Annex 7

Original: English October 2020

REPORT OF THE VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 6 – 8 October 2020

A virtual meeting of the OIE *ad hoc* Group on the evaluation of contagious bovine pleuropneumonia (CBPP) Status of Members (hereafter the Group) was held from 6 to 8 October 2020.

1. Opening

Dr Matthew Stone, Deputy Director General for International Standards and Sciences of the OIE, opened the virtual meeting and welcomed the Group. He thanked the experts for their availability and contribution to the work of the OIE and extended his appreciation to their institutes and national governments for allowing their participation in this meeting. He also thanked the Group for its commitment and its support towards the OIE in fulfilling the mandates given by Members. Dr Stone acknowledged the amount of work before, during, and after the *ad hoc* Group meeting in reviewing the dossiers and documenting the Group's assessment in the report.

Dr Stone highlighted the importance of the quality of the report to be scrutinised by Members before adopting the proposed list of Members free from CBPP. He also encouraged the Group to continue providing detailed feedback to Members with a negative outcome to support them in identifying the main gaps and points for improvement, as well as providing informative recommendations to those countries with positive outcomes for further improvement in maintenance of their CBPP free status.

Dr Stone highlighted the sensitivity and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the forms for undertaking of confidentiality. He also mentioned that one member of the Group had indicated a potential conflict of interest in the evaluation of a dossier, and that the expert would follow the established procedure and withdraw from the discussions and decision making of the particular application.

Dr Stone introduced Dr Zengren Zheng who represented the Scientific Commission for Animal Diseases in the meeting.

The Group and the OIE welcomed Dr Marcelo Fernandes Camargos as a new member of the Group and Dr Aurelio Cabezas who is part of the OIE Secretariat on activities related to official status recognition for CBPP.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr François Thiaucourt and Dr Chandapiwa Marobela-Raborokgwe acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

The terms of reference, agenda, and list of participants are presented as Appendices I, II and III, respectively.

3. Evaluation of applications from Members for official recognition of contagious bovine pleuropneumonia (CBPP) free status

a) Paraguay

In July 2020, Paraguay submitted a dossier for the official recognition of its CBPP free status based on historical grounds.

The Group requested additional information and received clarifications from Paraguay.

i. Animal disease reporting

The Group acknowledged that Paraguay had a record of regular and prompt animal disease reporting and that CBPP has been an exotic notifiable disease for at least the past ten years in accordance with Article 1.4.6. of the *Terrestrial Animal Health Code (Terrestrial Code)*. The Group acknowledged the reports submitted by Paraguay through OIE WAHIS. Nevertheless, the Group took note that the last record of an exceptional epidemiological event submitted through an immediate notification was reported in 2012. The Group took note that Paraguay provided additional information regarding the Animal Health Information System (SISA) and acknowledged that the system is in place for the management of information regarding occurrences of animal diseases although it is not specific for CBPP.

ii. Veterinary Services

The Group noted that Paraguay has a well-structured Veterinary Services with a regulatory central veterinary authority and operative sub-levels that regulate different animal health sectors and are distributed throughout the country. The official sector of the Veterinary Services of Paraguay is headed by the National Service for Animal Quality and Health (SENACSA) comprised by the National Animal Health Service, the Directorate of Livestock Protection, and the Directorate of Control Standards for Food of Animal Origin. SENACSA has 13 health departments and 86 zonal units under the Directorate of Animal Health, Identity, and Traceability (DIGESIT) that are responsible for the management and planning of the health plans and programmes throughout the country for all species of domestic and wild animals. Official veterinarians of SENACSA are responsible for these Health Departments and Zonal Units and are assisted by technical and administrative staff.

The Group also noted that Paraguay has the relevant legislation in place establishing the operational structures and activities of SENACSA.

The Group noted that all susceptible livestock are identified through the Paraguayan Traceability System (SITRAP), and all bovine owners and establishments are registered with SENACSA through the Regional Office Management Information System (SIGOR). The Group appreciated the additional information describing the SITRAP. The registration of new establishments follows SOPs starting from the request by owners, the assignation of an establishment code and the uploading of data of the livestock owner into SIGOR. These procedures are carried out through the Rural Directorate and in the Zonal Units. The animal identification methods include ear tags registered in the SITRAP for individual identification, and branding marks for group identification and traceability. The Group also noted that livestock owners are allowed to move their animals only if the owner is registered in the SIGOR.

The Group noted that movements of livestock are only allowed after SENACSA issues the Official Animal Transit Permit (COTA) which currently is issued in both the digital and printed forms. The Group took note that a fully digital system to issue movement permits is in the process of implementation and has begun with producers which have over 1000 heads which represents approximately 60% of the national cattle population. The electronic permit is accessible online through the SIGOR.

For internal movement control, live animals are accompanied by a movement permit and transported in officially sealed trucks. Additional document verification is carried out at the 14 animal movement control posts within the country by personnel of the Quarantine Directorate, and at a slaughter establishment in case of slaughtered animals by Official Veterinary Inspectors.

The Group noted that a PVS follow-up mission was conducted in 2017 which had detected a gap in the information reported regarding control and surveillance measures for CBPP. The Group took note that Paraguay implemented corrective measures, and that the information has already been submitted to WAHIS and will be available when the new OIE-WAHIS is launched.

The Group took note that Paraguay reported a strong collaboration between the private and public sector with regard to animal health activities relative to prevention, early detection, and eradication of transboundary infectious diseases such as the cooperation agreement with the Animal Health Services Foundation (FUNDASSA). The 20 Animal Health Commissions (CSA) accredited by SENACSA, and established through a legal instrument, operate at rural level. The CSA administers animal health programmes including verification of the health status of animals and immediate notification of any clinical signs compatible with any mandatory notifiable disease in Paraguay.

The Group noted that although simulation exercises, field exercises, and training programmes were conducted by the Veterinary Services and included the participation of the private sector, no simulation exercises have been conducted specifically for CBPP. The Group acknowledged the additional information provided on training activities and awareness programmes. Nevertheless, the Group highlighted the need to set up awareness activities targeting slaughterhouse technicians in the recognition of CBPP lesions.

The Group concluded that the Veterinary Services had current knowledge of and authority over the livestock population in the country.

iii. Situation of CBPP in the past 24 months

The Group acknowledged that cases of CBPP have never been registered in Paraguay and the disease has been notifiable for more than 10 years, therefore, Paraguay would be eligible for historical freedom from CBPP as described in Article 1.4.6. of the *Terrestrial Code*.

iv. Absence of vaccination in the past 24 months

The Group was informed that registration and use of vaccination against CBPP has never been authorized in the country according to the legislation in place.

v. Surveillance in accordance with Articles 11.5.13. to 11.5.17.

The Group acknowledged that Paraguay has a general passive surveillance and early detection systems in place based on field notifications and post-mortem inspections at slaughterhouses. In addition, the Group took note that a targeted CBPP surveillance system is not in place because the disease has never been reported in the country.

The Group noted that systematic and mandatory campaigns against FMD and Brucellosis are conducted twice a year which ensure a constant monitoring of the susceptible population. The Group took note that suspicious cases in the past 24 months were reported by Paraguay and these were ruled-out by clinical inspection. Nevertheless, the Group expressed their concerns that there was no information with regard to laboratory follow-up of these suspicious cases.

The Group took note that currently SENACSA's central laboratory is reported to carry out isolation of mycoplasma *spp* strains and to perform biochemical tests to characterise suspected isolates of *Mycoplasma mycoides* subspecies *mycoides* SC (*Mmm*), but does not have a specific diagnostic test to identify *Mmm*. On the other hand, the Group noted that Paraguay has agreements with OIE Reference Laboratories for other diseases (Plum Island, Panaftosa, and The Central Laboratory of SENASA) which perform CBPP diagnosis. The Group acknowledged the additional information provided on agreements with laboratories within the region including the ongoing arrangements to establish an agreement with an OIE Reference Laboratory for CBPP; however the Group highlighted that currently there are no written detailed procedures for sample management and submission.

The Group highlighted that the laboratory PCR capabilities for detection of mycoplasma *spp* strains and identification of *Mmm* are not currently available in the country. The Group took note that Paraguay plans to establish the diagnosis of *Mmm* through real-time PCR. The Group agreed that rapid detection of mycoplasmas with a generic PCR system and a specific *Mmm* PCR detection is recommended. In addition, the Group stressed that Paraguay should have a procedure in place for appropriate sample collection for laboratory diagnosis and the shipment of samples or mycoplasma isolates (or DNA) for confirmation at regional labs or OIE Reference Laboratories for CBPP.

vi. Regulatory measures for the prevention and early detection of CBPP

The Group noted that comprehensive measures for prevention and control of exotic infectious diseases, including CBPP, are in place according to legislation, but there is no specific plan targeting CBPP.

The Group took note that regulations and sanitary requirements for the importation of animals and animal products are based on risk analysis performed by SENACSA specialists and in line with the OIE *Terrestrial Code* and the MERCOSUR Manual of Procedures for the Importation of animals and products. The Group acknowledged that importation of live animals is only allowed from countries which are officially CBPP free accompanied by an international veterinary certificate, and a quarantine is systematically applied to all imported animals.

In addition, the Group noted that there is an early warning system in place and that Paraguay maintains a strict inspection system at borders and checkpoints. The Group took note that Paraguay reported agreements with neighbouring countries. The Group took note that Paraguay provided additional information regarding the measures to be taken in the event of a suspected CBPP outbreak.

vii. Compliance with the questionnaire in Article 1.10.1.

The Group agreed that Paraguay's dossier was compliant with the questionnaire in Article 1.10.1. of the *Terrestrial Code*.

Conclusion

Considering the information submitted in the dossier and the answers received from Paraguay to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 11.5., Article 1.4.6., and with the questionnaire in Article 1.10.1. of the *Terrestrial Code*. The Group therefore recommended that Paraguay be recognised as country free from CBPP.

The Group recommended that information on the following be submitted to the OIE when Paraguay reconfirms its CBPP status (also detailed in the relevant sections above):

- 1. A written protocol for CBPP sampling clearly indicating the responsibilities, tasks, sampling procedures, sample management, storage, shipping and timelines for reporting results. Submit evidence that specific trainings for all laboratories supporting the Veterinary Service have been performed to ensure awareness of the protocol to be followed in case of CBPP suspicions. Furthermore, Paraguay is requested to provide evidence of a formal agreement with an OIE Reference Laboratory for CBPP.
- 2. The implementation of a direct method (i.e. PCR) for detection of mycoplasmas and identification of *Mmm* in the surveillance system and to follow-up suspected cases; and perform these tests under quality management and take part in proficiency testing¹.
- 3. Set up awareness activities targeting slaughterhouse technicians and make sure that these activities include recognition of CBPP lung lesions.

b) Italy

In October 2019, Italy submitted a dossier to apply for the official recognition of its CBPP free status which was not accepted because it was after the deadline. Italy was encouraged to submit an updated dossier the following year. In July 2020, Italy submitted a dossier for the official recognition of its CBPP free status based on historical grounds.

In accordance with the established procedures, the participating expert working for the Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise (IZSAM), expressed a possible conflict of interest and withdrew from the decision making on Italy's application.

¹ See Botes *et al.*, 2005 as an example. The article can be found at <u>https://www.sciencedirect.com/science/article/pii/S0378113505003275?via%3Dihub</u>

The Group requested additional information and received clarifications from Italy.

i. Animal disease reporting

The Group acknowledged that Italy has a record of regular and prompt animal disease reporting and that CBPP has been a notifiable disease for at least the past ten years in accordance with national legislation and Article 1.4.6., of the *Terrestrial Code*.

ii. Veterinary Services

The Group noted that the relevant legislation was in place. The Group acknowledged that Italy has a well-structured Veterinary Services. The Group took note that in Italy most of the competencies for animal health, food and feed safety, animal welfare, risk assessment in the food chain and consultation of producers and consumers are assigned at national level to the Ministry of Health through different Directorates.

The Group appreciated the comprehensive information provided on demographics of livestock and noted that animal identification was mandatory in bovines, buffaloes, and small ruminants.

The Group noted that Italy applies EU regulation establishing the minimum requirements for the identification and registration of bovine animals, and manages all related data including on traceability and movement control through an information system. All susceptible livestock (cattle and water buffalo) are individually identified within seven days after birth (animal passport, two ear tags with a unique code, and electronic ruminal boluses) through a national animal registration system and farmers inform the veterinary services of new births or importations within seven days of ear tagging. The description of the actors and the process of animal identification, establishment/holding and owner registration were described in the dossier. The Group acknowledged the information provided on the controls of cattle and water buffalo movement and the data for 2018 and 2019.

The Group took note that cattle movements are controlled by the official veterinarians through the issuance of an electronic veterinary certificate. The Group acknowledged the information provided on the most frequent types of non-compliance on movements of susceptible animals reported and the kinds of the penalties imposed.

The Group acknowledged that all cattle and buffaloes are slaughtered in authorised abattoirs and that antemortem and postmortem inspections are performed by official veterinarians.

The Group concluded that the Veterinary Services had current knowledge of and authority over the livestock population in the country.

iii. Situation of CBPP in the past 24 months

The Group acknowledged that the last cases of CBPP were reported in Italy in 1993 and therefore, Italy would be eligible for historical freedom from CBPP as described in Article 1.4.6. of the *Terrestrial Code*.

iv. Absence of vaccination in the past 24 months

The Group noted that the use of CBPP vaccines in the European Union is prohibited and vaccination against CBPP had never been carried out in Italy and is prohibited by the Decree 27 June 1991, n. 248.

v. Surveillance in accordance with Articles 11.5.13. to 11.5.17.

The Group noted that a system for clinical and slaughterhouse surveillance based in the occurrence of mortality due to respiratory disease and post-mortem inspection at slaughterhouse is in place and performed by the Official Veterinarians. In addition, it was noted that farmers, private veterinarians or any person dealing with animals are obliged by the Veterinary Police Regulation to report all animal deaths and any suspicion of infectious disease to the Local Veterinary Officers. These officers are responsible for the investigation of the suspicion or cause of death, and sending samples to the IIZZSS laboratories in the different regions for further investigation.

The Group acknowledged the participation of stakeholders in surveillance activities. Upon the Group's request, Italy provided additional information on the involvement of the producer's organisations in training and awareness activities, although not specific to CBPP, aimed at strengthening general surveillance. Furthermore, the Group took note that a training course which will cover detection of suspected cases based on clinical signs and pathological lesions will be conducted in 2021. Nevertheless, considering that the last training reported was in 2013, the Group emphasised the need to conduct training courses for slaughter personnel and meat inspectors to strengthen CBPP surveillance.

While acknowledging that pathogen-specific surveillance was not required in accordance with Article 1.4.6. Point 2. of the *Terrestrial Code*, the Group was concerned about the absence of reporting of suspicious cases through passive surveillance. An effective surveillance system should periodically identify suspicious cases that require follow-up and investigation to confirm or exclude CBPP.

Upon receipt of the additional information, the Group concluded that this gap in the reporting of suspicious cases could limit the capability of early detection of CBPP and rapid response. Therefore, the Group emphasised the need of reporting suspicious cases to evaluate the sensitivity of the surveillance system, and following them up to rule-out CBPP. Upon request of additional information, Italy submitted information on the number of CBPP suspected cases, number of samples tested for CBPP, species tested, type of sample tested, testing methods, and the results including differential diagnosis and the types of mycoplasma *spp* identified in the past 24 months. The Group considered that Italy's answer was satisfactory and that Italy has an effective surveillance system at slaughterhouses.

The Group acknowledged that CBPP diagnosis is performed at the IZSAM, an OIE Reference Laboratory for CBPP. The Group took note that Italy has a laboratory network (IIZZSS) which is connected by couriers that continuously transfer and exchange samples and reagents. The Group noted that a detailed procedure for rapid collection and transport of samples from suspected cases is in place.

The Group took note about the information provided on CBPP test capabilities of the IZSAM to isolate mycoplasma *spp* strains and to identify *Mmm*. The Group noted that the IZSAM is ISO 17025 accredited which provides general requirements for the competence of testing and calibration for 3 CBPP diagnostic tests CFT, PCR, and immunoblotting. The Group appreciated the additional information provided with regard to results of ring-trials organised by two other OIE Reference Laboratories for CBPP but acknowledged that the IZSAM has not participated in a ring-trial since 2017. The Group took note that IZSAM will participate in a proficiency test for CBPP c-ELISA in 2020.

The Group therefore concluded that Italy complies with the requirements of Article 11.5.15 of the *Terrestrial Code*.

vi. Regulatory measures for the prevention and early detection of CBPP

The Group was of the opinion that regulatory measures to prevent and control foreign animal diseases in general, including CBPP, are in place and in accordance with EU legislation. The legislation has provisions on the veterinary checks to be applied to live animals and products of animals from countries outside European Union, import conditions, laboratory tests and controls, and veterinary certification requirements. The Group noted that there are regulations in place for the importation of embryos, oocytes, and semen.

The Group took note that Italy essentially imports live bovine and commodities of susceptible livestock from EU countries with requirements that they are free from CBPP for the past 12 months, where vaccination have not been practiced during the past 12 months, and imports of CBPP vaccinated domestic cloven-hoofed animals are not permitted.

The Group noted that live animals and their products entering the European Union are inspected at a Border Inspection Post (BIP) where Official Veterinarians ensure that they fulfil all the requirements provided for in the legislation. In addition, the Group acknowledged that non-discriminatory spot checks are carried out en-route and at the destination within Italy to ensure that consignments are in compliance with the guarantees stated in the accompanying health certificates.

The Group took note that a national contingency plan for veterinary epidemic emergencies is in place since 2014 and acknowledged receipt of the CBPP emergency manual of 2000 which outlines in detail the procedures for the follow-up of suspected CBPP cases.

vii. Compliance with the questionnaire in Article 1.10.1.

The Group found that the content of Italy's dossier was compliant with the questionnaire in Article 1.10.1.

Conclusion

Considering the information submitted in the dossier and the answers received from Italy to the requests for additional information, the Group considered that the application was compliant with the requirements of Chapter 11.5., Article 1.4.6., and with the questionnaire in Article 1.10.1., of the *Terrestrial Code*. The Group therefore recommended that Italy be recognised as country free from CBPP.

The Group recommended that information on the following be submitted to the OIE when Italy reconfirms its CBPP status (also detailed in the relevant sections above :

- Details of the training course targeting detection of suspected cases based on clinical signs and pathological signs in slaughterhouses to be conducted in 2021;
- Definition of the CBPP suspicion lesions at slaughterhouse.

4. Other matters

The OIE Secretariat and the Group evaluated the performance of the virtual meeting.

5. Adoption of report

The Group reviewed the draft report and agreed to circulate it electronically for comments before the final adoption. Upon circulation, the Group agreed that the report captured the discussions.

.../Appendices

Appendix I

VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 6 – 8 October 2020

TERMS OF REFERENCE

Purpose

The purpose of the *ad hoc* Group (The Group) on contagious bovine pleuropneumonia (CBPP) status of Members is expected to evaluate applications for official recognitions of CBPP free status and for endorsement of their official control programme of CBPP.

Background

In accordance with the OIE standard operating procedure (SOP) for official recognition of disease status and for the endorsement of official control programmes, OIE Members can be officially recognised as country/zone free from CBPP or to have their official control programme endorsed by the OIE through the adoption of a resolution by the OIE World Assembly of Delegates at the General Session in May every year. A Member wishing to be recognized as CBPP free or to have its official control programme for CBPP endorsed by the OIE should submit the required information to prove evidence that they comply with all the requirements specified in the *Terrestrial Animal Health Code (Terrestrial Code)* for CBPP. The assessment of the compliance with OIE standards of OIE Members' applications is conducted by the Scientific Commission for Animal Diseases (Scientific Commission) based on the recommendations formulated by a relevant *ad hoc* Group. The *ad hoc* Groups are convened under the authority of and report to the OIE Director General.

Specific issues to be addressed

The Group will screen and evaluate in detail two applications from Members to assess compliance of the Members with the requirements specified for CBPP in the *Terrestrial Code*. Based on those evaluations, The Group will provide recommendations to the Scientific Commission that will meet in February next year.

Prerequisites

Ad hoc Group members should:

- Sign the OIE Undertaking on Confidentiality of information (if not done before)
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between *ad hoc* Group meetings to ensure continuity of the work.

Actions to deliver

Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the relevant questionnaire, main sections of the questionnaire, regular notification to the OIE, payment of the fee, PVS report, etc.). If an information gap is identified, the SD requests additional information to the Member.

As the OIE Performance of Veterinary Services (PVS) reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS reports if not obsolete (no more than 5 years) or confidential.

The SD will send the working documents to the *ad hoc* Group, including the dossiers received from applicants, at least one month before the Group meeting (i.e., **7 September 2020**).

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The experts are expected to:

- Be familiar with Chapters <u>1.10</u> and <u>11.5</u> of the *Terrestrial Code* relative to CBPP;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to Chapter 1.10 requirements by completing the summary tables provided by the SD;
- Draft questions to the applicant Members whenever the evaluation of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions at least 10 days before the teleconference (i.e., 25 September 2020);

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. The SD will forward to experts all subsequent information and material provided by a Member prior to the teleconference.

During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Contribute to drafting the report.

If during the teleconference the Group decides that additional information should be requested to the applicant Members before an informed conclusion can be drawn, the SD forwards the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all Group members are taken into consideration.

Should the Group not be able to complete its Terms of Reference during this meeting, experts' contributions will be solicited after the meeting, including by teleconference if needed.

After the meeting

The SD will circulate the draft report after the teleconference is over. Experts are expected to contribute to the finalisation of the report within the following week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

Deliverables

A detailed report to recommend to the Scientific Commission whether the Member should be (or should not be) recognised with an official CBPP free status or have its official control programme endorsed by the OIE. The report should indicate any information gaps or specific areas that should be addressed in the future by the Member regardless of the final recommendation to the Scientific Commission.

Reporting / timeline

The OIE will circulate the draft report no more than seven days after the teleconference (no later than 16 October 2020) and the Group will finalise its report within the following week (deadline: 23 October 2020).

Appendix II

VIRTUAL MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 6 – 8 October 2020

Agenda

- 1. Opening
- 2. Adoption of the agenda and appointment of chairperson and rapporteur
- 3. Evaluation of applications from Members for official recognition of contagious bovine pleuropneumonia (CBPP) free status
 - Paraguay
 - Italy
- 4. Other matters
- 5. Adoption of the report

Appendix III

OIE AD HOC GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 6 – 8 October 2020

List of participants

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