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Nairobi, 13–18 May 2024
Item 7 of the provisional agenda*
Detection and identification of living modified organisms

Summary of the online discussions of the Network of Laboratories for the Detection and Identification of Living Modified Organisms**

Note by the Secretariat

I. Introduction

1. In decision [CP-10/11](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety recognized the importance of the Network of Laboratories for the Detection and Identification of Living Modified Organisms (“the Network”). Furthermore, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety invited Parties and relevant organizations to submit information on the detection and identification of living modified organisms (LMOs) and requested the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-sixth meeting to prepare a recommendation on the need to update Biosafety Technical Series 05: *Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety*¹ Furthermore, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to continue the work mandated in decision [CP-9/11](#), such as continuing online discussions of the Network of Laboratories for the Detection and Identification of Living Modified Organisms, among others.

2. In response to the request, the Secretariat convened online discussions of the Network² from 17 to 28 November 2023 to support the deliberations to be undertaken by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-sixth meeting and the Conference of the Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety at its eleventh meeting.

3. To facilitate the discussions, the following four topics were identified:

- Topic 1: New techniques for detecting and identifying living modified organisms;

* CBD/SBSTTA/26/1.

** The present document is being issued without formal editing.

¹ Available at: <https://bch.cbd.int/en/database/VLR/BCH-VLR-SCBD-260177-3>

² Notification 2023-099 <https://www.cbd.int/doc/notifications/2023/ntf-2023-099-bs-en.docx>

- Topic 2: Experience with detecting and identifying newly developed and unauthorized living modified organisms;
- Topic 3: Lessons learned from national and regional laboratory collaborations;
- Topic 4: Addressing capacity-building needs.

4. Topics 1 and 2 were moderated by Raja Chalghoumi from Tunisia and Topics 3 and 4 were moderated by Gretta Abou-Sleymane from Lebanon.

5. A total of 204 participants were registered for the online discussions. 25 participants from 22 Parties and 3 organizations actively participated. Of the total of 53 interventions made, 49 were from Parties and 4 were from organizations. The following table provide a breakdown of the interventions by topic:

Table

Breakdown of interventions

<i>Topic</i>	<i>Number of active participants</i>			<i>Number of interventions</i>		
	<i>Parties</i>	<i>Organizations</i>	<i>Total</i>	<i>Parties</i>	<i>Organizations</i>	<i>Total</i>
Topic 1	9	2	11	12	3	15
Topic 2	14	0	14	14	0	14
Topic 3	10	0	10	11	0	11
Topic 4	12	1	13	12	1	13

6. The present document provides a summary of the views shared during the online discussions of the Network. For a complete account of all interventions, it is recommended to refer to the original online interventions.³ In addition, the bibliographic references shared during the online discussions are presented in the annex to the present document.

II. Summary of the interventions

A. Topic 1: New techniques for detecting and identifying living modified organisms

7. Under this topic, participants were requested to provide information on technical developments in the field of detection and identifications of LMOs since the previous discussions of the Network in 2019.⁴ As suggested by the moderator, a particular focus of the discussions was on digital polymerase chain reaction (PCR), next-generation sequencing and isothermal amplification tools and techniques.

8. For digital PCR, it was recognized that the technique was reliable and would offer several advantages in comparison to real-time PCR, such as being more robust to the negative impact of high-copy template DNA and/or PCR inhibitors, distinguishing between LMOs or genetic elements that share a high homology, for genetic element assays that are reliant on only a few distinct nucleotides, for easier copy number or zygosity determination and for absolute quantification. Further, a recent capability with digital PCR is the ability to multiplex assays with some of the newer instrument platforms allowing for up to four reactions to be performed at once from a single sample reaction, which would allow for analyses of event-specific and member genetic element-specific of LMOs at one timepoint. While digital PCR in general is not considered to be high throughput, this multiplex functionality has greatly improved the output of the instrument as well as lowered the cost

³ <https://bch.cbd.int/en/portals/detection/network-of-labs>

⁴ Available at: <https://bch.cbd.int/en/portals/detection/past-activities/forum-2019>.

per sample. In addition, the accessibility and turnaround time for labeled probes with newer dyes suited to digital PCR was not anticipated to be a problem, noting that these reagents should be commonly available through oligonucleotide manufacturers. However, during the discussions, it was still raised that consumables for the instrument (e.g., plastic tubes, reagents) may be more expensive than those for real-time PCR.

9. Regarding the use of digital PCR in different countries, in some jurisdictions, such as Germany, the use of digital PCR has increased in control laboratories since 2019. In others, such as Belarus and China, it is mainly applied for the quantification of LMOs within samples or for detecting unknown LMOs. Despite the increasing use in some jurisdictions, it was noted that the use of digital PCR was not yet part of routine LMO analysis. It was also noted that work was ongoing to adapt the technique for detection and quantification for a greater number of targets. However, due to the more specific and costly consumables and reagents for digital PCR, some laboratories continue to implement real-time PCR for routine analysis, which has been reliable in quantifying low level persistence of LMOs. Further, there was a view that the throughput of the technique may also limit its use in control laboratories and further work might be required in relation to absolute copy number quantification variability between laboratories.

10. Regarding new techniques based on digital PCR, the development of nanoplate-type digital PCR was mentioned. It was suggested that nanoplate-type digital PCR improves on real-time PCR and potentially other digital PCR methodologies by allowing for quantification with a single copy endogenous gene as a ‘built-in’ certified reference material. For example, in plants, there could be multiple choices of genes with one or two copies that could function in this regard. Having a target gene within the sample was also mentioned to improve accuracy and consistency by reducing discrepancy in amplification between the target and the certified reference material because certified reference materials are run in separate partitions or wells. Further, it was suggested that the development of quantification methods for newly approved LMOs would be rapid using nanoplate-type digital PCR since the need for traditional certified reference materials could be avoided and based on nucleotide sequences of open reading frames or introduced genetic elements. Overall, this technique differs from how initial methodologies are developed and LMO quantification is carried out, such as in the European Union. It was suggested that this method could overcome some of the problems associated with the lack of availability of certified reference materials.

11. Regarding next-generation sequencing, it was suggested that unauthorized LMO analysis, LMO screening and molecular characterization of living modified events could be achieved utilizing next-generation sequencing. However, LMO quantification remains a challenge using these next-generation sequencing approaches. Despite the dramatic decrease in cost, the sequencing depth required to be equivalent to a quantitative limit of 0.1% or 0.01% would likely still be rather high. However, there was also a view that next-generation sequencing is a tool to complement the tools already implemented for the detection and identification of LMOs and could be the method of choice when the living modified line differs from the those that would be normally detected in the laboratory. It was noted that highly reproduceable tools in combination with data analysis are currently being evaluated for their applicability for LMO analysis and are thus at a research and development stage. Some applications of next-generation sequencing given as examples were:

- Next-generation sequencing with capture enhancement based on known genetic elements (for uncovering LMOs not detected by PCR screening);
- Simultaneous detection of multiple LMOs at once (provided the nucleotide sequences are known);
- Further molecular characterization and/or identification of LMOs using primer walking approaches that start from a common genetic element, whole genome sequencing or DNA re-sequencing and bioinformatic analysis (“Tran-Seq”, see paragraph 19 below);

- Next-generation sequencing with various pre-enrichment strategies (e.g., Large Integrated DNA Fragment Enrichment Sequencing⁵);
- Targeted deep-sequencing for distinguishing single nucleotide variations; and
- Untargeted sequencing to characterise known and unknown LMOs and organisms produced through new genomic techniques.

12. Furthermore, the importance of databases for sequences was highlighted to support the analysis of data, such as in the case of bioinformatic analysis of next-generation sequencing data, and improve access to information. Based on this, there was a suggestion that the availability of sequence data could also facilitate the detection of unauthorized LMOs through the development of artificial intelligence models trained on the appropriate datasets. However, it was noted that there is currently no mandatory need to provide sequences to a database and data availability may become complicated when considering organisms produced through new breeding techniques in relation to varied national legislation.

13. Regarding the use of isothermal techniques, it was noted that techniques, such as loop-mediated isothermal amplification, rolling circle amplification and recombinase polymerase amplification are used in China for rapid LMO screening. Further, new assays combining the use of CRISPR/Cas with loop-mediated isothermal amplification and with rolling circle amplification have been developed for LMO screening and have been confirmed by the Chinese Ministry of Agriculture and Rural Affairs. Further, it was noted that projects implementing microarrays and in field testing using isothermal amplification approaches were also under development in Mexico.

14. Beyond next-generation sequencing, isothermal techniques and digital PCR-based approaches, it was suggested that no new analytical techniques have been implemented, but further optimization of existing methods have occurred, including locked nucleic acids, minor groove binder probes and variations on real-time PCR systems. For example, the development of the Kompetitive Allele Specific PCR was noted. The methodology is an allele-specific PCR methodology based on an adaptation of a conventional quantitative PCR protocol and corresponding bioinformatic tools for designing probes to a specific single nucleotide polymorphism or insertion-deletion of interest. Further, it was highlighted that it is also being applied for rapid analysis and in field testing. In another example, the recent publication of taxon-specific reference assays for maize, cotton, soybean and rapeseed that were proven to amplify a single copy gene as well as demonstrate no allelic variation in the host plant genome⁶. These have also been extended to LMO quantification using digital PCR.

15. Regarding the identification and genotyping of genome-edited crops, it was noted that several new methodologies have been developed and are undergoing research, such as quantitative PCR high-resolution melting curve analysis, quantitative real-time PCR assisted by an in vitro CRISPR/Cas9 cleavage, Screening of CRISPR/Cas-induced Mutants via Argonaute derived from *Thermus thermophilus*, among others. In addition, the recent funding by the European Commission dedicated to develop new methods for detection, identification and quantification of products of new genomic techniques under the European Commission Horizon Europe Program Cluster 6⁷ was noted. Two projects were awarded to develop analytical tools for LMO analysis and digital methods (traceability). It was suggested that these would be likely based on next-generation sequencing and digital PCR methodologies and have relevant results in the future.

⁵ This method relies on universal tilling DNA probes to target transgenic elements and exogenous genes, facilitating specific enrichment of large inserted DNA fragments associated with transgenes from plant genomes, followed by PacBio sequencing.

⁶ Available at: <https://detection-methods.com/endogenous-methods/>

⁷ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/cluster-6-food-bioeconomy-natural-resources-agriculture-and-environment_en

B. Topic 2: Experience with detecting and identifying newly developed and unauthorized living modified organisms

16. Under this topic, the moderator noted that during the discussions of the Network in 2019, the detection and identification of newly developed and unauthorized LMOs was noted as a challenge. Thus, under this topic, participants were requested to share their experiences with detecting and identifying these types of LMOs, as well as any strategies that were implemented to overcome this challenge and any challenges foreseen in the near-future.

17. Regarding the experience with the detection and identification of newly developed and unauthorized LMOs, participants had varying levels of experience. For some, they only had experience with the detection of some of the following genetic elements: Cauliflower mosaic virus 35S promoter, Figwort mosaic virus 34S promoter, *Agrobacterium tumefaciens* 5-enolpyruvylshikimate-3-phosphate synthase and *A. tumefaciens* nopaline synthase terminator. In particular, it was mentioned that for some regions, such as Africa, and some countries, such as Bhutan, laboratories may only have experience with detecting the Cauliflower mosaic virus 35S promoter and *A. tumefaciens* nopaline synthase terminator. There was a view that LMOs containing other or novel genetic elements could be potentially missed during screening, especially if the laboratory relies on commercial kits with limited multiplexing options. Similarly, protein-based methodologies may also have limited multiplex options, as multiplexing would be based on the utilization of multiple single strips or targets. Thus, given this, it was noted that some participants had limited experience with the detection and identification of newly developed or unauthorized LMOs.

18. For those with more experience detecting and identifying of newly developed or unauthorized LMOs, different strategies are taken. For example, the laboratory of the Brazilian Ministry of Agriculture initially performs as screen of seven different targets, which is then followed up with further event-specific methods in the case of positive results. However, for unauthorized LMOs, the laboratory adapts the analytical strategy taken depending on the species and origin of the materials. For newly developed LMOs authorized by the National Technical Commission for Biosecurity, applicants provide methodologies and reference materials for method validation and market control. However, it was also noted that the problem of detecting and identifying newly developed and unauthorized LMOs could relate more to rarely used genetic elements, which may not be detected by standard screening approaches. To overcome this problem, laboratories in Germany have adapted their screening portfolio of standard screening methods to include further targets, new validated methodologies have been developed for LMOs authorized outside the European Union and the use of next-generation sequencing methodologies have been implemented.

19. Further to these strategies for detecting and identifying newly developed or unauthorized LMOs, the development of a next-generation sequence-based approach called “Tran-Seq” was shared. The methodology is based on DNA re-sequencing and bioinformatic analysis to comprehensively characterize the inserts of LMOs when knowledge of the DNA sequence(s) of the vectors and inserts is available, limited or even absent. The accompanying bioinformatics pipeline has three modules to allow for this flexibility: Module 1 was designed for use when the DNA sequence of the transformation vector is available; Module 2 was designed for use when the DNA sequence database of genetic elements and transgenic constructs from known LMOs are available and can be used as reference libraries; and Module 3 was designed for use when prior knowledge of the DNA sequence of the transformation vector or transgenic constructs is not available. However, in order to be implemented, the non-modified reference genome is required.

20. In addition, some participants noted that some institutions have experience with developing reference materials to support the work on detection and identification of LMOs. One example provided included the Mexican National Metrology Institute, which has developed certified reference materials for living modified maize.

21. In their responses, some participants noted that organisms produced through new genomic techniques may pose challenges due to the nature of the induced modification. In light of this, there was a view that current methodologies used for detection and identification of LMOs may not be sufficient for the detection and identification of organisms produced through new genomic techniques. Sequencing-based techniques were mentioned as a potential solution to address this, however, the high cost of implementation would be a drawback. In one recently published meta-analysis on the unintended genomic effects of current and emerging genetic modification techniques was highlighted. The authors reviewed the analytical methods used to detect the unconsidered outcomes of genetic modification using CRISPR-Cas. It found that 26% of the surveyed studies used PCR-based methods and 17% of the surveyed studies used sequencing methods for identifying the modifications made through CRISPR. Thus, it was suggested that although methods for detecting genetic modifications (intentional and unintentional) are mostly identified through sequencing methods, other techniques could also be utilized to suggest the presence of an organism produced through new genetic modification techniques.

22. In terms of challenges foreseen in the near future regarding newly developed and unauthorized LMOs, it was suggested that a lag in the development of screening kits for novel genetic elements and new events could have implications on the results of the laboratory-based analysis if kits for all market approved events are not available. However, it was also mentioned that the cost to produce screening kits was high. Thus, there was also a view that kits could be replaced with primer design to reduce some of the costs.

23. Another challenge mentioned was the adequacy of current techniques used for LMO analysis. There was also a view that current methodologies may not be sufficient for detecting and identifying newly developed and unauthorized LMOs. Next-generation sequencing was suggested as a potential solution, but the high cost of implementation was also noted. Other participants suggested the use of digital and real-time PCR tools as being reliable for detection and quantification of these kind of LMOs, however, it was noted that there would be a need for prior knowledge on the LMOs being tested. In that regard, access to information and reference materials would also be a challenge.

24. Further, there was a view that newly developed and unauthorized LMOs further exacerbate the current challenges that control laboratories face. Some examples mentioned include LMO quantification (e.g., the defining the limit of detection of the machine, measurement uncertainty), maintaining accreditation (e.g., ISO/IEC 17025), the limited financial resources to implement new detection techniques, lack of laboratory infrastructure, experience with processed products (e.g., foodstuffs, such as oils and sauces), the robustness of protein-based methodologies in comparison to DNA-based ones, among others. Furthermore, some participants noted that border control and biosafety regulations may need to be strengthened to assist with the porosity of borders, which allow for unauthorized LMOs to enter into their national markets and through ports-of-entry.

C. Topic 3: Lessons learned from national and regional laboratory collaborations

25. Under this third topic, the moderator suggested that networks of laboratories could be a solution to overcome challenges faced in the field of detection and identification of LMOs and improve global capacity. Further, she noted decision CP-10/11, in which the Conference of the Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety encouraged Parties to continue to cooperate to develop regional networks of laboratories to facilitate the exchange of experience, sharing of information and building of expertise in the field. Thus, under this topic, participants were requested to share information on the national and regional laboratory collaborations. Several examples from different regions were shared and detailed below.

26. In the southern African region, the Southern African Network of GM Detection Laboratories was mentioned. It was noted that the current membership includes 24 laboratories with varying capacities. However, this laboratory network provided a learning platform to address the identified technical and physical gaps in member laboratory capacity. There was a view that the laboratory networks, such as this one, would be important for the region given the anticipated increased demand

due to the rapid development in the field of biotechnology and continental trade. To support such networks, institutions, such as the Regional Agricultural and Environmental Innovations – Africa, would be important to ensure maintain operations.

27. In one example from Kenya, the National Biosafety Authority informally collaborated with other competent national authorities in the country involved in LMO analysis to exchange reagents, samples and perform inter-laboratory testing. Although not formalized in a network or framework, it was mentioned that the inter-laboratory testing has facilitated the exchange of ideas on optimizing existing protocols and the adoption new screening methodologies, which have participated a shift away from kit use. It was suggested that there have been reductions in cost and improvements to capacity-building within the country. Thus, due to this, further efforts were ongoing to train more personnel and create new partnerships.

28. In Tunisia, LMO detection capacities were being built through four public institutions: the National Gene Bank⁸; the Technical Center of Agrifood⁹; the Central Laboratory of Analysis and Assays¹⁰ and the Laboratory of Seeds Analysis of the Ministry of Agriculture. It was noted that these laboratories were undergoing ISO17025 accreditation and supported through the Ministry of the Environment, as well as by different institutes and research centres of biotechnology. Further, arrangements between the four institutions through a network convention were formalized and aim to better coordinate and exchange scientific and technical information regarding LMO detection and identification. Despite being operational, it was noted that the four laboratories were not legally and administratively entitled to perform analyses as the national biosafety law was pending adoption.

29. For West Asia and North Africa, the Middle East and North Africa Network of GMO Laboratories was highlighted as a regional network. Established in 2012, the laboratory network consists of 25 laboratories from Algeria, Bahrain, Egypt, Iraq, Jordan, Kuwait, Lebanon, Morocco, Qatar, Saudi Arabia, Sudan, Tunisia and United Arab Emirates. The aim of the network was to empower the member laboratories to face the challenges in the field of detection, identification and quantification of LMOs, as well as harmonize LMO analysis procedures between the countries in the Middle East and North Africa. The network has organized a series of workshops to support the work of its members:

- the first international workshop on harmonization of LMO detection and analysis in Middle East and North Africa region, which took place at the Dead Sea, Jordan in 2012
- Stage 1 of the Middle East and North Africa regional project “Comparative Testing Round in the MENA Region” in 2015
- the second international workshop on LMO analysis networking held in Varese, Italy in 2015
- Stage 2 of the Middle East and North Africa regional project “Screening of GMOs in food commodities – A study in the MENA region” in 2017
- the third Middle East and North Africa Regional Workshop on Harmonization of LMO Detection and Analysis, which was organized in Varese, Italy in 2017

30. Despite the previous activities, the Middle East and North Africa Network of GMO Laboratories have not restarted activities following the COVID-19 pandemic. It was suggested that communication and political challenges could have stalled a re-launch of the network. However, it was mentioned that activities would be hopefully restarting in the near future.

31. For the European region, the example of the § 28b GenTG working group in Germany was shared. It was founded on a legal mandate and consist of members of the competent national

⁸ Available at: <http://www.bng.nat.tn>

⁹ Available at: <http://www.ctaa.com.tn/accueil/>

¹⁰ Available at: <https://lcae.nat.tn/>

laboratories, as well as representatives of the industry and academia. The § 28b GenTG working group develops and/ or validates analytical methods for official control activities in Germany. These methods are considered legally valid and are published in an Official Collection of Methods. Thus, harmonization and standardization of sampling, detection, identification and quantification of LMO is achieved. At the European level, the European Network of GMO Laboratories was mentioned as serving the same goals.

32. For the Latin American and Caribbean Group region, the situations in Brazil and Mexico were shared. In Brazil, it was noted that the national laboratories are accredited by the National Institute of Metrology, Standardization and Industrial Quality based on the ISO 17025:2017 accreditation. Further, it was highlighted that Brazilian laboratories are also active in the Network of Official Laboratories for Detection of GMOs in Latin America and the Caribbean region.

33. In Mexico, the Mexican Law on Biosafety of Genetically Modified Organisms and other complementary regulations established a national network of laboratories to conduct activities related to detection and identification of LMOs. However, it was noted that the network has not operated in a continuous and harmonized manner since its establishment due to political, technical and economic reasons. It was noted that the GMO Laboratory from the Ministry of Agriculture was previously the central node of the Mexican national network of laboratories and part of the Latin American network of laboratories coordinated by the European Network of GMO Laboratories. However, both networks were noted as being currently inactive.

34. Despite this, recent efforts and collaborations have been established between public research centres and universities for monitoring transgene presence in native maize varieties, maize-derived foodstuffs and detecting living modified maize in fields. At the regional level, it was noted that a laboratory of the Metropolitan Autonomous University in Mexico City and the food molecular traceability laboratory of the University of the Republic in Montevideo, Uruguay have recently collaborated to update the molecular methodologies for detecting LMOs, to perform joint exercises for the detection and identification of living modified maize and exchange information on biosafety of LMOs. Further, it was noted that the GMO Laboratory from Ministry of Agriculture in Mexico has participated in the training of officials and laboratory personnel from Latin America, including hosting the “GRULAC Workshop on the Detection and Identification of Living Modified Organisms”.¹¹ Further, due to the inactivity of the Latin American regional network, it was highlighted that the GMO Laboratory from Ministry of Agriculture in Mexico works on a bilateral basis with laboratories in Cuba, Colombia, Peru, Venezuela and Bolivia.

35. In terms of the Asian region, one participant was unaware of any networks of laboratories operating in their region. The participant suggested that networks of laboratories could create opportunities for learning and technology transfer could be facilitated between laboratories. In their intervention, the participant noted the development of nanoplate-type digital PCR in the laboratories in the Republic of Korea (see paragraph 10 above) as a promising example and suggested that it would reduce costs and challenges related to procurement of conventional certified reference materials.

D. Topic 4: Addressing capacity-building needs

36. At its tenth meeting, the Conference of the Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety adopted a new Implementation Plan and Capacity-building Action Plan in decisions [CP-10/3](#) and [CP-10/4](#), respectively. Further, in decision CP-10/11 on detection and identification of living modified organisms, the Conference of the Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety noted goals A.6 to A.8 in both plans and the related capacity-building activities. Furthermore, in the same decision, the Conference of the Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety recognized the need for capacity-building activities on new detection techniques, as well as on detecting and identifying unauthorized

¹¹ Available at: www.cbd.int/meetings/BSDIWS-2016-02

living modified organisms. Given the above, the moderator requested participants to share information on capacity-building needs and solutions for addressing these needs with a particular focus on what measures could be considered the most effective under this topic.

37. Regarding capacity-building needs related to newly developed and unauthorized LMOs, the following were shared:

- Capacity for detecting, identifying and quantifying newly developed or unauthorized LMOs
- Capacity for detection of LMOs at ports-of-entry, local markets and laboratories
- Ability to quantify living modified content in a sample (e.g., defining the limit of detection of the machine, measurement uncertainty)
- Awareness of sample preparation and processing (e.g., avoiding cross contamination)
- Availability of detection techniques and methodologies (both qualitative and quantitative) for newly developed LMOs
- Availability of rapid analysis methodologies for monitoring LMOs in the field or in the case of emergency measures in accordance with Article 17 of the Cartagena Protocol
- Laboratory equipment and personnel to meet demand
- Reasonable costs of and/or lack of access to consumables, reagents and kits in all regions
- Access to certified reference materials
- Obtaining and maintaining laboratory accreditation (e.g., ISO/IEC 17025)
- Policies for newly developed LMOs

38. In terms of potential solutions, the following were offered:

- Capacity-building workshops and training courses
 - i. Opportunities for laboratory personnel on detection, identification and quantification of LMOs, as well as measurement uncertainty
 - ii. Support for LMO detection at port-of-entry, local markets and laboratories
 - iii. Periodic training for laboratory personnel to keep up-to-date on new detection techniques and methodologies
 - iv. Support and specialization opportunities for young personnel
 - v. Inclusion of vendors of the reagents and equipment used in the field of detection and identification
 - vi. Focus on quantitative PCR, digital PCR and next-generation sequencing
 - vii. Training on bioinformatics and analysis of genomic information
 - viii. Development of more comprehensive training programmes beyond screening for Cauliflower mosaic virus 35S promoter, Figwort mosaic virus 34S promoter and *A. tumefaciens* nopaline synthase terminator
 - ix. Generation of certified reference materials
- Development of new methodologies
- Generation of technical manuals for the detection, identification and quantification of LMOs

- Collaborate with regional and international bodies to align and standardize current detection and identification methods to minimizing disparities
- Consolidation of detection methods for newly developed LMOs
- Improved access to information
- Implement quality assurance programmes and obtain accreditation
- Ensuring availability of certified reference materials
- Provision of information on the Biosafety-Clearing House
- Partnerships with, visits to and/or technology transfer from advanced laboratories
- Increased networking opportunities, such as conferences, and forums for discussion and equitable participation
- Collaborations established through the Biosafety Clearing-House to bolster technical capabilities and exchange of experiences
- Increased budgetary funding for the installation of infrastructure, procurement of equipment, laboratory and equipment maintenance and acquisition of consumables
- Cost reduction through partnerships, procurement procurement strategies and developing kits within each region
- Improved governmental prioritization

39. When considering the potential solutions, the most effective measures mentioned were:

- A common platform, which offers access to technical information and guidance
- Networks of laboratories to share knowledge and experiences,
- Establishment of regional hubs to act as LMO testing and learning centres, which could offer training opportunities, proficiency testing and instrumentation
- Training and capacity strengthening workshops
- Encouragement to countries for maintaining modern laboratories in compliance with international accreditations and standards
- Strengthened regulatory capacity in each country
- Governmental and departmental support
- Mainstreaming biosafety

40. During the online discussion, participants mentioned that laboratory capacity varies. Some participants noted that their experience is based on the use of real-time PCR, such as those in line with the standards published by the International Organization for Standardization and the European Union Reference Laboratory for Genetically Modified Food and Feed. Others noted that endpoint PCR and lateral flow strips were still in use in some laboratories. A few participants mentioned having experience with digital PCR and next-generation sequencing. However, in some laboratories, these techniques are utilized for food fraud detection and pest identification and not for LMO analysis. However, in other countries, such as Kenya and Mexico, it was noted that newer detection techniques are not in use by regulators and are currently only implemented for research purposes.

41. In one example, a laboratory had just implemented real time PCR. It was suggested that it might be difficult for laboratories to keep up with the new methodologies in the field of detection and identification of LMOs. However, there was a view that the goal should be to perform detection in a routine and sustainable manner without high costs, noting that for some regions consumables,

kits and reagents amounted to the high source of costs, particularly for Africa. One proposal to specifically address this was to build capacity on developing kits within the region (e.g., African-based detection kits). In addition, it was also suggested that public research infrastructure could be utilized for standardization, training and transfer to LMO analytical laboratories within a country to address some of the needs.

42. Further, in some countries, it was noted that LMO detection laboratories rely on students to complement their capacity. However, it was noted that since students are studying, they often leave once their studies have been completed. Thus, it was suggested that there would be a need for periodic trainings for laboratories and at ports-of-entry on the use of kits to maintain a sufficient level of capacity within a country.

43. Regarding specific initiatives, the International Conference on GMO Analysis and New Genomic Techniques¹², which was held in March 2023 in Berlin, Germany, was highlighted. The conference provided opportunities for experts to exchange on their experiences and best practices in terms of detection and identification of LMO and to allow networking on a global level. In addition, the Euginius database¹³ was also highlighted as a means to support laboratory work on detection and identification of LMOs by providing information on authorization status, reference materials and detection methods for LMOs.

44. Further, there was a suggestion that the Network of Laboratories for the Detection and Identification of Living Modified Organisms could have a role in further developing training sessions and manuals, particularly for novel advances in biotechnology. It was further suggested that the Network could be strengthened to include an exchange-based discussion platform for experts to seek advice when facing a particular challenge.

45. Regarding access to information, it was mentioned that it could be helpful to establish and strengthen frames and channels of transparency on the information that biotechnology companies, research centers and universities provide to regulatory bodies and governments. Some of this information could include the unrestricted release of detailed molecular characterization of modified organisms, information on technologies used to modify the LMO and detailed methodologies used in the analysis of the LMO, among others. There was a view that the availability of this information would be considered useful in developing new LMO analysis tools and methodologies, while also potentially facilitating an update and consolidation of the governance of emerging LMOs.

46. Beyond capacity, there was a view that any actions or approaches for the detection and identification of LMOs should focus on routinely used and applicable methods for all Parties to the Cartagena Protocol on Biosafety. However, there was also a view that the techniques used for monitoring and detection of newly developed LMOs would still need to be updated and that there could be a need to further develop capacity in next-generation sequencing given the rapid development of LMOs and organisms produced through new genomic techniques.

47. In addition, there was a suggestion that intra- and inter-governmental regulation of newly developed LMOs within the framework of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity could acts as an initiative for strengthening exchanges of technical, technological and methodological information between countries, which could in turn lead to strengthened biosafety governance and improvements within the field of detection and identification of LMOs.

¹² Organized by the German Federal Institute for Risk Assessment, German Federal Office of Consumer Protection and Food Safety, German Federal Ministry of Food and Agriculture, Julius Kühn Institute, European Commission, Joint Research Centre and Secretariat of the Convention on Biological Diversity. More information available at : <https://www.bfr-akademie.de/english/archive/2023/gmo2023.html>; Recorded presentations are available at: https://www.youtube.com/playlist?list=PL4cxeorZOjEMhYyvgKhYICB_KbXilQJNN

¹³ A collaboration between the German Federal Office of Consumer Protection and Food Safety and Wageningen Food Safety Research. Available at: <http://www.euginius.eu/>

Annex

List of bibliographic references

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