Exhibit 1

Expert Report of Connie Welch-DuJardin

I. Introduction

1. I, Connie Baylor Welch-DuJardin, am the Vice President of toXcel, LLC, an expert consultancy firm that provides our clients with the scientific and regulatory expertise necessary to obtain and maintain their United States Environmental Protection Agency ("EPA") and Food and Drug Administration ("FDA") approvals.

2. I am an expert in the field of the regulation of pesticides and my background includes a seventeen (17) year career within the EPA's Office of Pesticide Programs ("OPP") where I held prominent leadership positions dealing with conventional pesticides, antimicrobial pesticides, and inert ingredients. I began my career at EPA as a Product Chemist in the Registration Division where I reviewed product chemistry data submitted by applicants and registrants in support of their pesticide registrations (fungicides, herbicides, and antimicrobials). I then became the Deputy Branch Chief of the Fungicide-Herbicide Branch. As the Deputy Branch Chief I was responsible for managing OPP's review of fungicides and herbicides. I later became a Product Manager within the Registration Division, responsible for the regulatory oversight of fungicides. As a Product Manager I was the liaison between EPA and the applicants/registrants, and was responsible for ensuring that all of the data requirements were met to support registration of active ingredients and formulated products. During the last eight years of my tenure at the EPA, I served as Chief of the Regulatory Management Branch II in OPP's Antimicrobial Division. As a Branch Chief within the Antimicrobial Division I was responsible for implementing the new Food Quality Protection Act. I was also responsible for the reregistration of all antimicrobial active ingredients. In doing so I managed within my

branch the first interdisciplinary team of scientists and regulatory staff responsible for the scientific and regulatory review of all antimicrobial pesticides.

3. I received several awards and other recognition during my seventeen-year employment at EPA. These include Albert Gore's Vice-Presidential Hammer Award for "contribution to building a government that works better and costs less" that I received for my role on the pesticide registration reinvention team during my tenure as a product manager. I also received the following four bronze medals for commendable service for: 1) contributing to the success of negotiations with manufacturers to reduce residential exposure to CCA treated wood and to improve consumer awareness of safe-handling of treating wood; 2) contributing to the harmonization of scientific and regulatory standards among nations, to successful work-sharing with other regulatory programs and to information sharing across national and organizational boundaries; 3) leadership of the first international conference on harmonizing biocide efficacy standards and contributions to strategic programs toward international standardization and cooperation; 4) contributing to EPA's interpretive guidance for the labels of chromated copper arsenate products and for effectively communicating to the general public the agency's position on wood treatments. I also received the recognition of superior accomplishment for my dedication and swift action to the stop sale and use ("SSURO") of contaminated Medaphene products.

4. I have a Bachelor of Science degree in Chemistry, a Masters of Divinity degree, and a Doctor of Ministry degree. A copy of my current curriculum vitae is attached.

5. I have been retained by the law firm of Hollingsworth LLP to provide an independent expert opinion on EPA's regulatory review of glyphosate and glyphosate-based formulations

6. I charge $395.00 per hour for time I spend reviewing, consulting and assessing the materials upon which I rely for my opinions (out-of-court time) and $450.00 per hour for deposition and in-court testimony (testimony time).

7. I have not authored any publications concerning environmental laws and regulations in the previous 10 years. In the previous four years I testified in one trial, *Arborjet, Inc. and Rainbow Treecare Scientific Advancements, Inc.* (Civil Action No. 14-14129-NMG) (D. Mass 2015).

II. Summary of Opinions

8. EPA has a comprehensive regulatory framework for reviewing and approving the registration of pesticides. As part of this framework EPA requires submission of a large number of studies and can require applicants and registrants to submit additional data as EPA deems necessary. EPA has the authority to limit a pesticide's use or to cancel or suspend the registration of that pesticide should it deem it necessary to do so.

9. It is my opinion that EPA followed its standard procedures and applied this rigorous regulatory framework with respect to the review and approval of the registration of glyphosate and glyphosate-based formulations.

10. EPA's OPP has reviewed glyphosate extensively since it was first registered in 1974. On multiple occasions and pursuant to several different review mechanisms, many EPA scientists have reviewed glyphosate for its carcinogenic potential (including review of more than 100 studies on glyphosate and glyphosate-based formulations that the Agency considered relevant to carcinogenicity) and EPA has repeatedly concluded that glyphosate is not a carcinogen.

11. The determination of regulatory authorities around the world who have conducted risk assessments on the carcinogenic potential of glyphosate is consistent with EPA's review and classification of glyphosate as non-carcinogenic, and supports my opinion that EPA followed sound procedures in reaching its conclusion.

12. Further discussion of my opinions and the bases for those opinions are set out below. I may also provide opinions within my expertise in response to EPA-related issues raised by Plaintiff or Plaintiff's experts, or which otherwise relate to EPA's regulatory framework for approval of pesticides and its review process for glyphosate or glyphosate-based formulations in particular.

III. EPA's Regulatory Framework for Pesticide Registration

13. EPA's mission is to protect human health and the environment. To achieve this, EPA has a prescribed set of data requirements for pesticide registration that relate to the product's use pattern, labeling claims and methods of application. EPA's OPP has sole authority within the federal government to approve pesticide registrations. According to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136, every pesticide sold and distributed in the United States must be registered by the EPA. Pursuant to FIFRA, EPA ensures that every pesticide will result in "no unreasonable risk to human health and the environment" (FIFRA) or for food use pesticides "a reasonable certainty of no harm." Food Quality Protection Act of 1996 ("FQPA"), 7 U.S.C. ch. 6 § 136 *et seq*.

14. EPA requires data to be submitted in support of pesticide active ingredients and end use formulations. Data to be submitted in support of an EPA registration include product performance, toxicology, hazards to non-target organisms, applicator and post-application human exposure, pesticide spray drift evaluation, environmental fate, and residue chemistry. *See* 40

C.F.R. Part 158. EPA has published specific guidelines for how to conduct studies in these categories. EPA, Office of Chemical Safety & Pollution Prevention, *Final Test Guidelines for Pesticides and Toxic Substances.*[1] EPA may require further testing if the guideline tests submitted are deemed insufficient "to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment." 40 C.F.R. §§ 158.175, 158.30. EPA also has the authority to waive data requirements if "it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risk or benefits of the product." 40 C.F.R. § 158.45. In addition, EPA has the authority to suspend or cancel the registration of a pesticide at any time if it has information indicating that continued use would pose unreasonable risk to man or the environment. FIFRA, 7 U.S.C. § 136d(b)-(c).

15. Registrants often conduct their own studies and collect their own data to meet FIFRA testing requirements, and accordingly must transmit these studies and other information to EPA when certain conditions are met. Generally, FIFRA § 6(a)(2) imposes a duty to report information "relevant to the assessment of the risks or benefits" of pesticide registrations, if the information falls within the below seven categories and is not subject to an exception:[2]

a. toxicological and ecological studies (40 C.F.R. § 159.165);

b. discontinued studies (40 C.F.R. § 159.167);

c. human epidemiological and exposure studies (40 C.F.R. § 159.170);

d. excess levels of pesticides in food, feed or water (40 C.F.R. § 159.178);

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[1] *Available at* https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic.

[2] The exceptions are set forth at 40 C.F.R. § 159.158(b) and include "clearly erroneous information," "previously submitted information," "publications," and "information concerning former inerts."

e. detection of certain metabolites, degradates, contaminants and impurities (40 C.F.R. § 159.179);

f. toxic or adverse effect incidents (40 C.F.R. § 159.184);

g. failure of pesticide performance studies (40 C.F.R. § 159.188).

16. If the information does not fall within the enumerated categories, then the information is only reportable if the registrant "knows or reasonably should know, that if the information should prove to be correct, EPA might regard the information alone or in conjunction with other information about the pesticide as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product." 40 C.F.R. § 159.195. Each category of reportable information is outlined in detail in the Code of Federal Regulations.

17. EPA's evaluation of pesticide products is a health protective approach. In a variety of ways, EPA utilizes safety factors or uncertainty factors to ensure in its risk assessments that there will be no unreasonable adverse effect to humans and the environment resulting from the use of the pesticide.

18. Pesticides are evaluated for carcinogenicity through a variety of studies including long term rodent carcinogenicity studies, mutagenicity studies, structure activity evaluations, and epidemiology studies.

19. EPA has sole authority to approve the initial product label and subsequent amended labeling. The information placed on the pesticide product label is specified in 40 C.F.R. Part 156 and must be reviewed and approved by EPA. The purpose of the label is to instruct the user on how to use the pesticide product such that it ensures pesticide use will not result in personal injury or "unreasonable adverse effects on the environment." 40 C.F.R.

§ 156.10. In reviewing and approving label language, EPA considers the most up to date science including the current toxicology database. *See* 40 C.F.R. Part 156, Subpart D. In conducting its label reviews, EPA must also consider its prior risk assessments. EPA's consideration in making labeling decisions based on the product's risk characterization serves to uphold the larger statutory framework applicable to all pesticides that requires consistency in applying proper and adequate labeling language. *See generally* 40 C.F.R. Part 156.

20. After a pesticide is registered it is subject to repeated review both as required by EPA's regulations and at EPA's discretion under its regulatory authority. EPA reviews and applies the most up to date science, technology and risk assessment guidelines as part of its ongoing regulatory review. EPA has methods of both internal and external peer review that it may utilize at any time during its review process.

21. Beyond EPA's review of studies submitted by registrants EPA also reviews public literature, public comments, regulatory risk assessments conducted by other regulatory authorities, and other related assessments of pesticide products.[3]

22. EPA reviews data on all formulated pesticide products. This includes a variety of toxicology, exposure and epidemiology data. For example, OPP utilizes its "Framework for Incorporating Human, Epidemiologic, and Human Incident Data in Risk Assessments for Pesticides" that allows EPA to categorize and rank these human studies when they are available. *See* EPA OPP, *Framework for Incorporating Human, Epidemiologic, and Human Incident Data in Risk Assessments for Pesticides* (December 28, 2016).[4]

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[3] I reviewed the glyphosate registration review docket in preparing my opinions. *See* https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361.

[4] *Available at* https://www3.epa.gov/pesticides/EPA-HQ-OPP-2008-0316-DRAFT-0075.pdf.

23. It is of utmost importance to EPA that the studies considered in its risk assessments are valid studies. The most preferred standard for ensuring valid studies and reliable data are studies conducted according to Good Laboratory Practices ("GLP"). Beyond GLP, EPA relies on other accepted worldwide testing standards and has issued its own guidance outlining what EPA considers valid studies in the open literature.

24. EPA's classification of a pesticide's carcinogenic potential is based on EPA's guidelines for carcinogenic risk assessment. The current 2005 cancer guidelines emphasize the importance of weighing all of the evidence in reaching a conclusion about the human carcinogenic potential of pesticides. EPA has issued new cancer guidelines approximately every ten years since starting in 1976, in order to take into account updated science, technology and risk assessment methodology. In 1986, EPA adopted the six-category alphanumeric classification system (A, B1, B2, C, D, and E), which focused primarily on tumor counts and long-term carcinogenicity studies. In the 1996 cancer guidelines, EPA placed an increased emphasis on discussing the characterization of hazard, dose-response, and exposure assessments in a weight of evidence review process. The hazard and weight of evidence process embraced an analysis of all relevant biological information and emphasized understanding the agent's mode of action in producing tumors to reduce the uncertainty in describing the likelihood of harm.

25. In 2005, EPA released its most recent cancer guidelines. *See* EPA, *Guidelines for Carcinogen Risk Assessment* (March 2005).[5] The evidence considered in the 2005 cancer guidelines includes: tumor findings, an agent's chemical and physical properties, its structure activity relationships ("SARs") as compared with other carcinogenic agents, and studies addressing potential carcinogenic processes and modes of action, either *in vivo* or *in vitro*. The

[5] *Available at* https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment.

updated guidelines throughout the years are based on the most up to date science, technology, and risk assessment methodology such that a review conducted pursuant to the 2005 cancer guidelines is a more thorough, robust, and refined review of the available data as compared to the 1986 guidelines.

26. EPA commonly communicates with applicants and registrants at any time during the life of the pesticide product's registration. EPA guidelines also provide for communications with any interested parties to meet with EPA concerning the product's registration including receiving and considering information, exchanging views, exploring factual and substantive positions, discussing regulatory options or for any other purpose deemed appropriate by the Agency. *See* 40 C.F.R. §§ 155.27, 155.30, 155.32. While these regulations facilitate communication between the Agency and the registrant they also make clear that "the Agency will not commit to take any particular action concerning a Registration Standard under development during discussions with any person or party outside of government. The Agency will make its final administrative decision on a wholly independent basis, and in accordance with law." 40 C.F.R. § 155.30(a). Moreover, "the Agency will not permit registrants to prepare, or assist in the preparation of, data reviews or other registration standard documents." 40 C.F.R. § 155.27.

27. EPA also provides a forum to communicate directly with the public about pesticide rule making and risk assessment reviews. For example, EPA initiates a public online docket at the beginning of its reregistration/registration review process that allows members of the public to comment, submit studies, or provide EPA with any other data that it wants EPA to consider. EPA considers these public comments and often directly responds to them in its final rulemaking process.

IV. EPA OPP's Review of Glyphosate and Glyphosate-Based Formulations

28. It is my opinion based on a review of materials in the public record that EPA applied the regulatory framework described above in its registration, re-registration, ongoing registration review, residue tolerance approvals, and label approvals of glyphosate and glyphosate-based formulations.

29. For example, as shown in the table below, in its ongoing registration review of glyphosate, EPA obtained and reviewed the required toxicity studies relevant to human health (or waived such requirements, where appropriate) in support of the continued registration of glyphosate and glyphosate-based formulations.

Table B.1. Toxicological Data Requirements for Glyphosate.

Study		Technical	
		Required	Satisfied
870.1100	Acute Oral Toxicity	yes	yes
870.1200	Acute Dermal Toxicity	yes	yes
870.1300	Acute Inhalation Toxicity	yes	no[1]
870.2400	Primary Eye Irritation	yes	yes
870.2500	Primary Dermal Irritation	yes	yes
870.2600	Dermal Sensitization	yes	yes
870.3100	Oral Subchronic (rodent)	yes	yes
870.3150	Oral Subchronic (nonrodent)	yes	no[2]
870.3200	21-Day Dermal	yes	yes
870.3465	90-Day Inhalation	yes	yes
870.3700a	Developmental Toxicity (rodent)	yes	yes
870.3700b	Developmental Toxicity (nonrodent)	yes	yes
870.3800	Reproduction	yes	yes
870.4100a	Chronic Toxicity (rodent)	yes	yes
870.4100b	Chronic Toxicity (nonrodent)	yes	yes
870.4200b	Oncogenicity (mouse)	yes	yes
870.4300	Chronic/Oncogenicity	yes	yes
870.5100	Mutagenicity—Gene Mutation - bacterial	yes	yes
870.5300	Mutagenicity—Gene Mutation - mammalian	yes	yes
870.5xxx	Mutagenicity—Structural Chromosomal Aberrations	yes	yes
870.5xxx	Mutagenicity—Other Genotoxic Effects	yes	yes
870.6100a	Acute Delayed Neurotoxicity (hen)	no	no
870.6100b	90-Day Neurotoxicity (hen)	no	no
870.6200a	Acute Neurotoxicity Screening Battery (rat)	yes	yes
870.6200b	90-Day Neurotoxicity Screening Battery (rat)	yes	yes
870.7485	General Metabolism	yes	yes
870.7600	Dermal Penetration	no	no
870.7800	Immunotoxicity	yes	yes

[1] The requirement for an acute inhalation LC_{50} study was waived.
[2] This is not considered a data gap because there is a chronic dog study in the database.

Source: EPA, *Draft Human Health Risk Assessment in Support of Registration Review*, at 29 (Dec. 12, 2017).

30. As addressed below, EPA's OPP has conducted numerous reviews of glyphosate over the 40-plus years of the herbicide's use. EPA first registered glyphosate for use in the United States in 1974. In 1993, EPA reregistered glyphosate (based on a statutory amendment

that required all pesticides registered before November 1984 to be reregistered) and classified glyphosate as Group E ("evidence of non-carcinogenicity in humans"). Since 1993, various components of the EPA OPP have reviewed glyphosate on multiple occasions, including numerous pesticide residue tolerance approvals, EPA internal peer reviews and risk assessments conducted in 1998 and 2015, and OPP risk assessments in 2016 and 2017 in connection with EPA's ongoing registration review. Over this time period, EPA has compiled an extensive database of studies on glyphosate and glyphosate-based formulations that consists of over 4,200 studies, including over 100 studies that the Agency considered relevant to carcinogenicity in its most recent review.[6] In each of these determinations, EPA concluded that glyphosate is "Not Likely to Be Carcinogenic to Humans."

A. Initial Registration and Review of Glyphosate

31. EPA first registered glyphosate in 1974.

32. In 1985, personnel from EPA's Toxicology Branch Review Committee met to evaluate the oncogenic potential of glyphosate and classified glyphosate as a Category C ("possible") oncogen. The Toxicology Branch based its classification on a limited database consisting of the required mutagenicity assays and a single mouse study. With respect to the review of the mouse study, they concluded the study showed an oncogenic response; however, the Toxicology Branch noted that "additional sectioning of new blocks of male kidneys might help in the interpretation of the study results" and specifically that "additional histopathology could resolve the issue of whether this is a valid observation or due to not 'finding' the tumors in

[6] *See* EPA, Glyphosate: Full Bibliography of Submitted Studies (Organized by Guideline Number) (EPA-HQ-OPP-2009-0361-0086), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0086.

the particular block analyzed." EPA OPP Toxicology Branch, Memorandum re: Consensus Review of Glyphosate (March 4, 1985).

33. The kidney slides from the long-term mouse study subsequently were reexamined and several independent pathologists concluded that there was an additional kidney tumor in control males. EPA then called a Scientific Advisory Panel ("SAP") meeting to review these findings. The SAP is an external peer-review process. The SAP is composed of scientists independent of EPA and selected by EPA's Office of Science Policy. The SAP will often conduct a review of EPA's pesticide risk assessments and provide comments and recommendations.[7] The SAP may meet several times a year to conduct these reviews. The SAP's comments and recommendations are non-binding, but are typically considered by EPA in conducting future risk assessments. EPA has utilized the SAP external review process on two occasions with respect to glyphosate.

34. The 1986 SAP proposed that glyphosate be classified as Group D ("inadequate animal evidence of carcinogenic potential"). The 1986 SAP noted that "a carcinogenic potential could not be determined from existing data and proposed that rat and/or mouse studies be repeated in order to clarify these equivocal findings." EPA Carcinogenicity Peer Review Committee, Memorandum re: Second Peer Review of Glyphosate, at 4 (Oct. 30, 1991).

35. Monsanto thereafter conducted an additional long-term rat study. Based on its review of that study and other carcinogenicity data, the EPA Carcinogenicity Peer Review Committee ("CPRC") concluded in 1991 that "Glyphosate should be classified as a Group E (evidence of non-carcinogenicity for humans), based upon lack of convincing evidence in adequate studies in two animal species." *Id.* As discussed in more detail below, EPA reaffirmed

[7] The SAP may also conduct reviews outside of a risk assessment, e.g., policy or guideline changes or any issue for which EPA solicits their comments.

this conclusion in its 1993 decision formally reregistering glyphosate for use in the United States and in all of its subsequent carcinogenicity determinations.

36. It is important to note that reevaluation and reclassification of pesticide products like glyphosate is not uncommon and is part of EPA's regular processes and procedures to ensure that its review is robust and its decisions are scientifically accurate and up to date.

B. 1993 Reregistration of Glyphosate

37. In 1988, Congress amended FIFRA and determined that all pesticides registered before November 1, 1984 had to be reevaluated under the reregistration program in order to ensure that they met the current more stringent standards required to remain on the market. As part of the reregistration process, EPA obtains and reviews the required studies from the pesticide producers, and also reviews decision documents from other regulatory agencies and reliable studies and data from the open literature describing the human health and environmental effects of each pesticide. EPA has explained that "the purpose of the Agency's review is to reassess the potential hazards from the currently registered uses of the pesticide; to determine the need for additional data for health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA." EPA, *Reregistration Eligibility Decision: Glyphosate* ("RED") (Sept. 1993).[8]

38. In 1993, EPA approved the reregistration of glyphosate in the United States. *Id.* In its RED document supporting the continued use of glyphosate and glyphosate-based formulations, EPA determined that the glyphosate database was substantially complete. As part of its evaluation, the Agency reviewed the long-term oncogenicity and mutagenicity studies on glyphosate and classified glyphosate as Group E ("evidence of non-carcinogenicity in humans").

[8] *Available at* https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf.

In addition, as part of the process of reviewing the glyphosate database, the RED document approved all current product labeling for glyphosate-based formulations and also provided instructions for required labeling changes pursuant to the RED. The reregistration decision was based on a comprehensive review of the glyphosate database conducted by an interdisciplinary team of scientists and regulatory staff in OPP.

C. Food Quality Protection Act ("FQPA")

39. On August 3, 1996, Congress enacted the Food Quality Protection Act ("FQPA"). FQPA established a single, health based standard for all pesticide residues in food. The new standard, "reasonable certainty of no harm", applied stringent safety factors to provide further protection for human populations, especially infants and children. FQPA required EPA to reassess all pesticide residue tolerances under this new standard. The new standard directed EPA to update and upgrade its risk assessment process as part of these tolerance setting procedures. This included use of an extra 10-fold safety factor and consideration of available information on:

- aggregate exposure from all non-occupational sources (i.e., dietary and non-dietary routes of exposure, such as through drinking water or as a result of household pesticide use);
- effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity;
- effects of in utero exposure; and
- potential for endocrine disrupting effects

EPA, FQPA Implementation Plan (March 1997).[9]

40. EPA conducts a risk assessment with respect to each new crop on which a pesticide is used. This assessment takes into account the total level of acceptable risk based on the exposure and toxicity information listed above. EPA uses the analogy of the "risk cup" to

[9] *Available at* https://archive.epa.gov/pesticides/regulating/laws/fqpa/web/pdf/impplan.pdf.

define all of the uses of a pesticide and the exposure to the general population from all of these uses, including any proposed new uses. In line with EPA's conservative risk assessments the risk cup assumes that 100% of the new proposed crop (e.g. treatment of all alfalfa across the US) is treated with glyphosate. *See* 67 Fed. Reg. 60,934 (Sept. 27, 2002); 62 Fed. Reg. 17,723 (Apr. 11, 1997).

41. EPA's pesticide tolerance approvals include a review of the pesticide's carcinogenic potential. This includes not only a review of the database on glyphosate, but also a rulemaking procedure wherein EPA publishes its initial findings and responds to comments posted on the public docket in the final rule. *See, e.g.*, 67 Fed. Reg. 60,934 (Sept. 27, 2002); 62 Fed. Reg. 17,723 (Apr. 11, 1997).

42. The registration and reregistration of pesticide products under FIFRA includes a determination that the pesticide product formulation meets the registration standard under FIFRA section 3 (including the lack of unreasonable adverse effects on the environment). The entire formulation, including the inert ingredients, must meet this standard. In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that inert ingredients in pesticide products used on food and feed crops, agricultural commodities, or livestock must have a tolerance or tolerance exemption under 40 C.F.R. Part 180.[10]

43. The 1996 FQPA also triggered EPA's reassessment of inert ingredients used in pesticide products to determine if they meet the Agency's current standards.[11] Inert ingredients

[10] *See, e.g.*, EPA, Pesticide Registration Manual: Chapter 8 - Inert Ingredients, *available at* https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-8-inert-ingredients#regulation.

[11] EPA has always regulated inert ingredients and required data submissions to support their use in pesticide products. *See* 1987 Inert Ingredient EPA Policy Statement; *see also* Inert Ingredients of Pesticide Products; Policy Statement; Revision and Modification of Lists, 54 Fed. Reg. 48,314

are those ingredients that are added to end use products that are not active ingredients, such as surfactants, solvents, fragrances, and dyes. Active ingredients are those that prevent, destroy, repel or mitigate a pest, or is a plant regulator, defoliant, dessicant, or nitrogen stabilizer. In response to the new FQPA safety standards, inert manufacturers developed and organized a significant amount of data on different classes or "clusters" of inert ingredients. By 2009, EPA determined that all inert clusters used in glyphosate-based formulations are non-carcinogenic based on a review of structural alerts that examines the carcinogenicity, chronic toxicity, and genotoxicity database of these compounds.[12]

D. Registration Review

44. The FQPA also created a process for registration review every 15 years. *See* 7 U.S.C. § 136a(g)(1)(iv). The purpose of registration review is to take into account the entire database of a pesticide to ensure that the intended uses and the labeling will ensure that use of the product will result in no unreasonable adverse effect to human health or the environment. The final registration review document may include modifications to the pesticide's use patterns, application methods, statements about whether additional data is needed, and specifications for any proposed labeling changes.

45. In 2009, EPA began its registration review process for glyphosate. This review process began with a preliminary work plan ("PWP") that summarized information EPA has on glyphosate and the anticipated path going forward including anticipated risk assessments and a request for additional data otherwise known as a Data Call-In ("DCI"). The DCI for glyphosate

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(Nov. 22, 1989), available at https://www.epa.gov/sites/production/files/2015-10/documents/fr54.pdf.

[12] *See, e.g.*, EPA, *Alkyl Amine Polyalkoxylates (JITF CST 4 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations* (Apr. 3, 2009).

led registrants to conduct several new studies to support the continued registration of glyphosate. EPA's registration review of glyphosate has included several human health and ecological risk assessments. These include, for example, a drinking water assessment, a residential and occupational exposure assessment, a systematic review of the open literature on glyphosate-based formulations, glyphosate adverse incident reports, human health risk assessment, dietary exposure analysis, and issue papers evaluating the carcinogenic potential of glyphosate. Some of the most relevant human health assessments are discussed below.

46. All food use pesticides are reviewed for their carcinogenic potential by the Cancer Assessment Review Committee ("CARC"). Initially, scientists in the Health Effects Division of OPP perform an independent review of studies conducted on mice and rats to determine the carcinogenic potential of pesticides in rodents. The results of the independent review are subject to internal peer-review by the CARC. CARC's review includes not only toxicology studies but also exposure and epidemiology studies where available. Each time the CARC reviews a pesticide it recommends a cancer classification.[13]

47. The CARC is made up of a team of interdisciplinary EPA scientists with specific expertise in cancer classification.[14] Each CARC member has voting rights, and the scientific review and classification of the pesticide is based on a majority vote from the committee. EPA may utilize CARC reports in conducting its overall risk assessment and approval/re-approval of a pesticide.

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[13] *See* https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential#1.

[14] The CARC is just one of several internal peer-review committees. For example, EPA also relies upon the OPP Health Effects Division's Hazard Identification Assessment Review Committee ("HIARC"), which also reviewed glyphosate in 1998 and concluded that the carcinogenic potential of glyphosate in two carcinogenicity studies in rodents was negative. EPA OPP, *GLYPHOSATE - Report of the Hazard Identification Assessment Review Committee* (Apr. 20, 1998).

48. In October 2015, thirteen EPA scientists signed a CARC report unanimously classifying glyphosate as "Not Likely to be Carcinogenic to Humans." CARC explained that it made this determination "[i]n accordance with the 2005 Guidelines for Carcinogenic Risk Assessment, based on the weight of the evidence. . . ." EPA CARC, *Evaluation of the Carcinogenic Potential of Glyphosate*, at 10 (Oct. 1, 2015) ("2015 CARC Report").

49. In 2016, EPA's OPP released an *Issue Paper on the Carcinogenic Potential of Glyphosate* ("Issue Paper") in which it reviewed and validated the CARC's classification of glyphosate as not likely to be a carcinogen. In that Issue Paper, EPA explained the scope of its review as follows:

> The recent peer review performed by CARC served as an initial analysis to update the data evaluation for glyphosate at that time. Based on an evaluation of the studies included in the recent analyses by IARC, JMPR, and EFSA, the agency then became aware of additional relevant studies not available to EPA. As a result, EPA also requested information from registrants about studies that existed, but had never been submitted to the agency. The current evaluation incorporates these additional studies. In addition, the Agency conducted a systematic review of the open literature and toxicological databases for glyphosate by using a draft 'Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment'. As such, the current evaluation also provides a more thorough evaluation than the 2015 CARC review.

EPA OPP, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 13 (Sept. 12, 2016). In its 2016 Issue Paper, EPA's OPP concluded that "the strongest support is for 'Not Likely to be Carcinogenic to Humans' at doses relevant to human health risk assessment," which is the category EPA uses for substances with the lowest carcinogenic potential. *Id.* at 141.

50. After the 2016 Issue Paper, EPA then solicited review of glyphosate's carcinogenic potential by a SAP. The SAP conducted a four-day public hearing in December

2016 on its glyphosate review and thereafter published a report providing its comments and recommendations with respect to the review of glyphosate's carcinogenic potential.

51. Following the SAP's review, on December 12, 2017, EPA issued a "Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate." In that response, EPA conducted a thorough review of the recommendations from the SAP and responded to each one.

52. Also on December 12, 2017, EPA published a *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* ("Revised Issue Paper"). This Revised Issue Paper took into account the comments of the SAP on which the SAP reached consensus and also brought EPA's literature review up to date, including incorporating an update of the Agricultural Health Study Cohort into the risk assessment.[15] In the 2017 Revised Issue Paper, EPA again concluded that "the strongest support is for 'Not Likely to be Carcinogenic to Humans'". EPA, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, at 143 (Dec. 12, 2017).

53. In the 2017 Revised Issue Paper, EPA explained that:

> An extensive database exists for evaluating the carcinogenic potential of glyphosate, including 63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate. These studies were evaluated for quality and results were analyzed across studies within each line of evidence.

[15] EPA, Memorandum from Ashlee Alridge, MPH, Epidemiologist, Toxicology and Epidemiology Branch (TEB), HED on Summary Review of Recent Analysis of Glyphosate Use and Cancer Incidence in the Agricultural Health Study to Monique M. Perron, Sc.D., Toxicologist, Risk Assessment Branch I (RAB1), HED (Dec. 12, 2017).

Id. at 144. EPA further explained that it considered the following studies relevant to its evaluation: (a) 23 epidemiological studies (including 22 studies judged as "high" or "moderate" quality and the findings of a recently published analysis of the Agricultural Health Study cohort), *id.* at 44; (b) 14 animal carcinogenicity studies, *id.* at 74; and (c) 84 genotoxicity studies, *id.* at 100-128.[16] EPA also considered 62 genotoxicity studies on glyphosate-based formulations. *Id.* at 203-15. Thus, in concluding that glyphosate is "Not Likely to Be a Carcinogen" in the 2017 Revised Issue Paper, EPA OPP evaluated a large volume of studies that it deemed relevant to evaluating the carcinogenic potential of glyphosate.

54. In sum, since EPA classified glyphosate as Group E for carcinogenicity (signifies "evidence of non-carcinogenicity in humans") in the 1993 RED (*see* RED at p. viii), there have been numerous determinations by EPA that glyphosate is not carcinogenic, including numerous pesticide residue tolerance approvals and the recent OPP reviews and risk assessments (i.e., 2015 CARC Report, 2016 OPP Issue Paper, and 2017 OPP Revised Issue Paper). In each of these determinations, EPA concluded that glyphosate is "Not Likely to Be Carcinogenic to Humans" based on OPP's review of the growing data set throughout this time period on glyphosate and glyphosate-based formulations.[17] In addition EPA has reviewed labels of glyphosate-based

[16] The genotoxicity studies include: 27 studies that involved *in vitro* tests for gene mutations in bacteria, Revised Issue Paper at 100; 4 studies that involved *in vitro* tests for gene mutations in mammalian cells, *id.* at 106; 8 studies that involved *in vitro* mammalian chromosomal aberration tests, *id.* at 108; 6 studies that involved *in vitro* mammalian micronucleus tests, *id.* at 109; 5 studies involving *in vivo* tests for chromosomal aberrations in mammals, *id.* at 117; 19 studies involving *in vivo* tests for micronuclei induction in mammals, *id.* at 118-121; and 15 studies involving assays for detecting primary DNA damage, *id.* at 125-128.

[17] EPA's registration review is ongoing.

formulations on numerous occasions and has not made any new findings or required any use restrictions based on carcinogenicity.[18]

V. The International Agency for Research on Cancer

55. In March 2015 a panel of scientists selected by the International Agency for Research on Cancer ("IARC") met in Lyon, France and assessed the carcinogenic potential of glyphosate and four other pesticides based on studies available in the open literature. IARC concluded that there is limited evidence in humans for the carcinogenicity of glyphosate, sufficient evidence for experimental animals, and strong evidence for genotoxicity. Based on its classification scheme, IARC classified glyphosate as "probably carcinogenic to humans."

56. In its October 2015 report unanimously classifying glyphosate as "Not Likely to be Carcinogenic to Humans," the EPA CARC conducted an extensive review of the IARC monograph on glyphosate and included discussion on how EPA's review and conclusions differed from IARCs. *See generally* 2015 CARC Report at 7-10.

57. In its 2016 Issue Paper and 2017 Revised Issue Paper, EPA OPP validated the CARC's classification of glyphosate as not likely to be a carcinogen, and in doing so, similarly addressed IARC's report and classification of glyphosate. *See, e.g.*, 2016 Issue Paper at 13; 2017 Revised Issue Paper at 13. As stated above, EPA continued to classify glyphosate as "Not Likely to Be Carcinogenic to Humans" after IARC's determination.

VI. Worldwide Regulatory Determinations

58. EPA's repeated determinations that glyphosate is not likely to be carcinogenic to humans are consistent with risk assessments conducted by foreign regulatory authorities both

[18] I have reviewed a representative sample of glyphosate-based formulation labels on an online database. *See* https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1].

before[19] and after[20] IARC's classification of glyphosate—including the European Food Safety Authority, the German BfR, the Canadian Pest Management Regulatory Agency, the Australian Pesticides and Veterinary Medicines Authority, and the New Zealand Environmental Protection Authority, among others—as well as with the risk assessments conducted by other branches of the World Health Organization.[21] The consistent determinations from around the world that

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[19] *See, e.g.*, Canada 1992 ("Health and Welfare Canada has reviewed the glyphosate toxicology database, which is considered to be complete. The acute toxicity of glyphosate is very low. The submitted studies contain no evidence that glyphosate causes mutations, birth defects or cancer."); European Commission, Review Report for the Active Substance Glyphosate 6511/VI/99-final (Jan. 21, 2002) (finding there was "[n]o evidence of carcinogenicity" and glyphosate is "[n]ot genotoxic."); The German Federal Institute for Risk Assessment ("BfR"), *Renewal Assessment Report: Glyphosate (Volume 1) Report and Proposed Decision* at 35 (Dec. 18, 2013) ("glyphosate was unlikely to pose a carcinogenic risk in humans").

[20] *See, e.g.*, Health Canada Pest Management Regulatory Agency, Summary of the Pest Management Regulatory Agency Proposed Re-Evaluation Decision (Apr. 13, 2015) ("In consideration of the strength and limitations of the large body of information on glyphosate, which included multiple short and long term (lifetime) animal toxicity studies, numerous in vivo and in vitro genotoxicity assays, as well as the large body of epidemiological information, the overall weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk."); EFSA, Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate at 2, EFSA Journal 2015;13(11):4302 (finding that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential. . . ."); New Zealand Environmental Protection Authority, Review of the Evidence Relating to Glyphosate and Carcinogenicity (Aug. 2016) (finding that "glyphosate is unlikely to be carcinogenic to humans or genotoxic."); European Chemicals Agency (ECHA), Opinion Proposing Harmonized Classification and Labelling at EU Level of glyphosate (ISO); N-(phosphonomethyl) glycine at 31 [Mar. 15, 2017] (noting the European regulatory body "concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction."); Australian Pesticides and Veterinary Medicines Authority (APVMA), Final regulatory position: consideration of the evidence for a formal reconsideration of glyphosate (Sept. 2016) (finding that "exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans."); Health Canada Pest Management Regulatory Agency, Re-evaluation decision, RVD2017 [Apr. 28, 2017] (finding "[g]lyphosate is not genotoxic and is unlikely to pose a human cancer risk").

[21] JMPR, Pesticide residues in food – 1986: Toxicological evaluations – Toxicological Monographs and Monograph Addenda, Joint FAO/WHO Meeting on Pesticide Residues (1987) (finding that "[g]lyphosate was without mutagenic activity both in vitro and in vivo" and that there is "no evidence of carcinogenicity"); Mensink, H. & P. Janssen, Environmental Health Criteria 159: Glyphosate, International Programme on Chemical Safety (IPCS) (1994) (finding

glyphosate is not carcinogenic supports my opinion that EPA followed rigorous and appropriate processes in reviewing glyphosate and glyphosate-based formulations.

Date: Nov. 27, 2018

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that the "available studies do not indicate that technical glyphosate is mutagenic, carcinogenic or teratogenic"); JMPR, Pesticide residues in food – 2004: Toxicological evaluations – Toxicological Monographs and Monograph Addenda, Joint FAO/WHO Meeting on Pesticide Residues (2006) (finding that "[i]n view of the absence of a carcinogenic potential in animals and the lack of genotoxicity in standard tests, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans"); Food & Agric. Org. of the U.N., World Health Org., Joint FAO/WHO Meeting on Pesticide Residues, Geneva, 9-13 May 2016 Summary Report (May 16, 2016) ("Glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet.").

Exhibit A

toXcel

Life Sciences

Toxicology & Regulatory Affairs

Connie B. Welch, DMin
Vice President

SUMMARY

Over 24 years of exemplary management/leadership experience in both the Federal and private sector as summarized below:

- *30+ years of experience interpreting and implementing environmental laws and regulations governing pesticides and toxic chemicals (the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), the Federal Food, Drug and Cosmetic Act (FFDCA), the Food Quality Protection Act (FQPA), the Safe Drinking Water Act (SDWA), the Toxic Substances Control Act (TSCA), and the Resource Conservation and Recovery Act (RCRA)*
- Over 26 years experience as a national and international speaker, representing the United States on controversial worldwide technical and regulatory issues.
- Extensive experience as a project manager (Federal and non-profit sector) and consultant (team management, project management, financial management).
- Successfully led an international team of scientist and regulatory staff to the cancellation of arsenic compounds used in treated wood products for the construction of children's playground equipment and other residential uses
- Met all Congressional mandates/deadlines for the scientific and regulatory review of chemicals and/or pesticide products used to provide the general public with safe drinking water, food, and hospital/home health care.
- Facilitated the issuance of the first Reregistration Eligibility (Scientific and Regulatory Review) Documents for the new Antimicrobial Division in the Office of Pesticide Programs, US Environmental Protection Agency (USEPA)
- Successfully managed an estimated $1.5 million operational budget to meet the program's goals and objects
- Successfully directed and coached the first multidisciplinary team of scientists and regulatory staff in a Regulatory Division at the US EPA
- Served as the USEPA Expert on the leading and most dangerous chemical warfare agents.

RELATED PROFESSIONAL EXPERIENCE

***toXcel*, LLC**
Gainesville, VA

Vice President — January, 2016- Present
Executive Director, Product Registration — August, 2012 – December, 2015

- Assist/represent the chemical industry (in the US and abroad) with EPA/FDA registration/approval requirements, environmental laws and regulations (PRIA, FIFRA, FQPA, FFDCA, TSCA) concerning chemicals sold and distributed in the US.
- Consult with clients on project management issues in US and abroad
- Direct junior and mid-level staff (scientist, regulatory) regarding client registration projects/issues and other special projects.

Connie Welch & Associates
Woodbridge, VA
Principal April, 2008-August, 2012

- Assist/represent the chemical industry (in the US and abroad) with registration requirements, environmental laws and regulations (FIFRA, FQPA, FFDCA, TSCA, RCRA) concerning chemicals sold and distributed in the US.
- Consult with clients on management and/or project management issues in US and abroad
- Business Coach

ChemReg International, LLC
Woodbridge, VA
Global Regulatory Consultant March, 2005 –July, 2006

- Served as a Global Regulatory Consultant representing clients in the chemical industry (both US and abroad) seeking registration/approval from the U.S. Environmental Protection Agency on chemical products for use by the hospitals (hospital disinfectants and sanitizers), the restaurant industry, and the agricultural industry to kill bacteria and food-borne pathogens.
- Served as Facilitator/Instructor for Pesticide Law/Regulation Courses
- Advised clients on environmental laws and regulations (FIFRA, FFDCA, TSCA, RCRA, SDWA) regarding the use of pesticides and toxic chemicals sold, used, and distributed in the US

US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division
Regulatory Branch Chief April, 1997-March, 2005

- Effectively directed and managed the regulatory and scientific review of all applications for the registration of antimicrobial (antibacterial) chemicals (agricultural, industrial, hospital, and homeowner use) within the jurisdiction of the branch.
- Supervised a diverse team of managers, scientists, regulators, and clerical staff.
- Through exemplary leadership met all Congressional deadlines and requirements according to federal laws and regulations (FIFRA, FQPA, FFDCA, RCRA, SDWA) for introducing safe and efficacious products into the US markets for use by hospitals and other major industrial institutions, farmers, and homeowners.

Registration Division
Product Manager February, 1995-April, 1997

- Managed the regulatory and scientific review of all applications for registration for chemicals for use on agricultural products in accordance to federal laws and regulations (FIFRA, FFDCA)
- Lead a diverse team of scientists, regulatory, and administrative staff
- As the subject matter expert, represented the Agency on all scientific and regulatory aspects regarding the use of pesticide chemicals within the jurisdiction of the team.

Registration Division
Acting Deputy Branch Chief March, 1988-February, 1995
Team Leader
Chemist

- Reviewed product chemistry data submitted in support of the registration/approval of chemicals and/or pesticide products for their conformance to US pesticide laws and regulations (FIFRA, FFDCA, TSCA).
- Managed the regulatory development of all pesticide inert ingredients and performed specialized analytical studies of significant pesticide issues.
- As a Team Leader, led a diverse group of chemists and clerical staff
- As the Deputy Branch Chief, supervised a diverse team of managers, scientists, regulators, and clerical staff.

OTHER RELATED EXPERIENCE

Valley Forge Christian College, Woodbridge, VA
Adjunct Professor July, 2006- December, 2008

Christ Chapel Academy, Woodbridge, VA
Middle/High School Science Teacher August, 2006-June, 2007

- Taught Life Science, Physical Science, and Earth Science to 7th, 8th, and 9th grade students.

EDUCATION

Doctor of Ministry: Virginia Union University, Richmond, VA
Masters/Div *cum laude*: Virginia Union University, Richmond, VA
Bachelor of Science, Chemistry: Virginia State University, Petersburg, VA

HONORS/AWARDS

Bronze Medals for Commendable Service/(US EPA), Al Gore's Vice Presidential Hammer Award,
Special Act Awards, Outstanding Performance Awards, Letters of Commendation

Exhibit B

Dr. Connie Welch Materials Considered List

1. Agency review of data, 40 CFR §155.27 (1996).
2. *Agricultural Biotechnology: A Look at Federal Regulation and Stakeholder Perspectives: Hearing Before the S. Comm. on Agric., Nutrition, & Forestry*, 114th Cong. (Oct. 21, 2015), https://www.agriculture.senate.gov/hearings/agriculture-biotechnology-a-look-at-federal-regulation-and-stakeholder-perspectives
3. Australian Pesticides and Veterinary Medicines Authority (APVMA), *Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, Australian Government (2016).
4. Australian Pesticides and Veterinary Medicines Authority (APVMA), *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, Australian Government (2017).
5. BfR Press Release, *BfR Contribution to the EU Approval Process of Glyphosate is Finalised* (Apr. 2, 2015).
6. BfR Press Release, *Does Glyphosate Cause Cancer?* (Mar. 23, 2015).
7. BfR, *Renewal Assessment Report: Glyphosate (Volume 1) Report and Proposed Decision* (Dec. 18, 2013).
8. Campt, D., *Inert Ingredients in Pesticide Products; Policy Statement; Revision and Modification of Lists*, EPA (Oct. 10, 1989), https://www.epa.gov/sites/production/files/2015-10/documents/fr54.pdf
9. Data Requirements for Pesticides, 40 CFR Part 158 (2012).
10. Donliner, L. and M. Stewart, *Decision Document: Pre-Harvest Use of Glyphosate Herbicide*, Agriculture Canada (June 5, 1992).
11. ECHA, *Opinion: Proposing harmonized classification and labelling at EU level of glyphosate (ISO); N-(phosphonomethyl)glycine*, Committee for Risk Assessment RAC (Mar. 15, 2017).
12. EFSA, *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate* at 2, EFSA Journal 2015;13(11):4302.
13. EFSA, *EFSA Statement Regarding the EU Assessment of Glyphosate and the So-Called "Monsanto Papers"* (June 8, 2017).
14. EPA, Cancer Assessment Review Committee, *Cancer Assessment Document: Evaluation of the Carcinogenic Potential of Glyphosate Final Report* (Oct. 1, 2015).
15. EPA, FIFRA SAP, *Meeting Minutes and Final Report No. 2017-01 – A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: EPA's Evaluation of the Carcinogenic Potential of Glyphosate* (Mar. 16, 2017).
16. EPA, *Glyphosate Final Work Plan (FWP) Registration Review Case No. 0178* (December 2009).

17. EPA, *Glyphosate: Full Biography of Submitted Studies (Organized by Guideline Number)* (Mar. 7, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0086

18. EPA, Memorandum from Theodore Farber, Ph.D. Chief, Toxicology Branch et al. on Consensus Review of Glyphosate Caswell No. 661A to Robert Taylor, Product Manager, Herbicide – Fungicide Branch, Registration Division (Mar. 4, 1985).

19. EPA, Memorandum from Stephen L. Johnson, Executive Secretary, FIFRA Scientific Advisory Panel on Transmittal of the Final FIFRA Scientific Advisory Panel Reports on the February 11-12, 1986 Meeting to Steven Schatzow, Director, Office of Pesticide Programs (Feb. 24, 1986).

20. EPA, Memorandum from William Dykstra, Reviewer, Toxicology Branch, Health Effects Division on Glyphosate – EPA Registration Nos. 524-318 and 524-333 – Historical Control Data for Mouse Kidney Tumors to Robert J. Taylor, Fungicide-Herbicide Branch, Registration Division (June 19, 1989).

21. EPA, Memorandum from William Dykstra, Ph.D., Toxicology Branch, Health Effects Division, and George Z. Ghali. Ph.D., Science Analysis and Coordination Branch, Health Effects Division, on Second Peer Review of Glyphosate to Robert Taylor, PM, Fungicide-Herbicide Branch, Registration Division and Lois Rossi, Chief, Reregistration Branch, Special Review and Reregistration Division (Oct. 30, 1991).

22. EPA, Memorandum from William Dykstra, Toxicologist, Registration Action Branch 1, Health Effects Division and Jess Rowland, Executive Secretary, Health Effects Division on Glyphosate – Report of the Hazard Identification Assessment Review Committee to Melba Morrow, Branch Senior Scientist, Registration Action Branch 1, Health Effects Division (Apr. 20, 1998).

23. EPA, Memorandum from Gregory Akerman, Ph.D. and Monique M. Perron, Sc.D., Health Effects Division on Response to the Final Report of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) on the Evaluation of the Human Carcinogenic Potential of Glyphosate to Caitlin Newcamp and Neil Anderson, Pesticide Reevaluation Division (Dec. 12, 2017).

24. EPA, Memorandum from Ashlee Alridge, MPH, Epidemiologist, Toxicology Epidemiology Branch (TEB), HED on Summary Review of Recent Analysis of Glyphosate Use and Cancer Incidence in the Agricultural Health Study to Monique M. Perron, Sc.D., Toxicologist, Risk Assessment Branch 1 (RAB1), HED (Dec. 12, 2017).

25. EPA, Office of Chemical Safety & Pollution Prevention, *Final Test Guidelines for Pesticides and Toxic Substances* (2016), https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-and-toxic

26. EPA, Office of Health and Environmental Assessment, *The Risk Assessment Guidelines of 1986* (Aug. 1987).

27. EPA, Office of Pesticide Programs, *Glyphosate. Draft Human Health Risk Assessment in Support of Registration Review* (Dec. 12, 2017).

28. EPA, Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (Sept. 12, 2016).

29. EPA, Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (Dec. 12, 2017).

30. EPA, Office of Pesticide Programs, *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment* (Aug. 28, 2012).

31. EPA, Office of Pesticide Programs, *Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides* (Dec. 28, 2016).

32. EPA, Office of Pesticide Programs, *PR Notice 98-3 & Attachment: Guidance on Final FIFRA 6(a)(2) Regulations for Pesticide Product Registrants* (Apr. 3, 1998), https://www.epa.gov/sites/production/files/2014-04/documents/pr98-3.pdf

33. EPA, Office of Pesticide Programs, *Pesticide Registration Manual: Chapter 8 – Inert Ingredients* (2017), https://www.epa.gov/pesticide-registration/pesticide-registration-manual

34. EPA, Office of Pesticides and Toxic Substances, *Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practice (GLP) Regulations* (Sept. 30, 1991).

35. EPA, Office of Prevention, Pesticides and Toxic Substances, *Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives (AAAPDs and AAASDs – JITF CST 2 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations* (June 8, 2009).

36. EPA, Office of Prevention, Pesticides and Toxic Substances, EPA, *Alkyl Alcohol Alkoxylates (AAA – JITF CST 1 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations* (July 14, 2009).

37. EPA, Office of Prevention, Pesticides and Toxic Substances, *Alkyl Amine Polyalkoxylates (JITF CST 4 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations*, (Apr. 3, 2009).

38. EPA, Office of Prevention, Pesticides and Toxic Substances, *Methyl Poly(Oxyethylene) C8-C18 Alkylammonium Chlorides (MPOACs – JITF CST 7 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations* (June 2, 2009).

39. EPA, Office of Prevention, Pesticides and Toxic Substances, *Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFCs – JITF CST 11 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations* (May 28, 2009).

40. EPA, Office of Prevention, Pesticides and Toxic Substances, *Reregistration Eligibility Decision (RED) Glyphosate* (Sept. 1993).

41. EPA, Office of Research and Development, *Proposed Guidelines for Carcinogen Risk Assessment* (Apr. 1996).

42. EPA, Prevention, Pesticides and Toxic Substances, *1996 Food Quality Protection Act: Implementation Plan* (Mar. 1997).

43. EPA, *PRN 97-1: Agency Actions Under the Requirements of the Food Quality Protection Act* (Jan. 31, 1997), https://www.epa.gov/pesticide-registration/prn-97-1-agency-actions-under-requirements-food-quality-protection-act

44. EPA, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005).

45. EPA Website, *Glyphosate Registration Review Docket*, Docket ID: EPA-HQ-OPP-2009-0361, https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361

46. EPA Website, *Evaluating Pesticides for Carcinogenic Potential* (2017), https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential

47. European Commission, *Review Report for the Active Substance Glyphosate 6511/VI/99-final* (Jan. 21, 2002).

48. Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 (1947).

49. Food Quality Protection Act, 7 U.S.C. ch. 6 § 136 *et seq* (1996).

50. Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,730 (Apr. 11, 1997) (to be codified as 40 C.F.R. pts. 180, 185 and 186).

51. Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,950 (Sept. 27, 2002) (to be codified as 40 C.F.R. pt. 180).

52. Glyphosate; Pesticide Tolerance, 69 Fed. Reg. 65,081, 65,088 (Nov. 10, 2004) (to be codified as 40 C.F.R. pt. 180).

53. Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,592 (Dec. 3, 2008) (to be codified as 40 C.F.R. pt. 180).

54. Glyphosate; Pesticide Tolerances, 78 Fed. Reg. 25,396, 25,401 (May 1, 2013) (to be codified 40 C.F.R. pt. 180).

55. Health Canada, *Proposed Re-evaluation Decision PRVD2015-01 – Glyphosate* (Apr. 13, 2015).

56. Health Canada, *Glyphosate Re-evaluation Decision RVD2017-01* (Apr. 28, 2017).

57. IARC Press Release, *IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides* (Mar. 20, 2015).

58. IARC, *Glyphosate in Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos*, Monograph Vol. 112 on the Evaluation of Carcinogenic Risks to Humans (2015).

59. JMPR, *Joint FAO/WHO Meeting on Pesticide Residues Geneva, 9-13 May 2016 Summary Report* (May 16, 2016).

60. JMPR, *Pesticide residues in food – 1986: Toxicological evaluations – Toxicological Monographs and Monograph Addenda*, Joint FAO/WHO Meeting on Pesticide Residues (1987).

61. JMPR, *Pesticide Residues in Food – 2004: Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20-20 September 2004* (2005).

62. Knezevich, A. & G. Hogan, *A Chronic Feeding Study of Glyphosate (Roundup® Technical) In Mice* (July 21, 1983).

63. Labeling Requirements for Pesticides and Devices, 40 CFR Part 156 (2010).

64. Lankas, G. & G. Hogan, *A Lifetime Feeding Study of Glyphosate (ROUNDUP® Techinal) in Rats – Final Report, Volume 1*, Bio/dynamics Inc. (Sept. 18, 1981).

65. Letter from Robert J. Taylor, Product Manager, Fungicide-Herbicide Branch, Registration Division on Roundup EPA Reg. No. 524-308 Your Application of December 22, 1975 to L.H. Hannah, Manager Product Registration, Monsanto Co. (Dec. 23, 1975).

66. Letter from L.H. Hannah, Manager Product Registration, Monsanto Co. on Roundp ® Pesticide Petition Nos. 5F1560, 6F1733, 6H5115, 6F1756, 6H5126, 6F1798, 6E1809, 6F1861, 6H5144, 7F1982, 7F1904 and 7F2016 EPA Reg. No. 524-308 to Edward Derrenbacher, Acting Product Manager, Fungicide-Herbicide Branch, Registration Division, U.S. EPA (Aug. 29, 1978).

67. Letter from Frank S. Serdy, Manager, Federal and State Registration Affairs, Monsanto Co. on Chronic Mouse Study with Glyphosate to Robert Taylor, Product Manager, Herbicide – Fungicide Branch, Registration Division, U.S. EPA (May 21, 1985).

68. Letter from Rick Colbert, Director, Agriculture and Ecosystems Division, Office of Compliance, U.S. EPA on Good Laboratory Practice Standards Inspection of September 14-17, 1993 to Roger Folk, Monsanto Agricultural Group, Environmental Health Laboratories (July 22, 1996).

69. Meetings and communications, 40 CFR §155.30 (1996).

70. Mensink, H. & P. Janssen, Environmental Health Criteria 159: Glyphosate, International Programme on Chemical Safety, World Health Organization (1994).

71. Moore, J.A., *Inert Ingredients in Pesticide Products; Policy Statement*, EPA (Apr. 13, 1987).

72. Public docket, 40 CFR §155.32 (2012).

73. Sauer, R., *Pathology Working Group Report on Glyphosate in CD-1 Mice* (Oct. 10, 1985).

74. Stout, L. & F. Ruecker, *Chronic Study of Glyphosate Administered in Feed to Albino Rats*, Pathco Inc. (Sept. 26, 1990).

75. Subpart D – Product Chemistry, 72. Fed. Reg. 60,969, 60,971 (Oct. 26, 2007) (to be codified at 40 C.F.R. pt. 158.310).

76. Subpart D – Reporting Requirements for Risk/Benefit Information, 40 CFR. §159.152 - §159.195 (2017).

77. Subpart F – Toxicology, 72 Fed. Reg. 60,975, 60,978 (Oct. 26, 2007) (to be codified at 40 C.F.R. pt. 158.500).

78. Temple, W., *Review of the Evidence Relating to Glyphosate and Carcinogenicity*, New Zealand Environmental Protection Authority (Aug. 2016).

79. Testimony of Anna B. Lowit, Science Advisor, OPP, EPA: Before the H. Comm. On Sci., Space, and Tech., 115th Cong. (Feb. 6, 2018).

80. Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180 (2014).

81. What information must be submitted, 40 CFR §15.158 (2012).

82. WHO Website, Food Safety, *Frequently Asked Questions* (May 16, 2016), http://www.who.int/foodsafety/faq/en/

Other Documents Reviewed:

1. California EPA, Office of Environmental Health Hazard Assessment, *Public Health Goal for Glyphosate in Drinking Water* (June 2007).

2. Email from Steven Levine to Donna Farmer re: Issuance of glyphosate Test Orders for the EDSP (Jan. 16, 2010, 18:52 CST) [MONGLY02162507-08].

3. Email from William Heydens to Charles Healy re: TNO dermal penetration studies: new issues and topics for the conf call of Tuesday, 2 April (8 A.M. STL time) (on file with author) (Apr. 2, 2002) [MONGLY03738295-96].

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6. Email from William Heydens to ldkier@ix.netcom.com re: meeting Prof Parry 15 Feb 2001 (Feb. 19, 2001) [MONGLY02626553-54].

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