

ECHA Committee Risk Assessment

From: ECHA Committee Risk Assessment
Sent: 13 March 2017 08:52
To: BOWMER Tim; [REDACTED]
Cc: [REDACTED]; ECHA Committee Risk Assessment
Subject: FW: Mouse Lymphoma in Kumar Study
Attachments: [REDACTED]statement_statistics Kumar study.pdf

Dear all,

See [REDACTED] message and attachment.

[REDACTED]
From: [REDACTED]@ecpa.eu]
Sent: 13 March 2017 08:49
To: ECHA Committee Risk Assessment <rac@echa.europa.eu>
Subject: Mouse Lymphoma in Kumar Study

Further to the discussion on mouse lymphoma with glyphosate. The GTF have asked me to forward the attached statement by [REDACTED] and the correction in mouse lymphoma that impacts the overall assessment of the study. I would be grateful if you could provide this to the rapporteurs please.

Many thanks and see you all tomorrow

Best regards

[REDACTED]
[REDACTED]
[REDACTED]
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Oberbuchsitzen, 09.03.2017

**Statement on Statistics on Malignant Lymphoma in Study No. TOXI: 1559.CARCI-M
Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice (Performed at
Rallys Research Center, Peenya, Bangalore, India**

Sir,

In the above mentioned study, the statistical analysis performed by the responsible CRO has been considered inadequate, as detailed in the report AnaPath Study Number 11921.: ‘Statistical Evaluation of Pre-Neoplastic and Neoplastic Lesions from Study: Study No. TOXI: 1559.CARCI-M Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice. Performed at Rallys Research Center, Peenya, Bangalore, India‘

In addition to the details given on the methodological weaknesses, there were differences in the total number of malignant lymphoma counted, as tabulated below. Differences are marked by a shadow.

Group	1		2		3		4	
Sex	M	F	M	F	M	F	M	F
AnaPath : Incidence	12	19	16	20	18	19	19	25
Rallys : Incidence	10	18	15	20	16	19	19	25

The animal numbers of lymphoma bearers in questionable groups and/or sexes were re-checked:

Group 1 Males:

12 animals are reported in the single animal data sheaths of the original report, including nos.: Ma1128, 1129, 1140, 1144, 1147, 1151, 1158, 1159, 1162, 1163, 1169, 1165.

Group 1 Females:

19 animals are reported in the single animal data sheaths of the original report, including nos.: Ma1321, 1325, 1328, 1333, 1334, 1335, 1337, 1339, 1341, 1345, 1346, 1348, 1350, 1354, 1355, 1360, 1362, 1365, 1366.



Group 2 Males:

16 animals are reported in the single animal data sheaths of the original report, including nos.: Ma1173, 1174, 1176, 1180, 1181, 1188, 1189, 1193, 1195, 1203, 1207, 1212, 1213, 1214, 1217, 1220.

Group 3 Males:

18 animals are reported in the single animal data sheaths of the original report, including nos.: Ma1232, 1230, 1234, 1236, 1242, 1243, 1244, 1247, 1248, 1251, 1252, 1254, 1257, 1263, 1265, 1266, 1268, 1269.

Therefore, and in addition to the comments on the statistical analysis in the original report, made in the AnaPath Study 11921, the number of malignant lymphoma per sex and group used in the original statistical analysis has been counted too low for both sexes in the controls, as well as in males of the low and mid dose groups. This however, affects the statistical analysis heavily. Two malignant lymphoma more in the control males and one lymphoma more in the control females changes the statistical results. Therefore, the statement given in the AnaPath Study 11921 is deemed to be correct and supported by the afore mentioned differences:

‘... When appropriate statistics are applied to the tumour incidence data and the incidence data of malignant lymphoma in particular, no statistically significant increase in tumour incidence is found in this analysis...’

AnaPath GmbH

March 9, 2017