of whole gene complexes that control such traits as drought- or salt-tolerance, and nitrogen fixation. These, again, are likely to bring more explicit consumer benefits than the first generation.

As far as we are concern, the use of GMO also could give rise to negative impact and issues such as in socio economics as well as socio cultural in response of the increased capital expenditure. For example, the command of the used seed from genetically modified have higher prices, which lead to compulsion of special knowledge in using insect-resistant plants due to evade progress insect lines which are resistant to the plants. Other than socio economics aspects, GMO also can be seen as one of the risky factors that could give such 'a big contribution' in economically aspects for small farmers in narrow agricultural settings.

Despite these negative effects, however, there are also positive ones. According to Nanda (2000), the manipulation on the process (genetic manipulation) brings value by increasing the quantity of world food supplies and improving the quality of the crops with certain favourable traits, for instance:

Insect-resistant corn and roundup-ready soybeans, which are impervious to roundup herbicide, manufactured by the giant biotech firm Monsanto, the largest producer of GM seeds. Major substantive issues related to the creation and use of and trade in GM products include the threat to biological diversity, economic considerations, intellectual property issues, ethical and religious concerns, risks to human and animal life or health, consumers' right to know, and food security.

The security interest, which may be affected in several ways, such as further consolidation of control over the methods of food production in the hands of a few large firms, excessive use of chemicals because of the increasing resistance of crops to herbicides, and reductions in crop diversity.

Moreover, it also been stated, a GM crop can be beneficial, or have a positive impact, in at least two distinct ways. It has been proved by Madsen et al. (2003), "profitable for the producer or by fulfilling important societal needs". Besides, when the general public insist on the usefulness of GM crops, it can give second definition which outlines its requirement to meet the societal needs. It can be achieved in several ways such as:

By giving more healthy food
By mitigating the environmental impact of agriculture
By producing raw material which at presents require costly industrial processing or
By improving the situation in developing countries and feeding a rising world population.

It should be noted that controversies over GMOs have the tendency to negatively shape the public perception and their willingness to accept GM products. Paarlberg (2002) recognizes that politicization and blockage of the national biosafety are the crucial factors that keep GM crops out from the developing countries. Another problem is that the technologies might not reach the poor farmers, due to the privatization of the rights of implementing and using the technologies.

In addition, Pavone et al. (2011) said that in narrowing the debate whether the GMOs constitute a threat to human health and the environment, it depends on the approaches by risk assessment in relation to reducing the

evaluation of GMOs merely to a question of how much risk a society can bear in exchange for the potential benefits of the technology. Therefore, the implications of GMOs are much more rather than risk/benefits relationship suggests. Considering the controversy that surrounds GMOs, studies are closely watched on both sides. On one hand, studies showing absence of health risks or demonstrating nutritional equivalence serve to justify commercialization and authorization by decision makers or studies indicating health or environmental risks have been used by environmental NGOs to criticize positions favourable to GMOs (Diels et al., 2011).

THE NEED FOR BIOSAFETY REGULATION OF GENETICALLY MODIFIED ORGANISMS (GMO) IN DEVELOPING COUNTRIES

Naylor et al. (2004) reported that, institutions and researchers have emphasized the need to accelerate the investments and knowledge creation for orphan crops. From a regulatory and a biotechnology innovation perspective, this implies a significant knowledge gap with regard to orphan crops in general, but also with regard to the potential protocols and processes used in manipulation and derivation of useful genes to address specific needs of developing world, including those located in tropical climates (Naylor et al., 2002). Therefore, only a few GM crops (all commercial) are presently approved for use in developing countries (Zepeda and Cohen, 2006). But, this scenario is slowly changing as new GM crops and livestock products have been developed from research conducted by developing countries and their collaborating partners (Cohen, 1999; Attasanov et al., 2004). In the meantime, all of these products require biosafety regulatory review and approval.

Zepeda and Cohen (2005) defines biosafety regulation as both the regulatory system and other risk analysis measures designed to ensure that applications of modern biotechnology are safe for human health, agriculture, and the environment. According to this definition, biosafety is a principle that tempers the adoption of a new technology with careful consideration of its potential effects on all stakeholders and on the environment. There are differences between the regulatory frameworks of developed countries, and those existing in developing countries. In developed countries, regulation is meant to ensure that GMOs are approved and attain required specifications. Apparently, the quality of regulation depends on the level of economic stability and advancement of the country concerned. For most developing countries, regulation is still in an embryonic stage, even as they try hard to achieve the objective of guiding against the likely effects of GMOs. Over the years, developing countries, particularly those with less sophisticated regulatory frameworks, have relied on the regulatory frameworks and protocols of developed countries as templates for establishing their own domestic regulatory systems. The protocols provide the specifications and provisions that should be included in the regulations. Those countries that already have protocols in place often have to review and bring them in line with their more standardised counterparts.

A good regulatory system should be comprehensive in scope. Such a system, as Gregory (2010) pointed out, must comprehensively address various areas; from the different stages of development through laboratory research and field trials to products that are commercially available and eaten by humans and/or animals. It should address not just the environmental issues highlighted by the biosafety protocol, but also food safety issues. And finally, it should address not just engineered plants that will be used for food or feed, but also plants engineered to produce non-food substances and transgenic animals. Regulation in some developed countries can be quite comprehensive, covering environmental and food safety issues associated with genetically engineered plants and animals in laboratory, when they are tested outdoors, and when they become commercial products consumed by humans and/or animals. This is in contrast with the situation in many developing countries, which is not yet as comprehensive, neither is such a level of comprehensiveness presently desirable, given that they do not yet have GMO field trials. They only focus on environmental issues and did not address food safety, as well. Thus, the comprehensiveness of biosafety regulatory systems in developing countries varies greatly. Gregory (2010) has also noted that, “many developing countries are focusing their biosafety systems on environmental issues surrounding the release of GMOs into the environment and have not established clear pathways for the food-safety assessment and approval process surrounding GMOs.”

The differences between the regulatory systems of developed and developing countries can be observed not only in terms of the level of comprehensiveness, but also in terms of scientific expertise in decision-making. For developed countries, there are expert scientists within the government who conduct the analysis, unlike in developing countries, which need external experts to review, analyse and assess data due to limited technical capacity. Owing to this limitation, some developing countries have established expert scientific advisory committees, charged with the task of assessing applications concerning GMOs, in order to advise government on their safety, or the lack of it.

However, this task should not be left wholly in the hands of scientific experts. Members of the public should also have a responsibility in order to assure the completeness of the regulatory system. Without doubt, the release and acceptance of GMOs depend highly on the consumers and on the general public. They need to have proper awareness about GMOs. In developed countries, the media, government publications, and the internet are vital tools for creating awareness among members of the public about their participation privileges. By contrast, in developing countries, financial constraints,

language barriers, and the lack of good communication vehicles significantly hinder the implementation of public participation requirements.

MALAYSIAN BIOSAFETY ACT 2007

Biotechnology is one of the five strategic technologies expected to accelerate Malaysia's transformation into a highly industrialized nation by 2020. The National Agriculture Policy (NAP 3) for 1998 to 2010, highlighted the importance of human resource development in order to generate highly skilled and innovative manpower in new and emerging sciences, such as, food, genetic engineering and biotechnology (Bhumiratana, 2002). Like many others ASEAN members, before the introduction of the Malaysian biosafety act in 2007, Malaysia has no laws addressing the biosafety issues in any holistic way. However, several laws from different governmental sectors do address specific segments such as the Food Act 1983, the Fishries Act 1963 (revised 1978), the Plant Quarantine Act 1976, the Poisons Act 1979 and the Pesticide Control Act of 1974. Even though it has been a rugged journey for this Act to be reality, it is a positive and promising beginning for Malaysia to take a proactive approach towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology as well as fulfil Malaysia's obligation under the Cartagena Protocol on Biosafety.

The Biosafety Act 2007 has been passed by the Malaysian Parliament in July 2007 and many activities have been initiated by the Ministry of Natural Resources and Environment (NRE) to work towards implementation of the Act. However, many are still in the dark about biosafety and the Biosafety Act itself, the status of biosafety around the region as well as its impact to research and industry. This is clearly seen through the queries and presumptions from various stakeholders that have been expressed through formal letters, verbal communications, in meetings and events. Natural Resources and Environment (NRE) sees the need to disseminate accurate information about the Act and Biosafety in general to all stakeholders and public in general (Ramatha, 2009).

The Act actually is been emphasized on circumstances and surface of the Act only. But the details of the regulations will be further discussed in the Biosafety Regulation itself. Since the regulation just been released recently, we can now go through all the details about. The new regulation consists of 7 parts, in which every part will give details according to the respective activities. In part 1, the regulation touches on the preliminary including citation and commencement, non-application, interpretation as well as fees pertaining to activities that will be carried on. While an establishment of an institutional biosafety committee is more elaborate in part 2. Next, approval for any release activity and importation of living modified organisms is put in part 3 of this regulation, which discuss on application for approval and fee not refundable as well as acknowledgement of receipt of application. Follow by part 4 and 5, whereby the discussion is on the certificate of approval and notification. Then appeal and miscellaneous are further conferred in part 6 and 7.

Under the Act, the Ministry of Natural Resource and Environment (NRE) is given the mandate to set up a National Biosafety Board (NBB) that will be responsible for the regulation of the release, importation, exportation and contained use of any living modified organism derived from modern biotechnology and products of such organisms. The Biosafety Core Team has been formed under NRE to implement the Biosafety Act through the NBB. This team will be the lifeline of biosafety regulatory activities for Malaysia. Biosafety regulatory activities and public awareness will become more visible in Malaysia through this team. This Act was developed in consultation with all stakeholders, such as representatives from the relevant ministries and agencies, biotechnology industry, local researchers, non-governmental organisations and also foreign embassies. It was also drafted to be in line with the National Biodiversity Policy (1998) and the National Biotechnology Policy (2005) and covers only modern biotechnology activities. During the late 1980s and early 1990s, the regulatory frameworks on both sides of the Atlantic had to deal with concerns about biosafety issues arising from the production and release of GMOs. These regulations focused on potential risks to human health and environmental safety (Madsen and Sandoe, 2007).

Although biosafety is a matter of vital concern, in Malaysia, there remains a considerable lack of awareness on the issue, and the precautionary measures that are needed. This study found that only Malaysians with a high knowledge base and involved in the science and technology disciplines have the requisite awareness. Hence, while the development of the technology is highly advanced, issues of safety and awareness should also be taken into account. Malaysians need greater exposure on these matters, and to this end, relevant information must be provided through appropriate education. For example, biosafety issues can be included as a minor subject of general knowledge in school curriculum, and as part of public enlightenment campaigns.

Other approaches such as workshops, seminars, as well as small advanced discussion groups can also be used. Any approach adopted should be as practical as possible, and the organisers should be equipped with the right skills. At secondary and tertiary levels, the approaches adopted must also demonstrate high standards. It is suggested that at the tertiary level, biosafety could be introduced as a major subject. More so, given that biosafety is one of the most important issues associated with modern biotechnology, as not all the

products derived through this process may be completely safe. Thus, biosafety education could be a useful means of getting students and other young person's informed in advance about the issues raised by modern biotechnology and GM products, thereby serving as an important precautionary measure.

CONCLUSION

In conclusion, there are differences between both developing and developed countries in their safety regulation. Although, there are differences but the main concern same is to provide and ensure the safety of the environment of respective country from any harm of the released of GMO. In other words, to overcome this situation, better tools and regulations should be provided to be sure safety standard required. GM application could bring lot of benefits in particular, to farmers, whereby they try to adopt the techniques and applications associated to GM crops. Although, genetic modification of foods is important and beneficial, it should be adopted under conditions that avoid the potential risks. Time and effort must be devoted to field testing before the release of any new genetically engineered organisms or food. GM products should be evaluated over a long period of time to establish their effects on health, agriculture pests, and the environment. Caution and suitable regulation are necessary to avoid possible environmental and safety problems, which can jeopardize the expected benefits of this new science. Even the GM technology has potential in widening the range of biotechnology; the technology itself cannot be transferred or spread without carefully and practically observing the above mentioned aspects and matters. In other words, the stakeholders such as, policy makers and researchers, particularly in developing countries should carefully assess the risk and hazard as well as the government should regain public and consumer confidence and acceptance to understand the regulation. Furthermore, private and public sector leaders should understand and recognize the level of public awareness in relation to the new products. It will enable them to plan strategy for effective promotion for a new GM products and foods.

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