

FROM FARM TO FORK: THE REGULATORY STATUS OF NON-GMO PLANT INNOVATIONS UNDER CURRENT EU LAW

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Short Introduction to New Breeding Techniques

In April 2017, the Scientific Advice Mechanism ('SAM') presented its explanatory note on 'New Techniques in Agricultural Biotechnology' to the European Commission ('the SAM Note').¹ The SAM Note provides a detailed description of the nature and characteristics of so-called 'plant breeding innovations' or 'new breeding techniques' ('NBTs'), and how they are similar to or different from conventional breeding techniques ('CBT', such as crossing and selection, or mutation breeding²) and established techniques of genetic modification³ ('GM', such as the use of recombinant nucleic acids).

According to the SAM Note, the term 'NBTs' refers to a wide range of new breeding methods, some of which are substantially different from established transgenic approaches in their way of introducing traits to an organism. Whereas some NBTs amount to a refinement of CBT and integrate genetic material that is derived from a sexually compatible species, some nevertheless are used in combination with established GM techniques. Some NBTs result in organisms that contain only point mutations and are practically indistinguishable from varieties bred through CBT.⁴ The NBTs that have attracted most attention in recent years (and are, presumably also for that reason, currently subject to a preliminary reference to the Court of Justice of the EU or 'CJEU'⁵) are the so-called genome editing techniques. The present article focuses specifically on those genome editing techniques.⁶

The SAM Note explains⁷ that genome editing aims to achieve a precise alteration of a DNA sequence in a cell, or random changes at precise locations. These results are obtained with the aid of the cell's DNA recombination/repair system activated with the use of a site-directed nuclease ('SDN'), exogenous nucleic acid molecule (oligonucleotide directed mutagenesis or 'ODM'), or the combination of both. ODM is based on the use of oligonucleotides for the induction of targeted mutations in the genome, usually of one or a few adjacent nucleotides. The genetic changes that can be obtained using ODM include the introduction of a new mutation (replacement of one or a few base pairs, short deletion or insertion) or the reversal of an existing mutation. SDNs, on the other hand, cut DNA at selected target sites to enable the insertion of random ('SDN1'), or non-random ('SDN2') mutations in precise locations, or to enable the insertion of large segments (such as genes) in precise locations ('SDN3'). Applications include so-called zinc finger nucleases ('ZFN'), transcription activator-like effector

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1) Explanatory Note 02/2017 on 'New Techniques in Agricultural Biotechnology', European Commission, DG Research and Innovation, 28 April 2017, available at <https://ec.europa.eu/research/sam/index.cfm>.

2) The SAM Note describes, at page 33, that because spontaneous DNA mutations resulting in a desirable trait are rare, plant breeders have attempted to increase and accelerate these events by inducing mutations and selecting for rare desirable traits. Mutation breeding involves exposing plants or seeds to physical (radiation, for example X-rays) or chemical (for example, ethyl methane-sulfonate mutagenic agents) treatments, which induce random changes in DNA sequences throughout the genome. The mutation can consist of changes in one nucleotide position only, or sometimes (more frequently after radiation with X-rays) more complex changes such as major rearrangements in the DNA (inversion, translocation) or the elimination of DNA fragments (deletion).

3) Which the SAM Note refers to in abbreviated form as 'ETGM'.

4) SAM Note, at 56.

5) Case C-528/16, *Confédération paysanne, Réseau Semences Paysannes, Les Amis de la Terre France, Collectif vigilance OGM et Pesticides 16, Vigilance OGM, CSFV 49, OGM : dangers, Vigilance OGM 33, Fédération Nature et Progrès v Premier ministre, Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, request for a preliminary ruling from the French Council of State lodged on 17 October 2016, in which Advocate General Bobek delivered his Opinion on 18 January 2018, ECLI:EU:C:2018:20 ('AG Opinion'). At the time of publication, the CJEU has not issued its preliminary ruling.

6) Other techniques, also described in the SAM Note, include cis- and intragenesis, grafting, agro-infiltration, RNA-dependent DNA methylation, reverse breeding, and synthetic biology.

7) SAM Note, at 56 onward.

nucleases ('TALEN') – proteins engineered to both recognise specific DNA sequences and to cut DNA in the region of such sequences – and RNA-directed SDNs based on the so-called bacterial CRISPR⁸ system and CRISPR-associated ('Cas') nucleases.

Compared to CBT and established GM techniques, the SAM Note states that:

... instead of random mutation of many genes at the same time (as in CBT) or random insertion of new genes (as in ETGM in plants and animals), genome editing allows the selective mutation of one or a few genes exclusively and the precise modification or replacement of entire genes, whether from closely or distantly related organisms. Other NBTs are not intended to alter the genome at all, but rather temporarily change gene expression patterns in order to adjust the traits of an organism.⁹

Furthermore, in terms of distinguishability from CBT-produced organisms such as plant material, the SAM Note explains¹⁰ that the genome editing techniques of ODM, SDN₁ and SDN₂ do not result in end products containing exogenous DNA and are thus, in that regard, comparable to the aforementioned CBT of mutation breeding and crossing and selection. When ODM, SDN₁ and SDN₂ are used, the induced changes are said to represent very limited modifications of a pre-existing gene in the edited genome. Typically, the function of this gene is well characterised and the new characteristics should be limited to the impact of a well-defined mutation/modification on a pre-existing function. The SAM Note explains that SDN₃, on the other hand, is designed to obtain end products containing exogenous nucleic acids from either related or foreign species.

Finally, in terms of unintended effects, the SAM Note concludes¹¹ that the use of gene editing does not exclude so-called 'off-target' effects.¹² It is emphasised that, by contrast with unintended effects resulting from established GM techniques and CBT, NBT off-target effects are rare and the frequency of unintended effects in NBT products is much lower than in products of CBT and established GM techniques. Off-target mutations are therefore considered to be much less an issue than with classical mutagenesis¹³ and where off-target changes occur, they are viewed to be of the same type as those produced by CBT.¹⁴ On that basis, the SAM Note observes that genetically and phenotypically similar products deriving from the use of different techniques are not expected to present significantly different risks.¹⁵

The Ongoing Discussion on the Legal Status of NBT Derived Products

NBTs – particularly those that use recombinant nucleic acid molecules, but even regardless of such use – have triggered a political and legal discourse around the question of whether the products (that is, depending on the stage of the agri-food production chain, propagating material, crops or food/feed) resulting from these methods fall within the scope of the European legislative framework for genetically modified organisms ('GMOs').

This framework includes, in particular, (i) Directive 2001/18/EC ('the GMO Deliberate Release Directive')¹⁶, (ii) Regulation (EC) No 1829/2003 on genetically modified food and feed ('the GMFF Regulation')¹⁷, and (iii) Regulation (EC) No 1830/2003 on the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs¹⁸ (jointly referred to as 'the GMO legislation'). As already mentioned, a

8) CRISPR stands for 'clustered regularly interspaced short palindromic repeats'.

9) SAM Note, at 25.

10) *Ibid.*, at 89 to 90.

11) *Ibid.*, at 18 to 19.

12) Described in the SAM Note as an effect where a precise change is made to a genetic sequence identical or similar to that in which the change is desired, but in another location.

13) SAM Note, at 63.

14) *Ibid.*, at 78 (specifically in relation to SDN₃).

15) *Ibid.*, at 19.

16) 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, OJ L106, 17 April 2001, pages 1 to 39.

17) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L268, 18 October 2003, pages 1 to 23.

18) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ L268, 18 October 2003, pages 24 to 28.

request for a preliminary ruling from the French Council of State is currently pending before the CJEU.¹⁹

This court case or the AG Opinion already issued in it are not within the scope of the present article.²⁰ This article instead focuses on the question of whether, assuming a product resulting from a NBT is not a regulated GMO (hereinafter referred to as ‘Non-GMO NBT Products’) and would thus be treated like any other product resulting from CBT, any alleged risk relating to such products in terms of their effects on human or animal health or the environment is sufficiently and adequately covered by the existing EU regulatory framework applicable to the agri-food production chain, without the need for introducing additional rules specifically targeted at Non-GMO NBT Products. We submit that this question must be answered affirmatively.

Non-GMO NBT Products Are Not Unregulated

When looking at the agri-food production chain and the way in which its constitutive steps are currently regulated, it is clear that many safeguards for the protection of human health and the environment are already in place both at the research and development stage (whether in the lab or during field trials), at the pre-harvest stage (production and commercialisation of plant reproductive material, such as seeds, and their cultivation into crops) and at the post-harvest

stage (processing of crops into food/feed and their commercialisation), and that such safeguards equally apply to Non-GMO NBT Products.²¹

At the R&D Stage

At the lab

Before Non-GMO NBT Products are placed on the market or ‘deliberately released into the environment’ (to use the GMO terminology), preliminary R&D is carried out in contained environments, such as in laboratories or greenhouses. To the extent that such R&D, and hence the early stages of creating the Non-GMO NBT Products, involve the use of GMOs or GM micro-organisms (‘GMMs’) (which, according to the SAM Note discussed above, occurs in certain techniques), that use will be subject to the conditions of Directive 2009/41/EC on the contained use of GMMs (‘the Contained Use Directive’),²² which was precisely designed to ensure that appropriate measures are taken to avoid any adverse effects on human health and the environment which might arise from such contained use.²³

On the face of it, the Contained Use Directive only covers GMMs, which are defined as ‘*any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant in cells in culture*’.²⁴ However, a significant number of Member States have transposed the Contained Use

19) Case C–528/16, *Confédération paysanne*, Note 5 above.

20) For literature on this topic, see for example (for those *against* an application of the GMO legislation to NBT derived products), R. Custers, ‘The regulatory status of gene-edited agricultural products in the EU and beyond’, *Emerging Topics in Life Sciences*, 2017, at page 1; J. Kahrmann, O. Bomeke and G. Leggewie, ‘Aged GMO Legislation Meets New Gene Editing Techniques’, *EurUP 2*, 2017, at 176; G. Glas and T. Carmeliet, ‘The European Court to rule on milestone in European GMO legislation: the Legal classification of mutagenesis in plant breeding’, [2017] 16(2) *Bio-Science Law Review* at 91; J. Robiński and M. Wasmer, ‘Products of site-directed mutagenesis are not GMOs according to Art. 3 and Appendix I B of the European Directive 2001/18/EC’, *Journal of Consumer Protection and Food Safety*, 2017, available at [https://doi.org/10.1007/s00003-017-1147-4\(0123456789\(..-volV\)\(0123456789\(..-volV\)\)](https://doi.org/10.1007/s00003-017-1147-4(0123456789(..-volV)(0123456789(..-volV))); G. Fernández Albúja and B. van der Meulen, ‘The EU’s GMO concept: analysis of the GMO definition in EU law in the light of the New Breeding Techniques (NBTs)’, *EFFL*, 2018, 1, at 14; and (for those *in favour* of applying the GMO legislation to NBT derived products): T. Spranger, ‘Recent developments of European gene technology regulation’, *EurUP 1*, 2016, at 39; T. Spranger, ‘Legal analysis of the applicability of Directive 2001/18/EC on genome editing technologies’, October 2015, available at https://bfm.de/fileadmin/BfN/agrogentechnik/Dokumente/Legal_analysis_of_genome_editing_technologie_s.pdf; L. Krämer, ‘The genome editing technique is covered by Directive 2001/18 – comment on Advocate Bobek’s Opinion in Case C–528/16, 2018, available at <https://www.testbiotech.org/en/content/legal-analysis-genome-editing-technique-covered-directive-200118>.

21) This was also confirmed by CJEU Advocate General Bobek in an *obiter* comment in his Opinion of 18 January 2018 in Case C–528/16, where he highlighted that it is ‘*perhaps called for, in particular in the view of the assertions repetitively made in these proceedings that organisms obtained by mutagenesis fall short of any control and supervision. It might be recalled that, as noted by the Commission, organisms obtained by mutagenesis, even those not caught by the Annex I B caveat and thus not regulated by the GMO Directive, may be subject, where applicable, to the obligations derived from other EU secondary law measures, such as the EU legislation on seeds or legislation on pesticides. Thus, it is clear that obligations deriving from several other EU secondary law instruments may also apply to organisms obtained by mutagenesis, in addition to those resulting from Directive 2002/53*’ (AG Opinion at paragraph 166).

22) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast), OJ L125, 21 May 2009, at 75 to 97, where ‘*contained use*’ is defined as ‘*any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment*’.

23) Contained Use Directive, Article 1.

24) *Ibid.*, Article 2.

Directive in a way that also covers *GMOs*, and not just *GMMs*.²⁵ The European Commission has validated this broad transposition to be compatible with the Contained Use Directive.²⁶ The Contained Use Directive thus covers any genetic modification²⁷ of (micro-)organisms and any subsequent contained use of (intermediate) *GMOs* and *GMMs* for the production of Non-GMO NBT Products in contained circumstances, as stipulated in national legislation.

In terms of control and supervision on the safety of such use, the Contained Use Directive imposes upon Member States an obligation to ensure that all appropriate measures are taken to avoid adverse effects.²⁸ To that end, the Contained Use Directive prescribes that users must perform a prior self-assessment²⁹ (to be reviewed periodically) of the risks that the contained uses could present to human health and the environment. A record of this assessment must be kept by the user and made available to the competent authorities as part of a notification procedure (described hereunder) or upon request. The risk assessment will result in a final classification into four classes of the envisaged contained use (with class 1 covering activities of no or negligible risk; class 2 activities of low risk; class 3 activities of moderate risk; and class 4 activities of high risk).³⁰ Following this classification, containment and protective measures need to be put in place to protect human health and the environment, as described in Annex IV to the Directive,³¹ and – except for class 1 uses which must only be notified once

the premises are to be used for the first time – a prior notification to the competent authorities is required for any subsequent class 2, 3 and 4 use.³² Users also have a duty to notify any new relevant information or significant changes to previously notified uses to the competent national authority, who can also act *ex officio*³³ and has the ability to take all appropriate control and other measures.³⁴

It is therefore clear that for Non-GMO NBT Products whose production requires the use of (intermediate) *GMOs* or *GMMs*, sufficient safeguards in terms of human and environmental harm prevention are in place at the lab stage. *A fortiori*, for Non-GMO NBT Products whose production does *not* involve any use of *GMOs* or *GMMs*, no such safeguards are or should be required.

In field trials

If, after leaving the lab, a NBT product contains recombinant nucleic acid molecules, it will be subject to the specific ‘Part B’ authorisation procedure under the *GMO Deliberate Release Directive* before it can actually be placed on the market. If it does not, activities involving Non-GMO NBT Products are, just like any activity involving conventionally bred crops, subject to the rules on (environmental) liability during subsequent field trials.

Specifically in relation to protected species, natural habitats, water and land,³⁵ the *Environmental Liability Directive 2004/35/EC*³⁶ provides that, according to the ‘polluter pays’

25) Commission Staff Working Document ‘Details from individual Member States on their experience with Directive 2009/41 of the European Parliament and of the Council of May 2009 on the contained use of genetically modified micro-organisms (recast) for the period 2009-2014’ accompanying the document Commission Working Document ‘Experience of Member States with Directive 2009/41 of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) for the period 2009–2014’, Brussels, 20 December 2016 SWD(2016) 445 final. See also Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to (then) EC Treaty Article 95(5), OJ L230, 16.9.2003, at page 34, paragraph 11, referred to in S. Mahieu, ‘Le contrôle des risques dans la réglementation européenne relative aux OGM: vers un système conciliateur et participatif’, in Nihoul and Mahieu, *La sécurité alimentaire et la réglementation des OGM – perspectives nationale, européenne et internationale* (Brussels: Larquier, 2005) at 170. In that context, see also L. Bodiguel and M. Cardwell, *The regulation of genetically modified organisms: comparative approaches* (Oxford, 2010) at 82.

26) Commission Decision of 2 September 2003, Note 25 above.

27) The techniques that are considered to amount to genetic modification are specified in Article 2(b) of the Contained Use Directive and are, except for some minor differences, essentially identical to the techniques listed in the *GMO Deliberate Release Directive*.

28) Contained Use Directive, Article 4(1).

29) *Ibid.*, Article 4(2).

30) *Ibid.*, Article 4(3).

31) *Ibid.*, Article 5(1).

32) *Ibid.*, Articles 6 to 9.

33) *Ibid.*, Article 11.

34) *Ibid.*, Articles 12 to 16.

35) Article 2(1) of the *Environmental Liability Directive* defines ‘*environmental damage*’ as follows: (a) ‘*damage to protected species and natural habitats*’, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species. The habitats and species concerned are defined by reference to species and types of natural habitats identified in the relevant parts of the *Birds Directive 79/409* and the *Habitats Directive 92/43*; (b) ‘*water damage*’, which is any damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential, as defined in the *Water Framework Directive 2000/60*, of the waters concerned; (c) ‘*land damage*’, which is any land contamination that creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms or micro-organisms.

36) Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, OJ L143, 30 April 2004, at 56 to 75.

principle, an operator³⁷ (i) must be held liable (either strictly, or fault-based, depending on the activity) if its activity involving, or leading to the production of, Non-GMO NBT Products causes environmental damage, and (ii) will be required to take both preventive actions and remedial actions. More precisely, where the environmental damage has not yet occurred but *there is an imminent threat* of such damage occurring, the operator must, without delay, take the necessary preventive measures and, where the imminent threat is not dispelled despite the preventive measures, inform the competent authority as soon as possible.³⁸ Where the environmental damage *has occurred*, the operator must equally, without delay, inform the competent authority and take: (a) all practicable steps to immediately control, contain, remove or otherwise manage any damage factors to limit or to prevent further environmental damage and adverse effects on human health; and (b) the necessary remedial measures.³⁹ In addition, the environment must be physically reinstated, and any significant risk of human health being adversely affected must also be removed.⁴⁰

The Environmental Liability Directive has designed a legal framework that aims at ensuring a high level of protection of the environment. Whereas the scope of this Environmental Liability Directive is limited⁴¹ to the prevention and remedying of (environmental) damage to protected species, natural

habitats and water and land contamination, any damage arising from the use of Non-GMO NBT Products beyond that limited scope will of course be covered by the general liability rules under tort law.

Furthermore, to the extent that a Non-GMO NBT Product which is grown in field trials would turn out to be a (pathway for a) plant pest, further safeguards are offered by Regulation (EU) 2016/2031 on protective measures against pests of plants ('the Plant Health Regulation').⁴² This – i.e. regulating Non-GMO NBT Products only by reference to their plant health characteristics – is the way they are dealt with in the United States.⁴³ The EU Plant Health Regulation '*establishes rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products ("pests") and measures to reduce those risks to an acceptable level*',⁴⁴ and is thus intended to ensure a high level of phytosanitary protection within the EU.⁴⁵ Whereas the Plant Health Regulation is obviously not specific to Non-GMO NBT Products, it was essentially designed to prevent environmental risks and, to that end, (i) ensures, as an *a priori* measure, that the movement of Non-GMO NBT plants and plant products may only take place after prior phytosanitary checks,⁴⁶ and (ii) foresees, as an *a posteriori* measure, safeguard measures for Non-GMO NBT Products that are

37) The notion of 'operator' (that is, the person that may be liable for the environmental damage) is defined broadly as '*any natural or legal, private or public person who operates or controls the damaging occupational activity or, where this is provided for in national legislation, to whom decisive economic power over the technical functioning of such an activity, has been delegated, including the holder of a permit or authorisation for such an activity or the person registering or notifying such an activity existence of a hazard or a serious risk should be the starting point of any risk analysis*'. This would thus include both the breeder and the cultivator (see in that regard also B. Voigt and J. Klima, 'CRISPR-Plants & Co. – the Quest for Adequate Risk Regulation', EurUP, 2017, 4, at 330).

38) Environmental Liability Directive, Article 5.

39) *Ibid.*, Article 6.

40) As far as remedying of land damage is concerned, the necessary measures must be taken to ensure, as a minimum, that the relevant contaminants are removed, controlled, contained or diminished so that the contaminated land no longer poses any significant risk of adversely affecting human health (see Article 8 of the Environmental Liability Directive).

41) In a Motion of 11 October 2017 '*on the application of Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (the "ELD")*', the European Parliament has called on the Commission (i) to broaden the scope of the definition of 'environmental damage' (see paragraph 24 of the motion), (ii) to extend strict liability to

non-Annex III activities for all environmental damage with adverse effects (paragraph 36), and (iii) to ensure that the Directive applies to environmental damage caused by any occupational activity (paragraph 37).

42) Currently, Council Directive 2000/29/EC still applies but will be repealed as of 14 December 2019, by Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC, OJ L317, 23 November 2016, at 4 to 104. Similar national legislation is already in place today, but the present article only refers to the Plant Health Regulation.

43) See USDA Statement of 28 March 2018 (available at <https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation>) where it was confirmed in relation to NBT produced plants that '*... USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests*'.

44) Plant Health Regulation Article 1(1).

45) Ultimately, the plant health regime aims at ensuring jobs, plant innovation and food security in the EU.

46) See, in particular, the Plant Health Regulation, Articles 71 and 78.

(pathways of) pests.⁴⁷ The Commission is empowered to adopt implementing acts to address emerging risks from certain plants for planting from certain third countries which require precautionary measures.⁴⁸ The Plant Health Regulation furthermore provides additional *a posteriori* remedies, including – among other things – surveys and multiannual survey programmes, demarcation of areas for the purpose of eradication, as well as enhanced requirements for the priority pests.⁴⁹

Finally, to the extent that, during field trials (or at any of the subsequent agri-food stages discussed below) the cultivation of Non-GMO NBT Products would be assisted by the use of *fertilisers* or *plant protection products*, clearly the specific safeguards of the sectoral legislation⁵⁰ for those types of products will also apply.

By means of these measures – and notwithstanding the application of the precautionary principle (see further below) – if a Non-GMO NBT Product is found to pose risks to the environment in the EU, then a prompt reaction will be ensured.

At the Pre-harvest Stage

Plant Reproductive Material

Once R&D activities have led to cultivars with potential interest, both the production and commercialisation of plant reproductive material ('PRM'), like seeds, bulbs or seed potatoes, and their subsequent cultivation into crops will be subject to the EU PRM legislation, which is currently composed of 12 Directives: one horizontal Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species ('the Common Catalogue Directive'),⁵¹ and 11 sectoral Directives that regulate the PRM of specific crops (that is, vegetables,⁵² beets,⁵³ cereals,⁵⁴ fodder plants,⁵⁵ forest material,⁵⁶ fruit plants,⁵⁷ oil and fibre plants,⁵⁸ ornamental plants,⁵⁹ potatoes⁶⁰ and vines⁶¹) (hereinafter jointly referred to as 'the Seed Marketing Directives'). A legislative proposal aimed at consolidating and updating the Seed Marketing Directives into a single regulation was presented by the Commission on 6 May 2013⁶² but was subsequently withdrawn following the European Parliament's negative opinion.⁶³

47) *Ibid.*, Article 9. Regarding the remedies to adopt *a posteriori* once a pest is detected, the Plant Health Regulation has introduced some 'safeguard measures'. In particular, when a Member State has evidence that there is an *imminent danger* of the entry of a Union quarantine pest into the EU territory or into a part of it where that pest is not yet present, it shall immediately proceed with the eradication of a Union quarantine pest. Economic operators must also immediately notify the competent authorities of any evidence they may have concerning such an imminent danger.

48) *Ibid.*, Article 40.

49) *Ibid.*, Articles 4 to 31.

50) For fertilisers that is Regulation (EC) No 2003/2003 of 13 October 2003 relating to fertilisers, OJ L304, 21 November 2003, at 1 to 194; for plant protection products or 'PPPs', Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L309, 24 November 2009, at 1. For the sake of completeness and despite the fact that these rules will typically only apply at the post-harvest stage (see below), reference can in that context also be made to the MRLs Regulation (Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L70, 16 March 2005, at 1) which sets maximum limit values for pesticide residues in food products from plant and animal origin, and under which those foods are deemed safe.

51) Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, OJ L193, 20 July 2002, at 1 to 11.

52) Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed ('the Vegetable Seed Directive') and Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed, OJ L193, 20 July 2002, at 33 to 59.

53) Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed, OJ L193, 20 July 2002, at 12 to 32.

54) Council Directive of 14 June 1966 on the marketing of cereal seed (66/402/EEC), OJ 125, 11 July 1966, at 2309 to 2319.

55) Council Directive of 14 June 1966 on the marketing of fodder plant seed (66/401/EEC), OJ 125, 11 July 1966, at 2298 to 2308.

56) Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material, OJ L11, 15 January 2000, at 17 to 40.

57) Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production, OJ L267, 8 October 2008, at 8 to 22 ('the Fruit Directive').

58) Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants, OJ L193, 20 July 2002, at 74 to 97.

59) Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants, OJ L226, 13 August 1998, at 16 to 23.

60) Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes, OJ L193, 20 July 2002, at 60 to 73.

61) Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine, OJ L93, 17 April 1968, at 15 to 23 ('the Vine Directive').

62) Proposal for a Regulation of the European Parliament and of the Council on the production and making available on the market of plant reproductive material ('Plant Reproductive Material Law'), COM/2013/0262 final – 2013/0137 (COD).

63) The European Parliament rejected the proposal in first reading in April 2014, and then asked the Commission to withdraw it in a letter of 11 September 2014, D(2014)41887, see https://ec.europa.eu/info/sites/info/files/cwp_2015_annex_ii_en.pdf.

The EU PRM legislation is essentially intended to ensure identification, performance and quality to the user of PRM⁶⁴ and is, to that end, based on two elements: (a) the *registration (or 'listing') of varieties*,⁶⁵ and (b) the *certification of PRM* that can be placed on the market.

In terms of identification and performance, the Seed Marketing Directives⁶⁶ dictate that varieties need to be entered into a (common) catalogue for their PRM to be eligible for certification and marketing. To be allowed such entry, the variety must typically be found to be distinct, uniform and stable ('DUS'), and additionally – for agricultural crops – to have value for cultivation and use ('VCU'). The first three parameters relate to the variety's identity; the latter to its performance.

In terms of quality, the Seed Marketing Directives prescribe that PRM of a listed variety can only be legally sold in the EU after it has undergone a procedure aimed at guaranteeing its varietal identity, health (absence of certain diseases or pests and thus partially overlapping with the Plant Health Regulation)⁶⁷ and quality. This procedure includes field inspections, seed sampling and testing, and results in an official label. Specific requirements for packaging, sealing, labelling and documentation also apply.⁶⁸

Although the variety registration and seed certification process do not include any pre-marketing risk assessment, the PRM legislation provides an important 'safeguard' clause that operates *a posteriori* (that is, once the PRM has been placed on the market) to deal with risks to human health and the environment.⁶⁹ More precisely, if it is proven that the cultivation of a variety included in the common catalogue could in any Member State be harmful from the point of view of plant health to the cultivation of other varieties, or presents

a risk for the environment or for human health, that Member State may, upon application to the Commission, be authorised, by a decision adopted under the comitology procedure, to prohibit the marketing of PRM of that variety in all or part of its territory. Where there is imminent danger of the spread of harmful organisms or imminent danger for human health or for the environment, that prohibition may be imposed by the Member State concerned as soon as its application has been lodged until such time as a final decision has been taken.

This safeguard clause allows the Member States and/or the Commission to adopt preventive measures (for example, prohibiting the placing of PRM on the market) in individual cases where it is established that marketed PRM can pose a risk for the environment or human health even when a risk assessment has not yet been carried out.

General Product Safety

In addition to this specific PRM legislation, any PRM that is placed on the market is of course also subject to the rules on (environmental) liability and plant health (discussed above), and to the general principle enshrined in and illustrated by the so-called General Product Safety Directive⁷⁰ that all products placed on the EU market must be safe.⁷¹

According to this Directive, a product is deemed safe (by presumption) if it conforms to any applicable national or EU health and safety standards.⁷² However, conformity of a product does not bar the Member State competent authorities from taking appropriate measures to impose restrictions on the placing on the market of a product, to require its withdrawal from the market or to recall it where there is evidence that, despite such conformity, it is 'dangerous', that is, it presents a risk.⁷³

64) In the *Kokopelli* case, Advocate General Kokott nevertheless considered that a 'high quality level [of seeds] may contribute indirectly to food security ...' (Case C-59/11, *Association Kokopelli v Graines Baumaux SAS*, ECLI:EU:C:2012:28, at paragraph 69).

65) Common Catalogue Directive, Article 1(2).

66) See, for example, the Common Catalogue Directive Article 3(1); the Vegetable Seed Directive, Article 3(1); Article 5 of the Vine Directive; and the Fruit Directive, Article 7.

67) See, for example, Annex II (1), point 2, to Council Directive 66/401/EEC; Annex I, point 6, to Council Directive 66/402/EEC; Annex I, point 5, to Council Directive 68/193/EEC; Annex I (B) point 2, to Council Directive 2002/54/EC; Annex I, point 3, to Council Directive 2002/55/EC; Annex II to Council Directive 2002/56/EC; Articles 4(a) and 14 of Council Directive 2008/90/EC.

68) See, for example, Council Directive 66/402/EEC on the marketing of cereal seed, Articles 7 to 12.

69) See, more particularly, the Common Catalogue Directive, Article 18 and the Vegetable Seed Directive, Article 18.

70) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L11, 15 January 2002, at 4 to 17.

71) General Product Safety Directive, Articles 1(1) and 3(1).

72) *Ibid.*, Article 3(2).

73) *Ibid.*, Articles 3(4), 2(b) and 2(c).

The Directive imposes on the producer⁷⁴ an obligation to provide consumers with the relevant information enabling them to assess the risks (if any) inherent in a product and to take precautions against those risks. Distributors, as far as they are concerned, must ensure that they do not place on the market products supplied by the producer which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with safety requirements. The products must be traceable for enforcement purposes.⁷⁵ Member States must furthermore organise market surveillance, enforce product safety rules and adopt penalties which must be effective, proportionate and dissuasive for breaches of national rules transposing the General Product Safety Directive.⁷⁶ Finally, the Directive also installed a Rapid Alert System and platform⁷⁷ (RAPEX) at EU level so as to inform authorities and consumers of the existence of non-compliant products, and of the measures adopted to withdraw them from the market or put them in conformity.

The main limitation of the General Product Safety Directive in the context of Non-GMO NBT PRM is that its primary purpose is to protect consumers.⁷⁸ According to a widely used EU definition, a ‘consumer’ is a natural person who is acting outside the scope of an economic activity.⁷⁹ Products supplied to professional users (such as, for example, farmers growing Non-GMO NBT Products) are excluded from the scope of the Directive, and so is food (which is, however, covered by similar provisions under the sectoral General Food Law, as discussed further below). Strictly speaking, only Non-GMO NBT PRM supplied to consumers (for example, in garden

centres) would thus fall within the scope of the Directive. However, to the extent that, on its way to the consumer, this PRM passes through the hands of professional users involved along the chain, non-GMO NBT PRM for professional use *de facto* benefits from the same high safety threshold as the one that applies to consumer PRM, so that this Directive – with its obligation for producers (and distributors) to place only safe products on the market – also (at least indirectly) offers a guarantee that Non-GMO NBT PRM is safe for human beings (in addition to the aforementioned legislation guaranteeing such safety to the environment).

At the Post-harvest Stage

Once PRM is planted or sown, it will become a crop that is in most cases destined for human or animal consumption. In other words, in this next and final step of the agri-food production chain, the Non-GMO NBT Product will turn into food or feed. Also at this stage, several control and supervision measures are in place.

General Food Law

Regulation (EC) No 178/2002 (‘the General Food Law’)⁸⁰ lays down the general principles and responsibilities governing food in general, and food safety in particular. The primary objective of this legislation is: ‘*the assurance of a high level of protection of human health and consumers’ interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market*’.⁸¹

74) Defined in *ibid.*, Article 2(e) as: (i) ‘*the manufacturer of the product, when he is established in the Community, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product*; (ii) *the manufacturer’s representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product*; and (iii) *other professionals in the supply chain, insofar as their activities may affect the safety properties of a product*’.

75) *Ibid.*, Articles 5(1) and 5(2).

76) *Ibid.*, Articles 7, 8 and 9.

77) On the Rapid Alert System, see the Commission website, available at https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm.

78) General Product Safety Directive, Article 2(a).

79) See, for example, M. Kingisepp and A. Väriv, ‘The notion of consumer in EU consumer acquis and the Consumer Rights Directive – a significant change of paradigm?’ *Juridica International* XVIII, 2011, at 2; and M. Ebers, ‘The notion of “consumer”’, in H. Schulte-Nölke, C. Twigg-Flesner and M. Ebers, *EC Consumer Law Compendium. Comparative Analysis* (Munich, 2008).

80) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L31, 1 February 2002, at 1 to 24. While the present article primarily discusses food, similar rules apply to feed, which is equally covered by the General Food Law, complemented by Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, OJ L229, 1 September 2009, at 1 to 28.

81) General Food Law, Article 1(1). In the recent REFIT evaluation, it has been concluded that the General Food Law Regulation has attained its core objectives, that is, ensuring a high level of protection of human health and consumers’ interests in relation to food and the effective functioning of the internal market (see ‘*Commission Staff Working Document – Refit Evaluation of the General Food law (Regulation (EC) No 178/2002)*’, Brussels, 15 January 2018 SWD(2018) 38 final part 1, at 113 to 114, available at https://ec.europa.eu/food/sites/food/files/gfl_fit_comm_staff_work_doc_2018_part1_en.pdf).

This Regulation covers all stages of production, processing and distribution of food and feed, thus this ‘*high level of protection*’ must be attained regardless of the technology used in the food/feed production process.

To ensure that effective, proportionate and targeted measures are adopted for protecting human life and health, the General Food Law is based on risk analysis, that is, risk assessment, risk management and risk communication.⁸² Contrary to the GMO legislation, however, this is not an officially validated risk analysis responding to a prescribed list of endpoints, but a self-assessment allowing the operator to satisfy itself that the food is not likely to cause harmful effects.

Under the General Food Law, the responsibilities for the implementation of the relevant framework are allocated among the main players operating at their respective levels. First, similarly to the General Product Safety Directive mentioned above, the primary responsibility for food/feed safety is borne by the food/feed business operators who place their products on the market; they must guarantee that ‘*food [or feed] shall only be placed on the market if it is safe*’.⁸³ Secondly, the Member States are in charge of the monitoring and verification that the relevant food/feed requirements are fulfilled, as well as the enforcement of food/feed legislation.⁸⁴ In that context, Member States can adopt interim protective measures where ‘*it is evident that*

food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment’ and the Commission has not adopted emergency measures (market suspension or other).⁸⁵ Finally, as just mentioned, the Commission may also adopt risk-based measures⁸⁶ and emergency measures in cases where it is evident that any food/feed is likely to constitute a serious risk to human health, animal health or the environment.⁸⁷

In addition, and with a view to coordinating the actions of the various players and ensuring an effective reaction to risks, the General Food Law has foreseen the Rapid Alert System for Food and Feeds (‘RASFF’) for the notification of ‘*any direct or indirect risk to human health in relation to food, food contact material or feed, as well as serious risks to animal health or environment in relation to a specific feed*’.⁸⁸ In a similar way to the RAPEX⁸⁹ for non-food products, the RASFF’s general objective is to enable the competent authorities to exchange and disseminate information on the risks detected on food and feed (and on the measures adopted to counter such risks) so that those authorities can take or recommend rapid remedial action.⁹⁰ According to the Commission, RASFF has proven to be an effective and relevant tool to immediately inform on direct and indirect risks related to food and feed.⁹¹

82) Ibid., recital 17. It is to be noted that the EU legislator does not use risk assessment wording consistently throughout different pieces of legislation. In the present context, these terms are defined as follows:

– ‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

– ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

– ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

– ‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

– ‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

– ‘hazard’ means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.

83) Ibid., Article 14(1) and (2). Food business operators also have specific obligations along the whole production-supply and distribution chain, including, among other things, (i) the verification of food law requirements; (ii) ensuring of compliance with traceability and labelling requirements; (iii) withdrawing allegedly hazardous food and feed products from the market and recalling such products from consumers; (iv) informing the competent authorities if they consider that a food or feed may be injurious to human health; and (v) cooperating with these authorities to avoid or reduce risks posed by any food or feed that has come into their possession (see *ibid.*, Articles 3, points 3 and 6, 18 and 19).

84) Ibid., Article 17(2).

85) Ibid., Article 54.

86) Ibid., Articles 6 and 7.

87) Ibid., Article 53.

88) Ibid., Article 50. Regulation (EC) No 1831/2003 of 22 September 2003 laying down requirements for feed hygiene, Article 29, has extended the scope of the RASFF to serious risks to animal health and to the environment.

89) See Note 77 above.

90) See DG SANTE, *The Rapid Alert System for Food and Feed 2016 – 2016 Annual Report*, available at https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2016.pdf.

91) See the reference in Note 81 above.

Novel food

Notwithstanding the general safety measures foreseen in the General Food Law, certain Non-GMO NBT Products used in or as food/feed may eventually also require a specific GMO-like pre-market risk assessment and authorisation if they fall within the scope of Regulation (EU) 2015/2283 ('the Novel Food Regulation').⁹² The main procedural regime under this Regulation is that of an EU-centralised pre-marketing authorisation, combined with a health risk assessment carried out by the European Food Safety Authority ('EFSA') where the novel food is liable to have effects on human health. This risk assessment is not identical,⁹³ but similar to the GMO health risk assessment. The Novel Food Regulation furthermore establishes conditions of use and specific labelling requirements for novel food to be placed on the market⁹⁴ to inform about any specific characteristic of the novel food. And finally, post-marketing monitoring requirements⁹⁵ and obligations are foreseen. For instance, the food business operator which has placed a novel food on the market must immediately inform the Commission of any new scientific or technical information which might influence the safety evaluation of the novel food, and any prohibition or restriction imposed by a third country in which the novel food is placed on the market.⁹⁶

Although the definition of a 'novel food' is rather complex, it essentially applies to the placing on the market of foods that had not been consumed to a significant degree in the EU before 15 May 1997 (the date of the entry into force of the first Regulation on novel foods⁹⁷) and fall under one of the categories listed in Article 3(2)(i) to (x) of the Regulation.⁹⁸ It follows from this list that novel foods can be newly developed innovative foods, traditional foods from outside the EU, and also food produced by using new technologies and production processes. In that latter context, the Novel Food

Regulation refers to a category of novel foods that, in short, consist of, or are isolated or produced from, a plant or a variety of the same species obtained by non-traditional propagating practices that give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances.⁹⁹ The three main criteria cumulatively determining whether a Non-GMO NBT food will fall within this category are: (i) whether NBTs are 'non-traditional propagating practices', (ii) whether they 'give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances', and (iii) whether it has a history of safe food use within the EU.

Regarding criterion (i) and although the language of the Regulation may suggest otherwise ('propagating' obviously not being the same as 'breeding'),¹⁰⁰ it can be argued, for the reasons outlined by Voigt and Klima,¹⁰¹ that despite the perhaps unfortunate and confusing choice of wording, the EU legislator actually used the terms interchangeably so that, under that logic, a new *breeding* method would also amount to a *propagating* practice within the meaning of the Novel Food Regulation.

Regarding criterion (ii), food derived from organisms resulting from 'non-traditional propagating practices' may fall within the novel food definition if they are (compared to the food obtained from their non-altered counterpart) *significantly* changed in the composition or structure affecting their *nutritional value, metabolism or level of undesirable substances*. According to the same authors,¹⁰² the question whether food consisting of or produced from Non-GMO NBT Products falls within the scope of this definition depends on the type of change that the NBT triggers in the plant and potentially the final food. They suggest that foods consisting

92) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L327, 11 December 2015, at 1 to 22.

93) For an overview of the differences between the GM Food and Feed regime and the Novel Food Regulation, see B. Voigt and J. Klima, Note 37 above, at 327 to 328.

94) Novel Food Regulation, Article 6.

95) *Ibid.*, Article 24.

96) *Ibid.*, Article 25.

97) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L43, 14 February 1997, at 1 to 6, as subsequently amended.

98) Novel Food Regulation, Article 3(2)(a).

99) *Ibid.*, Article 3(2)(a)(iv).

100) In plant terms, the term 'propagation' refers to the act of (re)producing material of the *same* variety, while 'breeding' refers to the act of creating *new* varieties.

101) B. Voigt and J. Klima, Note 37 above, at 324.

102) *Ibid.*, at 326.

of, or produced from, Non-GMO NBT Products only rarely change the composition and structure of the food. In our opinion, this will to a large degree depend on the *intention* behind the alteration and on the result it expresses in a product. In cases where a change in composition or structure is intended and targeted at the time that the NBT is applied to obtain the Non-GMO NBT Product (upstream in the food chain, such as, for example, the breeding of a vegetable or fruit variety with the specific aim of significantly enhancing/changing its vitamin or nutritional content), the resulting food may be covered by Article 3(a)(iv), second indent, of the Novel Food Regulation.

Finally, regarding criterion (iii), although the novel foods derived from Non-GMO NBT Products do not themselves have a 'history of safe food use within the Union', it has been argued, again by the same authors, that food products obtained from Non-GMO NBT Products *do* have an established history of safe food use in the EU if that history is assessed on the basis of the parent organism.¹⁰³

It follows also here that the protection of human and animal health and the environment seems sufficiently safeguarded under the General Food Law, without there being a need for Non-GMO NBT food or feed being regulated separately, as is the case for their GMO counterparts under the GMFF Regulation. The precautionary principle also plays an important role in the General Food Law to the extent that it allows the adoption of risk management measures *if* a risk of harmful effects on health is *identified*, but there is still scientific uncertainty around the evaluation of such effects.¹⁰⁴ While the General Food Law is essentially the food equivalent of the above-mentioned General Product Safety Directive (which excludes food from its scope) and thus guarantees the general safety of food for humans, the Novel Food Regulation will arguably apply to Non-GMO NBT food if it consists of or is isolated or produced from a plant or a variety of the same

species obtained by non-traditional propagating practices that give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances. If the Novel Food Regulation conditions apply, the Non-GMO NBT food in question will be subject to a GMO-like pre-market risk assessment and authorisation.

Official controls

Finally, in addition to the specific control obligations which Member State competent authorities may have under the various legal instruments mentioned above (such as those under the GMM Directive and the Seed Marketing Directives), Regulation (EU) No 2017/625 ('the Official Controls Regulation')¹⁰⁵ provides an additional framework for Member States to verify that operators comply with agri-food chain rules.

The responsibility to enforce EU agri-food chain legislation lies with the Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant EU requirements are effectively complied with and enforced.¹⁰⁶ In this context, the Official Controls Regulation has established a harmonised EU framework for the organisation of official controls, and official activities other than official controls, along the entire agri-food chain.

Under the Official Controls Regulation, official controls must be performed: (a) regularly, in accordance with a risk-based approach (that is, focusing on those areas where the risk, including the risk of non-compliance, is higher)¹⁰⁷ and with appropriate frequency; (b) without prior notice, unless prior notice to the operator concerned is necessary and duly justified; and (c) at all stages of production, processing, distribution and use of animals, goods, substances, plants, organisms or objects that fall within the scope of the agri-food legislation.

103) *Ibid.*, at 324 (and the reference to other literature at Note 37).

104) General Food Law Regulation, Article 7.

105) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the

Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L95, 7 April 2017, at 1 to 142. The Official Controls Regulation entered into force on 27 April 2017. It replaces Regulation (EC) No 882/2004 on official controls and other sectoral legislation which currently governs the control and enforcement of rules along the agri-food chain. The new rules will gradually become applicable with the main application date being 14 December 2019 (Article 147 of the Official Controls Regulation).

106) Official Controls Regulation, recital 15.

107) Thereby taking into account, among other things, the risk to human, animal or plant health, animal welfare or the environment (*ibid.*, Article 9).

The Official Controls Regulation regulates official controls to verify compliance with *inter alia* food and feed safety rules at any stage of production, rules on animal health and welfare, plant health, animal by-products, organics and plant protection products.¹⁰⁸ It hence applies horizontally to ensure compliance with all substantive rules in the agri-food chain and would thus also include plant health and safety checks of Non-GMO NBT food and feed.

Intermediate Conclusion

Against this backdrop, it can be concluded that, as Advocate-General Bobek already suggested in his above-mentioned Opinion in Case C-528/16, neither the production, the commercialisation nor the consumption of Non-GMO NBT Products in the EU would fall short of any control or supervision. It is arguable that the existing regulatory framework provides the necessary and sufficient safeguards to make sure that every operator along the entire agri-food production chain responsibly produces or markets products that do not cause harm to humans, animals or the environment and that, if a safety risk is identified, rapid and efficient preventive or remedial measures can be taken against the product concerned, be it on the basis of a specific safeguard clause or on the basis of the general precautionary principle.

Despite the existence of this vast set of rules, it has been argued by some authors¹⁰⁹ that none of the legislation above, either individually or taken in combination, offers a guarantee of safety to the same level as that under the GMO legislation.

Admittedly, when taken *individually*, none of the legal instruments discussed above offers a type of risk assessment equivalent to that contained in the GMO legislation and for each such instrument a number of gaps can be identified (in terms of the purpose of the instrument concerned, the mechanism it provides for achieving that purpose, and the subject-matter it seeks to regulate). This, however, does not only apply to Non-GMO NBT Products not regulated by the

GMO Directive, but also to all CBT-derived products, including those from organic agriculture. Furthermore, that conclusion, which is hardly surprising, does not automatically translate into a finding that the production, cultivation, commercialisation or consumption of Non-GMO NBT Products is an entirely unregulated area. On the contrary, because of the specific and exceptional nature of the GMO legislation, we submit that it serves little purpose to engage in individual, one-on-one comparisons between the abovementioned legal instruments, on the one hand, and the GMO legislation, on the other.

Instead, those instruments must be looked at *in combination* with one another, the one filling the gaps (compared to GMO legislation) of the other and vice versa, to determine the regulatory status of Non-GMO NBT Products *holistically*. Such a holistic examination of the existing EU legal framework (as visually exemplified in Figure 1) shows that every stage of the agri-food production chain, ‘from lab to fork’, in which Non-GMO NBT Products may play a role, is subject to restrictions and safety obligations dictated by harmonised rules, each of which arguably provides a sufficient degree of scrutiny, risk management, control, sanctions and remedial action. From that perspective, it seems difficult to maintain that the existing rules would be insufficient to reasonably ensure that Non-GMO NBT Products do not cause harmful effects. Claiming the opposite would be tantamount to saying that none of the existing rules are fit for purpose, since virtually all of the legal instruments discussed above claim to have been drafted precisely to protect either human health, animal health, the environment or a combination thereof.¹¹⁰

Despite all this, the main argument raised by those calling for additional regulatory oversight for Non-GMO NBT Products is essentially that, even when looked at in combination, the legal instruments discussed above do not rely on a pre-market risk assessment and authorisation, as the GMO legislation does.

108) *Ibid.*, Article 1(2).

109) T. Spranger, ‘In-depth analysis of various European directives and regulations with regard to their potential to regulate environmental effects of new technologies besides genetic engineering law’, October 2017, available at https://www.bfn.de/fileadmin/BfN/agrogentech/Dokumente/NT_Auffangerechte_RGutachten_Spranger_en.pdf; and B. Voigt and J. Klima, Note 37 above, at 324.

110) Thus, for example, Article 1 of the Contained Use Directive states that it is aimed at ‘*protecting human health and the environment*’; Article 1(1) of the General Food Law Regulation establishes ‘*the basis for the assurance of a high level of protection of human health and consumers’ interest in relation to food*’; Article 1(2) of the Novel Food Regulation specifies that it is intended to guarantee *inter alia* ‘*a high level of protection of human health and consumers’ interests*’; Article 1 of the General Product Safety Directive provides that it seeks to ensure the safety of consumer products placed on the market.

Do Non-GMO NBT Products Need a GMO-like Pre-market Risk Assessment and/or Authorisation?

Regulating Risk

It is indeed true that (with the exception of the Novel Food Regulation) none of the legal instruments discussed above were designed as pre-market risk assessment tools. Thus, even when holistically comparing the existing legal framework outlined above with the GMO framework, the absence of a marketing authorisation issued on the basis of a pre-market risk assessment is a gap that (other than for Non-GMO NBT foods falling under the Novel Food Regulation) cannot be filled. The question is, however, whether this gap justifies the submission of all Non-GMO NBT Products to a GMO-like pre-market risk assessment and authorisation regime. We submit that there is no indication that it should.

The starting point for this discussion is, as explained, the conclusion of the SAM Note that Non-GMO NBT Products are essentially not distinguishable from CBT products, that their unintended or 'off-target' effects are far less than those resulting from (unregulated) classical mutagenesis, and that therefore no (higher) risk should be expected.

In EU law, the decision whether or not a given product represents a serious risk which must be addressed through specific risk management measures must '*be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence*'¹¹¹ (that is, risk = hazard x exposure). Hazard alone is not sufficient to justify restrictive measures and must be distinguished from the concept of risk. The existence and identification of a specific risk must be at the origin of regulatory measures applying to a specific category of goods or activities. This is also why, under EU law, authorisation regimes providing for a risk assessment validated by a

designated independent agency or competent authority are not the general rule, but the exception. They exist only for a limited number of products or sectors (such as, besides the GMO legislation, plant protection products, biocidal products, and pharmaceutical products) where there is an identifiable risk which cannot be adequately and proportionately managed otherwise. Both the full risk assessment and authorisation regime set out by the GMO Deliberate Release Directive are thus *exceptional* in the sense that they aim to target a specific situation that goes *beyond* the default rule that persons who place products on the market are considered responsible for the general safety of these products, as is the case for all products (and thus also Non-GMO NBT Products) produced and/or commercialised under the sectoral and horizontal legislative instruments outlined above. Authorisation regimes based on pre-market risk assessments are *not* and should not be *the norm*.

The mere fact that Non-GMO NBT Products are not subject to pre-marketing authorisation and do not undergo a full risk assessment like GMOs does, therefore, not in itself mean that they would present an unacceptable risk or that they would require that similar, GMO-like risk management measures are put in place. Hence, it is submitted that in the absence of any identified risk which is more significant than the risk related to products resulting from CBT, a Non-GMO NBT Product should (i) not be considered less safe than any other such product or organism, irrespective of the (breeding) technique used to produce it, and (ii) be regulated to the same level as one resulting from CBT.¹¹²

The Precautionary Principle

Clearly, the absence of proof of a risk does not amount to a definitive conclusion on the product's safety. However, if a safety concern were to arise, the precautionary principle¹¹³ (or one of its specific applications in the form of safeguard

111) See, for example, Article 20(2) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L218, 13 August 2008, at 30 to 47. See also P. Dąbrowska-Kłosińska, *EU courts, global risks, and the health and environmental safety revisited: on nuances of a less deferential standard of review*, European University Institute Working Papers, Robert Schuman Centre for Advanced Studies Global Governance Programme-

62 RSCAS 2013/63, at 1; N. De Sadeleer, *The precautionary principle in EU law* (AV&S, 2010) at 177.

112) This position is also supported by R. Custers, Note 20 above, at 1.

113) For an overview of the precautionary principle, see, for example, L. Cruz Vilaça, 'The precautionary principle in EC law', in *EU law and integration: twenty years of judicial application of EU law* (Hart Publishing, 2014) at 347; and N. De Sadeleer, Note 111 above, at 173 to 184.

measures in the legislative instruments discussed earlier)¹¹⁴ may still come into play and justify the adoption of stricter risk management measures if knowledge of a previously unidentified risk arises. It would be an illusion to think that making a pre-market authorisation regime the norm for Non-GMO NBT Products (or any other product) would prevent all possible discussion about their safety with respect to human/animal health or the environment, as such discussions frequently take place despite the existence of such a regime.¹¹⁵

The precautionary principle, which is laid down in Article 191 of the TFEU regarding environmental policy and was recognised by the EU courts as a general principle of EU law,¹¹⁶ is not an alternative to a risk management approach, or to a scientific risk assessment in the context of the decision-making process, but rather a particular form of risk management. The Commission Communication on the precautionary principle,¹¹⁷ adopted in 2000, provides the Commission's view and guidelines on the way the precautionary principle should be implemented. There are essentially two conditions necessary to trigger the application of the precautionary principle: (a) the identification of the possibility of harmful effects in the environment or human, animal or plant health (that is, risk); and (b) a scientific evaluation of the risk which, because of the insufficiency of the data, their inconclusive or imprecise

nature, makes it impossible to determine with sufficient certainty the risk in question. It is understood that, pursuant to established case law, the level of protection envisaged by applying the precautionary principle does not necessarily have to be the highest that is technically possible and that a purely hypothetical approach to risk or a 'zero risk' approach is not allowed.¹¹⁸ This was also confirmed by Advocate-General Bobek in the AG Opinion: '[i]t follows from the Court's case-law that under the precautionary principle, "risk uncertainty" does not mean mere general doubts. Concrete risks for human health or the environment must be identified, supported by a minimum amount of serious and independent scientific research. A fear of a risk, or risk of a risk, is not enough'.¹¹⁹

It follows that whereas the precautionary principle is a strong safeguard for situations where a risk is identified and there is scientific uncertainty around such risk, it cannot be relied upon by Member States to generally impose restrictions on Non-GMO NBT Products, in the absence, as the SAM Note has clarified, of any concrete, science-based finding of risk. Any risk management measure must respond to a need to address an existing and identified risk, and be commensurate with the identified risk level. If not, it would violate the general EU law principles of proportionality,¹²⁰ legal certainty¹²¹ and legitimate expectations, as well as non-discrimination (equal treatment).¹²²

114) A specific application of the precautionary principle was thus, for example, laid down in Article 7 of the General Food Law Regulation: '1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment. 2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment'.

115) For a recent application, see, for example, Cases T-429/13 and T-451/13, *Bayer Cropscience and Syngenta v Commission*, 17 May 2018, ECLI:EU:T:2018:280.

116) See, for example, Case C-180/96, *United Kingdom v Commission*, ECLI:EU:C:1998:192, paragraphs 99 to 100; and Case T-199/96, *Laboratoires pharmaceutiques Bergaderm SA and Jean-Jacques Goupil v Commission*, ECLI:EU:T:1998:176, paragraphs 66 to 67.

117) Communication from the Commission on the precautionary principle, COM(2000)1 final, 2 February 2000, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN>.

118) Case T-257/07, *France v Commission*, EU:T:2011:444, paragraphs 79 to 80 (confirmed by the judgment of the Court of Justice in Case C-601/11 P, *France v Commission*, EU:C:2013:465). See also Case T-13/99, *Pfizer Animal Health SA v Council*, ECLI:EU:T:2002:209, paragraphs 152 to 153; and Case C-111/16, *Fidenato*, ECLI:EU:C:2017:676.

119) AG Opinion in Case C-528/16, *Confédération paysanne*, ECLI:EU:C:2018:20, paragraph 148.

120) The principle of proportionality is a general principle of EU law. According to the Court of Justice's case-law and Article 52 of the EU Charter of Fundamental Rights, 'measures adopted by European Union institutions must not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued' (see, for example, Case C-343/09, *Afton Chemical*, ECLI:EU:C:2010:419, paragraph 45; Joined Cases C-81/10 and C-629/10, *Nelson and Others*, ECLI:EU:C:2012:657, paragraph 71; Case C-283/11, *Sky Österreich GmbH v Österreichischer Rundfunk*, ECLI:EU:C:2013:28, paragraph 50; Case C-101/12 *Herbert Schaible v Land Baden-Württemberg*, ECLI:EU:C:2013:661, paragraph 30).

121) See, for example, Case C-322/16 *Global Starnet Ltd*, ECLI:EU:C:2017:985, paragraph 46 and the case law quoted therein.

122) See, for example, Joined Cases 117/76 and 16/77, *Albert, Ruckdeschel & Co. and Hansa-Lagerhaus Ströh & Co.*, ECLI:EU:C:1977:160, paragraph 7.

SPS

Finally, it should also be borne in mind that any new measure adopted at the EU or national level (including, therefore, the creation of a pre-market risk assessment and authorisation regime for Non-GMO NBT Products) will need to comply with the provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures ('the SPS Agreement'), an international agreement concerning the application of food safety and animal and plant health regulations which may, directly or indirectly, affect international trade.¹²³

Similar to the conditions governing the application of the precautionary principle, any trade-restrictive sanitary and phytosanitary measures¹²⁴ imposed by WTO members must be: (i) applied only to the extent necessary to protect human, animal or plant life or health;¹²⁵ (ii) based on scientific principles; and (iii) not maintained without sufficient scientific evidence.¹²⁶

Furthermore, any measure intended to regulate Non-GMO NBT Products would have to be based upon a proper risk assessment.¹²⁷ Also here, citing a mere possibility of risk will not be sufficient, while a probability assessment would only pass the test if it is sufficiently specific to the problem at issue.^{128,129} Under the SPS Agreement, any risk assessment must comprise the steps of: (i) identification of the adverse effects on human and animal health; (ii) where such adverse effects exist, evaluation of the potential of occurrence of those effects arising from the targeted substances or organisms (for example, Non-GMO NBT Products); and (iii) evaluation of possible alternative policy options.

Finally, as in EU law, under the SPS Agreement (phyto)sanitary measures must also be proportionate¹³⁰ and

non-discriminatory, in the sense that they cannot contain arbitrary or unjustifiable distinctions.¹³¹ To the extent that, as stated by the SAM Note, Non-GMO NBT Products do not present a higher risk than and are essentially non-distinguishable from CBT produced products, subjecting them but not the CBT produced products to additional pre-marketing requirements (for example, a pre-marketing authorisation) would arguably be an unjustifiable distinction resulting in a restriction on international trade contrary to the principles of the SPS Agreement.¹³²

Conclusion

In the present article, it is submitted that the existing EU regulatory framework, when considered holistically, provides efficient guarantees that every stage of the agri-food supply chain, from lab to fork, is subject to constraints and obligations dictated by harmonised legislations, each providing various degrees of scrutiny, risk management and control, sanctions and remedial action. A visual representation of this holistic approach is provided in Figure 1.

Comparisons between the existing non-GMO legal framework with the GMO legislation or with any other authorisation regime based on a full pre-market risk assessment are, by definition, of little practical relevance, since such regimes aim to address potentially serious risks, which, as the SAM Note clarifies, have not been identified in the case of Non-GMO NBT Products. In the absence of any such concrete, identifiable risk induced by (the use of NBTs for) Non-GMO NBT Products and in view of their non-distinguishability from CBT products, the protection of human/animal/plant health and the environment should thus be considered to be adequately ensured and Non-GMO NBT Products should not be treated

123) The SPS Agreement entered into force with the establishment of the World Trade Organization on 1 January 1995.

124) As defined in Annex A.1 to the SPS Agreement.

125) The 'necessity test' consists in assessing whether the envisaged measure goes beyond the obligations which are implied by the science-based requirements: see J. Scott, *WTO Agreement on Sanitary and Phytosanitary Measures – a commentary* (Oxford, 2009) at 85.

126) SPS Agreement, Article 2.

127) *Ibid.*, Article 5.1.

128) J. Scott, Note 125 above, at 137.

129) The Appellate Body Report in the Australia-Salmon dispute found that the risk assessment requirement under Article 5.1 of the SPS Agreement should be read together with Article 2.2, which states that SPS measures should be science-based, not maintained without sufficient scientific information and only applied to the extent necessary; thus if a measure is not based on a risk assessment, then it is not based on scientific principles (*Australia – Measures Affecting Importation of Salmon* – AB-1998-5 – Report of the Appellate Body, WT/DS18/AB/R, paragraphs 137 to 138).

130) SPS Agreement, Articles 5.4 and 5.6.

131) *Ibid.*, Article 5.5.

132) See also in that regard J. Kahrman, O. Bomeke and G. Leggewie, Note 20 above, at 182.

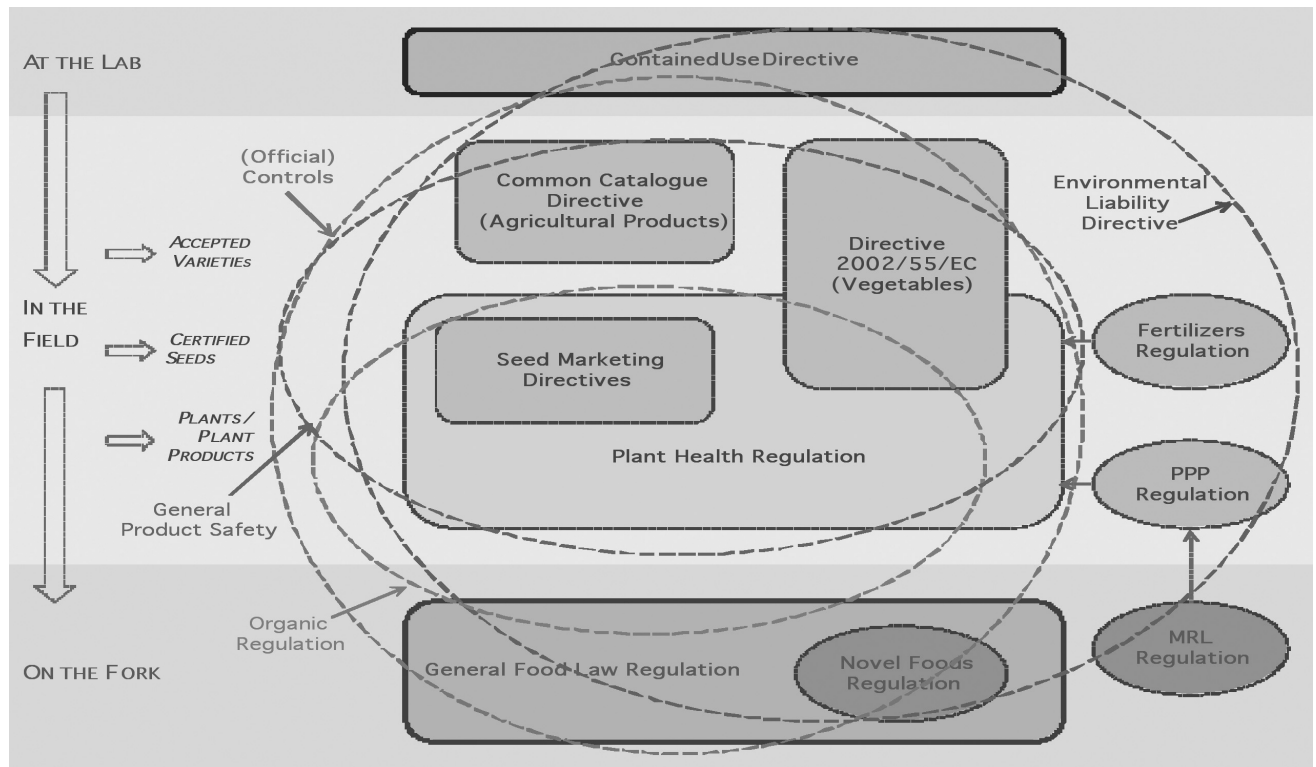
differently from products resulting from CBT. The opposite conclusion would not only raise serious concerns under the SPS Agreement but would essentially also mean that *all* non-GMO plant products on the market today must be considered inadequately regulated.

Just as Advocate-General Bobek concluded in his Opinion in Case C-528/16,¹³³ with regard to mutagenesis, that ‘one could hardly assume that a reasonable legislator could ever wish to state, *en bloc* and for the future, that something is

safe to such a degree that it does not need regulating at all’, one can neither assume that all NBT-products should *en bloc* be considered to only yield products suspect of causing unacceptable risks.

Against that backdrop, it is submitted that both the precautionary principle and the specific safeguard clauses in horizontal and sectoral legislation can justify and sufficiently guarantee the adoption of stricter risk management measures, if a previously unidentified risk arises.

Figure 1. Mapping of existing EU legislation in the agri-food chain from farm to fork



133) AG Opinion in Case C-528/16, *Confédération paysanne*, ECLI:EU:C:2018:20, at paragraph 120.