LTO Noord Conference	Thursday 22 December 2016, The Netherlands

Scene Setter

- [redacted]
- [redacted]

- **IMPORTANT:**

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AGRI D.2
☎ [redacted]

First key messages

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- Glyphosate is currently undergoing periodic renewal of approval in the EU.

- The Commission has extended the approval of **glyphosate** for a limited period of time, until the end of 2017 at the latest. Before this, EU Member States had failed to take responsibility for this decision.
- The risk assessment by Member States and EFSA (European Food Safety Authority) was overall favourable. The EFSA conclusion on carcinogenicity, supported by 27 Member States, was that **glyphosate** was unlikely to be carcinogenic.
- ECHA (European Chemicals Agency) is currently carrying out an assessment for harmonised classification, including an evaluation of carcinogenicity.
- The Commission has the power to decide, at any time, to request an update of the EU assessment and, as for any other substance; it will not hesitate to do so to ensure a high level of protection of human health.
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- [redacted]

Second key messages (defensive points)

First question:

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Second question:

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Third question: Why did the European Food Safety Authority (EFSA) and the International Agency for Research on Cancer (IARC) reach different conclusions on the issue of the carcinogenicity of glyphosate?

- The main reason was the use of different approaches: EFSA focused on the pure active substance, as foreseen in the legislation, whereas IARC also included in its assessment formulated products.

Fourth question: When will you take a decision about the possible renewal of glyphosate?

- In view of the time required by the European Chemicals Agency (ECHA) to assess the dossier concerning the harmonised classification, it was necessary to extend the approval period of the active substance until six months from the date of receipt of the ECHA opinion by the Commission – and until 31 December 2017 at the very latest.

- By that date, the Commission has to decide whether or not the approval of glyphosate shall be renewed. So far, the Commission does not have evidence that the use of glyphosate (under the conditions laid down in the Commission Implementing Regulation adopted on 29 June this year) would lead to a risk to human or animal health or to unacceptable risks to the environment.

Fifth question: When will you take a decision about the possible renewal of glyphosate?

- In view of the time required by the European Chemicals Agency (ECHA) to assess the dossier concerning the harmonised classification, it was necessary to extend the approval period of the active substance until six months from the date of receipt of the ECHA opinion by the Commission – and until 31 December 2017 at the very latest.

Background

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Glyphosate

Glyphosate is the world's most widely used herbicide. It is used in the EU by several MS on almost half of their total crop area. The substance is so widely used that it is commonly found in bread, beer and the urine of people in several countries across Europe. Glyphosate was authorised in the EU until 2015, the discussion was lead around the **renewal of authorisation.**

Rapporteur MS Germany did not find evidence of carcinogenic property. EFSA determined that glyphosate is unlikely to be genotoxic or cancer-causing (November 2015).

WHO's International Agency for Research on Cancer (**IARC**) **classified glyphosate as "probably carcinogenic to humans"** (spring 2015). The difference between IARC and EFSA evaluation is due to different results of their hazard assessments (different classification models) and to different 'Weight of evidence' approaches (for IARC *one* study concluding carcinogenic is sufficient).

The approval of the active substance has been extended by the Commission until 31 December 2017 to enable the ECHA to deliver its opinion on the hazard properties of glyphosate. Before this, EU Member States had failed to take responsibility for this decision.

According to EFSA, glyphosate is not proposed to be classified as carcinogenic under EU rules. Currently and until the end of 2017 ECHA is evaluating the substance. **Glyphosate is (currently) not proposed to be classified as carcinogenic** under the EU regulation for classification, labelling and packaging of chemical substances. In case of a proposal for a classification as carcinogenic, the Commission will have to react and retract the authorization.

Glyphosate is a non-selective herbicide. It has to be used prior to planting or emergence of the crop (**pre-plant/pre-emergence)** or on **glyphosate-resistant (GM) crops**. **Pre-harvest use** is applied in north western European countries for weed control and to enhance ripening of crops (desiccant properties). In summer 2016, the conditions of authorization for glyphosate have been tightened: scrutiny of pre-harvest uses has to be reinforced, use in specific areas has to be minimised and the co-formulant POE-tallowamine was banned from glyphosate-based products.

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