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Position Description

Toxicology Manager

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Document Type

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BUSINESS PERFORMANCE

Business Goals

Goul:

PROVIDE ONGOING TECHNICAL LEADERSHIP SUPPORTING GLOBAL REREGISTRATIONS AND

TOXICOLOGY EVALUATIONS OF GLYPHOSATE

- 1. EU Rapporteur and EFSA Reviews of Glyphosate Annex I Renewal (A1R) Dossier
- (a) As Chairperson of the glyphosate Toxicology Technical Working Group (ToxTWG), coordinate ToxTWG responses to regulator questions and draft Reevaluation Assessment Report (dDAR), including technical responses to NGO submissions (by October 31) and DARs (summer 2013).
- (b) Coordinate and complete ToxTWG literature review update for submission to align with key supporting publications anticipated in March/April, 2013. Ensure rebuttal position documents in Annex II Dossier address adverse health effects in the 2012 literature.
- (c) Identify potential future glyphosate data gaps under the new 1107/2009 regulation data requirements by end FY2013 if considered business critical.

Employee Comments

- 1 (a) Technical responses to two previously unanticipated NGO submissions were coordinated and submitted in a timely manner, before October 31st. Ensured comprehensive technical responses/comments to the Rapporteur's dRAR were submitted within the small window offered by the authorities # In response to Rapporteur#s proposed decrease in AOEL (0.2 to 0.1 mg/kg, based on Syngenta ADME data and revised lower NOAEL) and slight ADI increase (from 0.3 to 0.5 mg/kg/day), I responded with strong technical rationales for an increase in the AOEL and further increase in the ADI, in support of future market growth in Europe.
- 1 (b) Led the completion of 2012 toxicology literature review and rebuttal documents in alignment with other technical working groups and GTF strategy, including key supporting publications.
- 1 (c) No longer considered business critical.
- 2. No activity due to a lack of technical toxicology requests from Agencies regarding registration review.

EXHIBIT WIT: Michellan

DATE: 1415

D. Srebrenick, CRR, CLR

- US/Canada Registration Review as chair of the Joint Glyphosate Task Force (JGTF) ToxTWG, coordinate technical responses to the agencies as requested.
- 3. US EPA Endocrine Disruptor Screening Program Coordinate responses back to the EPA regarding glyphosate EDSP Tier I Screening Assay Test Order submissions
- 4. Respond to regional glyphosate ADI reviews and issues, initiated by regulators in Brazil, Argentina and Japan, as needed.

3 Await Agency review of data

4 (i) Coordinated a pathology peer review and Pathology Working Group (PWG) to address kidney effect concerns noted by the Japanese Food and Safety Commission in a chronic rat study owned by the Taiwanese consortium, TAC. The highly favorable results of the peer review and PWG, demonstrating an absence of glyphosate related kidney effects, are valuable in ameliorating FSC concerns and preventing a considerable decrease of the glyphosate ADI in Japan.

Additional: Researched and highlighted potential toxicological issues and data gaps for two inert chemistry groups under consideration by the chemistry formulations group, (1) poly beta-amino esters (as part of a consideration in a third party agreement) and (2) intermediate 210 18EO (under consideration as a global replacement for POEA)

Goal:

PROMOTE GLYPHOSATE FREEDOM TO OPERATE THROUGH PROACTIVE ENGAGEMENT OF EXPERTS. TECHNICAL PUBLICATIONS AND RESPONSES TO THIRD

PARTY ALLEGATIONS

- 1. Interface with internal and external experts to ensure high quality toxicology manuscripts are submitted for peer reviewed publication including (i) an updated in vitro cytotoxicity manuscript for resubmission by end of 2Q FY2013 (Hodges); (ii) cardiac malformations review manuscript to Critical Reviews in Toxicology by December 2012 (Williams, Kimmel, DeSesso); (iii) a single combined genetox review paper addressing published data and EU Glyphosate Task Force studies by January 2013 (Kier and Kirkland); (iv) a review manuscript of GTF member company proprietary rodent chronic/carcinogenicity studies by 2Q FY2013 in preparation for a possible IARC review of glyphosate (Greim); (v) weight of evidence manuscript for peer reviewed publication of glyphosate EDSP data and other scientifically relevant data, for journal submission by end of 2Q FY2013 (Williams, DeSesso and Levine).
- 2. In effort to enhance global long-term scientific outreach and freedom to operate, coordinate (i) an initial South American Toxicology Expert Panel meeting in Buenos Aires by the end of FY2013 and (ii) the 2012 EU

Employee Comments

- 1 (i) this paper was reprioritized to FY2014, based on more significant issues raised in 2013
- 1 (ii) published Feb 2013, lending significant expert endorsed positioning in support of (a) Monsanto responses to published Earth Open Source arguments, (b) the EU Rapporteur's scientific review for these important and controversial developmental toxicity endpoints with respect to glyphosate, and (c) the APVMA review of Earth Open Source media campaigns (see #Additional# below).
- 1 (iii) published genetox expert review manuscript with and unprecedented and extensive on-line data supplement of formerly proprietary data from multiple companies on the Glyphosate Task Force, April 2013. This landmark publication, also cited by APVMA, is a high value resource for scientific affairs and technical responses to the growing body of literature with contrary conclusions based on poorly constructed experiments and/or misinterpreted / over extrapolated data.
- 1 (iv) Final draft approved by MCF, but adopted a new strategy is to engage the TAC consortium in Taiwan/Japan and include their data, after developing sufficient confidence and rapport with TAC after the PWG report is finalized.

Glyphosate Expert Advisory Panel meeting in Harrogate, UK 8/9 November, 2012.

- 3. Provide the necessary technical review and input to enable (i) the EU Genius web portal to go live as a FTO and educational resource in the region and (ii) update the monsanto.com web site glyphosate safety and human health information.
- 4. As a member of the Monsanto Issues Management Team, respond to third party allegations in a timely manner, as required.

- 1 (v) delayed until outcome of the EPA's SAP3 on weight of evidence (held July/August) is made public (anticipated October, 2013).
- 2(i) Meeting not planned, but discussions with Argentina Scientific Affairs are now focusing on a workshop and side meeting in conjunction with an ILSI Argentina in 2014. This meeting will be driven by regional scientific affairs issues
- 2 (ii) COordinated the November EU Expert Panel meeting which provided opportunity for valuable interaction with experts and peers, consolidating strategies in addressing activist publications (eg. Seralini and Earth Open Source) and industry sponsored technical publications supporting FTO and glyphosate EU Annex I Renewal.
- 3 (i) Technical reviews were conducted as requested, leading to successful launch of the EU Genius Web Portal. This on-line resource was also provided to Monsanto Technical Development for use in a training manual for field and sales personnel.
- 3 (ii) No activity on monsanto.com updates, owing to successful launch and maintenance of the EU web portal.
- 4 (i) Provided input and updates on technical publications to the Monsanto Issues Management Team and provided support to scientific affairs response documents as requested.
- 4 (ii) Accepted the invitation to serve as an expert on the "GMOanswers.com" industry initiative and provided expert responses to questions posted on-line
- 4 (iii) Successfully facilitated numerous third party expert letters to the editor which were subsequently published, reflecting the numerous significant deficiencies, poor study design, biased reporting and selective statistics employed by Seralini. In addition, coauthored the Monsanto letter to the editor with Dan Goldstein and Bruce Hammond.

Additional: Conducted a thorough critique and provide technical feedback to Australian Pesticides and Veterinary Medicine Authority (APVMA)

technical review of published allegations against glyphosate health and safety by Earth Open Source. This review proved imperative as obsolete data, incorrect interpretation of select literature and absence of key recent expert review manuscripts on glyphosate were detailed in my comments. The APVMA final report was recently posted on-line (August 6, 2013) and included my corrections/clarifications and additional important citations. This authoritative review of activist accusations will prove a valuable and accurate expert resource in future product defense and maintaining FTO in Australia and abroad.

Additional: Contributing author on three published abstracts supporting two posters (ACT 2012, SOT 2013) and one symposium platform session (SETAC

2012) demonstrating favorable results for glyphosate EDSP Tier I assays, in alignment with our JGTF communication strategy to disseminate results at public scientific venues.

Goal:

IMPROVE ORGANIZATIONAL EFFECTIVENESS AND CULTURE AND PROMOTE SAFETY

- 1. Provide accurate and timely budget forecasts with the goal of actual within 5% of the forecast on a monthly basis.
- 2. Promote safety by actively participate in monthly Near Miss Network meetings.
- Circulate informative monthly email updates on glyphosate toxicology deliverables and milestones.
- 4. Continue mentoring / training Korean Regulatory Affairs Manager (Haeman Jang) to facilitate global technical support and knowledge transfer.

Employee Comments

- Provided frequent updates on multiple new unanticipated and upcoming budget items.
- 2. Actively participated on the Near Miss Network, attended monthly meetings (when not travelling), volunteered on the incentive award sub-committee and planned safety fair photo booth logistics.
- Provided multiple formal and informal updates throughout the year including detailed emails summarizing significant milestones for senior management as needed.
- 4. Prepared and executed regular (at least monthly) training teleconferences until Haeman changed roles and relocated to Singapore. I proposed an opportunity for him to broaden his network by rotating training with different STL toxicologists for different areas of expertise, which was approved and adopted by Haeman and STL toxicology colleagues.

Additional Accepted invitation to actively participate with colleagues from other disciplines on the RPCSC Engagement Committee, to help foster and maintain employee engagement within the organization.

Overall Business Comments
a 2013 Business Conduct Ethics Award for involvement on this project.
presentation and discussion on glyphosate safety and toxicology. Received
Additional: Provided technical input into Zarate, Argentina employee

PERSONAL DEVELOPMENT

Global Competencies

1. Relationships & Networks

- Expand internal Monsanto network and gain recognition for toxicology expertise through meeting with new and established Monsanto colleagues, presenting seminars and coordinating technical meetings.
- 2. Establish new relationships with external technical experts in Europe and South America through collaborative projects and expert meetings.

Employee Comments

- 1 (i) Considerable success in expanding my internal network in showing genuine interest in different regional interests, demonstrating concern and respect for locally established projects and time lines, as reflected in multiple requests from international colleagues in Australia, Europe, Brazil, Argentina, India and Japan and my consistently rapid technical responses.
- 1 (ii) Secured opportunities to increase internal visibility by presenting technical seminars/lectures/talks including
- # guest technical speaker on endocrine disruption at the Brussels Office "brainfood" seminar series;
- # Introduction to Toxicology at the most recent Global Regulatory Science Training program;
- # a glyphosate toxicology update at the first Chemistry Regulatory Affairs Portfolio meeting, April 2013;
- # Regulatory Sciences Review on variability in multiple toxicology data sets;
- # glyphosate toxicology and risk assessment (and tour the automated greenhouse facility)
- |#
- 1 (iii) Engaged in candid dialogue with colleagues in India and STL Regulatory Affairs, resolving differences of opinion and developing collaborative solutions to meet the regulatory science and business needs of both Monsanto and our business partner in India, Mahyco.
- 1 (iv) Assumed responsibility for coordinating Toxicology Technical Team monthly meetings, scheduled speakers and circulated meeting monthly meeting agendas and meeting reminders routinely, at least one week in

	advance of each meeting.
	2 (i) I successfully recruited a new expert in the field of genotoxicity for participation on the EU Glyphosate Expert Toxicology Panel, Professor David Kirkland. Subsequently was able to further develop this network by providing Monsanto partial sponsorship of the Environmental Mutagen Society's international genotoxicity workshop in Brazil.
	Additional: Actively sought to broaden and interact with my network of internationally recognized scientists outside Monsanto, successfully garnering their interest and involvement on collaborative projects. This has also opened doors to candidly exchange ideas and scientific information as well as to leverage these to execute Monsanto strategies. # Attended the PWG as an observer, developing rapport with internationally recognized pathology experts from New Zealand, Japan and the USA. # Throughout the late 2012 Seralini rat cancer publication and media campaign, I leveraged my relationship the Editor if Chief of the publishing journal, Food and Chemical Toxicology and was the single point of contact between Monsanto and the Journal. # Earned the trust and respect of Asian colleagues from the TAC consortium as reflected by enhanced cooperation and rapid feedback on short time lines, which strengthened the foundation for future collaborative efforts to support the global glyphosate market. # I was asked to represent Monsanto Toxicology on the HARC, attend regular meetings and disseminate relevant information to Toxicology team members. # Prepared and presented a technical toxicology and risk assessment seminar to an Indonesian academic scientist visiting Monsanto STL under a Society of Toxicology international scientist training program. # I accepted an invitation to be a peer reviewer for a high profile toxicology journal. Subsequently peer-reviewed several manuscript submissions, wherein my recommendations to reject those manuscripts were
	accepted/adopted by the reviewing Editor. # I was approached by the president of the Society of Toxicology Risk Assessment Specialty Section, with whom I have developed a strong external technical rapport, and accepted his invitation to join the technical committee reviewing abstracts and select award winners for the 2013 SOT national annual meeting in San Antonio.
. Courage & Candor	Employee Comments
3. Agility	Employee Comments

Demonstrate agility in meeting timelines for unanticipated Monsanto Issues Management Team technical responses (e.g. Seralini papers), while meeting critical regulator response time lines and CLA Endocrine Policy Forum technical working group deliverables (e.g. glyphosate EDSP Tier 1 data tables by Nov 2012).	(i) Effectively engaged on collaborative responses with Scientific Affairs to third party allegations and publications without compromising regulatory time lines. (ii) Effectively attended to the needs of the external Endocrine Policy Forum (EPF) by identifying and working with key individuals within the Glyphosate Task Force to meet important EPF strategic initiatives which will impact regulatory policy and testing paradigms. (iii) Having demonstrated proficiency is addressing urgent requests for technical input on issue responses, helped Monsanto strategically adapt to the external environment as a technical expert responding to questions on "GMOanswers.com". (iv) Demonstrated agility in meeting responsibilities while volunteering for interview panels for several open positions in Chem Reg Affairs (two positions and Ecotoxicology (one position), interviewing 13 candidates amidst a very demanding year of technical and leadership responsibilities. Adhered to key technical activity time lines including unanticipated regulatory responses (e.g. EU Rapporteur livestock risk assessment for glyphosate). (v) Effectively altered the technical/business strategy by delaying a glyphosate carcinogenicity review manuscript submission, in order to gain confidence of the TAC group through another project. The strategy was to allow time to develop/strengthen relationships with TAC, demonstrate Monsanto's sound scientific strategies and then collaborate to access TAC data for inclusion within the manuscript. Additional: Demonstrated agility in attenuating potential cultural misunderstandings/miscommunications between company representatives from Europe, Japan, Taiwan and the USA. Additional: Amidst significant growing technical and administrative responsibilities, accepted invitation to sit on the Engagement Committee, providing further opportunity to expand my internal network and influence RPCSC approaches to increasing engagement and productivity within the
4. Initiative & Foresight	organization. Employee Comments

5. Results Orientation	Employee Comments			
Func/Technical/Other Competencies				
Competency: 1. Establish a reputation for technical proficiency both internally and externally through chairing regional technical working groups, leading expert panels and interacting with/engaging internationally recognized experts in the field of toxicology. 2. Complete and submit American Board of Toxicology recertification examination and Continuing Education documentation for 2008-2012 on schedule. Ensure completion of 20 continuing education credits for 2013.	Employee Comments 1 (i) Based on feedback to senior management from Monsanto internal customers, a reputation for technical proficiency, both domestically and internationally, has been established (e.g. India Regulatory Affairs lead feedback to Nordine regarding my attention and responsiveness to multiple areas; glyphosate formulation registration, cotton RRF testing strategy and protocol development). External collaborators have overtly recognized the valuable contributions to high quality peer reviewed scientific publications in the printed acknowledgements (e.g. glyphosate genotoxicity review manuscript). 1(ii) Expressed interest in supporting the Global Regulatory Science Training program and was subsequently involved in refining and delivering "Introduction to Toxicology" to the most recent class. 1 (iii) Tracked and provided guidance to EU colleagues on EFSA Dermal Absorption Guidance Document in support of EU formulation product registrations. Mentored Elizabeth Webb in the preparation, design and conduct of human in vitro dermal absorption studies. Utilized external expert network (Jon Heylings, internationally recognized expert on dermal absorption) to better understand practical implications of the EFSA dermal absorption guidance.			
	1 (iv) Through a growing external network, my expertise in toxicology was acknowledged in being asked to # Undertake peer reviews of manuscripts submitted to a high profile Toxicology journa; I and # Actively participate on the judging committee for the SOT Risk Assessment Specialty Section for graduate student and postdoctoral awards at the annual national meeting. 2 (ii) Submitted ABT recertification application. 2 (iii) Completed ABT recertification examinations on schedule.			

	* Recognized by Rob Frailey as a "stellar contributor", February 2013 and attended the recognition event in Chesterfield. * Recognized in November 2012 with a Reggie Award, "Best Performance Existing Products International, Glyphosate Success In Europe Still Critical After All These Years - Defense and Renewals" for several years of effort chairing the EU Toxicology Technical Working Group of the Glyphosate Task Force and successful FTO activities, supporting glyphosate in Europe.
Competency:	Employee Comments
	Overall Development Comments