EUROPEAN COMMISSION



HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 20 MARCH 2015

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: https://circabc.europa.eu/w/browse/0305ed0c-ad9e-4559-80a4-28e6a0dba8ab

A.01 Summary Reports of previous meetings.

The Summary Report for the previous meeting has been uploaded on the EU Health and Food Safety website:

http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_e
n.htm

A.02 New active substances:

- 1. New admissible dossiers (to be noted):
 - i. Oxathiapiprolin
 - ii. XDE-777 (suggested ISO name: Lyserphenvalpyr)

Member States took note of the notes on admissibility sent by the respective rapporteur Member States.

- 2. European Food Safety Authority (EFSA) conclusions:
 - i. Flumetralin
 - ii. Rescalure
 - iii. 3-decene-2-one
 - iv. Flupyradifurone

Member States were informed that a number of EFSA Conclusions were available for new active substances and that draft Review Reports and Regulations would be made available in due course.

3. Commission draft Review Report and Regulation concerning the approval of:

i) Cyantraniliprole

No proposal was submitted to the Committee yet as Commission is waiting for a revised conclusion as announced by EFSA.

ii) Terpenoid blend QRD-460

An update was provided on the comments received from the applicant and Member States; changes to the latest versions of the draft Review Report and approval were explained, these were primarily related to how to express the identity/purity of the substance in the approval. Member States were asked to provide further comments on the updated documents by 24th April 2015.

iii) Pepino mosaic virus CH2

New active substance to be used as a virus inoculation for cross protection of tomatoes under greenhouse application. Proposal to approve this active substance as a low risk substance, restricted to greenhouse use. Adaptation to the Good Agricultural Practice (GAP) table in the annex of the review report.

iv) Halauxifen-methyl

New active substance to be used as a herbicide in winter and spring cereals. Proposal to approve this active substance. Used data based on batch data from pilot scale production so confirmatory data for:

- The technical specification of the active substance as manufactured (based on commercial scale production). The relevance of impurities present in the technical material should be confirmed.
- The compliance of the toxicity batches with the technical specification.

v) Ethametsulfuron-methyl

A first proposal for approval of ethametsulfuron-methyl was submitted in October 2014 and Member States were asked to comment.

These comments and the further procedure will be discussed in more detail, if possible, in May.

vi) Sulfoxaflor

A revised EFSA conclusion was provided to the Commission on 13 March. The Commission will now revise the draft proposal with a view to a discussion in the May meeting.

vii) Orthosulfamuron

The applicant has informed the Commission about a transfer of ownership of the active substance.

viii) Flumetralin

An EFSA conclusion was submitted in November 2014. The decision-making was delayed for technical reasons, but will now proceed as quickly as possible.

ix) Flutianil

The classification proposed by EFSA suggests that the substance meets the non-approval criteria. As for other substances in a similar situation, decision-making will advance as soon as the procedural questions are solved.

4. Chromobacterium subtsugae PRAA4-1 (MBI-203)

This biological insecticide is not a spore forming bacterium and the cells lose viability on completion of the fermentation process, to the extent that when the formulated product is packaged, living cells are not present in the product.

The issue which data requirements (chemical or microbial) apply will be further discussed in a small Working Group (together with Member States and EFSA) as an initial discussion between Rapporteur Member State (RMS), EFSA and the Commission did not resolve the issue.

A.03 Renewal of approval:

1. Draft Working Document Renewal Programme (doc. SANCO/11284/2012 Rev.15) (For information)

A new revision of the document is in preparation.

2. Applications for renewal of approval of active substances submitted under Article 14 of Regulation (EU) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (doc. SANCO/ 10148/2014 Rev. 4) (For information)

A new revision of the document is in preparation.

- 3. State of play Annex I Renewal Project (AIR):
 - Next stage of renewal programme

Regarding the next phase of the renewal programme it was indicated that as regards the procedure Regulation (EU) No 844/2012 will apply. A draft list of RMS and Co-RMS will soon be circulated for commenting

- 4. EFSA conclusions:
 - Metalaxyl-M

• Pyraflufen-ethyl

The Commission outlined the main issues reported in the relevant EFSA conclusion.

5. Draft Review Reports for discussion:

1. Flupyrsulfuron-methyl

A draft Review Report has been prepared. Before any decision on the renewal of flupyrsulfuron-methyl will be taken, the status of the proposed classification by EFSA has to be clarified. Comments are requested by 24 April 2015.

2. Thiabendazole

A draft Review Report has been prepared. Comments are requested by 24 April 2015.

3. Lambda-cyhalothrin

A revised EFSA conclusion was provided to the Commission on 11 March 2015.

4. Acybenzolar-S-methyl

The revision of the conclusion by EFSA is ongoing.

5. Amitrole

A draft Review Report has been prepared. Before any decision on the renewal of amitrole will be taken, EFSA has been requested to update the EFSA conclusion on amitrole with respect to the second interim criterion as regards possible toxic effects on endocrine organs.

6. Pyridate

A revised draft Review Report has been prepared. EFSA has published an updated conclusion on pyridate with respect to the second interim criterion as regards possible toxic effects on endocrine organs. Comments are requested by 01 April 2015.

7 Flumioxazin

The evaluation of the information submitted under Article 4(7) by Czech Republic was sent to the Commission and made available to the Commission will discuss internally on the path forward.

8. Sulfosulfuron

No changes to the draft review report and proposal were made. A few Member States repeated their request for a confirmatory data requirement regarding the relevance of certain groundwater metabolites. The Commission repeated that under Regulation (EC) No 1107/2009 no confirmatory data will be set for this situation. One Member State indicated its intention to vote against the proposal because of the leaching to

groundwater. The Committee was informed that the intention was to vote on this substance in May 2015.

9. Fenhexamid

The updated draft Review Report and draft renewal Regulation were explained to the Committee. Some small changes had been made to the Review Report to explain the open points in the EFSA conclusion. The Committee was informed that the intention was to vote on this substance in May 2015.

10. Prosulfuron

An update was provided to explain that a revised EFSA conclusion was available following expert discussion in February 2015 with regard the relevance of the common metabolite, triazine amine. Given the significant changes to the conclusion, the applicant had been invited to submit further comments. For that reason, a draft Review Report was not presented, but would be prepared for the May meeting. It was explained that a common approach would be taken to deal with the issue of the metabolite triazine amine, which is common to a number of sulfonylureas.

11. Pymetrozine

No changes had been made to the draft Review Report presented in the January 2015 meeting. Before any decision on the renewal of pymetrozine will be taken, the status of the proposed classification by EFSA has to be clarified. Comments on the existing proposal were requested by 24 April 2015.

12. Metsulfuron-methyl

A draft Review Report is still in preparation. As regards the metabolite triazine amine, which is a common metabolite for a number of active substances, a common approach will be taken.

13. Esfenvalerate

A draft Review Report has been prepared and presented to the Committee. One Member State indicated its intention to vote against the proposal because of risk to aquatic organisms. Comments were requested by 24 April 2015.

14. Florasulam

A draft Review Report is still in preparation.

15. Ferric phosphate

Molluscicide used as a slug and snail pellet on all edible and non-edible crops both with indoor and outdoor applications. Proposal to approve this active substance as a low risk substance.

A.04 Confirmatory data:

1. Tall oil pitch

An update was provided on the ongoing discussions with the applicant.

2. Etridiazole

A draft Review Report was presented to the Committee and comments on this text were requested by 24 April 2015.

3. Dazomet (updated review report to be noted)

The amended Review Report was noted. One Member State did not take note as they already voted against the inclusion of dazomet.

4. Dithianon

During the last meeting a draft review report was presented, based on the confirmatory data received. Member States were invited to send comments. One Member State suggested asking EFSA to review the data in relation to the nature of residues in processed products. The other Member States were requested to express their view.

5. Dodine

As announced in the previous meeting, the Commission requested EFSA to organise a peer review on confirmatory data. EFSA accepted the mandate. EFSA conclusions are expected by 31 July 2015.

6. Haloxyfop-P

No news.

7. Chlormequat

No news.

8. Metamitron (updated review report to be noted)

The amended Review Report was noted, taking note of the conclusions of the confirmatory data. No changes to the approval are necessary.

9. Buprofezin

A short update about the outcome of the confirmatory data assessment was given. The EFSA Technical Report is available. The Commission has mandated EFSA to further consider some aspects of the assessment and a revised conclusion would be made available by 31 July 2015. Member States were asked to consider the applicability of

the Margin of Exposure approach for metabolites or residues (formed from active substance) which are genotoxic and mutagenic.

10. Pyridaben

The Commission presented a draft amended review report in December 2014. Following comments received form one Member State, the Commission would like to request EFSA to organise a peer review of the confirmatory data with regard to the risk to herbivorous mammals.

11. Azoxystrobin (updated review report to be noted)

The amended Review Report was noted, taking note of the conclusions of the confirmatory data. No changes to the approval are necessary.

12. AOB

No further points.

A.05 Article 21 Reviews:

1. Diflubenzuron

Comments on the Addendum to the draft Assessment Report (DAR) are listed in the Reporting Table, some of which require further discussion. As regards risk assessment issues, the Commission sent a mandate to EFSA. As regards risk management issues, the Commission summarised the key points and asked for consideration by the Member States, to prepare for a discussion at the next meeting. Comments are requested by 24 April 2015.

2. *Chlorpyrifos – state of the dossier*

The Commission informed on the comments received on the proposal for restriction of approval to uses as insecticide with a maximum annual application rate of 245g/ha. Several Member States expressed their disagreement with the proposed restriction, few supported the draft proposal.

On the basis of new toxicological reference values identified in the EFSA conclusions of 2014, the Commission informed on the prioritisation of the re-assessment of Maximum Residue Levels (MRLs) of possible concern. A mandate has been sent to EFSA and a first opinion on MRLs should be available for discussion in June.

Some Member States asked the Commission to submit the new toxicological reference values to formal taking note by the Standing Committee. The Commission resumed the discussion and considering the time constraint proposed to launch the written procedure immediately after the meeting for taking note of the new toxicological reference values.

POST- MEETING NOTE

On 23 March, the Directorate General for Health and Food Safety (DG SANTE) will launch a written procedure requiring all delegates of the Standing Committee on Plants Animals, Food and Feed Committee (PAFF) to take note of the new toxicological reference values on the basis of the EFSA conclusion on the toxicological review under Article 21(2) of Regulation (EC) No 1107/2009 (i) published on 15 April 2014 [Conclusion on the peer review of the pesticide human health risk assessment for chlorpyrifos (ii)] as follows:

| | Reference value | Study | UF |
|------|---------------------------|---|-----|
| ADI | 0.001 mg/kg bw per day | 2 years rat and dog | 100 |
| AOEL | 0.001 mg/kg bw per day | Repeated Comparative cholinesterase assay (CCA) study rat | 100 |
| ARfD | 0,005 mg/kg bw | Acute Comparative cholinesterase assay (CCA) study rat | 100 |

- (i) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50
- (ii) European Food Safety Authority; Conclusion on the peer review of the pesticide human health risk assessment of the active substance chlorpyrifos. EFSA Journal 2014;12(4):3640. [34 pp.] doi:10.2903/j.efsa.2014.3640. Available online: www.efsa.europa.eu/efsajournal

As no member State objected to the written procedure, the new toxicological reference values on chlorpyrifos are considered as officially noted by the Member States.

A.06 Amendment of the conditions of approval:

• Bacillus subtilis QST 713

No new information.

A.07 Basic Substances:

1. Pilot projects: state of play

Considering the proposal which was presented by one Member State and supported by some others for an experts group to be re-organised on this topic, and also the experience gained, the Commission is going to ask EFSA assistance to further

develop the Guidance in terms of technical advice to be given in the preparation of the applications taking also into account evaluation already performed under other European Union legislative frames.

2. New dossiers received

No new dossiers received.

3. EFSA Technical Reports

No new technical reports to be discussed.

i) Salix alba

Discussion postponed.

ii) Vinegar

Discussion postponed.

iii) Lecithins

Discussion postponed.

iv) Artemisia vulgaris

Discussion postponed.

v) Artemisia absinthium

A draft review report and related draft proposal were made available to the Committee. Comments were requested by 24 April 2015.

vi) Tanacetum vulgaris

A draft review report and related draft proposal were made available to the Committee. Comments were requested by 24 April 2015.

vii) Fructose

A draft review report and related draft proposal were made available to the Committee. Comments were requested by 24 April 2015.

A.08 Exchange of views and possible taking note of the following Guidance Documents:

1. Draft Guidance Document on the assessment of certain applications for which reference is made to Article 34 of Regulation (EC) No 1107/2009 (doc. SANCO/11371/2014 Rev. 4) (to be noted)

Discussion postponed.

2. Draft Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (doc. SANCO/13170/2010 Rev. 12) (to be noted)

A new revision has been prepared which deals only with the renewal of authorisations. The Commission emphasised the importance of noting the guidance document at the earliest opportunity even if some details needed to be refined in a later revision.

As a number of Member States expressed strong reservations as regards the legality of the suggested approach described in this Guidance Document, it was decided to postpone the note taking and proceed with further discussions at the Workshop on the Zonal System (see Pt. A 15.04).

3. Draft Guidance document on the assessment of negligible exposure of an active substance in a plant protection product under realistic conditions of use (points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009) (doc. SANCO/12096/2014) (for information)

Discussion postponed.

4. EFSA Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014; 12(10):3874 (for discussion)

Discussion postponed.

5. Draft Annexes of the Guidance Document on the presentation and evaluation of dossiers according to Annex III of Directive 91/414/EEC in the format of a (draft) Registration Report - (Doc. SANCO/6895/2009) (to be noted)

The Commission thanked Germany for all the work they have done on this project. The revised templates of the (draft) Registration Report were noted, taking into account a comment from a Member State as regards efficacy.

The present templates (March 2015) should be used for applications for authorisation, amendment of authorisation and renewal of authorisation of plant protection products as from 1 January 2016.

Previous revisions of the templates may be used for applications for re-authorisation of plant protection products containing active substances renewed in accordance with Regulation (EU) No 1141/2010 ("AIR-2 active substances").

6. Draft Guidance Document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (doc. SANCO/11509/2013 Rev. 4) (for discussion)

Discussion postponed.

7. Draft Template to be used for the List of Endpoints (SANCO/12483/2014 Rev. 3) (to be noted)

Discussion postponed.

8. Guidance Document for applicants on preparing dossiers for the approval or renewal of approval of microorganisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/ 12545/2014 Rev. 2) (to be noted)

Discussion postponed.

The Chair added the following sub-point to the original agenda:

9. Guidance document concerning the parallel trade of plant protection products (doc. SANCO/10524/2012 Rev.5)

There was a discussion in relation to the proposed amendment. Some Member States had questions on how applications for parallel trade permits concerning a product placed on the market under a parallel trade permit should be handled. Some Member States indicated they would deal with these applications under national legislation. The note taking of the amended guidance document was postponed.

A.09 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

Chlorpyrifos (Belgium)

Lime sulphur (Belgium)

Aluminium potassium sulphate (Germany)

Cypermethrin (Germany)

Fipronil (Germany)

Metobromuron (Germany)

Fipronil (Estonia)

Dimethomorph (Spain)

Spinosad (Spain)

Thiacloprid (Spain)

Chlorpyrifos (Spain)

Fludioxonil (Spain)

Tefluthrin (Spain)

Fosetyl (Spain)

Oxamyl (Spain)

Pyraclostrobin (Spain)

Aureobasidium pullulans (Spain)

Dazomet (Spain)

Metrafenone (Spain)

Chlorthalonil (Spain)

Clomazone (Spain)

1-decanol (Croatia)

Pyroxsulam (Croatia)

Chlorophacinone (Hungary)

Diflovidazin (Hungary)

Erwiphage (Hungary)

Bacillus thuringiensis kurstaki strain ABTS 351 (Italy)

Spirodiclofen (Lithuania)

Sodium Silver Thiosulphate (Latvia)

Chlothianidin/Beta-cyfluthrin (Latvia)

Propiconazole (Portugal)

Clothianidin (Romania)

Imidacloprid (Romania)

Thiamethoxam (Romania)

Pyriproxifen (Slovenia)

Beauveria bassiana (Slovakia)

Chlorpyrifos (Slovakia)

Thiamethoxam (the United Kingdom)

The Committee took note of the notifications submitted by Belgium, Germany, Estonia, Spain, Croatia, Hungary, Italy, Lithuania, Latvia, Portugal, Romania, Slovenia, Slovakia and the United Kingdom.

The Commission recalled that under the provisions of Article 53, Member States concerned shall immediately inform the Commission and the other Member States of the measures taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

In addition, the Commission pointed out that even if a Maximum Residue Level (MRL) set under Regulation (EC) No 396/2005 cannot be met and a national MRL is set, a consumer risk assessment needs to be carried out and forwarded to the Commission, the European Food Safety Authority and Member States.

Member States were reminded that they shall put in place the necessary risk mitigation measures to ensure acceptable uses for human and animal health and the environment.

Furthermore, the Commission pointed out that for minor uses Member States should make use, whenever possible, of the provisions laid down in Article 51 of Regulation (EC) No 1107/2009. Member States should also take into account efficacious alternatives which are available among bio-pesticides and bio-control agents to promote low input techniques as required by Directive 2009/128/EC.

A.10 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

No notifications.

A.11 Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (to be noted).

A notification submitted by Belgium was noted by Member States.

A notification submitted by Sweden does not fall inside the scope of Article 36(3) and was not presented to the Committee for taking note.

A.12 Notifications under Article 56 of Regulation (EC) No 1107/2009 (to be noted).

No notifications.

A.13 Sustainable Use Directive (Directive 2009/128/EC):

Postponed.

A.14 News from the European Food Safety Authority (EFSA).

Postponed.

A.15 Report from working groups:

1. Authorisation database

Discussion was postponed but an update of key points would be provided to Member States via e-mail post-meeting.

2. Low risk

Discussion postponed.

3. Post Approval Issues

Discussion postponed.

4. Zonal Workshop

Discussion postponed.

5. OECD-Risk Indicators

Discussion postponed.

A.16 OECD

No news.

A.17 Bees:

1. Review of Neonicotinoids – state of play and next steps

No new points to discuss.

2. EFSA Guidance Document on the risk assessment of plant protection products on bees –and implementation plan (SANCO/10606/2014) "state of play"

No news.

3. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development.

Discussion postponed.

4. AOB

No other points.

A.18 Court cases:

• T-51/15 – PAN v. Commission - Request to annul a decision of the Commission pertaining to access to some documents

Discussion postponed.

A.19 Endocrine disruptors:

Discussion postponed.

A.20 Minor uses:

Discussion postponed.

A.21 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009

No new topics.

2. Questions and answers

No new questions.

A.22 Status of harmonised classifications under Regulation (EC) No 1272/2008.

Discussion postponed.

A.23 Glyphosate:

Discussion postponed.

A.24 Chlorpyrifos-methyl (revised review report to be noted).

The amended Review Report was noted, taking note of the conclusions of the confirmatory data and the conclusions of the assessment of new toxicological study for the setting of acute toxicological reference value. No changes to the approval are necessary. (One Member State abstained and one was against as they did not originally supported approval of substance).

A.25 EFSA Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid.

Discussion postponed.

A.26 Imidacloprid confirmatory data and review of the aquatic risk assessment (Art 21 Regulation (EC) No 1107/2009 (revised review report for discussion).

Discussion postponed.

A.27 Note taking procedures.

The note taking procedure is an informal procedure which is used in the pesticides sections of the Standing Committee on Plants, Animals, Food and Feed since more than a decade with success. It was developed with a view to consensual decision-making based on the principle of unanimity.

During the last years it appeared that a growing number of files (guidance documents, review reports) were blocked, as unanimous support could not be reached, due to some principle concerns in one or very few Member States.

In order to unlock the adoption process in particular cases, the Commission adapted the procedure and foresees the possibility of a support by a majority, in cases where the decision-making is blocked by a principle concern of a minority of Member States, which cannot be solved without compromising the majority view.

A procedure is suggested in a thought-starter paper. Member States were invited to submit comments in writing.

Some Member States question the lawfulness of the procedure and of the Commission suggestion to change it. The Commission clarifies that the note taking procedure is an informal procedure, which is not based on Comitology and has no legal implications.

A.28 Dialogue event on risk assessment of active substances in plant protection products.

Point not discussed.

A.29 Isopyrazam – deadline for submission of confirmatory information

The Chair added the following point to the original agenda:

For isopyrazam, confirmatory data were requested by 31 March 2015. The applicant had informed the Commission in early 2014, that this deadline might not be met for the whole data package, as some points need more extensive research.

A submission plan was provided by the applicant and endorsed by the rapporteur Member State. That plan foresees that a part of the information will be submitted immediately and a part will be delayed.

The Commission intends to present a proposal at the next Standing Committee, extending the submission of a part of the data package.

A.30 Topramezone – new information submitted by the applicant

The Chair added the following point to the original agenda:

The applicant for topramezone submitted a paper regarding the relevance of metabolites of the substance, which was distributed to Member States. Member States are asked to check the relevance of this submission for their internal decision-making.

The Commission will resubmit its initial approval proposal at the meeting in May.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the basic substance Rheum officinale root extract in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (Draft Review Report Doc. SANCO/12694/201 Rev. 0)

One Member State considers that the non-approval proposed by the Commission is a clear indication that the readings of the Article 23 of Regulation (EC) No 1107/2009 on basic substances are not harmonised and therefore asked to reconvene the working group on this topic. This Member State does not fully share the Commission readings and therefore abstained.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance Calcium hydroxide in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011 (Draft Review Report Doc. SANCO/10148/2015 Rev. 0)

Two Member States abstained: one because it considers that there was a lack of information on environmental assessment and that the substance should not be considered a basic substance due to its toxicological properties, and the other one because the substance has an inherent capacity to cause adverse effect on humans and is present in sufficient concentration to present risk. Another Member State voted against considering the classification and toxicological properties of the substance.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EU) No 284/2013 as regards the transitional measures applying to procedures concerning plant protection products

One Member Stated recalled that it disagreed with the adoption of the initial Regulation (EU) No 284/2013 and therefore abstained from a vote on the current draft to amend that proposal.

Vote taken: Favourable opinion.

M.01 News from the Food and Veterinary Office (FVO)

No discussion.

M.02 New scientific publications

No discussion.

M.03 AOB

No discussion.