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WTO Ministerial Statements: Creating *momentum* on trade and environmental sustainability, as well as on climate change mitigation

On 15 December 2021, the World Trade Organization (hereinafter, WTO) presented three Ministerial Statements supported by certain WTO Members: 1) The [Ministerial Statement on Trade and Environmental Sustainability](#); 2) The [Ministerial Statement on Plastics Pollution and Environmentally Sustainable Plastics Trade](#); and 3) The [Ministerial Statement on Fossil Fuel Subsidies](#). The three Ministerial Statements are the outcome of the work already undertaken by certain WTO Members at plurilateral level under three different tracks. According to WTO Deputy Director-General *Jean-Marie Paugam*, their common objective is to put environmental sustainability at the heart of WTO reform and to use trade “*as part of the solution*” to achieve greater environmental sustainability. The linkage between trade and the environment has steadily gained a place in the debate on sustainability, which is also having a growing impact on trade and businesses around the world. The three initiatives aim at providing the first holistic approach to address environmental sustainability and climate change at WTO level, thereby shaping trade policies that would directly or indirectly have an impact on the way trade is conducted.

Structured discussions on trade and environmental sustainability

Sustainable development and the preservation of the environment are fundamental objectives of the WTO underlined in the Marrakesh Agreement establishing the WTO. WTO rules allow WTO Members to “*adopt trade-related measures aimed at protecting the environment provided a number of conditions to avoid the misuse of such measures for protectionist ends are fulfilled*”. In recent years, certain WTO Members launched discussions on various fronts in the greater context of trade and environmental sustainability, as well as of climate change mitigation.

Most recently, in December 2017 in the context of the WTO’s eleventh Ministerial Conference, 12 WTO Members issued a [Ministerial Statement](#) calling on WTO Members “*to achieve ambitious and effective disciplines on inefficient fossil fuel subsidies that encourage wasteful consumption including through enhanced WTO transparency and reporting that will enable the evaluation of the trade and resource effects of fossil fuel subsidies programmes*”.

Before that, on 17 November 2020 in the context of the [WTO Trade and Environment Week 2020](#), various WTO Members had launched two initiatives to intensify the discussions on trade and environment. The [Communication on Trade and Environmental Sustainability](#), authored by 50 WTO Members (*i.e.*, Australia, Canada, Chad, Chile, Costa Rica, the EU and its 27 Member States, the Gambia, Fiji, Iceland, Japan, Republic of Korea, Liechtenstein, Maldives, Mexico, Republic of Moldova, Montenegro, New Zealand, North Macedonia, Norway, Senegal, Switzerland, the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, and the UK) launched the *Trade and Environmental Sustainability Structured Discussions* (TESSD), which aim at organising structured discussions among interested WTO Members and a dialogue with other stakeholders. The discussions aim at promoting multilateral environmental agreements, as well as collaborating on and prioritising discussions on trade and environmental sustainability not only among WTO Members, but also with external stakeholders, such as the business community and civil society. Secondly, seven WTO Members, namely Australia, Barbados, Canada, China, Fiji, Jamaica, and Morocco, initiated the *Informal Dialogue on Plastic Pollution and Environmentally Sustainable Plastic Trade* (IDP), which was to promote coordination among WTO Members to address the environmental and health impacts attributed to plastics pollution and how trade could positively contribute to solving this problem.

Despite the *Covid-19* pandemic, discussions on these issues and within these initiatives continued at the plurilateral level and involved WTO Members, underlining that “*environmental sustainability should be one of the guiding principles of the wider reform of the WTO*”. The Ministerial Statements presented on 15 December 2021 are the outcome of the three initiatives and define key areas of action in order to bring the issues of environmental sustainability and climate change onto the WTO trade agenda.

The WTO Ministerial Statements

Overall, in the three Ministerial Statements, WTO Members recall that “*sustainable development and the protection and preservation of the environment are fundamental goals of the WTO*” and that trade “*has been identified as a powerful enabling force*” necessary to progress towards sustainable development.

Ministerial Statement on Trade and Environmental Sustainability

The statement is supported by 71 WTO Members, including China, the EU and its Member States, Japan, Russia and the US. In the Ministerial Statement, the relevant WTO Members recognise that international trade and trade policy “*can and must support environmental and climate goals and promote more sustainable production and consumption*”. It identifies key drivers for action to intensify the work on areas of common interest and WTO Members also commit to identify concrete actions to expand opportunities for environmentally sustainable trade. Additionally, the signatories to the Ministerial Statement agreed to explore opportunities for promoting and facilitating access to environmental goods and services, to identify best practices to support the circular economy, to promote sustainable supply chains, as well as to “*strengthening capacity building and technical assistance on trade and environmental sustainability, including Aid for Trade*”. The WTO Members that signed up to this Ministerial Statement also agreed to adopt a roadmap to move the work forward and committed to review the progress after one year. In its Annex, the Ministerial Statement sets a timeframe for the TESSD work in 2022, which includes the dates for a series of meetings. The first meeting is scheduled to take place in February 2022 with the objective of adopting a workplan. Working meetings are scheduled to take place in April, July and October 2022, with a high-level stocktaking event expected to take place in December 2022 to review the progress achieved during the year.

Ministerial Statement on Plastic Pollution and Environmentally Sustainable Plastics Trade

The statement was supported by 67 WTO Members, including Canada, China, the EU and its Member States, and Russia. The Ministerial Statement recalls the need for further commitment

towards actions across the life cycle of plastics products and acknowledges the impact that plastic pollution has on economies and the environment. The Ministerial Statement identifies key areas for action to improve the understanding of global trade in plastics, including “*flows of plastics embedded in internationally traded goods or associated with them (such as plastic packaging)*”. It also calls for a sharing of experiences “*of effective approaches to move towards more circular, resource efficient and environmentally sustainable plastics trade*”, and for “*trade-related capacity building and technical assistance needs of developing members*”, in particular of least developed countries. Additionally, the Ministerial Statement states that the co-signatories commit to emphasise “*the importance of continuing to engage and support actions in other international processes*”, identifying best practices, sharing experiences on how trade-related cooperation could help to reduce unnecessary plastics and plastics products, including single-use-plastics and plastic packaging, and promoting the use of technologies that can reduce plastic pollution.

Ministerial Statement on Fossil Fuel Subsidies

The statement was supported by 45 WTO Members including the EU and its Member States, New Zealand, and the UK. The Ministerial Statement recognises that “*a phase out of fossil fuel subsidies would effectively contribute to the Paris Agreement objective of holding the increase in global average temperature below 2°C above pre-industrial levels*”. Additionally, it also recognises that such “*subsidies have continued to steadily increase in the past decade and were estimated at approximately USD 500 billion in 2019, and diverting funding from such subsidies will support a just transition towards a green, sustainable economy*”. While the statement stresses the importance to phase out “*inefficient fossil fuel subsidies*” and encourages WTO Members to join the discussions, it also recognises that the reform of fossil fuel subsidies needs to take into account “*the specific needs and conditions of developing countries and minimize the possible adverse impacts on their development*”. The Ministerial Statement notes that the WTO “*can play a central role in the reduction of trade and investment distortions caused by fossil fuel subsidies*”. However, the statement lacks support from key WTO Members, such as the US and China, and does not provide concrete actions to address the issue.

Towards specific plurilateral actions?

Environmental sustainability and climate change have become key drivers for legislative initiatives around the world and have found their place in trade negotiations and private sector policies. The lack of consensus among the 164 WTO Members has led to likeminded countries to take discussions on these issues to a plurilateral level, with the objective to move forward more swiftly.

The Ministerial Statements represent a joint effort by WTO Members to include issues related to environmental sustainability and climate change on the WTO trade agenda and to make them essential elements of WTO reform. Despite the positive *momentum*, the statements do not contain concrete or binding measures and it remains to be seen whether progress and concrete actions would follow in the coming months. Overall, the statements are rather vague and broad. While the three Ministerial Statements are a positive step, the statements on plastics pollution and fossil fuel subsidies do not provide any concrete timeframe of work. Therefore, the impact of these initiatives at the plurilateral and WTO level remains unclear.

The only statement that includes a timeframe for further action is the *Ministerial Statement on Trade and Environmental Sustainability*. A workplan, reflecting the timeframe for working meetings throughout this year, as noted above, is to be adopted in February 2022. Such plurilateral negotiations could provide the first holistic approach to addressing environmental sustainability and climate change at the WTO level and, ultimately, to lead to the adoption by WTO Members of (negotiated, as opposed to unilateral) enhanced environmental sustainability standards.

Important economies and WTO Members, such as Brazil, India and South Africa, did not sign any of the three Ministerial Statements, but can still join the negotiations at a later stage. European Executive Vice-President and European Commissioner for Trade *Valdis Dombrovskis* stated that the EU was “*proud to co-sponsor these initiatives at the WTO*” and that the EU believed that “*trade policy has a role to play in tackling climate change and environmental degradation*”. Notably, India has been strongly opposed to the initiatives and an Indian official reportedly stated that the WTO had “*no mandate to intervene in national or international environmental policies*” and that it is necessary to avoid that the environment “*be used as a tool to impose unjustified trade restrictions*”.

Next steps

It is likely that these initiatives will start gathering pace, as ‘*green trade*’ is becoming increasingly relevant and it is imperative to ensure that WTO Members’ necessary and urgent environmental and sustainability policies and measures be based on shared plurilateral or multilateral disciplines. Further unilateral initiatives would continue to fragment the regulatory landscape, increasingly result in trade irritants and disputes, and alienate many business sectors and countries. Even though many WTO Members may still need to be convinced, these initiatives could mark the beginning of a much-needed new dynamic for the WTO trade agenda.

The Government of Indonesia plans to impose a Bisphenol A (BPA) labelling requirement for bottled water

Pursuing public health objectives, Indonesia’s National Agency of Food and Drug Control (*Badan Pengawas Obat dan Makanan*, BPOM) plans to revise for a second time *BPOM Regulation No. 31 of 2018 concerning Processed Food Labels*, introducing a Bisphenol A (BPA) labelling requirement for bottled water products (*Air Minum Dalam Kemasan*, AMDK), including reusable water gallons. This proposed revision is still under discussion and is controversial, in particular given the narrow scope of the proposed labelling requirement.

Food labelling in Indonesia and additional labelling requirements since 2021

BPOM Regulation No. 31 of 2018 provides the labelling requirements for processed food products (*i.e.*, food or drink products that are processed in a certain way or method with or without additives). It was enacted to replace and harmonise numerous labelling requirements that were previously regulated in various other BPOM regulations. *BPOM Regulation No. 31/2018* regulates, *inter alia*, the labelling requirements for non-halal information and for processed foods containing pork and alcohol.

In 2021, Indonesia’s National Agency of Food and Drug Control imposed additional food labelling requirements and provided a certain number of clarifications through *BPOM Regulation No. 20/2021*, amending *BPOM Regulation No. 31 of 2018 concerning Processed Food Labels*, which was enacted on 2 August 2021.

The additional rules imposed through *BPOM Regulation No. 20/2021* apply to final food products, food products that still need further processing or business-to-business food (B2B), and food additives. *BPOM Regulation No. 20/2021* introduced, *inter alia*, the following additional restrictions: 1) Food additives for retail sale must identify the maximum permissible amount of the additive that can be used in a food product; 2) Any logo that is associated with environmental sustainability must be accompanied by supporting data; 3) Food labels that use words such as “*special*”, “*premium*”, “*extra*”, “*platinum*”, “*gold*”, “*plus (+)*”, or other similar words to compare the quality or the nutritional content of the product must include an asterisk (*), which must include information on the differentiating qualities; 4) B2B food products or food products that need further processing must be labelled with a disclaimer such as “*Not for Retail Sale*”, “*Not for Repackaging*”, “*Only for Hotels, Restaurants, and Catering*” or similar words; 4) The percentages of specific ingredient content must be stated in the list of ingredients on a

food label if: a) The ingredient gives a specific identity to the product; b) The ingredient appears on the label in text or photos; or c) The ingredient is included in the product name; and 5) Processed food containing allergens (e.g., peanuts, cereals containing gluten, eggs, fish, and crustaceans) must include information about the allergen content on the label instead of including it in the section providing the list of ingredients. BPOM *Regulation No. 20/2021* also clarifies that non-halal ingredients, which are exempt from halal certification, may still enter the Indonesian market.

Indonesia's initiative on Bisphenol A (BPA) labelling

Pursuing public health objectives, Indonesia's National Agency of Food and Drug Control plans to revise again BPOM *Regulation No. 31/2018* for purposes of Bisphenol A labelling. Bisphenol A, or BPA, is a chemical that is used as a protective lining on the inside of metal-based food and beverage cans, as well as in the manufacture of polycarbonate (i.e., a durable and heat-resistant plastic). Bisphenol A is present in polycarbonate plastics, which are commonly used in food and beverage containers. When used more than in the recommended quantity and at high temperatures, Bisphenol A is suspected of having detrimental health effects, particularly on babies, toddlers, and pregnant women.

On 29 June 2021, Indonesia's National Agency of Food and Drug Control had released a [statement](#) regarding Bisphenol A in reusable water gallons. In that statement, the National Agency of Food and Drug Control had clarified that Bisphenol A is harmful to health if ingested in excess of the maximum amount that the body can tolerate. Based on recent sampling and laboratory testing by Indonesia's National Agency of Food and Drug Control in 2021, the average amount of Bisphenol A migrating from food packaging to the beverages contained in reusable water gallons that use polycarbonate amounts to 0.033 parts per million (hereinafter, ppm). This value is well below (i.e., stricter than) the maximum migration limit set by Indonesia's National Agency of Food and Drug Control, which amounts to 0.6 ppm, as regulated under BPOM *Regulation No. 20 of 2019 concerning Food Packaging*.

In Indonesia, water containers, especially reusable water gallons, are commonly made from polycarbonate, which often contains Bisphenol A. With the planned revision of BPOM *Regulation No. 31/2018*, bottled drinking water that uses polycarbonate in its packaging must state that the packaging contains Bisphenol A. Bottled drinking water with non-polycarbonate packaging will be required to display a Bisphenol A-free label. However, according to the Head of Indonesia's National Agency of Food and Drug Control, *Penny Lukito*, the Bisphenol A labelling requirement will exempt Micro, Small and Medium Enterprises (MSMEs) and focus on large bottled water companies.

The Bisphenol A labelling revision has been planned since 2019 and has gone through various processes, such as public consultations, an expert consultation, and a comparative study regarding the standards that are applicable in other countries. Since March 2021, Indonesia's National Agency of Food and Drug Control has assessed the risk of Bisphenol A in bottled drinking water and whether changes should be made to the current standard. Even though the current migration level for bottled drinking water is still below the maximum migration level, Indonesia's National Agency of Food and Drug Control is concerned about the long-term effects of Bisphenol A exposure. Hence, the Bisphenol A labelling requirement is intended to raise public awareness and to provide the public with clear information on drinking water packaging that contains Bisphenol A.

Objections from the bottled water industry

Despite its harmful effects, the Bisphenol A labelling requirement is a novelty in Indonesia, as Indonesia has so far insufficiently regulated Bisphenol A. Therefore, the revision of BPOM *Regulation No. 31/2018* was generally welcomed, but the new labelling requirement also led to criticism, notably from the bottled water industry.

More specifically, the bottled water industry strongly objects to the plan to revise BPOM *Regulation No. 31/2018*. The Chairman of the *Association of Bottled Drinking Water Companies*, *Rachmad Hidayat*, stated that the Bisphenol A labelling requirement would have a negative impact on the bottled drinking water industry, especially for reusable water gallons, as the bottled water business depends on the image of the product. In his view, the inclusion of the Bisphenol A labelling would influence consumers to think that the product contains hazardous substances even though the amounts of Bisphenol A present and arguably migrating to the beverages are well below the maximum migration limits. Moreover, if all producers of reusable water gallons were to convert their packaging into single-use gallons, this would require a huge amount of investment and likely cause environmental problems. Chairman *Rachmad Hidayat* also stated that Indonesia's National Agency of Food and Drug Control must impose this requirement for all food products instead of focusing only on the bottled water industry.

Importantly, the new rules on Bisphenol A labelling have been criticised by other Government officials, notably on the basis of economic concerns. The Director responsible for the *Beverage, Tobacco Products and Refreshment Industries* within Indonesia's Ministry of Industry, *Edy Sutopo*, stated that there was no urgency for this revision, as the report from the National Agency of Food and Drug Control previously stated that the Bisphenol A migration in bottled drinking water is still far below the maximum permissible migration limit and, therefore, remained safe for consumption. Additionally, he stated that drinking water products are already subject to restrictive laws, including the water standard and licensing requirements, as well as rules related to the production process and packaging that are closely monitored by Indonesia's National Agency of Food and Drug Control, Indonesia's Ministry of Industry, and Indonesia's Ministry of Trade. In Indonesia, there are more than 900 bottled water producers, employing more than 40,000 people and, in 2020, Indonesia's businesses produced 29 billion litres of bottled water and 69% of the production is packaged in reusable polycarbonate water gallons.

It appears that the main reason why Indonesia's National Agency of Food and Drug Control focused on the bottled water industry, especially the reusable water gallon, is their widespread use and the impact on consumer awareness that such labelling would, therefore, have.

Is Indonesia's Bisphenol A labelling requirement discriminatory?

The proposed Bisphenol A labelling requirement under preparation for the bottled water industry is still a novelty in Indonesia and opens up the possibility for similar rules to be imposed on other food products in the future. Despite the large market for reusable water gallons in Indonesia, Bisphenol A and Bisphenol A-free labelling requirements should be introduced indiscriminately vis-à-vis all food/beverage products and the related packaging solutions. Most importantly, the waiver accorded to products made or distributed by MSMEs appears to be clearly discriminatory and not justifiable from a food safety and health protection standpoint. This preferential treatment should not stand, if such products are truly considered potentially harmful by BPOM, and could even result in trade discrimination with respect to imported products.

While researchers all over the world embrace new genomic techniques (NGTs), the regulation of such new plant breeding techniques is lagging behind

New genomic techniques (hereinafter, NGTs) and their products have developed rapidly in the last two decades in many parts of the world, with some applications already on the market and more applications in different sectors expected in the coming years. On 29 April 2021, the European Commission (hereinafter, Commission) published a [study](#), in which it defined 'new genomic techniques' (NGTs) as "techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001, when the current legislation on genetically modified organisms (GMOs) was adopted". There is considerable

interest in research on NGTs in the EU, but most developments appear to take place outside the EU, where regulation is often lagging behind scientific developments.

New genomic techniques (NGTs) around the world

Researchers around the world have successfully used NGTs for certain innovations, for instance to develop non-browning mushrooms, drought-tolerant soybeans, and a host of other creative traits in plants. In Israel, for example, research is being conducted on [gene edited lettuces](#). Lettuce plants naturally produce a range of nutrients, such as vitamin C, beta-carotene, and thiamine (vitamin B). However, they only produce a limited amount of each of these nutrients, only in the amount required for the lettuce itself. Israeli researchers applied NGTs (in particular, the CRISPR-Cas9 technology - CRISPR stands for *Clustered Regularly Interspaced Short Palindromic Repeats* for a family of DNA sequences and Cas9 is an enzyme that uses CRISPR sequences as a guide to recognise and cleave specific strands of DNA that are complementary to the CRISPR sequence) to target areas in the native lettuce genes that regulate the production and accumulation of these specific nutrients. By slightly altering their components through NGTs, the lettuce plants can produce or accumulate more of them. The existing genes are edited “*in a way that could spontaneously occur in nature or when using traditional breeding methods*”, the researchers state.

After the UK’s withdrawal from the EU, for the first time in Europe, the UK Department of Environment, Food and Rural Affairs (DEFRA) [granted permission](#), in October 2021, for a series of field trials of gene edited wheat created via the gene editing tool CRISPR, marking a significant move away from the restrictive EU’s stance on the matter. The journal [Nature](#) reports that, in Japan, gene-edited food made with CRISPR-Cas9 technology is being commercialised on the open market for the first time, where regulators approved, in December 2020, the Tokyo-based *Sanatech Seed’s* (a start-up from the University of Tsukuba) Sicilian Rouge tomatoes, which are genetically edited to contain high amounts of gamma-aminobutyric acid (*i.e.*, GABA, a health-promoting compound). Since September 2021, fresh tomatoes produced with this technology have been sold directly to consumers in Japan and, a month later, the seedlings were commercialised for the next growing season. In the US, many gene edited plants have received approval from regulators, but before *Sanatech’s* tomato in Japan, no CRISPR-edited food crops were known to have been commercialised. According to the journal [Nature](#), the US Department of Agriculture (USDA) has repeatedly ruled that genome-edited crops fall outside of its purview and plant biotechnologists who submit inquiries typically obtain a response within a few months and “*receive a green light to grow their genome-edited plants without further oversight*”.

New genomic techniques (NGTs) in the EU

In the preliminary judgment of the Court of Justice of the European Union (hereinafter, CJEU) of 25 July 2018, in Case C-528/16 *Confédération Paysanne and Others v Premier Ministre and Ministre de l’Agriculture, de l’Agroalimentaire et de la Forêt* (France), the CJEU established that organisms obtained by *mutagenesis* are GMOs and are, in principle, subject to the obligations laid down by *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*.

In order to modify the genetic heritage of a living organism, a number of NGTs can be used, including *transgenesis* and *mutagenesis*. *Directive 2001/18* itself does not provide any general definition of these techniques. The CJEU’s Advocate General (hereinafter, AG) in charge in Case C-528/16 referred to the relevant working definitions provided by the referring French court, according to which *transgenesis* is an NGT that consists of inserting one or more genes from one species into the genome of another species. *Directive 2001/18* does not explicitly refer to the notion of *transgenesis*. However, substantively, the Directive covers various techniques, which could be considered as transgenic. *Mutagenesis* does not entail the insertion of foreign DNA into a living organism. It nonetheless involves an alteration of the genome of a living species. Conventional or random methods of *mutagenesis* are applied *in*

vivo (i.e., within living organism) to entire plants (chemically and by irradiation) in order to select, from the resulting mutants, interesting deviations and to use them in breeding, without apparently creating any identifiable risks for the environment or health.

Gradually, NGTs have been developed. As further explained by the referring French court in Case C-528/16, not only have random *mutagenesis* techniques been applied *in vitro* (i.e., in a test tube) to plant cells, but targeted *mutagenesis* methods applying NGTs have also been devised, such as oligonucleotide-directed *mutagenesis* (ODM, which provides a means to alter a defined site within a region of cloned DNA) or directed nuclease *mutagenesis* (SDN, which is based on small deletions or insertions at a precisely defined location in the genome). Whereas conventional *mutagenesis* involves random mutations, some of the new techniques cause a precise mutation in a specific gene. *Directive 2001/18* does not apply to organisms obtained by means of untargeted *mutagenesis* techniques listed in its Annex I B, namely those that have conventionally been used in a number of applications and have a long safety record. Some NGTs, in particular CRISPR-Cas9, are not based on the introduction of foreign genetic material into the DNA, but cause more or less precise changes (“*targeted mutations*”) of the DNA in order to change the properties of the organism. However, unlike traditional genetic engineering techniques, gene-editing does not involve the introduction of DNA from another organism. Indeed, it is virtually impossible to detect whether the DNA of a plant or animal has been edited or not, because the changes involved are indistinguishable from naturally occurring mutations.

In the preliminary judgment in Case C-528/16, the CJEU established, on 25 July 2018, that organisms obtained by *mutagenesis* are GMOs and are, in principle, subject to the obligations laid down by *Directive 2001/18* (see *Trade Perspectives, Issue No. 4 of 28 February 2020*). The CJEU held that crops obtained by *mutagenesis* are GMOs, because the techniques and methods of *mutagenesis* alter the genetic material of a plant in a way that does not occur naturally. The CJEU stated that it follows “*that those organisms come, in principle, within the scope of Directive 2000/18 and are subject to the obligations laid down by that directive*”. The ruling came as a surprise, as it had been widely expected to follow the same line taken by the CJEU’s AG in charge of that case, who, in his January 2018 opinion, had stated that organisms obtained by *mutagenesis* were, in principle, exempt from the obligations in *Directive 2001/18*.

European Commission study regarding the status of NGTs under EU law

On 8 November 2019, *Council Decision (EU) 2019/1904* requested the Commission to submit a study in light of the CJEU’s judgment in Case C-528/16 regarding the status of NGTs under EU law, and a proposal, if appropriate in view of the outcomes of the study. On 29 April 2021, the Commission published the requested study, defining NGTs and making it clear that “*organisms obtained through new genomic techniques are subject to the GMO legislation*”. However, the study further notes that “*developments in biotechnology, combined with a lack of definitions (or clarity as to the meaning) of key terms, are still giving rise to ambiguity in the interpretation of some concepts, potentially leading to regulatory uncertainty*”. The study states that, following the ruling of the CJEU in Case C-528/16, there had “*been reports of negative impacts on public and private research on new genomic techniques in the EU due to the current regulatory framework*”. The study emphasises that “*several of the plant products obtained from NGTs have the potential to contribute to the objectives of the EU’s Green Deal and in particular to the ‘farm to fork’ and biodiversity strategies and the United Nations’ sustainable development goals (SDGs) for a more resilient and sustainable agri-food system*”. Examples given in the study include plants more resistant to diseases and environmental conditions or climate change effects in general, improved agronomic or nutritional traits, and reduced use of pesticides.

Experts at EU and national level consulted by the Commission noted “*the need for flexibility and proportionality in risk assessment, although not all stakeholders share this view. Another aspect that has been raised is the need to develop risk assessment procedures that are specific to NGTs*”. The Commission states that “*in light of the different regulatory oversight for NGTs in other countries, the above difficulties could lead to trade limitations and disruptions,*

and put EU operators at a competitive disadvantage, with further negative consequences. This could also lead to the creation of technical barriers to trade, potentially leading to disputes between the EU and its trade partners". To enable consumers to make informed choices, the study states that the *"provision of consumer information (e.g. via labelling) is key. However, stakeholders have opposing views, both on the need to continue labelling NGT products as GMOs and on the effectiveness of such labelling in informing consumers"*. For the Commission, the key question is whether legislation, that raises implementation challenges and whose application to NGTs requires contentious legal interpretation, is still fit for purpose or needs updating in light of scientific and technological progress.

The Commission concludes that the follow-up to this study should consider possible policy instruments *"to make the legislation more resilient, future-proof and uniformly applied"*. The Commission aims at a proportionate regulatory oversight, which would maintain a high level of protection of human and animal health and of the environment, allowing though to gather benefits from innovation. Any further policy action by the Commission *"should be aimed at reaping benefits from innovation while addressing concerns"*. According to the Commission, *"a purely safety-based risk assessment may not be enough to promote sustainability and contribute to the objectives of the European Green Deal and in particular the Farm to Fork and Biodiversity strategies"*. The Commission argues that benefits contributing to sustainability would also need to be evaluated, so an appropriate mechanism to accompany risk assessment may be required. As next steps, the Commission plans to initiate a policy action on plants produced by targeted *mutagenesis* and *cisgenesis*, which will involve an impact assessment including a public consultation.

Conclusions and outlook

The CJEU ruled that organisms obtained by *mutagenesis* are GMOs and fall under the strict and burdensome rules applicable to GMOs. It may, however, be scientifically sound to distinguish between NGTs and transgenic GMOs with the consequence of applying different rules to the different techniques, taking into consideration the different levels of risks, if they exist. The EU's regulatory framework applicable to genetic engineering and GMOs may indeed no longer be appropriate in view of scientific developments and technological advancements.

Calls have been made to adjust the EU's regulatory framework to better address the relevant matters, such as NGTs. At the same time, the Commission's statement that *"a purely safety-based risk assessment may not be enough to promote sustainability and contribute to the objectives of the European Green Deal and in particular the Farm to Fork and Biodiversity strategies"*, while making sense and evidencing the existence of other legitimate policy objectives that are at least as important and urgent as human, animal and plant life and health (safety), could have far reaching and fundamental impacts on long-standing EU policies and approaches, as evidenced for instance in several previous trade disputes at the WTO under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), *inter alia* the famous disputes brought against the EU on *"Measures Concerning Meat and Meat Products"* (i.e., the 'Beef Hormones' case) and on *"Measures Affecting the Approval and Marketing of Biotech Products"* (i.e., the 'GMO' case).

Interested stakeholders are advised to carefully monitor developments on NGTs in the EU and to seek adequate legal advice to take action and ensure that their legitimate interests are properly voiced and represented within all relevant *fora*.

Recently adopted EU legislation

Trade Law

- *Council Decision (CFSP) 2022/52 of 13 January 2022 amending Decision 2014/512/CFSP concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine*

Trade Remedies

- *Commission Implementing Regulation (EU) 2022/56 of 14 January 2022 amending Implementing Regulation (EU) 2018/921 imposing a definitive anti-dumping duty on imports of tartaric acid originating in the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council*
- *Commission Implementing Regulation (EU) 2022/57 of 14 January 2022 amending Implementing Regulation (EU) 2019/1379 imposing a definitive anti-dumping duty on imports of bicycles originating in the People's Republic of China as extended to imports of bicycles consigned from Indonesia, Malaysia, Sri Lanka, Tunisia, Cambodia, Pakistan and the Philippines, whether declared as originating in these countries or not, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036*
- *Commission Implementing Regulation (EU) 2022/58 of 14 January 2022 imposing a definitive anti-dumping duty on imports of certain grain-oriented flat-rolled products of silicon-electrical steel originating in the People's Republic of China, Japan, the Republic of Korea, the Russian Federation and the United States of America following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council*

Customs Law

- *Commission Implementing Regulation (EU) 2022/36 of 11 January 2022 amending Annex III to Implementing Regulation (EU) 2020/2235 as regards model certificates for the entry into the Union of consignments of certain live aquatic animals and products of animal origin (1)*
- *Commission Implementing Regulation (EU) 2022/37 of 12 January 2022 amending Implementing Regulation (EU) 2021/403 as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain species and categories of poultry and captive birds and germinal products thereof (1)*
- *Commission Implementing Regulation (EU) 2022/38 of 12 January 2022 amending Annexes V and XIV to Implementing Regulation (EU) 2021/404 as regards the entries for the United Kingdom in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry and fresh meat of poultry and game birds (1)*

Food Law

- *Commission Implementing Regulation (EU) 2022/43 of 13 January 2022 renewing the approval of the active substance flumioxazin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing*

of plant protection products on the market, and amending the Annexes to Commission Implementing Regulation (EU) No 540/2011 and to Implementing Regulation (EU) 2015/408 (1)

- *Commission Implementing Regulation (EU) 2022/47 of 13 January 2022 authorising the placing on the market of Coffea arabica L. and/or Coffea canephora Pierre ex A.Froehner dried cherry pulp and its infusion as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (1)*
- *Commission Implementing Regulation (EU) 2022/34 of 22 December 2021 amending Annexes III, VIII, IX and XI to Implementing Regulation (EU) 2021/405 as regards the lists of third countries or regions thereof authorised for the entry into the Union of certain wild game birds intended for human consumption, of consignments of certain bivalve molluscs, echinoderms, tunicates and marine gastropods, of certain fishery products, and of frogs' legs and snails, and repealing Decision 2007/82/EC (1)*
- *Commission Implementing Regulation (EU) 2022/35 of 6 January 2022 amending and correcting Implementing Regulation (EU) 2021/404 laying down the lists of third countries or territories, or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (1)*

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