



GM and non GM supply chains: Their CO-EXistence and TRAcability

Outcomes of Co-Extra

Detecting unauthorised and unknown GMOs

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The global trade and spread of technological competence and capacity to develop genetically modified (GM) organisms (GMOs) such as plants, in combination with the cultural and regional differences in terms of suitability, need and acceptance of GMOs is a potential cause of disputes. Within the European Union (EU) as well as several other jurisdictions, no import, use or release of GMO derived material is legal without prior authorisation. Among the requirements that need to be met prior to authorisation of a GMO in the EU is the availability of a validated and specific, quantitative detection method and corresponding reference material for the GMO in question.

Field trials are a part of the performance assessment of GMOs. These field trials potentially lead to low level contamination of neighbouring fields. Birds or rodents may spread grains or seeds and incomplete sanitation or other human error may lead to unintended spread of viable material. Finally, intended distribution into the environment or food/feed chain can not be completely ruled out. Validated detection methods as well as reference materials are usually not made available in these cases.

Most of the GMOs commercialised in the world at present are herbicide resistant and/or insect tolerant. The trait genes inserted into these GMOs are usually well known and belong to a few

groups: *pat/bar*, *epsps* and various *cry*-genes. Genetic elements associated with the genes to facilitate and regulate their expression are also with few exceptions well known and belong to a few groups, e.g. the cauliflower mosaic virus (CaMV) 35S promoter and terminator (P35S and T35S) or the *Agrobacterium tumefaciens* nos terminator (3'-nos). The availability of other trait genes and regulatory elements is, however, increasing rapidly. Commercial or other interests may prevent relevant information from being disseminated to stakeholders such as competent authorities and laboratories performing GMO detection.

There is no single genetic marker that can be traced as a "GMO label". Instead, it is necessary to use methods specific to particular genetic markers such as regulatory elements or trait genes (screening methods), fusion motifs between regulatory elements and trait genes (construct specific methods) or fusion motifs between inserted DNA and the recipient DNA (event specific markers). The number of GMOs that may be detected with the methods depend on the targeted genetic marker, and the analyst may need to balance broadspectrum screening against ability to specifically identify the GMOs that may be detected. Detection of unauthorised GMOs may often be achievable by using screening methods. However, with these methods it may be quite difficult to determine that the detected GMO material is coming from an unauthorised GMO. On the other hand, the absence of specific detection methods and reference materials for most unauthorised GMOs leaves few options for identification. GMOs that can not be detected with the commonly used screening methods because the introduced DNA sequences or genetic elements are unusual (novel) may be classified as unknown GMOs. These are of course particularly difficult to detect and identify. Presence of non-declared ingredients (e.g. "botanical impurity") may further complicate the analytical work.

Any presence of unauthorised or unknown GMO or derived material in the food/feed supply chain in the EU is by definition illegal, and may pose a risk to society and economy, the environment and/or human and animal health. Socio-economic risk is exemplified by the restrictions on import of rice from the USA to the EU as a consequence of contamination of American rice with the Liberty Link 601 rice in 2006. Risk to the environment is exemplified by potential spread of the trait gene to a wild relative of the GMO. Introducing for example an herbicide resistance or insect tolerance gene to a wild plant species may improve the fitness of the wild plant relative to competing plant species in its environment, or it may affect the diversity and/or abundance of insects that birds depend upon for feeding their brood. Risk to human and/or animal health is exemplified by the possibility that a food/feed plant used as a biogenerator for pharmaceuticals is introduced into the food/feed chain. Ability to detect, identify and characterise unauthorised or unknown GMOs is therefore necessary to be able to define, delimit, prevent and remove problems.

Traceability facilitates the identification of the origin of material, and global information networks, databases, etc. may provide information about developments of new GMOs, novel genetic elements that are potentially exploitable and authorisations outside the stakeholder's own jurisdiction. This type of information can be used by stakeholders to improve their ability to detect, identify and characterise unauthorised or unknown GMOs, as well as to prioritise developments and applications of particular analytical methods.

Development of analytical methods and strategies for detection, identification and characterisation of unauthorised and unknown GMOs has been a major priority within the Co-Extra project. In parallel a modular decision support system (DSS) has been developed in which traceability and other information can also be taken into consideration. These developments together are expected to significantly reduce the challenges posed by unauthorised and unknown GMOs.

This presentation will give an overview of the state-of-the-art technologies and developments from the Co-Extra project relevant to the detection, identification and characterisation of unauthorised and unknown GMOs, and will also point out some of the remaining and possible future challenges of relevance.