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VIA FEDERAL EXPRESS

Office of Environmental Health Hazard Assessment
1001 I Street
Post Office Box 4010, MS 23B (#58c)
Sacramento, CA 95812-4010

Re: Declassified Documents Relating to Monsanto and Roundup

To Whom it May Concern:

Thank you for protecting the public and environmental well-being of Californians. The decision to list glyphosate pursuant to Proposition 65 demonstrates that OEHHA are the standard bearers in matters of public and environmental health. We appreciate that OEHHA is working hard to ensure that the decision to recognize glyphosate as a probable human carcinogen is supported by a robust evaluation of the available scientific data. To that end, we would like to assist OEHHA in its consideration of an appropriate No Significant Risk Level (“NSRL”) for glyphosate by bringing to the agency’s attention a number of documents discovered during the course of the pending federal multidistrict litigation (MDL) against Monsanto Company.

On June 30, 2017, our firm, working in collaboration with the Plaintiffs’ Steering Committee assigned to spearhead the federal litigation against Monsanto, sent a letter to Monsanto (attached, Tab B) challenging the confidential designation of the documents that we are now turning over to you. Monsanto met with us and stated it would not retract claims of confidentiality over the documents we specifically challenged. However, pursuant to Paragraph 16.3 of the Protective Order entered in the MDL (attached, Tab A), Monsanto was required to file a motion within 30 days of Plaintiffs’ June 30, 2017 letter in order to seek continued protection of the documents. Failure to file such motion within 30 days, i.e., July 31, 2017, “automatically waive[s] the confidentiality designation for each challenged designation.” *Id.* ¶ 16.3. Since Monsanto did not file any motion seeking continued protection of the documents, it waived confidentiality over them.

It is imperative that OEHHA appraise the human and environmental risks of glyphosate with due consideration of these documents which tell an alarming story of Monsanto’s manipulation of scientific data and literature, refusal to thoroughly investigate risks of serious

adverse health effects associated with glyphosate, previously undisclosed information about how glyphosate is absorbed by the human body, and collusion with U.S. regulatory officials. The documents lend strong support to the position that the proposed glyphosate NSRL of 1100 micrograms may be too high and should be revised or rejected in its entirety.

All of the declassified documents are included with this letter as well as a chart that we sent to Monsanto as an attachment to our June 30, 2017 correspondence, which groups the documents by category and provides a description of each (attached, Tab C). The documents (listed in the corresponding numbered tabs) are organized according to four different “issues”: “Ghostwriting, Peer-Review & Retraction”; “Surfactants, Carcinogenicity & Testing”; “Absorption, Distribution, Metabolism & Excretion”; and “Regulatory & Government.” A review of the categories of documents demonstrates (1) the extent to which Monsanto was aware of the dangers of glyphosate and other substances in its commercially formulated product, Roundup, but refused to conduct further research into the potential carcinogenicity of glyphosate and Roundup (under *Surfactants, Carcinogenicity & Testing* at 10-16); (2) Monsanto’s manipulation of the scientific literature through ghostwriting and retraction of unfavorable studies (under *Ghostwriting, Peer-Review & Retraction* at 1-10); (3) the extent to which Monsanto misrepresented glyphosate’s rate of absorption by the human body and Monsanto’s termination of studies which conflicted with the company’s commercial interests because the studies demonstrated higher absorption rates that would increase the likelihood of adverse health effects (under *Absorption, Distribution, Metabolism & Excretion* at 16-18); and (4) Monsanto’s collusion with various U.S. regulatory officials in an effort to influence the assessment and classification of glyphosate (under *Regulatory & Government* at 19-28).

Of particular interest to the NSRL issue, the documents indicate that Monsanto failed to conduct extensive tests on the commercially available formulated product, Roundup, as expressed by Dr. Donna Farmer: “you cannot say that Roundup is not a carcinogen...we have not done the necessary testing on the formulation to make that statement.” MONGLY00922458 at *1-2. This was also confirmed by Monsanto employee, Mr. Stephen Adams: “With regards to the carcinogenicity of our formulations we don’t have such testing on them directly...” at MONGLY01155974 *1. Indeed, as far back as 1999, Dr. Farmer was reluctant to evaluate glyphosate, the various ingredients in the Roundup formulation, or the Roundup formulation itself: “I will not support doing any studies on glyphosate, formulations or other surfactant ingredients at this time with the limited information we have on the situation.” MONGLY00877683 at *2.

Such concerns over the potential carcinogenicity of its product and reluctance to conduct further tests explains Monsanto’s apprehension towards the important analysis conducted by IARC which was then adopted by OEHHA for a Prop 65 determination: “Just wanted to let you that what we have long been concerned about has happened. Glyphosate is on for an IARC review in March of 2015.” MONGLY01208470 at *1. However, Monsanto’s head-in-the-sand approach regarding the harmful effects of its product were not limited to a refusal to conduct studies, but included terminating studies which demonstrated that glyphosate may be absorbed by the human body in greater rates than expected. Monsanto ceased such studies, (such as the

“TNO” study, *available at* MONGLY00888353) “because a further study was not likely to help us meet the project objective.” MONGLY03737014 at *2. Monsanto personnel even conceded that terminating the study would mean that “[w]e are left behind with too many questions after all this.” at *Id.* *1. Dr. William Heydens of Monsanto had previously stated that rodent deaths observed in a study titled “An Acute Nose-Only Inhalation Toxicity Study in Rats with Mon 78623” could be “treatment-related.” MONGLY06722561 at *2; *study available at* MONGLY02335784.

A safe NSRL must also reflect the fact that the public and environment are never exposed to glyphosate in isolation; rather, it is the formulated Roundup product which is absorbed in alarming rates. Absorption of Roundup entails “[l]ow level presence of formaldehyde (carcinogen by inhalation) in Roundup; and “[l]ow level presence of NNG (N-nitroso-glyphosate) in Roundup - many N-Nitroso compounds are carcinogenic.” MONGLY00990361. Monsanto was aware that the formulated product was absorbed by human bodies at higher rates due to the cocktail of other ingredients in Roundup: “certain co-formulants like humectants that will make it highly likely we will get large amounts penetrating the skin.” at *1. MONGLY06653096 at *1. Specifically, the presence of surfactants results in greater rates of absorption by the GI tract, as observed in a 2002 Monsanto study: “Absorption was at least 56% of dose at dosages of 1 and 10 mg/kg. Approximately 17-27% of the dose was eliminated in the urine and approximately 31-36% of the dose was found in the bile... [b]asically what we demonstrated was that the material is absorbed through the GI tract as shown. Nothing I am aware of that needs to be reported. We were hoping that we could demonstrate that the material was not absorbed as a means to obviate the need to perform toxicity testing with similar inert ingredients. Obviously that hope was not realized.” MONGLY06424476 at *2.

Indeed, Mr. Richard Garnett, Monsanto’s European liaison, knew that there were several unanswered questions with respect to glyphosate absorption, distribution, metabolism and excretion (“ADME”) when he acknowledged that: “[t]he ADME has always been the weak link in our argument... and the Spanish response highlights that we have not got rid of the problem.” MONGLY06385823 at *1. Monsanto proactively sought to foster a public perception that glyphosate is safe for humans by influencing the scientific discourse through strategies such as not disclosing Monsanto employees’ contributions to studies and articles. This was acknowledged by Monsanto Toxicology Manager, Dr. David Saltmiras, who in his own words “ghost wrote cancer review paper Greim et al. (2015)[.]” Indeed, based on the notes we have seen regarding the meeting OEHHA had with Monsanto, it appears that Monsanto relied on the results of the Greim article to support an NSRL—we doubt, however, that Monsanto disclosed to OEHHA that portions of the article were, in Monsanto’s employee’s own words, ghostwritten.

Adverse public health and environmental repercussions can be mitigated if OEHHA has at its disposal critical information to calculate an appropriate NSRL. Such a goal must necessarily entail evaluation of relevant data that entrenched commercial interests endeavor to conceal from public and scientific scrutiny. We hope that OEHHA will be better informed in proceeding with its NSRL determination for glyphosate as a result of having access to such

documents. If you have any questions, I would happy to speak with you. Please be advised that, in furtherance of true transparency, I have copied Monsanto's attorney, Joe Hollingsworth, on this letter.

Best,
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By: 
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Encls.
CC without enclosure: Joe Hollingsworth