BfR review of the IARC monograph of glyphosate brought into the European assessment process

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The Federal Institute for Risk Assessment (BfR) has reviewed the monograph of the International Agency for Research on Cancer (IARC) on the health assessment of glyphosate and given its evaluation to the Federal Office of Consumer Protection and Food Safety (BVL) within the specified timeframe. In the next stage of the process, the BVL forwarded the German evaluation to the European Food Safety Authority (EFSA) which will in turn send it to all EU member states for consultation. By doing so, it will be achievable to make the review of the IARC monograph as part of the reassessment of glyphosate within the scope of the EU examination of active substances. The evaluation of the IARC monograph will be finally discussed and coordinated at a Pesticide Risk Assessment Unit (PRAS) Meeting of experts at the EFSA under consideration of all comments from the EU member states so that the result of the joint consultation can flow into the final EFSA recommendation to the EU Commission.

Like all other active substances contained in plant protection products, glyphosate is reassessed according to schedule with regard to its risks for health and the environment, as well as its effectiveness, within the scope of the joint EU approval process for active substances. Germany was appointed by the EU Commission as the Rapporteur Member State (RMS) for the joint assessment of the active substance glyphosate. Within the reassessment process, the BfR was commissioned with the assessment of the health risks of the active substance. After consultation with the member states and general public in December 2014, all of the requested preliminary work was then sent to the BVL which in turn forwarded the entire report to the EFSA

Following a PRAS-Meeting of experts at the EFSA in February 2015, the Renewal Assessment Report (RAR) on the health assessment of the pesticidal active substance glyphosate, which had already been prepared and revised by the Federal Institute for Risk Assessment (BfR), was reviewed again. This amended version was sent to the Federal Office of Consumer Protection and Food Safety (BVL) on 1 April 2015 for forwarding to the EFSA.

The International Agency for Research on Cancer (IARC), an institution of the World Health Organization (WHO), has classified glyphosate as “probably carcinogenic to humans (Group 2A)”. The complete monograph on glyphosate (Volume 112) was published on 29 July 2015. As the RMS for the European renewal process for the approval of the active substance glyphosate, Germany was commissioned by the EFSA to prepare a review of the IARC monograph by the end of August 2015 so that this scientific report (an addendum to the RAR can be taken into consideration in the reauthorisation process. The EFSA is sending this evaluation to all EU member states for consultation. By doing so, it will be achievable to make the review of the IARC monograph as part of the reassessment of glyphosate within the scope of the EU examination of active substances. The evaluation of the IARC monograph will be finally discussed and coordinated at a further PRAS-Meeting of experts on mammalian toxicology at EFSA.

under consideration of all comments from the EU member states so that the result of the joint consultation can flow into the final EFSA recommendation to the EU Commission. Oberservers from IARC, the WHO-panel of the Joint Meeting of pesticide residues (JMPR) and the US Environmental Protection Agency (US-EPA) will be invited. To protect the official decision-making process on a European level, the supporting documentation of the report is not made available to the general public until the process has been completed.

The EFSA will prepare a recommendation for the European Commission on the basis of the revised entire report. In consultation with all EU member states, the European Commission makes a decision on the first-time authorisation or reauthorisation of the active substance contained in a plant protection product. Only approved active substances can be included in the zonal authorisation process for plant protection products and authorised for individual member states.

For the latest status of the authorisation of the plant protection product active substance glyphosate, please refer also to the Background information of the BVL:

http://www.bvl.bund.de/DE/08_PresseInfothek/01_FuerJournalisten/01_Presse_und_Hintergrundinformationen/04_Pflanzenschutzmittel/2015/2015_09_10_HI_Glyphosat.html