CBD/SBSTTA/26/6

Distr.: General
6 February 2024

Original: English

Subsidiary Body on Scientific, Technical and Technological Advice
Twenty-sixth meeting
Nairobi, 13–18 May 2024
Item 7 of the provisional agenda*
Detection and identification of living modified organisms

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Note by the Secretariat

I. Introduction

1. In its decision CP-10/11, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety welcomed the publication of *Biosafety Technical Series 05: Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety*. In the same decision, it invited Parties and relevant organizations to submit information on their experience with new detection techniques, detecting newly developed and unauthorized living modified organisms and developing reference materials, as well as ongoing collaborations involving national and regional laboratories. Also in the same decision, it requested the Executive Secretary to continue the work mandated in decision CP-9/11, such as convening online discussions of the Network of Laboratories for the Detection and Identification of Living Modified Organisms.

2. Also in its decision CP-10/11, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Subsidiary Body on Scientific, Technical and Technological Advice to consider the information submitted by Parties and relevant organizations and prepare a recommendation regarding the need to update the aforementioned training manual for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its eleventh meeting.

3. The present document contains information on the activities carried out during the intersessional period under the programme of work on the detection and identification of living modified organisms. In addition, it contains an overview of the work undertaken by the Secretariat pursuant to paragraph 7 of decision CP-10/11, namely, the submission of information on the detection and identification of living modified organisms (sect. II) and the online discussions of the Network of Laboratories (sect. III), as well as other relevant activities and developments (section IV). Recommendations for consideration by the Subsidiary Body can be found in section V.

* CBD/SBSTTA/26/1.

II. Overview of the submission of information on the detection and identification of living modified organisms

4. In response to the request in decision CP-10/11, the Secretariat issued a notification[1] to invite Parties, other Governments and relevant organizations to submit relevant information related to the detection and identification of living modified organisms. The Secretariat received five submissions: four from Parties and one from an organization.[2]

5. Regarding new techniques for the detection and identification of living modified organisms, no new tools were shared through the submissions. However, in some submissions, it was indicated that while digital polymerase chain reaction (PCR) and next-generation sequencing methodologies had been refined, they were still at a research and development stage in relation to the detection and identification of living modified organisms. Certain control laboratories were evaluating the applicability of digital PCR and reproducible next-generation sequencing tools to the analysis of living modified organisms. In addition, research groups had also designed new protocols based on targeted sequencing and digital PCR for detecting single nucleotide variations in genome-edited organisms.

6. Those developments notwithstanding, some countries were still relying on real-time PCR methodologies for the analysis of living modified organisms. Furthermore, there were varied levels of experience and familiarity with digital PCR and next-generation sequencing. For example, in one country, digital PCR and next-generation sequencing had been used for pest identification and food authenticity, rather than the analysis of living modified organisms. Furthermore, it was mentioned that research was also ongoing in the use of next-generation sequencing and digital PCR for detecting organisms produced through new genomic techniques.

7. Less information was shared with regard to experience in detecting newly developed and unauthorized living modified organisms. Specific examples were given by Germany, where a few strategies had been implemented, such as developing new genetic element screening methods, using pre-spotted plates with oligonucleotides corresponding to new events and characterizing unknown living modified organisms. Additional examples were provided by Brazil, where a case-by-case approach for analyses had been adopted on the basis of the species and origin of the living modified organism being tested. It was also noted that, in general, applicants were responsible for providing methodologies and reference materials for newly authorized events.

8. Similarly, different levels of experience with developing certified reference materials were reported, and different approaches had been adopted. In some countries, such materials were either purchased or provided by the developer, rather than being developed by national institutions. In other countries, however, the materials were being developed by national institutions. For example, in Germany, the National Reference Laboratory for Genetically Modified Organisms of the Federal Office of Consumer Protection and Food Safety had produced certified reference materials on an ad hoc basis, while the Laboratory of Genetically Modified Detection of the Department of Agriculture of Thailand had developed an in-house reference material for wheat event MON71800 based on a plasmid.

9. Lastly, several national, regional and international collaborations were indicated in the submissions. The formation of laboratory networks facilitated the development, validation, harmonization and standardization of means and methods for the sampling, detection, identification and quantification of living modified organisms. There was also mention of contracting private laboratories, which acted as accredited proficiency testing providers. In addition, some laboratories,

[1] Notification No. 2023-100.

[2] Belgium, Brazil, Germany, Thailand and the Outreach Network for Gene Drive Research (see https://bch.cbd.int/en/submissions-to-notifications?schema=submission&currentPage=1&notification=2023-100 for the full text of the submissions).

such as in Belgium, also participated in working groups on the development of new detection techniques for genome-edited organisms.

10. A complete synthesis of the information submitted pursuant to Notification No. 2023-100 will be made available as an information document.[3]

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

11. To complement the information submitted by Parties and relevant organizations and continue the work mandated in decision CP-9/11, the Secretariat convened online discussions of the Network of Laboratories from 17 to 28 November 2023.[4] Discussions were held on four topics, namely: (a) new techniques for detecting and identifying living modified organisms; (b) experience with detecting and identifying newly developed and unauthorized living modified organisms; (c) lessons learned from national and regional laboratory collaborations; and (d) addressing capacity-building needs.

12. A total of 25 participants from 22 Parties and three organizations actively participated in the online discussions. Fifty-three interventions were made, of which 48 came from experts nominated by Parties and 5 from experts nominated by organizations.

13. Regarding new techniques for detecting and identifying living modified organisms, participants indicated that various techniques had been refined since 2019. Discussions were therefore mainly focused on developments in digital PCR and next-generation sequencing. The most advanced development shared was that of nanoplate-type digital PCR, which used endogenous reference genes in place of conventional certified reference materials and could thus allow for the rapid development of quantification methodologies for newly developed living modified organisms. Other developments mentioned included new assays combining the use of clustered regularly interspaced short palindromic repeats-associated protein (CRISPR/Cas) with loop-mediated isothermal amplification and rolling circle amplification for living modified organism screening, targeted sequencing approaches for characterizing known and unknown living modified organisms and real-time PCR approaches for detecting organisms harbouring a single nucleotide variant, such as those produced through genome editing.

14. While sharing information on new developments in the field of detection and identification of living modified organisms, both digital PCR and next-generation sequencing were compared to real-time PCR. For digital PCR, it was recognized that the technique was reliable for the detection, identification and quantification of living modified organisms, including newly developed living modified organisms. It could offer advantages over real-time PCR, such as being more robust to high copy number DNA and PCR inhibitors, distinguishing among genetic elements or living modified organisms with high homology and allowing for absolute quantification. However, there were also concerns about the current cost of consumables for digital PCR systems and the limited throughput of the technique. In addition, it was noted that digital PCR was not yet being used widely for the analysis of living modified organisms.

15. Regarding next-generation sequencing, digital PCR was suggested as a powerful tool for the molecular (genetic) characterization of both known and unknown living modified organisms, and its importance was mentioned in relation to new developments in biotechnology, such as for organisms produced through new genomic techniques. The quantification of living modified organisms and high implementation cost, however, remained significant drawbacks. In addition, the wide use of next-generation sequencing was not suggested for the analysis of living modified organisms, and its applicability in the field was still being explored.

[3] CBD/SBSTTA/26/INF/1.

[4] See https://bch.cbd.int/en/portals/detection/network-of-labs.

16. The online discussions highlighted the variety of experience in the field of detection and identification of living modified organisms. Some experts noted that certain laboratories had experience with many tools and techniques, such as next-generation sequencing, digital PCR and isothermal amplification techniques. Many laboratories in developing countries, however, only had experience with detecting a limited number of genetic elements using end point or real-time PCR and could thus potentially miss living modified organisms during screening, such as those that were newly developed or not authorized.

17. Since the challenge with detecting and identifying newly developed and unauthorized living modified organisms related to novel genetic elements, which might not be detected by standard screening approaches, German laboratories had adapted their portfolio of standard screening methods to include additional targets, developed new validated methodologies for living modified organisms authorized outside the European Union and implemented next-generation sequencing methodologies. In Brazil, laboratories relied on a case-by-case analytical strategy based on the species and origin of the materials to detect and identify unauthorized living modified organisms. For newly developed living modified organisms authorized by the National Technical Commission on Biosafety of Brazil, applicants provided methodologies and reference materials for method validation and market control.

18. With respect to national and regional laboratory collaborations, several examples from Africa, Asia, Latin America and the Caribbean and Europe were shared. In general, it was felt that the networks of laboratories had been successful at cost reduction, knowledge-sharing and addressing gaps in capacity, as well as harmonizing and standardizing methodologies for the sampling, detection, identification and quantification of living modified organisms. Funded projects, legal frameworks and bilateral agreements had led to the establishment of those networks. Their membership could also be varied and consist of public institutions, academia and private laboratories. It was mentioned, however, that not all the networks had continued to operate after their initial establishment.

19. Lastly, several capacity-building needs and potential solutions were shared during the online discussions. The needs tended to be related to methodologies and techniques, infrastructure, consumables and legal agreements. Workshops, the development of technical materials, improved inter-laboratory collaboration, knowledge-sharing and cost-reductions or increased financing were highlighted as potential solutions.

20. A summary of the online discussions of the Network of Laboratories will be made available as an information document.[5]

IV. Other relevant information on the detection and identification of living modified organisms

A. Capacity-building activities

21. In its decision CP-10/11, the Conference of the Parties serving as the meeting of the Parties to the Protocol recognized the need for capacity-building activities on new detection techniques and encouraged Parties and international organizations to fund the capacity-building of personnel involved in the field of detection and identification of living modified organisms. In the same decision, it requested the Executive Secretary to further enhance capacity-building in that field, including by convening, in cooperation with relevant organizations, subject to the availability of resources, regional and subregional capacity-building activities, such as online training and face-to-face workshops.

22. Accordingly, with the financial support of the Government of Germany, the Secretariat co-organized an international conference on genetically modified organism[6] analysis and new

[5] CBD/SBSTTA/26/INF/2.

[6] The term “genetically modified organism” was used to align the terminology with that used by researchers in the field but can be considered as interchangeable with the term “living modified organism”, as defined in the Protocol, in the context of the conference.

genomic techniques with the German Federal Institute for Risk Assessment, the Federal Office of Consumer Protection and Food Safety, the Federal Ministry of Food and Agriculture of Germany, the Julius Kühn Institute and the Joint Research Centre of the European Commission. The conference was held in Berlin from 14 to 16 March 2023.

23. The goals of the conference were to provide an opportunity to experts to learn about recent developments in the field of detection and identification of living modified organisms, facilitate technical, science-based discussions on those developments and provide a networking opportunity for international collaboration. The conference was the second international event held on the analysis of living modified organisms only since 2008, when the first conference had been held.[7]

24. Seventeen participants from 17 Parties attended the conference in person, while an additional three participants from 3 Parties attended online.

25. Further information, including recordings and presentations, have been made available online.[8] In addition, the proceedings of the conference are expected to be published as an open-access, peer-reviewed journal article in the course of 2024.

B. Further relevant activities undertaken by the Secretariat and relevant developments

26. In addition to actions taken pursuant to the requests of the Conference of the Parties serving as the meeting of the Parties to the Protocol, the Secretariat has been involved in ongoing activities that may be relevant to the field of detection and identification of living modified organisms.

27. At its twelfth meeting, held in May 2023, the Informal Advisory Committee on the Biosafety Clearing-House was in favour of the creation of a registry of records of laboratories for the detection and identification of living modified organisms to provide prominence to the important role played by those laboratories. At the time of reporting, there were 78 laboratories registered on the Biosafety Clearing-House, and the Network of Laboratories had grown to 204 members, representing roughly a 25 per cent increase in membership since 2019.

28. Lastly, in its decision CP-10/7, on the assessment and review of the effectiveness of the Protocol (Article 35) and final evaluation of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011–2020, the Conference of the Parties serving as the meeting of the Parties to the Protocol commended the large number of Parties that had established the capacities to detect, identify, assess and monitor living modified organisms or traits that might have adverse effects on the conservation and sustainable use of biological diversity, and it welcomed the fact that almost all Parties had trained some laboratory personnel in the detection of living modified organisms, while recognizing that about half of those Parties had indicated that more training would be required. In the same decision, it therefore urged Parties, and invited other Governments, donors and biosafety capacity-building initiatives, to make resources available to support Parties in their efforts to strengthen capacities and enhance the implementation of the Protocol in the priority area of, inter alia, the detection and identification of living modified organisms.

V. Recommendations

29. In view of the information contained in the present document, the Subsidiary Body may wish to conclude that *Biosafety Technical Series 05* is still relevant and useful to the detection and identification of living modified organisms, and that there is no need to update the training manual at this time.

[7] The first conference, entitled "Global Conference on GMO Analysis", was organized by the Joint Research Centre and the European Network of GMO Laboratories of the European Commission and held in Como, Italy, from 24 to 27 June 2008 (see https://cordis.europa.eu/event/id/29342-global-conference-on-gmo-analysis-como-italy).

[8] See https://www.bfr-akademie.de/gmo2023/.

30. Furthermore, the Subsidiary Body may wish to recommend that, at its eleventh meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol adopt a decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,

Recalling decisions CP-10/11 and CP-10/7 of 10 December 2022 and the need for capacity-building activities on new detection techniques and on detecting and identifying unauthorized living modified organisms,

Reiterating the importance of the field of detection and identification of living modified organisms for the Cartagena Protocol on Biosafety and its relevance and applicability to other fields,

Recognizing that newly developed and unauthorized living modified organisms pose challenges for the analysis of living modified organisms,

Noting the limited information available on new techniques for detecting and identifying living modified organisms and the limited experience with detecting and identifying newly developed and unauthorized living modified organisms,

1. *Invites* Parties, other Governments, relevant organizations and the Network of Laboratories for the Detection and Identification of Living Modified Organisms to share through the Biosafety Clearing-House technical reference materials and publications related to digital polymerase chain reaction and next-generation sequencing in order to complement *Biosafety Technical Series 05: Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety*;

2. *Encourages* Parties to explore the formation of regional networks of laboratories to support activities in the field of detection and identification of living modified organisms;

3. *Urges* Parties, and invites international organizations, to provide financial resources to laboratories to strengthen the infrastructure for the detection and identification of living modified organisms, the formation of regional networks of laboratories and capacity-building activities;

4. *Requests* that the Secretariat:

(a) Continue to collect publications and technical resource materials and make them available on the Biosafety Clearing-House;

(b) Explore ways to enhance access to information through a dedicated section within the Biosafety Clearing-House;

(c) Prepare a summary of materials and publications submitted in response to the request in paragraph 1, for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its twelfth meeting;

(d) Continue efforts to collaborate with relevant organizations and provide capacity-building support to Parties in the field of detection and identification of living modified organisms.