我國基因改造生物之跨境管制規範

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摘 要

台灣在農業生技領域的發展，尤其是基因改造動，植物及水產動物皆有具體成效。台灣自 2005 年實行植物品種及種苗法以管制基因改造植物，相關子法包括基因轉殖植物田間試驗管理辦法，基因轉殖植物輸出入許可辦法及基因轉殖植物之標示及包裝準則，亦陸續生效實施。基因轉殖植物規範系統之建立，不僅具體落實一個全面性的管制制度，同時政府部門更投入相當多資源以加強軟，硬體部分之能力建構。除此之外，相關資源之投入也見於基因轉殖動物及水產動物管制上。對於一個非卡塔赫納生物安全議定書之會員國而言，台灣的投入值得全球更多的肯定及協助。 具體而言，包括科技合作，技術移轉，防檢疫對策，資訊交換，和越境轉移前之預警制度等方面，皆是重點合作的方向。無疑地，基因改造生物仍許多風險疑慮。在與台灣有貿易往來的各國邊境管制政策寬鬆不一的現況下，如何摒棄基因改造產品的成見，同時加強合作談判才是積極的雙贏策略，畢竟全球性的生態風險絕不可能憑藉各國各自的國土政策而能免除。如果環境衝擊，食品安全與科學怪物真正成為人類生存的重大風險，在國境上管制基因改造生物充其量只能暫時維護國家安全，唯有凝聚國際共識及建立環球性的效率管控方是長遠之道。

關鍵詞：基因改造生物、卡塔赫納生物安全議定書、植物品種及種苗法、基因轉殖動物、基因轉殖水產動物。

Regulations Covering Cross-border Movement of Transgenic Organisms in Taiwan

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Abstract

Taiwan has made certain achievements in the field of genetically modified organisms, including plants, animals and aquatic plants and animals. After enacting the Plant Variety and Plant Seed Act in 2005, bylaws such as ‘Regulations for Approving Import/Export of Transgenic Plants’, ‘Regulations for the Field Trial of Transgenic Plants’ and ‘Guidelines on Transgenic Plant Labeling And Packaging’ have subsequently been made and implemented. These legal instruments work together to form a workable regulatory framework on transgenic plants. Moreover, the government also invests resources to help carry out capacity building needed to execute implementation. Such voluntary actions taken with great effort by the Taiwanese government apparently represent the paradigm for non-contracting members to the *Catagena Protocol*, and in response, more international support shall be poured in to help improve the current regulatory framework in Taiwan. Specifically, scientific liaisons, technology licensing, quarantine measures, information sharing and precautions warnings are areas to be enhanced in cooperation with the international community. Given the varied GMO border policy of different countries, especially those with trade relationships with Taiwan, the challenge to offset negative feelings towards GMO before coming to the negotiation table to work together deserves high priority in the cooperation agenda. After

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all, even though borderlines can be defined by political jurisdiction, no artificial intervention can define the borderlines of the global ecological system. If environmental impact, food safety and science-created monsters are really threats to human kind, border control of GMO can only play the role of temporarily securing national security, while international consensus and effective regulatory framework should be the ultimate solution in the long run.

Keywords: Transgenic Organisms, *Catagena Protocol*, Plant Variety and Plant Seedling Act, GM Animals, GM Aquatic Animals.

I. Introduction

In Taiwan, currently annual import of genetically modified (hereinafter: GM) corn and soy beans account for 180 tons and 150 tons respectively.[1] There are also domestically produced transgenic products, such as papaya, banana, watermelon, broccoli, balsam pear, tomato, rice, potato, chrysanthemum, oncidium, and calla lily. Among those plants, tomato, rice, potato and broccoli have all entered the field trial stage. In transgenic animals, transgenic ox, pig and milking goat have been available in laboratory. GM aquatic animals, such as loach, catfish, abalone, shrimp, and fluorescent fish have been developed successfully.[2] According to a survey done in 2007, more than 80 % of the respondents have already been aware that there are already GMO products in the market in Taiwan.[3] Almost all the respondents have been advocating since then that the compulsory labeling of GM product is necessary. With respect to border control, the 2007 survey has also shown that 88.8% of the surveyed organizations and 79.4% of the respondents deem that a special law is needed to safeguard the borderline in addition to the prevalent regulations.[4] Although the government published the draft of Genetic Modification Technology Management Act in 2005 and won the growing support from the public, the progress to further lawmaking, and by which to set up an overall regulatory framework is unsatisfactory.

In general, the border control of genetically modified organisms in Taiwan adopts the precautionary principle to regulate transboundary movements. The overall regulatory framework, though executed by different competent authorities can be discussed by the biological properties of such organisms, being plants or animals, habitats, being terrestrial or aquatic or by end use of the import or export.

Although the *ad hoc* task force of Bio-industry Instruction Committee has been set up under Administrative Yuan to direct the development and management of genetic engineering and the special inter-ministerial workforce to carry out the substantial work,[5] the bureaucratic efficiency is however, way below expectation. Consequently, there is still in short of a powerful governmental agency in effect to orchestrate the efficient border control of transgenic products, taking into consideration of the public concerns. Issues such as potential risks, genetic drifting, and potential hazardous to the eco-system, food safety, environmental security and scientific

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[1] Ya-fen Yuan. (2012). The Current Management of GMO Products in Taiwan. http://www.pabp.gov.tw/AreaBus/libA/aa503.asp (last visited: Jan 24. 2015).

[2] Ibid.

[3] Julie Sun. (2007). *A Study on Genetically Modified Products in Taiwan*. Taiwan Institute of Economic Research Report. http://www.biotaiwan.org.tw/download/core3/3-4%E7%94%A2%E6%A5%AD%E8%AA%BF%E6%9F%A5/%E5%9F%BA%E5%9B%A0%E6%94%B9%E9%80%A0%E7%A7%91%E6%8A%80%E6%94%BF%E7%AD%96%E6%94%AF%E6%8C%81%E5%BA%A6%E8%88%87%E6%84%8F%E8%A6%8B%E8%AA%BF%E6%9F%A5%E5%88%86%E6%9E%90(200709).pdf (last visited 2015.1.24.).

[4] Ibid.

[5] See supra note 3.

uncertainties[6] are still subject to each ministry's administration and a successful bridging platform for reciprocal dialogue is needed. This paper will brief the current regulations in Taiwan with respect to the custom's control for both import and export of transgenic organisms seen in different laws. Also, critical review of the prevalent regulatory framework will also be raised and discussed.

II. Border Regulatory Framework of GMO in Taiwan

1. GM Plants

(1) International Transport of GM Plants

According to Plant Variety and Plant Seed Act (hereinafter: PVPSA), Art. 52 Para. 1, without the approval of the central competent authority in advance, i.e. Council of Agriculture, it is prohibited to import or export transgenic plants regardless of the use.[7] Moreover, Art. 52 Para. 4 further upholds the concerns for food and environmental safety that should there be any cases for importation or exportation of transgenic plants for such purposes, to comply with the prevalent bylaws concerning identification of genetic characteristics, transgene profiling, biosafety assessment and risk managements are mandated. In order to enact PVPSA, Art. 52, two further implementing regulations are substantiated to address the issues of permission for crossing the national border and the subsequent filed trial.

Pursuant to PVPSA, Art. 52 Para. 1, the 'Regulations for Approving Import/Export of Transgenic Plants (hereinafter: RAIETP)' were made and published in 2005. The promulgation of RAIETP is to set up clear procedures and binding criteria to safeguard the borderline in case of any transboundary movements of transgenic plants. To date, RAIETP is the most comprehensive bylaw regulating cross-border movement of GM plants in Taiwan. Further discussion of RAIETP will be as follows.

(2) Regulations for Approving Import/Export of Transgenic Plant (RAIETP)

This legal document was made in accordance with PVPSA, Art. 52 Para. 1 and has become the most comprehensive bylaws regulating cross-border movement of GM plants in Taiwan. Taiwan though not a member to CBD and was not obliged to carry out duties prescribed by the *Catagena* Protocol in the international community,[8] the government however are very aware of the international development on GMO issues. In light of the international trend, taking public concern into consideration, Taiwan set forth a series of international dialogues by means of hosting workshops and conferences to interact with world scholars and experts. Among the participants, cooperation with the Japanese scholars and experts appeared to be the most beneficial. Especially in the 28th of Nov. 2002, the highlight happened when the 'Association of East Asian Relations (AEAR)' of Taiwan and the 'Interchange Association of Japan (IAJ)' reached an agreement in the 27th Economic and Trade Meeting. Beside other issues, in Item 5 of the Section of Technology、Agriculture and Fishery, Taiwan acknowledged the previous visit of the Japanese experts on instructing local GM plants Issues and subsequently made an initiative that both parties could further cooperate on the evaluation of the *Catagena* protocol. Furthermore, Taiwan hope that Japan can help Taiwan by means of sending experts to instruct and draft substantial measures to set up the ecological and environmental safety assessment and management system of transgenic plants in Taiwan.

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[6] T. H. Hsu. et al. (2004). *GMO/GMF Risk Evaluation and Management. From Dispute to Prospective*. Edited by Nu H.Z et al. Bureau of Animal and Plant Health Inspection and Quarantine, Council of Agriculture, Executive Yuan. Taipei.

[7] Plant Variety and Plant Seed Act, Art. 52 Para.1.

[8] C.H. Lee. (2006). Comparative Study on GMO. Management and Policies. *Sci-Tech Policy Review.* 2006. April.

Moreover, Japan can provide assistance to help Taiwan make 'Regulations for Approving Import/Export of Transgenic Plant'. The initiatives won positive feedback from IAJ. IAJ did not only acknowledge the reciprocal discussions between Japan and Taiwan but also mention that the biotechnological task force of Agricultural Technical Cooperation Working Group, ATCWG under Asia-Pacific Economic Cooperation, APEC could serve a good platform to forge the link of both countries. IAJ also consented to provide assistance to send Japanese experts to Taiwan when necessary. This agreement was later substantiated to give birth to the 'Regulations for Approving Import/Export of Transgenic Plant', which was published in 2005. Apparently, the drafting of the border measures of transgenic plants in Taiwan has been heavily influenced by Japan.

Regulations for Approving Import/Export of Transgenic Plant have been implemented since July 2005. First, in order to ensure investigation efficiency in the customs house, whatever the purposes may be for importation, RAIETP empowers the competent authority right to sample imported goods without paying any remuneration fee that may occur. Such official action is not subject to the importer's consent.[9] Followed by the frontline inspection, according to Art. 2, measures of controlling GM crops for propagation and culturing use shall be separated from those for trial or research and development in laboratories.[10] Reasons for establishing separate mechanisms are obvious. Owing to the high unknown risks are more likely to occur in research, importation of GM plants for laboratory use therefore, should be under stricter scrutiny. With regard to importation, RAIETP require applicant to provide necessary information, such as personal information of the importer (name, telephone number, address), purpose and use of the importation, origin of the goods, departing port, name and quantity, etc.. Additional information may also be demanded. Pursuant to Art. 3, such information can be listed as follows:[11]

- **a.** Host plant origin and the botanical features of the host transgenic plant, for example characteristics, propagation and pollination etc.;
- **b.** Origin and function of the transgene(s);
- **c.** Institution Location where the trial or R&D have taken place;
- **d.** List of facilities and equipment within (3);
- **e.** Working force of the original plan;
- **f.** Constitution of the original biosafety committee and the member list;
- **g.** Biosafety control plan for the transgenic plant to be imported;
- **h.** Packaging method and labeling; and
- **i.** Transportation routes, available methods and emergency measures during transportation from origin to destination.

Notably, one *ad hoc* biosafety committee was demanded to establish with the task to review and monitor any resulted biosafety issues. Duties of the committee include planning and supervising the safety assessment protocol, which is to be implemented accordingly by the staff.[12] In order to ensure the above objectives to be met, qualifications of the members are stipulated in Art. 4 Para. 3 that committee members should be limited but from the following fields, such as biotechnology, crops breeding, biodiversity and plant protection.

In comparison to the rather careful measures implemented to counter minimize the potential risks, the managerial approach toward GM crops importation for propagation and culturing use appear more relaxing. In light of importation purposes, the reason why there exist differences in regulating measures between research and culturing and breeding purposes can be attributed to the fact that importation for the later purposes have normally

[9] Regulations for Approving Import/Export of Transgenic Plant, Art. 6.

[10] Ibid, Art. 2.

[11] Ibid. Art. 3.

[12] See supra note 9. Art. 4.

gone through field trials and risk assessment in the original production country before such goods can be exported and shipped to another international port as the *Catagena* protocol mandate so. Given that, as long as the importer in Taiwan has obtained the field trial approval and sale permission in advance abiding by Art. 52 Para 2[13], it is deemed redundant to demand information concerning the details of the foreign laboratory location, laboratory facilities and equipment, the member list of the biosafety committee and the biosafety control plan where the biosafety assessment has been taken place in the production country.[14]

Regarding exportation, it is worthy to note that although the essential information required for exportation may appear of little differences from those required for importation, to file for permission to export GM plants that are not originally produced in Taiwan to another country, further documentation submission consisting of the original import permission is essential to make sure that the GM plants to be exported are not smuggled or illegally grown and propagated in Taiwan in the first place.[15]

In case there may be some confidential information concerning trade or technology to be breached during bioassay and risk assessment, RAIETP oblige the competent authority to implement measures to safeguard the applicant's right of confidentiality.[16]

Moreover, durations of processing the applications are also prescribed in the regulations. RAIETP, Art. 8 stipulates that the duration for reviewing paperwork should not exceed 60 days before any decision to be made. If the application involves sampling evaluation, maximum of 270 days are allowed for the Agency of Agriculture and Food to make the final decision. All the applications and references have to abide by the official templates published in additional ordinances.[17]

(3) Regulations for the Field Trial of Transgenic Plants

Another related regulations regarding work to be done before exporting to another country or after importing into Taiwan will be the field trial regulations. Published in 2014, the regulations entitled: 'Regulations for the Field Trial of Transgenic Plants' (hereinafter: RFTTP) have gone through several amendments. RFTTP stipulate detail facility requirement for GM plant field trial and publish necessary information regarding identifying transgenic traits and biosafety evaluation protocol. By means of adopting appropriate procedure and scientific sound standards to investigate the potential impact of GM plants toward environment and human health, RFTTP was made and enacted to respond to the public concerns for risks likely incurred by new technology.

In the history of making RFTTP, the government used to refer to countries capable of adopting advanced technologies to managing and developing genetic engineering. Council of Agriculture has sent out staff for study trips to countries such as Japan, the Netherlands, UK, France, Germany and Canada. The government referred to the international experiences and combined the then three sets of regulations, i.e. 'Regulations for Field Trial Management of Transgenic Plants', 'Guidelines for Entrusting Transgenic Plants Field Trials' and 'Guidelines for Establishing Official Transgenic Plant Evaluation Committee' and drafted 'Regulations for the Field Trial of Transgenic Plants'.[18] The RFTTP was later promulgated in 2014, which served as the substantial embodiment of PVPSA, Art. 52 para.2 and lays a milestone for both regulatory efforts and technological achievement of GM plants.

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[13] Supra note 7. Art. 52 Para. 2.

[14] See supra note 9. Art. 3.

[15] See supra note 9. Art. 5.

[16] See supra note 9. Art. 7.

[17] Ibid. Art. 9.

[18] Ming Ze Wu, Lieh Fu Chen. (2008). The Establishment of GM Plants Field Trial Management and Biosafety Assessment. *Agricultural Biotech Quarterly,* No 13, pp 20-27.

RFTTP consist of 4 chapters and have 35 articles in total. The regulations empower the authority to set up an *ad hoc* transgenic plant evaluation committee to evaluate, monitor and review matters with regard to field trials of transgenic plants. Owing to the impact of transgenic plants can be multi-folds, RFTTP stipulate that the committee shall be chaired only by person from the competent authority and would be assisted by another staff from the same organization. Furthermore, for coordination efficiency, representatives from the government shall be limited from Ministry of Science and Technology, Department of Health and Welfare, and Department of Environmental Protection respectively. Additionally, 4-8 experts from biotechnology, crop breeding, biodiversity, and plants protection are required to help constitute such committee.[19] This *ad hoc* committee bears responsibility to fulfill the following works:

a. field trial institution review;
b. review of applications for conducting field trial and reports;
c. review of applications for biosafety assessment and reports;
d. review of handling measures in emergency;
e. decision on entrusting capable institution;
f. technical and policy consultation;[20]

RFTTP allows any public or private research institution or legal person to apply for certification of capacity in order to carry out transgenic plant field trial. Article 9 and 10 detail the requirements for infrastructure building and management scheme. To efficiently assess the potential risk, 4 levels of contained facility for trial are depicted. They are sealed green house, semi-sealed green house, contained greenhouse/net-house, and contained field, respectively.

Separate criteria are set for air-borne spores, pollen, seeds, pest, insects control; water treatment; waste transportation and disposal; as well as cleaning protocol for experimental tools and agricultural instruments and machinery in each level of risk management.[21]

Any protocol shall be reviewed by the central authority before it can be published and implemented by the entrusted trial agency. The testing protocol shall include the following items, such as sign of the location, testing material, staff, machinery, and vehicles control plans, regular check for staff execution, facilities and equipment; documentation management; and alert system for emergency and violation of code of conduct. Once the certification is approved, it is valid for 10 years. Any post-modification of facility or risk assessment protocol will be subject to further approval. In case of failing to abide by due administrative procedure or any unauthorized modification or changes, certain grace period of time for improvement will be granted. If the criteria would not be met, the authority can revoke the permission and announce the decision to the public.

Field trial consists of 2 steps. The first step is the study of genetic traits of the transgenic plants. To apply for studying genetic traits of transgenic plants, it must be filed either after laboratory experiment or before import of such GM plants from outside country. Only the result of the study would be evaluated as in line with the domestic standard should the second step of biosafety evaluation initiate. However, for plants which hardly blossom or produce pollen, the committee can decide to combine the 2 steps evaluations. For imported plants which have gone through genetic traits assessment, it is allowable to enter step 2 biosafety evaluation if the experimental data and legal import documentation pre-submitted have already been endorsed by the biosafety committee.[22]

The step 1 field trial can be made by submitting no more than 10 GM lines of the same recipient plant kind,

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[19] Regulations for the Field Trial of Transgenic Plants, Art. 6.
[20] Ibid. Art. 5.
[21] Ibid. Art. 11.
[22] See supra note 19. Art. 18.

which has been inserted with the identical gene by the identical laboratory protocol. However, for deliberate control of environmental risk, step 2 only allows one GM line of stable genetic traits assessed by step 1 per application for biosafety evaluation.[23]

For all the documentation and material submitted to the authority for field trial, the authority bears the self-contained responsibility to keep such data confidential. These documentation and material may include testing protocol, standard operating procedure, risk management plan and measures for emergency.

Pursuant to RFTTP, Art. 21 and 22, more details concerning the required items for applications, for example objectives of the trial, duration, material and method, construction of contained facility, safety management plan and prevention measures, literature review and potential impact of the transgene(s) toward environment, waste/surplus material treatments before/after the trial are all stated.

For material and method, detail information such as the propagation traits, genotype description, potential rate of hybridizing with relative type or wild type of the same plant species or genera, expression loci of the inserted gene in the recipient plant and the genetic stability, hazardous analysis of the inserted gene and the transgenic plant, etc.[24]

Description of the transgenic traits shall disclose the following information:[25]

a. Information for the host plant: name, source, taxonomy, practical use, local cultivation scale, characteristics, sexual or asexual propagation, pollination, related species in Taiwan;

b. Information of the transgene: source, classification, number, recipients, control mechanism, gene expression, location and expression in the host plants;

c. Information for the vector: source, molecular characteristics, and the host cell.

d. Information for gene-transfer method: theory, protocol of gene transfer, identification, molecular marker, expression marker, etc.

As for step 2 assessment of biosafety in the contained field, the biosafety assessment plan of transgenic plants shall state the following items:

e. goal for field trial and duration;

f. uses of the transgenic plant and its products;

g. assessment methods and items;

h. the contained field of growing the GM plants;

i. vegetation in the neighboring areas;

j. cultivation and management measures;

k. Containing strategies for physiological or biological isolation;

l. literature review of the likelihood of genetic drifting and impact to the environment;

m. preventive and remedy measures for emergency;

n. Waste management during and after the trial;

o. Trial site regeneration.

The assessment items stipulated in subparagraph 3 of the preceding paragraph shall cover issues, such as the evaluation of genetic drifting to wild species, potential to become super weed, likelihood of impacting on target and non-target organisms, negative effect to the existing eco-system, etc..

The central authority shall publish the approved biosafety assessment plan, stating name of the plan, applicant and institution, the characteristic of the transgenic plant and duration of the plan. In case the plan takes more than

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[23] Ibid. 19.

[24] See supra note 19. Art. 19.

[25] See supra note 19. Art. 23.

one year, applicant is obliged to submit annual report at the end of a fiscal year. Moreover, applicant is required to submit test report for evaluation by the authority no later than 6 months after the plan is finished. Failing to submit either annual report or test report after the deadline or when further notice is due is considered in violation of the RFTTP.

Evaluation Committee member can demand in situ supervision and if necessary require modification of trial practice or put the trial on hold in case of emergency. In later situation, the committee shall report to the central authority and demand for revocation of the permission. For long term monitoring of the released transgenic plants, the central authority may subcontract to capable institution of good capacity building for periodical scrutiny.

Only after the trial results being endorsed by the competent authority and permission for promotion and sale obtained, marketing and commercialization activities for such transgenic plants become possible. As for the administrative procedures, such as the trial method submission, application and examination procedures, binding regulations, and testing fees, etc. they have all been prescribed by the central competent authority.

Due to food security and environmental safety concerns, transgenic plants shall be appropriately packaged and labeled for import, export, transport, marketing, and sale. The packaging and labeling regulations are entitled 'Guidelines on Transgenic Plants Labeling and Packaging' and will be later discussed.

(4) GM Plant Packaging and Labeling for Direct Use

With regard to packaging and labeling, regulations are dispersed in several laws depending on the purpose for importation or exportation. For example, if GM plants are for direct sale, PVPSA, Art. 52 Para. 4 elucidates a set of detail guidelines, 'Guidelines on Transgenic Plants Labeling and Packaging' to regulate packaging and labeling of such GM plants. This guideline also extends to cover related issues, such as import, export, transport, marketing of the GM plants within domestic jurisdiction.

However, if GMO importation is intended for research and development, regulations with respect to administrative procedures as well as contained use are all in place.

Finally for GM material imported for food material or food additives, the competent authority of Ministry of Health and Welfare also publish regulations to address the application procedure for permission as well as packaging and labeling stipulations.[26]

Regarding GM import for human consumption, more discussion will be seen in the later section.

2. GM Animals—Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment

So far, there are still no regulations concerning transgenic animals import or export in Taiwan. However, in fact for research purposes, especially for breeding and scientific research and presentation, there are still imports of GM livestock from abroad. Any imports of transgenic animals shall go through genetic traits investigation and safety assessment before any further scientific and commercial applications can take place.

Pursuant to Animal Industry Act, Art. 12-1, the transgenic animals intended for promotion or sale have to undergo field trial and safety assessment prior to marketing.[27] Implementing details of such stipulation can be found in 'Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment'

[26] Act Governing Food Safety and Sanitation, Art. 22 Para. 1.

[27] Animal Industry Act, Art.12-1: 'Breeding flock or breeding stock involving the transfer of genetic material shall undergo field tests and creatures' safety assessment before it can be promoted and made use of. The regulation measures on the transfer of genetic material will be set forth by the central competent authority.'.

(RFTBA). There are altogether 10 articles in RFTBA and have been in effect since 2002.

With respect to border control of GM animals, RFTBA set up separate measures to differentiate various uses of the transgenic animals. If GM animal experiment would be conducted in any organisation for research purposes, the requirement for biosafety assessment can be exempted. However, if to be used for promotion or application outside research, field trial as well as biosafety assessment are compulsory.[28] More clauses are prescribed in RFTBA concerning application for biosafety assessment. Requirements to be met include:

a. objectives;
b. origin and genetic source of the breeding stock (both in Chinese and English);
c. characteristics of the breeding stock;
d. transgene information: name, source, DNA sequence, molecular traits;
e. vector;
f. gene transfer protocol, theory, available bio-assay result;
g. in situ expression of the transgene, genetic stability and potency of expression;
h. phenotype differences resulted for genetic engineering;
i. likelihood of transforming into a harmful species and gene drifting;
j. precautionary measures against (9);
k. experimental design and the anticipated results;
l. other items to be reviewed.

There is also a review board of transgenic breeding stock and fowl set up in the Department of Animal Industry to carry out the task of evaluation and supervision of the field trial application. In order to effectively control the field trial, uses of the transgenic breeding stock and fowl are strictly limited to the scope being approved in advance. Although there are still no GM animal product available on the market, in any attempt to initiate marketing activities toward consumers, Act governing Food Safety and Sanitation shall prevail. This will be further discussed in the later section.

In case when the application for field trial is rejected, life of the transgenic breeding stock and fowl to be tested shall be terminated in a humane way and the carcass, cremated.[29]

3. GM Aquatic Organisms

(1) Regulations for the Field Trial of Transgenic Aquatic Plants and Animals

The Fisheries Act, Art. 69 para.3 stipulates: ‘any aquatic organisms that involved in genetic breeding and transference shall run prior field tests and safety assessments before promotion and utilization. The regulations on the field test and breeding management of genetic bred and transferred aquatic organisms shall be prescribed by the central competent authority.’

In accordance with the above law, responsible authority of Fisheries Agency promulgate ‘Regulations for the Field Trial of Transgenic Aquatic Plants and Animals’ (hereinafter: RFTTAPA) in May 2012. Pursuant to RFTTAPA, Art. 13, before any domestic GM aquatic plants and animals to be transferred outside laboratory, or said organisms to be imported from abroad, filing for field trail is compulsory. If for research exhibition in another country outside Taiwan, applicants should also apply for permission to export.

Owing to that the source law is Fisheries Act, although the title of RFTTAPA intends to cover both transgenic aquatic plants and animals, the content of the regulations still put considerable portion on regulating aquatic

[28] Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment, Art. 3.
[29] Ibid. Art. 9.

animals.[30] Little concerning aquatic plants has been addressed or stipulated in the regulation. Apparently this appears to be a loophole in the whole regulatory framework as aquatic plants are plants to be managed by the Fisheies Agency under Council of Agriculture rather than the competent authority of Agriculture and Food Agency for plants in general. No efforts have been put to mend such flaw because this issue does not raise any attention to the lawmakers nor the public, unfortunately.

In situation of intended export for exhibition purposes, one should submit information, including personal information of the applicant, invitation letter or cooperation agreements and exhibition plan. The exhibition plan should constitute biological data of the organism, origin of the inserted gene, genetic traits, physiological mechanism, quantity, location, duration, and transportation methods and route, personnel, and the approval letter from the exporting country, if not domestically produced, etc.. [31]

In order to counter prevent any potential disaster during local exhibition, action plan shall contains safety assurance in case transgenic organisms escape, being stolen, hybridize with wild type, being mass-contamination or encounter natural disaster and associated report procedure to the competent authority.

The regulatory framework of transgenic aquatic plants and animals appear similar to that of terrestrial transgenic plants. The two-step regulatory mechanism, including investigation of genetic traits and biosafety assessment are applicable to transgenic aquatic plants and animals. However, what is more is that in order to prevent GM aquatic animal from escaping and hybridizing with other species, contained facility and infertile technology may be adopted to this end.[32]

Also, because the propagating material are water-borne for aquatic animals, the building for contained pools, related equipment and the management of wastes, including solid residue and disposable trash, waste water treatment, and draining standard are of great importance.[33] Any institution wishing to conduct field trial of GM aquatic plants and animals shall apply for certification in advance. The certification is valid only for 5 years but is extendable, in comparison to 10 years for the one for terrestrial GM plants. This difference is mainly attributed to the complexity of maintaining standard hygienic facilities and staff as well as disease control. A shorter term of valid permission will enable the competent authority to review the field trial environment more frequently.

In addition, even though there can be up to 10 transgenic lines of the same species allowed to be subject to biosafety assessment in terrestrial GM plants each time, no such regulation concerning the number of transgenic lines in aquatic plants and animals.[34] What stipulates in Art. 15 is that only one species is allowed for field trial per application. Details concerning standards of genetic traits investigation and biosafety assessment can be seen in RFTTAPA, Art.19-21. Like terrestrial GM plants, if the end product is intended for human consumption, Act governing Food Safety and Hygiene shall prevail.

(2) Regulations For Transgenic Aquatic Plants and Animals Propagation and Breeding

With regard to GM aquatic plants and animals propagation and breeding, ‘Regulations For Transgenic Aquatic Plants and Animals Propagation and Breeding, RTAPAPB ’ is the binding regulations. Pursuant to RTAPAPB, Art. 4, only certificated farms are allowed to propagate or breed GM aquatic plants and animals.[35] The competent authority should set up a panel consisting of experts, scholars and government representatives to

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[30] Y.F. Hu, et al. (2012). *The establishment of risk assessment platform of Transgenic Aquatic organisms. 2012 Annual Report*. Fisheries Research Institute.

[31] Regulations for Field Trial of Transgenic Aquatic Plant and Animal Propagation and Breeding, Art. 16.

[32] Regulations for Field Trial of Transgenic Aquatic Plant and Animal, Art. 18.

[33] Ibid. Art. 11.

[34] See supra note 32. Art. 15.

[35] See supra note 31. Art. 4.

evaluate import and export application of transgenic aquatic plants and animals. The decision has to be made within 2 months after the application has been filed but the time limit can be extendable for another two months subject to certain situations. However, this time restraint excludes the time needed to carry out the following tasks:

a. sampling and examination time in case of necessity

b. proof check toward international organization, foreign government, stakeholders

c. other interferences to pause the examination that are not attributed to the authority.

The authority shall state clearly in the import permission that should there be any risk to jeopardize the ecological system, the authority shall abolish the permission and demand to cremate all the biological material.[36]

In consideration of the illegal import or export of transgenic aquatic animals will likely lead to irritating the operation of fishing grounds and fishing vessels,[37] Illegal import or export of such goods will be liable to administrative sanction and monetary fine in Taiwan. According to Art 20 of the Rule, in case of illegal import/export, the competent authority shall exercise power to cremate goods and enact Fisheries Act, Art. 65 para.8 to fine the law breaker between thirty thousand and one hundred and fifty thousand New Taiwan Dollars.

In case of substantial concern for causing negative effect toward the ecological system, the competent authority shall demand manager, importer or exporter to improve within prescribed time period. If violated or the situation became urgent, the competent authority shall demand the stakeholders to cremate the source organisms as well as those contaminated ones.[38]

III. GMO labeling

So far, it appears that with respect to GMO labeling and packaging, regulations are dispersed in varied regulations subject to different competent authority. As seen in different applicable regulations, packaging and labeling required for GM plants, GM animals, and GM aquatic plants or animals all exist differences. No uniform regulations to address GMO packaging and labeling can be attributed to the diversity of biological species, habitats, growing methods, propagation, transport, storage, media of contamination, potential use, and lifestyle, etc..

However, there is still a comprehensible principle behind the requirement of packaging and labeling. As long as that the consumer's right to know is satisfied, sufficient information for safe handling is provided, and preventive measures are adopted, packaging and labeling are tools to present sign of warning or reminding. Therefore, packaging and labeling to the end use of the transgenic products will be deemed practical.

Taking transgenic plants for direct use in agriculture for example, PVPSA, Art. 52 prescribed guidelines for labeling and packaging. Guidelines for Transgenic plants Packaging and Labeling, Art. 4 states that before importation, labeling of transgenic plants in Chinese language is mandatory and the label with the associated code of approval have to be presented in the most obvious fashion. There should also be flyers printed and distributed by the traders to acquaint potential consumers with the ingredients and product information.

Such information shall include the scientific and common name of the inserted gene, name and address of the sales agent or nursery, location of production, weight and quantity, product characteristics, use and purpose of cultivation, name and address of distributor and importer, transportation, handling and storage, emergency

[36] See supra note 31. Art. 17.

[37] Fisheries Act, Art. 64 (8) and 54(5).

[38] See supra note 31. Art. 21.

measures, and the percentage of germination should they be seeds.[39]

It is also the responsibility of the producer to package transgenic plants solely with strong and unbreakable material and should not be mixed with other plants in case of transportation, import or export. However if further packaging into small quantities is needed, the small package seller shall examine the quantity and quality and repackage into small quantities with additional label.

All the detail requirements may seem tedious at first glance as they consists of some trade information, however taking into consideration the knowledge gap of potential users, retrievable track record of GM plants, unknown risks to eco-system, the indications of the above information may still be appropriate.

In contrast, if transgenic material or additives are for human consumption as food, a centralized law is in place. Dated back to Jan.1. 2003, Ministry of Health and Welfare issued an ordinance stipulating that it is prohibited to produce, process, condition, import or export any GM maize or GM soy bean without any prior examination and safety announcement by MHW. Later on Sep. 26 of the same year, MHW amended the previous regulation and published the ordinance of 'shi tze (food) No. 1021350531' to impose compulsory registration on all GM maize and soybean materials. Along with the parental law of Act Governing Food Safety and Sanitation was amended in 2004, the regulation of GM food and food additives has become even stricter than before.

To date, the prevailing Act Governing Food Safety and Sanitation stipulate high level of tracking system to potential users and consumers in Taiwan. Pursuant to Art. 21 Para 2 & 3 promulgated by Ministry of Health and Welfare, transgenic materials are prohibited to be used for food or food additives prior to official review of the health risks. Anyone wishing to import GMO for food or food additives shall file application to Ministry of Health and Welfare in advance. This stipulation shall apply to all GM crops. At present, registered GM crop kinds include soybean, maize, canola, and cotton. Furthermore, importers that have filed product registration and granted permission from the authority shall establish a set of documentation management system in aid of tracking back the source of origin and product flow of transgenic materials when needed.[40] Within the system, lot information, custom's code, paper and electronic records, data of imported products, genetically modified food raw materials are all to be kept for 5 years.[41]

According to Art. 22, 24 and 25, products contains GM ingredient for more than 3% either as raw material or additives must be properly labeled in Chinese on the package: 'containing genetically modified food raw materials/additives'. Moreover, Art. 30 stipulates that: 'application for inspection with the central competent authority and declaration of the relevant information of the product are required and shall be in accordance with the customs commodity code and classification when importing foods, genetically modified food raw materials, food additives, food utensils, food containers or packaging and food cleansers designated by the central competent authority in a public announcement.'

Furthermore, in order to keep track record of GM material for food, Art. 30 stipulated that all the imported GM material for food shall be listed in an *ad hoc* category. In response, the Bureau of Foreign Trade of Ministry of Economic Affairs and Customs Administration of Ministry of Finance worked together to publish a set of rules to regulate GM material for food, which took effect since November 1st, 2014. There are basically two import rules, F01and F02 to categorize GM maize and soybean for food. F01 contains most of the items than F02 for corn flour. Applicable rules as well as associated import tariff numbers can be seen in the following table.

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[39] Guidelines on Transgenic Plants Labeling and Packaging, Art. 3.

[40] Act Governing Food Safety and Hygiene, Act. 9 para.2. However, the proviso in the same paragraph states that: for the unregistered genetically modified food raw materials mentioned in Paragraph 2 prior to the amendment of this Act on 28th January 2014, shall complete review and registration within two years after promulgation of this Act.

[41] Ibid. Art. 32.

Table 1 Tariff Numbers for GM Material for Food

F01	
Product Classification	Description of Goods
1005.90.00.91-4	Other genetically modified maize(corn)
1005.90.00.92-3	Other non-genetically modified maize(corn)
1103.13.00.10-7	Groats and meal of genetically modified corn (maize)
1103.13.00.20-5	Groats and meal of non-genetically modified corn (maize)
1104.23.00.10-4	Other worked genetically modified maize (corn)
1104.23.00.20-2	Other worked non-genetically modified maize (corn)
1201.90.00.91-6	Other genetically modified soybeans, whether or not broken
1201.90.00.92-5	Other non-genetically modified soybeans, whether or not broken
1208.10.00.10-4	Flours and meals of genetically modified soya beans
1208.10.00.20-2	Flours and meals of non-genetically modified soya beans
F02	
1102.20.00.10-9	Genetically modified maize(corn) flour
1102.20.00.20-7	Non-genetically modified maize(corn) flour

(modified from source: http://www.fda.gov.tw/TC/siteContent.aspx?sid=3958#.V0bsJvl97X4, last visited: 2016/05/26)

Generally speaking, the import control of GM food material can be illustrated in the following flow chart seen next page.

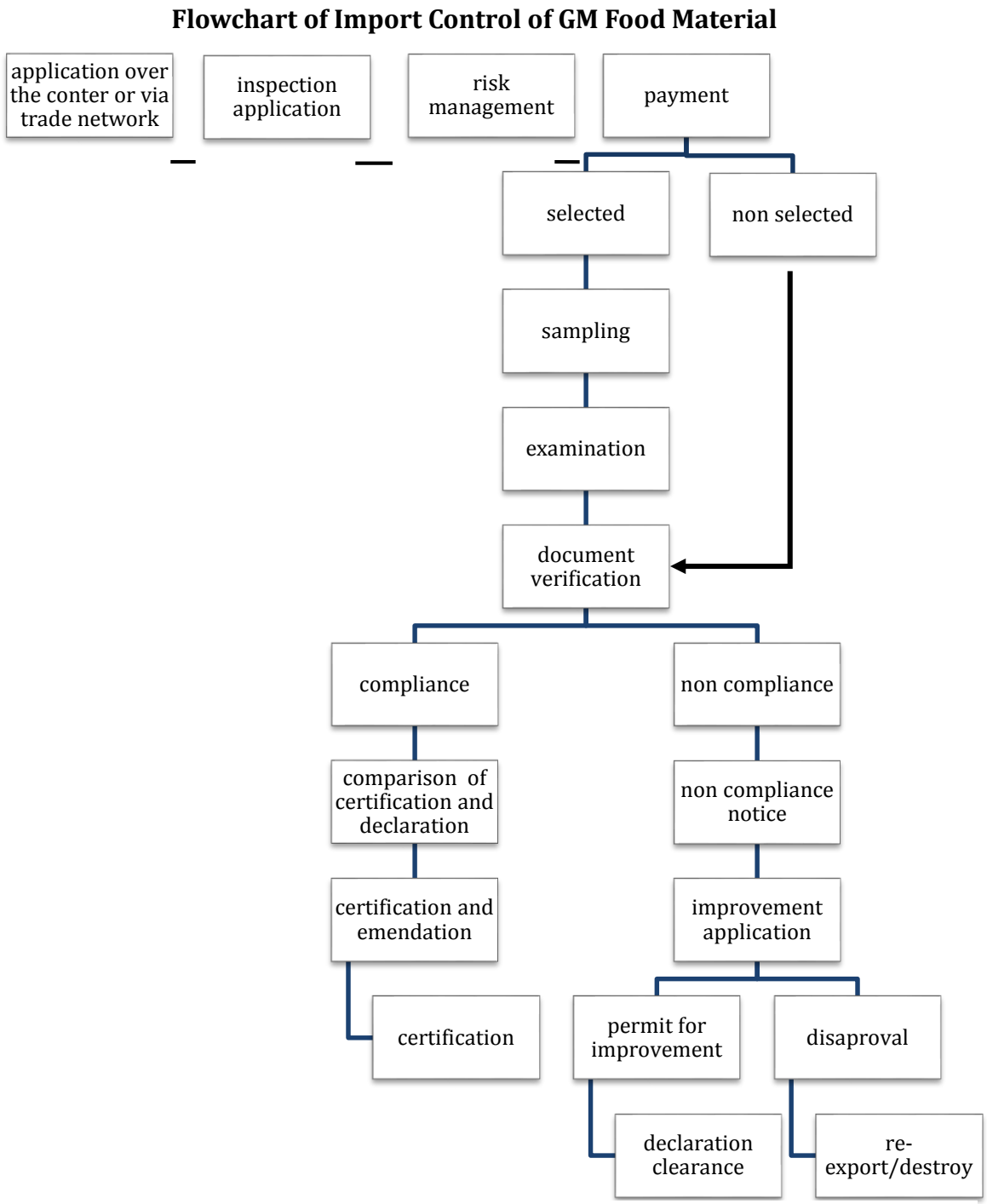
So far, there have been 81 products registered within MHW.[42] Among those, there are 19 products for soybean, 59 for maize, 2 for canola and 1 for cotton. Major companies include Monsanto, Du-Pont, Syngenta and Bayer.[43] Owing to the strict regulation on field trial in Taiwan, so far there is no locally produced GM product that has passed the field trial and approved for sale. Hence no locally produced GM product has been registered.

IV. Conclusion

Taiwan has done certain achievements in modern biotechnology. Especially in the field of agricultural biotechnology, researches in genetically modified organisms, including plants, animals and aquatic plants and animals have born substantial fruits. Taiwan has been enacting Plant Variety and Plant Seed Act since 2005 to regulate transgenic plants. Pursuant to PVPSA, bylaws such as 'Regulations for Approving Import/Export of Transgenic Plant', 'Regulations for the Field Trial of Transgenic Plants' and 'Guidelines on Transgenic Plants Labeling And Packaging' are subsequently made and implemented since. PVPSA and the bylaws altogether interweave a workable regulatory framework on transgenic plants. Moreover, the government also invest resources to help carry out capacity building needed to execute practical work. Similar efforts are also seen in transgenic animals and aquatic plants and animals. For a country with outstanding achievements in transgenic organisms but is still excluded from the international regulatory framework, Taiwan deserve a big applause from the international world. Moreover, the voluntary actions taken with great efforts input by the Taiwanese government apparently is the paradigm for non-contracting members to the *Catagena* Protocol. For that, more international support shall be poured in to help improve the current regulatory framework in Taiwan. Specifically,

[42] For both single product and stacked product.

[43] See https://consumer.fda.gov.tw/Food/GmoInfoEn.aspx?nodeID=300 (last visited: April 2 2015)



Modified from 'Flowchart of Imported Food & Drug Inspection Application, TFDA, (source: http://www.fda.gov.tw/TC/siteContent.aspx?sid=397200) (last visited: 2015/4/2)

scientific liaisons, technology licensing, quarantine measures, information sharing and precautious warning are areas to be enhanced with the international community. Undoubtedly there are still worries for unperceived risks of GMO. Given that the varied GMO border policy in countries, [44] especially those with trade relationships with Taiwan,[45] how to put aside negative feelings towards GMO before coming to the negotiation table to work

[44] W. L. Yang. (2002). The Differences of GMO Regulations under WTO- from the Perspective of SPS. *Science & Technology Law Review*. July 2002.

[45] Y. H. Lai. (2009). Open or Defense? The Policy Choice on Genetically Modified Organisms (GMOs) Regulation. *Public Administration &*

together deserve high priority in the cooperation agenda. After all, even though borderlines can be defined by political jurisdiction, no artificial intervention can define the borderline of global ecological system. If environmental impact, food safety and scientific Frankenstein are really threats to human kind, border control of GMO can only play the role of temporarily securing national security, international consensus and effective regulatory framework shall be the ultimate solution for the long run.

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