

## Monsanto Manuscript Clearance Form Global Regulatory

**NOTE:** this form needs to be completed and submitted for review at least 4 weeks prior to manuscript submission and a minimum of 2 weeks prior to abstract/presentation submission

Questions regarding completion of this form can be directed to Jeanna Graf [REDACTED] or Kevin Glenn [REDACTED]

Date: 2/29/2012

Please indicate type of publication:  Manuscript  Conference/meeting presentation  Abstract

Has this information been publicly disclosed previously?  No  Yes If yes, where & when? This manuscript reviews glyphosate genotoxicity publications since the Williams et al. (2000) review

(If the information has previously been published, no need to include Patent Scientist & Patent Atty review)

Title: Review of Genotoxicity of Glyphosate and Glyphosate Based Formulations

Author(s): David Saltmiras, Larry Kier (consultant)

Author Handling Correspondence: David Saltmiras

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Is this related to a Monsanto collaboration?  No  Yes If yes, Other

Meeting Date & Location at which Manuscript will be presented:

Journal Submitted To: Reg. Toxicol. Pharmacol.

**Lead Author's Comments:** (Please provide information on purpose of presentation/publication and any relevant patents or manuscript disclosures.) This manuscript provide a comprehensive quality check on the large number of genotoxicity publications on glyphosate since the Williams et al. (2000) glyphosate toxicology review manuscript. This work falls under the scope of the EU Glyphosate Task Force and will be a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic.



**Requestor must first collate all the signed pages and then send them to Gracie Williams, BB1B (Chesterfield Valley).**

## **Monsanto Manuscript Clearance Reviewer Guidelines Form** **Global Regulatory**

**Reviewers:** Please complete your review of this manuscript within 7 working days (abstract/presentation) and 21 working days (publication/manuscript). If timely review is not possible, please communicate this to the lead author within 2 – 3 days of receipt of this MCF indicating a delegate within your organization that can perform the review. Also, please note, reviews are being completed **concurrently**, not sequentially.

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Determine if this is the first TC publication on this trait or MON # and that the publication follows past TC practices with earlier Monsanto publications. Ensure that the scientific conclusions (e.g. of compositional equivalence, natural variability) are justified by presented data. Ensure that individuals that have contributed substantial, direct, intellectual work to this manuscript are included as authors and other significant contributions are appropriately acknowledged.

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Determine that the scientific conclusions are clearly stated and supported by the data. Review assessment of the TC Program Lead (if available). Determine if other TC representatives need to review and provide additional scientific insights and input. Ensure that individuals that have contributed substantial, direct, intellectual work to this manuscript are included as authors and other significant contributions are appropriately acknowledged.

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Ensure that descriptions of MOA, product concepts, etc. are consistent with Product Core Team (PCT) standards, any prior Biotechnology communications, submission documents, etc. Ensure that the manuscript is consistent with the Regulatory and Biotechnology publication strategy.

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Ensure that publication of MON # (or other invention) is legal and does not compromise Monsanto FTO.

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Responsibility	Program Lead, TC	TC Lead	Regulatory TL	Crop/Chem TL	Regulatory Law	Scientific Affairs	Biotechnology	Patent Scientist	Patent Attorney	Regional Lead
Scientific conclusions are clearly stated and supported by the data	x	x								
Determine whether publication is first TC publication on this event and follows past TC publication practices	x									
Forward MCF to other TC representatives for review		x								
Description of MOA, product concept, etc. is consistent with PCT and Biotech standards			x	x		x	x			
Manuscript fits with crop team's overall strategic positioning and publication strategy			x	x		x	x			x
Confirm no comparative assessments or statements between different MONs and that reference to other MONs is accurate and consistent with prior communications				x						
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Verify authorship and acknowledgements	x	x								x