

Extracts from Coordination meetings related to the renewal of the active substance glyphosate

Document 14. Ares(2015)5492447. COORDINATION MEETING, Monday 30 November
Hearing in ENVI Committee on glyphosate: XPM and [REDACTED] will attend the hearing on 1 December. The same day will also see a lunch on this topic organised by the Greens (MEP Haüsling). [REDACTED] will attend. A meeting with the Cabinet should be organised asap on this matter (Cab to propose a date.)

Document 15. Ares(2015)5492609. COORDINATION MEETING Monday 9 November
- Glyphosate: Communication on this issue should be carefully crafted. A factsheet will be prepared that summarises the procedural history of the file and explain the next steps of the process (**Action: DDG2 with support from 04**). Cabinet will then decide on the way forward, consulting V-P and President's Cabinet, as the process for a new decision needs to be initiated soon. COMENVI will discuss the issue on 01/12.

Document 16. Ares(2015)5492822. COORDINATION MEETING Monday 16 November
- Glyphosate: good technical briefing for the journalists by EFSA last week. Only one question in the Press room. Discussion in COMENVI on 01/12. Cabinet asked for a new mandate to EFSA on the Endocrine Disrupting properties of glyphosate and on import tolerances. Action: Dir E to prepare a note to Cabinet on the next steps.

Document 20. Ares(2015)5895228. COORDINATION MEETING Monday 7 December
- Glyphosate: the DG took part in a debate in COMENVI last week, together with IARC and EFSA. Commission's intervention focused on process rather than scientific evidence, the latter heavily criticised by the parliamentarians. Communication on this issue should be carefully crafted, especially at the time a Commission decision will be proposed. A factsheet should be prepared explaining to non-specialised journalists how such authorisations are issued. Action: unit 04, in cooperation with EFSA. Action: unit 04, in cooperation with EFSA. The decision on renewal of the authorisation will need to be processed quickly so as to respect the tight deadline set up in the recent decision for a prolongation.

Document 22. Ares(2016)168923. COORDINATION MEETING Monday 11 January
- Glyphosate: Cabinet would like to receive the draft measure in advance on the committee meeting on 28-29/01. **Action: unit E3.**

Document 26. Ares(2016)274592. COORDINATION MEETING Monday 18 January
IARC: The Commissioner met Prof. Wild on 14 January, mainly focusing on cooperation on cancer prevention. Prof. Wild will further meet J. Ryan this week. Regarding glyphosate the two sides felt that fuelling public controversy would be counterproductive. EFSA and IARC will meet soon to discuss differences in methodology.

Glyphosate: feedback from the two Vice Presidents is still awaited. In parallel, the EP is organising a conference on 2 March (MEP Poc). This being the management seminar day, SANTE senior and middle managers are not available to attend. In any case, a clear LTT and defensives will be needed to accompany all communication around the next steps on glyphosate Dir E and 04 to follow up still this week.

Document 30. Ares(2016)449305. COORDINATION MEETING Monday 25 January
- Glyphosate: Commissioner met with Professor Portier and other scientists who put into question the overall evaluation process of EFSA. It would be important to invite also the rapporteur of the opinion on glyphosate, so as to balance the representation of the diverging views. Action: L. Miko will

make the first contact, in view of organising a meeting with the Commissioner at the earliest possible date. Before exploring the idea of an evaluation of the EFSA process, in particular on transparency and conflicts of interest, one should check if such an audit has not been done in the past, also in the frame of the Court of Auditors' work (Action: unit 03). Also the existence and necessity of long-term bio-monitoring studies should be examined, especially with DG RTD (Action: unit E3). The ISC for the renewal of the authorisation will be launched this week.

Document 35. Ares(2016)926001. COORDINATION MEETING Monday 22 February
Exception Article 4(3) Regulation (EC) No 1049/2001 applies.

Document 37. Ares(2016)1046278. COORDINATION MEETING Monday 29 February

Glyphosate: [REDACTED]

[REDACTED] In any case, the debate should focus on the scrutiny that will be needed for products containing glyphosate, rather than on the substance itself. Dir E, Cab to follow up.

Document 44. Ares(2016)1292651. COORDINATION MEETING Monday 14 March

Glyphosate: After meeting the German State Secretary on 14 March, XPM will send feedback to Cabinet. Clarity is also needed on what the EC needs to do over the coming months in the absence of a clear decision, in order to comply with the legislation. The Commissioner's letter asking for the disclosure of the relevant studies should emphasise the argument of the public interest.

Document 45. Ares(2016)1292573. COORDINATION MEETING Monday 7 March
Exception Article 4(3) Regulation (EC) No 1049/2001 applies.

Document 47. Ares(2016)1615594. COORDINATION MEETING Monday 29 March
Exception Article 4(3) Regulation (EC) No 1049/2001 applies.

Document 48. Ares(2016)1615860. COORDINATION MEETING Monday 4 April
Exception Article 4(3) Regulation (EC) No 1049/2001 applies.

Document 50. Ares(2016)1726022. COORDINATION MEETING Monday 11 April

Glyphosate – requests for urine tests: MEPs invite the President and several Commissioners, incl. Commissioner Andriukaitis to take urine tests to "scientifically detect traces of glyphosate". EFSA is preparing a LTT for Monday cob, to communicate on substance of such tests, regardless of whether the Commissioners will take them or not. DDG2 and 02 to coordinate the reaction to this invitation.

[REDACTED]

Document 54. Ares(2016)1983806. COORDINATION MEETING Monday 18 April

- Glyphosate: Cabinet asked for the production of a new study on the carcinogenic/ toxicological/ mutagenic effects of glyphosate that could be either performed by JRC or ordered by RTD. The possibility of a new study by the EU should be handled cautiously, so as not to undermine the credibility of the EU authorisation system and not put into question the re-approval of the substance. A note will be produced summarising the situation and options for a new study (Action: Dir E). An update of the MS positions on the renewal of the authorisation of glyphosate will be sent to Cabinet on Friday 22/04, in view of the Hebdo meeting on 25/04 (Action: Dir E).

Document 55. Ares(2016)1984012. COORDINATION MEETING Monday 25 April

Glyphosate: The point will be addressed at the College meeting on 27 April. More information about the possible direction of the discussion will be known after the meeting between A. Vinciunas and M. Selmayr on 25 April. This would give an indication on the possibly needed defensives. It is to be noted that the Scientific Advice Mechanism was asked by President Juncker to produce a report on the process towards the renewal of glyphosate. Results are expected in early May.

Document 58. Ares(2016)2313863. COORDINATION MEETING Monday 2 May

- Glyphosate: The ISC went well and a decision for a 9 years re-authorisation of the substance will soon be presented. In case a qualified majority would not be attainable in Council, a duration of 10 years could be proposed. Action: unit 02 with support from Dir E to prepare a LTT on the issue before the draft is uploaded and becomes visible to the other institutions. In the margins of the short College debate on glyphosate last week, a general College discussion on comitology was announced for 31/08.

Document 60. Ares(2016)2313966. COORDINATION MEETING Tuesday 17 May 2016

- Glyphosate: WHO JMPR will publish on 17/05 the results of their assessment of glyphosate, which appears to be in line with the EFSA one. The DE State Secretary will visit the same day the Director-General to present the DE position on the substance. Support of DE is essential to adopt the decision. Cabinet will be immediately debriefed. Commissioner will present an update of the situation to the College on 18/05. Vote is expected on 19/05.

Document 62. Ares(2016)2418987. COORDINATION MEETING Monday 23 May

- Glyphosate: While no agreement could be found by MS during last week's committee, the Commission is now envisaging an extension of the current authorisation, its duration linked to the receipt of the ECHA opinion on the potential carcinogenic effects of the substance, which, together with the time needed for the EC follow up of ECHA results, could lead in practice to a 2 years prolongation. The next standing committee will take place on 06/06 and would allow for the organisation of an Appeal committee by the end of June, if no agreement could be found and if deemed necessary by the College. At the next committee two options could be presented as draft decisions: the renewal for 9 years or the prolongation of the current authorisation. A document explaining the whole case and its possible impact will be circulated to the MB in case its members get questions on the issue (Action: Dir E, by 24/05 c.o.b.). A specific LTT on the potential extension will also be prepared. (Action: unit 02 and Dir E). To note that S. Jülicher will participate to an event in the EP on 24/05, discussing the risk assessment system for pesticides and using the glyphosate example as an illustration of the matter.

Extracts from Management Board meetings related to the renewal of the active substance glyphosate

Document 17. Ares(2015)5492917. MANAGEMENT BOARD MEETING Monday 9 November

The MB recalled the necessity of a good preparation of communication on the upcoming EFSA opinion on glyphosate.

Document 18. Ares(2015)5492972. MANAGEMENT BOARD MEETING Monday 16 November

Glyphosate: **Dir E** will prepare a note regarding the approach to MRL (import limits), as well as the pros and cons of tackling the issue of endocrine disrupting properties in this context.

Document 29. Ares(2016)449242. MANAGEMENT BOARD MEETING Monday 25 January

Glyphosate: **DDG2** will contact the German lead that prepared the assessment report for submission to EFSA, in order to set up a meeting with the Commissioner, in view of dispelling the doubts as regards the regularity and robustness of the process.

Document 59. Ares(2016)2313916.MANAGEMENT BOARD MEETING Monday 2 May

Glyphosate: The LTT on the proposed 9-year authorisation should minimise the hype around the choice of the number of years.

Extracts from 03 Weekly Reports and unit meetings related to the renewal of the active substance glyphosate

Document 12. Ares(2015)4648211. 03's Weekly Report (21-28 October 2015)

Glyphosate

On 22 October, SANTE 04, 03, E3 had a teleconference with EFSA on the next steps concerning the EFSA glyphosate review and the intention of EFSA to hold an information session on it. Given the high public sensitivity of the matter and the fact that a number of MEPs have written to Commissioner Andriukaitis raising a number of specific scientific points, it was agreed that the EFSA press action will be a technical background information event rather than a fully-fledged press conference, and it will be held on 10 November 2015 rather than the originally scheduled 3 November. In addition, it was decided that EFSA will prepare a document addressing the points raised by the MEPs which will serve as the basis for the Commissioner's response and will be part of the press event materials. All documents will be shared and agreed by all involved, and the EFSA press action should not precede the response by Commissioner to the MEP letters. The EFSA documents should be ready for internal review by 5 November 2015.

Document 19. Ares(2015)5915801. SHORT MINUTES OF 03'S UNIT MEETING DATE 8 DECEMBER 2015

DG took part in a debate in COMENVI on Glyphosate together with IARC and EFSA. Communication on this issue should be carefully crafted; a factsheet should be prepared explaining to non-specialised journalists how such authorisations are issued.

Document 28. Ares(2016)501881. SHORT MINUTES OF 03'S UNIT MEETING DATE 26 JANUARY 2016

Glyphosate: Commissioner met scientists who put into question the overall evaluation process of EFSA. Should be checked if an audit on transparency and Col has not been done in the past, also in the frame of the Court of Auditors' work. Action: unit 03.

Document 36. Ares(2016)952570. D1's Weekly Report (17 - 24 February 2016)

2. BILATERAL MEETING SANTE/EFSA (17 FEBRUARY 2016)

Participants: X. Prats Monné, M. Scannell, [REDACTED]

XPM opened the meeting by stressing that SANTE and EFSA have to "stick together" in general terms and in particular when the EU regulatory framework is questioned.

The following points were discussed:

Glyphosate: joint aim now is to defend the EU system and to provide to the Commissioner the arguments to defend himself. Next steps envisaged:

[REDACTED]

- Concerted assessment of Glyphosate co-formulants. EFSA might have a coordination/prioritisation role on the MS activity (500 substances envisaged of which 50 are of major relevance).
- Address criticism to the independence of the MS systems of pesticides assessment.