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Regulatory Options for Importation of Genome-Edited Foods in Taiwan

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ABSTRACT

With rapid advancement in modern biotechnology, the agro-food industry has been engaged in producing foods derived from genome-editing technology to meet the growing demand for food security and nutrition worldwide. Unlike those traditionally recognized as safe, these “novel foods” bring regulatory challenges to the insurance of food safety and legal issues over consistency with existing framework of food safety governance. Despite the thriving cultivation of genome-edited crops worldwide, Taiwan’s Council of Agriculture (COA) adopted the policy that neither genetic modified nor edited crops are allowed to plant in the field. Therefore, the genome-edited food products in Taiwan, if any, will come most likely from abroad through importation, and the regulatory pressure will fall stressfully on Taiwan’s Food and Drug Administration (TFDA) rather than the COA. Against such background, this paper will examine possible legal challenges for importing genome-edited food products under current food laws, and explore policy options and considerations for regulation of genome-edited foods in Taiwan. This paper argues that Taiwan FDA could adopt a more cautious strategy toward imported genome-edited foods, in contrast to genome-edited crops as currently permitted for plantation in some countries. Moreover, a categorical case-by-case regulatory approach mixed with product-and-process based considerations can be adopted in tandem with early consultation in order to achieve a more balanced

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outcome in accommodating various policy objectives and multiple interests involved in the field of newly advanced genome-editing technology.

Keywords: *Genome-Editing Technology, Genome-Edited Foods, Food Regulation, Food Safety, Import Control, Safety Assessment, GMOs*

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I. INTRODUCTION

With the discovery of the CRISPR/Cas9 genetic scissors, the modern biotechnology gains a huge progress in life sciences such as medicines and agriculture.¹ Despite the controversy over the creation of genome-edited twins by a Chinese researcher,² the advance in modern biotechnology has prompted the agro-food industry to engage expansively in producing foods derived from genome-editing technology to meet the growing demand for food security and nutrition worldwide.³ Unlike those foods traditionally recognized as safe, these “novel foods” bring regulatory challenges to the insurance of food safety.⁴ However, under current genetic laws in Taiwan, neither genetic modified nor edited crops/animals are allowed to plant or breed in the fields according to the agricultural policy proclaimed by the Council of Agriculture (COA).⁵ Therefore, the genome-edited foods, if any, will come most likely from abroad through importation, and the pressure to regulate genome-edited foods will fall on the Taiwan Food and Drug Administration (TFDA) rather than the COA in Taiwan. Against such background, this paper will examine possible legal challenges for importing genome-edited food products under current laws governing food safety, and explore policy options and considerations for regulation of genome-edited foods in Taiwan.

With a brief description of different types of genome-editing technology such as clustered regularly interspaced short palindromic repeats (CRISPR), zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and oligonucleotide-directed mutagenesis (ODM), this paper will survey current regulatory status of genome-edited foods or crops in selected

1. The Royal Swedish Academy of Sciences has decided to award the Nobel Prize in Chemistry 2020 to Emmanuelle Charpentier and Jennifer A. Doudna for the development of a method for genome editing, the CRISPR/Cas9 genetic scissors. This technique can change the DNA of animals, plants and microorganisms with extremely high precision and has a revolutionary impact on the life sciences. See The Nobel Prize, *Press Release: The Nobel Prize in Chemistry 2020* (Oct. 7, 2020), <https://www.nobelprize.org/prizes/chemistry/2020/press-release/>.

2. See Dennis Normile, *CRISPR bombshell: Chinese researcher claims to have created gene-edited twins* (Science, Nov. 26, 2018), <https://www.science.org/content/article/crispr-bombshell-chinese-researcher-claims-have-created-gene-edited-twins>.

3. Y. Zhang, K. Massel, I. D. Godwin et al., *Applications and Potential of Genome Editing in Crop improvement*, 19 *GENOME BIOL.* 1, 1-11 (2018).

4. Julia Jansing et al., *Genome Editing in Agriculture: Technical and Practical Considerations*, 20 *INT. J. MOL. SCI.* (2019), <https://www.mdpi.com/1422-0067/20/12/2888/htm>.

5. Council of Agriculture of Taiwan had posted a news release stating that “Taiwan has neither approved nor promoted the growing of genetically modified crops thus far”. See Council of Agriculture, Taiwan, *Taiwan’s Agricultural Genetic Modification Technology Development Follows the “Active R&D and Efficient Management” Policy. GM Crops have not yet been Approved for Growing in Taiwan* (Feb. 9, 2015), https://eng.coa.gov.tw/theme_data.php?theme=eng_news&id=409.

major countries such as United States,⁶ European Union,⁷ Canada,⁸ Australia,⁹ New Zealand¹⁰ and Argentina,¹¹ and summarize different regulatory approaches toward genome-edited foods and/or crops, ranging from product-based to process-based approaches. In search of appropriate regulatory approach for Taiwan, this paper will evaluate multiple policy objectives such as scientific innovation, development of agro-food industry and consumer safety for food consumption. Potential conflicting interests will also be identified particularly for those involved with different stakeholders including scientists, agro-food industry, food importers, consumers and regulators.

Therefore, this paper will in the beginning of Part II briefly describe the meaning of genome-editing technology together with different types of such techniques, and survey current regulatory status of genome-edited foods or crops in selected major countries with a summarized landscape of different regulatory approaches toward genome-edited foods and/or crops, ranging from product-based to process-based approaches. In Part III, this paper introduces the preliminary debate over the possibility of regulating genome-edited foods in Taiwan, and discuss various policy options for the adoption of appropriate genome-edited food regulations in Taiwan. To assess these policy options, this paper identifies potential legal issues, relevant public interest considerations and recent development of international standards regarding gene-editing in Part IV. Finally, Part V concludes.

This paper argues that Taiwan FDA should adopt a more cautious strategy to regulate imported genome-edited foods, in contrast to genome-edited crops as currently permitted for plantation in some countries. Moreover, a categorical case-by-case regulatory approach mixed with product-and-process based considerations can be adopted in tandem with early consultation in order to achieve a more balanced outcome in accommodating various policy objectives and multiple interests involved in the field of newly advanced and rapid growing genome-editing technology.

6. See generally Sally L. McCammon & Mike Mendelsohn, *Innovation and the Regulation of Products of Agricultural Biotechnology in the United States of America*, 28 TRANSGENIC RES. 183, 183-86 (2019).

7. See generally, Chantal Bruetschy, *The EU Regulatory Framework on Genetically Modified Organisms (GMOs)*, 28 TRANSGENIC RES. 169 (2019).

8. See generally, Kenneth W. Ellens et al., *Canadian Regulatory Aspects of Gene Editing Technologies*, 28 TRANSGENIC RES. 165 (2019).

9. See generally Lisa Kelly, *Clarifying the Regulation of Genome Editing in Australia: Situation for Food*, 28 TRANSGENIC RES. 161 (2019).

10. See Steffi Fritsche, Charleson Poovaiah, Elspeth MacRae & Glenn Thorlby, *A New Zealand Perspective on the Application and Regulation of Gene Editing*, 9 FRONT. PLANT SCI. 1, 1-8 (2018).

11. See generally, Martin Alfredo Lema, *Regulatory Aspects of Gene Editing in Argentina*, 28 TRANSGENIC RES. 147 (2019).

II. GLOBAL LANDSCAPE OF GENE-EDITING REGULATIONS

A. *Technical Aspects of Gene-Editing: A Brief Overview*

Unlike traditional technique of “genetic modification” which involves the introduction of sequences that are foreign to the organisms’ gene pool, genome-editing technology creates additional genetic variation within an existing gene pool in a very precise and directed manner.¹² The genome-editing technique is different from traditional breeding techniques such as chemical mutagenesis, which results in entirely random mutations. Generally speaking, gene editing refers to “a set of novel techniques for manipulating the genome that can achieve much greater precision than pre-existing forms of genetic engineering”.¹³ Specifically, such techniques use “site-specific nucleases” or “site-directed nucleases (SDN)” where engineering of the nuclease allows for highly specific targeting to any given gene of interest.

These techniques include engineered mega-nucleases (EMNs), zinc-finger nucleases (ZFNs), transcriptional activator-like effector nucleases (TALENs), and clustered regularly interspaced short palindromic repeats (CRISPR) in conjunction with the associated Cas9 endonuclease (CRISPR/CAS9).¹⁴ In addition, earlier technique involved oligonucleotide directed mutagenesis (ODM) to cause site-specific gene targeting using chemically synthesized oligonucleotides with base replacement or addition caused by endogenous DNA-repair enzymes.¹⁵ Unlike SDN, ODM does not deliver a nuclease to the site of action.

B. *Regulatory Status of Gene-Edited Organisms in Selected Countries*

Despite widely discussed by regulators and the scientific community, the rules have not yet been fully harmonized on the regulatory status of genome-edited crops. The common understanding shows that the level of regulatory scrutiny on genome-edited crops will be determined by the nature of the DNA-repair process used, the characteristic and intended use of the phenotype that is developed, and the existing regulatory stricture within the

12. Rene Custers, *The Regulatory Status of Gene-edited Agricultural Products in the EU and Beyond*, 1 EMER. TOP. LIFE SCI. 221, 221 (2017).

13. Anu Shukla-Jones, Steffi Friedrichs & David E. Winickoff, *Gene Editing in an International Context: Scientific, Economic and Social Issues Across Sectors*, OECD Science, Technology and Industry Working Papers, 2018/04, p. 8, OECD Publishing, Paris.

14. Jeffrey D. Wolt, Kan Wang & Bing Yang, *The Regulatory Status of Genome-edited Crops*, 14 PLANT BIOTECH. J. 510, 510 (2016).

15. See Maria Lusser, Claudia Parisi, Damien Plan & Emilio Rodríguez-Cerezo, *Deployment of New Biotechnology in Plant Breeding*, 30 NATURE BIOTECHNOLOGY 231, 232 (2012).

geopolitical region of release.¹⁶ In other words, the regulatory scheme varies among countries and differs in terms of the degree of scrutiny depending on different types of SDN technique used in producing a crop. There are roughly three aspects of regulatory approaches, namely the GMOs equivalence, categorical case-by-case and early consultation procedures in which the third approach is not mutually exclusive to the first two. States can adopt one of the first two approaches and also conduct an early consultation process.

1. *Treated as GMOs*

The most stringent approach towards gene-edited foods or crops is to treat them as the “genetically modified organisms” (GMOs) and subject them to a full-fledged GMO regulation. The European Union adopted such a process-based approach since the European Court of Justice (ECJ) ruled that organisms derived from gene-editing shall be regulated as GMOs in 2018.¹⁷

The EU has a long history of the governance of GMOs and its legislation on genetic engineering is laid down in various legal acts. In 1990, the first Directive on GMOs was promulgated¹⁸ and later replaced by the 2001 Directive¹⁹ together with an amendment to the 2001 Directive in 2015.²⁰ Moreover, the EU adopted Regulation (EC) No 1829/2003 on genetically modified food and feed providing rules on environmental risk assessment, safety assessment, as well as tracing, labelling and monitoring requirements.²¹ In addition, the EU established a comprehensive regulatory framework on the transboundary movement of GMOs²² and the traceability

16. See Wolt et al., *supra* note 14, at 513.

17. See Eva Gelinsky & Angelika Hilbeck, *European Court of Justice Ruling Regarding New Genetic Engineering Methods Scientifically Justified: A Commentary on the Biased Reporting about the Recent Ruling*, 30 ENVIRON SCI EUR 52 (2018).

18. Council Directive 90/220/EEC, of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, 1990 O.J. (L 117), 15-27 (Establishing the definition of a GMO and a legal framework for the development of the biotechnology).

19. Directive 2001/18/EC, of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 O.J. (L 106,) 1, 1-39 (Strictly regulating the process of developing organisms altered through genetic modification and prescribing environmental risk assessment as well as traceability, labelling and monitoring obligations).

20. Directive 2015/412, of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory Text with EEA relevance, 2015 O.J. (L 68), 1-8 (EU) (allowing member states to restrict or prohibit the cultivation of GMOs in their territory without requiring new scientific evidence).

21. Commission Regulation 1829/2003, of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

22. Commission Regulation 1946/2003, of the European Parliament and of the Council on transboundary movements of genetically modified organisms, 2003 O.J. (L 287), 1-10 (establishing a common system of notification and information for transboundary movements of GMOs).

and labelling of GMOs²³ as well as the contained use of genetically modified micro-organisms²⁴ and the agricultural plant varieties.²⁵ Despite so, the threshold debate is whether the organisms derived from gene-editing technology fall under the definition of GMOs so that the full-fledged GMO laws apply to the genome-edited foods or crops.

This issue hasn't clearly addressed under the EU's legal framework on GMOs until the ECJ delivered a judgment in 2018.²⁶ The ECJ's decision was made in response to a request of the Council of State of France for a preliminary ruling regarding the regulatory status of an organism obtained by means of techniques of mutagenesis under Directive 2001/18/EC and Regulation (EC) No 1829/2003.²⁷ While four specific issues were asked by the Council of State,²⁸ the main controversy lied at different interpretations on the elements of the GMO definition under the Directive as well as its

23. Commission Regulation 1831/2003, of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, 2003 O.J. (L 268), 24-28 (providing a framework for the traceability of products consisting of or containing GMOs, facilitating accurate labelling, monitoring the effects on the environment and health, and implementing appropriate risk management measures).

24. Directive 2009/41/EC, of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance), 2009 O.J. (L 125), 75-97 (providing common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment).

25. Council Directive 2002/53/EC, of 13 June 2002 on the common catalogue of varieties of agricultural plant species, 2002 O.J. (L 193), 1-11 (providing the common catalogue of varieties of agricultural plant species).

26. See Case C-528/16, *Confédération paysanne and Others v. Premier ministre and Ministre de l'agriculture, de l'Agroalimentaire et de la Forêt*, Judgment of the Court (Grand Chamber) (July 25, 2018), <http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-528/16#>.

27. The background of this case originated from a dispute in French court. Back in March 2015, a French agricultural union and eight associations asked the Council of State of France to annul the implied decision of the Prime Minister refusing their request to revoke Article D. 531-2 of the Environmental Code which excludes mutagenesis from the definition of GMOs, to ban the cultivation and marketing of herbicide-tolerant rape varieties obtained by mutagenesis, and to order the Prime Minister to take all steps to introduce a moratorium on herbicide-tolerant plant varieties obtained by mutagenesis. See *Confédération paysanne and Others*, *id.* at para. 20.

28. These four questions are: (1) Do organisms obtained by mutagenesis constitute GMOs within the meaning of Article 2 of the 2001 Directive, although they are exempt under Article 3 of and Annex I B to the Directive from the obligations? (2) Do varieties obtained by mutagenesis constitute genetically modified varieties within the meaning of Article 4 of Directive 2002/53 which would not be exempt from the obligations laid down in that directive? (3) Does the 2001 Directive constitute a full harmonization measure prohibiting Member States from subjecting organisms obtained by mutagenesis to the obligations laid down in the directive, or do the Member States have discretions to define the regime to be applied to organisms obtained by mutagenesis? (4) May the validity of the Directive [2001/18] with regard to the precautionary principle guaranteed by Article 191(2) of the Treaty on the Functioning of the European Union, be called into question, taking account of the development of genetic engineering processes, the appearance of new plant varieties obtained by means of those techniques and the current scientific uncertainty as to their impacts and the potential risks they represent for the environment and human and animal health? See *Confédération paysanne and Others*, *id.* at para. 25.

Annexes.²⁹

As mentioned, the 2001 Directive regulates the deliberate release into the environment of GMOs and their placing on the market within the Union. For those organisms covered by the Directive, they must be authorized after an environmental risk assessment and also subject to traceability, labelling and monitoring obligations. Despite so, Article 3(1) of the Directive,³⁰ read in conjunction with Annex I B,³¹ provides that the 2001 Directive shall not apply to organisms obtained through certain techniques of genetic modification, such as mutagenesis. The rationale of such mutagenesis exemption could be method used that is distinct from genetically modified one. While mutagenesis involves an alternation of the genome of a living species, it does not, in principle, entail the insertion of foreign DNA into a living organism. However, the techniques of mutagenesis have evolved over time and the applicants in original proceedings consider that some of the most recently developed techniques present risks for health and the environment.³² Therefore, they brought judicial proceedings before the Council of State, seeking the annulment of a national provision that exempts organisms obtained by mutagenesis from the obligations applying to GMOs. It is under this background that the ECJ is requested to clarify the exact scope of the Directive, more specifically the ambit, rationale and effects of the mutagenesis exemption.

Before the final judgment, the Advocate General Bobek delivered an opinion on above issues in January 2018.³³ He took a stand more inclined to

29. The definition of GMO is provided under Article 2(2) of the Directive, which means “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination”. Within the definition, the use of the techniques listed in Annex I A, part 1 are deemed to be genetically modified, namely, (1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules . . . (2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism, . . . (3) cell fusion (including protoplast fusion) or hybridisation techniques. However, the techniques listed in Annex I A, part 2, are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B, namely, (1) in vitro fertilization, (2) natural processes such as: conjugation, transduction, transformation, (3) polyploidy induction.

30. Article 3(1) provides: “This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.”

31. Annex I B to Directive 2001/18, under the heading “Techniques referred to in Article 3”, provides: “Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are: (1) mutagenesis . . .”

32. These applicants in original proceedings are the associations mainly concern with the protection of the environment and the dissemination of information on the dangers of GMOs including Confédération paysanne, Réseau Semences Paysannes, Les Amis de la Terre France, Collectif Vigilance OGM et Pesticides 16, Vigilance OG2M, CSFV 49, OGM dangers, Vigilance OGM 33, Fédération Nature et Progrès.

33. Case C-528/16, Opinion of Advocate General Michael Bobek delivered on 18 January 2018,

support French government's decision to exempt mutagenesis from subjecting to the GMO Directive. According to his opinion, an organism obtained by mutagenesis can be a GMO under Article 2(2) of the Directive if it fulfils the substantive criteria laid down in that provision.³⁴ Whereas for the exemption of the use of mutagenesis, he considered the term should logically encompass all those techniques either at the time the Directive promulgated (e.g. traditional breeding) or at the moment for the case in question as any new techniques might be developed such as targeted or directed mutagenesis techniques. Therefore, the exemption laid down in Article 3(1) of Directive read in conjunction with its Annex I B covers all organisms obtained by any technique of mutagenesis, irrespective of their use at the date of the adoption of that directive, on the condition that they do not involve the use of recombinant nucleic acid molecules. . . .³⁵ However, he concludes with regard to the understanding of the mutagenesis exemption that the EU legislations did not prevent its Member States from adopting measure to regulate organisms obtained through mutagenesis provided that they respect the overall obligations under EU laws.³⁶

Contrary to Bobek's opinion, the ECJ's final ruling adopted a process-based approach in favor of the applicants' position to exclude the mutagenesis with newly developed targeted or directed techniques from the scope of mutagenesis exemption. While the Court shared the same interpretation with Advocate General Bobek that organisms obtained by means of techniques of mutagenesis constitute GMOs within the meaning of Article 2(2) of the 2001 Directive,³⁷ it held a different view on the interpretation of the mutagenesis exemption provision. Relying on recital 17 of the Directive,³⁸ the Court held that the exemption for organisms obtained from mutagenesis only applies to organisms obtained by techniques of mutagenesis which have conventionally been used in a number of applications and have a long safety record.³⁹ Given that the risks associated with techniques of directed mutagenesis have not thus far been established with certainty,⁴⁰ the Court decided that organisms modified with targeted

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=198532&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=135991>.

34. *See id.* at para. 64 (further stating that the fact that that organism might later be exempted by virtue of Article 3(1) of the GMO Directive read in conjunction with its Annex I B has no impact on the legal characterization as a GMO: such organisms remain GMOs under the directive).

35. *See id.* at para. 107.

36. *See id.* at para. 124.

37. *See Confédération paysanne and Others, supra* note 26, at para. 38.

38. Recital 17 provides that "This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record."

39. *See Confédération paysanne and Others, supra* note 26 at para. 45.

40. *See id.* at para. 47.

mutagenesis techniques based on genome editing are not exempted from applying to the 2001 Directive.⁴¹

2. *Categorical Case-by-Case*

Unlike the EU, most countries adopt a categorical case-by-case approach to regulate organisms derived from gene-editing technology such as the US, Canada, Australia, New Zealand and Argentina.

In the United States, there is no single underlying legislation to regulate GMOs. Instead, the existing authority has been shared by three different federal agencies, namely, the United States Department of Agriculture (USDA), Food and Drug Administration (FDA), and Environmental Protection Agency (EPA), each with separate regulations for food, plant pests and pesticides derived from GMOs.⁴² Such coordinated framework for the regulation of biotechnology has evolved with several updated amendments since 1986.⁴³

In 2017, the White House Office of Science and Technology Policy (OSTP) issued the latest update to the Coordinated Framework for the Regulation of Biotechnology, which clarified the current roles and responsibilities of and coordination among FDA, EPA, and the USDA.⁴⁴ Among others, it recommended that relevant agencies should consider clarifying that “genetic engineering” also encompasses genome editing.⁴⁵ Later in 2019, the President signed an executive order directing the USDA, FDA and EPA to exempt low-risk products from regulation and to create a unified platform that clearly outlines all regulatory requirements for approval

41. *See id.* at para. 51 (in addition, the Court refers to Recital 8 and states that its finding is in accordance with the precautionary principle aiming to protect human health and the environment).

42. *See* OFFICE OF SCI. & TECH. POL’Y (O.S.T.P.), Coordinated Framework for the Regulation of Biotechnology (1986) (announcing the policy of the federal agencies involved with the review of biotechnology research and products), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

43. In 2015, the Executive Office of the President sent a memorandum on modernizing the regulatory system for biotechnology products to the heads of the FDA, EPA and USDA on July 2, 2015 directing them to update the Coordinated Framework for the Regulation of Biotechnology. *See Memorandum on Modernizing the Regulatory System for Biotechnology Products* (July 2, 2015), https://www.epa.gov/sites/production/files/2016-12/documents/modernizing_the_reg_system_for_biotech_products_memo_final.pdf. In 2016, the White House Office of Science and Technology Policy (OSTP) issued the National Strategy for Modernizing the Regulatory System for Biotechnology Products, aiming to develop a long-term strategy to ensure that the Federal regulatory system is equipped to efficiently assess the risks, if any, of the future products of biotechnology. *See* O.S.T.P., *National Strategy for Modernizing the Regulatory System for Biotechnology Products*, Product of the Emerging Technologies Interagency Policy Coordination Committee’s Biotechnology Working Group, (Sept., 2016), <https://www.fda.gov/media/102667/download>.

44. *See* O.S.T.P., *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology* (Jan. 4, 2017), <https://www.fda.gov/media/102658/download>.

45. *See* O.S.T.P., *id.* at 55.

of products developed with biotechnology.⁴⁶

Followed by the 2018 policy statement declared by the Secretary of Agriculture Sonny Perdue,⁴⁷ the USDA's Animal and Plant Health Inspection Service (APHIS) finalized its new biotechnology regulation, Movement of Certain Genetically Engineered Organisms (also called the SECURE Biotechnology Regulations)⁴⁸ in 2020, which would exempt gene-edited plants that otherwise could have been developed through conventional breeding under existing GMO regulations.⁴⁹ Specifically, the SECURE Regulations apply to those organisms modified or produced through genetic engineering⁵⁰ but exempt three types of organisms from subjecting to the Regulations:⁵¹ (a) plants that have been modified such that they contain either a single modification of a type listed in this Regulations⁵² or additional modifications as determined by the Administrator;⁵³ (b) a plant with plant-trait-mechanism of action combination that has been analyzed and determined by APHIS not to regulate or to maintain non-regulated status retained prior to August 17, 2020; (c) plants determined by APHIS not to require regulation under this part pursuant to the "Am I Regulated" process.

It should be noted that except for the USDA having prescribed above rules for gene-edited products, the FDA and EPA have not announced if their existing policies and regulations related to GMOs would be used to regulate gene-edited crops and food.

In Canada, the Canadian Food Inspection Agency (CFIA) and Health Canada are the competent authorities in charge of regulating gene-edited

46. See Exe. Order No 13874, 84 F.R. 115, *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* (June 11, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-06-14/pdf/2019-12802.pdf>.

47. See U.S. DEP'T. OF AGRIC. Press Release No. 0070.18, *Secretary Perdue Issues USDA Statement on Plant Breeding Innovation* (Mar. 28, 2018), <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>.

48. The proposed and final rule is referred to as the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule. The SECURE rule is the nomenclature used by USDA to discuss the rule with stakeholders.

49. APHIS, Final Rule, Movement of Certain Genetically Engineered Organisms, 7 C.F.R. Parts 330, 340, and 372 (U.S.D.A. Aug. 17, 2020) (Sections 340.4 and 340.5 are applicable beginning Apr. 5, 2021), <https://www.regulations.gov/document/APHIS-2018-0034-6192>.

50. The scope of the Regulations is prescribed in Section 340.2.

51. See 7 C.F.R. § 340.1 (a).

52. The listed types of modification include either of the following: (1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or (2) The genetic modification is a targeted single base pair substitution; or (3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool. See 7 C.F.R. § 340.1(b)(1)-(3).

53. The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated or in response to a request made by any person. See 7 C.F.R. § 340.1(b)(4).

crops and food.⁵⁴ Canada adopted an outcome-based approach to regulate gene-edited products through three different laws and its corresponding regulations, namely Feeds Act, Food and Drugs Act and Seeds Act.⁵⁵ In other words, Canada regulates any feed, food and plants that contain novel traits regardless of the process or method used to develop the product. Even if a product is developed by means of conventional breeding, let alone mutagenesis, transgenesis or gene editing, the product is subjected to the regulation so long as it contains a novel trait. Despite so, the CFIA evaluates products on a case-by-case basis to decide whether they contain novel traits, and if so, requires environmental and safety assessments for them to be approved for marketing. The CFIA does not require a pre-market assessment for products that do not contain a novel trait.⁵⁶

In Australia, the governance of GMOs began with the enactment of Gene Technology Act in 2000 and its corresponding Gene Technology Regulations promulgated in 2001.⁵⁷ In 2019, the Gene Technology Regulator⁵⁸ conducted a technical review of the Gene Technology Regulations 2001 to clarify the regulatory status of organisms developed using a range of new technologies and ensure that the new technologies are regulated in a manner commensurate with the risks they pose.⁵⁹ The 2001 Regulations were amended in 2019 to the existing definitions of the GMO in order to better address new techniques such as gene-editing. Accordingly, the 2019 Amendment does not regulate the use of gene-editing techniques in plants, animals and human cell lines that do not introduce new genetic materials. In other words, the SDN-1 type of genome editing technique is beyond the scope of GMO regulation.⁶⁰ In New Zealand, the Hazardous Substances and New Organisms Act 1996, administered by the Ministry for the Environment, regulate the creation and release of non-native organisms (including GMOs) into New Zealand.⁶¹

54. The CFIA is responsible for the regulation of the environmental release of plants with novel traits, and novel livestock feeds, and Health Canada is responsible for the regulation of novel foods.

55. Feeds Act, R.S.C. 1985, c. F-9; Food and Drugs Act, R.S.C. 1985, c. F-27; Seeds Act, R.S.C. 1985, c. S-8.

56. See Ellens et al., *supra* note 8, at 166.

57. *Gene Technology Act 2000*, No. 169, 2000 (Austl.), <https://www.legislation.gov.au/Details/C2016C00792>. *Gene Technology Regulations 2001* (Austl.), <https://www.legislation.gov.au/Details/F2016C00615> (defining gene technology as any technique for the modification of genes or other genetic material . . . and aiming to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.)

58. The Office of Gene Technology Regulator (“OGTR”) under the Department of Health is the authority in charge of GMO governance.

59. See OGTR, Technical Review of the Gene Technology Regulations 2001, <https://www.legislation.gov.au/Details/F2019L00573>.

60. See Smriti Mallapaty, *Australian gene-editing rules adopt ‘middle ground’* (Nature News Apr. 23, 2019), <https://www.nature.com/articles/d41586-019-01282-8>.

61. Hazardous Substances and New Organisms Act 1996 (N.Z.).

As for food regulation, Australia and New Zealand established a joint system of Food Standards Australia New Zealand (FSANZ)⁶² in 1991, and developed Australia New Zealand Food Standards Code in which Standard 1.5.2 provides standards for “food produced using gene technology” setting pre-market regulations and labeling standards.⁶³ In December 2019, FSANZ released its Final Report, concluding its review of how the Food Standards Code should apply to food derived using New Breeding Techniques (NBTs).⁶⁴ The Report offered three recommendations on how NBTs should be regulated and subject to pre-market approval: (1) revise and modernize the definitions in the Code to better accommodate existing and emerging biotechnologies; (2) give consideration to process and non-process based definitions and the need to ensure that NBT foods are regulated in a manner that is commensurate with the risk they pose; and (3) ensure open communication and active engagement with all interest parties and raise public awareness about GM and NBT foods.⁶⁵

As for Argentina, it is one of the first countries establishing a regulatory framework with specific working regulation for products derived from New Breeding Techniques (NBTs).⁶⁶ In 2015, the Argentina Ministry of Agriculture, Livestock and Fisheries, promulgated Resolution 173/2015⁶⁷ setting a mechanism for a case-by-case assessment to determine if a product or crop submitted to the National Advisory Committee on Agricultural Biotechnology (CONABIA) will be regulated as GMOs in light of the concept of “novel combination of genetic material”.⁶⁸ If no external gene is inserted in the product, the gene-edited crops will not be subject to GMO regulations.

<https://legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html#DLM382982> (last visited July 20, 2021).

62. Food Standards Australia New Zealand (“FSANZ”) is an independent statutory agency established by the Food Standards Australia New Zealand Act 1991 (“FSANZ Act”). FSANZ is part of the Australian Government’s Health portfolio, <https://www.foodstandards.gov.au/about/Pages/default.aspx>.

63. FSANZ Act, Standard 1.5.2, Food produced using gene technology, <https://www.foodstandards.gov.au/code/Documents/1.5.2%20GM%20foods%20v157.pdf> (last visited July 22, 2021).

64. See FSANZ, *Final Report, Review of Food Derived Using New Breeding Techniques 5* (2019), <https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBT%20Final%20report.pdf>.

65. See *id.* at 7.

66. See Global Agriculture Information Network Report (“GAIN Report”), *Argentina-Annual Biotechnology Report 2* (2016), https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Agricultural%20Biotechnology%20Annual_Buenos%20Aires_Argentina_12-27-2016.pdf.

67. Ministerio de Agricultura, Ganadería y Pesca [Ministry of Agriculture, Livestock and Fisheries], Resolución 173/2015 [Resolution 173/2015], Bs. As., 12/5/2015, <http://servicios.infoleg.gob.ar/infolegInternet/anexos/245000-249999/246978/norma.htm>.

68. See GAIN Report, *supra* note 66, at 2.

3. *Early Consultation Procedures*

Given the new and emerging nature of gene engineering technology, the categorical case-by-case approach is commonly adopted in tandem with an early consultation mechanism to regulate foods or crops derived from gene-edited techniques. Such a coordinated procedure provides a more predictable guidance for developers and a more comprehensive information and regulatory oversight for the regulators.

To ensure the compliance with food laws and regulations, the FDA implements the Plant Biotechnology Consultation Program and Early Food Safety Evaluation Program (New Protein Consultations) to work with developers of new plant varieties intended for use in human and animal foods to help ensure that their products are safe and lawful prior to marketing.⁶⁹ Despite being a voluntary program, food developers routinely participate in such program to seek the agency's guidance on the safety and regulatory issues involved in the products. Moreover, the FDA can be better informed the newly developed technology, and conduct the safety assessment of the product derived from such techniques. This program is also available for foods derived from genome-edited plant varieties. In February 2019, FDA completed its first consultation on a genome edited plant variety, a soybean variety modified to have increased levels of a fatty acid called oleic acid.⁷⁰

As for the crops, certain categories of modified plants are exempted from GMO regulations under the revised SECURE Regulations because they could have been developed through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. The APHIS provides a confirmation request process allowing developers to request a confirmation from APHIS that a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR 340.⁷¹ The APHIS will provide a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request, and will post both the confirmation requests and the issued confirmation letters on its website.⁷²

Unlike the US, Argentina adopts a mandatory mechanism for an early

69. See USFDA, *Consultation Programs on Food from New Plant Varieties* (2020), <https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties>.

70. *Id.*

71. USDA-APHIS & Biotechnology Regulatory Services, *Guidance for Submission of Confirmation Request* (U.S.D.A. 2020), <https://www.aphis.usda.gov/brs/pdf/requesting-confirmation-of-exemption.pdf>.

72. See APHIS, *Confirmation Request Process* (U.S.D.A. 2021), <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmation-s/confirmation-process>.

consultation. Under Resolution 173/2015, Argentina establishes a procedure to determine when a crop, obtained from new breeding techniques that use modern biotechnology techniques, is subject to the GMO regulation (Resolution No. 763/11). To this end, the interest party must submit a “prior consultation instance” in which provides information on the improvement methodology used to obtain and select the crop, on the new trait or characteristic introduced, and evidence of the genetic changes present in the final product, and requests the CONABIA to confirm whether the result of the improvement process constitutes a new combination of genetic material.⁷³ The procedure will carry out for a 60-day period and the applicant will receive a reply from Ministry of Agriculture, Livestock and Fisheries upon the recommendation made by CONBIA stating if the product described falls under the GMO regulation or not.⁷⁴ In case where the project to obtain crops derived from new improvement techniques that are still in the design stage, the interested party may carry out a preliminary consultation with the sole purpose of anticipating whether the hypothetical expected product would be reached by the aforementioned Resolution No. 763/11 and its complementary regulations.⁷⁵

The regulatory approaches adopted by selected countries can be summarized as Figure 1.

Figure 1: Regulatory approaches adopted by selected countries

Regulatory approach	Countries
Treated as GMOs	European Union
Categorical case-by-case	United States (Department of Agriculture) Canada Australia & New Zealand Argentina
Early consultation procedures	Argentina United States (Food and Drug Administration)

To sum up, most countries adopted a case-by-case approach while some treated certain types of genome-editing techniques as non-GMOs, beyond the scope of regulatory review. Depending on the methods used to generate a double strand break (DSB) at a specific location in the genome, the SDN contains three approaches to repair the DSB, namely SDN-1 through random mutation involving non-homologous end-joining (NHEJ) with gain or loss of base pairs, SDN-2 through homologous recombination (HR) involving one

73. See Resolution 173/2015, *supra* note 67, Article 2.

74. See *id.* Article 4 and 5.

75. See *id.* Article 7.

or very few nucleotides, and SDN-3 involving site-directed transgene insertion.⁷⁶ Current uses of ODM are analogous to SDN-1 in terms of regulatory scrutiny.⁷⁷ The regulatory approaches can be sorted in accordance with different gene-editing techniques as Figure 2.

Figure 2: Categorical case-by-case approach sorted by genome-editing methods

Genome-editing technique	Regulatory approaches
SDN-1 & ODM	Non-GMOs (Unregulated): USDA (FDA not yet decided), Australia & New Zealand Case-by-case: Canada
SDN-2	Case-by-case: USDA, Canada, Argentina Non-GMOs: Australia & New Zealand
SDN-3	GMOs: USDA, Australia & New Zealand, Argentina Case-by-case: Canada

III. REGULATORY OPTIONS FOR IMPORTATION OF GENOME-EDITED FOODS IN TAIWAN

As a number of newly emerged biotechnologies have rapidly developed and used by many countries in recent years, Taiwan Food and Drug Administration (TFDA) considered introducing regulations on foods derived from genome-edited crops. Given the genome-edited crops have been legally permitted in some countries such as US and Argentina, it becomes more likely to have imported foods being produced by using genome-edited crops as ingredients. As a Member of the World Trade Organization (WTO), Taiwan will inevitably face a regulatory challenge on how to regulate those

76. The site-directed nuclease technology can be divided into three categories according to whether the template sequence is delivered and whether it is finally embedded in the host chromosome: (1) The first type of site-directed nuclease (SDN-1) is a nuclease that recognizes a specific position and produces a DNA double-stranded break, initiating cell non-homologous end joining (NHEJ) repair mechanism, and resulting in one or a few bases to be cut or inserted, which silences genes or changes gene performance; (2) The second type of site-directed nuclease (SDN-2) is a nuclease that recognizes a specific position to produce a DNA double-stranded break, and at the same time sends a DNA fragment as a template. This DNA template is similar to the target gene sequence with only a few base differences. It uses cell homologous recombination (homology directed repair, HDR) repair mechanism, where specific positions and specific bases are replaced; (3) The third type of site-directed nuclease (SDN-3) is a nuclease that recognizes a specific position and produces DNA double-stranded breaks. A DNA fragment is used as a template. The front and back ends of this DNA template are similar to the target gene sequence, and the middle contains the sequence of the exogenous gene. The cell HDR repair mechanism is used to insert a specific exogenous gene at a specific location. See EFSA Panel on Genetically Modified Organisms (GMO), *Scientific Opinion Addressing the Safety Assessment of Plants Developed Using Zinc Finger Nuclease 3 and Other Site-Directed Nucleases with Similar Function*, 10 EFSA JOURNAL 1, 6-14 (2012).

77. See Wolt et al., *supra* note 14, at 514.

cross-border trades in food products using the genome-edited technology. On one hand, the TFDA should comply with international trade rules to streamline the cross-border trade in food products without imposing unnecessary regulatory obstacles to international trade. On the other hand, the TFDA should ensure the safety of imported food products when a novel genome-editing technology is used in the course of production.

To this end, the TFDA commissioned Food Industry Research and Development Institute to conduct a research project in exploring possible approaches to regulate genome-edited foods for a reference of policy-making in 2018.⁷⁸ In the course of consultation and discussion with experts in relevant fields, the experts group discussed the pros and cons of different policy options and debated over the need for such regulations. With the view to summarize the opinions and arguments exchanged between the experts during the discussion, this paper first discusses the initial debates over the timing of introducing such new regulations, and then examines the pros and cons of possible regulatory options for a new genome-editing regulation on foods.

A. Initial Debates Over the Timing and Necessity for a New Regulation

Before assessing possible regulatory approaches, the debate started with the timing and necessity for introducing the genome-editing regulation of food products mainly imported from foreign countries in which the genome-edited crops are allowed to be planted. More specifically, whether it is a good timing to establish rules or regulations on genome-edited foods in Taiwan? Do we need such regulations at current stage of technological development? Basically, there are two contrasting views discussed as follows together with its arguments for or against the need for such regulations.

1. Opposing Views on Introducing a New Regulation

Some experts had expressed their concerns that it was too early to have a sound and balanced regulation because the genome-editing technology was just at the initial stage of development and needed further breakthroughs to be fully commercialized in Taiwan. Some experts worried that the proposed

78. See TFDA, A Study on the safety assessment and management principle of emerging biotech foods, MOHW107-FDA-F-114-000375, 2018. Later in 2020, the TFDA further commissioned Taiwan Institute of Economic Research (Biotechnology Industry Study Center) to conduct a similar research project focusing on international regulatory trend and policy response of gene-edited foods, see TFDA, A Study on international regulatory trend and policy response of gene-edited foods, MOHW109-FDA-F-114-000372, 2020.

regulation on genome-edited foods would interfere with or even stifles the potential advancement of genome-editing technology in Taiwan's food or agricultural industry. It was recommended that the TFDA should let this germinated technology thrive and become capable of commercialization without too much regulatory interference. Early regulations would restrain the progress and space for the development of such technology. Such worrisome was based on the past experience of GMOs regulations that make Taiwan's biotechnological industry difficult to seize the opportunity for R&D and rare market niches for commercialization at the initial stage of development.

Moreover, the international regulatory strategy is still developing and not yet settled. Not all industrial countries regulated genome-edited foods while some allow planting crops using genome-editing technology. TFDA could wait for introducing such regulations until a more explicit regulatory structure being established among industrial countries to have a more concrete assurance on food safety concerns. For example, the U.S. Department of Agriculture (USDA) clearly stated that USDA does not regulate plants that could otherwise have been developed through traditional breeding techniques. This includes a set of new techniques that are used by plant breeders to produce new plant varieties that are indistinguishable from those developed through traditional breeding methods, including genome editing method.⁷⁹ However, the U.S. Food and Drug Administration (USFDA) has not yet decided how to regulate genome editing in new plant varieties used for foods.⁸⁰ The draft guidance is under the process of public comment and expected to release by US FDA in 2017.⁸¹

In addition, the USFDA established the Plant Biotechnology Consultation Program in 1990's providing developers the opportunity to engage with the FDA to help them ensure foods made from their new

79. See USDA, *Secretary Perdue Issues USDA Statement on Plant Breeding Innovation* (U.S.D.A. 2018) (stating "Under its biotechnology regulations, USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests. This includes a set of new techniques that are increasingly being used by plant breeders to produce new plant varieties that are indistinguishable from those developed through traditional breeding methods. The newest of these methods, such as genome editing, expand traditional plant breeding tools because they can introduce new plant traits more quickly and precisely, potentially saving years or even decades in bringing needed new varieties to farmers.".), <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>.

80. In 2017, the FDA published a notice titled "*Genome Editing in New Plant Varieties Used for Foods*" seeking public input to help inform its regulatory approach to human and animal foods derived from plants produced using genome editing. See USFDA, *New Plant Variety Regulatory Information* (2020), <https://www.fda.gov/food/food-new-plant-varieties/new-plant-variety-regulatory-information>.

81. See FDA & HHS, *Genome Editing in New Plant Varieties Used for Foods; Request for Comments*, 82 FED. REG. 6564, 6564-66 (No. FDA-2016-N-4389) (Jan. 19, 2017), <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-00840.pdf>.

varieties are safe and lawful prior to marketing.⁸² The purpose of such program is to provide individualized advice from the agency's knowledgeable biotech and food safety experts before new plant-derived products are made available for human or animal consumption.⁸³ Nonetheless, this program is voluntary without legal obligations or consequences if the developers choose not to submit for consultation, and as of March 2019, there is only one successful completion case under the consultation program.⁸⁴ This indicates the USFDA may need to consider adopting a clear regulatory mechanism on genome-edited foods.

2. *Supportive Views on Setting a Clear Regulatory Guidance*

On the other hand, some experts believed that it was just about the time to regulate, or at least start to assess the necessity of establishing a better policy guidance for the agro-food industry in developing the genome-editing technology. Formulating a clear policy direction on the genome-editing technology through regulations will provide a necessary legal framework to ensure researchers, developers or plant breeders conducting further researches and experiments without fearing to run against the laws. Unclear regulatory guidance would discourage further development of genome-editing technology in Taiwan.

Another practical reason associates with the concern over the food trade. Since some countries allows farmers to plant crops using genome-editing technology so long as such new plant varieties are indistinguishable from those developed through traditional breeding methods, the TFDA may face the question whether to allow the importation of foods derived from the crops used the genome-editing technology, and if so, what regulatory criteria to be complied with. Having a clear regulation or policy guidance would be necessary for the custom or competent authority to administer the importation of food products derived from genome-edited crops. Therefore, no matter how the genome-edited foods were regulated, TFDA should at least start the preparatory work on the rule-making process or at least to

82. See FDA, *Consultation Programs on Food from New Plant Varieties* (2020), <https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties>.

83. See Susan Mayne & Dennis Keefe, *FDA's Voluntary Plant Biotechnology Consultation Program Eases Pathway to Marketplace* (2019), <https://www.fda.gov/news-events/fda-voices/fdas-voluntary-plant-biotechnology-consultation-program-eases-pathway-marketplace>.

84. The FAD2KO high-oleic soybean is the first "genome-edited" plant to complete USFDA's Plant Biotechnology Consultation Program. After evaluation of data and information submitted by developer Calyxt, Inc., USFDA reassured the findings made by Calyxt, Inc. that oils produced using the FAD2KO soybean are similar to other high oleic oils that are currently on the market and safely consumed by humans, such as olive oil, high oleic sunflower oil, canola oil, safflower oil, and other soybean oils with increased oleic acid content. See *id.*

assess possible regulatory options for prospective regulations of genome-edited foods.

B. *Policy Options for Regulating Genome-Edited Foods: Pros and Cons Analysis*

With respect to regulatory approaches, there are roughly three major options proposed after surveying current regulatory status of other countries. Ranging from the most stringent to lenient, each policy options are based on different regulatory principles and have their pros and cons in terms of policy-making considerations. Despite several minor variations being explored, following three options reflected the common understanding of the expert groups on the possible directions for TFDA's prospective policy-making approaches.

1. *Option One: Treat Genome-Edited Foods as GMOs*

The first option is to treat foods derived from genome-edited crops as the genetically modified foods subjecting to the same level of pre-marketing reviews as those required by the GMOs regulations. In other words, food manufacturers or importers have to submit relevant data or information, and apply for the risk assessment, the same regulatory process with the GMO foods. But unlike the GMOs, the process of risk assessment for genome-edited foods may be designed in a more simplified mode in terms of the types or quantity of data submitted for review, which will be discussed later.

This approach is mainly rooted from the process-based principle on genome-editing regulations similar to the approach adopted by the European Union. With the release of judgment by Court of Justice of the European Union on 25 July 2018, the European Union seemed to adopt the process-based approach toward the genome-editing regulations. The EU Court of Justice ruled that organisms obtained by mutagenesis techniques are GMOs and are, in principle, subjected to the obligations laid down by the GMO Directive.⁸⁵ However, if such techniques have conventionally been used in a number of applications and have a long safety record, they are exempted from those obligations under the GMO Directive.⁸⁶ This court ruling clearly didn't accept Advocate General's Opinion, released in January 2018, suggesting that organisms obtained by mutagenesis are, in principle, exempted from the obligations in the GMO Directive.⁸⁷

85. See Confédération paysanne and Others, *supra* note 26, at para. 86.

86. *Id.*

87. See Bobek, *Opinion of Advocate General Bobek delivered on 18 January 2018, Case C-528/16*

This approach has clear benefits of comprehensive governmental supervision on the safety of genome-edited foods in order to reduce the risks of food safety for consumers. It also provides a simple and clear rule requiring all foods derived from the genome-edited crops to be reviewed by the TFDA without confusing which methods of genome-editing should be subjected to the risk assessment review. The regulatory burden or compliance costs could be manageable as the review process could be abbreviated according to the types of genome-edited techniques used in the applications.

Nonetheless, the first option may have negative implications on having disincentives for R&D investment and the lack of techniques for verification of certain types of genome-edited products. Treating genome-edited foods as GMOs provides little incentive for investing more resources on research and development partly because of the deterrence caused by rigid regulatory reviews. For the food industry, treating genome-edited foods as GMOs would not only increase their costs for pre-market review process, but also affect the post-market sale or distribution of the products because of the GMO label attached. This approach could reduce their incentives to invest more resources in developing genome-editing technology in the agro-food industry.

Moreover, such one-size-fit-all approach will make it difficult, if not impossible, for the competent authority to enforce the rule. Some genome-editing techniques, such as SDN-1 and ODM, may not be able to detect the difference from those traditional breeding methods simply based on the end-products given the fact that no exogenous gene is left by using SDN-1 and ODM. For the purpose of regulation, lacking a reliable verification tool to enforce the rule will weaken the effectiveness of regulation, and may create potential controversies or litigations over the way to enforce the rules.

2. *Option Two: Categorical Case-by-Case Approach*

Unlike the first approach, the second option subjects the genome-edited foods to different categories of regulations, either treating as GMOs or traditional non-GMOs, depending on the types of genome-editing techniques used in the foods. In other words, different levels of regulatory intensity would apply to the genome-edited foods based on different types of genome-editing methods. Specifically, the first category involves food products using SDN-1 or ODM. They are treated as traditional foods, and do not subject to any pre-market risk assessment reviews because the

end-products using above techniques are unable to distinguish from those using traditional mutagenesis techniques. The second category associates with food products using SDN-3, being treated as GMOs and subject to the pre-market review as products arising from SDN-3 carry a foreign DNA derived from added recombinant DNA. The third category involves those products using SDN-2. The authority has to review each application on a case-by-case basis to determine if specific product should be treated as GMOs or traditional foods.

Compared with the first option, the categorical approach has a slightly lower regulatory scrutiny. In principle, genome-edited foods are classified into three types of regulations according to different methods used. This approach is more in line with the product-based principle on genome-editing regulations. Depending on whether the end-product can be detected any alternation of genome (e.g. containing exogenous gene), the food products would be treated as GMOs or traditional foods subjecting to risk assessment reviews or without any pre-market reviews. Such categorical approach tends to strike a more balanced solution between the protection of food safety and interests of biotechnological development and the agro-food industry. Setting a clear categorical standard would make the business applicants and the governmental authority easier to follow, and help the industry to clear away regulatory uncertainty on genome-editing foods.

However, this categorical approach may contain some issues worthy of concerns. Firstly, under this approach, it simply relies on the food manufacturer or importers' self-determination on which type of techniques they used in the food products. For those products using SDN-1 or ODM tools, they won't be undergone pre-market review process and the authority won't be even informed since these products are considered as traditional foods and categorically excluded from regulatory oversights. Given that such technique may have potential risks such as off-target effects, the government authority may not be able to respond without relevant data or information provided by the business entity. Moreover, it is for the developers to decide if the genome-editing technique used in their products fall into the unregulated category. It would be difficult, if not impossible, for the authority to verify if the business applicant fraudulently claims the method used is either SDN-1 or ODM but actually using SDN-2 instead. Such approach will provide loopholes for applicants to avoid pre-market reviews.

3. *Option Three: Early Consultation Process*

The third option is to establish an early consultation procedure, requiring all producers or developers to submit their applications for the competent authority to determine whether the end-product contains a new

combination of genetic material or the methods used in the derived crops fall under the category requiring further risk assessment. Argentina adopted similar mechanism pursuant to Resolution No. 173/2015 of the Secretariat of Agriculture, Livestock and Fisheries.⁸⁸ A procedure is established to determine in which cases a crop obtained by breeding techniques involving modern biotechnology does not fall under genome-editing regulations.⁸⁹ The procedure sets a 60-day time limit and the applicant receives a reply from the authorities stating if the submitted product falls under the genome-editing regulation in the end.⁹⁰

This approach helps the authority being well informed for the relevant information of all foods derived from genome-edited crops in the market since all of the foods using genome-editing technology have to submit their applications or inquires for early-stage consultation. The authority will be able to manage and monitor all cases using genome-editing technology, and the developer can receive a clear response from the regulator, giving them the needed regulatory certainty and incentives to further their project on the proposed genome-editing method.

However, current regulatory system in Taiwan does not provide legal basis for the adoption of consultation process mechanism, and TFDA needs to promulgate new rules if the third approach is going to be adopted. Moreover, the success of such approach relies on whether the process can be designed to accommodate various concerns over food safety and the development of biotechnology in the food industry. To achieve this end, the authority could implement the early consultation process on a case-by-case basis depending on the types of genome-editing techniques used in the food. It is recommended that the consultation mechanism can include both “simplified procedures” for the category being considered as traditional foods, and “general procedure” for those being considered as GMOs. The principles or criteria for regulatory review under different procedures should be explicitly provided in the regulation.

88. Resolution 173/2015, *supra* note 67.

89. To such end, applicants shall submit each product (NBTs-derived crop) to establish whether the result of the breeding process is a new combination of genetic material or not. A genetic change shall be always regarded as a new combination of genetic material when a stable and joint insertion of one or more genes or DNA sequences that are a part of a defined genetic construct have been introduced permanently into the plant genome. Also, if appropriate, it must be established the existence of enough scientific evidence to support the absence of the transgenes that may have been used transiently during the crop breeding process.

90. Applicants are also allowed to file preliminary inquiries, aiming at anticipating whether a hypothetical expected product would fall under the GE event regulation. This is applicable to projects still in the design stage. In these cases, the governmental assessment is performed partially on the basis of expectations from the developer, so it will have only a preliminary status. When the new crops are finally obtained, the applicant must still submit factual determinations about the genetic modification actually generated. Only in the event that the product possesses those features anticipated in the preliminary inquiry, the earlier assessment regarding its regulatory status would remain.

IV. LEGAL CHALLENGES AND PUBLIC INTEREST CONSIDERATIONS FOR A
NEW REGULATION

Given the novelty and evolving nature of genome-editing technology, the TFDA will be inevitably facing a difficult challenge to adopt an appropriate regulatory policy on the foods derived from genome-edited crops. No matter which policy option is chosen, several legal issues have to be addressed before TFDA's introduction of a new regulation on genome-edited foods. Moreover, TFDA should take into account various aspects of public interests involved with multiple stakeholders.

A. *Potential Legal Issues Need to Be Addressed*

There are three legal issues worth noting if new rules or guidelines are introduced to regulate genome-edited foods. The first two relates to the definitional issues regarding whether and how the concept of genome-editing foods connect with the existing regulatory framework of GMOs and “non-traditional” foods. The third issue relates to the regulatory process of conducting the risk assessment.

1. *Distinction with Foods Using “Genetic Modification” Techniques*

The first legal issue is how and to what extent the genome-edited foods, if regulated, will be subjected to or fit into the existing legal framework of governing GM foods in Taiwan. The law governing GM foods in Taiwan was implemented on February 5, 2014 through the amendment of the Act Governing Food Safety and Sanitation or the Food Safety and Sanitation Act (FSSA). The Act requires that the genetically modified food ingredients contained in foods should be subjected to the regulations of the central competent authority for the health risk assessment and pre-market reviews.⁹¹ This Act provides a necessary legislative basis for a regulation governing

91. Article 21.2 of the FSSA provides “None of the genetically modified food raw materials shall be used as the food raw materials without being reviewed by the central competent authority in the health risk assessment, filing product registration with and procuring a permit document.” Article 21.3 provides “Importers of genetically modified food raw materials, that have filed product registration with and procured a permit document from the central competent authority, shall establish a traceability system for tracing the source and tracking the flow of the genetically modified food raw materials in accordance to Paragraph 5 of Article 9.” Article 21.7 further provides “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.” See Shipin Anquan Weisheng Guanlifa (食品安全衛生管理法) [Act Governing Food Safety and Sanitation] (promulgated Jan. 28, 1975), english version available at Quanguo Fagui Ziliaoku (全國法規資料庫) [Law and Regulation Database of Republic of China], <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0040001> [hereinafter FSSA].

safety assessment methods for GM foods promulgated by the Ministry of Health and Welfare (MHW),⁹² the competent authority in charge of GM food regulations in Taiwan. This Act elevated the legal status of GM food regulations into an official law to ensure a sound management of GM foods.

Pursuant to Article 3.11 of the FSSA of Taiwan, the term “genetic modification” is defined to mean “the transferring of genetic materials or implant of live cells or organisms via genetic engineering, molecular biotechnology, or other related technologies to produce genetic recombination, exogenous genetic characteristics, or to suppress certain genes of the recipient. However, this does not include traditional breeding methods or techniques such as the merging, hybridization, mutation, in-vitro fertilization, soma clonal variation, and chromosome doubling of plants of the same species and protoplasts.”⁹³

Based on this legislative definition, it is uncertain whether the genome-editing technology falls into the definition of “genetic modification” under Article 3.11. The first part defines the required elements of genetic modification whereas carving out several technologies that fall outside the scope of genetic modification in the second part of the provision. The legislative definition includes four cumulative elements, namely, the use of genetic engineering or molecular biological technology, the transfer or implant of genetic materials into live cells or organisms, the generation of genetic recombination, and creation of exogenous genetic characteristics or suppression of certain genes of the recipient. These four elements have the equivalent weight and mixed with product-based and process-based principles in delineating the contour of genetic modification.

Therefore, it is hard to tell from the legal texts of GM definition whether this legislature adopts a “product-based” or “process-based” approach. This definition mentions three times the term “technology”, and refers to the use of genetic engineering or molecular biotechnology, which seems to emphasize the methods used in the process development or manufacture of a food product. Focusing on the techniques used seems to indicate the adoption of a “process-based” approach in defining GM foods. However, this definition also describes the result of using such technology to produce the outcome of genetic recombination, either appearing the exogenous genetic characteristics or suppressing certain gene. These elements of definition seem otherwise to adopt a more “product-based” approach. This

92. Long before the FSSA being amended to incorporate GM foods, a regulation entitled “Genetically Modified Food Safety Assessment Method” had been promulgated by the Ministry of Health and Welfare on November 7, 1989 to assess whether the genetically modified food is equivalent or similar to the existing food. Since then, the MHW has approved soybeans, corn, cotton, rapeseed and sugar beet for the genetically modified food raw materials in Taiwan. They are all varieties developed abroad, and no domestically developed products have submitted an application.

93. FSSA, § 3.11.

legislative definition of GM complicates the scope of coverage of the GM law. Namely, whether the genome-edited foods are within the GM definition?

The answer depends on different types of genome-editing techniques used in the food productions. While SDN-3 seems well fit into the definition of GM, the method of ODM does not. As for SDN-1 or SDN-2, it requires a case-by-case review to determine if a specific technique will satisfy the definition of GM. In addition, another issue is whether the genome-editing technology may fall into one of the technologies described in the carve-out provision, especially the method of mutagenesis. These are the threshold legal issues to be addressed before introducing new regulations on genome-edited foods.

2. *Potential Regulatory Overlap with “Non-Traditional Foods Ingredients”*

The second legal issue relates to the potential regulatory overlap of genome-edited foods with the existing regulation of “non-traditional food ingredients”. With the advancement of science and technology and liberalization of international trade, there are more imported food products contained new food ingredients. Moreover, many traditional food materials have undergone non-traditional cultivation, reproduction or use of novel processing technology which results in changes of its original composition or component content, as well as its physical and chemical properties. In response to those “non-traditional food raw materials”, the MHW promulgated the “Guidance on Application for Non-traditional Food Ingredients”⁹⁴ (Guidance) on June 24, 2013 and amended on May 10, 2018 to ensure the safety and edibility of such non-traditional food ingredients without having harmful effects on the human health.⁹⁵

This Guidance provides a clear definition of non-traditional food ingredients,⁹⁶ application and operating procedures⁹⁷ and the information and application form⁹⁸ required for the safety assessment. This Guidance not only provides a clear set of rules for the food industry to follow, but also facilitates the review process of the MHW.⁹⁹ The potential issue lies at

94. Weisheng Fuli Bu Shipin Yaowu Guanli Shu (衛生福利部食品藥物管理署) [Taiwan Food and Drug Administration], *Feichuantongxing Shipin Yuanliao Shengqing Zuoye Zhi Yin* (非傳統性食品原料申請作業指引) [Guidance on Application for Non-traditional Food Ingredients] (promulgated May 10, 2018), <https://www.fda.gov.tw/TC/siteContent.aspx?sid=10811>.

95. *Id.* § 1.

96. *Id.* § 3.

97. *Id.* § 4.

98. *Id.* § 5.

99. *Id.* § 2.

Article 3 of the Guidance prescribing the definition of “non-traditional food ingredients”, which includes two types of food ingredients, namely, the lack of sufficient edible history and the use of novel process of production.

Specifically, the first type refers to materials that does not have a history of safe food use in Taiwan; or, does have a history of food use but not used for human consumption to a significant degree, for example, only in a specific territory or among a particular group of people. As for the duration of safe use, the history of safe food uses shall be longer than 25 years. The second type refers to traditional food materials that are produced with “non-traditional breeding, planting methods or manufactured by novel processes that change the composition or properties of food”. However, it does not include food categories that are already regulated, such as genetically modified food or irradiated food.

The potential issue lies at the second type of non-tradition food ingredients, which refers to the use of “non-traditional breeding methods” or “novel process” that change the composition or properties of food. It is worth clarifying whether the genome-editing technology is considered to be the “non-traditional breeding methods” or “novel process” prescribed under the Guidance for non-traditional food ingredients. If so, the producers or importers should follow the Guidance to submit the applications for the safety assessment of non-traditional food ingredients. Otherwise, the new regulation may need to carve out genome-edited food ingredients from subjecting to this Guidance if a separate set of regulatory mechanism on genome-edited food is preferred.

Under this Guidance, whether the genome-editing technology will fall under the second type of novel food processing methods depends on different types of techniques used in the process of food production. The use of SDN-1 or ODM technique may be considered to be traditional foods ingredients without subjecting to any regulatory oversight. While the use of SDN-2 technique may be decided on a case-by-case basis, the SDN-3 technique won’t be subjected to this Guidance not because it is not considered as “novel process” but it is considered genetically modified foods, subjecting to a more stringent process of premarket reviews for GM foods.

Such a preliminary assessment largely depends on the products-based approach in determining the nature of genome-editing techniques whereas the approach taken by the Guidance on the determination of the second type of non-traditional foods seems to rely more on a process-based principle. This seemingly inconsistency of regulatory approaches may need to be addressed by the MHW if a new regulation of genome-edited foods is going to introduce in order to clarify the relationship between genome-edited foods and non-traditional food ingredients.

3. *Applications and Pre-Market Review Procedure*

The third issue relates to the design of regulatory mechanism on applications and pre-market review procedures for the risk assessment. While reference can be made to current regulations on GM foods and non-traditional foods ingredients, it may be worth discussing whether it is desirable to have two tracks of regulatory review process with different level of regulatory oversights as opposed to a one-size-fit-all procedure. In other words, unlike the safety assessment of GM food, the reviewing procedure for genome-edited foods could consider adopting a bifurcated track of review, either a simplified or standard procedure depending on the categories of genome-editing techniques used in foods. Such a tiered reviewing process would be more proportionate to the level of potential risks involved with the techniques used, taking into account the regulatory costs and feasibility.

The next has to decide what kinds of data or information the applicant have to submit in its application for a regulatory review. The scope of information for a review may vary depending on the specific type of genome-editing technique used in the food production. For example, the use of SDN-3 requires a full-fledged GM review so that the safety assessment method governing GM foods should be followed. As for the use of SDN-1/ODM technique, a more expedient and consultative process would be sufficient with the submission of basic information including the description of genome-editing process, evidence of non-existence of exogenous DNA or RNA fragment, molecular properties of genome-edited foods, relevant data on off-target effect.

With respect to the use of SDN-2 technique, a more standardized process can be established for regulatory review on a case-by-case basis. In addition to the basic information, the applicant requires to submit analytical data on the target traits and data regarding the possibility of allergenicity and toxicity if existence of new protein is found.

4. *Labeling Requirement and Import Control Regulation*

Finally, food labelling requirements and rules governing import control can also be considered incorporating into a new genome-edited food regulation. Despite so, the introduction of these rules may confront following legal issues.

The issue related to food labelling will be whether to impose mandatory requirements on importers or manufactures to label their products as “genome-edited foods” as the same with current labelling requirement on GM foods. According to Article 22 and 24 of the FSSA, if food products or food additives contains genetically modified food raw materials, such matter

shall be conspicuously indicated in Mandarin and common symbols on the container or external packaging of such food product or food raw materials.¹⁰⁰ Given that the genetically modified material is explicitly listed as one of the items required to be labelled, it is less problematic for the TFDA to promulgate implementing rules to enforce the food labeling law.¹⁰¹

Nonetheless, the TFDA could face more legal challenges if a labeling requirement for genome-edited food products is introduced because of the lack of explicit legislative mandate under the FSSA. Except for the use of SDN-3 technique that could be considered as genetically modified materials through interpretation, the use of other genome-edited techniques are not one of the items explicitly provided to be labelled under the FSSA. Unless the FSSA is to be amended, the possible solution is for the TFDA to announce the genome-edited food raw materials to be one of the matters to be labeled if the TFDA choose to do so. Such solution is also within the mandate of the FSSA as Article 22 and 24 respectively provides a catch-all clause authorizing the TFDA to enforce labelling requirement on “other matters announced by the central competent authority”.

Lastly, the importation of genome-edited foods should be subjected to the same import control rules with general foods in accordance with Article 30 of the FSSA, which provides that all importing foods, genetically modified food ingredients, food additives, food utensils, food containers or packaging, and food detergents announced by the TFDA shall submit product-related information and apply for verification and inspection in accordance with the specific tariff number for customs clearance.¹⁰² More detailed rules are provided in “Regulations of Inspection of Imported Foods and Related Products” (the Regulation), in which Article 3 of the Regulation stipulates that the obligatory inspection applicant¹⁰³ or representative shall

100. Article 22 of the FSSA provides labeling requirements for foods while Article 24 of the FSSA provides the same requirements for food additives.

101. Under the mandate of FSSA, the TFDA promulgated three regulations to implement the labeling law on GMO, namely, “Labelling requirements for prepackaged food containing ingredients of genetically modified organisms (GMOs)”, “Labelling requirements for food additives containing ingredients of genetically modified organisms (GMOs)”, and “Labelling requirements for unpackaged food containing ingredients of genetically modified organisms (GMOs)”. See Weisheng Fuli Bu Shipin Yaowu Guanli Shu (衛生福利部食品藥物管理署) [Taiwan Food and Drug Administration], 公告修正「包裝食品含基因改造食品原料標示應遵行事項」、「食品添加物含基因改造食品原料標示應遵行事項」及「散裝食品含基因改造食品原料標示應遵行事項」 [Announcement of Amending “Labelling requirements for prepackaged food containing ingredients of genetically modified organisms (GMOs)”, “Labelling requirements for food additives containing ingredients of genetically modified organisms (GMOs)”, and “Labelling requirements for unpackaged food containing ingredients of genetically modified organisms (GMOs)”] (May 29, 2015), <https://www.fda.gov.tw/tc/siteContent.aspx?sid=3962>.

102. FSSA, § 30.

103. Article 2(1) of the Regulation defines the term “obligatory inspection applicant” as the “business who imports food, food additives, food utensils, food packaging, or food cleansers, and other related products”. Shipin Ji Xiangguan Chanpin Shuru Chayan Banfa (食品及相關產品輸入查

file an application for inspection to the inspection authority¹⁰⁴ at the port of entry within 15 days prior to the entry date. After the products applied for inspection conform to the regulations, the inspection authority, pursuant to Article 22 of the Regulation, shall issue an import license to the obligatory inspection applicant.

Moreover, all imported foods, except for genetically modified foods subjecting to additional safety assessment review, must be inspected in accordance with the procedure prescribed under the Regulations before entering into Taiwan's market. According to Article 8 of the Regulation, the inspection measures the authority may adopt includes the "batch-by-batch inspection",¹⁰⁵ "randomly-selected batch inspection",¹⁰⁶ "batch-by-batch verification",¹⁰⁷ "certification inspection"¹⁰⁸ and "oversee inspection".¹⁰⁹ The competent authority may determine the method of inspection at the border based on the level of risks involved in the imported foods. The intensity of inspection method can be elevated to a higher level of inspection rate if the imported foods fail to meet standards required by the FSSA when inspected based on the usual inspection rate.

While current regulations governing imported foods will also apply to genome-edited foods, there are at least two relevant issues to be addressed for effective implementation. Firstly, the authority may need to create a separate custom classification category exclusively reserved for imported genome-edited foods as the same with the genetically modified foods. Secondly, the authority may need to decide how import control rules apply to the imported genome-edited foods and which specific inspection method should be adopted based on the level of risk assessment of the technique used in the imported foods. This paper suggests that a less intensive

驗辦法) [Regulations of Inspection of Imported Foods and Related Products] § 2(1) (promulgated June 10, 2019).

104. Article 2(2) of the Regulation defines the term "inspection authority" as "the central competent authority or its commissioned organization, institution, corporation or group". *Id.* § 2(2).

105. "Batch-by-batch inspection" refers to "inspect each submitted batch of product by on-site verification and sampling analysis basis". *Id.* § 8(1).

106. "Randomly-selected batch inspection" refers to "randomly select each submitted batch of product by following inspection rate, and inspect the chosen product by on-site verification and sampling analysis". It includes (1) regular randomly-selected batch inspection: The inspection is performed based on a 2-10% inspection rate; (2) reinforced randomly-selected batch inspection: The inspection is performed based on a 20-50% inspection rate. *Id.* § 8(2).

107. "Batch-by-batch verification" refers to "on-site inspect each submitted batch of product".

108. "Certification inspection" refers to "inspect certificate document issued by an eligible certification institute which is recognized in the agreement signed by the competent authority and the health and safety competent authority of the exporting country where the inspection is carried out based on the certificate document submitted by the applicant". *Id.* § 8(4).

109. "Oversee inspection" refers to the inspection of specific products, in which each submitted batch of product shall be inspected by the method of on-site verification and sampling analysis, and the inspection rate will not be changed no matter the inspection result meets the standards or not. *Id.* § 8(5).

inspection method can be appropriate if a more comprehensive premarket regulatory oversight is adopted by the TFDA. Given that a full-fledged safety assessment procedure is taken by the TFDA to ensure the compliance the safety standards of imported foods, regulatory focus should place more on the post-market monitoring rather than the inspection or verification of genome-edited foods at the border.

B. *Public Interest Considerations and Steps for Policy-Making*

A sound regulation needs to accommodate various interests of stakeholders, and tries to balance different public interests as part of the process of risk communication¹¹⁰, one of the three components of risk analysis as defined by the Codex Alimentarius Commission.¹¹¹

The genome-editing regulation involves at least four groups of stakeholders, namely, scientists in biotechnology, the agro-food industry, relevant government authorities, and the consumers in the food markets. Each stakeholder has special interests to be considered and evaluated in the process of rule-making. For example, regulations should follow the principle of neutrality and provides incentives to encourage technological innovations. For the agro-food industry, the proposed regulation should be able to provide sufficient incentives for developers to engage in research and development activities, and encourage further commercialization of their innovative products.

As for the regulator, the government should take into account the regulatory costs, compliance costs and the technological feasibility of the proposed genome-editing regulations. Finally, the major goals for the regulation should make sure the safety of genome-edited foods and encourage the public awareness of such new technology. In a word, the proposed regulation needs to evaluate multiple policy objectives such as scientific innovations, the development of agro-food industry and the consumer safety for food consumption, and to balance potential conflicting interests especially for those involved with different stakeholders including scientists, the agro-food industry, food importers, consumers and regulators.

To sum up, this paper suggests that following steps should be taken to

110. The term “risk communication” is defined by the Codex as “the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.” See Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, in PROCEDURAL MANUAL (26th Session of the Codex Alimentarius Commission, 2003), <http://www.fao.org/3/Y4971E/y4971e00.htm>.

111. See *id.*

enact a sound and balanced regulation for imported genome-edited foods.

Firstly, the TFDA could start to engage the public dialogue with different groups of stakeholders, and to raise the public awareness about the essence of the genome-editing technology, including its benefits and risks. The TFDA may cooperate with other government agency in addressing ethical and social issues involved in the application of genome-editing technology. Moreover, the term “precision biotechnology” can be used to avoid the public misunderstanding or possible hesitancy on the use of genome-editing technology.¹¹² This term has been used by a group of WTO members supporting a joint statement presented at the meeting of SPS Committee in November 2018.¹¹³

Secondly, the government should consider if a more integrated strategy should be taken to address such a novel biotechnology. In addition to the potential risks of food consumption, the gene-editing technology also triggers the environmental or ecological risks if a gene-edited product is released to the environment. Therefore, an across-the-board strategy is needed to formulate the policy through cooperating with different governmental agencies. The communication and coordination between the food or health authority (TFDA) and the authority in charge of crops plantation (Council of Agriculture) and environment (Environmental Protection Agency) is essential to establish a national-wide policy toward such modern biotechnology.

Thirdly, given that the proposed regulation simply focuses on foods, not crops, a more cautious approach is recommended since it is the public health that is so sensitively at stake.¹¹⁴ Specifically, the TFDA could take a more cautious step towards the introduction of a new regulation on genome-edited foods in Taiwan waiting until a more concrete regulatory framework established by other countries such as the US to ensure the safety of genome-edited foods consumption by human beings.

Finally, the policy on genome-edited foods should follow relevant international norms such as the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Cartagena Protocol on Biosafety.¹¹⁵ While Taiwan is not a signatory or has not even

112. See WTO, International Statement on Agricultural Applications of Precision Biotechnology, UN Doc. G/SPS/GEN/1658/Rev.3 (Oct. 26, 2018).

113. WTO Members supporting this initiative to date are Argentina, which raised the issue in the Committee, as well as Australia, Brazil, Canada, Colombia, the Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, the United States, Uruguay and Viet Nam.

114. See Motoko Araki, Kumie Nojima & Tetsuya Ishii, *Caution Required for Handling Genome Editing Technology*, 32 TRENDS BIOTECH. 234 (2014) (suggesting that researchers should act with more caution in research and development using genome editing technology compared to traditional genetic engineering technology for the accountability of science).

115. As an international agreement under the Convention on Biological Diversity, the Cartagena Protocol on Biosafety aims to ensure the safe handling, transport and use of living modified organisms

ratified the Cartagena Protocol on Biosafety,¹¹⁶ relevant rules under the Protocol should be taken into account in policy-making process. Given that this Protocol applies to the transboundary movement of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity,¹¹⁷ Article 11 provides relevant procedural rules for living modified organisms intended for direct use as food or feed or for processing. It recognizes the right of a Party to take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing so long as its domestic regulatory framework follows the rules of this Protocol such as risk assessment and risk management. The Party shall conduct the risk assessment in a scientifically sound manner,¹¹⁸ and establish a risk management mechanism that is necessary to prevent adverse effects of living modified organisms on the conservation and sustainable use of biological diversity.¹¹⁹

As a WTO member, Taiwan is obliged to comply with the SPS Agreement whenever a SPS measure is proposed or adopted. If a new regulation is introduced to ensure the safety of imported genome-edited foods, such measure is considered to be a SPS measure and has to comply with trade rules under the SPS Agreement.¹²⁰ Among others, a Member shall

resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003. See Convention on Biological Diversity, *The Cartagena Protocol on Biosafety*, <https://bch.cbd.int/protocol> (last visited July 12, 2021); Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Sept. 11, 2003, 2226 U.N.T.S. 208.

116. See Yulan Kuo & Hui-ming Huang, *Agricultural law in Taiwan: overview* (Practical Law Thomson Reuters Practical Law, 2020), [https://uk.practicallaw.thomsonreuters.com/6-606-6505?transitionType=Default&contextData=\(sc.Default\)&firstPage=true](https://uk.practicallaw.thomsonreuters.com/6-606-6505?transitionType=Default&contextData=(sc.Default)&firstPage=true).

117. With an exception to the living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations. See Cartagena Protocol, *supra* note 115, Art. 5.

118. See *id.*, Art. 15. Moreover, Annex III to the Protocol provides detailed rules on how to carry out risk assessment. In case of insufficient scientific evidence in support of the decision with regard to the import of the living modified organism, Article 10.6 of the Protocol recognizes that the lack of scientific certainty regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import shall not prevent that Party from taking a decision, as appropriate, in order to avoid or minimize such potential adverse effects.

119. See *id.* Art. 16.1.

120. According to Annex A to the SPS Agreement, it provides a definition of a SPS measure which includes a measure adopted “to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs”. Moreover, a SPS measure can be in a variety of legal forms including all relevant laws, decrees, regulations, requirements and procedures. It can cover various aspects of regulations such as end product criteria, processes and production methods, testing, inspection, certification and approval procedures, sampling procedures and methods of risk assessment and packaging and labelling requirements directly related to food safety. If a gene-editing regulation is adopted to insure the safety of gene-edited foods for human consumption, such regulation is considered to be a SPS measure and subjected to the obligations prescribed under the SPS Agreement.

ensure that a SPS measure is based on scientific principles and is not maintained without sufficient scientific evidence.¹²¹ Moreover, a Member shall ensure that its SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members, and shall not be applied in a manner which would constitute a disguised restriction on international trade.¹²² More importantly, a Member shall ensure that a SPS measure is applied only to the extent necessary to protect human, animal or plant life or health, and in order to fulfill this obligation, a Member can take the benefit of presumptive provision by aligning its SPS measure with the international standards, guidelines and recommendations established by the Codex Alimentarius Commission as a gene-editing regulation is adopted for food safety purposes.¹²³

C. *Development of International Standards and Guidelines*

Given the novelty of gene-editing technology, the international community continues to conduct ongoing discussions among policy makers, academia, innovators scientific experts and other stakeholders in order to build up a global consensus on formulating international standards or guidelines for regulating the gene-editing technology.

The Organization for Economic Co-operation and Development (OECD) Working Group for the Harmonization of Regulatory Oversight in Biotechnology held a conference in June 2018 discussing the safety and regulatory considerations of genome-edited organisms, with the aim to favor a coherent policy approach to facilitate innovation involving genome editing.¹²⁴ Moreover, the Food and Agriculture Organization of the United Nations (FAO) maintains an online database entitled “FAO GM Foods Platform” for Codex Members to share information on the results of genetically modified food safety assessment. The Platform held a global community meeting in 2019 to exchange views on conducting risk-based

121. See article 2.2 of the SPS Agreement. In cases where relevant scientific evidence is insufficient, according to article 5.7 of the SPS Agreement, a Member may still provisionally adopt the SPS measures on the basis of available pertinent information and shall seek to obtain the additional information necessary for a more objective assessment of risk and review the SPS measure accordingly within a reasonable period of time.

122. See article 2.3 of the SPS Agreement.

123. See article 3.3 of the SPS Agreement, providing that a SPS measure which confirms to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

124. See OECD, OECD Genome Editing Hub, *OECD Conference on Genome Editing: Applications in Agriculture-Implications for Health, Environment and Regulation* (June, 28-29, 2018), <http://www.oecd.org/environment/genome-editing-agriculture/>.

food safety assessment and regulatory management in which gene-editing technology is one of the issues addressed by the participants.¹²⁵

Under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, there is an ongoing debate over whether organisms derived from genome-editing technology are “living modified organisms” as defined by the Protocol.¹²⁶ In other words, whether the definition under the Protocol can include all forms of genome-editing technology is not clear as the scope of the Protocol is limited to the living modified organisms resulting from term “modern biotechnology”.¹²⁷ It has been argued that if the Cartagena Protocol’s definition of “modern biotechnology” was strictly applied to the technology that can overcome the natural physiological or reproductive or recombination barriers and that are not techniques used in traditional breeding and selection, some recombinant DNA (e.g. cisgenesis) and “new” technologies (e.g. genome editing) may be excluded from its scope.¹²⁸ In sum, the definition under the Cartagena Protocol has triggered the debate over the regulatory status of “new techniques” such as genome editing throughout the world.

Such definitional issue is also relevant in examining relevant international standards and guidelines developed under Codex Alimentarius, one of the international organizations recognized by the WTO/SPS Agreement. As indicated, WTO Members adopted a joint statement on agricultural applications to precision biotechnology in order to engage in collaborative work to promote constructive dialogue with trading partners and agricultural stakeholders on potential trade issues related to precision biotechnology, so as to support open and fair trade and encourage research and innovation.¹²⁹ Under the WTO/SPS Agreement, the most relevant international standards associated with the gene-editing technology could be those international guidelines for risk analysis and safety assessments of foods from genetically engineered plants established by Codex, including:

125. See Food and Agricultural Organization, *Global community meeting of the FAO GM Foods Platform: Towards effective risk-based food safety assessment and regulatory management* (Sept. 10-13, 2019), <http://www.fao.org/3/ca8945en/CA8945EN.pdf>.

126. See Silja Vöneky, *Legal Framework*, in DISCUSSION PAPER FOCUSING ON THE SCIENTIFIC RELEVANCE OF GENOME EDITING AND ON THE ETHICAL, LEGAL AND SOCIETAL ISSUES POTENTIALLY INVOLVED 17 (The Ethic Council of the Max Planck Society ed., 2019), <https://www.mpg.de/13811476/DP-Genome-Editing-EN-Web.pdf>.

127. Article 3 of the Protocol defines the term “modern biotechnology” to mean the application of: (a). In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b). Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

128. See Felicity Keiperl & Ana Atanassova, *Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols*, 8 FRONT. BIOENG. BIOTECH. (2020), <https://www.frontiersin.org/articles/10.3389/fbioe.2020.00310/full>.

129. See WTO, *supra* note 112.

Principles for the Risk Analysis of Foods Derived from Modern Biotechnology¹³⁰ and Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.¹³¹ It is noteworthy that these guidelines are not established specifically for the gene-editing technology as the scope of these guidelines is also limited to the use of “modern biotechnology”, which refers to the same definition under the Cartagena Protocol.¹³² The debate over whether the gene-editing technology falls under the scope of “modern technology” remains to be solved if these Codex guidelines or principles are considered to be the international standards under the WTO/SPS Agreement. Nonetheless, these guidelines provide a framework for conducting risk analysis on the safety and nutritional aspects of foods derived from modern technology.¹³³ Together with the Codex Working Principles for Risk Analysis¹³⁴ as well as general decisions of Codex governing the conduct of risk analysis,¹³⁵ these guidelines and principles can be considered as relevant international standards for a Member undertaking risk analysis on foods derived from genome-editing technology.

V. CONCLUDING REMARKS

With the advancement of modern biotechnology, the food regulators face increasing challenges on how to regulate foods derived from genome-edited crops. Given that genome-edited crops are not allowed to plant in Taiwan, the foods derived from genome-edited crops will mainly originate from other countries, which allow planting genome-edited crops. Therefore, the mounting pressure is expected to fall on the TFDA, the agency in charge of food safety and the control of food imports. After surveying different regulatory approaches adopted by different agencies worldwide, this paper argues that TFDA could adopt a more cautious

130. See Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003 (2003), http://www.fao.org/fileadmin/user_upload/gmfp/resources/CXG_044e.pdf.

131. See Codex Alimentarius Commission, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, CAC/GL 45-2003 (2003), http://www.fao.org/fileadmin/user_upload/gmfp/docs/CAC.GL_45_2003.pdf.

132. This definition of “modern biotechnology” is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

133. This Principle does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods.

134. See generally Codex Alimentarius Commission, *supra* note 110.

135. These decisions include the Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account and the Statements of principle relating to the role of food safety risk assessment (See generally Codex Alimentarius Commission Procedural Manual; Thirteenth edition Codex Alimentarius Commission, *supra* note 110).

strategy to introduce a new regulation on the importation of genome-edited foods. A categorical case-by-case approach in tandem with early consultation could be a better regulatory response to a rapid evolving genetic engineering technology. Moreover, a regulatory approach mixed with product-and-process based can be considered in order to achieve a more balanced outcome in accommodating various policy objectives and multiple interests involved in the field of newly advanced genome-editing technology. More importantly, this paper recommends TFDA start a platform for expert discussions, policy research and risk communications among stakeholders, and join with other authorities to develop action strategies, in order to make appropriate policy response to the fast evolving genome-editing technology.

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臺灣對基因編輯食品進口 之管理方案

楊 培 侃

摘 要

隨著現代生物技術的快速發展，為能滿足全球對糧食安全和營養日益增長的需求，農產食品行業致力於研發基因組編輯技術，並以此等技術種植之作物為原料從事食品之生產。此等基因編輯食品與傳統上認為安全的食品不同，此等「新興食品」的出現，為食品安全的確保帶來管理層面的挑戰，並衍生出與現有食品安全治理架構相容性的法律問題。儘管基因編輯作物的種植已於世界各國蓬勃發展，但臺灣農業委員會目前採取的政策，原則上係禁止基因改造或編輯作物在田間種植。因此，臺灣境內市場上之基因編輯食品，如果允許的話，應該是從國外進口的為主，從而，針對基因編輯食品之政策制訂與管理壓力，主要將落在臺灣食品藥物管理署身上。在此背景下，本文將探討在現行食品安全管理法制下針對基因編輯食品之進口可能面臨的法律挑戰，並探討臺灣於研訂基因編輯食品政策與管理方案之選擇和考量因素。本文認為，鑑於目前部分對基因編輯技術持開放態度之國家，僅係允許基因組編輯作物之種植，對於供人類食用之食品，臺灣政府對基因組編輯食品的進口可以採取更為謹慎的管理策略。此外，本文建議可以採用依不同技術型態分類的個案管理方法，綜合考量產品屬性與生產過程等因素，並結合早期諮詢程序之機制，期能平衡兼顧此等先進的基因編輯技術領域所涉及的各種政策目標和多重利益。

關鍵詞：基因編輯技術、基因編輯食品、食品管理、食品安全、進口管制、安全評估、基因改造生物