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NO.			
Tijdschrift			
Auteurs			
Titel			
Aanpak			
Bijlage			
Opdrachtgever			
Aanvraagnummer			
Dossier			

Re: SUBMISSION OF POTENTIALLY ADVERSE CHEMISTRY DATA RELATING TO *Zapper Spray*, 15562 N

Dear Mr 5.1.2.e WOO,

On behalf of SBM Développement, SBM Life Science is making this submission relating to the ambient storage stability data that has been generated for the product *Zapper Spray*. The formulation is also known as 'DFF+GIP AL 2.8' (102000028338).

When SBM received the long term GLP stability study there was an apparent loss of glyphosate (GIP) observed at ambient temperature following the 24 month period.

No observed loss of active substance was detected during the earlier accelerated 2-week study at 54°C.

After further investigation, it has become evident that the values for GIP content were too high in the earlier study possibly as a result of a failure in the calibration and should be considered as outliers. Analysis of additional data (non-GLP) provide clear evidence that the apparent decline in GIP seen in the ambient storage study was not a real effect and the actual levels of GIP present continue to meet acceptable tolerances. However, these data are being submitted in accordance with Article 56(1) of Regulation 1107/2009. The data have been submitted to the UK, with a request to evaluate this data on behalf of the central zone.

An associated statement prepared by SBM explains the issue in further detail.

Please contact me if you need further information.

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ix Regulatory Manager