New Plant Breeding Techniques

Executive Summary:
Genetically modified organisms (GMOs) are organisms that have undergone genetic modification according to the scope of Directive 2001/18/EC[1]. The EU regulatory framework establishes the need for risk assessment, traceability and labelling of GMOs for (non-organic) food/feed products containing or produced from authorised GMOs as regulated by Regulations (EC) No. 1829/2003[2] and 1830/2003[3]. For organic agriculture genetically modified organisms are prohibited under Regulation (EC) No. 834/2007[4]. Collectively these legislative requirements for GMOs provide a supportive framework permitting transparency and informed decision making.

New plant breeding techniques (NPBTs) have been supported by the EU Commission[5]. To date however, no legal interpretation has been provided by the EU Commission concerning the definition of GMOs in relation to organisms produced by NPBTs, and whether NPBTs fall within the scope of Directive 2001/18/EC. Independently, two recent legal opinions have concluded that NPBTs, and the organisms produced by NPBTs, fall under the scope of Directive 2001/18/EC.[6,7]

Natural and organic cosmetics are an officially undefined sector of the tightly regulated cosmetic industry. Private standards exist to provide certifiable criteria to define natural and organic cosmetics for hundreds of SMEs who supply raw materials and manufacture finished products, and the thousands of consumers who buy them.

The absence of a vital legal interpretation represents a fundamental problem of regulatory uncertainty that can impact both assurance and authenticity of the sector. Critically, for consumers, who consciously choose to purchase certified natural/organic personal care products based on confidence that ingredients of genetically modified origin are prohibited, this assurance will not be achievable by manufactures unless NPBTs, the organisms and products from them fall within the scope of GMO legislation.

The principles and evaluation of environmental care and responsibility, protection of biodiversity, and any effects on human health should be equally in the foreground. To-date, empirical data concerning the safety and environmental impact of organisms produced by NPBTs is missing, and in addition there is an inability to analytically detected genetically modified plants engineered using NPBTs, which means that re-tracing any effects on human beings and environment will be impossible.

NATRUE therefore urges the EU Commission to consider NPBTs as genetic modification techniques resulting in GMOs according to the scope of Directive 2001/18/EC, and so enabling a clear and conscious choice via mandatory traceability and labelling for manufactures and consumers alike.

NPBTs in the context of the EU regulatory framework for GMOs

A genetically modified organism (GMO) is defined in Article 2(2) of Directive 2001/18/CE as "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*". Furthermore, those techniques considered genetic modification or not (Article 2(2); Annex 1A) and genetic modification yielding organisms excluded from the scope of the Directive 2001/18/EC (Article 3(1); Annex 1B) are outlined.

Specifically for organic agriculture, as regulated by the Regulation (EC) No. 834/2007, GMOs, as defined in the Directive 2001/18/EC, are prohibited.

Since April 2015, as an amendment to Directive 2001/18/CE, a new Directive 2015/412[8] has provided the possibility to any EU Member State of an 'opt-out' to prohibit or restrict the cultivation of GMOs on part or all of their territory. This 'opt-out' may occur during or after the authorisation procedure for a GMO, and for already authorised GMOs.

The New plant breeding techniques (NPBTs) considered by the EU Commission's New Techniques working group are5:

- Oligonucleotide Directed Mutagenesis (ODM)
- Zinc Finger Nuclease Technology (ZFN - ZFN-1, ZFN-2 and ZFN-3)
- Cisgenesis and Intragenesis
- Grafting (into a GM rootstock)
- Agro-infiltration
- RNA-dependent DNA methylation (RdDM)
- Reverse breeding
- Synthetic genomics

This list includes a diverse group of the state-of-art of plant biotechnology techniques to produce new varieties of plants[5,9] where the legal status is still unknown. Consequently, it remains unclear if such techniques will be regulated by GMO legislation (Directive 2001/18/CE; Regulation (EC) No. 1829/2003; Regulation (EC) No. 1830/2003) or not.

The final decision about the regulation of NPBTs will be contributed by factors considering the Plant Biotechnology Industry and Breeders (as the cost and risk assessments requirements will vary depending on their GMO status or not) versus the needs of the end consumers (as non-GMOs do not require any specific labelling).

What are the major concerns about NPBTs?

The European Commission has previously requested two scientific opinions, and assessment of the state of adoption and the potential economic impact of NPBTs from two separate bodies: The European Food Safety Authority (EFSA) Panel on GMOs[10,11] and the Joint Research Centre (JRC)[8]. These reports have pointed out the advantages of these techniques for producing genetic variation and making the breeding process faster and cheaper compared to classic techniques.

However, even when organisms produced by NPBTs do not contain foreign DNA, the organism's genome or the regulation of some genes may be modified using genetic engineering techniques, which could result in a wide range of unintended effects to genes other than the one targeted. Moreover, NPBTs are still very new and limited data is available on crops, as most of the research is carried out on model plants[8,10,11]. Consequently, there is little data regarding the short and long-term impact of NPBT plants on the environment and on human health.

In order to be placed on the market, GMOs have both a pre-market authorisation procedure and post-market environmental monitoring. GMOs must have undergone environmental risk assessment (Article 2(8) and Annex II of Directive 2001/18/EC), have an opinion by EFSA and be accepted by the EU Commission and the Member States[12]. Those authorised GMOs are then included in a database[13] with a unique ID code and details of the method to identify and trace it as necessary. Assessment include the analysis of the direct and indirect effects, immediate or delayed, and the cumulative long-term effects on human health or the environment.

Yet, if the new plant varieties obtained as result of the NPBT application are unregulated, and so effectively classified as non-GMOs, they will be placed in the market without any legal requirement for labelling. In addition, after release it will be impossible to trace these plants as any genetic modifications cannot be detected analytically, or if these plants might be responsible for any potential health (e.g. allergies) or environmental (e.g. species displacement; loss of biodiversity) impact since NPBTs will have not undergone any risk assessment.

Why is it important to be able to identify plants derived from NPBTs and have traceability for the natural and organic cosmetic sector?

The European natural and organic cosmetic manufacturers are leaders in the authentic sector, and the market is growing. Sixty-eight percent of the EU market consists of certified products and consumers are ever more concerned about the origin and nature of the products that they buy. When they choose to buy a cosmetic product claimed as 'natural' and 'organic', consumers want to be assured that their product does not contain GMOs.

NATRUE sets a private standard to provide a clear regulatory framework for certification of natural and cosmetic sector to ensure consumer trust in authentic products. Natural and organic cosmetic manufactures using the NATRUE Standard use ingredients that come from organic and non-organic agriculture but in all cases GMOs are prohibited (as regulated under Article 9 of Regulation (EC) No. 834/2007).

NATRUE needs to give clear regulatory guidance to suppliers and manufacturers who must be able to establish if the origin of the plant is genetically modified, and details of the regulatory compliance status of a plant's natural origin is critical for evaluation by third-party certifiers in order to verify whether a cosmetic raw material from plant origin is accepted or not.

Using this self-regulatory framework for the definition of natural and organic ingredients, manufacturers are able to both offer products that meet consumers' expectations and provide consumers with honest and transparent information so they know what they are buying. A recent NATRUE commission consumer expectation study by GfK revealed that 90% of those interviewed associated the terms natural and organic with the absence of GMOs[14].

For the standard holder, raw material suppliers and cosmetic manufacturers, accounting for hundreds of SMEs who use these certifiable private standards, problems will arise in terms of setting, regulating, implementing, tracing and assessing the compliance of those raw materials, which can be used in natural and organic cosmetics, that may come from plants bred using NPBTs.

For the thousands of consumers worldwide, who consciously choose to purchase certified personal care natural/organic cosmetic products under the confidence that ingredients of genetically modified origin are prohibited, the absence of a clear legal interpretation results in the inability to honestly fulfil consumers' expectations and trust in the natural and organic cosmetic sector, its ingredients and products.

What NATRUE recommends concerning NPBTs

NATRUE's mission is a commitment to the protection and promotion of the natural and organic cosmetic sector for the benefit of consumers worldwide. A strict definition of natural and organic cosmetics products and ingredients regulation go hand-in-hand in order to ensure that consumers are provided with finished products they expect.

Two recent independent legal interpretations[6,7] have concluded that NPBTs have to be considered as genetic modification according to the scope of Directive 2001/18/EC. This evaluation rests in the fact that despite not being listed in the Annexes of Directive 2001/18/EC, NPBTs imply the use of genetic engineering to modify the plant genome specifically. In addition, the fact that such techniques are not explicitly listed as methods in the Annexes of the Directive should not be interpreted as a green light to by-pass regulation but rather that there is an unmistakable need to update legislation as science advances.

An advantage claimed for NPBTs is the shortened time, and therefore incurred costs, to obtain a new plant variety with specific characteristics. However, such biotechnological innovative advancements also need to account for the human and environmental impact through scientifically-based risk assessment, and appropriate management of risk through regulation. To-date the scientifically assessed impact on the environment or humans remains completely unknown. As a consequence, objective evaluation is required and this can only be done if the products of NPBTs are treated as GMOs.

In such a scenario where the organisms produced by NPBTs are not regulated as GMOs it will be impossible for producers at the start of the value chain to know what the origin of their seeds is. Equally, for consumers at the end of the value chain there is a clear absence of transparency, meaning that consumers are therefore unable to carry out their fundamental right to informed decision making.

It is the case that alternatives to NPBTs and innovative EU platforms[15] are currently available or being developed in order to obtain new plant varieties that are well-adapted to the environmental or soil conditions of a specific location. Advancements in natural breeding technology such as smart-breeding or marker-assisted selection[16,17,18] allows the producer to efficiently pool traits related to (a) specific gene(s) through natural plant breeding to increase genetic resilience, assemble desirable combinations of genes in new plant varieties that confer desired characteristic(s), and bring new varieties more quickly to the market. Subsequently, conventional breeding secures that only the plants resulting from the crosses with the desired characteristics are further propagated since only plants with a stable genome are available for cultivation.

As plants bred using NPBTs have their DNA artificially manipulated in a manner that does not occur naturally by mating and/or natural recombination, it is therefore important to that NPBTs fall under the scope of Directive 2001/18/EC as genetically engineering techniques that result in GMOs. Being subject to obligatory GMO labelling will permit traceability to ensure the needed clarity for natural and organic cosmetic manufacturers undergoing certification, and in turn freedom of choice and trust for consumers.

Conclusions

The NPBTs deliver new plant varieties making use of the state-of-the-art of biotechnology. However, these techniques imply a manipulation of the genetic material of the plants consistent with having "*been altered in a way that does not occur naturally by mating and/or natural recombination*" (Directive 2001/18/EC).

To continue to meet consumer expectations certified products must assure that the origin of their cosmetic ingredients is truly non-GMO. If the NPBTs are not regulated under GMO legislation, and methods to detect and trace plants created with these techniques are not available, it will no longer be possible to know what the origin of a plant is or whether the raw materials from that plant (natural and organic) is consistent with current private standard regulatory requirements and consumer expectations.

In placing consumers' interests at the heart of its mission, NATRUE believes consumers should be given the option to be able to make a conscious and informed purchase decision based upon clear, transparent information. A key challenge for natural and organic cosmetics is to maintain and develop, not loose, consumer trust and confidence.

It is now that a clear and transparent regulatory framework should be established. Consequently, NPBTs should fall under the scope of Directive 2001/18/EC; making the plants and products from them clearly traceable.

References

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About NATRUE:
NATRUE is an international not-for-profit organisation located in Brussels. It has promoted and protected authentic Natural and Organic Cosmetics since October 2007. The NATRUE Label sets a high standard which guarantees quality and integrity so people worldwide may identify and enjoy natural cosmetics truly worthy of that name. Products are listed on the publicly accessible website and database http://www.natrue.org/ which can be used as a check list if you want to confirm whether a product is natural or organic.