第一章
基因轉殖植物之生物安全議題

Why and How to Verify the Safety of Genetically Modified Crops

Jong-Ching Su, Ph.D.
Former Director
National Science and Technology Program on Agricultural Biotechnology

Abstract

The genetically modified organisms (GMO) are produced by the introduction of foreign genes using the molecular biological techniques usually to existing excellent mother stocks. They are unnatural in genetic constitution in comparison to the naturally propagated ones, and thus are regarded as exotic to their relatives. The introduction of GM crops in the agroecosystem elicits public concerns because of its massive nature of introduction and the analogy derived from the invasion by exotic species. Therefore, the governmental regulation on the verification of GMO safety puts the primary emphasis on whether their introduction causes environmental disturbances or not. In order to implement such verification protocols, facilities suitable for obtaining rigorous scientific data must be setup and operated according to the best knowledge of biological sciences. The regulatory measures to be taken at different steps of GMO development and facilities suited for their safety verification were discussed, and the needs to develop individual regulatory protocols for the application of GMO in specific practical purposes were stressed.

Introduction: Disturbance of ecosystem by invasion of exotic species

Although gene flows among closely related biological species had been occurring probably soon after the biological system evolved on the earth and started diversifying, the long history of evolutionary pathways resulted in innumerable number of well defined individually segregated species as we now see around us. All biological species are not distributed evenly on the earth surface, and niches specific to certain species are found according to the differences in ecological conditions.

Ecological systems are established according to a balancing relationship among inhabiting species with the natural environment, and we human beings, as a member species constituting the system, should respect the harmonious conditions

established in nature. Sudden invasion of exotic species into an ecosystem may disturb the balance to bring about some disastrous effects, such as the extinction of native species or the hazard to human health, as we are now much disturbed by the invasion by a venomous ant species from South America, just to cite an example. The fact that the regulatory measures of biological quarantine is a practice enforced by all countries in the world attests to the importance of the issue.

Why GMO are regarded as invading exotic species?

Undoubtedly, genetically modified organisms, or GMO in short, created by the gene transfer technology in the laboratory, albeit with very little differences in their gene constituents from the mother stocks they are derived, are regarded as exotic in the biological world because the introduced genes are usually obtained from other biological species. Contrary to the technological merit of crossing species barrier breeding, GMO also caused certain dislike or dismay of religious minds, and this also intensified the fear toward GMO in certain cultural communities. Besides, since mostly being created to be resistant against biological, physical or chemical stresses and introduced into the agroecosystem for mass cultivation, they may compete with existing wild species to bring about unfavorable ecosystem disturbances and become weeds. Therefore, we will say that the introduction of GMO to our environment should be regulated in reference to the existing laws that are set for the prevention of foreign species invasion.

GMO trade is distinct from the mode of exotic species invasion

GM crops are developed for the purposes of bringing certain merits in agricultural practices, such as the reduction in the application of agrochemicals, improvements in environmental stresses and post-harvest treatments, etc. However, they came to a societal dispute when they were announced as possible cultivars to be introduced into the agroecosystem for mass cultivation, especially when they became items of international trade to cross country barriers as seeds and gain products. Invasion of exotic species, except for intentional introduction of some genetically favorable gene stocks for the improvement of existing agricultural species, is mostly brought about by accidents, unintentional events, or even smuggling. Dangers associated with the invasion of exotic species have been long recognized and rules and regulations concerning the bringing over of them across country boundaries are well established in most countries. It is then quite natural

that the criteria in allowing introduction of exotic species are applied in the safety verification of GMO. However, we should recognize that the introduction of GMOs is through the economic activities while the exotic species invasion is not, though the biological principles underlying them are not much different, therefore they should be handled distinctively. It should also be noted that, in case of the invasion of foreign species, the country barriers are set as equal to the barriers of species migration, however, GMO may be originated from within the own country domain. Therefore, the approval of GM crop release to the agroecosystem should be implemented without any discrimination on their origin.

Regulations on GMO should cover from bench work to field release

The main concern on exotic species invasion is whether the biodiversity in an ecosystem is affected by the invading species or not. In the case of GMO, the criteria of safety verification are whether the genes used in the modification may be given off to the natural species surrounding them, and whether the gene modification will transform them to become weeds to dominate and disrupt the ecosystem. The safety verification of GMO is targeted to the genes used in modification only when the mother stocks are already acclimated in the ecosystem of concern. Therefore, the verification protocols should be worked out case by case, although the examples obtained in other places may serve as good and useful references to make final judgments.

In contrast to the natural origin of exotic species, GMOs are the product of human intervention to the natural biological species by unnatural breeding, or so called molecular breeding technologies. The process of GM plant breeding goes through stages of DNA manipulation, cell biological procedures, plant regeneration and offspring screening. Earlier stages are laboratory operations and the confinement of gene flow is easy to make because the materials of concern are small in volume and may be confined in sealed tubes, covered dishes and jars, and are disposed of properly according to the long established principles and techniques of microbiology. In Taiwan, the stage of GMO research and development is regulated according to the long standing rules set by the National Science Council. If the practice involves the use of radiological tools and materials, the approval from the Atomic Energy Agency is also required. The implementation of experimental licenses must be overseen by the respective special-task committee setup at the research institution.

However, the offspring screening process deals with plants through their life cycle. Thus one has to deal with much bigger biomass and easily escapable gene vehicles such as coexisting microbes and pollen. This author maintains that, before being proved as safe, the organisms should be handled in a total confinement. On accepting this principle, it follows that the offspring crop screening operation must be confined in a closed greenhouse. Only those selected through agronomical evaluation procedures under such conditions may go into the final stage of isolated field trial for environmental safety verification.

Principles of GMO verification facilities design and operation

At the early days of gene transfer technology application, very strict rules on the confinement of laboratory operation were proposed. It was then suggested to build special laboratory space, such as the so called P2 and up facilities, and to implement the bench work in total isolation. Nowadays, after accumulation of experiences and appropriate scientific reasoning, the laboratory practice may be implemented with enough care of confinement under adequate supervision in the ordinary laboratory space. Such regulatory changes enhanced greatly the development of GMO application in Taiwan, and undoubtedly, worldwide.

As mentioned above, we deem that before being approved for release to the field, the early stage of GM crop evaluation through its whole life cycle should be done in total confinement. Building such greenhouse facility and maintaining its operation are expensive. In the subtropical country like Taiwan, the energy cost to keep the facility cool in the summer season is high. Keeping it cool by applying water curtain, installation of easy cleaning facility and implementation of appropriate cleaning techniques to keep the light penetration adequate, instituting flexibility in the adjustment of operating units for running economic operational protocol, etc., will be essential in the facility design and operation.

The final stage of GMO safety trials should be done in a field facility that also accommodates a net house in a test block to prevent biological interferences from outside through the open air space. Of course, the same test block should also have an open field space for testing pollen dispersal and possible cross fertilization with closely related wild species. Because the final stage of test must use soil as the growing medium, the land after experiment should be subjected to rest for a period to allow adequate decay of crop residues left over from the test. An experimental plot does not need to be large but should be able to accommodate big crop stands

such as corn. A mobile type of net-house design is preferred. The number of testing blocks is to be determined according to the needs. It should be confined in a well isolated land patch surrounded by, in sequence, tall tree stands, fence and a surrounding draining ditch connected to a septic tank type facility for waste water treatment. The experimental field patch should be self-sufficient in having dedicated incinerator for residual GM plant disposal, equipment such as tractors for farming operation, cleaning facility for farm equipment, a warehouse for equipment and tool storage, and a small laboratory for preparing GMO samples to bring out for laboratory tests.

Educational and international collaboration roles of the facility

Even the officially approved GM crops, when used as food, should be designated as such in the labeling of food ingredients according to the official regulation in many countries including Taiwan. This aspect of GMO regulation is a strong reflection of social consensus on the GMO safety problems. How GMO is approved thus should be a transparent government operation open to the society. It is hoped that the facility built for GMO safety verification, well confined on one hand, should also be open to the general public for inspection. The facility and its mode of operation should also provide educational functions, especially to the educational institutions at different levels. Besides, since the GMO issue is of worldwide concern with respects to environmental safety, public health and international trade, the level of its facility and operational sophistication should be up to the topnotch international scientific and technological levels. Only through vigorous international exchanges, the GMO policy formulated and GMO produced in Taiwan may obtain international recognition and endorsement. Thus the facility should be designed as a venue of international exchanges of GMO science and technology.

A future prospect:

It should be emphasized that, besides being used as foods, GMO such as pest resistant cotton, tree for better pulp making, crops for bio-fuel production, etc., are becoming more popular to invade the agroecosystem, and environmental safety issues must be dealt with by taking into consideration the diversified types of GMO in the future.

More than those rather innocent types as discussed above, the use of GMO as

bioreactors in the production of medicinal agents is also coming up. The development of vaccines, for example, an antigen harboring fruit for direct use as an oral vaccine, has been much discussed and being tried. Such fruit products, if not marked and handled distinctively from the start in the field cultivation up to its post-harvest application, its misuse may pose unfavorable, or even disastrous social havoc. How to accommodate such advanced technology into the agriculture and health regulatory system should be designed and implemented before being too late. The agony we have experienced in the delayed governmental approval, due to the delayed regulatory protocol formulation, in hampering the commercialization of excellent ring-spot virus resistant GM papaya should not be forgotten. The horizon of using GM products is widening, and they should be regulated according to the specific uses they are aimed at. This author, as a concluding remark, would like to call the attention of relevant government agencies to take up actions on this issue as soon as possible.

Note: This article was drafted based on the experiences gained during the author's tenure as the director of the National Science and Technology Program on Agricultural Biotechnology from 1999 to 2004. So, please be excused for not citing any references as required by the editorial guideline.

爲何以及如何驗證基因轉殖作物的安全性

蘇仲卿
農業生物技術國家型科技計畫前總主持人

摘　要

一般基因轉殖生物(Genetically Modified Organism, GMO)是將非該生物種所有的「外來基因」，依分子生物學手段導入於特性優良母本而育成。因為它的基因組成與依自然繁殖方法所得者不同，被認為是與其母本生物不同的「外來種」。將基因轉殖作物（GM crop）引進於農業生態系栽培引起社會大眾的關心，重要的理由是此一行為可被看做「外來生物種」大量侵襲原來平衡的農業生態系。因此，有關 GMO 管制與其安全性認證的政府規章，以本土生態系的生物多樣性是否受到 GMO 引進的干擾為主要內容。為要執行規章所定認證工作，必須建立合適的設施，並且依據頂尖生物科學知識予以運作以獲得嚴密科學資料。本文討論在 GMO 研發各階段所必要管制辦法的原則，以及安全性認證設施所必備的條件，並且強調必要針對 GMO 的個別用途，建立個別的管制與認證辦法。