

The Consistency of the new EU Organic Regulation with the WTO law

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Master Thesis



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The Consistency of new EU organic regulation with WTO law

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Abstract:

To respond to the strong growth of the organic market in the EU, the Regulation (EC) 2018 / 848 was introduced in 2018, repealing the previous organic regime, Regulation (EC) 834/ 2007 and its implementing acts. While the reform improves some of the deficiencies found in the previous legislative framework, it is also criticized that it might have impact on trade. In particular, the import regime under the 2018 Regulation seems much restricted than the previous regime. Whether the concern signifies that the current design of the new Regulation is not consistent with the relevant WTO disciplines is explored in this research. The analysis demonstrates that the requirements of the TBT Agreement shall be observed as the Regulation falls within the definition of technical regulation and conformity assessment procedure as referred to in the Agreement. By applying doctrinal method in this research, the result of the analysis suggests that, while the distinction made on the authorization of certain substances could be regarded discrimination, the 2018 Regulation is likely to be TBT- consistent.

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List of abbreviation:

The 1991 Regulation

Regulation (EEC) 2092/91 of 24 June on organic production of agricultural products and indications referring thereto on agricultural products and foodstuff

The 2007 Regulation

Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

The 2018 Regulation

Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

AB

Appellate Body

CA

Control Authority

CB

Control Body

EU

European Union

ECA

European Court of Auditor

IFOAM

The International Federation of Organic Agriculture Movements

ISO

International Organization for Standardization

OFFC

The Official Feed and Food Control (OFFC) Regulation

TBT

Technical Barrier to Trade

WTO

the World Trade Organization

1. Introduction:

1.1. Background:

The rise of private and public regulations on organic agriculture was an accumulated result of a social movement, which emerged as a protest to the impact caused by conventional farming on the environment in 1920s. In contrast to the conventional farming, the movement aimed to promote a holistic production management system that are socially, ecologically, and economically sustainable. With increasing public attention on agro-ecological issues, many private standards were introduced. The first organic standard, Demeter, was introduced in 1928. In 1950s, many non-governmental organizations started to develop guidelines and standards on organic farming.¹ During 1970 to 1990s, the social movement of organic agriculture welcomed its expansion era, and around that time, international trade of organic products was commenced. The International Federation of Organic Agriculture Movements (IFOAM) was founded in this context by organic farmers and associations. IFOAM, played a role as a transnational umbrella organization in the movement, became the main organization to set organic standards. In 1980s, 'Basic Standards for Organic Agriculture' (hereinafter IFOAM Basic Standards) was issued in response to the need of the define of organic agriculture, an organic guarantee system on the international level.²

The IFOAM Basic Standards had a profound influence on private standards and public regulations of organic agriculture worldwide. The primary example was Codex Alimentarius Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL32-1999).³ Seeing the need to regulating organic sector, the EU introduced its first regulation on organic sector in 1991, Council Regulation (EEC) No 2092/91 (hereinafter 1991 Regulation).⁴ The main aim of the 1991 Regulation was to augment the development of organic sector by ensuring fair competition and to protect the definition of and term organic farming. On the one hand, the introduction of a single European regulation was helpful to reduce consumer confusion and increase consumer confidence in organic products. However, on the other hand, distortion of competition remained a concern mainly due to its inexplicit definition and principles of organic production and some areas of productions that were not fully covered by the scope of the regulation, such as aquaculture.⁵ Such worries had the EU conduct a review of Regulation (EEC) 2092/91 in 2004, which in the end led to the adoption of the Council Regulation (EEC) 834/2007 in 2007 (hereinafter the 2007 Regulation).⁶ Following this regulation two implementing regulations

¹ KRISTIANSEN, P. & MERFIELD, C. 2006. Overview of organic agriculture. *Organic agriculture: A global perspective*, 1, MA, S.-M. & JOACHIM, S. 2006. Review of History and Recent Development of Organic Farming Worldwide. *Agricultural Sciences in China*, 5, 169-178.

² GEIER, B. 2007. IFOAM and the History of the International Organic Movement. *Organic Farming: an international history*, 175-186.

³ CODEX ALIMENTARIUS COMMISSION. 1999. Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods. GL 32-1999. Available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BG L%2B32-1999%252Fcxg_032e.pdf.

⁴ EUROPEAN COMMISSION 1991. COUNCIL REGULATION (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, CODEX ALIMENTARIUS COMMISSION. 1999. Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods. GL 32-1999. Available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BG L%2B32-1999%252Fcxg_032e.pdf.

⁵ PADEL, S., JESPERSEN, L. M. & SCHMID, O. 2007a. Research to support the revision of the EU Regulation on organic agriculture. Available: https://cordis.europa.eu/docs/publications/1267/126792331-6_en.pdf, PADEL, S., LAMPKIN, N. & LOCKERETZ, W. 2007b. The development of governmental support for organic farming in Europe. *Organic farming: An international history*, 93-122.

⁶ EUROPEAN COMMISSION 2007. Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and

were adopted in 2008, which provided the detailed rules on production, labelling, control, and arrangements for imports from third countries.⁷

The 2007 regulation and its implementing acts aimed to further strengthen consumer recognition of organic produce as well as to simplify the legislative framework of organic production. Its initiatives include clearly stipulating the objectives and principles of organic production, which as opposed to the 1991 Regulation that were scattered in various provisions. The amendment was expected to ensure the consistence of national and private standards with the EU requirements on organic production, while allow regional flexibility among Member States. Another amendment that should be noted was the introduction of EU organic logo, which intended to facilitate the communication with consumers regarding the integrity of organic products.⁸

Nevertheless, the strong growth and development of the organic sector again spurred the need to introduce a reform on the organic legislative framework in 2014. The growth can be seen both in supply and demand. In 2014, when the Commission proposed a reform on organic legislative framework, organic farming land in the EU had increased by 35 % since 2008. Meanwhile, the retail sales of organic products exceeded 24 billion euros, a remarkable increase of 52% compared to 2008.⁹ Those data indicated that organic market was no longer a niche market in the EU agri-food sector. Within this context, it was regarded that the Regulation (EEC) 834/2007 and its implementing regulations can't sufficiently meet the current needs of the organic agriculture sector anymore, and that a simpler and more harmonized approach was preferred.¹⁰ After years of negotiations among EU institutions and stakeholders of organic sector in the EU, the new EU organic regulation, Regulation (EC) 2018/848 was adopted in 2018 and will be applicable in 2021.¹¹ The newly reformed regulation is expected to create a level playing field for operators and ensure that consumer confidence on the integrity of organic products is sustained. Details of the changes introduced by the 2018 to the previous legislative framework will be illustrated in this research.

However, while some improvements are made, there are also some concerns toward the new regulation. The concerns are mostly arisen from the change in the import regime. The change will abolish the recognition of equivalence of control bodies and control authorities and replace unilateral equivalence recognition of third countries with equivalence recognition under a trade agreement. The principle of equivalence has been recognized as an effective import scheme to support the growth of international organic trade and is adopted by numerous countries, such as the United States and Japan.¹² As the second largest organic market (33. 5 billion

labelling of organic products and repealing Regulation (EEC) No. 2092/91.

⁷ EUROPEAN COMMISSION 2008a. Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, EUROPEAN COMMISSION 2008b. Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries.

⁸ PADEL, S., LAMPKIN, N. & LOCKERETZ, W. 2007b. The development of governmental support for organic farming in Europe. *Organic farming: An international history*, 93-122.

⁹ RESEARCH INSTITUTE OF ORGANIC AGRICULTURE (FIBL). n.d.-a. *FiBL Statistics - European and global organic farming statistics* [Online]. Available: <https://statistics.fibl.org/about.html> [Accessed 10th January 2019].

¹⁰ EUROPEAN COMMISSION 2014d. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007.

¹¹ EUROPEAN PARLIAMENT & COUNCIL OF THE EUROPEAN UNION 2018. Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007.

¹² IFOAM-EU & FAIR TRADE ADVOCACY OFFICE. 2016. Briefing on Import Aspects in the Proposed New Organic Regulation, RESEARCH INSTITUTE OF ORGANIC AGRICULTURE (FIBL). n.d.-b. *OrganicExportInfo* [Online]. Available: <https://www.organicexport.info/about.html> [Accessed 10th January 2019].

in 2016) behind the United States, the change of the EU in import policies have inevitably raised some concerns over its impact on trade. For operators, it is foreseen that there is an increase in their cost due to duplication of certification, if the countries where they originate is not able to conclude trade agreements with the EU. In addition, operators in developing countries in particular might be the most affected by the amendment as it might be difficult, if it is not impossible, for them to meet the standards that the EU set out. Meanwhile, the EU has been a WTO member since 1995. WTO rules are binding as international laws, which means that the EU shall be obliged to follow the disciplines set out by WTO.

1.2. Aim and Research question:

The aim of this thesis paper is therefore to study whether the new legislative framework meets the requirements of WTO disciplines. The study will begin with an overview of the legislative framework with the focus on 2007 Regulation to provide a better understanding of the deficiencies of the previous regulations. The 2018 Regulation will then be explored to identify the changes that the regulation introduced. Finally, based on the understanding of the EU organic legislative framework, the consistency of the regulation with WTO laws is analyzed.

This main research question of this paper is: is the EU new organic regulation compatible with WTO law? To answer this question, the following questions are relevant:

1. What were the deficiencies of 834/2007 that lead to the changes?
2. What were the changes introduced by the new organic regulation?
3. Which WTO agreement is applicable? SPS, TBT, or/and GATT?
4. Is the EU new organic regulation consistent with the agreement(s) mentioned above?

1.3. Method

This research adopts doctrinal methods to study relevant laws with the respect to the research questions. Doctrinal method is a method used to “identify, analyse and synthesis the content of the law” with the aim of establishing “an arguably correct and complete statement of the law on the matter in hand”.¹³ To begin with, the deficiencies of the previous organic legislations, with a focus on the 2007 Regulation, will be explored to have a better understanding of the context of the new EU organic regulation. An overview of the new regulation (i.e. Regulation 2018/848) will be conducted to demonstrate what the changes are introduced. Then the paper goes further to examine what relevant WTO laws were. Finally, when analysing the consistency of the matter at issue with WTO laws, relevant law on interpretation in international law and WTO law will be applied. Notably, Articles 31, 32 and 33 of the Vienna Convention on the Law of Treaties (hereinafter VCLT) has been recognized by the Appellate Body that such approach could be exercised in interpreting WTO laws¹⁴. More specifically, interpretation approach should be based on the ordinary meaning of the text in the relevant provision, the context of the provision, and the object and purpose of the agreement.

2. The deficiency of Regulation (EEC) 834/2007

To have a better understanding the context of the reform in organic regulations proposed by the Commission in 2014, it was helpful to explore what were the deficiencies of previous legislative framework found at that time.

¹³ HUTCHINSON, T. 2017. Doctrinal research: Researching the jury. In: WATKINS, D. & BURTON, M. (eds.) *Research methods in law*. Routledge, 7-33.

¹⁴ See for example, Appellate Body Report. 1996b. *United States — Standards for Reformulated and Conventional Gasoline*. WT/DS2/AB/R at p23; Appellate Body Report. 1996a. *Japan — Taxes on Alcoholic Beverages*. WT/DS8/AB/R ; WT/DS10/AB/R ; WT/DS11/AB/R at p10.

It was found that, accompanied with the expanding market of organic products, risks also emerged to both supply and demand. This led to the failure of achieving the overall objective of “the sustainable development of organic production”, stipulated in Article 1 (1) of Reg. 834/2007.¹⁵ An overview of the deficiencies that are relevant with this research is provided below.

Scope

The scope of previous legislative framework was unclear, which created uncertainties for food business.¹⁶ Although Article 2 (2) stipulated the scope of application of Regulation (EEC) 834/2007, it still caused confusion for food business about whether certain products were included. In practice, companies often needed to seek for clarifications from the Commission as to whether their products could be sold as organic.¹⁷ This in the end might discourage food business to produce organic products and risk the development of organic supply.

Production rules

There were a number of weaknesses pertaining to the production rules. According to the evaluation made by THÜNEN Institute in 2013, the legal status of objectives and principles of organic production could be clearer as it was observed that some control bodies and control authorities were uncertain if they are legally binding. Certain terms of the production rules were also considered to be ambiguous (e.g. sustainable use of natural resources, high animal welfare). Therefore, further clarification and constantly dialogue on the interpretation of the rules among the Commission, MS, control bodies and control authorities were recommended.¹⁸

Another issue in production rules was the authorization of new substances and products used for organic production. Certain inputs used in organic productions should be authorized by the Commission in accordance with Articles 16 and 21 of Regulation (EEC) 834/2007. To implement the rules, the Commission had established an expert group for technical advice on organic production, of which the mission was to evaluate whether requested inputs can be considered compatible with the objectives and principles of organic farming. However, the process of evaluation was regarded to be “complex, technical and time-consuming”, which created technical obstacles to organic farmers and producers.¹⁹

In addition, it was noted that the sustainable use of energy, management of environmental impacts and animal welfare should be improved.²⁰ The previous production rules were regarded too flexible to provide organic producers the incentives to manage their environmental performance proactively. Thus, concerns regarding that the core value of organic farming, i.e. reducing the environmental impacts of farming, would be undermined were raised. This also led to the situation where operators needed to acquire multiple certifications to access certain

¹⁵ European Commission. "Commission Staff Working Document Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Organic Production and Labelling of Organic Products, Amending Regulation (Eu) No Xxx/Xxx of the European Parliament and of the Council [Official Controls Regulation] and Repealing Council Regulation (Ec) No 834/2007." 2014

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE. p. 277 and 292.

¹⁹EUROPEAN COMMISSION 2014b. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 1 to 8.. Annex 7

²⁰EUROPEAN COMMISSION 2014a. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007. p.18; SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE.

markets as consumers preferred more stringent private schemes. As for animal welfare, worries about practices were not consistent with organic principles existed. This was mainly resulted from the exceptions stipulated in the law, such as exceptions to the prohibition of mutilation and isolation, and the lack of approach for monitoring producers' performance on animal welfare.²¹

The last issue, which was also the one that many stakeholders regarded as troublesome, was the exceptions to production rules. Exceptions were stipulated originally in response to the need of adaption to local farming conditions and to the problem that inputs might not be sufficient or available in organic form. The allowance of exceptions indeed in a way did support the growth of organic sector in the EU. However, after years of implementation, it seemed that the risks had outweighed the benefits it could contributed to the organic sector. The problem could be understood from both the aspects of supply and demand. From the supply point of view, exceptions created obstacles for the development of the production of organic inputs, notably young animals, seeds or protein feed. For instance, it was found that the supply of organic pullets was generally insufficient in Member States that granted exceptions to use non-organic pullets. In contrast, those countries that prohibited such exceptions did not have such an issue. Another impact that exceptions had on the development of supply was unfair competition. This was resulted from the improper use of exceptions by MS as well as control bodies operating in third countries. The fact that MS did not have sufficient resources to manage those exceptions led to different application of exceptions among Member States. As for imports, recognized control bodies under equivalence regime were reported to have incentives to lower standards with exceptions, which might generate commercial benefit for operators under their control. As regards the impacts on demand, the results of a public consultation in 2013 showed that the majority of respondents (around 60%) did not support the use of exceptions to organic production rules.²² The disapproval attitude among the public indicated that the use of exceptions could possibly erode consumers' confidence of the integrity of organic products, which was the essential factor of the growth of organic market.

Labelling

The discussion on the weakness of labelling rules mainly focused on the use of EU organic logo, which became obligatory since 2012. It was noted that the awareness of the EU organic logo should be strengthen as there were multiple private organic logos competing with the EU logo in the market, which might confuse and mislead consumers.²³ In addition, the fact that EU organic logo did not clearly connect to organic farming also weaken the awareness of consumers toward the logo. Although Regulation (EEC) 834/2007 required that the indication such as BIO, ECO, ORG were mandatory and should be adjacent to the logo, the link between the logo and terms abovementioned were doubted to be clear enough for consumers.²⁴

Control system

²¹ EUROPEAN COMMISSION 2014c. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 9 to 17. Annex 14; SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE.

²² *ibid*; EUROPEAN COMMISSION 2013. Report On The Results Of The Public Consultation On The Review Of The Eu Policy On Organic Agriculture Conducted By The Directorate General For Agriculture And Rural Development. p.51

²³ EUROPEAN COMMISSION 2014a. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007.

²⁴SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE. p.285-286

Consumer's trust plays a key role in the development of organic market. To ensure consumer's confidence on the integrity of organic products, control system constitutes the essential part of organic regulations. Reviews of previous legislation found that there were several deficiencies in control system, which could hamper the future development of organic supply and demand. First of all, the legislation of control system was found to be problematic because it was complex, unclear and incomplete. Official control was regulated both by regulations on organic products (i.e. Regulation (EC) 834/2007 and Regulation (EC) 889/2008) and official controls on food and feed (hereinafter OFFC).²⁵ It was found that there were "gaps, overlaps, grey areas and inconsistencies".²⁶ For instance, the terms used in 2004 OFFC and organic regulations were different in the situation where non-compliance occurred. While the former used the terms "non-compliance" and "sanctions", the later referred to "irregularities", "infringements" and corresponding "measures". In addition, 2004 OFFC did not allow the competent authorities to assign control bodies the competence to take actions on non-compliances, which was not consistent with organic regulations.²⁷

Apart from the problems caused by the unclear link with OFFC, the control rules of organic regulations were lack of some requirements that shall be harmonized at the EU level. For example, there were no specified rules on the minimum number of laboratory test, sampling procedures, criteria for the interpretation of pesticides residues detection and the approach to deal with irregularities. This led to the enforcement of controls varied among Member States and even within the same Member States and thus weaken the effectiveness of the control system on organic products.²⁸ Incomplete coverage of the control system was another issue mentioned. Retailers might be exempted from control system, however the interpretation on the conditions for granting exemption differed across Member States.²⁹ Additionally, whether exporters and subcontractors were covered by control system were unclear.

Thirdly, weakness was also found where private control bodies carried out the controls, either inside or outside the EU. It was noted that control bodies might lower control requirements to compete for more operators under their controls. The certification fees charged by CB were not regulated and varied across and within MS. In some cases, the certification cost paid by an operator was not disproportionate to his income. This accompanied with other obligations imposed by control regulations, such as record keeping, were burdensome for producers, small farmers in particular.³⁰ Finally, the requirement of annual inspection of all operators was overall the most debated

²⁵ i.e. Regulation (EC) No 882/2004, which was later repealed by Regulation (EU) 2017/625.

²⁶ European Commission. "Commission Staff Working Document Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Organic Production and Labelling of Organic Products, Amending Regulation (Eu) No Xxx/Xxx of the European Parliament and of the Council [Official Controls Regulation] and Repealing Council Regulation (Ec) No 834/2007." 2014. Annex 9 at p.8

²⁷ European Commission. "Commission Staff Working Document Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Organic Production and Labelling of Organic Products, Amending Regulation (Eu) No Xxx/Xxx of the European Parliament and of the Council [Official Controls Regulation] and Repealing Council Regulation (Ec) No 834/2007." 2014. Annex 9 at p.28

²⁸ EUROPEAN COURT OF AUDITORS 2012. Audit Of The Control System Governing The Production, Processing, Distribution And Imports Of Organic Products.; Of Regulation (EC) No. 834/2007 Annex 9 at p.29; DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY (EUROPEAN COMMISSION) 2015. Pesticide residue control in organic production.

²⁹ European Commission. "Commission Staff Working Document Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Organic Production and Labelling of Organic Products, Amending Regulation (Eu) No Xxx/Xxx of the European Parliament and of the Council [Official Controls Regulation] and Repealing Council Regulation (Ec) No 834/2007." 2014. Annex 9 at p.10

³⁰ EUROPEAN COMMISSION 2014c. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 9 to 17. Annex 9 at p.13

topic. Operators were obliged to receive at least one on-site check annually. The aim of the regulation was to ensure the integrity of organic products; however, it was criticized that the requirement did not allow an efficient use of resources and was not helpful to supervise riskier operators.³¹ The topic was controversial because it was regarded as an essential measure to ensure the integrity of organic products.³²

Import rules

Regarding that the compliance regime only became applicable in 2014, the discussion of the deficiency of import regime mainly focused on the rules of recognition of third countries and control bodies as providing equivalent guarantees. It was found that the equivalence assessment of third countries was too complex and resource-consuming. This led to very long delays for a third country to acquire a recognition. Specifically, only eight countries out of twenty-five applications between 2000 and 2011 were recognized, while thus far there has been only thirteen countries recognized.³³ In addition, supervision over third countries under equivalence regime was regarded to be insufficient. ECA in its report pointed out that there were no detailed procedures of the Commission for the review of the list of equivalent third countries and that information received from third countries' annual report was not sufficient to carry out further monitoring. This created a potential risk to the control system. To address the issues, the Commission responded that a guideline on the information needed in annual report was provided to recognized third countries in 2011.³⁴

For the import regime which recognized control bodies as providing equivalent guarantees, the procedure of recognition was also regarded to be burdensome for the Commission.³⁵ Additionally, as stated previously, control bodies might be tempted to use exceptions improperly, and even more troublesome was that the use of exceptions could hardly be detected. This might lead to unfair competition between producers in the EU and third countries. Apart from that, the main concern was the effectiveness of control system under this regime. Some weaknesses indicated that there was room for improvement. Some cases showed that control bodies did not guarantee that only organic products or products covered by the equivalence recognition were exported to the EU. In addition, control bodies were criticized that they did not conduct proper risk assessment when planning controls and sampling activities. Furthermore, inspection performance of control bodies was found to be particularly worrisome in situation where group certification existed. The internal control system of certified group was sometimes not under adequate control of control bodies.³⁶

³¹ European Court Of Auditors, supra note 80; *ibid.* Annex 9 at p.22

³² See stakeholders' opinion for example: EUROPEAN ORGANIC CERTIFIERS COUNCIL. 2014. EOCC Statements on the proposal for the new organic EU regulation. Available: https://eocc.nu/wp-content/uploads/2015/11/EOCC_new_organic_reg_position_20140422.pdf [Accessed 20th December 2018].

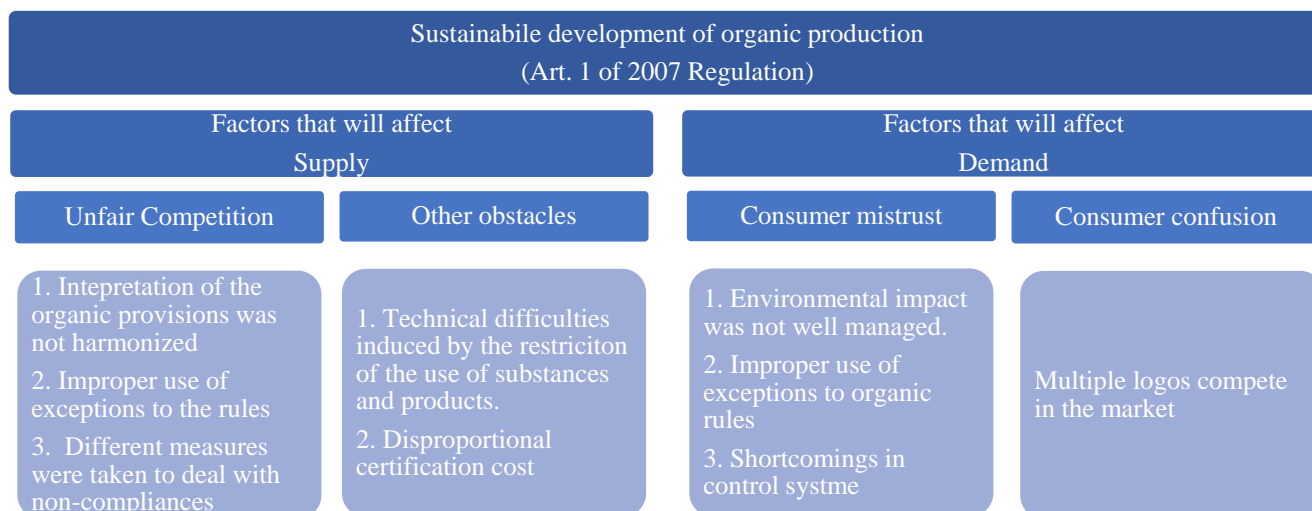
³³SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE., p.283-284; EUROPEAN COMMISSION 2012. Report From The Commission To The European Parliament And The Council On The Application Of Council Regulation (Ec) No 834/2007 On Organic Production And Labelling Of Organic Products.; EUROPEAN COURT OF AUDITORS 2012. Audit Of The Control System Governing The Production, Processing, Distribution And Imports Of Organic Products. p.37

³⁴ EUROPEAN COURT OF AUDITORS 2012. Audit Of The Control System Governing The Production, Processing, Distribution And Imports Of Organic Products., p.38 & p.65

³⁵ EUROPEAN COMMISSION 2014c. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 9 to 17. Annex 12

³⁶ DIRECTORATE FOR HEALTH AND FOOD AUDITS AND ANALYSIS (DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY). 2016. Organic production-Recognised control bodies operating in third countries. Available: <http://www.sinab.it/sites/default/files/FVO%20Report%20-%20Organic%20Production%20-%20Recognised%20Control%20Bodies%20in%20Third%20Countries%20-%202015.pdf> [Accessed 20th December 2018].

The deficiencies abovementioned could be summarized as the graph below,



Considering the issues abovementioned, it is understandable that the EU policy makers felt the need to introduce a new regulation. However, a number of provisions in the new Regulation raise the concern of potential barriers to trade, and that leads to the doubts of consistency with the WTO disciplines. These issues will be considered below after a look at the 2018 Regulation.

3. The new Regulation and concerns:

3.1 Changes introduced by Regulation (EU) NO.2018/848

The Regulation (EU) NO.2018/848 introduced a number of changes to the previous organic legislation in response of many deficiencies mentioned in the previous Chapter. The main changes include the following: a) making the legislative framework become clearer and much harmonized, b) production rules are more in line with organic objectives and principles, c) the adoption of risk-based control system, and d) applying one-set rules to both products originated from the EU and from third countries.³⁷ An overview of the changes is provided below.

Scope

The scope of the 2018 Regulation is clearer than the 2007 Regulation. Previously, there was uncertainty of the scope of products regulated by the EU organic legislative framework, and that made some operators hesitate to get involve in the business of organic products. The 2018 Regulation addresses the problem by referring to Annex I to the TFEU and introducing a list of products that are not clearly covered by the categories stipulated in the law.³⁸

Objectives and Principles

³⁷ IFOAM-EU Group. "The New Eu Organic Regulation, What Will Change?" (2018). https://www.ifoam-eu.org/sites/default/files/eb_ifoameu_regulation_what_will_change_1.pdf; European Commission. "European Commission - Fact Sheet the New Organic Regulation." http://europa.eu/rapid/press-release_MEMO-17-4686_en.htm.

³⁸ Article 2.1 of Regulation (EU) NO.2018/848, "... This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union."

To achieve a higher consumer confidence in organic products, several new objectives and principles are added to the 2018 Regulation. Those objectives are, a) the encouragement of short distribution channels and local production, b) maintaining the long-term fertility of soils, c) contribution to a non-toxic environment, d) fostering the development of organic plant breeding activities and e) the exclusion of food containing, or consisting of, engineered nanomaterials.³⁹ In addition to the new objectives, the principles of the connection to soil and biodiversity are reinforced.⁴⁰ This can be seen in the production rules, which clearly regulates the exceptions to the principle of soil-related organic production and the use of diverse plant genetic material to achieve a high level of biodiversity. Such relevant production rules are mentioned below.

Production rules

A. Production rules for farmers

Production rules for organic farming are more in line with organic objectives and principles. As mentioned previously, the principles of biodiversity and soil-related production are reinforced and reflected by production rules. To achieve a high level of biodiversity, the 2018 Regulation lifted the restriction of the use of heterogeneous material.⁴¹ Previously, organic farmers could not use such materials because its high level of genetic and phenotypic diversity does not fulfil the EU marketing requirements on plant reproductive material. However, using such material could be beneficial for organic production as its characteristic of genetic diversity might reduce the spread of diseases and improve resilience.⁴² As for the concept of soil-related production, it is reinforced by making the exceptions to this principle clearer.⁴³ For instance, ornamentals and herbs are allowed to be planted in pots if they are to be sold together with the pot to the final consumer. In addition, ‘demarcated beds’ is in principle prohibited in organic farming, but for some operators in Finland, Sweden and Denmark have been certified as organic under 2007 Regulation are allowed to maintain their production surfaces till the end of 2030.⁴⁴

Another major amendment to the production rules for farmers is derogations. There were three types of derogations used frequently in practice allowed by the 2007 Regulation, namely the use of non-organic seed, young animals and feed. Those derogations are still allowed by the new regulation with similar conditions and authorization procedure as the 2007 Regulation.⁴⁵ The difference of the 2018 Regulation from the 2007 Regulation is that the termination of the derogations abovementioned is stipulated. The derogations from the use of organic plant reproductive material and organic young animals will expire in 2035, while the use of non-organic protein feed will phase out in 2025.⁴⁶ The termination of such derogations is expected to make organic production rules to be much closely linked to organic objectives and principles.

B. Production rules for food processors

³⁹ Article 4 (b), (d), (f), and (j) and Article 7 (e) of Regulation (EU) NO.2018/848.

⁴⁰ Article 5 (f) (ii) and Articles 4 (c) (j) and 6 (g) and (j) of Regulation (EU) NO.2018/848.

⁴¹ Article 13.1 of Regulation (EU) NO.2018/848.

⁴² Recital 36 of Regulation (EU) NO.2018/848.

⁴³ Point 1.3 to 1.5 of Part 1 of Annex II to Regulation (EU) NO.2018/848, which

⁴⁴ Point 1.5 of Part 1 of Annex II to Regulation (EU) NO.2018/848

⁴⁵ Relevant articles are Article 12.1, points 1.8.1, 1.8.5 of part I of Annex II to Regulation (EU) NO.2018/848 for plant reproductive material, Article 14, points 1.3.1 and 1.3.4 of part II of Annex II to Regulation (EU) NO.2018/848 for animal production, and Article 24.1, points 1.4.1 (h) (i), 1.9.3.1 (c), 1.9.4.2 (c) of part II of Annex II to Regulation (EU) NO.2018/848 for feed.

⁴⁶ Article 53 set the expiration date for the derogations from the use of organic plant reproductive material and from the use of organic animals, while points 1.9.3.1 (c), 1.9.4.2 (c) of part II of Annex II to Regulation (EU) NO.2018/848 for protein feed.

The production rules of processed food is slightly stricter than the 2007 Regulation. It is reflected mainly from the provisions regarding the ingredients that can be used in organic processed food and cleaning and disinfection products for use in processing. First of all, only natural flavours originating from the mentioned ingredients can be used in organic processing, while compared to the previous regulation, such restriction does not exist.⁴⁷ The use of non-organic ingredients is also subject to stricter regulation. The authorization of a Member State on the use of non-organic products can last 6 months (Article 25), which is 6 months shorter than the previous law.⁴⁸ In addition, the number of times that the authorization may be prolonged is reduced from 3 times to 2 times. In the case that MS consider it is necessary to make additional authorization after two prolongations, MS need to submit a request to the Commission.⁴⁹ Finally, a restricted list for cleaning and disinfection products is required to be established, according to Article 24.1 of the 2018 Regulation. Such list did not exist under the 2007 legislative framework.

C. Precautionary measures

The 2018 Regulation specifies the responsibility of operators to take precautionary measures for the prevention of the contamination of unauthorized substances. In comparison with the 2007 Regulation and its implementing act, the new legislation clearly stipulated what precautionary measures should be taken. In addition, it lays down the legal effect that the contaminated products shall not be marketed as organic or in-conversion products or used in organic production if operators do not apply precautionary measures.⁵⁰

Control System

The 2018 Regulation has made clearer relationship between the organic control system and the official controls on food and feed. The change is explicitly stated in the recital to the Regulation that official controls on organic products should be in accordance with Regulation (EU) 2017/625.⁵¹ Article 37 also stipulates that control rules are rules “in addition to the rules laid down in Regulation (EU) 2017/625”.⁵²

Apart from the harmonization of the laws, there are also some novelties in the control system. First of all, group certification is introduced to the EU operators for the purpose of reducing the certification cost for small-scale operators. Member States may also exempt small-scale operators from certification, provided that they sell small quantities of organic products directly to the final consumers.⁵³ New measures as such are expected to largely support small-scale operators to engage in organic production. Secondly, there are slight improvements on the issue of the presence of unauthorized substances. At the level of operators, as noted previously, they are responsible of taking precautionary measures to prevent organic products they sell from being contaminated by unauthorized substances. Where the presence of unauthorized products is substantiated, official investigations should be conducted immediately. The products concerned may not be sold as organic products before the result of investigation.⁵⁴ The novelty of the 2018 Regulation is that the methodology to detect and evaluate of

⁴⁷ Point 2.2.2. of part IV of Annex II to Regulation (EU) NO.2018/848; IFOAM-EU GROUP. 2018. The new EU organic regulation, what will change? Available: https://www.ifoam-eu.org/sites/default/files/eb_ifoameu_regulation_what_will_change_1.pdf; LEONE, L. 2018. Lost in Translation? The EU Law Reform of Organic Farming. *European Food & Feed Law Review*, 13.

⁴⁸ Article 29 of Regulation (Ec) No 889/2008

⁴⁹ Article 25 of Regulation (EU) NO.2018/848; Article 29 of Regulation (Ec) No 889/2008

⁵⁰ Articles 28 and 29.2 (b) of Regulation (EU) NO.2018/848

⁵¹ Recital 69 of Regulation (EU) NO.2018/848

⁵² Article 37 of Regulation (EU) NO.2018/848

⁵³ Articles 36 and 38.2 of Regulation (EU) NO.2018/848

⁵⁴ Article 29 of Regulation (EU) NO.2018/848

unauthorized substances is to be harmonized by implementing acts introduced by the Commission.⁵⁵ This responses to the deficiencies that the detection methods and follow-up interpretation varies among competent authorities, control bodies or control authorities.⁵⁶ However, the 2018 Regulation does not harmonize control actions to be taken when residues of unauthorized substances are detected. Member States can continue to apply rules for decertifying organic products containing non-authorized products or substances above a certain level, provided that these rules do not prohibit, restrict or impede the placing on the market of products produced in other Member States.⁵⁷

Another major change to organic control system is in regard to annual physical inspection. In the previous legislative framework, every operator shall receive one inspection per year. The new regulation changes such requirement to be more risk-based. Operators present a low likelihood of non-compliance and have a clean record at least three consecutive years could be inspected every 24 months instead of every year.⁵⁸ This measure is expected to focus the control resources on risks to the integrity of organic products. Finally, the regulation on the delegation and supervision of control bodies is stricter. More tasks can not be delegated to control bodies. In addition to the tasks regulated by the 2007 Regulation, such tasks include the authority to receive notifications of operators' activities, the assessment of the risk of non-compliance of imported products, and the establishment of a common catalogue of measures to be applied for cases of suspected and established non-compliance.⁵⁹ Regarding supervision of control bodies, the 2018 Regulation requires that an audit should be carried out by the competent authorities every year. In contrast, the previous regulations only stated that audit of control bodies should be conducted when competent authorities consider it is necessary.

Labelling

There is no much difference in labelling requirements between the 2018 Regulation and the previous legislative framework. One novelty is worth to be noted is that the flexibility is slightly increased in the indication of the origin of ingredients. While the 2007 Regulation stipulated that the indication of "EU agriculture" referred to at least 98 % of ingredients originated from the EU, the new provisions, in response to the opinion of the organic sector, lower the percentage to 95%.⁶⁰ However, for other issues raised concerns, the new legislative framework does not amend existing measures or introduce new ones to address the deficiencies. For instance, in its working document in 2014, the Commission mentioned multiple logos might create consumer confusions. However, the new regulation still allows the use of national logos and private logos to be used for advertising organic products.⁶¹

Imports

⁵⁵ Article 29.8 of Regulation (EU) NO.2018/848

⁵⁶ European Court of Auditors. "Audit of the Control System Governing the Production, Processing, Distribution and Imports of Organic Products." 2012; Directorate-General for Health and Food Safety (European Commission). "Pesticide Residue Control in Organic Production." 2015.; EUROPEAN ORGANIC CERTIFIERS COUNCIL. 2018. Eocc Presentation On Pesticide Monitoring. Available: <https://eocc.nu/news/eocc-presentation-pesticide-monitoring-biofach-2018/>.

⁵⁷ Article 29.5 of Regulation (EU) NO.2018/848.

⁵⁸ Article 38.3 of Regulation (EU) NO.2018/848.

⁵⁹ Article 40.4 of Regulation (EU) NO.2018/848.

⁶⁰ Article 32.2 of Regulation (EU) NO.2018/848.;Annex 8 of EUROPEAN COMMISSION 2014b. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 1 to 8. P.96

⁶¹ Article 33.3 of Regulation (EU) NO.2018/848; *ibid.* p. 91 to 92.

The 2018 Regulation makes a significant change to the import policies, where the principle of equivalence is replaced by compliance, with the exemption of equivalence recognized under a bilateral trade agreement.⁶² The change is expected to reduce the administration burden of the Commission and strengthen the control of imported products. Third countries which are currently recognized as equivalent need to renegotiate trade agreements with the EU before 2025. As for control bodies and control authorities recognized as equivalence under the 2007 Regulation, the recognition will expire by 2023.

The protection of the objectives that the Regulation pursues is also strengthened by the import rules. The 2018 Regulation stipulates that where an urgency associated with unfair practices or practices incompatible with the other objectives the regulation pursues, the Commission shall immediately act upon it. Measures that the Commission can take include verifying the product concerned the integrity of organic before placing in the market, prohibit the product concerned marketed as organic, or withdraw the recognition of the control authorities and control bodies.⁶³

Finally, in response to the concerns that the adoption of compliance import policy might ignore various conditions within third countries, Article 45 lays down authorizations for the use of products and substances in third countries. It specifies that the Commission should take into account the differences in farming conditions and traditions between the third country concerned and the EU when making authorization. Such considerations are also applied when the Commission determines whether a situation qualifies as catastrophic circumstances.⁶⁴

3.2 Concerns over the impact of 2018 Regulation on trade

The newly reformed organic regime clearly aims to foster the development of organic sector throughout the EU countries. It indeed makes some commendable changes to the previous legislative framework; however, it also triggers concerns regarding the implication of the Regulation to trade. Such concerns were induced mainly due to the amendment in import regime.

Recognition of equivalence is a process that assess different standards or technical regulations whether they can achieve the same objectives and principles. The introduction of the scheme to the EU import policies was in the context that a plethora of standards, labels, and certifications exists in the market. Regulation system on organic products in the world was and still is comprised of various private standards, national regulations and international provisions. This inevitably caused problems for operators engage in organic trade and might risk the development of organic sector in the long run. To reduce the duplication and cost of certification, equivalence recognition was therefore brought up as a solution to the organic sector. The International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF), created by a partnership between IFOAM, UNCTAD, and FAO between 2003 to 2008, considered equivalence as a core solution to the fragmented regulation system on organic products.⁶⁵ The scheme allows organic products produced in accordance with the standards or regulations of their own countries, as long as that standards or regulations are assessed as equivalent to those of the importing countries. Applying the principle does not only considerably facilitate the global trade of organic products but also closely connect to the organic principle as regards the adaption to regional differences in climate and local conditions.

In such context, it is not surprising that some stakeholders in organic sector expressed their concerns to the change

⁶² Articles 45 and 47 of Regulation (EU) NO.2018/848

⁶³ Article 46.9 of Regulation (EU) NO.2018/848

⁶⁴ Article 45 of Regulation (EU) NO.2018/848.

⁶⁵ INTERNATIONAL TASK FORCE. 2009. Harmonization and Equivalence in Organic Agriculture. Volume 6. Available: https://unctad.org/en/PublicationsLibrary/ditcted2009d1_en.pdf. p.5-6

in import rules of the EU. The greatest implication of the change would be on the operators in countries which currently are not recognized equivalence by the EU. For those operators in those countries, they currently have to comply with a production standard and controls rules of a CB or a CA that is recognized equivalence by the EU. The abolishment of the equivalence recognition of a CB or a CA means that the operators have to comply with a new set of rules, and thus the compliance cost might increase. The IFOAM-EU and the Fairtrade Advocacy Office had presented their opposition to the change.⁶⁶ They emphasized that the import scheme based on equivalence was “recognized the best practice for import regulation” that allowed the adaption to the diversity of organic farming. In contrast, the change might cause negative impact on operators in third countries and in the end constrain the availability and affordability of organic imports in the EU market. Operators in developing countries in particular would face difficulties, if not impossible, to meet the requirements of the EU. Even though there is a possibility to be recognized equivalence under a trade agreement, it might still not ease the difficulties as the negotiation process is resource consuming and more politically driven than technical driven.

The compliance difficulties induced by agro- climatic differences was also stated by some trade associations, such as AFRUIBANA, an African trade association of fruit producers and exporters.⁶⁷ The implication of the new import regime on trade was expressed explicitly by the Grain and Feed Trade Association (Gafta), which represents the interests of over 1800 importers in the UK. It demonstrated its worries in 2014 when the process of the reform began that,

*“.....The EU rules are not designed for imports and are very tailored to fit EU processes and does not take into account varying agro ecological conditions and stages of development and not designed for global applicability.this provision will mean that many countries will no longer be able to supply to the EU as many will never have the means to negotiate trade agreements, especially developing countries that do not have significant domestic organic markets eg Peru and Thailand or those that do not have a fully fledged systems in place ie Russia. From experience, we also know that trade agreements are very long and take years to negotiate. This provision could restrict imports and supply shortages for products used in EU processing.”*⁶⁸

The opinions abovementioned all mentioned a worry that the abolishment of the current import scheme based on equivalence is not likely to facilitate the trade with developing countries. For operators in those countries, they need to produce their products in conformity with the EU organic rules and be certified by control bodies recognized by the EU. This means that there might be a duplication of certification and an increase to their cost. Nevertheless, a much difficult situation might occur to operators in third countries if organic rules of the EU become stricter. Although it might be too soon to conclude whether it is stricter or not as many details of the 2018 Regulation are to be supplemented by implementing acts and delegating acts, the new regulation itself is enough to merit concerns to operators.

First of all, the 2018 Regulation have an ambition to use 100% organic seed in organic farming, and thus the derogation from the use of organic seeds requires authorization and will be terminated in 2035. It might be too early to know that whether third countries are able to meet such requirement before 2035; however, it seems already troublesome for operators in third countries to obtain an authorization of the use of non- organic seeds.

⁶⁶ IFOAM-EU & FAIR TRADE ADVOCACY OFFICE. 2016. Briefing on Import Aspects in the Proposed New Organic Regulation.

⁶⁷ EUROPEAN BUREAU FOR CONSERVATION AND DEVELOPMENT 2017. The end of the European Organic Label? : European Bureau for Conservation and Development.

⁶⁸ THE GRAIN AND FEED TRADE ORGANIZATION. 2014. Negotiations On Eu Proposal On Organic Production. Available: https://www.gafta.com/write/MediaUploads/Trade%20Policy/Position%20Papers/EU_proposal_on_Organic_Production.pdf.

The provision only requires that MS should set up a database and that the operators in the EU should consult the database to prove the supply of organic seed is not sufficient to meet their needs. However, the law does not regulate the same requirement on third countries and operators thereof. Instead, the regulation leaves the competence to authorize the use of non-organic seeds to control authorities and control bodies conduct certification in third countries.⁶⁹ It is not clear, though, how to prove the criterion of “not available in sufficient quality or quantity in the territory of the third country”. If the requirement of internet database is also applied to third countries, the measure might lead to cease of the export of organic products from third countries that do not have and might be difficult to establish such infrastructure, such as coffee beans from Ethiopia.⁷⁰

Another change of the regulation that might catch the attention of operators in third countries is the use of authorized substances and products, such as fertilizers, plant protection products, food additives, and non-organic products. For farmers, either in third countries or in the EU, the substances and products (e.g. fertilizers and plant protection products) that they can use in their farms should be authorized by the Commission. Given that there are the differences in farming conditions in third countries, a specific authorization of inputs used in third countries is allowed by the law, which in a way reduce the impact of compliance import policy on operators in third countries. However, considering that what the inputs can be used in organic farming will largely affect the production and quality of organic products, how the EU make authorization in the future is therefore critical for organic operators.

Similarly, the use of non-organic agricultural ingredients should be authorized by recognized control bodies or control authorities (Article 25). However, the provision seems problematic. According to Article 25, organic food processors can request for authorization for a maximum period of 6 months and such authorization can be prolonged twice. After two time of prolongation, it is possible for processors in the EU to continue use the non-organic ingredients requested as long as the Commission permits the request made by the MS (Article 25.5). In contrast, it seems impossible for operators in third countries to continually use the ingredients they need in their production as the provision only specify the MS can make such request to the Commission. The options of non-organic ingredients that operators in a third country have will possibly be restricted if further prolongation is not possible. This in the end might put operators in third countries in a less competitive position than their counterparts in the EU.

4. Applicability of WTO Laws

To examine the consistency of the Regulation with WTO laws, the first question should be addressed is which WTO agreement(s) is (are) applied. Thus far, there are 60 agreements under WTO, which could be categorized into three aspects: goods, services and intellectual property. Among those agreements, the General Agreement on Tariffs and Trade 1994 (GATT), the agreement of sanitary and phytosanitary measures (SPS) and the agreement of Technical Barriers to Trade (TBT) are relevant.⁷¹ GATT is relevant because trade in ‘goods’ are subject to the regulation. As for SPS and TBT, they are two specific WTO agreements laying down disciplines for goods trade involving standards or regulations of food safety and animal and plant health and safety, and product standards in general. Those agreements are relevant in this research as the EU organic regulation is involved, which sets forth the rules on the productions and labelling of organic products. Nevertheless, the applicability of the WTO rules are to be analyzed as the scope of

⁶⁹ Point 1.8.5.2 of Part I of Annex II of Regulation (EU) NO.2018/848.

⁷⁰ SCHMIDT, H. 2018. Das neue Unionsrecht der Biolebensmittel: Krieg in den Dörfern und Konformität statt Gleichwertigkeit. *Zeitschrift für das gesamte Lebensmittelrecht*, 434-485.

⁷¹ WORLD TRADE ORGANIZATION 1994c. General Agreement on Tariffs and Trade 1994. Geneva: WTO, WORLD TRADE ORGANIZATION 1994a. Agreement on Technical Barriers to Trade. Geneva: WTO, WORLD TRADE ORGANIZATION 1994b. Agreement on the Application of Sanitary and Phytosanitary Measures. Geneva: WTO.

application of each rule differs. The analysis is presented below.

4.1. Applicability of GATT

GATT lays down the basic principles for trade in goods, and based on the principles that GATT established, there are additional agreement, such as TBT and SPS, dealing with specific sector or issues. In other words, the application scope of GATT is the broadest. The agreement applies to any measure imposed on the trade of goods, including customs duties, charges, and rules and formalities in connection with importation and exportation.⁷² Thus, the provisions of the EU organic laws, which regulate or have effect on import or export of organic products, would fall within the scope of GATT.

4.2. Applicability of TBT

The scope of TBT agreement is laid down in Article 1, of which the key terms: “technical regulations”, “standards” and “conformity assessment procedures” are defined in Annex 1. Thus, the applicability of TBT Agreement is determined by whether the 2018 Regulation is regarded to be one of the technical barriers as defined in Annex 1 to the Agreement. Before going into detailed analysis, it should be noted that the 2018 Regulation is comprised of production rules, labelling rules, and rules of control. This analysis will first focus on exploring the rules of production and labelling as to whether they are technical regulations or standards as defined by the TBT agreement. If the result of the analysis is positive, then the control rules on organic products will be analysed if they are the conformity assessment procedure as defined by TBT agreement.

4.2.1 regulations or standards?

To determine whether the 2018 Regulation is a regulation or standard, the definitions of technical regulations and standards stipulated in points 1 and 2 of Annex 1 of TBT agreement should be examined respectively. When examining the language of these two provisions, it is noticeable to find that some of the constituents of a regulation and a standard are identical. That is, it should be a ‘document’ laying down ‘product characteristics’ or ‘related processes and production methods’, and it may include or deal exclusively requirements on labels, symbols, terminology, etc. used on a product, process or production method. Critical distinction between a standard and a regulation lies on whether a measure is ‘mandatory’. Simply put, a regulation is a technical barrier with mandatory characteristic, whereas a standard is not.

To examine whether the 2018 Regulation is a technical regulation, a three-tiered test adopted in the case of *EC – Asbestos* and in the later cases is applied.⁷³ A document is regarded to be a technical regulation if it meet the following criteria: a) there is an identifiable product or group of products, b) the subject matter of a regulation should include one or more product characteristics or related process and production methods, and c) compliance must be mandatory. The following sections will analyse the three criteria respectively.

I. identifiable product:

To begin with, the test of “identifiable” was illustrated by the abovementioned case law that it is not necessary to mention explicitly a product or group of products in a document. If a product or group of products could be identified through the enforcement and compliance of the document, then it can be regarded to be identifiable as well. In other words, case law adopted a broad interpretation of “identifiable”, ruling that the test is satisfied as

⁷² Those terms used in e.g. Articles I and III of GATT.

⁷³ Appellate Body Report. 2001a. *European Communities — Measures Affecting Asbestos and Products Containing Asbestos*. WT/DS135/AB/R. para. 66-70; Panel Report. 2002a. *European Communities - Trade Description of Sardines*. WT/DS231/R. para. 7.24-7.35; Appellate Report. 2002b. *European Communities - Trade Description of Sardines*. WT/DS231/AB/R. para. 173-195

long as a product is able to be recognized through either the language or the effect of the document concerned. In the case of the 2018 Regulation, arguably, the regulation expressly states an identifiable group of products. Products which are subject to the regulation can be recognized in Article 2 as

“... products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union”.

In addition, recalled that, in order to make the scope of products clearer than the 2007 Regulation, a list of products is specified by Annex 1 of the regulation, it is another evidence that a group of products can be identified through the language of the regulation.

II. product characteristics

The second test is whether the 2018 Regulation lays down product characteristics of the products concerned. The language of Annex 1.1 is not that clear and thus in some previous TBT cases further interpretation was required. In this section, the interpretation adopted by case law and compelling views of the text of Annex 1.1 will be demonstrated. Subsequently, based on the understanding of the article, the production rules and labelling requirements of the 2018 Regulation will be then analyzed in light of the characteristics of the measures.

Firstly, the meaning of “product characteristics” stipulated in Annex 1.1 was interpreted by case law that they should be any “objectively definable "features", "qualities", "attributes", or other "distinguishing mark" of a product.” For instance, “a product' s composition, size, shape, colour, texture, hardness, tensile strength, flammability, conductivity, density, or viscosity” can be regarded as product characteristics. Furthermore, WTO adjudicators viewed the second sentence of the article as “certain examples of "product characteristics” and concluded that product characteristics include both the features and qualities intrinsic to the product itself and “related characteristics, such as the means of identification, the presentation and the appearance of a product.”⁷⁴

As for the language of “their related process and production methods” (hereinafter PPMs), an issue is worth to be noted is the interpretation of the term “related”. In the case of *EC-Seals*, Appellate Body regarded that the word “their related” suggested that the PPMs concerned should “have a **sufficient nexus**” to product characteristics (*emphasis added*).⁷⁵ However, the meaning of “sufficient nexus” is not clearly specified by the case law and is not able to solve the question regarding whether non- product- related PPMs (NPR-PPMs) falls within the ambit of TBT agreement. It is uncontested that product-related PPMs are covered by TBT; however, the prevailing view regards that PPMs as stipulated in Annex 1.1 does not include NPR-PPMs.⁷⁶ Proponents of such view seems to understand “product characteristics” as “physical” characteristics, and thus “their related PPMs” should be interpreted as PPMs that would have impact on physical characteristics. In addition, a further evidence can be seen in the negotiation history of TBT agreement. The term “their related” was proposed by Mexico and adopted in the final TBT text to be put before process and product methods during the Uruguay Round negotiations. The purpose of the proposal as stated by Mexico was to leave out PPMs unrelated to product

⁷⁴ Appellate Body Report. 2001a. *European Communities — Measures Affecting Asbestos and Products Containing Asbestos*. WT/DS135/AB/R. para. 67; The interpretation was reiterated and adopted in later cases, such as *EC- Sardines* and *EC-SEALS*

⁷⁵ Appellate Body Report. 2014. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*. WT/DS400/AB/R ; WT/DS401/AB/R. para. 5.12.

⁷⁶ For example, WORLD TRADE ORGANIZATION. 2004. *Trade and Environment at the WTO*. at p.17; OECD. 1997. *Processes and Production Methods (PPMs): Conceptual Framework and Considerations on Use of PPM- Based Trade Measures*. OCDE/GD(97)137.. p.11.

characteristics from the scope of the TBT Agreement.⁷⁷

However, alternative view argues that the negotiation history is only a supplementary means of interpretation and in practice WTO adjudicators seldom resorts to that approach.⁷⁸ Instead, by strictly applying the interpretation approach of VCLT, the plain text of Annex 1.1 does not suggest that it excludes NPR-PPMs from the scope of TBT. In addition, some scholars argue that the proper understanding of the word “their related” should be that PPMs concerned are connected to an identifiable product, instead of product characteristics.⁷⁹ Such argument is in a way supported by Annex 1.2 as the immediate context. In other words, the prevailing view will lead to an inconsistent understanding of Annex 1.1 and 1.2 that NPR-PPMs could be technical standards but could not be technical regulations because Annex 1.2 does not include the word “their”.⁸⁰ Similarly, the prevailing view could also lead to a highly counter-intuitive result between the first and second sentence of Annex 1.1. That is, the prevailing interpretation of the second sentence appears to be that as long as the measure concerned is regarding requirements on product packaging, marking or labelling applying to PPMs, regardless that they are PR-PPMs or NPR-PPMs, TBT is applicable. Such understanding, however, will constitute an ironic result that measures based on the same NPR-PPMs, one of which is labelling requirement (e.g. cage- free eggs) and the other is not (e.g. ban on batter- cage eggs), will be treated under different WTO laws.⁸¹ Finally, from the point of view that TBT aims to address concerns over the protectionist or unilateralist abuse of technical barriers, some comments stated that the exclusion of NPR- PPMs is not logical as such measures are sometimes more problematic to trade.⁸²

The final element of Annex 1.1 that should be noted is the second sentence of the provision. A relevant issue with this research is whether the second sentence should read with the first sentence and be limited to labelling requirements on PR-PPMs. As noted previously, the prevailing view of this issue considers that the second sentence applies to all labelling requirements, regardless of PR- or NPR-PPMs.⁸³ Indeed, the textual reading of the sentence seems support such opinion., the word “also” in the second sentence indicates that the second sentence is additional to the first sentence. It seems that in the case of *EC- Asbestos*, the Appellate body took the same view and stated that product characteristics also include “related characteristics, such as the means of identification, the presentation and the appearance of a product.”⁸⁴ Another textual evidence can be seen in the omission of “related” before PPMs in second sentence, which indicates that a wider range of PPMs is covered by

⁷⁷ WORLD TRADE ORGANIZATION. 1995. *Negotiating History of the Coverage of the Agreement on Technical Barriers to Trade with regard to Labeling Requirements, Voluntary Standards, and Processes and Production Methods Unrelated to Product Characteristics*. WT/CTE/W/10.. para. 146.

⁷⁸ E.g. DU, M. 2017. What is a “Technical Regulation” in the TBT Agreement? *European Journal of Risk Regulation*, 6, 396-404.; DUR N, G. M. 2015. NTBs and the WTO Agreement on Technical Barriers to Trade: The Case of PPM-Based Measures Following US – Tuna II and EC – Seal Products. In: HERRMANN, C., KRAJEWSKI, M. & TERHECHTE, J. P. (eds.) *European Yearbook of International Economic Law 2015*. Berlin, Heidelberg: Springer Berlin Heidelberg, 87-136. (p. 108)

⁷⁹ E.g. HOWSE, R. 2013. Introduction. In: EPPS, T. & TREBILCOCK, M. J. (eds.) *Research Handbook on the WTO and Technical Barriers to Trade*. Edward Elgar Publishing, p. 3-4.

⁸⁰ DUR N, G. M. 2015. NTBs and the WTO Agreement on Technical Barriers to Trade: The Case of PPM-Based Measures Following US – Tuna II and EC – Seal Products. In: HERRMANN, C., KRAJEWSKI, M. & TERHECHTE, J. P. (eds.) *European Yearbook of International Economic Law 2015*. Berlin, Heidelberg: Springer Berlin Heidelberg, 87-136. (p. 104)

⁸¹ Ibid. (p. 102-103)

⁸² E.g. Ibid. (p. 106) and DU, M. 2017. What is a “Technical Regulation” in the TBT Agreement? *European Journal of Risk Regulation*, 6, 396-404.

⁸³ DU, M. 2017. What is a “Technical Regulation” in the TBT Agreement? *European Journal of Risk Regulation*, 6, 396-404.; CONRAD, C. R. 2011. *Processes and production methods (PPMs) in WTO law: interfacing trade and social goals*, Cambridge University Press. p. 386

⁸⁴ Appellate Body Report. 2001a. *European Communities — Measures Affecting Asbestos and Products Containing Asbestos*. WT/DS135/AB/R. para. 67

the second sentence than the first one. In fact, such view was also confirmed by WTO adjudicators. In the case of *US- Tuna II*, both of the panel and Appellate body ruled that the US “dolphin- safe” labelling requirements for tuna products, which were based on NPR-PPMs, were technical regulation.

Turning to the case of the 2018 Regulation, first of all, it seems that the labelling requirements on organic products satisfy the criteria of second sentence of Annex 1.1. The labelling requirements, specified in Chapter IV of the 2018 Regulation, include the conditions under which products may be labelled organic or its derivatives and diminutives (Article 30), the information that should be presented in the labelling (Article 32), and the use of the EU organic logos (Article 33). All these provisions “convey criteria to be fulfilled” in order to qualify for organic label, and that qualifies the definition of “labelling requirements” laid down in the ISO/IEC Guide 2: 1991.⁸⁵ The reason that the definition set forth by the Guide can be applied in this case is that TBT agreement does not define “labelling requirements” and it stipulates that the terms used in the agreement have the same meaning as the terms defined by the Guide.⁸⁶ Furthermore, as noted previously, labelling requirements based on NPR-PPMs are also covered by the second sentence. Therefore, although some of the production rules of the 2018 Regulation might be regarded as NPR-PPMs, it can still be concluded that the 2018 Regulation, which includes labelling requirements apply to organic products, satisfies the criteria of the second sentence of Annex 1.1.

Secondly, to examine whether the production rules of the 2018 Regulation fulfil the meaning of product characteristics or related PPMs, the interpretation of Annex 1.1 of TBT agreement mentioned previously is applied. To begin with, it seems that the production rules of the 2018 Regulation does not lay down “objectively definable” product characteristics, such as viscosity, shape, size or ingredients of a product. In fact, a product can be defined as organic product depends on the production and process methods it applied. In other words, whether a product is organic or not is not defined by the qualities or features of the end product but the production methods it applies. An evidence for that is Article 3 of the 2018 Regulation, which stated that “ ‘organic product’ means a product resulting from organic production”. In addition, by examining the production rules, it is indeed found that the production rules of the 2018 Regulation are PPMs, instead of product characteristics as stipulated in Annex 1.1 of TBT agreement. For instance, such regulations include the inputs (e.g. fertilizer) that can be used in the production of organic products, protection of animal welfare and environment, and measures to be taken to ensure organic integrity (e.g. precautionary measures).

Following that, the remaining question is that whether the production rules of the 2018 Regulation are “PPMs” as defined by Annex 1.1 of TBT. Production rules of the 2018 Regulation could be categorized into PR-PPMs and NPR-PPMs. Those of PR-PPMs include, for example, regulations on authorization of the use of certain inputs (e.g. fertilizer and plant protection products; Article 9.3) and exclusion the use of GMOs and products produced from or by GMOs (Article 5). Those measures prescribe PPMs that are detectable in final products and thus are PR- PPMs. On the other hand, many provisions of organic production rules are NPR- PPMs. Primary examples are the requirements of the use of organic inputs (e.g. organic seed and young animal), measures to ensure organic integrity (e.g. holding managed entirely organic and precautionary measures), and protection of environment and animal welfare (e.g. preventive measures to avoid negative environmental impact and requirements on livestock husbandry practices). Those measures do not or hardly have detectable or tangible influences on end products and thus are regarded as NPR- PPMs. It is uncontested that PR-PPMs are PPMs as defined by Annex 1.1 of TBT agreement; however, whether Annex 1.1. covers NPR- PPMs is a contentious issue. Recalled the debate illustrated previously, it seems that the opinions which regard that NPR- PPMs are within the meaning of Annex 1.1. is much reasonable. It is because by textual reading, context of the article, and the aims of TBT, there is no reason

⁸⁵ INTERNATIONAL ORGANIZATION FOR STANDARDIZATION 1991. ISO/IEC Guide 2:1991. 6 ed.

⁸⁶ First paragraph of Annex 1 of TBT agreement

to exclude NPR- PPMs from the scope of PPMs of Annex 1.1. Even though the negotiation history of the agreement indicated that the negotiators did not have the intention to include NPR- PPMs, the negotiation history is, however, in practice only a supplementary means to interpret WTO laws. By adopting such view of “PPMs” of Annex 1.1, it therefore can be concluded that production rules of the 2018 Regulation prescribes PPMs as defined by Annex 1.1.

III. Mandatory

To explore the meaning of “mandatory”, there are two views to be noted. One view of the term is that complying with specified product characteristics is compulsory for the products to be marketed.⁸⁷ For example, CE marking is required for a certain group of products to be marketed in the European Economic Area. Nevertheless, the Panel and Appellate body of *US-Tuna II* took a different view of the meaning of “mandatory”. The panel of the case found that the US “dolphin-safe” labelling scheme was mandatory because they were “in a binding and exclusive manner”, which regulated the use of the term “dolphin-safe” and alternative terms and required a specific standard should be complied with.⁸⁸ Panel’s opinion was supported by the Appellate Body, but critics have been made as such interpretation might extend the meaning of mandatory too broad to leave little room for voluntary labelling scheme.⁸⁹ In fact, one of the panel members dissented the prevailing opinion of the panel and instead supported the first view abovementioned. The dissenting opinion further clarified that *de facto* mandatory is within the meaning of Annex 1.1 of TBT, and it added that in a *de facto* mandatory situation (i.e. label for certain products are required by the private sector), such compulsory condition should be “sufficiently connected” to governmental actions.”⁹⁰ By applying this understanding, the dissenting opinion viewed the US regulation was not a technical regulation as, firstly, tuna products could still be sold in the US market without “dolphin-safe” label; secondly, the complainant could not demonstrate that it was the regulation at issue or other US government actions that led private sector to refuse to buy tuna products without such label.

When following the prevailing opinion of *US- Tuna II*, it seems that the 2018 Regulation is prone to be considered mandatory. It can be seen from the language of Article 30 of the regulation, which stipulates that “... **the terms listed in Annex IV and their derivatives and diminutives**, such as ‘bio’ and ‘eco’, whether alone or in combination may be used.....for the labelling and advertising of products referred to in Article 2(1) which **comply with this Regulation.**”⁹¹ In addition, in the second paragraph of the same Article, it clearly states that “for the products referred to in Article 2(1), **the terms referred to in paragraph 1 of this Article shall not be used...** for the labelling, advertising material or commercial documents of a **product which does not comply with this Regulation.**” Such provisions seem similar with the US regulation on “dolphin-safe” tuna products as they prescribe the use of the term “organic” and related terms; additionally, production requirements are specified and applied as the exclusive means of asserting “organic” status for a product. Thus, following the prevailing view of the Tuna case, the measures set forth by the 2018 Regulation could be mandatory.

However, considering that it is “trade of goods” that the TBT agreement regulates, it seems that the other view is

⁸⁷ E.g. NORPOTH, J. 2013. Mysteries of the TBT Agreement Resolved? Lessons to Learn for Climate Policies and Developing Country Exporters from Recent TBT Disputes. *Journal of World Trade*, 575-600.

⁸⁸ Panel Report. 2011. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/R. para. 7.142 to 7.144.

⁸⁹ E.g. ANKERSMIT, L. J. & LAWRENCE, J. C. 2012. The Future of Environmental Labelling: US–Tuna II and the Scope of the TBT (2012). *Legal Issues of Economic Integration*, 39, 127–47., and ARCURI, A. 2012. Back to the Future: US-Tuna II and the New Environment-Trade Debate. *European Journal of Risk Regulation*, 3, 177-189.

⁹⁰ Panel Report. 2011. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/R. para. 7.172 & 7.175.

⁹¹ Article 30.1 of the 2018 Regulation.

more reasonable. After all, whether the legal effect of a measure is mandatory or not should not only be determined by the language of a document but also by its effect on the behaviour of a business operator. In other words, concerning the ordinary meaning of the term and the aim of TBT agreement, it seems appropriate to interpret “mandatory” as “a condition that compliance with certain rules is compulsory for goods to be marketed.” Following this interpretation, then it is understandable that dissenting opinion of the Tuna case did not view the US regulation as mandatory as the trade of tuna products without “dolphin-safe” labelling was still possible and thus there was no compulsory condition. However, even agreeing with such a view, it is still doubtful whether “compulsory condition” should be caused by governmental actions. Recalled that the dissenting opinion held a view that when assessing whether there is a *de facto* mandatory situation, the compulsory condition should be sufficiently connected to the measure at issue or other governmental actions. Such opinion, however, seems to make the meaning of “*de facto* mandatory” too narrow. In fact, by plain reading of the language of Annex 1.1, it can not exclude a situation that the compulsory condition is made by the private sector. In addition, the view seems not sensible in a situation that it is very difficult to trade goods without certain claims or labels on products. Take the Tuna case for example. Supposed that at the time when the US regulation is introduced, consumer preference toward “dolphin-safe” tuna becomes dominant in the US market and that leads to hugely decrease in the sale of tuna products without such label. This might leave food business not much choice but to label tuna products as “dolphin-safe” in order to access the US market. By doing so, the use of the label and specific production methods should be applied in accordance with the US rules. In this case, could such a scenario not be regarded as “a condition that compliance with certain rules is compulsory for goods to be traded”?

The rationale behind the doubt abovementioned is that obligations introduced by TBT agreement are stricter toward technical regulations than to technical standards.⁹² Adding to that, the example mentioned previously exemplifies that it is particularly susceptible to discrimination against foreign business in a market condition like that, even such condition is not created or connected to governmental actions. In short, based on the plain reading of Annex 1.1 and the aim of TBT agreement to prevent disguised protectionism measures, it seems much reasonable to understand the meaning of “mandatory” as “a condition, that compliance with certain rules made by central governmental bodies, is compulsory for goods to be marketed, regardless such condition is made by governmental actions or not.”

Applying this understanding in the case of the EU organic regulation, it is then needed to examine whether there is a compulsory condition for exporters to comply with the EU rules. First of all, it should be noted that the organic regulation does not require products to be labelled “organic” in order to access the EU market. In other words, compliance of the regulation is not *de jure* mandatory. The remaining question is then whether it is *de facto* mandatory.

Although there is no sufficient market data to prove that the competitiveness of products produced organically in accordance with other organic standards would be hugely decreased without the EU organic label, however, there are several facts that indicated that compulsory condition could occur. Firstly, it is noteworthy that the price of organic food is generally higher than non-organic products, which is mainly caused by the higher production cost of organic products.⁹³ The fact alone is already put products produced organically in a less competitive position

⁹² This research is not intended to analyze whether the obligations toward technical regulations and technical standards are differentiated. Nevertheless, it is noteworthy that there are discussions about it. Some scholars view that there is not much difference in obligations applied to those two TBT instruments, while in the case of *US- Cool* the panel’s interpretation of the term mandatory indicated that it is possible that the obligations toward the two instruments are different. Relevant discussion could be seen in e.g., DAVIES, A. 2014. Technical regulations and standards under the WTO Agreement on technical barriers to trade. *Legal Issues of Economic Integration*, 41, 37-63.

⁹³ Relevant data could be seen in the report: EUROPEAN COMMISSION. 2005. *Organic Farming In The European Union*

if such products are not labelled organic. Additionally, consumer awareness of sustainability, health or safety etc. is increasing. In fact, the future growth of the EU organic market is projected to be largely affected by the demand based on such awareness.⁹⁴ It is then reasonable to assume that the sale of products without labels or claims that show the attributes abovementioned would suffer a huge negative impact. Plus, among the labels that deliver similar value to consumers, organic labels might be one of the most well-known in the EU market. One research on the sustainable market found that among all the sustainability standards it investigated (e.g., UTZ, Global G.A.P.), organic standards is the biggest in terms of certified area and product variety.⁹⁵ It is thus reasonable to assume that consumer awareness toward organic labels is higher than other sustainable labels due to its availability in the market. Additionally, a study researched in four countries on label schemes which deliver the value of reduced pesticides in apples showed that “the highest WTP (*wiliness to pay*) after information on pesticide use always goes to organic apples”.⁹⁶ Considering all the facts above mentioned, it is thus reasonable to assume that producers, who produce products in compliance with other organic standards than the one of the EU, might be forced to comply with the EU organic rules in order to access the EU market. In this regard, compliance with the EU organic regulation is mandatory.

Based on the analysis from 2.1.1 to 2.1.3, this research is prone to view the 2018 Regulation is a technical regulation rather than technical standard. Indeed, it should be acknowledged that the assessment of the term “mandatory” requires more quantitative market data to prove whether a compulsory condition exists. However, for the purpose of this research, i.e., analyzing whether the organic measures introduced by the EU would discriminate foreign exporters, the reason that compulsory condition does possibly exist is sufficient for further examination of the measure under the stricter obligations stipulated for TBT technical regulations.

4.2.2 Conformity assessment procedure

As discussed above, the labelling requirements and production rules set forth by the 2018 Regulation are TBT technical regulations. Following that, the certification requirements in chapter V and official controls provisions in chapter VI of the EU regulation could be regarded as “conformity assessment procedure” within the meaning of TBT agreement. The conformity assessment procedure is defined by the TBT agreement that “any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.”⁹⁷ The explanatory note of the definition further provides examples that could be considered as conformity assessment procedure in the context of TBT, such as procedures for sampling and inspection. In the case of the 2018 Regulation, certification is used for proving that products are produced and labelled in accordance with the requirements of the regulation. It can be seen in Article 35, which states that products should be produced in accordance with the regulation so that it can be certified organic. As for rules of official controls, it aims to verify the compliance with the regulation by laying down requirements such as frequency of inspection,

Facts And Figures. G2 EW - JK D(2005) , which stated that price premium of organic products could be varied from 0 to over 200% depending on the country and the products surveyed.

⁹⁴ USDA FOREIGN AGRICULTURE SERVICE. 2018. EU Organic Boom Brings Opportunities for U.S. Exporters. Available: https://gain.fas.usda.gov/Recent%20GAIN%20Publications/EU%20Organic%20Boom%20Brings%20Opportunities%20for%20U.S.%20Exporters_Berlin_Germany_2-6-2018.pdf [Accessed 18th Feb. 2019].

⁹⁵ LERNOUD, J., POTTS, J., SAMPSON, G., GARIBAY, S., LYNCH, M., VOORA, V., WILLER, H. & WOZNIAK, J. 2017. The State of Sustainable Markets 2017. Available: http://www.intracen.org/uploadedFiles/intracenorg/Content/Publications/State-of-Sustainable-Market-2017_web.pdf [Accessed 27th Feb. 2019].

⁹⁶ BAZOCHE, P., COMBRIS, P., GIRAUD-H RAUD, E., SEABRA PINTO, A., BUNTE, F. & TSAKIRIDOU, E. 2013. Willingness to pay for pesticide reduction in the EU: nothing but organic? *European Review of Agricultural Economics*, 41, 87-109.

⁹⁷ Annex 1.3 of TBT agreement

actions should be taken (e.g. sampling) and actions in case of non-compliance.⁹⁸ By plain reading of those provisions of the 2018 Regulation, they could be considered as conformity assessment procedure for verifying the technical regulations (i.e., production rules and labelling requirements) of the 2018 Regulation are fulfilled.

To conclude from the analysis of section 4.2.1 and 4.2.2, the 2018 Regulation is comprised of technical regulation and conformity assessment procedure in the context of TBT agreement, and thus obligations set forth by the agreement seems applicable. However, before drawing this conclusion, the applicability of the SPS agreement is needed to be examined. It is because Article 1.5 of the TBT Agreement stipulated that TBT measures exclude sanitary or phytosanitary measures as defined by the SPS Agreement. In other words, if SPS is applicable, then TBT is not. The applicability of the SPS agreement will be explored in the next section.

4.3. Applicability of SPS

As for SPS Agreement, its scope was stipulated in Article 1 of the SPS Agreement, that the SPS Agreement shall apply to sanitary or phytosanitary measure. Those measures as defined in Annex A were intended to protect human, animal or plant life or health. To illustrate, those measures involve the prevention from the spread of pests and diseases and from risks resulted from unsafe food, drink and feed. They can be in the form of laws, testing requirements, product criteria, process methods, etc.⁹⁹ In other words, a measure is not one of those stipulated in Annex A of the agreement, then SPS is not applicable. Following such an understanding, it is then necessary to examine the objectives pursued by the 2018 Regulation. The purposes of the Regulation, which are indicated in the recital (6) and Article 4, are to increase environmental protection, animal welfare, and biodiversity, to improve fair competition, and to strengthen consumer confidence toward organic products. None of those are the objectives defined by the SPS Agreement, and thus it seems that SPS is not applicable.

However, one could argue that the restriction of the use of plant protection products and additives have the incidental effect of protecting human health from such risks, and therefore the measure falls within the scope of SPS agreement. Indeed, typical SPS measures include those deal with additives and residues of pesticides in food and drink, and the restriction of the use of such substances under previous organic regulations did include the consideration of the risks to human health. This can be seen in the evaluation reports of the expert group for technical advice on organic production (EGTOP), which is established by the Commission to conduct the evaluation. More specifically, in order to identify whether the use of a substance complies with organic principles, as required by Articles 16 and 21 of 2007 Regulation, considerations involved, a) whether there is an authorization in general production and in organic production, b) necessity for use and whether known alternatives exist, c) origin of raw materials and methods of manufacture, d) potential risks to environment and animal welfare, e) potential risks to human health, f) potential risks to food quality and organic authenticity, g) the history of the use of the substance, h) regulation or standards of other countries (mainly the United States) and international institution (mainly Codex).¹⁰⁰

Considering that the authorization criteria under the 2018 Regulation are similar to 2007, it is reasonable to assume that the considerations abovementioned will be applied in the future evaluation after the application of 2018 Regulation.¹⁰¹ In other words, risks to human health are possibly taken into consideration of the authorization on the use of additives, plant protection products and fertilizers etc. Nevertheless, as illustrated

⁹⁸ Relevant Articles are 38, 41, and 42 of the 2018 Regulation.

⁹⁹ Point 1 of Annex A to SPS Agreement.

¹⁰⁰ Commission Decision 2009/427/EC established EGTOP; the evaluation reports published by EGTOP can be accessed by: https://ec.europa.eu/agriculture/organic/eu-policy/expert-advice/documents_en

¹⁰¹ Relevant provisions under 2018 Regulation are chapter II (organic principles) and art. 24 of 2018 Regulation, and under 2007 Regulation, title II (organic principles) and Articles 16 and 21 are relevant.

previously, the risks to human health are just one factor among multiple considerations. In fact, it can be seen from the considerations abovementioned that there are multiple purposes that the measure aims to achieve. For example, the consideration of organic authenticity reflects the objective of ensuring consumer confidence in organic products, which is not within the scope of the SPS agreement. The legal question here would then be, is SPS applicable if a measure serves multiple purposes that some of which are beyond the scope of SPS?

This question is relevant with the interpretation of Article 1.5 of the TBT Agreement, which specifies the mutual-exclusive relationship between SPS agreement and TBT agreement.¹⁰² A broad interpretation of this provision could be that TBT agreement should not be applicable where some of the purposes of a measure fall within the scope of SPS agreement. Nevertheless, the problem of this approach is that it is too simplified to capture the genuine objectives of a measure. It would also lead to a very bizarre result in the situation that the SPS consideration is only a minor one, and yet the whole measure would fall under the SPS Agreement.¹⁰³ Considering this, WTO panel in its ruling of *EC-Biotech* was thus not in favour of such interpretation; instead, the panel stated that both SPS and TBT agreement can be applied if a single measure could be divided into separate sub-measures. In other words, SPS is applicable to the extent that a sub-measure is applied for one of the purposes stipulated in Annex A (1) of SPS agreement.¹⁰⁴ Panel's interpretation seems much plausible in comparison with the first one. It is compatible with the textual meaning of Article 1.5 of the TBT agreement, while it respects the autonomy of WTO members to regulate measures with multiple purposes.

However, the panel's approach can not be applied in the case of the EU organic regulation as the measure concerned can not be divided into separate requirements serve independent purposes. Recall the considerations involved in the evaluation conducted by EGTOP, the expert group is required to review all the factors as a whole and can not authorize or prohibit the use of additives or plant protection products based on the consideration of risks to human health alone.¹⁰⁵ The panel did not provide an answer to the question regarding how to interpret Article 1.5 if a measure is indivisible as it was not an issue in the *EC-Biotech* case. The appropriate answer to this question seems to be "primary- ancillary" approach, where the predominant objectives decide the applicability of SPS agreement. This approach is reasonable as it is on the one hand in accordance with the textual reading of Article 1.5; on the other hand, the impact on the freedom of WTO members to regulate is minimized.¹⁰⁶ Applying this interpretation to the case of the EU organic regulation, it can be concluded that SPS agreement is not applicable because the predominant objectives of the EU regulation are not as those stipulated in the agreement.

In light of the discussion in this section, both TBT agreement and GATT are applicable. However, since the disciplines of TBT Agreement are inspired from GATT, questions arise regarding the order of application, and as to whether it is necessary to analyse the other if an inconsistency is found with one of the agreements. For the first question, WTO case law has stated that the TBT Agreement should be analysed prior to GATT, given that it is more specific on technical regulation. As for the latter question, WTO Case law also recognized that it is no need to examine additional claims "if the matter in dispute is sufficiently resolved by the findings on the first

¹⁰² Article 1.5 of TBT agreement

¹⁰³ GRUSZCZYNSKI, L. 2010. Regulating health and environmental risks under WTO law: a critical analysis of the SPS agreement. International Economic Law, p.63-66.

¹⁰⁴ Panel Report. 2006. *EC — Approval and Marketing of Biotech Products*. WT/DS291/R ; WT/DS292/R ; WT/DS293/R. para. 7.165

¹⁰⁵ See Article 24 of 2018 Regulation stipulated that, ".....The authorization of the products and substances..... shall be subject to the principles laid down in Chapter II and to the following criteria, which **shall be evaluated as a whole:**" (*emphasis added*)

¹⁰⁶ GRUSZCZYNSKI, L. 2010. Regulating health and environmental risks under WTO law: a critical analysis of the SPS agreement. International Economic Law, p.63-66.

claims examined (i.e. TBT Agreement)”¹⁰⁷ It seems also appropriate to apply such opinion in this research. It is due to that the purpose of this research is to explore whether the EU violates its obligation as a Member of WTO. Once inconsistency with the TBT Agreement is established, then it has sufficiently suggested that the EU is in violation of WTO obligations. It is therefore not necessary to apply GATT. Besides, logically, the result of the application of these two agreements should not be contradictory. In this regard, the following section will focus on the analysis of the TBT agreement.

5. Consistency analysis

Having discussed the applicability of the TBT agreement, the research then moves on to analyse the obligations of the agreement on technical regulations and conformity assessment procedure. In this section, key principles of TBT agreement are analysed: non-discrimination, avoidance of unnecessary barriers to trade, the use of international standards and technical assistance and special and differential treatment for developing countries. In addition, Articles 2.7 and 6 will also be examined as the abolishment of the equivalence principle in import policy is of concerned to foreign exporters. Nevertheless, since the focus of this research is on the content of the 2018 Regulation, the requirements regarding transparency (e.g. Article 2.9 of TBT agreement) will not be discussed in this research.

5.1 Non-discrimination principle:

5.1.1 consistency with Article 2.1:

Article 2.1 of TBT Agreement stipulated the principle of non-discrimination, which contains a national treatment and a most-favoured-nation treatment (MFN) obligation. Specifically, the TBT Agreement requires a WTO Member to accord products treatments no less favourable than those to “like products” produced within its territory and from other Members. Such a requirement prohibits both *de jure* and *de facto* discrimination.¹⁰⁸ Generally, in a TBT dispute, whether products at issue are like will be firstly examined, which is followed by the analysis of the second element, “no less favourable treatment”.

5.1.1.1 like products:

The meaning of “like products” was not defined in TBT disciplines and the WTO/ TBT case law has referred to the interpretation approach adopted in GATT case law. One of the important rulings in the context of GATT was *EC — Asbestos*. In that case, the AB interpreted the term “like products” of GATT Article III: 4 through analysing whether there is “competitive relationship” among products in the market.¹⁰⁹ In addition, four factors, namely physical characteristics, HS classification, consumers’ tastes and habits, and product end uses, were also considered in the test of likeness. Such opinion was then adopted by the first case addressed the issue in the TBT context, *US — Clove Cigarettes*. The Appellate Body ruled that “likeness” in Article 2.1 of TBT Agreement “has to be based on the text of that provision as read in the context of the TBT Agreement and of Article III:4 of the GATT 1994”¹¹⁰ The view has been adopted by WTO/ TBT case law

¹⁰⁷ Panel Report. 2011. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/R. para. 7.743

¹⁰⁸ Appellate Body Report. 2012a. *United States - Certain Country of Origin Labelling (COOL) Requirements*. WT/DS386/AB/R. para. 269; Appellate Body Report. 2012b. *United States — Measures Affecting the Production and Sale of Clove Cigarettes*. WT/DS406/AB/R. para. 181.

¹⁰⁹ Appellate Body Report. 2001a. *European Communities — Measures Affecting Asbestos and Products Containing Asbestos*. WT/DS135/AB/R. para. 103.

¹¹⁰ Appellate Body Report. 2012b. *United States — Measures Affecting the Production and Sale of Clove Cigarettes*. WT/DS406/AB/R. para. 120

afterwards.

For the purpose of this research, the likeness of organic products produced in- and outside the EU, in general, is assessed. This research views that there is a competitive relationship between imported organic products and organic products produced in the EU. Taking into account the factors above mentioned, except for HS classification, there isn't much difference in organic products produced in- and outside the EU.¹¹¹ It is understandable that the two types of products are like on the market. After all, the labelling and certification system for organic production serves the exact purpose of ensuring products bearing with organic term to be recognized on the market as products satisfying the same minimum quality requirements.

5.1.1.2 No less favourable treatment:

The second element of the analysis of Article 2.1 of TBT, i.e., “less favourable” was assessed through a two-step analysis by WTO adjudicators.¹¹² It was firstly opined by the Appellate Body of *US – Clove Cigarettes* that the term should be interpreted as detrimental impacts to trade that do not exclusively stem from legitimate regulatory distinctions.¹¹³ The rationale behind such interpretation is that the TBT Agreement does not contain a general exception clause similar to Article XX GATT. This interpretation was then crystallized in subsequent cases. That is, to assess whether a measure is less favourable or not, it should be examined, i) whether the measure modifies the competition condition of the products at issue vis-à-vis like products in the market, and ii) whether such detrimental impact stems exclusively from a legitimate regulatory distinction.

When considering the first element of the test of “less favourable”, i.e., whether competition condition is modified, Appellate Body of *US- COOL* noted that “any adverse impact on competitive opportunities” is relevant to the assessment. It also clarified that such impact might be the result of “the design and structure of the measure itself, as well as all features of the particular market at issue that are relevant to the measure's operation within that market”.¹¹⁴ As for the second element, “exclusively stems from legitimate regulatory distinctions”, the WTO adjudicators opined that whether the measure at issue is even-handed should be examined, in particular in the assessment of *de facto* discrimination. In assessing “even-handedness”, the Appellate Body further noted that the particular circumstances of the case, that is, the design, architecture, revealing structure, operation, and application of the technical regulation at issue should be scrutinized.¹¹⁵

It is worthy to be noted the relevance of the jurisprudence of the chapeau in Article XX of the GATT 1994 with the test of even-handedness under the TBT Agreement. Some research viewed that the test of “arbitrary or unjustifiable” in the context of GATT seems to be slightly different from what has been applied in the

¹¹¹ In the EU, there is no specific classification for organic products and thus HS classification is not applicable in this research.

¹¹² Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 215; Appellate Body Report. 2012a. *United States - Certain Country of Origin Labelling (COOL) Requirements*. WT/DS386/AB/R. para. 271; Appellate Body Report. 2015. *United states - Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products - Recourse to article 21.5 of the DSU by Mexico*. WT/DS381/AB/RW. para. 7.26.

¹¹³ Appellate Body Report. 2012b. *United States — Measures Affecting the Production and Sale of Clove Cigarettes*. WT/DS406/AB/R. para. 174.

¹¹⁴ Appellate Body Report. 2012a. *United States - Certain Country of Origin Labelling (COOL) Requirements*. WT/DS386/AB/R. para. 286.

¹¹⁵ Appellate Body Report. 2012b. *United States — Measures Affecting the Production and Sale of Clove Cigarettes*. WT/DS406/AB/R. para. 182

case law of TBT Agreement.¹¹⁶ In their opinion, factors, such as whether the measures at issue was applied in an excessively inflexible manner, or whether efforts were made to negotiate a multilateral solution before the adoption of unilateral measures, are considered when determining whether the measure at issue is arbitrary or unjustifiable in the context of GATT. Such elements, however, seem not to be applied in the TBT context. Following that, they concluded that this might result that measures were much easily justified under the TBT Agreement because respondent bears less burden to prove their good faith. However, it could be argued that TBT case law already suggested that the elements considered in the context of Article XX under GATT are also relevant to the test of even-handedness under the TBT Agreement. Firstly, in the case of *US-COOL*, the AB noted that a manner is not even-handed because it is “designed and applied in a manner that constitutes a means of arbitrary or unjustifiable discrimination”. The language used is similar to the language of GATT XX chapeau. In addition, in the recent case of *US – Tuna II (Article 21.5 – Mexico)*, the AB confirmed that “the jurisprudence under the chapeau of Article XX is relevant to understanding the content of the second step of the 'treatment no less favourable' requirement under Article 2.1 of the TBT Agreement.”¹¹⁷ It further clarified that the correlation of the discrimination and the pursuit is “one but not the only one” element to assess even- handedness.¹¹⁸

To explore whether the 2018 Regulation might cause discrimination to organic products from some countries, the following analysis will firstly examine the conformity of the requirement of national treatment and then the consistency with the most-favoured-nation obligation.

I. The conformity of national treatment:

- *Does the 2018 Regulation constitute de jure discrimination?*

The 2018 Regulation, in contrast to the previous legislative framework, adopts one-set rule approach to regulate the organic sector. This means that, in principle, all the products bearing the organic term on the EU market shall be produced in compliance with the same rules. Only products from countries that are recognized equivalence under a treat agreement with the EU may be produced in accordance with different but equivalent rules.

The concept of one-set rules indicates that the EU should not treat products of the EU and of the countries outside the EU differently. By examining the Regulation, it is indeed designed in that way. However, it is also discovered by this research that when addressing the use of non-organic substances and agricultural ingredients for processed organic food, a different treatment is accorded, and that difference might be problematic to operators outside the EU.

The EU regulates the use of non-organic substances by introducing a restricted list. Operators may only use the substances listed on the list in organic production. The list is applicable to all the operators who intend to sell their products in the EU market. However, while the EU Member States has the right to request the Commission to add or withdraw certain substances from the list, the CBs or CAs do not have such right.¹¹⁹

¹¹⁶ KIM, H. 2013. Do Trade Liberalization and International Trade Law Constrain Domestic Environmental Regulation? *Environmental Law Reporter*, 43 (9), p. 10836-10838.; DUR N, G. M. 2015. NTBs and the WTO Agreement on Technical Barriers to Trade: The Case of PPM-Based Measures Following US – Tuna II and EC – Seal Products. In: HERRMANN, C., KRAJEWSKI, M. & TERHECHTE, J. P. (eds.) *European Yearbook of International Economic Law 2015*. Berlin, Heidelberg: Springer Berlin Heidelberg, 87-136.

¹¹⁷ Appellate Body Report. 2015. *United states - Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products - Recourse to article 21.5 of the DSU by Mexico*. WT/DS381/AB/RW. para.7.88

¹¹⁸ Ibid. para. 7.93 & 7.94

¹¹⁹ Article 24 (7) of the 2018 Regulation.

This might put the operators who export their products to the EU under the compliance scheme at a less competitive position. Similarly, the use of non-organic agricultural ingredients may be approved in two ways. On the one hand, a restrictive list is introduced by the Commission according to Article 24 of the Regulation; on the other hand, Member States can provisionally approve such use within their territory under the conditions set out by Article 25. For imports, producers either are obliged to comply with the restrictive list introduced by the Commission or can request an approval from CBs or CAs. Basically, the request of such use from an operator, regardless that he is based in or outside the EU, can be approved under the following conditions,¹²⁰

- i. such ingredients are not available in organic form in sufficient quantity,
- ii. the period of the use is limited for a maximum of six months,
- iii. the authorization may be prolonged for two times for a maximum of six months each.

The distinction between products from and outside the EU lies in the procedure of adding non-organic agricultural ingredients in the restrictive list made by the Commission after the two times of prolongation. According to Article 25(5), MS in the EU can request the Commission to add new ingredients to the restrictive list as referred to in Article 24, provided that the availability of such ingredients in organic form remains insufficient to meet the needs of EU operators after two times of prolongation. However, such provision seems not applicable to operators outside the EU as it specifies that only MS could make such request to the Commission. The implication of this Article might be that the ingredients that could be used by operators outside the EU would be limited and thus could negatively affect their competitiveness.

This research is aware that so far, there has no comment on these provisions in the available literature and no evidence has shown that this distinction will have an impact on trade. However, the impact on trade arisen from this distinction can not be excluded; thus, it is interesting to further explore whether such distinction could be view as “a less favourable treatment” within the meaning of TBT. For the purpose of illustration, an imaginary case is established. That is, the production of product A in country X requires the use of ingredient B, which is non-organic. The availability of the ingredient B in organic form, however, is not sufficient and not listed in the restrictive list made by the Commission. According to the 2018 Regulation, product A can not be certified organic if it still contains non-organic B after two times of prolongation of the authorization on the use of B. Country X, therefore, complains that the EU measure discriminates products originated from its territory because the product at issue can not access the EU organic label due to the impossibility of the use of the ingredient B.

The legal question here then would be whether product A is accorded treatment less favourable than that accorded to its like products without ingredient B. To assess the question, recalled that WTO case law applies a two-step test, i.e., whether there is detrimental impact and whether such impact stems exclusively from a legitimate regulatory distinction. In the analysis of detrimental impact, country X needs to prove that the competitive conditions of product A are modified by the measure at issue. In the case of *US- COOL*, the Appellate Body further clarified that “any adverse impact on competitive opportunities” is relevant to the assessment.¹²¹ In addition, recalled that in the case of *US- Tuna II*, the Appellate Body found that the detrimental impact on Mexican tuna products is caused by the fact that Mexican tuna products are not

¹²⁰ Article 25 (1) through (4) of the 2018 Regulation.

¹²¹ Appellate Body Report. 2012a. *United States - Certain Country of Origin Labelling (COOL) Requirements*. WT/DS386/AB/R. para. 286.

qualified for a “dolphin-safe” label.¹²² Country X could use the views abovementioned as a useful reference. Thus, it could claim that the *de jure* distinction made by Article 25.5 modifies the competitive condition of product A as the product which requires the use of the ingredient B can not be marketed with the organic label in the EU market.

A possible argument made by the EU could be that Article 25 does not prohibit the use of certain non-organic agricultural ingredients and that it is possible for operators in country X to replace ingredient B with other agricultural ingredients. Besides, even though there is an adaption cost for operators in country X due to the change of ingredient, the cost alone does not necessarily imply that discrimination exists. This is because a technical regulation, by prescribing certain requirements, would naturally have a different impact on operators in the market.¹²³ In this regard, the EU could rebut that there is no adverse impact on product A.

Indeed, Article 25 does not specify the ingredients that are banned. It seems different from previous WTO cases, such as *EC- Asbestos* and *US- Clove*. The measures at issue in those disputes prohibited the use of certain ingredients and thus were regarded as having a detrimental impact on imports. Contrarily, in the case in question, it lays down the conditions that MS could make a request to the Commission for authorization. In other words, Article 25 only provides a possibility for certain non-organic products to be included in the restrictive list and does not make any prohibition. However, such an argument seems not persuasive enough. Arguably, Article 25 should be read with Article 7. That is, organic processed food should be produced from “organic” agricultural ingredients and only under certain circumstances that non- organic ingredients can be used. Thus, without being provisionally authorized by MS or recognized control bodies (Article 25) or being authorized by the Commission (Article 24), non- organic ingredients can not be used. In this regard, although Article 25 does not directly ban on the use of certain ingredients, for exporting countries without the possibility to make a request to the Commission for the inclusion of the ingredients used in their production, it is in effect a ban on the use of such ingredients.

As for the evaluation of the adverse impact on trade, by examining previous case law, it seems that WTO jurisprudence would not support the view that there is no impact on trade in such a case. In particular, when determining the detrimental impact on Mexican tuna products induced by the lack of access to “dolphin-safe” label, the ruling of the AB seems based on the “current status” of the practices of Mexican and US tuna fleets.¹²⁴ It indicates that whether there are alternatives to prohibited PPMs or ingredients is not a consideration in the assessment of detrimental impact. Following that, country X could argue that as the current status of the production of A and its like product, product A containing ingredient B is not eligible for the organic label, while products without such ingredients are potentially eligible for the label. As a result, country X could argue that the lack of access to the label causes an adverse impact on product A.

It is also possible for the EU to claim that such distinction stems exclusively from regulatory distinction. However, in the view of this research, it is difficult to imagine a justification for this distinction. Therefore, based on the discussion abovementioned, this research considers that it is likely that in the imaginary case given, Article 25.5 could be regarded inconsistent with Article 2.1 of the TBT agreement.

□ *Does the 2018 Regulation constitute de facto discrimination?*

¹²² Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 284.

¹²³ See Panel Report. 2011. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/R. para. 7.345.

¹²⁴ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. paras. 234 and 235.

As demonstrated previously, some stakeholders in the organic sector have already voiced their concerns toward the impact on trade that the 2018 Regulation might cause. However, the rationale behind their disapproval is not clear. To demonstrate how the 2018 Regulation could be problematic for the operators in non-EU countries, some of the provisions of the 2018 Regulations, where its difference from the previous EU organic regulations and other organic norms is obvious, are selected to be further explored. Those are the regulation of the use of organic inputs, the use of authorized substances and livestock production rules.

To begin with, the use of organic inputs is one of the essential principles in the Regulation.¹²⁵ The 2018 Regulation reinforces the principle as compared to the 2007 Regulation. It is stricter than the previous EU regulations in the sense that the derogations from the principle will be much restricted. In particular, the EU set the goal to prohibit the use of non-organic seeds and non-organic young animal by 2035.¹²⁶ Operators in developing countries or LDCs might find it challenging to fulfil the requirement. To illustrate, take the provision regarding the use of organic seed for example. It is doubtful that operators in developing countries or LDCs could achieve the goal of 100% use of organic seeds by 2035, while it seems also challenging for the EU organic sector. This can be seen from the project LIVESEED coordinated by IFOAM EU and FiBL. The project identifies several challenges to be overcome and involves in efforts from multiple institutions to improve the use and production of organic seeds in the EU.¹²⁷ This indicates that to achieve the goal, extensive knowledge and resources might be required. Thus, it is reasonable to doubt that whether operators in developing countries or LDCs are able to source sufficient organic seeds when they might have less institutional resources than the EU to promote the development of organic seeds.

Even if it might be too early to speculate whether the goal of the use of 100% organic seeds will be problematic for operators in the countries of concern, the condition that should be met to acquire a derogation from the requirement could also be troublesome, as mentioned previously in chapter 3.2. Point 1.8.5 of Annex II to the 2018 Regulation lays down the conditions that the derogation can be allowed. The EU operators are required to consult the database established by MS to justify their needs of the use of non-organic seeds; however, it is not clear if operators in third countries are required to do so. Considering that the EU emphasized one- set rules to all the organic operators as one essential part of the legislative reform, it is possible that operators in third countries are required to take a similar burden of proof as the EU operators do. If it is the case, it could be expected that some operators in countries with less- developed infrastructures would find it, if not impossible, troublesome to justify their needs of the use of certain non-organic seeds.

Apart from the requirements on the use of organic inputs, the provisions regarding the use of authorized substances are also of concerned. The differences in farming conditions among countries might lead to the substances necessary for farming vary between countries. In fact, the authorization of the use of certain substances in organic farming could be a critical issue for trade negotiations of organic products between countries.¹²⁸ It is also noted by experts in the organic sector that organic standards are actually similar but the details, such as particular input used for pest control, are different.¹²⁹ It thus could be worrisome for

¹²⁵ Relevant Articles are Articles 6 to 8 of the 2018 Regulation.

¹²⁶ Article 53 of the 2018 Regulation.

¹²⁷ LIVESEED. n.d. *Our objectives and aims* [Online]. Available: <https://www.liveseed.eu/> [Accessed 6th March 2018].

¹²⁸ See FRATINIVERGANO. 2019. *New Zealand to introduce national legislation on organic production and the EU amends its legal framework for organic products – an issue for EU-New Zealand trade negotiators?* [Online]. Available: http://www.fratinivergano.eu/en/issue-number-1-11th-january-2019/#_New_Zealand_to [Accessed 7th March 2019].

¹²⁹ INTERNATIONAL TASK FORCE. 2009. *Harmonization and Equivalence in Organic Agriculture. Volume 6.* Available: https://unctad.org/en/PublicationsLibrary/ditcted2009d1_en.pdf.

operators in third countries if the substances authorized by the EU is oriented toward the needs of the EU operators. Finally, the livestock production rules might also be troublesome for operators outside the EU. It is noted by Seufert et al. that the specific requirements of livestock production vary substantially among regulations. For example, the EU specifies the minimum surface for indoor and outdoor areas for specific livestock species, while the regulation as such is not commonly seen in other organic standards.¹³⁰

Following the discussion above, it is understandable that some operators in developing countries and least developed countries (LDCs) in particular might feel that they are accorded less favourable treatment than those within the EU. They might complain that, comparing to their competitors in the EU, they have less opportunity to access the organic label in the EU market. The differences in climatic and geographic conditions between those countries and the EU could make organic farmers in some countries particularly difficult to comply with the EU production rules. In addition, they might have less capability and resources that are needed for complying with the technical rules and CAPs of the EU than their competitors in the EU. It is thus possible for operators in the third countries concerned to establish a *prima facie* case. Importantly, following the view of *US- Tuna II* regarding detrimental impact, the complainant could claim that the Regulation hinders their organic operators from accessing the EU organic label as their operators are difficult, and in some cases not possible, to access the EU organic label.

However, even though a complaining Member could prove the claim abovementioned, it does not necessarily mean that the 2018 Regulation is not consistent with WTO disciplines. Importantly, the second element of the assessment of “less favourable treatment”, i.e., whether detrimental impact stems exclusively from regulatory distinctions, should be further assessed. To assess the element, as mentioned previously, the WTO adjudicators practice the test of even-handedness, in which factors considered in the test of GATT XX chapeau are also applied. It is also observed that, in the context of TBT, WTO adjudicators would find a distinction not legitimate if it is not calibrated to or is reconciled with the objectives of the concerned measure.

Turning to the examination of the 2018 Regulation, it is firstly noted that the correlation between the measures and the objectives pursuit may not be difficult to be established. Taking the three regulations discussed above for instance. The use of organic seeds, on the one hand, serves the purpose of environmental protection by ensuring that the whole production chain, from the beginning to the end, is in line with the organic production rules. On the other hand, it also ensures organic integrity and thus maintains consumer confidence in organic products. As for rules regarding the burden of proof for requesting the derogation from the use of organic seeds, the EU could claim that placing similar burden of proof on operators in third countries would prevent inappropriate and excessive use of such derogation and ensure fair competition. Similarly, the provision of the use of authorized input aims to restrict the use of external input in organic farming. When comparing to the previous legislative framework, where the various private standard may apply, the EU could have better control over the use of such substances under the new regulation. This could contribute to the reduction of environmental impact resulted from food production activities. As for livestock production rules, many of them are obviously set out for the purpose of the protection of animal welfare. For example, the requirement of minimum surface for indoor and outdoor areas for animals aims to “ensure that the developmental, physiological and ethological needs of animals are met”.¹³¹

As to whether the EU Regulation is designed and applied in an even-handed manner, two case law might be

¹³⁰ SEUFERT, V., RAMANKUTTY, N. & MAYERHOFER, T. 2017. What is this thing called organic?—How organic farming is codified in regulations. *Food Policy*, 68, 10-20.

¹³¹ Article 13 (b) of the 2018 Regulation.

helpful to understand how adjudicators practice the test. In the case of *US- Clove*, the Appellate Body noted that menthol cigarettes had the same product characteristic, i.e., the flavouring that appeals to young people, that justified the prohibition of clove cigarettes. To the adjudicators, it is not even-handed when the two types of cigarettes apparently present the same risks to the objectives pursued by the US regulation.¹³² Similarly, in the case of *US-Tuna II*, the adjudicators opined that the measure of the US is not calibrated to the risks to dolphins arising from different fishing methods in different areas of the ocean. While acknowledging the objective of the measure is to reduce the mortality of dolphins resulted from the fishing of tuna, the US did not justify why only the risk from setting on dolphins is fully addressed, while the adverse effects from other fishing methods are not. Therefore, the design and application of the measure are regarded as not even-handed.¹³³

A common concept can be seen in the two case law. That is, when the risks presented by like products to the objectives pursued are the same, the regulating Members should not make differential treatments to the like products concerned. Following that, when assessing the test of even handedness, whether products presenting the same level of risk are treated differently should be examined. In the case of the 2018 Regulation, it can be seen that the EU establish an acceptable level of risk through a combination of various measures. Products that can not meet such an acceptable level can not access the EU organic label, regardless it is produced within or outside the EU. In this sense, the 2018 Regulation is designed and applied in an even-handed manner. Although complying with the EU rules might be particularly difficult for products from certain developing countries or LDCs, however, it should be the issue of whether the EU fulfil the requirement of providing technical assistance and special treatment (Articles 11 and 12), instead of Article 2.1 of TBT.

II. the conformity of most favoured nation principle:

The other concern that developing countries and LDCs may have is that it seems much difficult for them to be recognized equivalence under a trade agreement as referred to in Article 47 of the 2018 Regulation, while developed countries might have more possibility to do so. This in a way put developing countries and LDCs in a less favourable condition as other countries can comply with a set of adjusted production rules through trade negotiation, which is expected to lower the compliance cost for operators in those countries. This then leads to the legal question: can developing countries and LDCs claim that such difficulties in concluding a trade agreement with the EU constitute “less favourable treatment” within the meaning of Article 2.1 of the TBT agreement?

It is noteworthy that in the case of *US- Shrimp*, the Appellate Body viewed that regulating Members has the duty to negotiate in good faith. The principle of good faith is generally regarded as a principle of law, which requires states to establish an honest and fair relationship and be guided by truthful motives and purposes.¹³⁴ This principle was first introduced in Article XX GATT jurisprudence under *US-Shrimp*. By linking the principle to the Chapeau of GATT XX, the adjudicators further derived the duty to negotiate in good faith from the GATT -specific non-discrimination obligation. Such an obligation prohibits a WTO Member State from negotiating only with some and not with other WTO Members.¹³⁵ Considering the similarity of the

¹³² Appellate Body Report. 2012b. *United States — Measures Affecting the Production and Sale of Clove Cigarettes*. WT/DS406/AB/R. para. 225.

¹³³ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 297

¹³⁴ PANIZZON, M. 2006. *Concepts and Contents of Good Faith in International Law. Good faith in the jurisprudence of the WTO: The protection of legitimate expectations, good faith interpretation and fair dispute settlement*. Bloomsbury Publishing, 11-48.

¹³⁵ Appellate Body Report. 1998. *United States - Import Prohibition Of Certain Shrimp And Shrimp Products*. WT/DS58/AB/R.

test of GATT XX and Article 2.1 of TBT, the view abovementioned could be applied in the analysis of Article 2.1 of TBT agreement.

However, this does not lead to an obligation for WTO members to “conclude” a trade agreement with other countries. The Appellate Body of *US- Shrimp (Article 21.5)* explicitly stated that Members are not required to conclude a trade agreement with other Members as it would provide other Members with veto power over negotiation.¹³⁶ In light of the view abovementioned, it is thus not likely that the EU import regime would be considered inconsistent with Article 2.1 if a complaining Member establishes its argument solely based on that it can not conclude an agreement with the EU while others can.

While it seems unlikely to oblige the EU to conclude a trade agreement in good faith, it is still possible for a complainant to protect its trade interests by proving that the EU does not negotiate in a “serious good faith efforts to reach an agreement”. When assessing whether a regulating Member does negotiate in a serious good-faith manner, the adjudicators considered that the conduct of negotiation should be “comparable from one forum of negotiation to the other”.¹³⁷ Following that, where Members find that the negotiation process of a trade agreement with the EU is not comparable with the negotiations between the EU and other countries, it is likely that the 2018 Regulation would be regarded not TBT-consistent.

5.1.2 Consistency with Article 5.1.1:

Article 5.1 and 5.1.1 of TBT agreement stipulated non- discrimination principle for the right to accessing conformity assessment procedure, of which the language is similar to Article 2.1. It is however noticeable that Article 5.1.1 adds that the principle is applied “in a comparable situation”. Such difference with Article 2.1 raises the question regarding whether the interpretation of Article 5.1.1 should be different from Article 2.1; specifically, how the test of no less favourable should be done is at question.

Before entering into the issue, it is noteworthy the interpretation of “comparable situation” applied by the case of *Russia — Railway Equipment*, which is the first and thus far the only one WTO case law assessed the elements of Article 5.1.1.¹³⁸ The panel of the case opined that, to determine “comparable situation”, it is necessary to consider relevant factors which are connected to “assessing conformity assessment procedure and conducting conformity assessment activities.”¹³⁹ In addition, the adjudicators considered Article 5.1.2 and 5.2.7 as useful context and concluded that the ability of an importing Member to undertake conformity assessment procedure is relevant. Following that, the Panel ruled that due to the risks to life and health of Russian inspectors in the territory Ukraine, Russia is not able to conduct on-site inspections. Thus, such a situation is not comparable to other countries which export railway equipment to Russia.¹⁴⁰

In the case of *Russia — Railway Equipment*, it seems that the Panel took a relatively broad interpretation of “comparable situation”. Following such interpretation, it is then understandable that the Panel views the term “less favourable” differently from Article 2.1. The Panel clearly stated that the two-step test of Article 2.1 is not needed in the context of Article 5.1.1 as textual reading is different. Specifically, the fact that Article 5.1.1 qualifies the obligation of non- discrimination by including the phrase "in a comparable

para. 172.

¹³⁶ Appellate Body Report. 2001b. *United States – Import Prohibition Of Certain Shrimp And Shrimp Products Recourse To Article 21.5 Of The Dsu By Malaysia*. WT/DS58/AB/RW. para. 123

¹³⁷ Ibid. para. 122.

¹³⁸ Panel Report. 2018b. *Russia - Measures Affecting the Importation of Railway Equipment and Parts Thereof*. WT/DS499/R.

¹³⁹ Ibid. para. 7.283

¹⁴⁰ Ibid. para. 7.283 & 7.387.

situation" should be considered when interpreting "less favourable" in the context of Article 5.1.1. Furthermore, although it is not clearly stated, the Panel seems to take into account the objectives of TBT agreement and thus noted that "(t)he phrase "in a comparable situation" preserves a degree of flexibility for the importing Member to design and apply its conformity assessment procedures in a situation-appropriate manner".¹⁴¹ Following that, the Panel then concluded that, to determine whether a less favourable condition exists, whether competition condition of the products at issue is modified should be examined.¹⁴²

There are little prior studies on the elements of Article 5.1.1, and the available research tends to support that the test applied in Article 2.1 can be applied in Article 5.1.1 as both provisions regulate national treatment and MFN.¹⁴³ However, it seems that the Panel's interpretation is reasonable as it is much in line with the reading of the provision. Moreover, the Panel applied a broad interpretation of "comparable situation", which provides importing Members a degree of discretion to design or apply its conformity assessment procedures. This is in a way in conformity with the objectives of TBT agreement, i.e., establishing the balance between the pursuit of trade liberalization and Members' right to regulate. In addition, the rationale behind two-step analysis in Article 2.1, i.e., the context provided by Annex 1.1 and Article 2.2, seems not to exist in the context of Article, 5.1.1. In this regard, it seems appropriate to apply the Panel's interpretation of the provision in the following analysis.

Turning to the discussion of the 2018 Regulation. It is firstly noted that there are two types of discrimination-related issues in the aspect of CAPs are often raised by WTO Members.¹⁴⁴ One of them is that importing countries do not apply certain procedures to domestic producers but only apply it to foreign suppliers, while the other is that CAPs applied to foreign suppliers are much burdensome than it is for domestic producers. By examining the language of the 2018 Regulation, the researcher does not find the issues abovementioned. Nevertheless, it is also noteworthy that the details of CAPs under the new organic regulation has not yet been introduced. Thus, it can only be concluded that at this point, there are no such discrimination concerns.

While the issues abovementioned appears not to exist in the case of the 2018 Regulation, the researcher, however, finds another discrimination-related issue interesting to be explored. Recalled the discussion above regarding that it might be difficult for certain countries to conclude a trade agreement with the EU. The effect of not being able to conclude a trade agreement is that exporters of those countries are required to follow the rules of the EU, instead of the rules of the country where they locate. In the aspect of CAPs, it means that imports need to undergo duplicative conformity assessment, which is expected to increase their cost. In this regard, it would be interesting to explore the question: would the situation that the EU does not apply same consideration in the recognition of CAPs under negotiation of a trade agreement be regarded as in violation of Article 5.1.1?

It is noted by prior research that Article 5.1.1 does not impose an obligation on the recognition of CAPs of other WTO Members.¹⁴⁵ The provision merely regulates "access" to CAPs of an importing country. In addition, the provision specifies the meaning of "access" as "suppliers' right to an assessment of conformity under the rules of the procedure". Thus, by plain reading Article 5.1.1, it appears unlikely that the MFN

¹⁴¹ Ibid. paras. 7.271 to 7.273.

¹⁴² Ibid. para. 7.260

¹⁴³ E.g., APPLETON, A. E. 2013. Coformity Assessment Procedures. In: EPPS, T. & TREBILCOCK, M. J. (eds.) *Research Handbook on the WTO and Technical Barriers to Trade*. Edward Elgar Publishing, 81-119.

¹⁴⁴ MCDANIELS, D. & KARTTUNEN, M. 2016. Trade, Testing and Toasters: Bringing Conformity Assessment Procedures into the Spotlight. *Journal of World Trade*, 50, 755-792.

¹⁴⁵ BARTELS, L. 2005. The legality of the EC mutual recognition clause under WTO law. *Journal of International Economic Law*, 8, 691-720, RIGOD, B. 2013. TBT-plus rules in preferential trade agreements. *Legal Issues of Econ. Integration*, 40, 247.

obligation is imposed by Article 5.1.1 to a WTO Member on giving recognition of CAPs of other Members. In this regard, it is not inconsistent with Article 5.1.1 in the situation that the EU only recognized CAPs of some countries but not those of others through a trade agreement.

An alternative view argued the opinion abovementioned. Zell stated that “by recognizing another member’s CAPs, a member is ‘adopting’ and ‘applying’ those CAPs in a way which grants favourable access for the second member’s products.”¹⁴⁶ It is also opined that the test of less favourable within the meaning of Article 5.1.1 is similar to the test of Article 2.1. That is, the two-step analysis is also applied. Following that, this view regards that there is a detrimental impact on countries of which the CAPs are not recognized as imports from those countries concerned are not allowed to followed familiar domestic CAPs but with one of importing country. Moreover, the distinction would be regarded as not legitimate if a complaining country can prove that its CAPs could provide assurance of conformity in equivalence with other countries’ CAPs recognized by the EU under trade agreements. In this regard, Article 5.1.1 is violated.

The alternative view seems much reasonable. First of all, the interpretation is not against the ordinary meaning of the provision. In particular, Article 5.1.1 does not specify that CAPs refer to “domestic CAPs”. It is possible that CAPs within the meaning of Article 5.1.1 refer to domestic CAPs and CAPs being recognized by the importing country. Secondly, although the researcher does not agree with the opinion that the two-step test of Article 2.1 should be applied in the test of Article 5.1.1, it appears that there is little difference in the result of the application of those two interpretation approaches (i.e., application of the second step of the test or not). Recalled that the panel of *Russia — Railway Equipment* appears to adopt a broad interpretation of “comparable situation”, it is likely that equivalent CAPs could be regarded as comparable situation. Thus, when different considerations are taken into account in the negotiation of a trade agreement, it is likely to be regarded as granting access CAPs for suppliers under less favourable conditions. Finally, the reasonableness of the view lies on that there is no any other TBT discipline to regulate the discriminatory behaviour in the process of a trade agreement. Although it is noted by Rigod that such discrimination is regulated by Article 6.1 of the TBT agreement, however, the researcher does not agree with this opinion.¹⁴⁷ Article 6.1 only imposes a Member the obligation of accepting CAPs of other countries which is equivalent to its CAPs. In other words, it is not designed for regulating discrimination behaviours. In addition, it is doubtful that whether the discrimination behaviour in the negotiation of a trade agreement could be fully regulated by Article 6.1 considering the strong subjective element of the provision, such as “whenever possible”.

In conclusion, the researcher views that if the EU does not apply same consideration in the recognition of CAPs of other countries which could provide equal assurance of conformity, such application of Article 47 of the 2018 Regulation is likely to be inconsistent with Article 2.1 of TBT.

5.2 Unnecessary barriers to trade:

5.2.1 Consistency with Article 2.2:

Article 2.2 requires a Member, while introducing a technical regulation, to avoid creating unnecessary barriers to trade. For this purpose, it specifies that a technical regulation should not be more trade restrictiveness than necessary in order to fulfil a legitimate objective. The Article goes on to suggest that legitimate objective entails, “*inter alia*: national security requirements, the prevention of deceptive practices

¹⁴⁶ ZELL, J. A. 2016. Just between You and Me: Mutual Recognition Agreements and the Most-Favoured Nation Principle. *World Trade Review*, 15, 3-23.

¹⁴⁷ RIGOD, B. 2013. TBT-plus rules in preferential trade agreements. *Legal Issues of Econ. Integration*, 40, 247.

and the protection of human health or safety, animal or plant life or health, or the environment”. Such list of legitimate objectives is opined by WTO case law that it is not an exhaustive list.¹⁴⁸

WTO jurisprudence further clarified the analysis approach of this provision. That is, a factual finding should demonstrate “(i) the degree of contribution made by the measure to the legitimate objective at issue; (ii) the trade restrictiveness of the measure; and (iii) the nature of the risks at issue and the gravity of consequences that would arise from non-fulfilment of the objective(s) pursued by the Member through the measure”. To determine whether a measure is “more trade restrictiveness”, a comparative analysis is also conducted in most previous cases. Such analysis should be made in light of the nature of the risks at issue and the gravity of consequences that would arise from non-fulfilment of the objective.¹⁴⁹

Turning to the analysis of WTO consistency of the 2018 Regulation, the following steps are taken. First of all, whether the objectives pursued are legitimate is examined. It is then followed by the analysis of restrictiveness of the 2018 Regulation. Thirdly, the degree of contribution of the 2018 Regulation to its objectives is explored, and a comparative analysis is conducted in the final step.

Legitimate Objectives

To identify what the objectives of a measure are, the Appellate Body of US-Tuna II opined that “the texts of statutes, legislative history, and other evidence regarding the structure and operation of the measure” may be taken into consideration.¹⁵⁰ By reviewing the texts of the 2018 Regulation, it is firstly noted that the title of the regulation is “Regulation (EU) 2018/848... on organic production and labelling of organic products”. It is thus clear that the legislative framework aims to regulate both aspects of organic production and organic labelling. The specific objectives pursued in the aspect of organic production can be found in Article 4, which entails the objectives of environmental protection and animal welfare. In addition, this research also finds the sixth recital to the regulation is a useful context, which stated that,

“In view of the objectives of the Union’s organic production policy, the legal framework established for implementing that policy should aim at **ensuring fair competition and the proper functioning of the internal market** in organic products, at **maintaining and justifying consumer confidence in products labelled as organic**, and at providing conditions under which the policy can progress in line with production and market developments.” (emphasis added)

According to the recital abovementioned, ensuring fair competition and maintaining consumer confidence in organic products appears to be the objectives pursued. Indeed, the objective of maintaining consumer confidence is indicated by the design of organic labelling requirements. For example, Article 30 stipulates the terms can be used on organic products and that only products produced in accordance with the regulation can be labelled as organic products. On the other hand, the objective of ensuring fair competition is stated in Article 46, which requires the Commission to adopt immediately applicable actions to prevent unfair practices of imports. Apart from the provision, the legislative history of the regulation also indicates that fair competition serves as one of the objectives. In particular, the introduction of one- set rules and stricter rules on derogation of the use of organic inputs aims to reduce unfair practices occurred under the 2007 Regime.

Having regarded the texts and legislative history of the 2018 Regulation, this research regards that the protection of the environment and animal welfare, ensuring fair competition and maintaining consumer

¹⁴⁸ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 313

¹⁴⁹ *Ibid.*, para. 320 - 322.

¹⁵⁰ *Ibid.* para. 314

confidence in organic products are objectives pursued. The remaining question is whether those objectives are legitimate within the meaning of Article 2.2. According to Article 2.2 of the TBT agreement, it is uncontested that the objective of protection of the environment and animal welfare is legitimate. Regarding the protection of consumer confidence in organic products through labelling requirements, the opinion of WTO adjudicators in the case of *US- Tuna II* appears to be applicable. The Panel of the case regarded that the objective of consumer information which is set forth for “preventing consumers of tuna products from being deceived by false dolphin-safe allegations falls within the broader goal of preventing deceptive practices”.¹⁵¹ Similarly, the objective of maintaining consumer confidence in organic products also intends to protect the consumer from the false organic label, and thus it could be regarded as falling within the broader goal of “the prevention of deceptive practices”. Finally, the legitimacy of the objective of ensuring the fair competition was confirmed by the case law of *EC- Sardines*.¹⁵² Thus, fair competition could be regarded to be a legitimate objective within the meaning of Article 2.2.

Trade restrictiveness:

According to WTO case law, trade restrictiveness is defined as “limiting effect on international trade”.¹⁵³ Concerning the 2018 Regulation, it could be complained by exporting countries that the EU measure ignores different farming conditions in other countries and thus could create adaption cost for operators outside the EU. For example, operators in disadvantageous areas might face the difficulty to acquire sufficient quality and quantity of organic seeds. This could increase and weigh on production costs.

The increased cost arises from the reform of the EU organic regulation might indeed modify the competition opportunity of operators in third countries. However, the existence of such increased costs seems not necessarily substantiate a complainant’s claim regarding trade restrictiveness. It was noted by the panel of *Australia- Tobacco Plain Packaging* that “the existence of some initial adaptation costs would (not) in all cases be sufficient, in and of itself, to indicate that a technical regulation has a limiting effect on trade”. It is because a technical regulation “may also create a regulatory environment in which operating costs are reduced, thereby enhancing competitive opportunities and facilitating trade”.¹⁵⁴ Importantly, to determine trade restrictiveness within the meaning of Article 2.2 of the TBT Agreement, the panel regarded that the existence of costs should be with certain magnitude or nature.¹⁵⁵ Therefore, a complainant in the case of the 2018 Regulation needs to demonstrate not only that the 2018 Regulation will create additional cost for operators but also that why the cost will have a limiting effect on trade.

In this regard, it is also possible for the EU to rebut that, even though the 2018 Regulation would create additional costs, such costs would not constitute trade restrictiveness. In particular, considering that most of the products from third countries were previously certified through group certification, the new legislation keeps the scheme of group certification with the aim to balance the potential impact induced by compliance regime.¹⁵⁶ In addition, a review of some of the recognized equivalent standards under the 2007

¹⁵¹ Panel Report. 2011. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/R. para. 7.437.

¹⁵² Appellate Report. 2002b. *European Communities - Trade Description of Sardines*. WT/DS231/AB/R. para. 286-291.

¹⁵³ See e.g., Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 319; Panel Report. 2018a. *Australia — Tobacco Plain Packaging (Cuba)*. WT/DS435/R ; WT/DS441/R ; WT/DS458/R ; WT/DS467/R. para. 7.1166 & 7.1167

¹⁵⁴ Panel Report. 2018a. *Australia — Tobacco Plain Packaging (Cuba)*. WT/DS435/R ; WT/DS441/R ; WT/DS458/R ; WT/DS467/R. para. 7.1235

¹⁵⁵ *Ibid.*

¹⁵⁶ EUROPEAN COMMISSION 2014a. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and

Regulation conducted by the EU Commission showed that many standards under the review were already stricter than the EU rules. Such a result indicates that compliance with more stringent EU production rules is possible.¹⁵⁷ Based on the evidence abovementioned, the EU could argue that the existence of costs asserted by complainants would not reach a magnitude or nature that would have a limiting effect on trade.

Degree of contribution:

The term “fulfil” in the context of Article 2.2 was read in previous WTO case law as “degree of contribution”.¹⁵⁸ The interpretation is supported by the sixth recital of the preamble of the TBT Agreement, which states that a Member shall not be prevented from taking measures necessary to achieve its legitimate objectives “at the levels it considers appropriate”. To analyse the term “degree of contribution”, previous case law stated that it is not an abstract concept but rather should be examined through the design, structure, operation and application of a technical regulation.¹⁵⁹ Turning to the case of the 2018 Regulation, considering that the law has not entered into force yet, the following analysis thus relies on the examination of the design, structure and expected operation of the 2018 Regulation to explore the degree of contribution of the 2018 Regulation to the achievement of the legitimate objective pursued by the EU.

It is recalled that four objectives pursued by the 2018 Regulation are identified by this research, namely environmental protection, animal welfare protection, fair competition, and consumer confidence. The objectives of the protection of the environment and animal welfare are expected to be achieved by the design of the production rules of the 2018 Regulation. On the other hand, the achievement of objectives of fair competition and consumer confidence depends on the overall design of the regulation. The production rules of the 2018 Regulation address the goal of environmental protection in various aspects, such as improving biodiversity, maintaining soil- fertility, minimizing air and water pollution, and responsible use of energy and natural resources.¹⁶⁰ Following the organic production objectives and principles, specific rules are stipulated. For instance, the use of heterogenetic seeds is allowed in order to enhance biodiversity.¹⁶¹ In addition, limitation on the use of fertilizers and crop protection products could contribute is designed for maintaining soil fertility and minimizing pollution induced by farming.¹⁶² The restriction of the use of external inputs is also relevant with reducing the use of energy.¹⁶³ Thus, from the design of the production rules, it seems able to be concluded that the measures introduced by the regulation could contribute to achieving the goal of environmental protection.

As regards animal welfare, relevant production rules can be seen in point 1. 7 of part II of Annex II of the

labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007. p. 59.

¹⁵⁷ EUROPEAN COMMISSION 2014c. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 9 to 17. P. 70

¹⁵⁸ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 316

¹⁵⁹ Appellate Body Report. 2012a. *United States - Certain Country of Origin Labelling (COOL) Requirements*. WT/DS386/AB/R. para.373

¹⁶⁰ See Articles 4 and 5 of the 2018 Regulation

¹⁶¹ See Articles 4 (i), 6 (g) and 13

¹⁶² See e.g., Articles 5 (g), 24, and points 1.9.4 and 1.9.8 of part I of Annex II of the 2018 Regulation; with respect to the contribution of the measures to the organic principles, see SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE.

¹⁶³ Article 5 (g) of the 2018 Regulation; with respect to the contribution of the measures to the organic principles, see SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE.

regulation. Detailed rules, for example, include appropriate husbandry practices, permanent access to open-air areas, the prohibition of tethering or isolation of livestock, and avoidance of any suffering, pain and distress. As for the protection of consumer confidence, the design of conformity assessment procedures and labelling requirements are essential measures. Labelling regulations prohibit the term “organic” and its derivatives and diminutives to be used on non-organically produced products.¹⁶⁴ This is designed for establishing the trust of consumers toward organic products in the EU market. Conformity assessment procedures involve certification scheme conducted by third parties as well as official controls in the market. The introduction of one-set rules would ensure the same set of CAPs will apply to products originated inside and outside the EU. This is expected to create consistent control result and thus would be helpful with enhancing consumer confidence in organic integrity of products marketed in the EU. In addition to labelling requirements and CAPs, stricter rules seem to be able to provide higher consumer confidence.¹⁶⁵ By examining the design of the 2018 Regulation, the production rules appear to be stricter than the 2007 Regime, in particular in the aspect of the use of non-organic inputs and the authorization of certain substances. Thus, the design of the production rules of the new regime could also contribute to the achievement of maintaining and enhancing consumer confidence. Finally, the objective of fair competition could be achieved by the introduction of a clearer one- set rules. In particular, the change in import regime would address the issue of unfair practices arising from the overuse of exceptions in third countries.

As discussed above, it appears that the design of the 2018 Regulation is able to contribute to the achievement of the objectives pursued by the regulation. Apart from that, it might be also helpful to understand the actual contribution of the measures through studies of the 2007 Regime. It is because the two regimes are quite similar in terms of the objectives pursued and the structure they apply. Most of the measures of the 2007 Regulation are also followed by the 2018 Regime, except for some detailed rules being amended. Hence, it would be reasonable to consider studies of the 2007 Regulation regarding the contribution of its measures to the objectives pursued as relevant evidence when determining the potential contribution of the 2018 regulation. Following that, the evaluation report conducted by THÜNEN INSTITUTE is then considered to be a useful one. In that report, the adequacy of the previous organic legislative framework in achieving the goals pursued was analysed. By taking into account scientific evidence and stakeholders’ opinions, it concluded that the previous legislative framework was in general adequate in achieving the pursuit of the goal.¹⁶⁶ Considering that the design of the 2018 Regulation is overall stricter than the previous regime of organic products, it thus could be speculated that its degree of contribution is higher than the previous regime.

In contrast, a complainant could argue that the 2018 Regulation still allows the existence of exceptions does not create a high contribution and thus not qualify the term “fulfil” within the meaning of Article 2.2. For example, the use of non-organic seeds would reduce organic integrity and thus could hamper the achievement of consumer confidence and environmental protection. Such an argument, however, might not be accepted by WTO adjudicators. A similar argument was made in *EC-Seal Products*, in which complainants stated that the EU Seal regime with exceptions made for IC (Inuit or other indigenous communities) and MRM (Marine resource management) did not create a high level of contribution to the objective of seal protection and public moral concern. The panel of the case, however, did not support such

¹⁶⁴ Article 30 of the 2018 Regulation.

¹⁶⁵ EUROPEAN COMMISSION 2014a. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007. p. 9.

¹⁶⁶ SANDERS, J. (ed.) 2013. *Evaluation of the EU legislation on organic farming*: THÜNEN INSTITUTE.

a claim. While acknowledging the exceptions would diminish the degree of actual contribution made by the regime, the panel still found that the EU Seal Regime is “capable of making and does make some contribution to its stated objectives”.¹⁶⁷ Moreover, the Appellate Body of the case further explained that a panel is not required to determine if the contribution is “material” in the necessity test in the context of Article XX of GATT.¹⁶⁸ Although the Appellate body did not address the issue under Article 2.2 as it found that the EU Seal Regime is not a technical regulation within the meaning of TBT, the opinion is instructive. From the opinions abovementioned, it seems that WTO Case law gave a fairly broad interpretation of “degree of contribution”. In this regard, the EU could assert that, although exceptions might have a negative impact on the contribution to the objectives the Regulation pursues, the design, structure and expected operation of the Regulation still reveals that it is still capable of achieving its goals. Moreover, to make a solid argument, the EU could state that the negative impact of the exceptions on the degree of contribution is limited as exceptions are required to be strictly assessed its necessity and will be terminated in the future. In sum, by examining the design, structure and expected operation of the 2018 Regulation, it is likely that the regulation is able to contribute to the achievement of the objectives it pursues to a certain degree.

Comparative analysis:

Having discussed the trade restrictiveness and degree of contribution of the 2018 Regulation, the final step of the necessity test under Article 2.2 of TBT agreement is a comparative analysis to explore whether there is an alternative measure with less trade-restrictive effect. When determining whether a measure proposed by a complainant is alternative to the challenged regulation, WTO jurisprudence found it is necessary to explore whether the measure proposed could “make an equivalent contribution to the relevant legitimate objective” and “whether it is reasonably available”.¹⁶⁹

One could imagine that a complainant might claim that having two systems, i.e., compliance regime and equivalence regime, in parallel could be an alternative measure with less impact on trade. This is because a large portion of imports to the EU is currently based on the system of recognized control bodies. An import regime which keeps the system of recognition equivalence of control bodies could be less trade restrictive than the one only based on the compliance system. In addition, the system of recognition of equivalence to control bodies is able to make an equivalent contribution to the objectives pursued. In essence, the assessment of equivalence is designed to evaluate whether a different standard from the EU rules could contribute to the goals pursued by the EU organic rules.¹⁷⁰ Thus, the design of the system, per se, should be able to make an equivalent degree of contribution to the legitimate goals. Furthermore, the deficiencies discovered in the previous legislative framework, notably unfair competition induced by inadequate management of exceptions and insufficient controls, could be addressed through conducting a stricter equivalent assessment and strengthening supervision of control bodies. Therefore, it seems not necessary to abolish the system of recognition of equivalence to control bodies.

¹⁶⁷ Panel Report. 2013. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*. WT/DS400/R ; WT/DS401/R. para. 7.448 to 7.460.

¹⁶⁸ Appellate Body Report. 2014. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*. WT/DS400/AB/R ; WT/DS401/AB/R. para.5.213 to 5.216

¹⁶⁹ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. para. 322.

¹⁷⁰ This can be seen in Article 11 of No 1235/2008. A control body which requests to be recognized by the EU are required to submit a technical dossier, which shall comprise a description of the production standards and control measures applied in the third countries, including an assessment of the equivalence of these standards and measures with Titles III, IV and V of Regulation (EC) No 834/2007 as well as with the associated implementing rules laid down in Regulation (EC) No 889/200.

The EU could, however, argue that the measure proposed neither could make an equivalent contribution to the goals pursued nor is reasonably available. First of all, the sixth recital of the preamble of TBT agreement stated that the EU has the right to take measures necessary to achieve legitimate goals at the level it considers appropriate. Such right to determine its desired level of protection of legitimate objectives is also confirmed by WTO case law.¹⁷¹ The analysis of the degree of contribution of the 2018 Regulation reveals that the desired level of the achievement of the goals pursued is higher than the previous regime. In particular, a higher level of protection of consumer confidence and unfair competition could be achieved by a stricter one- set rules. A legislative framework consists of multiple standards is doubtfully able to make an equivalent degree of contribution. Previous experience also shows that the assessment of equivalence could potentially involve mistakes and cause unfair practices. In addition, controls are regarded to be complex as any non-compliance has to be assessed against each CB standard.¹⁷² Even though the weakness of multiple recognized standards can be compensated by stricter assessment and strengthening supervision, it seems not reasonably available for the EU. WTO case law has established that a reasonably available measure is the one that a regulating country is capable of taking it, or the one does not impose an undue burden on that country, such as prohibitive costs or substantial technical difficulties.¹⁷³ The EU could thus invoke the case law and assert that the implementation of equivalence scheme is already burdensome for the EU under the previous regime.¹⁷⁴ Stricter assessment and supervision, while might address the issues found previously, would require many intensive resources. Thus, the measure could not be an alternative measure to the 2018 Regulation.

Based on the discussion above, it seems that the 2018 Regulation does not violate Article 2.2. The objectives pursued by the 2018 Regulation are indeed legitimate and could be achieved at a higher level by the design of the regulation. Although compliance cost might increase, sit can not be determined whether such costs could reach a magnitude that constitutes trade restrictiveness. Finally, comparative analysis discusses that keeping the scheme of equivalence could not be an alternative measure, given that it could not make an equivalent degree of contribution and is not reasonably available.

5.2.2 Consistency with Article 5.1.2:

Article 5.1.2 of TBT stipulates that a Member’s CAPs should not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. It specifies that,

“conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, inter alia, that conformity assessment procedures shall not be more strict or be applied more strictly than is

¹⁷¹ Appellate Body Report. 2000. *Korea — Measures Affecting Imports of Fresh, Chilled and Frozen Beef*. WT/DS161/AB/R ; WT/DS169/AB/R. para. 176; Panel Report. 2013. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*. WT/DS400/R ; WT/DS401/R. para. 5.261

¹⁷² EUROPEAN COMMISSION 2014c. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 9 to 17. p. 57-60.

¹⁷³ Appellate Body Report. 2000. *Korea — Measures Affecting Imports of Fresh, Chilled and Frozen Beef*. WT/DS161/AB/R ; WT/DS169/AB/R. para. 665; Panel Report. 2013. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*. WT/DS400/R ; WT/DS401/R. para. 5.261

¹⁷⁴ EUROPEAN COMMISSION 2014c. Commission Staff Working Document Impact Assessment Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007 Annex 9 to 17. p. 55-56.

*necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.*¹⁷⁵

The panel of the case *EC – Seal Products* noted that “inter alia” in the second sentence indicates that “the provision consists of general obligations, set out in the first sentence, and an example of the general obligations, set out in the second sentence”¹⁷⁶ The following analysis will start with the question as to under what kind of situation that the 2018 Regulation could be regarded in violation of the general obligation set out in the first sentence. Following that, whether the CAPs of the 2018 Regulation is more strict than necessary is examined.

Situation that the 2018 Regulation could be regarded in violation of the general obligation

In the *EC – Seal Products*, the panel did not clarify what kind of situations that the preparation, adoption and application of CAPs would be regarded as unnecessary obstacles to trade. Nevertheless, the panel addressed the issue of the complainants as to whether the situation that a CAP is not capable of allowing trade in conforming products to occur from the date of its entry into force could constitute a violation of the general obligation of Article 5.1.2 of TBT. In that case, the CAPs of the Seal Regime involve a third-party accreditation by a recognized body, which shall meet certain requirements to be approved by the EU. However, the specific requirements were published three days prior to the entry into force of the EU Seal Regulation. This caused additional time necessary to examine and approve such a body according to specific criteria and thus made it impossible for the trade of conforming seal products to occur on the date of the entry into force of the EU Seal Regime. Based on the factual finding abovementioned, the panel then concluded that the CAP had the effect of creating unnecessary obstacles to international trade inconsistently with the first sentence of Article 5.1.2.¹⁷⁷

The opinion above seems relevant to the case of the 2018 Regulation. CAPs under compliance scheme of the EU organic regulation requires imports to be certified by recognized control authorities and control bodies. An entity seeking to be recognized by the EU shall meet the requirements stipulated in the 2018 Regulation and implementing rules.¹⁷⁸ While the recognition of CBs and CAs under the equivalence scheme will expire from 1 January 2023, according to the current working plan proposed by the Commission, the adoption procedure of implementing rules of trade is expected to be finalized in late 2020.¹⁷⁹ This might create a risk that all of the control bodies and control authorities can not be recognized timely under the compliance scheme before the date of entry into force of the Regulation and thus make it difficult for qualifying products to be certified and marketed in the EU market. Such a situation, according to the Panel’s view, would be regarded as in violation of Article 5.1.2.

Is the CAP of the 2018 Regulation more strict than necessary?

The analysis approach of Article 2.2, i.e., weighing and balancing of a measure's trade-restrictiveness, was also applied for analysing the second sentence of Article 5.1.2 by WTO adjudicators due to the similarities of the text and structure of those two provisions.¹⁸⁰ However, unlike there might be multiple legitimate

¹⁷⁵ Article 5.1.2 of TBT agreement.

¹⁷⁶ Panel Report. 2013. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*. WT/DS400/R ; WT/DS401/R. para. 7.512

¹⁷⁷ Ibid. para. 7.525- 7.528

¹⁷⁸ Article 46 of the 2018 Regulation.

¹⁷⁹ EUROPEAN COMMISSION. 2018b. Suggested work plan - IAs and DAs Available: <https://ioas.org/wp-content/uploads/2018/12/EU-Organic-Regulation-timetable.pdf> [Accessed 3rd April 2019].

¹⁸⁰ Panel Report. 2013. *European Communities - Measures Prohibiting the Importation and Marketing of Seal Products*.

objectives to be fulfilled, there is only one objective in Article 5.1.2, namely giving positive assurance that the relevant requirements of the technical regulation are fulfilled. In this regard, the analysis below follows the order of strictness, degree of contribution and comparative analysis.

Strictness

The meaning of strictness is not defined in the TBT agreement. The panel of the *EC- Seal Products* appeared to regard “strictness” as “restrictiveness” and thus conducted an analysis as to whether the CAPs of the EU Seal Regime is trade-restrictive or not.¹⁸¹ The panel’s opinion seems reasonable as the purpose of the weighing and balancing analysis is to, on the one hand, ensure trade liberation, and on the other hand, protect a Member’s right to take measures necessary to the achievement of the goals pursued at the level it considers appropriate. Therefore, the determination of whether CAPs are strict or not should depend on the effect of the CAPs in question on trade.

It is noted by the panel of the *EC- Seal Products* that “the CAP necessarily has some restrictive effect to the extent that it imposes additional conditions in order for the trade of seal products to be permitted”.¹⁸² However, the panel did not address the issue whether such a restrictive effect should amount to a magnitude or nature of trade restrictiveness in the context of Article 5.1.2. Considering the similarity of Article 2.2 and Article 5.1.2, it seems reasonable to regard that the standard of the weighing and balancing analysis should not be different. In other words, a complainant should be able to prove that the strictness of CAPs could cause a magnitude of trade restrictiveness. Following that, in the case of the 2018 Regulation, a complainant needs to prove that the new regulation creates additional requirements or costs for operators in third countries which could cause barriers to trade. The cost of duplication certification arisen from the compliance import scheme might thus not sufficient to prove this element. Importantly, from the current design of the 2018 Regulation, it seems that the change in the control system is minor when comparing to the previous regulations. Thus, it might be difficult for a complainant to prove the strictness of the 2018 Regulation.

Degree of contribution:

CAPs of the EU organic regulation rely on third-party certification. For imports, according to Article 46, the third party means a recognized control body or control authority. Therefore, the contribution of the CAPs for organic products to the assurance of conformity largely depends on the capability and credibility of the recognized bodies or authorities.¹⁸³ Such capability and credibility of recognized bodies is determined by the design and application of the 2018 Regulation and its implementing acts and delegating acts. It might be too early to be certain what the exact degree of contribution of CAPs of the 2018 Regulation would be as the IAs and DAs have not been introduced yet. However, the design of the 2018 Regulation could be an indication. Article 46 lays down the criteria shall be met for a control body or control authority to be recognized. Notably, the requirements on control bodies and control authorities, that they should have the capacity to carry out controls and have the expertise, equipment, infrastructure and a sufficient number of qualified and experienced staff to carry out control tasks, are designed to ensure the capability of third parties.¹⁸⁴ Further, the credibility of a control body or a control authority could be established through the requirement of offering adequate guarantees of objectivity and impartiality and being free from any conflict

WT/DS400/R ; WT/DS401/R. para. 7.539.

¹⁸¹ Ibid. para. 7.540

¹⁸² Ibid.

¹⁸³ See *ibid.* para. 7.542

¹⁸⁴ Article 46.2 of the 2018 Regulation.

of interest.¹⁸⁵ Finally, the scheme of compliance under the import regime, where one- set of CAP is to be applied, also indicates that the new regulation could possibly provide the EU with a higher degree of confidence in the conformity of imports. Therefore, based on the requirements abovementioned, it seems that the design of CAPs of the 2018 Regulation can make a degree of contribution to the assurance of conformity of imported products.

Comparative analysis:

As discussed in the analysis of Article 2.2, an alternative measure possibly proposed by the complainants could be having two systems, i.e., compliance regime and equivalence regime, in parallel. However, similarly, this research does not regard that the measure proposed would be an alternative measure to the 2018 Regulation. In particular, the degree of contribution to the assurance of conformity made by a scheme that having multiple sets of control rules in place seems not equivalent to the contribution made by a system of one- set rules. That is, one- set of CAPs can improve the consistency of the conduct of control bodies and control authorities, which can reduce the risk of non-equivalent CAP measures being applied, and thus it can provide the EU with a higher confidence in the conformity of imports. Further, even though strengthening the supervision of the conduct of control bodies and control authorities might reduce the risk abovementioned and have an equivalent contribution as the system of one- set rules, it appears to be too burdensome for the EU, given that the equivalence scheme requires intensive human and technical resources. The previous experience already showed that it was difficult for the EU to meet the degree of contribution under the 2007 Regime. Logically, it can be assumed that applying equivalence scheme under the 2018 Regime might require many intensive resources, given that the level of assurance of conformity is expected to be higher than the previous regime. Thus, strengthening supervision, even if it is not impossible, would be too burdensome for the EU to apply.

Having discussed the parameters abovementioned, it seems that the CAPs of the 2018 Regulation is likely consistent with the disciplines of Article 5.1.2. Although the change in import regime will create additional cost for operators, in particular for those export products based on the scheme of recognized control bodies, the existence of such cost does not necessarily constitute strictness within the meaning of Article 5.1.2. Furthermore, it is also doubtful that having both the scheme of compliance and equivalence in place will contribute an equivalent degree of confidence in the conformity of imports. Finally, expecting the EU to strengthen supervision of control bodies and control authorities under an equivalent regime would impose an undue burden on the EU and thus could be regarded as not a reasonably available measure. Weighing and balancing the factors above, it thus could be regarded that the CAPs of the 2018 Regulation is not likely in violation of the requirements of Article 5.1.2.

5.3 International standard, recommendation and guides:

Articles 2.4 and Article 5.2 of the TBT Agreement respectively lays down the requirement for Members to use the international standard as the basis of their technical regulations and conformity assessment procedures. Considering the high similarity of those two provisions, the consistency with the WTO requirements will be assessed together below.

To begin with, it is helpful to adapt the three-step analysis in the WTO case law *US-Tuna II* under Article 2.4 to the analysis in this section¹⁸⁶:

¹⁸⁵ Ibid.

¹⁸⁶ Panel Report. 2011. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/R. para. 7.627 (referring to Panel Report, EC – Sardines, paras. 7.61-7.139 and Appellate Body Report, EC – Sardines, paras. 217-291).

- i. whether a relevant international standard to the EU organic production and labelling rules exist or their completion is imminent; in terms of CAPs, whether a relevant guide or recommendation to the EU CAPs of organic agriculture exist or their completion is imminent;
- ii. whether the international standard, guide or recommendation above has been used as a basis for the technical regulation and the conformity assessment procedure;
- iii. whether the international standard is an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued by the technical regulation; in terms of CAPs, whether it is inappropriate to be used as the basis of the CAPs of the Members concerned.

The three steps will be addressed in turn below.

5.3.1 Relevant international standard, guide or recommendation:

There are two standards recognized as international standards for the organic sector, namely the Guidelines introduced by Codex Alimentarius (CAC/ GL 32) and the IFOAM Norms (2014) introduced by IFOAM.¹⁸⁷ It is uncontested that the guidelines established by Codex Alimentarius (Codex) is an international standard within the meaning of WTO law. Importantly, the SPS Agreement makes an explicit reference to the standards, guidelines and recommendations established by Codex when defining “international standards, guidelines and recommendations” for the purpose of the Agreement.¹⁸⁸ Although the TBT Agreement does not refer to which international standards are within the meaning of the TBT Agreement, the WTO jurisprudence indicates that the Codex is also applied to the TBT.¹⁸⁹

In contrast, whether the IFOAM Norms is within the meaning of the TBT Agreement needs further exploration. IFOAM Norms are composed of three documents: (i) the Common Objectives and Requirements of Organic Standards (COROS); (ii) the IFOAM Standard for Organic Production and Processing (the IFOAM Standard), and (iii) the IFOAM Accreditation Requirements for Bodies Certifying Organic (the IFOAM Accreditation Requirements). COROS is used for assessing whether an organic standard is equivalent with the IFOAM Norms, whereas the IFOAM Standard, which can be applied directly for certification, covers the aspects of organic production, processing and labelling. As for the Accreditation Requirements, it lays down the rules regarding the operation of a certifier on the basis of ISO norms. Considering that the discussion of the 2018 Regulation only covers the organic production provisions and CAPs, the COROS will not be included in the analysis below.

5.3.2 Whether the IFOAM Standard and the Requirements is an international standard and guides

Before proceeding the analysis as to whether the IFOAM Standard and the Accreditation Requirements is the international standard, guide or recommendation within the meaning of the TBT Agreement, it is worthy to note the opinion of *US-Tuna II* regarding the definition of international standard. The TBT agreement

¹⁸⁷ INTERNATIONAL TASK FORCE. 2009. Harmonization and Equivalence in Organic Agriculture. Volume 6. Available: https://unctad.org/en/PublicationsLibrary/ditcted2009d1_en.pdf; CODEX ALIMENTARIUS COMMISSION. 1999. Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods. GL 32-1999. Available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BG%252FL%252B32-1999%252Fexg_032e.pdf; INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). 2014. The IFOAM NORMS for Organic Production and Processing. Version 2014. Available: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf.

¹⁸⁸ WORLD TRADE ORGANIZATION 1994b. Agreement on the Application of Sanitary and Phytosanitary Measures. Geneva: WTO.

¹⁸⁹ Panel Report. 2002a. *European Communities - Trade Description of Sardines*. WT/DS231/R. para. 7.139.

does not provide the definition of “international standard, guide or recommendation”. To interpret the term “international standard”, the Appellate Body of *US-Tuna II*, according to the introductory clause of Annex 1 to the TBT Agreement, found the ISO/IEC Guide 2: 1991 as a useful contextual element. The term “international standard” is defined as “a standard that is adopted by an international standardizing organization and made available to the public” in the ISO/IEC Guide 2: 1991. Furthermore, the WTO adjudicators also noted that, where a term has been defined by Annex 1/ TBT, the definition contained in the Annex prevails over the definition set out in the ISO/IEC Guide 2: 1991. In this regard, Annex 1.2 regarding the definition of standard and 1.4 regarding the definition of an international body or system were considered a relevant context. Based on the ISO/IEC Guide 2: 1991 and these contextual elements in the TBT Agreement, the Appellate Body thus concluded that an international standard for the purpose of TBT Agreement is a standard that is made available to the public and approved by an international standardizing body, which has recognized activities in standardization and whose membership is open to the relevant bodies of at least all Members.¹⁹⁰

As regards the meaning of guide and recommendation in Article 5.4, it has not been interpreted by WTO adjudicators and limited literature is available. However, it should be noted that, in contrast to the definition of international standard within the meaning of Article 2.4, Article 5.4 specified that the guide or recommendation as set out in the provision shall be issued by international standardizing bodies.

Following the elaboration above, there are thus three elements to be further explored: (i) are the IFOAM Standard and Requirements a standard, guide, or recommendation within the meaning of the TBT Agreement, (ii) whether IFOAM is an international standardization organisation, and (iii) whether the Standard and the Requirements are made available to the public.

I. Is the IFOAM Norm a standard, guide or recommendation within the meaning of the TBT Agreement?

As stated previously, the TBT Agreement does not lay down the definition of international standard, guide or recommendation, and the WTO jurisprudence regards that the definition of standard as set out in Annex 1.2 should apply.

The definition of standard in Annex 1.2 to the TBT Agreement:

*“Document approved by a recognized body, that provides, **for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory.** It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.” (emphasis added)¹⁹¹*

In addition, in the case of *EC- Sardines*, the Appellate Body agreed with the opinion of the Panel that, according to the Explanatory note to Annex 1.2, an international standard is not necessarily prepared on the basis of consensus.¹⁹² Previous studies had a similar conclusion as the AB; however, criticism has been made to the approach applied by the WTO adjudicators. By plain reading the Explanatory note, it is equally possible that the term “documents” in the last sentence of the note, i.e., “[t]his Agreement covers also documents that are not based on consensus.”, refers to standards in general.¹⁹³ In addition, the TBT

¹⁹⁰ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R, paras. 351-359.

¹⁹¹ Annex 1.2 of the TBT Agreement.

¹⁹² Appellate Report. 2002b. *European Communities - Trade Description of Sardines*. WT/DS231/AB/R. para. 227

¹⁹³ HOWSE, R. 2006. A new device for creating international legal normativity: the WTO technical barriers to trade agreement and “international standards”. *Constitutionalism, multilevel trade governance and social regulation*, 390.; HORN, H. &

committee has made an opinion regarding the principles for the development of international Standards, guides and recommendation, which was then regarded by the AB of *US-Tuna II* as a "subsequent agreement" within the meaning of Article 31(3)(a) of the Vienna Convention when interpreting the term "openness" in that dispute.¹⁹⁴ Following the approach, some studies thus regard that the explanation of the term "consensus" in the TBT Committee Decision is a relevant contextual element for understanding the definition of international standard within the meaning of TBT. In the Decision, the principle regarding consensus is explained as,

*"All relevant bodies of WTO Members should be provided with meaningful opportunities to contribute to the elaboration of an international standard so that the standard development process will not give privilege to, or favour the interests of, a particular supplier/s, country/ies or region/s. Consensus procedures should be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments."*¹⁹⁵

Based on the elaboration above, studies made a similar interpretation with the case of *EC-Sardines* that consensus is not required for the adoption of an international standard; instead, it is a "best-effort" obligation that a procedure should be established to take into account the views of all parties and providing no privilege to particular interests.¹⁹⁶

According to the views above, the characteristics of a standard for the purpose of the Agreement are summarized as (i) being intended or designed for common and repeated use; (ii) containing rules, guidelines or characteristics for products or related PPMs; and (iii) compliance with the document is not mandatory, and (iv) consensus is not required for the adoption of the international standard concerned but a consensus procedure should be established to be in line with the TBT Committee Decision stated above.

As for the terms used in Article 5.4, although there is no case law and limited literature available for understanding the term, it seems that the characteristics mentioned above could be also applicable. Firstly, the term "recommendation" is defined by the ISO/IEC Guide 2: 1991 as "provision that conveys advice or guidance"¹⁹⁷ When looking up the ordinary meaning of a "guidance" and of a "recommendation", it is elaborated as "help and advice about how to do something or about how to deal with problems" and "a suggestion that something is good or suitable for a particular purpose".¹⁹⁸ The definition as set out in the ISO Guide and the ordinary meaning of the term, such as "advice" and "suggestion", suggest the non-mandatory characteristic. Furthermore, considering the purpose of the provision is to promote harmonization of CAPs among Members, it is also reasonable to expect that the guide and recommendation

WEILER, J. H. 2005. European communities–trade description of sardines: Textualism and its discontent. *World Trade Review*, 4, 254-256.

¹⁹⁴ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R paras. 374-375.

¹⁹⁵ COMMITTEE ON TECHNICAL BARRIERS TO TRADE 2017. Decision Of The Committee On Principles For The Development Of International Standards, Guides And Recommendations With Relation To Articles 2, 5 And Annex 3 Of The Agreement. *Decisions and recommendations adopted by the WTO Committee on Technical Barriers to Trade since 1 January 1995*. 54-57.

¹⁹⁶ DU, M. & DENG, F. 2016. International standards as global public goods in the world trading system. *Legal Issues of Economic Integration*, 43, 113-144, PAUWELYN, J. 2014. Rule-Based Trade 2.0? The Rise of Informal Rules and International Standards and How They May Outcompete WTO Treaties. *Journal of International Economic Law*, 17, 750.

¹⁹⁷ See sub-clause 7.4 of the ISO/IEC Guide 2: 1991.

¹⁹⁸ CAMBRIDGE ONLINE DICTIONARY. 2019. *Meaning of recommendation in English* [Online]. Cambridge University Press. Available: <https://dictionary.cambridge.org/dictionary/english/recommendation> [Accessed 1st May 2019]; CAMBRIDGE ONLINE DICTIONARY. 2019. *Meaning of guidance in English* [Online]. Cambridge University Press. Available: <https://dictionary.cambridge.org/dictionary/english/guidance> [Accessed 1st May 2019]

within the meaning of Article 5.4 should be designed for or intended to be used commonly and repeatedly. Finally, considering the TBT Committee Decision is also applicable for international guide and recommendation as set out in Article 5 of the TBT Agreement, it appears that the adoption of a recommendation or guide is not required to be based on consensus.

It is uncontested that the IFOAM Standard and the IFOAM Accreditation Requirements fulfil the criteria-“voluntary compliance” and “organic production methods, labelling and CAPs as the subject of the two documents”. The criteria needed further discussion is whether the documents are for common and repeated use and whether the procedure of the adoption of the documents could fulfil the principle of consensus as stated in the TBT Committee Decision.

When solving the dispute of *Australia — Tobacco Plain Packaging (Cuba)*, the Panel noted that the phrase "for common and repeated use" in Annex 1.2 of the TBT Agreement has never been interpreted by previous WTO case law. By considering the ordinary meaning of the phrase and the objective of the provision, i.e., promoting harmonization of technical regulations, the adjudicators thus ruled that “a document for common and repeated use” should be understood as a document with a degree of specificity that can be frequently shared alike by all persons or things in question.¹⁹⁹ While acknowledging that the degree of specificity should be determined on a case-by-case basis, the Panel also noted the contextual element of ISO /IEC Guide 2:1991 regarding the definition of standardization.²⁰⁰ The definition of standardization in the Guide which also uses the phrase “for common and repeated use”, suggests that a standard should aim to achieve “the optimum degree of order in a given context”. For this purpose, therefore, the minimum degree of specificity of a standard within the meaning of TBT Agreement should be understood as “a degree of clarity and precision sufficient to allow them to be implemented in a consistent and predictable manner”.²⁰¹

As stated previously, the IFOAM Standard is intended to be applied directly for certification. For this purpose, the IFOAM Standard Committee stated that the standard was intended to introduce “fewer recommendations and more firm requirements which spell out what operators must do or must not do”.²⁰² This suggests that the standard has a degree of specificity that allows being used commonly and repeatedly. As for the Accreditation Requirements, it lays down detailed rules covering the eligibility of a certification body, document controls, certification procedures, and inspection procedures. Provisions in the Requirements can be applied directly by a certification body. Take inspection frequency for example. It requires a certification body shall have an inspection policy, in which a certified operator is obliged to receive at least one inspection annually. Alternatively, where certain conditions are met, the type and frequency of inspections can be determined by risk analysis with respect to the individual operator.²⁰³ The degree of clarity and precision of the Requirements thus appears to be sufficient to allow it to be implemented in a consistent and predictable manner.

Turning to the question as to whether the IFOAM Standard and the IFOAM Requirements follow the

¹⁹⁹ Panel Report. 2018. *Australia — Tobacco Plain Packaging (Cuba)*. WT/DS435/R ; WT/DS441/R ; WT/DS458/R ; WT/DS467/R, paras. 7.360-7.366

²⁰⁰ See sub-clause 1.1 of the ISO/IEC Guide 2: 1991: “[a]ctivity of establishing, with regard to actual or potential problems, provisions for common and repeated use, *aimed at the achievement of the optimum degree of order in a given context*” (emphasis added).

²⁰¹ Panel Report. 2018. *Australia — Tobacco Plain Packaging (Cuba)*. WT/DS435/R ; WT/DS441/R ; WT/DS458/R ; WT/DS467/R, paras. 7.368- 7.370.

²⁰² INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). 2012. Open motion period on the IFOAM Standard version 2.0- Introduction from the IFOAM Standard Committee to the membership. Available: https://www.ifoam.bio/sites/default/files/page/files/introtothedraftstandard_20111107final.pdf [Accessed 29th May 2019].

²⁰³ Point 7.5.2 of the IFOAM Accreditation Requirements.

principle of consensus as set out in the TBT Committee Decision, the procedure of the adoption and revision of the IFOAM Norm is explored. The development and approval processes of the IFOAM Norm is regulated by IFOAM's Policy 20.²⁰⁴ According to the procedure regulated in the Policy, it appears that the adoption of the Norm follows the principle of consensus. There are five stages in the procedure: initiation, decision to commence, the revision process, decision making, and implementation. In each stage before the implementation of the new Norm, the members of the IFOAM and stakeholders have the right to participate in the procedure. In particular, there will be two revision drafts subject to consultation with the IFOAM members and other stakeholders lasted at least 60 days from the electronic mailing of the norms. A new version of the Norm will then be approved by the World Board of the IFOAM and presented to the members for motion and vote. For the IFOAM Standard and the IFOAM Accreditation Requirements, the version for vote will be presented to members after a membership motion process and a motions reconciliation process have been done by the standard committee of IFOAM. Although the final decision is taken by a simple majority of the votes cast, according to the procedure above, it can be seen that the members of IFOAM all enjoy sufficient and equal opportunities to have their views be considered in the process of revision. This fulfils the principle that a consensus procedure should be established in order to take into account the views of all parties.

Having analysed the elements abovementioned, it could be concluded that the IFOAM Standard and the Accreditation Requirements are within the meaning of a standard and a guideline respectively for the purpose of the TBT Agreement.

II. Is IFOAM an international standardization organisation?

As stated earlier, according to the case law of the TBT Agreement, it is principally the characteristics of the entity which adopts a standard and a guideline that provides the standard and the guideline its international character. Recalled that WTO adjudicators further noted that the characteristics of an entity are: a) the entity has recognized activities in standardization, and b) its Membership is open to the relevant bodies of at least all WTO members.

□ *Does IFOAM have recognized activities in standardization?*

The elements that are used to assess whether an entity has recognized activities in standardization was elaborated in the case of *US- Tuna II*. The Appellate Body of the case noted that the term “recognized”, by its ordinary meaning, “fall along a spectrum that ranges from a factual end (acknowledgement of the existence of something) to a normative end (acknowledgement of the validity or legality of something)”. To understand the term from a factual and normative end, the Appellate Body further held that the TBT Committee Decision informs the interpretation and application of the term. From a factual perspective, an entity could be regarded as having recognized activities in standardization if it disseminates information about its standardization activities, as set out by the transparency procedures of the TBT Committee Decision. From a normative perspective, it would be easier for a body to be acknowledged the validity and legality of its standardization activities if it has complied with the principles and procedures of the TBT Committee Decision which WTO Members have decided ‘should be observed’ in the development of international standards.²⁰⁵

²⁰⁴ INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). 2010. Policy on the Revision of the IFOAM Norms. Available: https://www.ifoam.bio/sites/default/files/page/files/policy_20_revision_of_norms.pdf [Accessed 29th May 2019].

²⁰⁵ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. paras. 361, 362, and 376.

Apart from taking into account of the design of the procedure, the number of the countries participate in the development of a standard is also relevant when assessing whether activities of a body are recognized or not. The larger the number, in particular, the number of WTO Members and national standardization bodies, is, the more likely the activities of the body would be considered as being recognized.²⁰⁶

Based on the interpretation above, one of the factors used to assess whether IFOAM has recognized activities in standardization or not is the procedure of the adoption of the IFOAM Norms. According to the policy regarding revision of the Norms, it appears that the principle of transparency as set out in the TBT Committee Decision is applied to the procedure of IFOAM. That is, in each step of the revision process, except for the steps of decision making and implementation, IFOAM would inform its members as well as stakeholders its standardization activities. For example, once the decision to commence a revision process is taken by the IFOAM World Board, a summary of the revision plan, including steps and timelines, should be communicated to the membership and other stakeholders. In addition, at least 60-day comment period is given to members and stakeholders, except that with public justification the World Board may shorten the period to no less than 30 days. This is also in line with point L of Annex 3 to TBT Agreement regarding code of good practice for the preparation, adoption and application of standards.²⁰⁷ Furthermore, according to the policy set out by IFOAM, “other stakeholders” referred to in the policy encompasses parties that are subject to or uses the Norm, entities that set standards and CAPs in organic and other environmental and social fields, intergovernmental and governmental agencies that are concerned with organic standards and CAPs. According to the procedure described above, it appears that IFOAM disseminates information regarding its standardization activities to a wide range of parties in the organic sector. Thus, from a factual perspective, IFOAM could be regarded as having recognized activities in standardization.

It seems also true that IFOAM follows some of the other principles of the Decision. Recall the analysis above that the procedure complies with the principle of consensus. Furthermore, it appears that IFOAM also follows the principle of coherence. This is demonstrated by IFOAM’s works on promoting harmonization of organic standards and CAPs with other intergovernmental and governmental agencies, e.g., the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF) resulted from the partnership between IFOAM, UNCTAD, and FAO, also complies with the principle of coherence. The implementation of the principle of effectiveness and relevance can be seen in the design of the procedure of the revision of the Norms. Through welcoming a wide range of stakeholders to participate in the process of revision, it ensures the Norms can respond to regulatory and market needs as well as reflect scientific and technological developments, as required by the principle. As for the principle of openness, while it will be elaborated in detail below, the membership to IFOAM, which is available to relevant bodies in all of the WTO Members, shows that the principle is also implemented by IFOAM.

Based on the discussion above, it appears that from a normative perspective, it is likely that IFOAM would be regarded as having recognized activities in standardization by WTO members. Apart from the factual and normative perspective, the number of members of IFOAM also indicates the fact that the activities of IFOAM have been recognized. To date, there are around 600 bodies worldwide that are members of IFOAM.²⁰⁸ A large number of members, who have the right to participate in the process of the revision of

²⁰⁶ Ibid. para. 390.

²⁰⁷ Point L of Annex 3 of the TBT Agreement, “Before adopting a standard, the standardizing body shall allow a period of at least 60 days for the submission of comments on the draft standard by interested parties within the territory of a Member of the WTO. This period may, however, be shortened in cases where urgent problems of safety, health or environment arise or threaten to arise.”

²⁰⁸ INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). n.d.-a. *Directory of Affiliates* [Online]. Available: <https://directory.ifoam.bio/> [Accessed 19th April 2019].

the Norms, increases the possibility that IFOAM's activities in standardization are recognized.

□ *Is the Membership of IFOAM open to the relevant bodies of at least all WTO members?*

With reference to the ordinary meaning of the term “open”, case law ruled that a body will be open if membership to the body is not restricted to the relevant bodies of only some WTO Members. Furthermore, by taking into account the principle of openness in TBT Committee Decision, the WTO adjudicators additionally clarified that a body may be regarded “open” if it is open at every stage of standards development on a non-discriminatory basis.²⁰⁹ It is also noted by previous studies that when case law above using the phrase “relevant bodies”, it implicitly stated that rules may be adopted with the participation of, or even exclusively by, private bodies.²¹⁰

According to the terms and conditions of IFOAM membership, only organizations or departments of institutions that endorse the mission & goals of IFOAM and the principles of Organic Agriculture and dedicate over 50% of its budget or activities to the organic sector can become members of IFOAM. Anybody that is interested in joining IFOAM can make an application. IFOAM World Board has the power to approve or reject a request. However, only in rare cases, where an applicant does not fulfil the criteria mentioned above, e.g., the operation of the applicant concerned threaten the integrity of organic production, a request will be rejected by IFOAM.²¹¹ It appears that IFOAM does not set any prior restriction to relevant bodies of only some WTO members. In addition, by reading its policy on the revision of the Norms, it can be seen that members of IFOAM may equally participate in every stage of the revision. By considering the elements above, it thus can be concluded that IFOAM is open to all the WTO members.

III. Are the IFOAM Standard and the Requirements available to the public?

When assessing whether the Agreement on the International Dolphin Conservation Program (AIDCP) in the dispute of *US- Tuna II*, the Panel of the case regarded that the transparency procedures of AIDCP fulfils the criterion as it aims at communicating with market operators about the AIDCP and its objective and the procedures for the dolphin-safe certificate and the dolphin-safe label.

Similar procedures are also laid down in IFOAM's policies regarding the revision of the Norms (policy 20) and the use of the Standard (policy 41). In policy 20, it states the publication of the Norms as follow,

“The revision plans and all decisions related to Norms revisions shall be announced promptly. Approved Norms shall be published promptly and shall be made available for free in electronic format.”

In addition, according to the policy 41 of IFOAM, the IFOAM Standard is made publicly available for free download on the website of IFOAM. Based on the policies abovementioned, it could be regarded that the IFOAM Standard and the Requirements are made available to the public.

Based on the analysis above, it could be concluded that the IFOAM Standard and the Requirements are international standard and guides within the meaning of Articles 2.4 and 5.4.

²⁰⁹ Appellate Body Report. 2012c. *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*. WT/DS381/AB/R. paras. 364, 374 and 375.

²¹⁰ PARTITI, E. 2013. The Appellate Body Report in *US–Tuna II* and Its Impact on Eco-Labeling and Standardization. *Legal Issues of Economic Integration*, 40, 91-93, PAUWELYN, J. 2014. Rule-Based Trade 2.0? The Rise of Informal Rules and International Standards and How They May Outcompete WTO Treaties. *Journal of International Economic Law*, 17, 750.

²¹¹ INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). n.d.-c. Membership Terms & Conditions. Available: https://www.ifoam.bio/sites/default/files/ifoam_oi_membership_terms_and_conditions.pdf [Accessed 1st June 2019].

5.3.3 Are the IFOAM Norms and the Codex Guidelines used as a basis of the 2018 Regulation?

The use of international standards and guides as the basis of national regulations or standards is regarded as the primary mean to achieve one of the objectives of the TBT agreement, i.e., promoting regulatory convergence among WTO Members. However, it is not clarified by the Agreement that to what extent the use of an international standard or guide would be regarded as “using as the basis” for a technical regulation or a CAP for the purpose of the Agreement. In the case of *EC-Sardines*, the adjudicators based on the ordinary meaning of the term “basis” ruled that the international standard or guide concerned should be “used as the principal constituent or fundamental principle for the purpose of enacting the technical regulation”. In addition, a very strong and close relationship between the international rules and the technical regulation or CAPs at issue should exist.²¹²

Some criticisms have been made to the WTO adjudicators’ textual interpretation abovementioned. It is argued that it is not appropriate to understand the phrase without considering the context and the objective of the provision. H. HORN and J. H. WEILER, and R. HOWSE opined that when assessing the relationship between an international standard and a domestic rule, the evaluation should encompass both procedural and substantive elements. The approach applied by the case law mentioned above, in which only substantive elements are evaluated, would equip international standards considerable, automatic legal force. and thus may not give Members the freedom to decide the content of the domestic regulation or CAPs concerned. On the other hand, a procedural approach allows Members to determine the acceptable degree of risk and the approach which could address such risks while keeping an international standard or a guide as the benchmark against which amendments could be made.²¹³

It seems that the interpretation above is much reasonable. If applying the interpretation of the previous case law, it appears that the requirement “on the basis of” can only be fulfilled in the case that the regulation is identical to relevant international standards. Such interpretation appears, however, against the objective of TBT as it might exclude the situation where the regulation concerned adopted the principle elements of the international standards while some variations exist. In this regard, taking into account the procedural elements in the assessment of “basis” seems much reasonable.

It is not clear whether the development of the 2018 Regulation had taken into consideration of the international standards and guides concerned, i.e. the guidelines of CODEX, and the IFOAM Standards and the Accreditation Requirements. In the Commission’s proposal of the Regulation, there is no mention to the international standards and guides. However, based on the content of the Regulation, which will be analysed further below, it can be seen that the Regulation and the international rules are highly similar. Thus, the possibility that the international rules were used as the benchmark for the development of the Regulation in the legislative process should not be excluded.

I. Is the CODEX Guideline used as the basis for the 2018 Regulation?

Recalled that the AB of *EC-Sardines* considered that where an international standard is the principal constituent of domestic regulation, the international standard would be regarded as the basis of the regulation concerned. To find out if the CODEX Guidelines (GL 32) is the principle constituent of the 2018

²¹² Panel Report. 2002a. *European Communities - Trade Description of Sardines*. WT/DS231/R. para. 7.110. and footnote 90 thereto; Appellate Report. 2002b. *European Communities - Trade Description of Sardines*. WT/DS231/AB/R. para. 245.

²¹³ HORN, H. & WEILER, J. H. 2005. European communities–trade description of sardines: Textualism and its discontent. *World Trade Review*, 4, 254-256.; HOWSE, R. 2006. A new device for creating international legal normativity: the WTO technical barriers to trade agreement and “international standards”. *Constitutionalism, multilevel trade governance and social regulation*, 390.

Regulation, this research compares several dimensions of the two rules, *inter alia*, the objectives, the structure and the content.

The objectives and the structure of the Guidelines appear comparable with the 2018 Regulation. The objectives are laid down in point 2 of Section 1 of the Guidelines. Apart from the goal to harmonize provisions for organic production, the Guidelines aims at protecting consumers' interest against deception and fraud as well as maintaining and enhancing organic agricultural systems in each country so as to contribute to local and global preservation.²¹⁴ Such objectives appear little different from the ones pursued by the 2018 Regulation.

As regards the structure, the Guidelines contains 7 sections, which cover, *inter alia*, the scope of the guidelines, definitions, general provisions on labelling and claims, rules on production and preparation, requirements for permitted substances in the organic practice, general provisions on inspection and certification; and general provisions on imports. The main text of 2018 Regulation follows closely the structure of the Codex Alimentarius Guidelines. Importantly, in order to make the structure much concise, the Regulation places detailed production rules as part of its Annex. This is a different approach from the 2007 Regulation, which places detailed rules in Regulation 889/ 2008, and it is much in line with the structure of the Guidelines.

Finally, the details of the Guidelines also appear comparable with the Regulation. It should be noted, though, the scope of the Guidelines does not cover the production of organic aquaculture as the EU Regulation does. Nevertheless, this does not mean that aquaculture production is prohibited or discouraged in organic farming; instead, it is simply because the rules of aquaculture production are still under development at the international level.²¹⁵ As regards other provisions of the Guidelines, the study of E. Morgera, B. N. Caro, and M. N. Durán indicates that the Guidelines constitutes the principle elements of the 2018 Regulation. Although it is the 2007 Regulation that the study compares with the Guidelines, the result of the study could also apply to the comparison of the 2018 Regulation with the Guidelines as the provisions of the 2007 Regulation analysed in the study are also laid down by the 2018 Regulation. Based on the study, there are many elements found similar or identical in both provisions, such as,

- i. The products of hunting or fishing of wild animals are excluded from both the scope of the Guidelines (section 2.2) and the 2018 Regulation (Article 3 (2));
- ii. Conversion period only starts at the earliest when the production unit has been placed under the established control system and organic production methods shall be applied throughout this period (Annex 1 A.2 of the Guidelines and Article 10.1 and 10.2 of the Regulation).
- iii. The use of certain products and substances, e.g., plant protection products, shall be authorized. The authorization shall at least consider the criteria as to whether the use of such substances and products is in line with the principles of organic production (e.g., no harmful effect on the environment and no negative effect on human or animal health), whether the use is necessary for its intended use, and whether approved alternatives are not available in sufficient quantity and/or quality (Section 5.1 of the

²¹⁴ Point 2 of Section 1 of CODEX ALIMENTARIUS COMMISSION. 1999. Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods. GL 32-1999. Available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCAC%2BG L%2B32-1999%252Fcxg_032e.pdf.

²¹⁵ The footnote to the definition of “livestock” laid down by the Codex Guidelines states that “provisions for aquaculture will be elaborated at a future date”. Section 2.2 of the Codex Guidelines (GL 32) and footnote 9 thereto.

Guidelines and Article 24. 3 of the Regulation);

- iv. Organic seeds and vegetative reproductive material shall be used and may only be regarded as organic if they are obtained from plants grown in accordance with organic practices for one generation, or in the case of perennials, two growing seasons. In the case that organic materials are not available, non-organic materials may be used only if they are not treated with plant protection products other than those authorised for the treatment of seed (Annex 1, A. 8 of the Guidelines and point 1.8.5 of Part I of Annex II to the Regulation);
- v. In terms of livestock origin, both the Guidelines and the Regulation require that livestock used in the production of organic products must have been raised on organic holdings since birth or hatching and throughout life. When derogating from such requirement, the 2018 Regulation specifies the conditions which shall be met and that is closely following the suggestion of the Guidelines (Annex 1, B. 7 and 8 of the Guidelines, and point 1.3.1 and 1.3.4 of part II of Annex II to the Regulation);
- vi. In terms of product composition, the Regulation requires that organic processed food contain mainly ingredients of organic agricultural origin (excluding added water and cooking salt) and only non-organic agricultural ingredients authorised by the EU in a restrictive list (Point 2.1 and 2.2 of part IV of Annex II to the Regulation). This also follows the Codex Alimentarius Guidelines (Annex 1, C.86);
- vii. As regards controls, both the provisions require the conformity assessment procedure for organic production shall establish a system of inspection and certification (Section 6 of the Guidelines and Article 34 of the Regulation). Where any non-compliance is found, the legal consequences are differentiated depending on the severity of the non-compliance concerned (Section 6.9 of the Guidelines and Articles 42.1 and 42.1 of the Regulation).
- viii. The organic term may only be allowed to be used on processed food in the case that the processed food is produced in accordance with organic production rules and contains at least 95% of organic agricultural ingredients. The Regulation also lays down rules that allow operators to use the organic term in relation to ingredients where the products contain less than 95% of organic ingredients. This also follows the Guidelines (Section 3 of the Guidelines and Article 30 of the Regulation).

The examples shown above are the key provisions as regards the scope of the Regulation, organic production, labelling, and CAPs. There are also other detailed rules that are found equivalent or identical to the Guidelines.²¹⁶ In this regard, it appears that the Regulation reflects the Guidelines.

It is noteworthy that two amendments made by the Regulation seem to depart from the Guidelines. One is that the replacement of the previous import scheme based on the recognition of equivalent exporting countries with the scheme based on a trade agreement, while the other is the change in the frequency of inspections. With respect to import rules, to facilitate the trade of organic products, the Guidelines introduce the procedure of the recognition of equivalent countries, which may cover the unilateral and bilateral acceptance of equivalent systems of other countries. This was followed by the 2007 Regulation as one of the applicable import schemes. However, the 2018 Regulation replaces the scheme with an equivalence recognition of third countries based on a trade agreement, in order to improve the access of

²¹⁶ For example, the code number of control bodies shall appear in the labelling (Section 3.2 (d) of the Guidelines and Article 32 of the Regulation). Other examples can be seen in production rules in terms of the cultivation methods for plant production, preventive measures on pest, diseases, and weeds, collection of wild plants, and preventive measures on livestock diseases. The relevant requirements are Annex 1 A.5, A.6, A.9, and B. 20 of the Guidelines and in Annex II to the Regulation, points 1.9.2, 1.10, 2.2 of part I and point 1.5.1 of part II.

organic products produced in the EU to the international market.²¹⁷ According to Article 47 of the Regulation, read with Article 48, apparently, the recognition of equivalent systems will only be conducted on a bilateral basis.

As regards the frequency of inspections, the Guidelines requires that a physical inspection should be conducted by CBs or CAs at least once a year on each production unit. While the 2007 Regulation followed the Guidelines, the 2018 Regulation allows a derogation from such requirement if the operator concerned does not have any non-compliance record during at least three consecutive years, and if, based on risk assessment low likelihood of non-compliance is presented.²¹⁸

The difference abovementioned, however, would not change the conclusion that the 2018 Regulation is developed on the basis of the CODEX Guidelines. Recalled that the term “basis” should be understood from both substantive and procedural perspectives. This means that even though some of the provisions of the Regulation depart from the Guidelines, it does not necessarily mean that the Regulation is not based on the Guidelines. In addition, the high similarity of the Guidelines and the Regulation in terms of the objectives, the structure and the key provisions could suggest that the Guidelines is evaluated in the procedure of the development of the Regulation. This research thus regards that even though the two amendments abovementioned do not follow the Guidelines, it is likely that the Guidelines is used as the benchmark against which the amendments are made.

II. Are the IFOAM Norms used as the basis for the 2018 Regulation?

The structure of the Regulation and the IFOAM Norms appears similar, except that CAPs are regulated in the Accreditation Requirements, an independent document, in the IFOAM Norms. Still, the main text of the Regulation follows the IFOAM Standards and the Accreditation Requirements. That is, both the rules (i.e. the 2018 Regulation and the Norms) are formulated for organic principles, crop production and animal husbandry, aquaculture, processing and handling, labelling, and certification and control system. One obvious difference in the structure is that the IFOAM Standards involve additional requirements for social justice.²¹⁹ These provisions require the production of organic products shall respect human rights and social justice. However, the missing of such elements in the EU organic regulation might be due to the fact that they are already regulated by other EU regulations.

As regards the conformity of the Regulation to the IFOAM Norms, it might be useful to take into account of the equivalence assessment of the EU organic regulations against Common Objectives and Requirements of Organic Standards (COROS) set out in the IFOAM Norms.²²⁰ COROS is developed as a tool by the IFOAM for evaluating the equivalence of organic standards and regulations. The document was compiled on the basis of the IFOAM Basic Standards and Codex Alimentarius, and through the review of a significant number of existing standards and regulations across the world. The COROS contains only requirements that were commonly found in organic standards and regulations globally. Such requirements involve the broad objectives generally pursued by organic standards and regulations and the common

²¹⁷ The point 93 of the preamble to the 2018 Regulation states that “...there is a need to revise those arrangements in order to respond to consumer expectations that imported organic products meet standards as high as those of the Union, *as well as in order to better ensure the access of Union organic products to the international market*” (emphasis added).

²¹⁸ Article 38.3 of the 2018 Regulation.

²¹⁹ Article 9 of the IFOAM Standards.

²²⁰ INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). n.d.-d. Summary of the Equivalence assessment of the EU organic regulation (Council and Commission regulations as of May 2011) against the Common Objectives and Requirements of Organic Standards. Available: https://www.ifoam.bio/sites/default/files/coros_2011_eu_reg_summary.pdf [Accessed 10th June 2019].

detailed requirements that relate to these various objectives. The scope of the equivalence assessment covers requirements related to general organic management, crop and animal production, beekeeping, processing and handling and social justice.²²¹

The IFOAM Standards complies with the principles and requirements set out by COROS, and thus it is reasonable to assume that standards and regulations assessed equivalent with COROS would be equivalent to the IFOAM Standards as well. The IFOAM has assessed the EU organic regulations (i.e. Regulation 834/ 2007 and Regulation 889/ 2008) with the COROS and concluded that within the scope of crop production, animal production, wild collection, processing and handling, the regulations are equivalent with the COROS.²²²

It should be noted that, while acknowledging the EU organic regulations is equivalent to the COROS, the assessment also pointed out some negative variations of the EU regulations from the COROS. Those are the absence of regulations in inert ingredients in agricultural inputs, social justice, biodiversity, water, protection of high conservation value areas, sanitizing and pest control substances in processing, the use of nanotechnology, burning of vegetation, and location of beehives. Nevertheless, it can be seen that the 2018 Regulation has made some improvements. First of all, biodiversity is emphasized in the Regulation. The primary example is that the Regulation allows the use of heterogeneous material in organic farming in order to contribute to a high level of biodiversity.²²³ The protection of species of conservation interest is also added to the principles of organic farming.²²⁴ Furthermore, the provision regarding the authorization of the use of cleaning and disinfection substances in processing premises is also added to the EU organic production rules.²²⁵ This responds to the negative variation regarding the absence of substances allowed for pest controls in processing units. Finally, the use of engineered nanomaterials is forbidden by the Regulation.²²⁶

Based on the discussion above, it appears that the amendments made by the 2018 Regulation to the previous regulations response to part of the negative variations and thus the Regulation could be regarded as being much in line with the IFOAM Standards than the previous EU organic regulations.

As regards CAPs, by comparing the two norms (i.e. the Accreditation requirements and the 2018 Regulation), it can be seen that the principle content of the Requirements is adopted by the Regulation, while the Regulation lays down more technical details suitable for the EU context.²²⁷ Specifically, the Requirements stipulates the qualification of a certification body (Article 1), the code of good practice (Articles 1, 2, and 3), certification procedure (Articles 5, 6, 7, and 8), and the procedure for accepting products certified by other CBs (Article 9). In comparison, the Regulation requires the qualification of

²²¹ INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). 2014. The IFOAM NORMS for Organic Production and Processing. Version 2014. p. 12- 24. Available: https://www.ifoam.bio/sites/default/files/ifoam_norms_july_2014_t.pdf.

²²² It should be noted that the assessed version of the Regulation 889/ 2008 is amended version by Commission Implementing Regulation (EU) No 426/2011. In addition, the EU regulation has requirements regarding aquatic plants and animals, organic yeast production and mushroom production, which have not been included in the scope of this assessment, since they are not covered by the COROS. EU requirements regarding record keeping and specific rules for the EU logo have been considered as not relevant to this assessment and therefore have also not been taken into account.

²²³ See Articles 4 (i), 6 (d) and (g), and 13 of the 2018 Regulation.

²²⁴ Article 6 (q) of the 2018 Regulation

²²⁵ Article 24. 1 (g) of the 2018 Regulation.

²²⁶ Article 7 (e) of the 2018 Regulation

²²⁷ For example, rules regarding competent authorities' delegation of control tasks to control bodies (Article 40) is specifically designed for the EU context.

control bodies, as well as their code of good practice, shall be in accordance with the standard of Conformity assessment — Requirements for bodies certifying products, processes and services (ISO/IEC 17065:2012).²²⁸ The difference between the Requirements and the ISO standard appears little as the Requirements is developed and revised based on the ISO standard.²²⁹ With respect to the comparison of other provisions, it is summarized as the table in the Annex. The result of the comparison shows that the current design of the Regulation principally adopted the main components of the Requirements. However, it should also be noted that the Regulation emphasizes more on the controls of non-conformance and thus lays down much detailed rules on measures that shall be taken where a suspected or a confirmed non-conformance is found.

Having considered the discussion above, it seems that the Regulation is developed based on the two IFOAM norms. It can be seen that the principle components of the norms are adopted by the Regulation. In fact, although there is no official record of the EU stating that the norms are used as the benchmark in the process of developing the Regulation, the reason for such high similarity between the norms and the Regulation could be indicated by the history of the harmonization of organic standards at the global level. In particular, the International Task Force on Harmonization and Equivalence in Organic Agriculture (ITF), jointly led by FAO, IFOAM and UNCTAD and convened from 2003 through 2008, provided a platform for dialogue among public and private stakeholder. Participants have come from government agencies of twenty-nine countries, including the EU commission, eight inter-governmental agencies and twenty-five civil society and other private organizations. With the main objective to stimulate access of developing country producers to international markets and facilitate international trade of organic products, the ITF developed two tools for equivalence assessment; that is, the Guide for Assessing Equivalence of Standards and Technical Regulations (EquiTool), which focuses on production and processing standards, and the International Requirements for Organic Certification Bodies (IROCB), which focuses on the requirements for certification. Following the works of the ITF, the Global Organic Market Access (GOMA, 2009-2012) was established to implement the two tools at the level of country and regions. Together with IFOAM, the tools then were harmonized into COROS, which was then adopted as one of the IFOAM norms. While the tools were initially designed for equivalence assessment, they later also served as a benchmark in support of harmonization of standards and technical regulations.²³⁰

5.4 Recognition of equivalence:

Considering that the process of developing an international standard can be lengthy and costly, negotiators thus introduced in the TBT Agreement an alternative approach to technical harmonization, known as equivalence. Article 2.7 and relevant part of Article 6 of TBT Agreement lay down the requirement for Members to accept technical regulations and CAPs which are different from their own but could fulfil the

²²⁸ See Articles 40.3 and 46.2 of the 2018 Regulation refers to ISO/IEC 17065:2012 as stated in official journal OJ C 209 of 15/06/2018 (EUROPEAN COMMISSION 2018a. Commission communication in the framework of the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision No 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 1221/2009 of the European Parliament and of the Council.)

²²⁹ INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS (IFOAM). n.d.-b. *THE IFOAM ACCREDITATION REQUIREMENTS* [Online]. Available: <https://www.ifoam.bio/en/ifoam-accreditation-requirements> [Accessed 16th June 2019].

²³⁰ MORGERA, E., CARO, B. N. & DURÁN, M. N. 2012. *Organic agriculture and the law*, Food and Agriculture Organization of the United Nations.41-43; PEKDEMIR, C. 2018. On the regulatory potential of regional organic standards: Towards harmonization, equivalence, and trade? *Global Environmental Change*, 50, 289-302.

same policy objectives as their domestic rules do. This way helps eliminate technical barriers to international trade.

The way Article 2.7 regulates the requirement is,

*“Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.”*²³¹

A similar requirement for CAPs can be seen in Article 6.1, which requires Members to accept results of CAPs in other countries equivalent to the CAPs of the importing countries concerned.

The 2018 Regulation introduces an import regime under which imports shall be produced either in compliance with the EU rules, or in conformity with the regulations recognized equivalence by the EU under trade agreements.²³² When regulating the recognition of equivalence, the EU regulation lays down as the following requirement,

*“A recognised third country referred to in point (b)(ii) of Article 45(1) is a third country which the Union has recognised under a trade agreement as having a system of production meeting the same objectives and principles by applying rules which ensure the same level of assurance of conformity as those of the Union.”*²³³

By comparing the language of the EU regulation and the TBT requirement, it seems that there isn't much difference between the two rules. However, due to the phrase “under a trade agreement” in the EU provision, it causes some concerns as to whether the application of equivalence recognition will be restricted. In particular, for countries with fewer bargain powers in the negotiation of a trade agreement, they may face difficulties to have their technical regulations be recognized equivalent by the EU.

When reading carefully Articles 2.7 and 6.1 of the TBT Agreement, it although appears to be an obligation of the Members, however, this requirement is weakened by the second part of the sentence (‘provided they are satisfied’). WTO members thus appear to have the discretion to offer or reject recognition of the importing country.²³⁴ In this regard, it might be difficult for a country in a weaker position in the trade agreement with the EU to claim that the application of the 2018 regulation is in violation of Article 2.7 or 6.1 of the Agreement.

However, in extreme case, where the EU obviously weighs trade benefits much more than the other factors in the evaluation of equivalence, the application of Article 47 of the Regulation is then likely to violate the requirements of the Agreement. The possible argument could be based on the prohibition of *abus de droit*. The prohibition of *abus de droit* was introduced by WTO adjudicators to the case *US-Shrimp* as an application of the principle of good faith. AB of that case regarded that the doctrine of *abus de droit* requires a State to exercise its rights reasonably and not abusively. Specifically, as described by Cheng, the doctrine is a line delimiting the rights of both parties to a point where there is a reasonable balance between the conflicting interests involved.²³⁵

²³¹ Article 2.7 of TBT Agreement.

²³² Articles 45.1 and 47 of the 2018 Regulation. Although the equivalence recognition under the 2007 Regulation will be valid till 2025 (Article 48 of the 2018 Regulation), it is not within the scope of discussion in this research as the scheme is going to be abolished in the future.

²³³ Article 47 of the 2018 Regulation.

²³⁴ HOLZER, K. & COTTIER, T. 2015. Addressing climate change under preferential trade agreements: Towards alignment of carbon standards under the Transatlantic Trade and Investment Partnership. *Global environmental change*, 35, 514-522.

²³⁵ CHENG, B. 1987. *General principles of law as applied by international courts and tribunals*, Cambridge University Press.

When looking into Articles 2.7 and 6.1 of the Agreement, two conflicting interests are involved. On the one hand, Members have the right to decide on whether the technical regulations and CAPs of other countries meet a satisfactory level; on the other hand, other Members have the right to request a regulating Member to give “positive consideration” of equivalent technical regulation and CAPs. The phrase “positive consideration” in the provision may suggest a limitation to the discretion of Members as regards the recognition of equivalence. In other words, it may require that Members shall pay its best effort to objectively evaluate the equivalence of other countries with the aim of reducing the negative impact to trade arisen from the introduction of technical regulation. In this regard, where an extreme case abovementioned happens, it is likely that the EU is regarded to abusively exercise the discretion allowed by the Agreement and thus violate the requirements as set out in Articles 2.7 and 6.1 of the Agreement.

5.5 Technical assistance and special and differential treatment

Recognizing the difficulties and challenges that developing-country members may face with implementation, the TBT Agreement contains provisions which give developing countries special rights in terms of requesting technical assistance (Article 11) and of special and differential treatment (Article 12) from developed countries.

This is relevant to this study as the import regime of the 2018 Regulation, adopting the scheme of compliance and equivalence recognition under a trade agreement, might particularly impact the trade with developing countries. As described in the previous section, developing countries might face difficulties to be recognized equivalence under a trade agreement when they have less bargaining power in the negotiation. This then leads to the result that producers in those countries are required to comply with the EU organic regulation in order to export their products to the EU. It might be even problematic for those producers as the design of the Regulation suggests that production rules might be stricter than the previous regulation. In cases that there is a huge difference in local conditions between a third country and the EU, it might be too difficult for imports to be produced fully in compliance with the EU rules.

Articles 11 and 12 of the Agreement are designed to address the impact on exports of developing countries caused by the technical regulation or CAPs. Article 11 requires Members to provide advice and technical assistance to other members, especially developing country Members. This includes assistance with the establishment of national standardizing, regulatory bodies or conformity assessment bodies (Articles 11.2, 11.3 and 11.4). The assistance also encompasses help the requesting countries to participate in international standardizing bodies, or in international or regional systems for conformity assessment (Articles 11.2 and 11.6). Finally, Members are also required to advise on the preparation of technical regulations, how best to meet these technical regulations, and steps to be taken by producers to gain access to systems for conformity assessment (Articles 11.1, 11.3 and 11.5).

On the other hand, Article 12 deals with special and differential (S&D) treatment for developing country members. Specifically, S&D treatments apply to i) the preparation and application of technical regulations, standards and conformity, and assessment procedures (Article 12.3) ii) related technical assistance (Article 12.7) and harmonization (Articles 12.4, 12.5 and 12.6), iii) time-limited exceptions from obligations under the Agreement (Article 12.8), and iv) consultations with the awareness of special difficulties experienced by developing country Members (Article 12.9).

Based on the provisions abovementioned, developing countries facing difficulties in complying with or being recognized as equivalent to the EU organic regulation can request the EU provide technical assistance and special and differential treatment. In particular, Articles 11.1 and 11.3 of the Agreement could be helpful for a developing

country acquiring the assistance of the EU to establish a legal framework that could be recognized equivalence by the EU; on the other hand, developing country Members could request the EU, while developing implementing and delegating acts of the 2018 Regulation, to take into account the special development, financial and trade needs of developing country Member in accordance with Article 12.3.

However, it should also be noted that the providers of technical assistance and special treatments are not fully obliged to provide such assistance or treatments or not. The language “shall ...grant [other Members, especially developing country Members] technical assistance” used in Article 11 is always accompanied with softening language such as “based on mutually agreed terms and conditions.” This, arguably, make the provision of technical assistances largely depends on the “good will” of Members receiving such requests.²³⁶ Similarly, the obligation laid down in Article 12.3 was recognized by the panel of *US- COOL* that it is merely a requirement for Members to give consideration to the needs of developing countries along with other factors before reaching a decision. It does not amount to a requirement for WTO Members to conform their actions to such needs. The panel further noted that such a requirement does not oblige Members to “actively reach out to developing countries and collect their views on their special needs”, nor “to document specifically in their legislative process and rule-making process how they actively considered the special development, financial and trade needs of developing country Members. ” Such an interpretation could weaken the obligation and leave the providing country, in this case, the EU, the autonomy to decide how to prepare and apply its technical regulation and CAPs.

6. Conclusion

The organic sector has been regulated at EU level for around two decades, during which two times of legislative reforms were made in 2007 and 2018 respectively. The booming growth in the EU organic sector in the recent years resulted in the latest revision, the Regulation 2018/ 848, which aims to resolve the decencies found in the Regulation No. 834/ 2007 and its implementing regulations. The newly reformed regulation is expected to create a level playing field for operators and ensure that consumer confidence in the integrity of organic products is sustained.

However, while some improvements are made, concerns toward the impact on trade, which may be resulted from the change in the import regime of organic products, also emerge. The design of the import regime, requiring organic products exported to the EU through either the compliance scheme or a trade agreement, could create an impact on trade. Recognition equivalence under a trade agreement is criticized not helpful to reduce the impact on trade as the negotiation of an agreement normally takes years. For countries that have less bargaining power, it is even difficult for them to conclude a trade agreement with the EU. While a trade agreement seems not a feasible approach, the only option left for operators in non-EU countries is the compliance scheme. Nevertheless, this might lead to an increase in the compliance cost and cause duplication of certification.

The research seeks to examine whether such concerns signify that the 2018 Regulation is inconsistent with the WTO disciplines. The TBT Agreement is regarded applicable in this study, given that the 2018 Regulation is composed of a technical regulation and CAPs as defined by the TBT Agreement and that the predominant objectives of the Regulation do not fall within the scope of the SPS agreement.

While recognizing the difficulties that operators in non-EU countries might have under the 2018 Regulation, the analysis of relevant TBT disciplines provided in this research suggests that it is likely that the 2018 Regulation conforms with the Agreement. The only measure that could be regarded inconsistent with the Agreement is the distinction on the right of requesting the Commission to amend the list of authorized substances and products.

²³⁶ EPPS, T. & TREBILCOCK, M. J. 2013. The TBT Agreement in context. *Research Handbook on the WTO and Technical Barriers to Trade*. Edward Elgar Publishing, 72.

The distinction might negatively affect the competitiveness of operators outside the EU and there seems no justification for such a distinction. Thus, it could violate the requirement of non-discrimination.

When assessing the obligation of non-discrimination, the reasonableness of the claims, regarding the difficulties of complying with the EU rules or of concluding a trade agreement with the EU, is examined. The analysis demonstrates that, while there might be a detrimental impact on trade, it does not necessarily lead to the conclusion that the EU does not satisfy the obligation of non-discrimination. On the one hand, the WTO case law already explicitly stated that a regulating Member does not have the duty to conclude an agreement but need to negotiate in good faith. This means that the EU is only obliged to provide comparable efforts in the negotiation with every trading countries. On the other hand, the difficulties of complying with the EU rules are not sufficient to establish that the EU applies its measures in an even-handed manner. The difficulties of complying the EU rules should instead be discussed under Article 11 and 12 of the Agreement.

The analysis of unnecessary obstacles to trade explores the requirements of Article 2.2 and Article 5.1.2. It is doubted that whether the increase in compliance cost or the cost arisen from duplication of certification would be regarded “trade-restrictive” when it was noted in WTO jurisprudence that the proof should be able to demonstrate a magnitude of restrictiveness. Even though the restrictiveness or strictness could be proved, it is likely that the measures of the 2018 Regulation would be considered as necessary as it could make a meaningful degree of contribution to the objectives pursuit and the comparative analysis suggests that there are no alternatives would contribute to the objectives to an equivalent degree.

Harmonization of technical regulations and CAPs is another important objective of the TBT Agreement. Under the objective, two TBT disciplines are explored, i.e., the use of international standards as the basis of technical regulation and CAPs and positive consideration of accepting equivalent norms of other Member countries. In the analysis of the former discipline (i.e. Articles 2.4 and 5.4), two international standards, the IFOAM Norms and the Codex Guidelines (GL 32), are analysed. It is found that, by comparing the similarity of the 2018 Regulation and the two standards, the 2018 Regulation is composed of the principle components of the two standards. Thus, it is regarded fulfils the requirement that a technical regulation and CAPs should be developed on the basis of a relevant international standard. As to the other discipline under the objective of harmonization (i.e. Articles 2.7 and 6.1), it seems to have less mandatory character. The language used in Article 2.7 and 6.1 of the Agreement appears to leave the discretion for a regulating Member to decide whether a technical regulation and CAPs of another Member country is accepted or not. Thus, it might be difficult to establish that the EU does not conform with the requirement if the complainant can not prove that the discretion is exercised in a way that violates the principle of *abus de droit*.

While the current design of the 2018 Regulation seems consistent with most of the TBT disciplines, requiring the EU to provide technical assistance and special differential treatment might be a way to addressing the concerns of developing countries. However, the language of Article 11 and 12 and the interpretation made by previous case law suggests that whether assistance and special treatments could be provided will mainly depend on the good will of the EU.

Having analysed relevant disciplines of TBT Agreement above, the result of the research shows that the Regulation is TBT-consistent, except that the distinction of the use of certain substances might violate the requirement of non-discrimination. What should be noted here is that the implementing acts and delegating acts of the Regulation have not been introduced yet. Therefore, whether the completed EU organic regime is consistent with the relevant WTO disciplines is pending on further studies.

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Annex

Comparison table of the IFOAM Accreditation Requirements and CAPs of the 2018 Regulation

Explanatory note:

1. This comparison table only covers principle rules in the both norms.
2. Result is based on plain reading the provisions. There are four types of result, E, PV, NV, N/A. E refers to equivalence, applying in cases that provisions compared are highly similar. PV refers to positive variation, applicable in cases that the Regulation lays down additional or stricter rules. NV refers to negative variation, applicable in cases that the Regulation does not have such rules as set out by the IFOAM Norm. N/A refers to not applicable, used in cases where the EU regulations is introduced specifically for the context of the EU.

Summary of the provisions	2018 Regulation	IFOAM Requirements	Result
Qualification of a certification body	Article 88 of Regulation no. 2017/625 and the ISO 17065: 2012 applies.	Article 1 regarding the structure of a certification body.	E
Code of good practice of a certification body	Article 88 of Regulation no. 2017/625 and the ISO 17065: 2012 applies.	Article 1 and 2.1	E
Quality system of a certification body	The ISO 17065: 2012 applies.	Article 3	E
Confidentiality provisions	The ISO 17065: 2012 applies.	Article 4	E
Documentation and document control	The ISO 17065: 2012 applies.	Article 5	E
Application and inspection procedure	The ISO 17065: 2012 applies.	Articles 6 except for 6.7 and 6.8	E
Certification procedure	The ISO 17065: 2012 applies.	Articles 7.1 and 7.2	E
Organic products shall be subject to a certification system	Article 34.1 Operators and groups of operators referred to in Article 36 which produce, prepare, distribute or store organic or in- conversion products, which import such products from a	2.2.3 Any entity in the chain of custody that has produced, processed, packaged, or labelled an organic product shall have been certified.	E

	third country or export such products to a third country, or which place such products on the market shall be subject to certification system		
Derogation from certification system	Article 34.2 Operators that sell prepacked organic products directly to the final consumer or user.	Guidance to 2.2.3 The certification body is not obliged to have a system for inspection of products that are further handled after being packed in the final consumer package.	E
Certification in the case of subcontracting	Article 34.3 Both the operators or groups of operators and the third parties to whom those activities have been subcontracted shall be subject to certification system, except that the operator or group of operators has declared in the notification referred to in paragraph 1 that it remains responsible as regards organic production and that it has not transferred that responsibility to the subcontractor.	2.3 The certification body shall have policies and procedures for regulating subcontracted production or processing, which shall prescribe the circumstances where the subcontracted party is not required to be certified.	E
Specific inspection requirements for the conversion period	- <i>Note: The inspection rule as set out by Article 6. 7 of the Requirements is not specified by the Regulation. However, Article 35.1 requires that organic certificate shall certify that the activities of an operator comply with the Regulation. The conversion period is specified by the Regulation, and thus according to Article 35.1, it is reasonable that the inspection shall be carried out during the conversion period.</i>	6.7 Inspection of conversion products shall be carried out during the conversion period.	E
Issuance of a certificate	Article 35.1 The certificate shall: (a) be issued in electronic form	7.4 confirming compliance of a certified operation. These shall include at least:	E

	<p>wherever possible;</p> <p>(b) allow at least the identification of the operator or group of operators including the list of the members, the category of products covered by the certificate and its period of validity;</p> <p>(c) certify that the notified activity complies with this Regulation; and</p> <p>(d) be issued in accordance with the model set out in Annex VI.</p>	<p>a. the name and address of the operator;</p> <p>b. the name and address of the certification body;</p> <p>c. the program under which the operator is certified;</p> <p>d. the scope of the certification including reference to the applicable standards, the products or product categories, and the certification status (conversion or organic) of each;⁴⁹</p> <p>e. the date of issuance;</p> <p>f. the period of validity;</p> <p>g. an authorized signature of the certification body.</p>	
Multiple certification	<p>Article 35.4</p> <p>Multiple certification is not allowed</p>	<p>7.11.2</p> <p>Multiple certification is allowed and the certification body shall supply the other certification body (or bodies) with copies of transaction certificates or information regarding sales and inform them in event of de-certification or major non-conformities.</p>	PV
Exception for in the possession of a certificate	<p>Operators that sell unpacked organic products other than feed directly to the final consumer may be exempted from possessing a certificate, provided that those operators do not produce, prepare, store other than in connection with the point of sale, or import such products from a third country, or subcontract such activities to a third party, and provided that:</p> <p>(a) such sales do not exceed 5 000 kg per year;</p> <p>(b) such sales do not represent an annual turnover in relation to unpacked organic products exceeding EUR 20 000; or</p> <p>(c) the potential certification cost of</p>	-	PV

	the operator exceeds 2 % of the total turnover on unpacked organic products sold by that operator.		
	<p>35.5 Members of a group of operators shall not be entitled to obtain an individual certificate for any of the activities covered by the certification of the group of operators to which they belong.</p> <p>36.1</p> <p>Each group of operators shall:</p> <p>(a) only be composed of members who are farmers or operators that produce algae or aquaculture animals and who in addition may be engaged in processing, preparation or placing on the market of food or feed;</p> <p>(b) only be composed of members:</p> <p>(i) of which the individual certification cost represents more than 2 % of each member's turnover or standard output of organic production and whose annual turnover of organic production is not more than EUR 25 000 or whose standard output of organic production is not more than EUR 15 000 per year; or</p> <p>(ii) who have each holdings of maximum:</p> <ul style="list-style-type: none"> — five hectares, — 0,5 hectares, in the case of greenhouses, or — 15 hectares, exclusively in the case of permanent grassland; <p>(c) be established in a Member State or a third country;</p> <p>(d) have legal personality;</p> <p>(e) only be composed of members whose production activities take place</p>	<p>8.3.3.1 The certified entity shall be the group as a whole. This means that individual group members may not use the certification independently (by marketing as individual producers outside of the group).</p> <p>8.3.2.1 The certification body shall limit the scope of such systems to groups that fulfil the following requirements:</p> <ul style="list-style-type: none"> a. the group shall be constituted of operations with similar production systems; b. large farming units, processing units and traders shall not be included in the inspection arrangements for such groups and shall be inspected by the certification body in accordance with the requirements of 7.5.2. Simple on-farm processing and storage units may be included; c. group members shall be in geographic proximity; d. the group shall be large enough and have sufficient resources to support a viable internal control system that assures compliance of individual members with production standards in an objective and transparent manner; e. the group shall have coordinated marketing. 	E

	<p>in geographical proximity to each other;</p> <p>(f) set up a joint marketing system for the products produced by the group; and</p> <p>(g) establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group</p>		
Internal control systems for group certification	<p>36.1 (g)</p> <p>Each group of operators shall establish a system for internal controls comprising a documented set of control activities and procedures in accordance with which an identified person or body is responsible for verifying compliance with this Regulation of each member of the group</p>	<p>8.3.3.2 An effective and documented internal control system shall be in place.</p> <p>Guidance: The system shall include a documented management structure of the internal control system</p>	E
Internal control	<p>36.3</p> <p>The Commission is empowered to adopt delegated acts as regards the set-up and functioning of the system for internal controls, including the scope, content and frequency of the controls to be carried out and the criteria to identify deficiencies in the set-up or functioning of the system for internal controls.</p>	<p>8.3.3.3 Documented inspections of all group members with the specific purpose of checking compliance with production standards shall be carried out by the internal control system at least annually.</p> <p>8.3.3.7 The group shall at least comply with the following requirements:</p> <p>a. there are competent personnel implementing the internal control system;</p> <p>b. the personnel is provided with regular training;</p> <p>c. the group has a mechanism to address potential and actual conflicts of interests.</p> <p>d. the core documentation is complete, which includes:</p> <ul style="list-style-type: none"> · appropriate maps/sketches, 	TBD

		<ul style="list-style-type: none"> · a complete list of group members, · farm/field or processing records, · signed member agreements, · yield estimates; <p>e. the internal inspection protocol is described and implemented;</p> <p>f. a monitored and documented conversion period is in place;</p> <p>g. a mechanism to enforce corrective actions by group members, and remove non compliant group members from the list as well as non- conforming product from the supply stream, is in place and executed;</p> <p>h. Group management shall have a description of the product flow and full records at each step, including any non-compliant products;</p> <p>i. there are procedures to accept new members, ensuring that acceptance happens only after internal inspections;</p> <p>j. decision making is separate from internal inspections;</p> <p>k. risk assessment is conducted and acted upon accordingly.</p>	
Withdraw group certification	<p>Article 36.2</p> <p>Competent authorities, or, where appropriate, control authorities or control bodies, shall withdraw the certificate referred to in Article 35 for the whole group where deficiencies in the set-up or functioning of the system for internal controls referred to in paragraph 1, in particular as regards failures to detect or address non-compliance by individual members of the group of operators, affect the integrity of organic and in-conversion products.</p>	<p>8.3.5.2 The certification body shall have a clear sanctions policy in event of non-compliance by the group and/or its members. Failure of the internal control system to detect and act on non-compliances shall invoke sanctions on the group as a whole.</p> <p>8.3.5.3 Certification should not be granted or should be revoked in case of ineffectiveness / systematic failure of the internal control system.</p>	E

Use of Licenses, Certificates and Certification Marks	Covered by the labelling rules in this Regulation	7.8 Use of Licenses, Certificates and Certification Marks	E
Compliance verification in particular on preventive and precautionary measures, parallel production, group certification, and the requirements for exemption of certification	<p>38.1</p> <p>Official controls performed in accordance with Article 9 of Regulation (EU) 2017/625 for the verification of compliance with this Regulation shall include, in particular:</p> <p>(a) the verification of the application by operators of preventive and precautionary measures, as referred to in Article 9(6) and in Article 28 of this Regulation, at every stage of production, preparation and distribution;</p> <p>(b) where the holding includes non-organic or in-conversion production units, the verification of the records and of the measures or procedures or arrangements in place to ensure the clear and effective separation between organic, in- conversion and non-organic production units as well as between the respective products produced by those units, and of the substances and products used for organic, in-conversion and non-organic production units; such verification shall include checks on parcels for which a previous period was recognised retroactively as part of the conversion period, and checks on the non-organic production units;</p> <p>(c) where organic, in-conversion and non-organic products are collected simultaneously by operators, are prepared or stored in the same preparation unit, area or premises, or are transported to other operators or units, the verification of the records and of the measures, procedures or arrangements in place to ensure that</p>	<p>6.8.2</p> <p>In cases of split production the certification body shall require and verify by inspection:</p> <p>a. that the documentation regarding the production or processing, storage and sales is well managed and makes clear distinctions between certified and non-certified products;</p> <p>b. that the measures taken to safeguard against the risk to the organic integrity is understood at all levels of the operation.</p> <p>d. that no operator is inspected less than once in three calendar years;</p> <p>e. the certification body installs mechanisms to monitor operators to assess their risk level between very spread out inspections.</p> <p>8.3.4.3 The inspection visit shall include an assessment of the internal control system, of its effective application and of compliance with the standards.</p>	PV

	<p>operations are carried out separated by place or time, that suitable cleaning measures and, where appropriate, measures to prevent substitution of products are implemented, that organic products and in-conversion products are identified at all times and that organic, in-conversion and non-organic products are stored, before and after the preparation operations, separated by place or time from each other;</p> <p>(d) the verification of the set-up and functioning of the internal control system of groups of operators;</p> <p>(e) where operators are exempted from the notification obligation in accordance with Article 34(2) of this Regulation or from the obligation to be in the possession of a certificate in accordance with Article 35(8) of this Regulation, the verification that the requirements for that exemption have been fulfilled and the verification of the products sold by those operators.</p>		
<p>Risk assessment factors</p>	<p>Article 38.2</p> <p>The verification of non-compliance shall be on the basis of the likelihood of non-compliance, which should take into account,</p> <p>(a) the type, size and structure of the operators and groups of operators;</p> <p>(b) the length of time during which operators and groups of operators have been involved in organic production, preparation and distribution;</p> <p>(c) the results of the controls performed in accordance with this Article;</p> <p>(d) the point in time relevant for the activities carried out;</p>	<p>2.2.4 Certification bodies shall conduct a risk assessment to determine the necessity for, or frequency of, inspection of all storage facilities including port facilities. Where this reveals a need for inspection to protect organic integrity, inspection shall be done</p> <p>8.3.4.5 The inspection shall include an assessment of the risks to organic integrity within the group itself and the environment in which it functions</p>	<p>PV</p>

	<p>(e) the product categories;</p> <p>(f) the type, quantity and value of products and their development over time;</p> <p>(g) the possibility of commingling of products or contamination with non-authorized products or substances;</p> <p>(h) the application of derogations or exceptions to the rules by operators and groups of operators;</p> <p>(i) the critical points for non-compliance and the likelihood of non-compliance at every stage of production, preparation and distribution;</p> <p>(j) subcontracting activities.</p>		
Annual inspection	<p>38.3</p> <p>In any case, all operators and groups of operators, with the exception of those referred to in Articles 34(2) and 35(8), shall be subject to a verification of compliance at least once a year.</p> <p>The verification of compliance shall include a physical on-the-spot inspection, except where the following conditions have been satisfied:</p> <p>(a) the previous controls of the operator or group of operators concerned have not revealed any non-compliance affecting the integrity of organic or in-conversion products during at least three consecutive years; and</p> <p>(b) the operator or group of operators concerned has been assessed on the basis of the elements referred to in paragraph 2 of this Article and in Article 9 of Regulation (EU) 2017/625 as presenting a low</p>	<p>7.5.2 The certification body shall have a written policy on inspection frequency of already certified operators. The policy shall require that certified operators are inspected at least annually. Alternatively, (except in the cases of new applicants, operators wholly in conversion or group certification) the policy shall fulfill the following requirements:</p> <p>a. the frequency and type of inspections are based on the risks with respect to the individual operator;</p> <p>b. the risk analysis take into account any relevant threat to the organic integrity of the production and products;</p> <p>c. the total number of inspections per calendar year at least equals the total number of already certified operators;</p> <p>d. that no operator is inspected less than once in three calendar years;</p> <p>e. the certification body installs mechanisms to monitor operators to assess their risk level between very spread out inspections</p>	E

	<p>likelihood of non- compliance.</p> <p>In this case, the period between two physical on-the-spot inspections shall not exceed 24 months.</p>		
Additional inspections	<p>Article 38.4 (b)</p> <p>a minimum percentage of additional controls to annual inspections of Article 38.3 shall be carried out.</p> <p>Article 38.9</p> <p>The Commission may adopt implementing acts to specify the minimum percentage.</p>	<p>7.5.4 The certification body shall have a policy for deciding the frequency of additional inspections that takes into account risk assessment. The risk assessment methodology shall be documented and include factors such as type, size and complexity of production, and risk of non-compliance.</p>	E
Unannounced inspections	<p>Article 38.4 (a)</p> <p>a minimum percentage of all official controls of operators or groups of operators are carried out without prior notice.</p> <p>Article 38.9</p> <p>The Commission may adopt implementing acts to specify the minimum percentage.</p>	<p>7.6.1 The certification body shall have a documented policy requiring that at least annually 5% of the operators are subject to unannounced inspection.</p>	E
Additional rules on actions to be taken by the operators and groups of operators	<p>39</p> <p>In addition to the obligations laid down in Article 15 of Regulation (EU) 2017/625, operators and groups of operators shall:</p> <p>(a) keep records to demonstrate their compliance with this Regulation;</p> <p>(b) make all declarations and other communications that are necessary for official controls;</p> <p>(c) take relevant practical measures to ensure compliance with this Regulation;</p> <p>(d) provide, in form of a declaration to be signed and updated as necessary:</p> <p>(i) the full description of the organic</p>	<p>-</p> <p><i>NOTE:</i></p> <p><i>The Regulation lays down the obligations of an operator as regards notification and documentation. Although a few of the requirements can be seen in the IFOAM Norm, however, such requirements are much detailed in the Regulation.</i></p>	PV

	<p>or in-conversion production unit and of the activities to be performed in accordance with this Regulation;</p> <p>(ii) the relevant practical measures to be taken to ensure compliance with this Regulation;</p> <p>(iii) an undertaking:</p> <ul style="list-style-type: none"> — to inform in writing and without undue delay buyers of the products and to exchange relevant information with the competent authority, or, where appropriate, with the control authority or control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established, — to accept the transfer of the control file in the case of change of control authority or control body or, in the case of withdrawal from organic production, the keeping of the control file for at least five years by the last control authority or control body, — to immediately inform the competent authority or the authority or body designated in accordance with Article 34(4) in the event of withdrawal from organic production, and — to accept the exchange of information among those authorities or bodies in the event that subcontractors are subject to controls by different control authorities or control bodies. 		
Notification of changes in licensee’s operation and	May be covered by article 39.1 (b) and 39. 2	7.7 The certification body shall require the operator to give notification, in a timely	TBD

extension of scope		manner, of significant changes such as modification to the products, the manufacturing process, extension of acreage or changes to management, or ownership. The certification body shall require of the operator that he shall not release certified products resulting from such changes until the certification body has granted permission.	
Additional rules on the delegation of official control tasks and tasks related to other official activities	Article 40	- <i>Note:</i> <i>The delegation of official control tasks to control bodies or control authorities is specific for the EU context, and thus there are not such rules in the IFOAM Norm.</i>	N/A
Actions in case of suspected non-compliance	Articles 29 and 41	-	PV
Actions in case of non-compliance	Article 42 non-compliance affecting the integrity of organic or in-conversion products throughout any of the stages of production, preparation and distribution, control authorities and control bodies, shall ensure, that no reference is made to organic production in the labelling and advertising of the entire lot or production run concerned In the event of serious, or repetitive or continued non-compliance, competent authorities, and, where appropriate, control authorities and control bodies, shall ensure that the operators or the groups of operators concerned, in addition to the measures laid down in paragraph 1 and any appropriate measures taken in particular in accordance with Article 138 of Regulation (EU) 2017/625, are prohibited from marketing products	7.9.3 Where a non-conformity that affects organic integrity is found, the certification body shall require that the certification mark or any other indication of certification is removed from the entire production run or product affected by the non-conformity concerned 7.9.4 The certification body shall have procedures for immediate suspension of certification in cases where the inspector detects manifest non-conformities or fraudulent activity.	E

	which refer to organic production for a given period, and that their certificate referred to in Article 35 be suspended or withdrawn, as appropriate.		
Non-conformities and sanctions	<p>Article 41.4</p> <p>Competent authorities shall provide a common catalogue of measures for cases of suspected non-compliance and established non-compliance to be applied in their territory, including by control authorities and control bodies.</p>	<p>7.9</p> <p>The certification body shall have a documented range of non-conformities and corresponding sanctions including measures to deal with minor non-conformities with the standards.</p>	E
Appeals	The ISO 17065: 2012 applies.	<p>7.10</p> <p>The certification body shall have procedures for the consideration of appeals against its certification decisions</p>	E
Exchange of information between competent authorities	<p>Article 43.1</p> <p>information exchange between competent authorities, as well as with the Commission, on any suspicion of non-compliance that affects the integrity of organic or in-conversion products</p>	-	N/A
Exchange of information between control bodies	<p>Article 43.2 through 43.4</p> <p>In cases where suspected or established non-compliance has been identified with regard to products under the control of other control authorities or control bodies, control authorities and control bodies shall immediately inform those other control authorities or control bodies.</p> <p>Control authorities and control bodies shall exchange other relevant information with other control authorities and control bodies.</p> <p>Upon receiving a request for information that is justified by the need to guarantee that a product has been produced in accordance with this</p>	<p>The certification body shall require operators to notify it of all previous and current certifications within the scope. The certification body shall communicate with the other certification body to ascertain if there were any major issues. Alternatively, the certification body shall require the operator to submit the most recent certification decision issued by the other certification body.</p> <p>In cases of multiple certification with the same certification scope, the certification body shall supply the other certification body (or bodies) with copies of transaction certificates or information regarding sales and inform them in event of de-certification or major non-</p>	E

	Regulation, control authorities and control bodies shall exchange with other competent authorities, as well as with the Commission, information on the results of their controls.	conformities.	
Certification of Wild Products	-	8.1 Certification of Wild Products	NV
Approval or Certification of Inputs	-	8.2 Certification bodies should have an approval system for evaluating the input products compliance with the certification body's standards	NV
	Regulated in ISO STANDARD	7.8 Use of Licenses, Certificates and Certification Marks 7.8.1 The certification body shall exercise control over the use of its licenses, certificates and certification marks. 7.8.2 A certification body may permit its mark to be applied by a non-licensee on behalf of a licensee ⁵³ provided:	
Acceptance of other product certification	- <i>In EU, acceptance of products based on compliance and bilateral equivalence recognized under trade agreements</i>	9.2 Acceptance of Products Based on the Recognition of a Certification Body's Program the certification body's program is based on a standard approved in the IFOAM Family of Standards. In addition, the certification body has obtained an accreditation (for the scope of that specific standard) which is recognized as an equivalent accreditation program by IFOAM-Organics International	PV