



Mr Pesonen started his presentation by providing an overview of the missions and activities performed by ETP: ETP is an EU *ad-hoc* Platform comprising EU associations, individual companies, and academia with the aim of promoting research in the area of plant genomics and plant biotechnology. By doing this, this Platform aims to respond to global challenges relating to food security, food safety, environment and employment.

Mr Pesonen continued by deploring the fact that 'European leadership' in agro-food research activities is threatened by the general public's hostility to new technologies. This situation weakens the competitiveness of the EU agro-food sector and hinders job creation in this sector as reflected by the recent decision taken by the company 'BASF Plant Science' to relocate its European headquarters to the US.

By way of conclusion, Mr Pesonen pleaded for continuous investments in the area of research for biotechnologies and thus welcomed the recent leaked Commission Road Map, which defines research and innovation as priority area of action for the EC over the next 5 years.

The Chair congratulated Mr Pesonen for his presentation and underlined the benefits that NBTs present for society in relation to food safety, sustainability and employment issues.

- **BLOCK 1 - The New Breeding Techniques explained**

- ❖ General introduction of the techniques and presentation of Reverse Breeding, Agro-infiltration *stricto sensu*, grafting and RdDM by MeioGenix)

made a general introduction of plant breeding technologies. He explained that plant breeding already started an estimated 9.000 to 11.000 years ago with the selection and domestication of the first agricultural plants. Breeding methods then modernized and now consist of improving varieties by favourable traits while discarding unfavourable ones. However, the achievement of these goals through classical breeding methods has now reached its limits, as these techniques usually require a very long time span (i.e. between seven to twenty years or more, depending on the variety) to generate the desired characteristics. NBTs allow for breeding objectives to be achieved more rapidly and more precisely (e.g. molecular breeding decreases the time required for breeding by 30%, while directed mutagenesis helps to reduce this time span by 50%).

then provided a comprehensive overview of 4 of the 7 principal techniques which are classified as 'New Breeding Technologies'.

- **Reverse breeding:** this technique is used to reconstitute inbred parental plants from a selected 'elite' hybrid plant with desired traits for which access to, or the exact identity of, the parental plants is not available. The reconstituted parental plants will consistently lead to the same elite hybrid offspring when crossed. This is achieved by a genetic modification step in the process, to suppress natural meiotic recombination in

the plant's genome. After obtaining the desired intermediate plants and subsequently crossing out the GM events, the desired parental plants are selected. This technique helps to create desired elite hybrid plants with greater speed and precision.

- **Agro infiltration *stricto sensu*:** this technique consists of the use of a genetically modified *Agrobacterium* as a vector to produce certain effects in certain tissues of the plant, but not in the reproductive organs. Typically the *Agrobacterium* is applied to a plant leaf. This technique is mainly used to identify the individuals that possess natural resistance and resistance mechanisms, from a population of plants. The identification and selection of natural resistance genes allows for protection of crops against pests and pathogens. By applying this technique, the genetic material introduced in the vegetative tissue of the plant is not incorporated in the germ line and therefore the seeds (and progeny) are free of *Agrobacterium* and foreign DNA; they have not been altered in any way.
- **RNA dependent DNA methylation (RdDM):** with RdDM, short double-stranded RNA molecules (dsRNA) homologous to the target site are introduced into plant cells. This dsRNA is subsequently recognised by the plant's natural defence mechanism, which methylates the DNA of the target site. As a consequence the target gene is silenced without changing the DNA sequence. This is called an epigenetic change. RdDM can be used to improve a wide variety of plant traits in most plant species by the down-regulation of an endogenous gene, without alteration of the DNA sequence. The epigenetic change is temporary and will disappear after a number of generations.
- **Grafting on a GM crop:** this technique consists of the insertion of the upper part of a plant (termed the 'scion') onto the root-bearing part of a different plant (termed the 'rootstock'). Any shoots of the rootstock are usually eliminated so that all the leaf-, flower- and fruit-bearing parts of the grafted plant have the characteristics of the scion, whilst the plant as a whole benefits from the rootstock's characteristics, such as resistance to soil-borne disease or more efficient nutrient uptake. Grafting on a GM rootstock can be used in horticulture with fruit trees and vegetables: the beneficial characteristics of GM rootstocks are used to improve the fruit quality of the non-GM scion without transmitting the genetic alteration of the rootstock to the scion, with the result that harvested fruits and seeds do not carry a genetic alteration.

❖ Questions & Answers led by

A discussion was held about the reliability of NBTs techniques, in terms of stability over time: the speaker clarified the fact that in the particular case of RdDM, the silencing effect usually disappears after several generations.

Several questions were raised about the grounds for clarifying the legal status of the different techniques above-mentioned since it would clearly appear that these clearly differ from GM technologies. A brief discussion then ensued on that subject.

❖ Presentation of Cisgenesis, Oligo-Directed Mutagenesis and Site Directed Nucleases  
by (VIB)

provided an overview of the 3 remaining principal 'New Breeding Technologies'.

- **Cisgenesis:** cisgenesis relies on the transfer of naturally occurring genes between closely related (crossable) species. The technique consists of the isolation of a natural gene which contains a specific trait - such as natural disease resistance - and introducing it directly into another plant. This technique allows for a more specific transfer of desired genes, without further change to the recipient plant's genetic composition, thus leaving its variety properties intact. Cisgenesis allows the introduction of traits to occur up to 4 times faster and in a more controlled manner than the use of classical breeding. Cisgenesis is often used to enhance the durable resistance to diseases of a plant while maintaining its variety properties, and is especially useful for plants which are difficult to breed or which have long generation times.
- **Oligo-Directed Mutagenesis (ODM):** ODM makes use of oligonucleotides to produce a specific single base change within the DNA of a plant. The oligonucleotide is applied to a single plant cell, from which a whole plant is then generated. The oligonucleotide acts as a template for the plant's natural DNA repair mechanism, which detects the mismatch between the template and the endogenous genetic material, and copies the intended change into the plant's DNA. The oligonucleotide is degraded after a short period of time and, as a consequence, is not inserted into the DNA of the plant. This

technique therefore allows to produce a specific and precise change in the plant's genetic material without the use of recombinant nucleic acid techniques or the insertion of foreign DNA.

- **Site-Directed Nucleases (SDN):** the three main categories of SDN technology (SDN 1, SDN 2 and SDN 3) rely on protein complexes that are designed to bind to a predetermined DNA sequence to introduce a break at that location in the plant's DNA. The plant's natural DNA repair mechanism recognizes this break and repairs the break using enzymes that are naturally present in the cell. In this way, SDN technologies can be used to introduce specific desired changes, like small deletions or substitutions – in the case of SDN-1 and SDN-2 – or the incorporation of a stretch of genetic material – in the case of SDN-3.

❖ Questions & Answers led by

**A new discussion took place on the effectiveness of NBTs in terms of stability:** in particular several participants asked about the possibility of assessing the stability of end-products obtained through the use of NBTs. Some precisions were provided by experts who pointed out significant differences according to the type of technique considered. For a number of technologies such as reverse breeding and agro-infiltration *strictu-sensu* stability is not an issue because in the end product no genetic changes have been generated. For techniques that lead to heritable genetic changes such as SDN, ODM and cisgenesis, there is no reason to suspect any problems with stability. Also classical mutagenesis leads to stable heritable changes that are passed to the next generations in a Mendelian way, and changes generated with SDN, ODM and cisgenesis will behave in exactly the same way. It is different for RdDM which leads to an epigenetic change that will disappear over a number of generation.

**A conversation then ensued on the way of classifying the different techniques:** in particular some questions were raised amongst the audience about whether the different categories of techniques can be clearly differentiated from one to another and whether breeders can consequently be sure as to which of the techniques they apply. Experts assured that these techniques clearly differ from one to another. SDN-2 and SDN-3 were cited in example: in this case, the categories chosen allow drawing a clear distinction between modifications that are capable of occurring naturally – in the case of SDN-2 – and those potentially incapable of occurring naturally and result in the introduction of foreign DNA – such as for SDN-3. New site-directed modification techniques which would most probably be developed in the near future could *a priori* be classified according to the same categories described above.

Finally, some questions were raised about the placing on the market of products obtained through NBTs.

▪ **BLOCK 2 - The socio-economic importance of NBTs**

❖ Presentation by \_\_\_\_\_ (Plantum)

By way of introduction, the Chair informed participants that \_\_\_\_\_ – the speaker who was expected to address block 2 – had to cancel his participation due to illness. He was however replaced by \_\_\_\_\_ of Plantum, the Dutch association of organisations involved in the production and sale of plant reproduction materials.

\_\_\_\_\_ started his presentation with a short movie showing the innovative nature of the Dutch plant breeding sector, and its socio-economic impact on a local and a worldwide scale.

\_\_\_\_\_ then underlined the importance of plant breeding as a 'strategic sector' with the view of responding to several major global challenges, among which:

- Food security;
- Adaptation to changing climatic and farming conditions;
- The reduction of dependence on chemical crop protection (therefore contributing to Integrated Pest Management);
- The increase of plant varieties diversity;
- The creation of new resources for bio-based industries;
- Enhancing product quality and diversity;
- The creation of new jobs outside urban areas and attracting qualified students in the agro-food sector.

For \_\_\_\_\_, the EU plant breeding industry may therefore contribute to create benefits for the EU economy and the society as a whole: in his view, these positive effects can only be achieved if plants breeders can get access to appropriate tools – the so-called ‘tool box’ – which include NBTs and other technologies. Additionally, the plant breeding sector should be supported by funding opportunities for fundamental research as well as a clear, workable legislative framework.

Finally, \_\_\_\_\_ recommended the public opinion and EU policy makers ‘to change the angle from which they usually look at the issue of new plant technologies’: in his view NBTs would most probably not replace classical breeding, these new techniques would however contribute to overcome the current ‘ceiling’ of what can be achieved in the plant breeding sector and accelerate the breeding cycle.

❖ Questions & Answers led by \_\_\_\_\_

A discussion was held about the opportunities for EU SMEs to avail NBTs. A number of participants concurred with the fact that the wider availability of new breeding technologies would most probably contribute to foster the entry of ‘small players’ on the EU market in particular on ‘niche markets’ but also possibly on organic markets (i.e. NBTs may present some benefits for organic breeders by enabling them to focus more precisely on disease resistance).

A number of participants agreed with the fact that **the absence of legal certainty with regard to the status of NBTs** may by contrast contribute to weaken further the entire agri-food chain and, in the worst case scenario, lead to the complete extinction of a large part of the plant breeding sector from Europe. On the other hand, several participants pointed out that the options opened up to the EU legislators to clarify the status of NBTs are limited by the strict requirements imposed by the GMO legislation.

▪ **BLOCK 3 - The regulatory status of NBTs in the EU**

❖ Presentation by \_\_\_\_\_ (KeyGene)

\_\_\_\_\_ introduced the subject by informing participants of the legal analysis of Directive 2001/18/EC on the deliberate release of GMOs, which the NBT Platform completed in 2013 with the help of an external legal counsel. The aim of this analysis was to determine whether NBTs are covered by the directive and therefore to clarify the scope of the legal text in this particular respect.

\_\_\_\_\_ then outlined the main conclusions which were drawn from this analysis, including the following:

- **Directive 2001/18/EC is both a ‘product’ and ‘process’ based legislation**, which in concrete terms means that a GMO is to be defined by a combination of the process used to generate the plants and the characteristics of the resulting end product. This finding

can be deduced from a literal analysis of the definitions that are provided for in article 2(2) and art. 3 of the directive.

- Based on the above mentioned definitions, a ‘cumulative analysis’ has been developed: this analysis is **composed of 7 questions** (The first 4 questions relate to the characteristics of the end-products while the 3 last ones refer to the techniques that are being used) for which every question needs to be answered in the affirmative in order to lead to a GMO covered by the directive. These 7 questions are outlined below:
  - ✓ Is it an organism?
  - ✓ Is it non-human?
  - ✓ Has the genetic material been altered (by 20bp or more) vis-à-vis the starting genetic material?
  - ✓ The genetic alteration does not (and cannot) occur naturally?
  - ✓ Does the genetic modification occur at least through the use of the techniques listed in Annex 1 A part 1 of the Directive?
  - ✓ Is the genetic modification not among the techniques listed in Annex I A Part 2?
  - ✓ Is the genetic modification not among the techniques/methods listed in Annex I B?

❖ Questions & Answers led by

Some precisions were asked by the audience on how directive 2001/18/EC would interplay with directive 2009/41/EC on the ‘contained use of GMs’ on the particular issue of ‘self cloning’. Experts pointed out that self-cloning was included in directive 2001/18/EC, mainly for practical reasons. ‘Self cloning’ may however *de facto* be considered as exempted from the



application of the GMO legislation given that this alteration can be regarded as comparable to 'occurring naturally'.

The audience also asked for experts' opinion as to the legal status of classical mutagenesis, in particular in the light of the legal definitions set out by article 2 (2) of directive 2001/18/EC. It was mentioned that although classical mutagenesis may be regarded as a GM process, the resulting end product does not qualify as a genetically modified organism since the resulting genetic alteration can occur naturally. For several experts, the same argument could be used to exempt cisgenesis from the scope of directive 2001/18/EC, given the alteration resulting from the use of this technique can also be regarded as 'occurring naturally'.

Finally, a discussion took place on the issue of the detection of a genetic modification: several participants pointed out that sequence changes in the genome of a given organism can only be detectable above a threshold of 20 base pair.

#### ▪ PANEL DISCUSSION

The Chair briefly introduced the panel which was composed the following experts

- [redacted] (ESA);
- [redacted] (JRC);
- Eric Poudelet (Director, DG SANCO European Commission);
- Pekka Pesonen (Copa-Cogeca Secretary General);
- Frank Hartung (Julius Kühn Institute, representing EPSO).

#### ❖ First, the members of the Panel reacted to the questions from the audience

One participant questioned Mr Poudelet about the EC's plans to regulate/clarify the legal status of NBTs. Mr Poudelet pointed out the difficulties of modifying the existing legislation, due to the absence of consensus amongst the main political EU actors. In his view, this situation mainly reflects broad hostility to GMOs amongst EU citizens. This is one of the factors explaining why the European Commission is currently developing a guideline document on these techniques, instead of adopting a legislative proposal.

[redacted] deplored the fact that the EC's delays in clarifying the legal status of these techniques for more than four years has led to considerable economic losses for the EU plant breeding industry, especially in a context of increasing competition originating from third countries' companies. In his view, the EC already avails solid scientific and legal arguments and enjoys sufficient support from Member States (MS) and stakeholders 'to show leadership and move ahead' on this dossier.

Mr Poudelet reacted by underlining the existence of strong divergences of views amongst MS and stakeholders on this subject. In this context, the EC needs to anticipate any potential legal proceeding before the European Court of Justice (ECJ) and therefore building solid legal arguments prior to making any proposal.

❖ A discussion on that subject then ensued between the different members of the panel

Mr Pesonen made clear that the *status quo* on that dossier would dramatically impact the situation of EU farmers, who already suffer unfair competition from farmers in third countries in the access to NBTs.

Mr Hartung pointed out the problems of job destruction and 'intelligence leakage' resulting from the absence of legal certainty on NBTs.

These arguments were tempered by \_\_\_\_\_ who expressed the general view that NBTs and GM issues may only contribute 'marginally' to solve upcoming society's worldwide challenges.

Whilst acknowledging the relevance of the arguments presented by the different experts of the panel, Mr Poudelet expressed the opinion that the public's resistance to new technologies could only be changed if the plant breeding sector and the promoters of these new breeding technologies are able to change the public perception in that respect.

In response to this argument, Mr Pesonen deplored the lack of support enjoyed by the EU Commissioner for Health and Consumers amongst the EU college of Commissioners on this particular subject. In his view, the introduction of a new organisational structure within the EC (i.e. responsibilities on agricultural biotechnologies to be shared between 2 or 3 different DGS) would help to solve this particular problem.

The Chair questioned Mr Poudelet about the timing for the adoption of a legislative framework on NBTs and insisted on the importance for the EC to come to a decision on determining their legal status with regard to the EU GMO legislation (i.e. do NBTs fall outside the scope of directive 2001/18/EC? If not, are these NBTs exempted from its application?) Mr

**Poudelet** replied that informal discussions with MS had already started. These discussions would then be followed by consultation with stakeholders and NGOs.

**The Chair concluded the discussion by underlining the importance for EC to create favourable regulatory conditions for the European plant breeding sector to maintain its position of worldwide leadership in the area of research and innovation.**

**The Chair concluded the meeting**

- by congratulating the speakers for their enlightening presentations;
- by thanking the panel members as well as the audience for their active contribution to the debate
- and by inviting interested participants to 'follow up' on the subject of NBTs (by contacting the NBT Secretariat at the following address

