Določanje in identifikacija gensko spremenjenih organizmov (GSO)

"Detection and identification of Genetically Modified Organisms (GMOs)"

Delavnica posvečena praznovanju 10. obletnice uveljavitve Kartagenskega protokola o biološki varnosti

"Workshop Dedicated to the Celebration of the 10th Anniversary of the entry into force of the Cartagena protocol on Biosafety"

Organized by: Ministry of Agriculture and the Environment and National Institute of Biology (Slovenian National Reference Laboratory)

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Zaključki (Conclusions)

Backgroud

Genetically modified organisms (GMOs) have been widely approved for commercialisation at a global scale, being diverse in their taxon, genetic constructs and elements. Numerous countries in their legislation have implemented authorization, labelling, and compliance control of GMOs, products containing GMOs, or materials derived from GMOs.

In Article 18 of the Cartagena protocol on Biosafety which addresses the issue of the handling, transport, packaging and identification of GMOs, the detection and identification of GMOs plays an important part in the ability of national authorities to distinguish whether or not there are GMOs in a shipment both through proper packaging and labeling of shipments and through the analytical, laboratory based analysis of the contents of a shipment to detect unauthorized and or unintended GMOs.
Furthermore the identification of GMOs is also vital to the activities relating to risk management as outlined in Article 16 which requires adoptions of measures and strategies for preventing adverse effects and for managing and controlling risks identified by risk assessments (e.g. detection and identification can be used as a tool). This can be further applied also to the provisions of implementing Articles 17 and 25 on unintentional and illegal transboundary movements.

National Institute of Biology as National Reference Laboratory together with Ministry of Agriculture and the Environment of Republic of Slovenia organized this Workshop for experts in handling issues related to GMOs (e.g. regulators, inspectors, custom officials) with the aim to provide information on new approaches for testing and identifying of GMOs as well as to discuss the potential gaps and possibilities relevant to detection and identification of GMOs in the future. The workshop is also dedicated to the celebration of the 10th anniversary of the entry into force of the Cartagena Protocol on Biosafety which is international agreement promoting safety in the use of biotechnology.

GMOs detection and identification

With the constant increase in the number and diversity of GMOs, testing laboratories facing challenge to establish reliable, efficient, high throughput and cost-affordable system for GMOs testing in place. Classical approach to GMOs testing is through different phases: first screening targeting most common genetic elements in GMOs, then identification phase to identify individual GMO and quantification phase (when threshold in regulation is set) to see if labelling is required and if the sample is in compliance with legislative claims.

To be effective in the field of detection and identification of GMOs, Slovenia as a small country is even more obliged to rationalize use of capacities, personnel and laboratory facilities. Therefore we are very active in research and development of strategies and approaches for reliable and efficient GMO detection, such as bioinformatic tools, implementation of new technologies, etc.

Bioinformatic tools and availability of screening methods

Regarding the number of GMOs and genetic elements **matrix** approach is becoming the basis for selection of screening targets to be tested. Even some project based attempts are made to establish the information on matrix components (GMOs and elements) like recently published GMOseek matrix, there is no worldwide regularly maintained and updated matrix available (Block et al. 2013). Therefore the establishment and maintenance of such reliable matrix would be beneficial for laboratories in the future.

Another challenge with new GMOs is availability of **validated screening methods**. Recently pentaplex method was published (Huber et al., 2013), but with five screening elements aligned, coverage of GMOs, even those approved in EU, is not complete. In consequence, for example, GMOval project (http://www.gmoval.com/) is dedicated to validation of some screening methods.

The specific **computer programmes** can be of great help to handle large number of information on GMOs and genetic elements. They can support decisions on selection of screening elements and on methods for selected elements to be developed. They can also include decision support system enabling laboratories to facilitate their daily decisions during testing, as selection of screening methods and further individual GMOs to be tested. One of such tools is recently released and publicly available GMOseek programme (Morisset et al., in preparation, http://www.gmoseek.com/gmoseek). The programme uses matrix in excel form, which can be tailored to each laboratory requirements.

Future perspectives

Slovenia sees the perspective in methods for quick detection on one hand and reliable identification and quantification of GMOs on the other hand.

Some immunological methods for **quick detection** are already available; even they target only limited number of proteins and therefore cover only few GMOs.
Isothermal methods, like loop mediated isothermal amplification (LAMP), are quick nucleic acid based qualitative detection methods, which are perspective for fast and on-site qualitative analysis of GMOs (more papers, e.g. Li et al., 2013).

Regarding increasing number of GMOs, **high throughput** approaches for detection and identification are becoming necessary. Usage of prespoted plates enabling detection of several GMOs simultaneously can reduce the workload (Quercy, 2009).

qPCR is the most widely used method for quantification of GMOs, using relative quantification, dependant on appropriate reference materials, characteristics of sample and reference materials. Digital PCR for absolute quantification, especially those more affordable

versions, can be important step forward to more **precise and harmonized quantification** (Morriset et al., 2013).

Additional challenge are unknown GMOs where next generation sequencing can be the technology of choice which can help in detection without prior knowledge of the sequence (ENGL ad hoc working group on "unauthorised GMOs 2011, Yang et al. 2013).

GMOs laboratories network

One of the most important activities in GMO detection and identification is exchange of information, experience and knowledge. Therefore Slovenia considers networking as the most appropriate approach. Slovenian NRL is a member of European Network of GMO Laboratories (ENGL).

The **European Union Reference laboratory for GM food and feed (EU-RL GMFF) and the European Network of GMO Laboratories** (ENGL), inaugurated in 2002, play an eminent role in the development, harmonisation and standardisation of means and methods for sampling, detection, identification and quantification of Genetically Modified Organisms (GMOs) in a wide variety of products, ranging from seeds, grains, to food and feed stuff. ENGL was formed as by the European Union and the National Reference Laboratories (NRLs) that in the context of the enforcement of the European Union (EU) regulations of GMOs are responsible for the correct detection, identification and quantification of GMOs by the enforcement authorities in the EU-Member States. Its secretariat and chair is provided by the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF).
The large number of challenges that enforcement laboratories face are discussed and guidance documents are published (http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm).

Slovenia cooperates also globally, and sees networking on global scale as very important and challenging issue. Exchange of information and experience enables among others harmonization of testing approaches for safe handling, storage, transport and use of GMOs globally. The **"Network of Laboratories for LMO Detection & Identification« under the Cartagena Protocol on Biosafety** would be a good example of attempt to develop strategies and needs regarding detection and identification of GMOs through international agreement. The network also enabling compilation of laboratory methods for the detection of GMOs, in particular for those unauthorized or unintentionally released into the environment on a global scale. Notwithstanding, Biosafety Clearing-House (BCH) would be the proper place where exchange of information on variety of scientific, technical, legal and capacity building information regarding detection and identification of GMO would be accessible globally.

Capacity building

As the number and diversity of GMOs constantly increase the capacity building in technical, human and financial resources is ongoing need. Particularly of importance would be stable financing which on a long run allows effective, reliable and efficient detection and identification system of GMO.

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