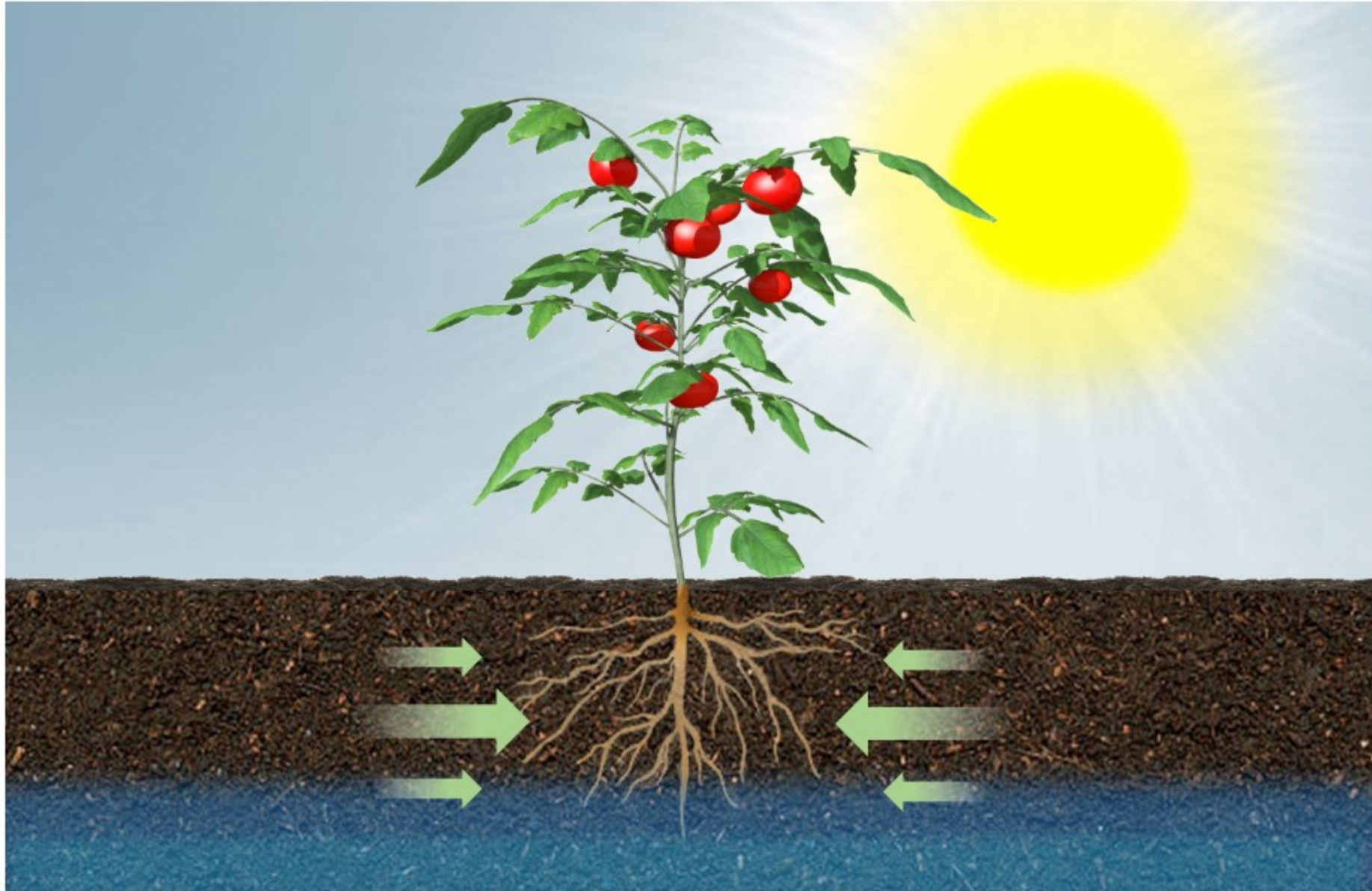


The Need for Herbicides



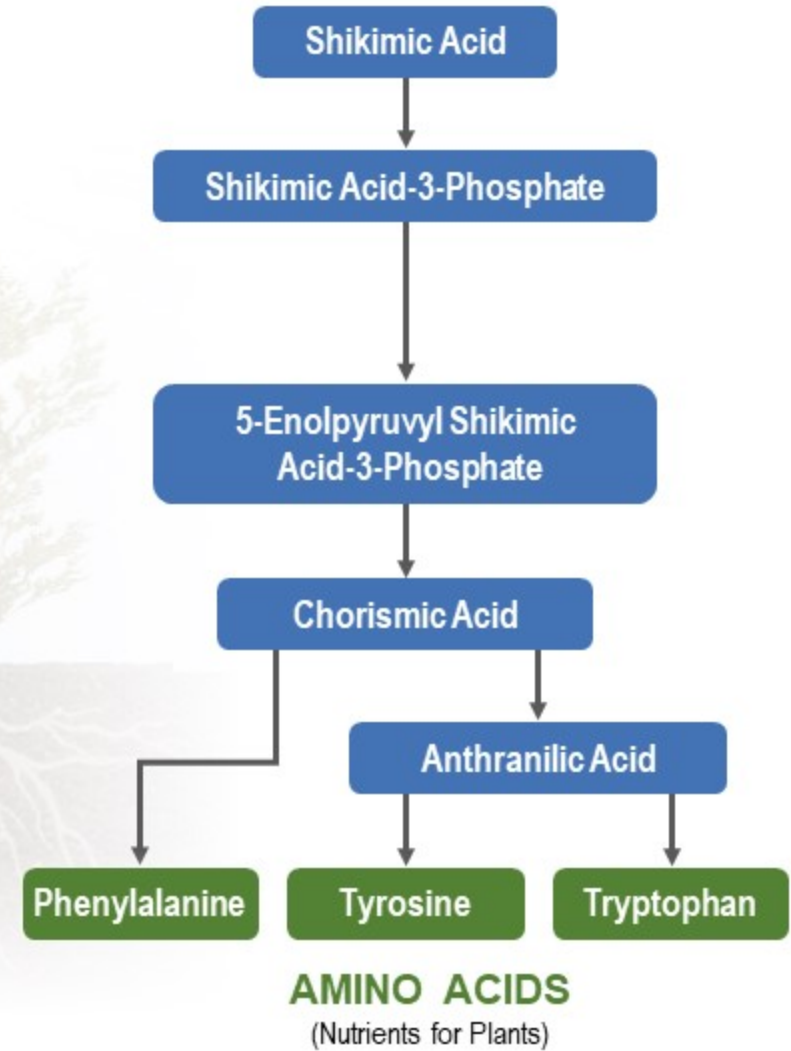
The Need for Herbicides



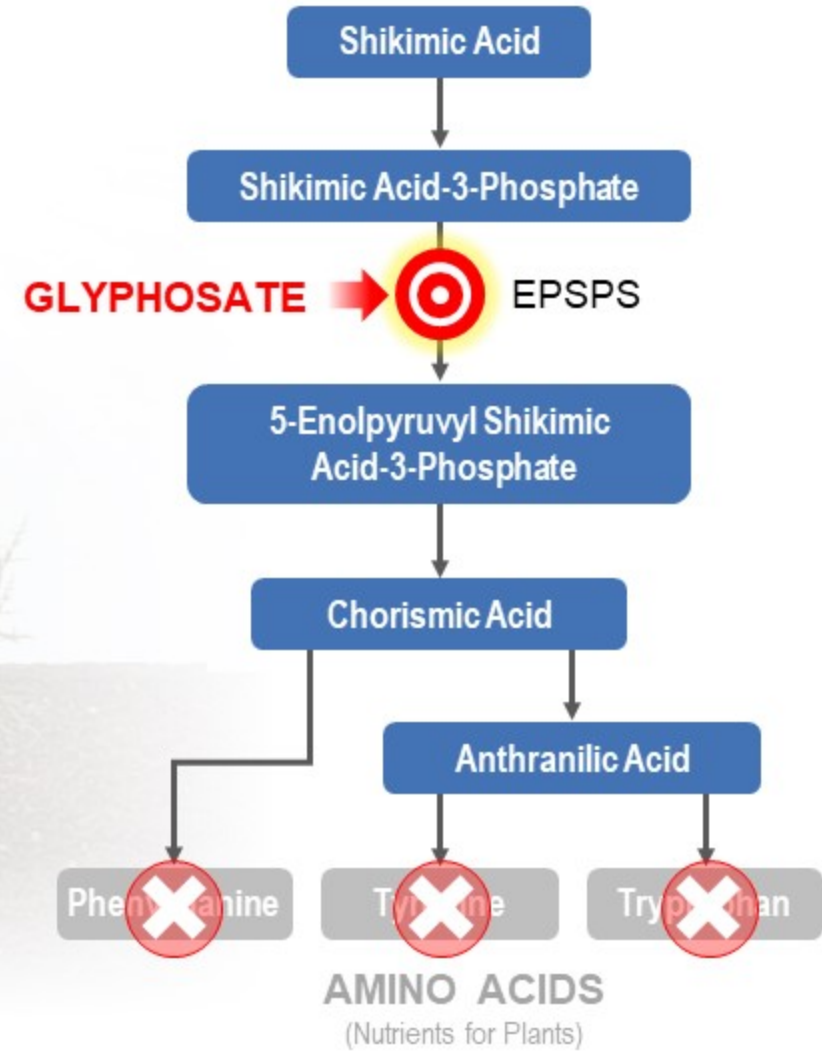
The Need for Herbicides



How Glyphosate Works



How Glyphosate Works



Science on Glyphosate and Glyphosate Formulations

Human Studies

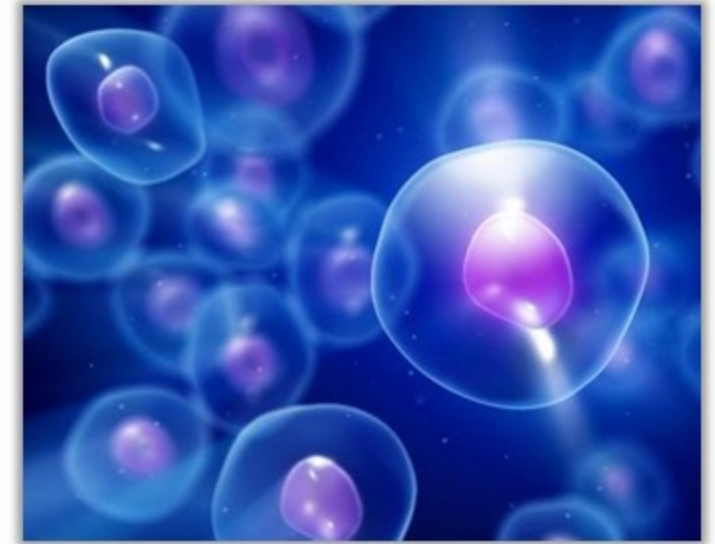


63

Animal Testing



Cell Testing



NHL Associated with Farming

British Journal of Industrial Medicine 1988;45:25-28

Farming and malignant lymphoma in Hancock County, Ohio

R DUBROW,¹ J O PAULSON,² R WINDIAN²

From the Division of Surveillance, Hazard Evaluations, and Field Studies,¹ National Institute for Occupational Safety and Health, Cincinnati, Ohio 45226, and the Chronic Disease and Special Studies Unit,² Ohio Department of Health, Columbus, Ohio 43216, USA

ABSTRACT Raised death rates have been reported for non-Hodgkin's lymphoma (NHL) and Hodgkin's disease (HD) among white male residents of Hancock County, Ohio, United States, for

ABSTRACT Raised death rates have been reported for non-Hodgkin's lymphoma (NHL) and Hodgkin's disease (HD) among white male residents of Hancock County, Ohio, United States, for 1960-79. As a surveillance activity, to assess the possibility of workplace exposures contributing to

The death rate for non-Hodgkin's lymphoma (NHL) among white male residents of Hancock County, Ohio, United States, showed a statistically significant rise during 1960-79¹ (table 1). Among the 377 US counties with 20 or more deaths from NHL in white

in a preliminary and relatively quick and inexpensive way, researchers from the National Institute for Occupational Safety and Health (NIOSH) and the Ohio Department of Health have conducted a case-control study, based on death certificates, of NHL

unremarkable. This small study adds to the growing body of reports linking farming and malignant lymphoma, particularly NHL.

HD to men suggests that these excesses may have been due to a workplace exposure(s) particular to men. As a surveillance activity, to test this possibility

Hancock County	9.0 (25)	10.4 (29)	3.0 (7)	2.4 (7)
Ohio	6.0	6.2	2.5	1.8
United States	3.6	6.0	2.3	1.6

*Data taken from reference 1.
†Numbers in parentheses are the number of deaths.
‡Significantly raised over the United States rate, $p < 0.05$, according to the Poisson test.

Accepted 12 January 1987

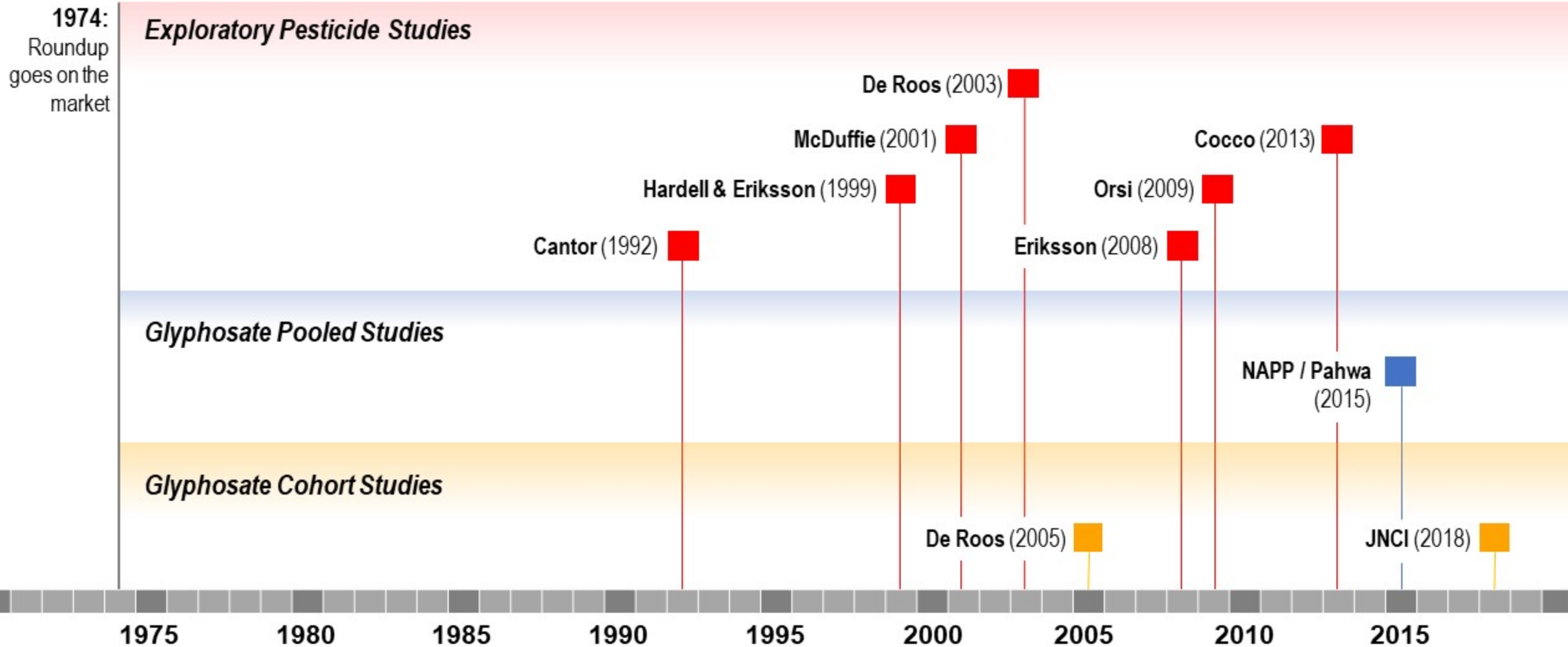
25



Defendant's Exhibit 2312_0001

Def. Ex. 2312_0001

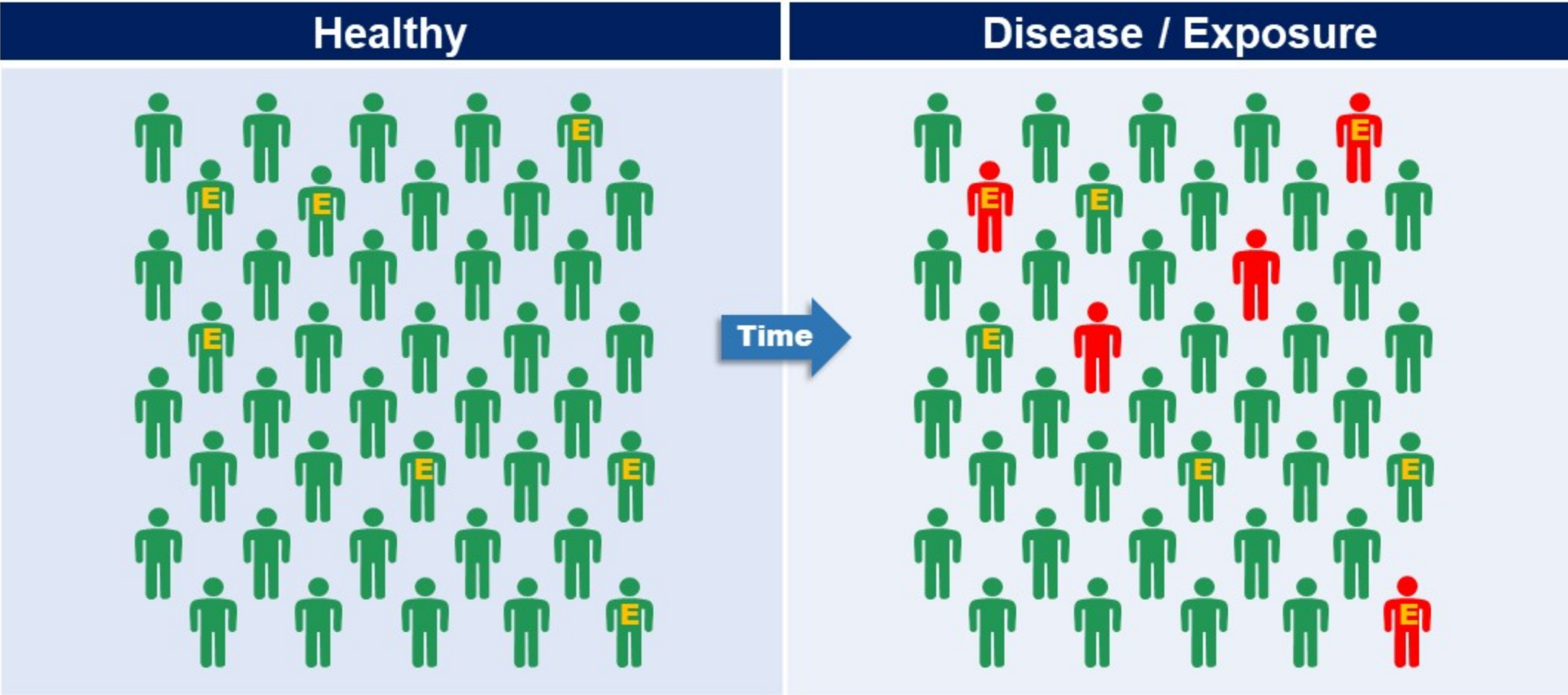
Human Studies of NHL and Pesticides



Cohort Studies

HEALTHY INDIVIDUALS
WHAT EXPOSURES?

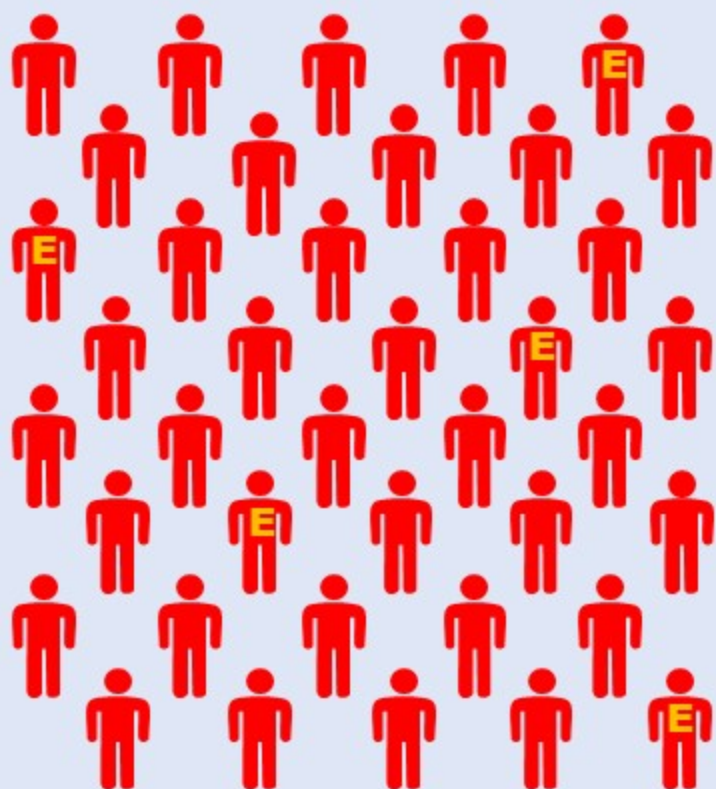
What DISEASES?



Case Control Studies

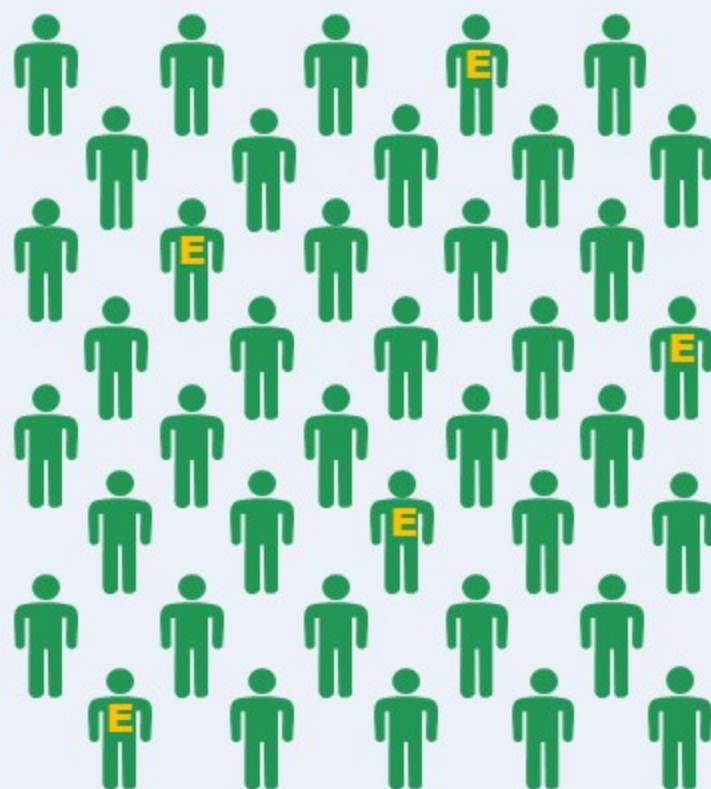
HAVE THE DISEASE
WHAT **EXPOSURES?**

Cases



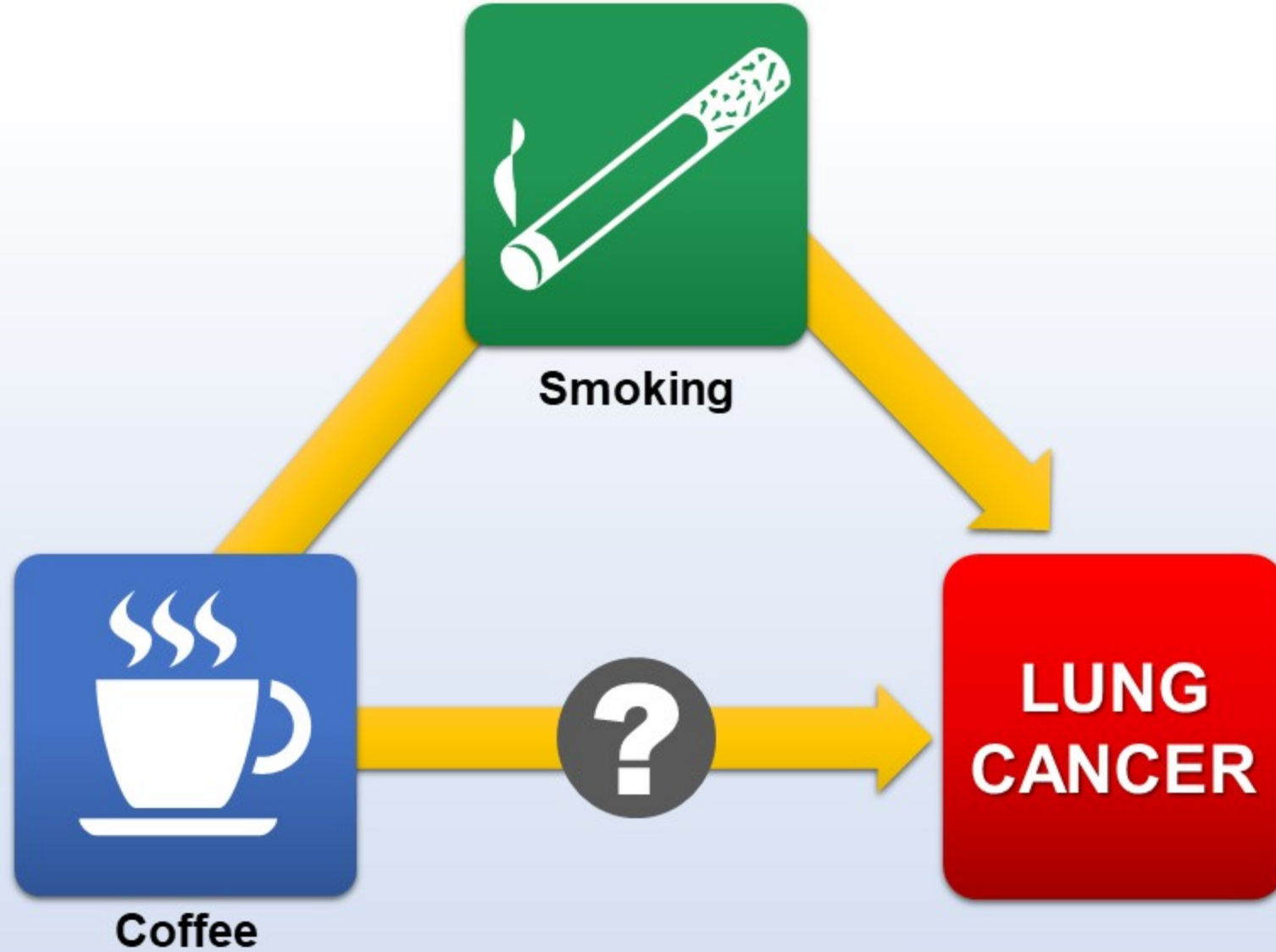
DO NOT
HAVE THE DISEASE

Controls

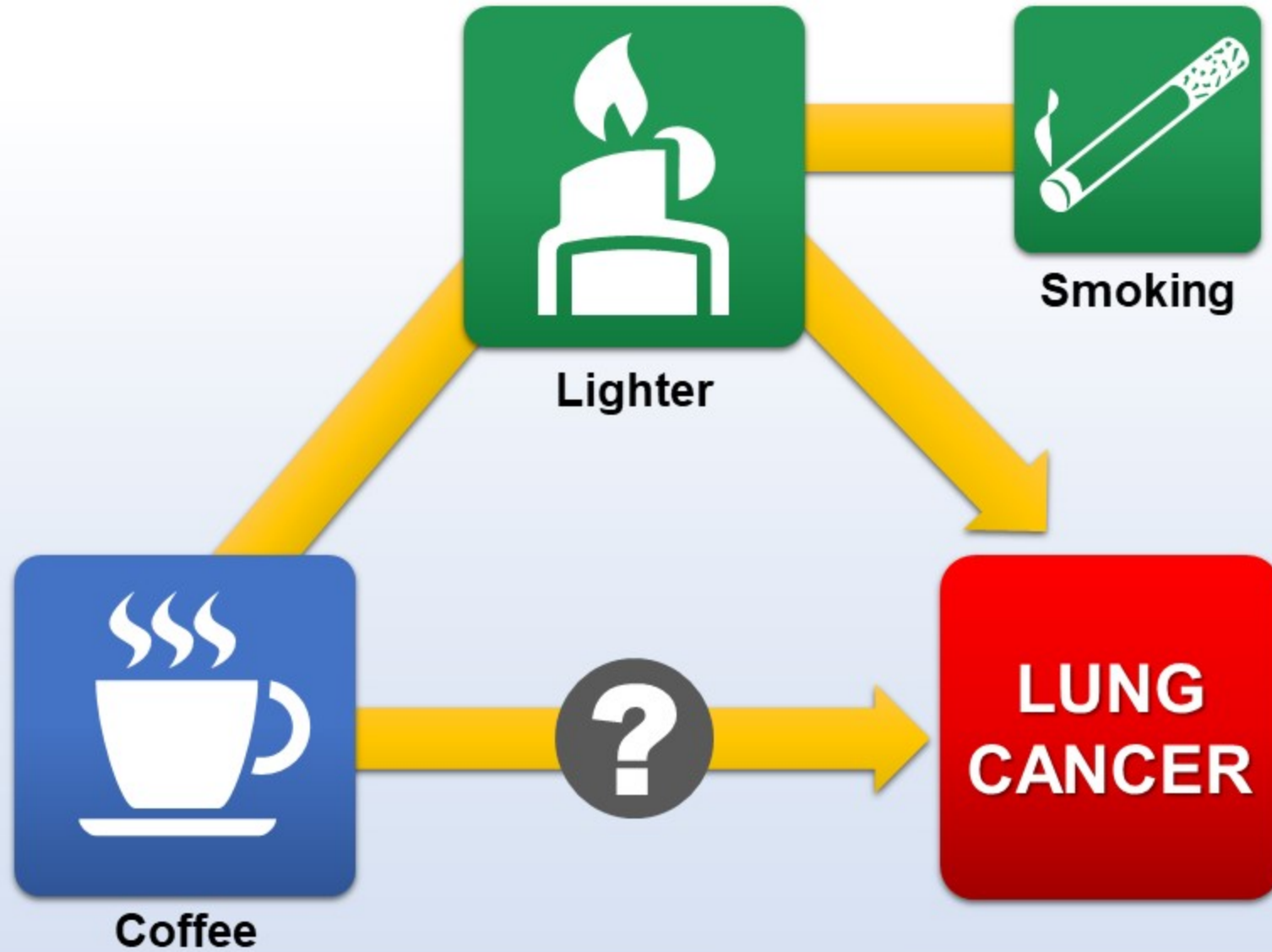


What Exposures Does Each Group Have?

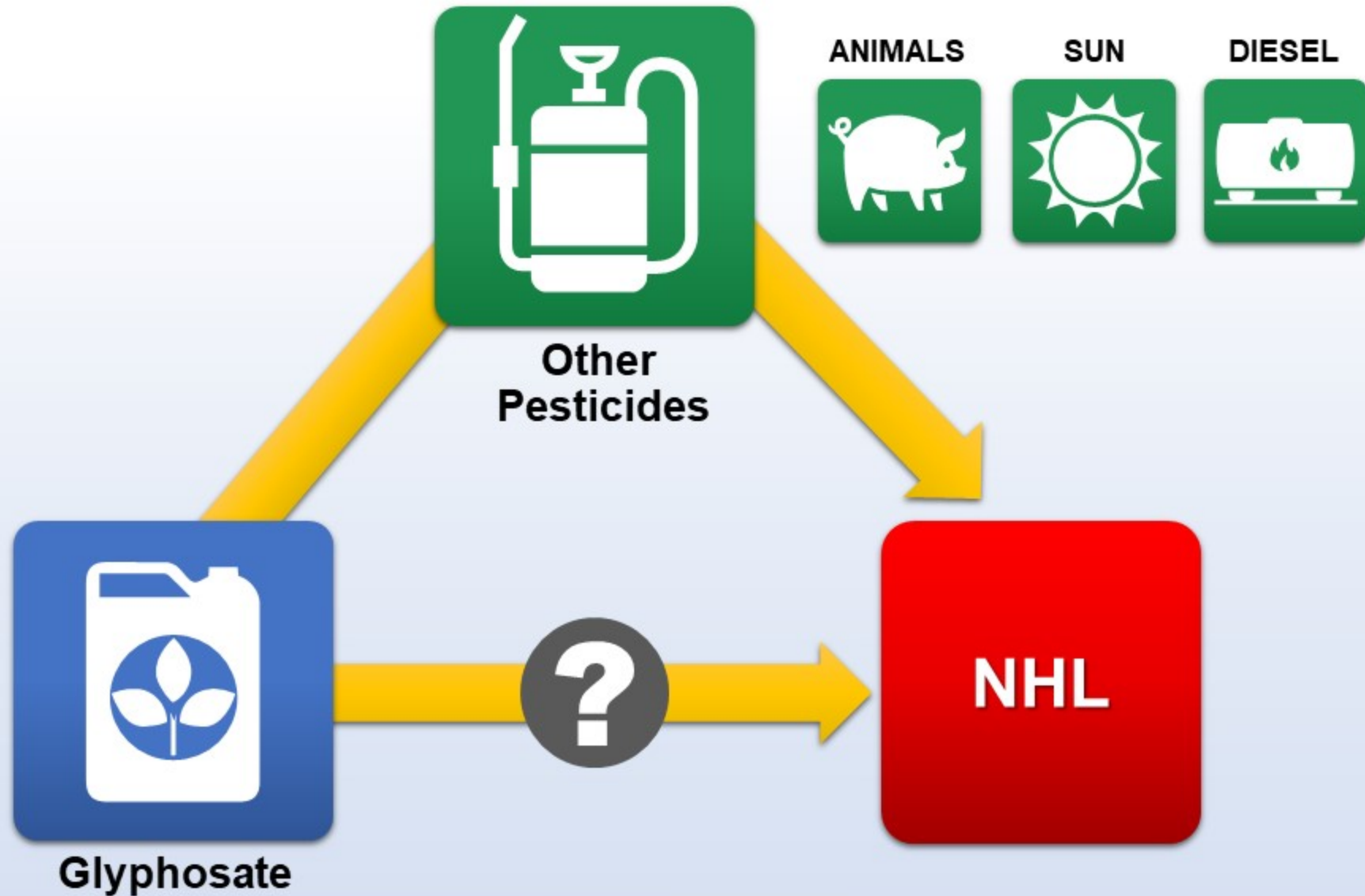
Confounding



Confounding



Confounding



Dorothy Johnson v.
Monsanto Company
Defendant's Exhibit 2191_0001
www.secdcf.com

Research | Article

Cancer
Agriculture

Anneclaire
Dale P. S.

*Program in
Seattle, WA
Department
Health Sci

Glyphosate
the world,
from its
effects of gly
in the Agric
applicators
was obser
(1993-199
glyphosate
personally

Cancer Incidence among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study

Anneclaire J. De Roos,¹ Aaron Blair,² Jennifer A. Rusiecki,² Jane A. Hoppin,³ Megan Svec,¹ Mustafa Dosemeci,² Dale P. Sandler,³ and Michael C. Alavanja²

cumulative exposure days (years of use \times days/year) and *d*) intensity-weighted cumulative exposure days (years of use \times days/year \times estimated intensity level). Poisson regression was used to estimate exposure-response relations between glyphosate and incidence of all cancers combined and 12 relatively common cancer subtypes. Glyphosate exposure was not associated with cancer incidence overall or with most of the cancer subtypes we studied. There was a suggested association with multiple myeloma incidence that should be followed up as more cases occur in the AHS. Given the widespread use of glyphosate, future analyses of the AHS will allow further examination of long-term health effects, including less common cancers. **Key words:** cancer, cohort study, farming, glyphosate, pesticide. *Environ Health Perspect* 113:49-54 (2005). doi:10.1289/ehp.7349 available via <http://dx.doi.org/> [Online 4 November 2004]

specific cancer incidence associated with glyphosate use among pesticide applicators in the Agricultural Health Study (AHS) cohort.

Materials and Methods

Cohort enrollment and follow-up. The AHS is a prospective cohort study in Iowa and North Carolina, which includes 57,311 private and commercial applicators who were licensed to apply restricted-use pesticides at the time of enrollment. Recruitment of the applicators occurred between 1993 and 1997 (Alavanja et al. 1996). Cohort members were matched to cancer registry files in Iowa and North Carolina for case identification and to the state death registries and the National Death Index (National Center for Health Statistics 1999) to ascertain vital status. Incident cancers were identified for the time period from the date of enrollment until 31 December 2001 and were coded according to the *International Classification of Diseases, 9th Revision* (WHO 1977). If cohort members had moved from the state, they were removed in the year they left. The median time of follow-up was 6.7 years.

Exposure assessment. Using a self-administered enrollment questionnaire, we collected comprehensive-use data on 22 pesticides, ever/never use information for 28 additional pesticides, and general information on pesticide application methods, personal protective equipment, pesticide mixing, and equipment repair. Data were also collected on basic demographic information.

Address correspondence to A.J. De Roos, Fred Hutchinson Cancer Research Center and University of Washington Department of Epidemiology, 1100 Fairview Ave., N., M/S 3874, Seattle, WA 98101 USA. Telephone: (206) 667-7315. Fax: (206) 667-4787. E-mail: doros@fhcr.washington.edu

The authors declare they have no competing financial interests.

Received 21 June 2004; accepted 3 November 2004.

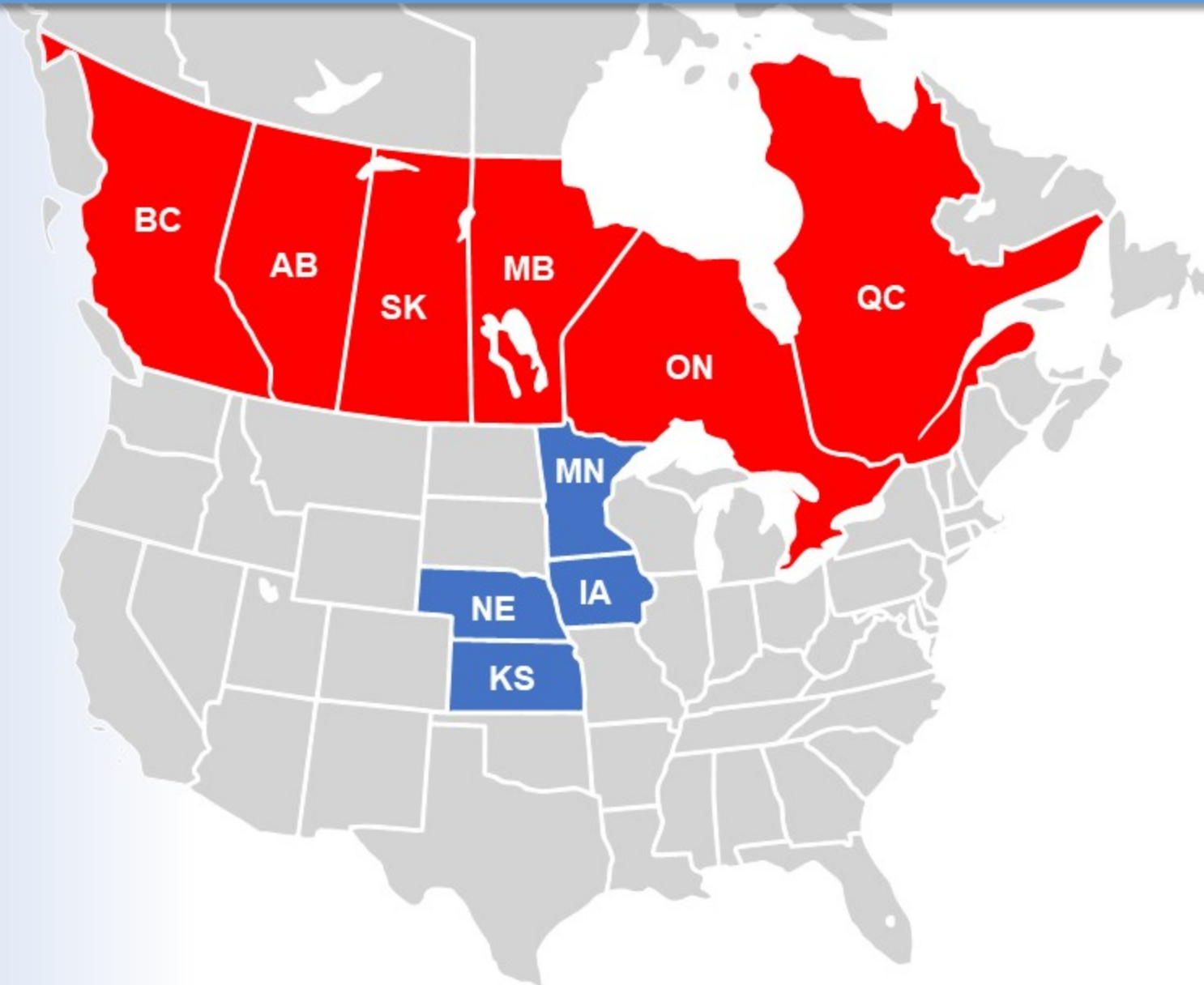
Glyphosate [N-(phosphonomethyl)glycine], commonly sold in the commercial formulation named Roundup (Monsanto Company, St. Louis, MO), has been a frequently used herbicide on both cropland and noncropland areas of the world since its introduction in the 1970s (Williams et al. 2000). Roundup is a combination of the active ingredient and other chemicals, including a surfactant (polyoxyethyleneamine) that enhances the spreading of spray droplets when they contact foliage. Glyphosate is a broad-spectrum herbicide of which the primary mechanism is inhibition of the enzyme 5-enolpyruvylshikimate 3-phosphate synthase, which is essential for the formation of aromatic amino acids in plants (Steinrücken and Amrhein 1980). Because this specific biologic pathway operates only in plants and microorganisms, the mechanism is not considered to be a risk for humans. Nevertheless, genotoxic, hormonal, and enzymic effects in mammals have been reported (Bolognesi et al. 1997; Darulich et al. 2001; El Demerdash et al. 2001; Hietanen et al. 1983; Lioi et al. 1998a, 1998b; Olorunsogo et al. 1979; Peluso et al. 1998; Walsh et al. 2000; Yousef et al. 1995).

Results from genotoxicity studies of glyphosate have been conflicting. Glyphosate did not show any genotoxic activity in a battery of assays (Garry et al. 1999; Grisolia 2002; Li and Long 1988; Wildeman and Naur 1982). However, other studies observed that glyphosate treatment of human lymphocytes *in vitro* resulted in increased sister chromatid exchanges (Bolognesi et al. 1997), chromosomal aberrations (Lioi et al. 1998b), and indicators of oxidative stress (Lioi et al. 1998b). Some studies found slightly greater toxicity of the Roundup formulation compared with glyphosate, in terms of both acute toxicity (Folmar et al. 1979; Martinez et al. 1990; Mitchell et al. 1987) and genotoxicity (Bolognesi et al. 1997; Vigfusson and Vise 1980). Roundup was associated with increased DNA adducts in mice (Peluso et al. 1998) and a weak mutagenic effect in the *Salmonella* assay (Kale et al. 1995; Moriya et al. 1983; Rank et al. 1993), whereas glyphosate alone did not show these effects. Chronic feeding studies of glyphosate have not provided evidence of a carcinogenic effect in mice or rats (Williams et al. 2000).

The U.S. Environmental Protection Agency (U.S. EPA 1993) and the World Health Organization (WHO 1994) reviewed the toxicology data on glyphosate and concluded that glyphosate is not mutagenic or carcinogenic. The U.S. EPA classified glyphosate as category E, indicating "evidence

exposure (results not shown). No association was observed between NHL and glyphosate exposure in any analysis, including an analysis

North American Pooled Project (NAPP) (2015)



NAPP is funded by National Institutes of Health

Proxy vs. Self Respondents



OR (95% CI) for NHL Overall

Glyphosate Use	Proxy and Self Respondents ^a	Self Respondents Only ^b
Never used	1	1
Ever used	1.13 (0.84, 1.51)	0.95 (0.69, 1.32)

Glyphosate Use	Proxy and Self Respondents ^a	Self Respondents Only ^b
Never used	1	1
Ever used	1.13 (0.84, 1.51)	0.95 (0.69, 1.32)
>7	1.08 (0.66, 1.77)	1.06 (0.62, 1.81)

a. ORs adjusted for age, sex, state/province, lymphatic or hematopoietic cancer in a first-degree relative, use of a proxy respondent, use of any PPE, use of 2,4-D, use of dicamba, use of malathion; b. ORs adjusted for age, sex, state/province, lymphatic or hematopoietic cancer in a first-degree relative, use of any PPE, use of 2,4-D, use of dicamba, use of malathion

Proxy vs. Self Respondents



OR (95% CI) for NHL Overall

Glyphosate Use

Proxy and Self Respondents^a

Self Respondents Only^b

Glyphosate Use

Proxy and Self Respondents^a

Self Respondents Only^b

Lifetime days (# years x # days/year)

0 and ≤7

0.87 (0.52, 1.45)

0.82 (0.46, 1.44)

>7

1.08 (0.66, 1.77)

1.06 (0.62, 1.81)

Lifetime days (# years x # days/year)

0 and ≤7

0.87 (0.52, 1.45)

0.82 (0.46, 1.44)

>7

1.08 (0.66, 1.77)

1.06 (0.62, 1.81)

a. ORs adjusted for age, sex, state/province, lymphatic or hematopoietic cancer in a first-degree relative, use of a proxy respondent, use of any PPE, use of 2,4-D, use of dicamba, use of malathion; b. ORs adjusted for age, sex, state/province, lymphatic or hematopoietic cancer in a first-degree relative, use of any PPE, use of 2,4-D, use of dicamba, use of malathion

OXFORD

JNCI | Natl Cancer Inst | 2018 | 110(5) | djc233

doi:10.1093/jnci/djz233
First published online November 9, 2017
Article

Dwayne Johnson v. Monsanto Company
Defendant's Exhibit 2052_0001
Case No. 1:17-cv-00012-JE

ARTICLE
Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Gabriella Andreotti, Stella Koutros, Jonathan N. Hofmann, Dale P. Sandier, Jay H. Lubin, Charles F. Lynch, Catherine C. Lerro, Anneclaire J. De Roos, Christine G. Parks, Michael C. Alavanja, Debra T. Silverman, Laura E. Beane Freeman

Abstract
Background: Glyphosate is the most 2015, the International Agency for its strong mechanistic evidence and previous evaluation in the Agricultural associations with glyphosate use are **Methods:** The AHS is a prospective of the previous evaluation of glyphosate Lifetime days and intensity-weighted (1985-1997) and follow-up over intervals (2) using Poisson regression tests were two-sided. **Results:** Among 54 251 applicators, 44 In unlagged analyses, glyphosate was applicators in the highest exposure or never users (RR = 2.46, 95% CI = 0.94 to 6.41) were similar with a five-year (RR_{5-year} = 2.04, 95% CI = 1.05 to 3.97) **Conclusions:** In this large, prospective or lymphoid malignancies overall, in the highest exposed group that required

Glyphosate was introduced as a broad-spectrum herbicide in 1974, and it quickly became one of the most heavily used herbicides worldwide. With the introduction of genetically engineered glyphosate-tolerant crops, glyphosate use increased dramatically in the late 1990s and 2000s. In addition to agricultural uses, glyphosate is one of the most common residential

Received: August 13, 2017; Revised: September 30, 2017; Accepted: October 6, 2017
Published by Oxford University Press 2017. This work is written by US Government employees and is in the public domain in the US.

509

Downloaded from <https://academic.oup.com/jnci/article-abstract/110/5/djc233/5191802>
by National Library of Medicine user
on 01 June 2018

Defendant's Exhibit 2052_0001



Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Def. Ex. 2052_0001

Cohort Studies



Nurses'
Health Study



A+ CALIFORNIA TEACHERS STUDY



HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH

**Health Professionals
Follow-Up Study**

Agricultural Health Study Collaborators





- **Gabriella Andreotti**
- **Debra T. Silverman**,
Branch Chief, Occupational &
Environmental Epidemiology
- **Stella Koutros**
- **Jonathan D. Hofmann**
- **Catherine C. Lerro**
- **Laura E. Beane Freeman**
- **Jay H. Lubin**
- **Michael C. Alavanja**



- **Dale P. Sandler**, Chief, Epidemiology Branch, Division of
Intramural Research
- **Christine G. Parks**, Co-Principal Investigator, AHS



Anneclaire J. De Roos,
Associate Professor



Charles F. Lynch,
Medical Director and Principal
Investigator, State Health Registry
of Iowa / Iowa Cancer Registry

Journal of the National Cancer Institute Study (2018)

OXFORD

JNCI Natl Cancer Inst (2018) 110(5): dje233
doi:10.1093/jnci/djz203
First published online November 9, 2017
Article

Dawayne Johnson v. Monsanto Company
Defendant's Exhibit 2052_0001

ARTICLE
Glyphosate Use and Cancer Incidence in the Agricultural Health Study
Gabriella Andreotti, Stella Koutros, Jonathan N. Hofmann, Dale P. Sandler, Jay H. Lubin, Christine C. Johnson, and Laura E. Beeson

Abstract
Background: Glyphosate, the most widely used herbicide in the world, is a strong mechanistic carcinogen. Previous evaluations in the Agricultural Health Study (AHS) with follow-up through 2001 found no statistically significant associations with glyphosate use and cancer at any site.
Methods: The AHS is a prospective cohort of licensed pesticide applicators from North Carolina and Iowa. Here, we updated the previous evaluation of glyphosate with cancer incidence from registry linkages through 2012 (North Carolina) and 2013 (Iowa). Lifetime days and intensity-weighted lifetime days of glyphosate use were based on self-reported information from enrollment (1993–1997) and follow-up questionnaires (1999–2005). We estimated incidence rate ratios (IRRs) and 95% confidence intervals (CIs) using Poisson regression, controlling for potential confounders, including use of other pesticides. All statistical tests were two-sided.
Results: Among 54 251 in unlicensed small applicators in the newer users (IRRs for AHS were 1.04, 95% CI = 0.99–1.09).
Conclusions: In the AHS, glyphosate use was associated with the highest exposure.
Keywords: glyphosate, cancer, agricultural health study, pesticide applicators, herbicide.

Received August 11, 2017
Published October 11, 2017

Downloaded from <https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djz203/5051104> by National Library of Medicine user on 21 June 2018

Defendant's Exhibit 2052_0001



Among 54 251 participants, 44 932 (82.8%) reported ever using glyphosate at enrollment or follow-up. Among the participants

Def. Ex. 2052_0003

ticide use was ascertained prior to cancer diagnosis. Second, this AHS analysis includes only licensed pesticide applicators who have been shown to reliably report their pesticide use (28,29). In

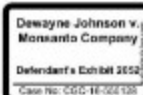
Def. Ex. 2052_0007

Journal of the National Cancer Institute Study (2018)



JNCI Natl Cancer Inst (2018) 110(5): djz333

doi:10.1093/jnci/djz333
First published online November 9, 2017
Article



ARTICLE

Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Gabriella Andreotti, Stella Koutros, Jonathan N. Hofmann, Dale P. Sandler, Jay H. Lubin, Charles F. Lynch, Catherine C. Lerro, Anneclaire J. De Roos, Christine G. Parks, Michael C. Alavanja, Debra T. Silverman, Laura E. Beane Freeman

In our study, we observed no associations between glyphosate use and NHL overall or any of its subtypes. This lack of associa-

Results: In our study, we observed no associations between glyphosate use and NHL overall or any of its subtypes. This lack of association was consistent across all subgroups, including by sex, race, and duration of glyphosate use. In addition, we observed no associations between glyphosate use and other solid tumors, including prostate, lung, and colorectal cancer. However, we observed an increased risk of acute myeloid leukemia (AML) among users of glyphosate compared with nonusers (RR = 2.44, 95% CI = 0.94 to 6.32, $P_{trend} = .11$), though this association was not statistically significant. Results for AML were similar with a five-year ($RR_{5years} = 2.32$, 95% CI = 0.98 to 5.51, $P_{trend} = .07$) and 20-year exposure lag ($RR_{20years} = 2.04$, 95% CI = 1.05 to 3.97, $P_{trend} = .04$).
Conclusions: In this large, prospective cohort study, no association was apparent between glyphosate and any solid tumors or lymphoid malignancies overall, including NHL and its subtypes. There was some evidence of increased risk of AML among the highest exposed group that requires confirmation.

Glyphosate was introduced as a broad-spectrum herbicide in 1974, and it quickly became one of the most heavily used herbicides worldwide. With the introduction of genetically engineered glyphosate-tolerant crops, glyphosate use increased dramatically in the late-1990s and 2000s. In addition to agricultural use, glyphosate is one of the most common residential

Received: August 23, 2017; Revised: September 26, 2017; Accepted: October 6, 2017.
Published by Oxford University Press 2017. This work is written by US Government employees and is in the public domain in the US.

503

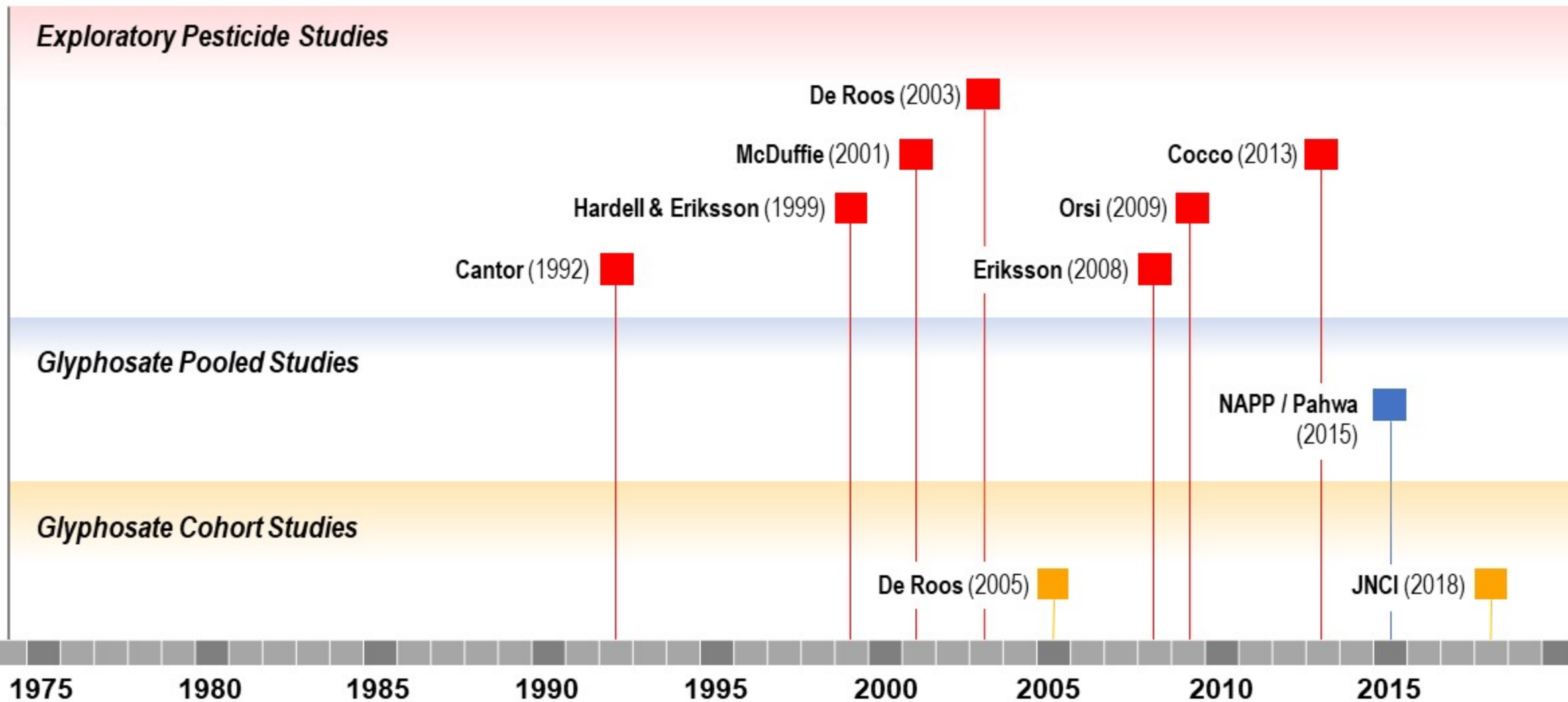
Downloaded from <https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djz333/5511004>
by National Library of Medicine user
on 21 June 2018

Defendant's Exhibit 2052_0001

Def. Ex. 2052_0007

Human Studies of NHL and Pesticides

1974:
Roundup
goes on the
market



Science on Glyphosate and Glyphosate Formulations

Human Studies



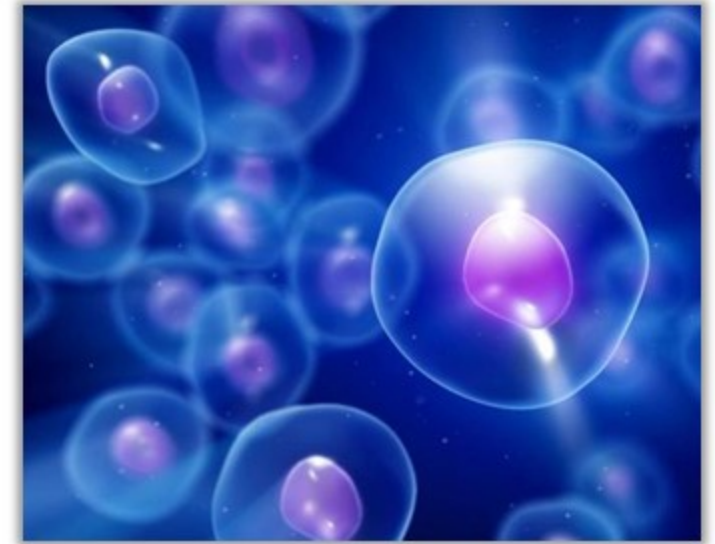
63

Animal Testing



14

Cell Testing



What is Evaluated?

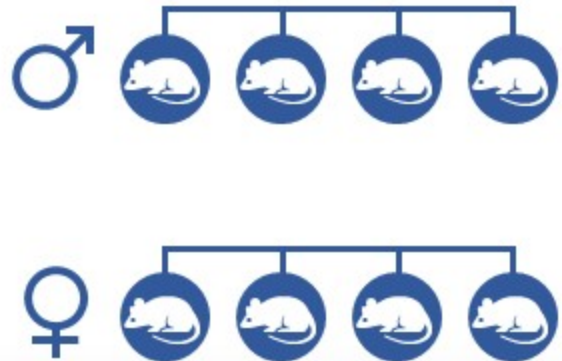
Every Tissue

Heart, pancreas, stomach, adrenal gland, ileum, parathyroid gland, aorta, jejunum, peripheral nerve, testis, brain, kidney, pituitary, thymus, caecum, lacrimal gland, prostate, thyroid, cervix, liver, rectum, tongue, coagulating gland, lung, salivary gland, trachea, colon, lymph nodes, seminal vesicle, urinary bladder, duodenum, mammary gland, skeletal muscle, uterus, epididymis, upper respiratory tract, skin, ureter, eye, esophagus, spinal cord, urethra, femur with joint, olfactory bulb, spleen, vagina, gall bladder, ovary, sternum, bone marrow, Harderian gland

Every Animal



Each Group



For a rodent bioassay, pathologists grossly and microscopically examine approximately 40 tissues per animal per sex per group, meaning there are:

16,000 Diagnostic Interpretations

Rodents Are Not Tiny People



- Used in carcinogenicity studies primarily because cheap, plentiful, and short lifespans
- **Major biological differences** between rodents and people
- Although both rodents and humans get cancer, **some rodent tumors develop and progress differently** than human cancers

Individual Rodent Studies

RAT STUDIES	Compound-related tumors?	
Lankas (1981)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Stout and Ruecker (1990)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Brammer (2001)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Wood (2009a)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Atkinson (1993)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Suresh (1996)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Enemoto (1997)	<input type="button" value="YES"/>	<input type="button" value="NO"/>

MOUSE STUDIES	Compound-related tumors?	
Knezevich and Hogan (1983)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Atkinson (1993)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Sugimoto (1997)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Wood (2009b)	<input type="button" value="YES"/>	<input type="button" value="NO"/>
Kumar (2001)	<input type="button" value="YES"/>	<input type="button" value="NO"/>

Danger of Misinterpretation of False Positive Data



Improperly assumes statistically significant difference in number of tumors between groups shows compound-mediated effect



Scientifically invalid to ignore other factors necessary to assess whether tumors are compound-mediated



Creates misleading interpretations of data given expectation of false positives

Function of Surfactants

No Surfactant



Surfactant



Science on Glyphosate and Glyphosate Formulations

Human Studies



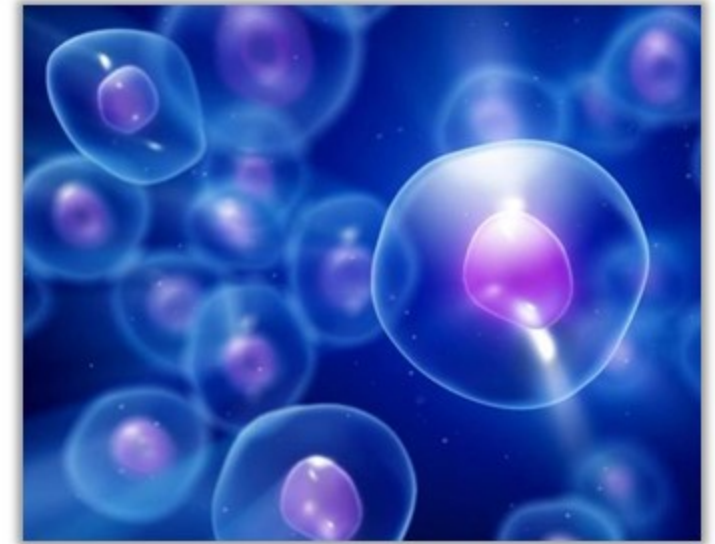
63

Animal Testing



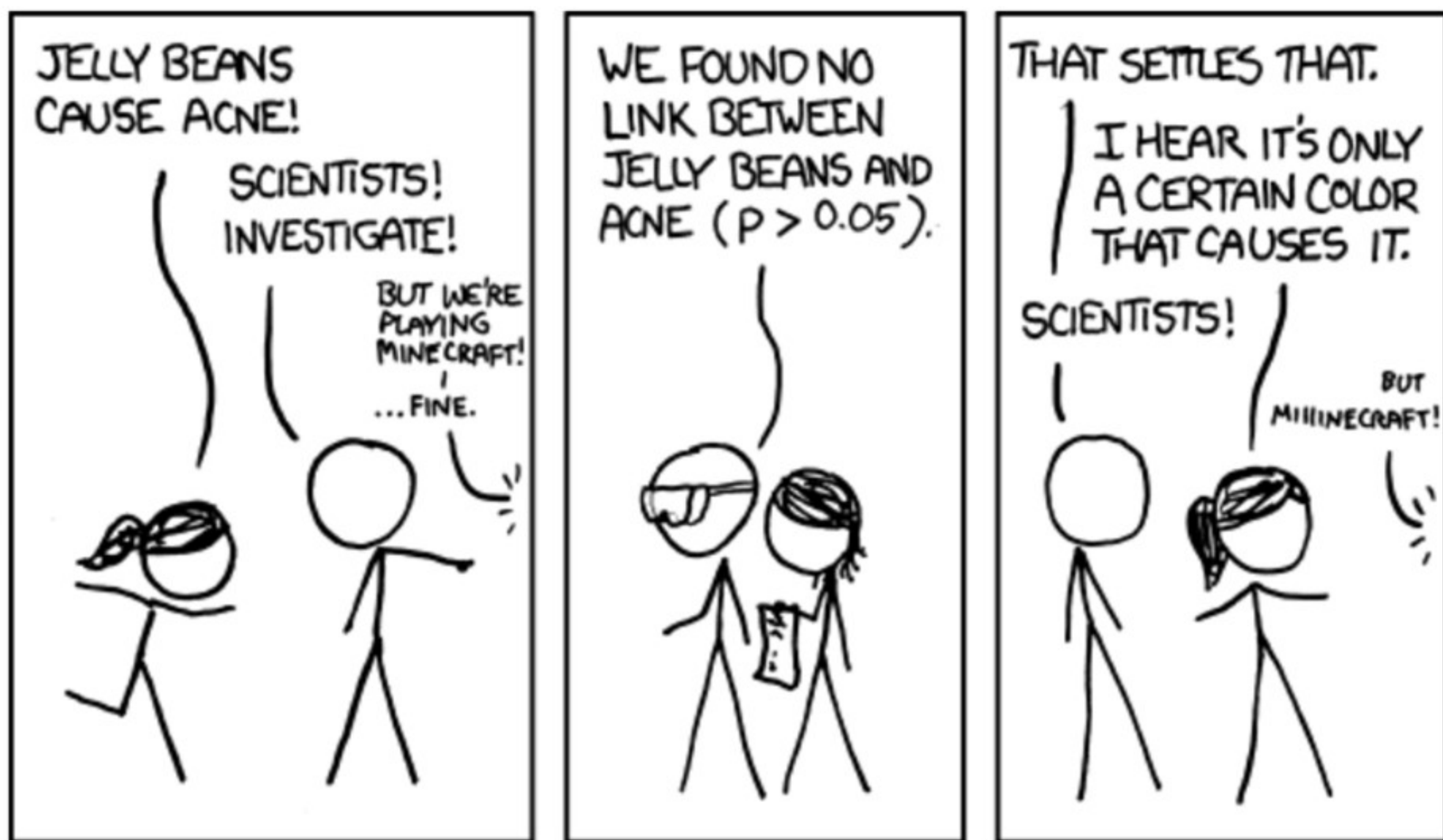
14

Cell Testing



140+

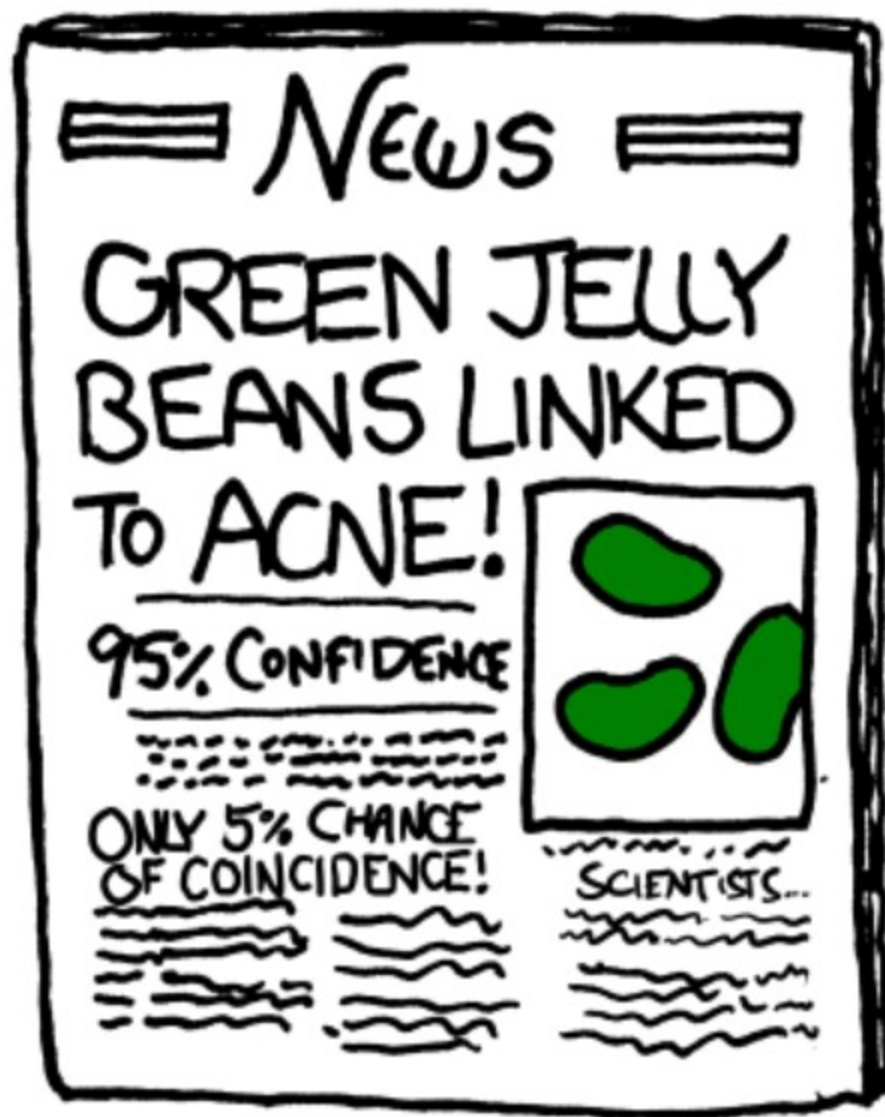
The Curse of Multiple Testing



The Curse of Multiple Testing



The Curse of Multiple Testing





Glyphosate Animal and Cell Studies Considered by EPA

	1970s	1980s	1990s	2000s	2010s
Rodent Carcinogenicity Studies		Lankas (1981) Knezevich and Hogan (1983)	Stout and Ruecker (1990) Atkinson (1993a) Atkinson (1993b) Suresh (1996) Excel (1997) Enemoto (1997) Sugimoto (1997)	Chruscielska (2000) Kumar (2001) Brammer (2001) Wood (2009a) Wood (2009b)	
Cell Testing					
Ames Tests	Flowers and Kier (1978) Shirasu (1978)	Majeska (1982a) Wilderman and Nazar (1982) Moriya (1983) Majeska (1985a)	Jensen (1991a) NTP (1992) Suresh (1993a) Akanuma (1995) Thompson (1996) Callander (1996) Callander (1999)	Chruscielska (2000) Ranzani (2000) Sokolowski (2007a) Sokolowski (2007b) Sokolowski (2007c) Ribeiro do Val (2007) Miyaji (2008) Sokolowski (2009a) Sokolowski (2009b) Flugge (2009a)	Flugge (2010b) Sokolowski (2010) Schreib (2010) Wallner (2010)
In Vitro Mammalian Gene Mutation Assays		Li (1983a) Majeska (1985b)	Jensen (1991b) Clay (1996)		
In Vitro Tests for Chromosomal Abnormalities and Micronuclei Induction in Mammals		Majeska (1985c)	Matsumoto (1995) Wright (1996) Fox (1998) Lioi (1998a) Lioi (1998b)	Piesova (2004) Piesova (2005) Sivikova (2006) Mladinic (2009a) Mladinic (2009b) Manas (2009)	Koller (2012) Roustan (2014)
In Vivo Tests for Chromosomal Aberrations and Micronuclei Induction in Mammals		Rodwell (1980) Majeska (1982c) Li (1983b) Majeska (1987)	Jensen (1991c) NTP (1992) Suresh (1992) Rank (1993) Suresh (1993b) Suresh (1994) Fox & Mackay (1996) Zaocaria (1996) Bolognesi (1997) Jones (1999) Marques (1999)	Chruscielska (2000) Gava (2000) Honarvar (2005) Durward (2008) Zoriki Hosomi (2007) Honarvar (2008) Costa (2008) Manas (2009) Flugge (2009b)	
Assays for Detecting Primary DNA Damage	Shirasu (1978)	Majeska (1982b) Li and Long (1988)	Bolognesi (1997) Peluso (1998) Lioi (1998a) Lioi (1998b)	Sivikova (2008) Manas (2009) Mladinic (2009a)	Koller (2012) Manas (2013) Alvarez-Moya (2014)

Glyphosate Database



Glyphosate Issue Paper: Evaluation of Carcinogenic Potential

EPA's Office of Pesticide Programs
September 12, 2016

A large database is available for evaluating the carcinogenicity potential of glyphosate.

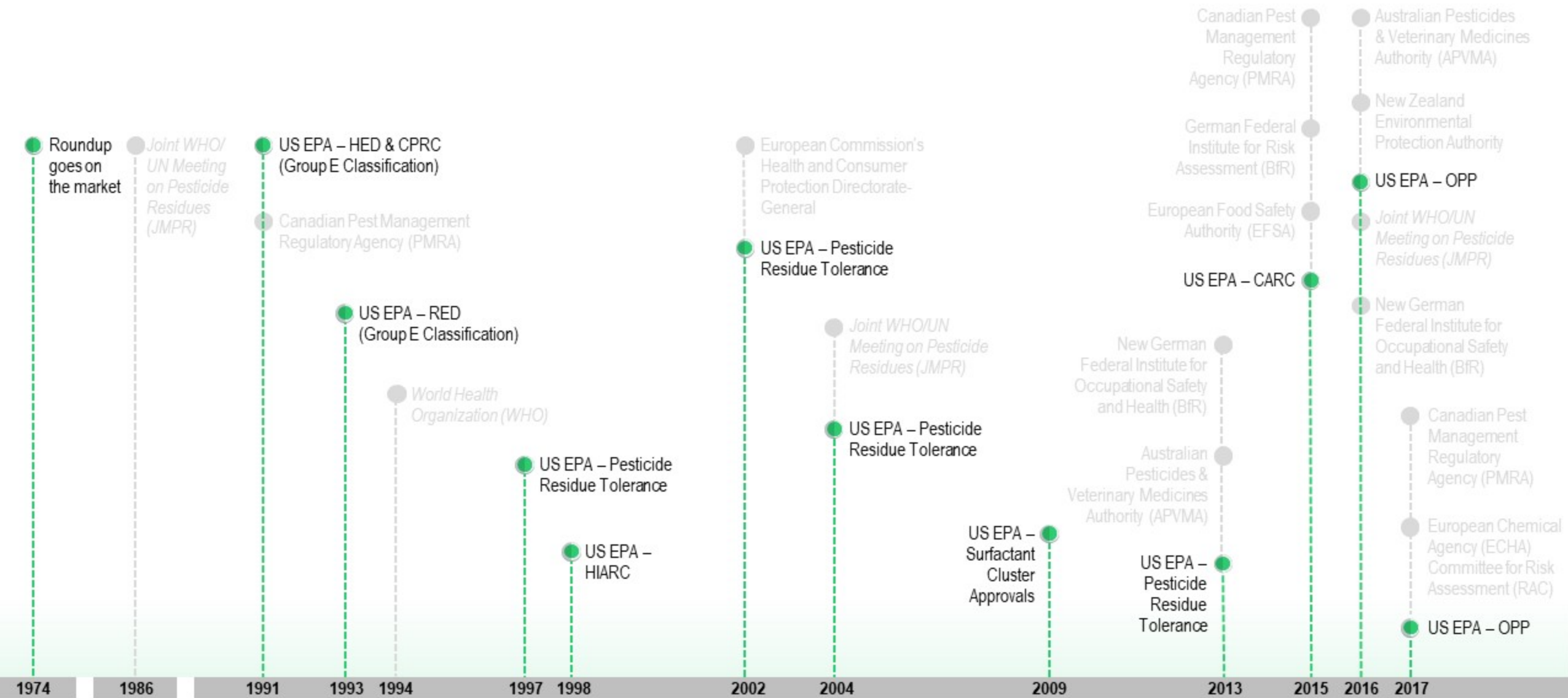
Def. Ex. 2482_0130



The glyphosate dossier consists of an exceptionally large database, therefore the toxicological evaluation adopted by the RMS and agreed during the peer review rely on a magnitude of valid studies rather than on one 'key study' for each endpoint. Glyphosate is rapidly but incompletely absorbed

Def. Ex. 2323_0010

Environmental Protection Agency: Selected Events



EPA on Glyphosate



Glyphosate Issue Paper: Evaluation of Carcinogenic Potential

EPA's Office of Pesticide Programs
September 12, 2016

2016
United States EPA
(OPP)



in the weight-of-evidence should be considered". Based on all of the available data, the weight-of-evidence clearly **do not support the descriptors** "carcinogenic to humans" and "likely to be carcinogenic to humans" at this time. According to the 2005 Cancer Guidelines, "carcinogenic

Def. Ex. 2482_0135

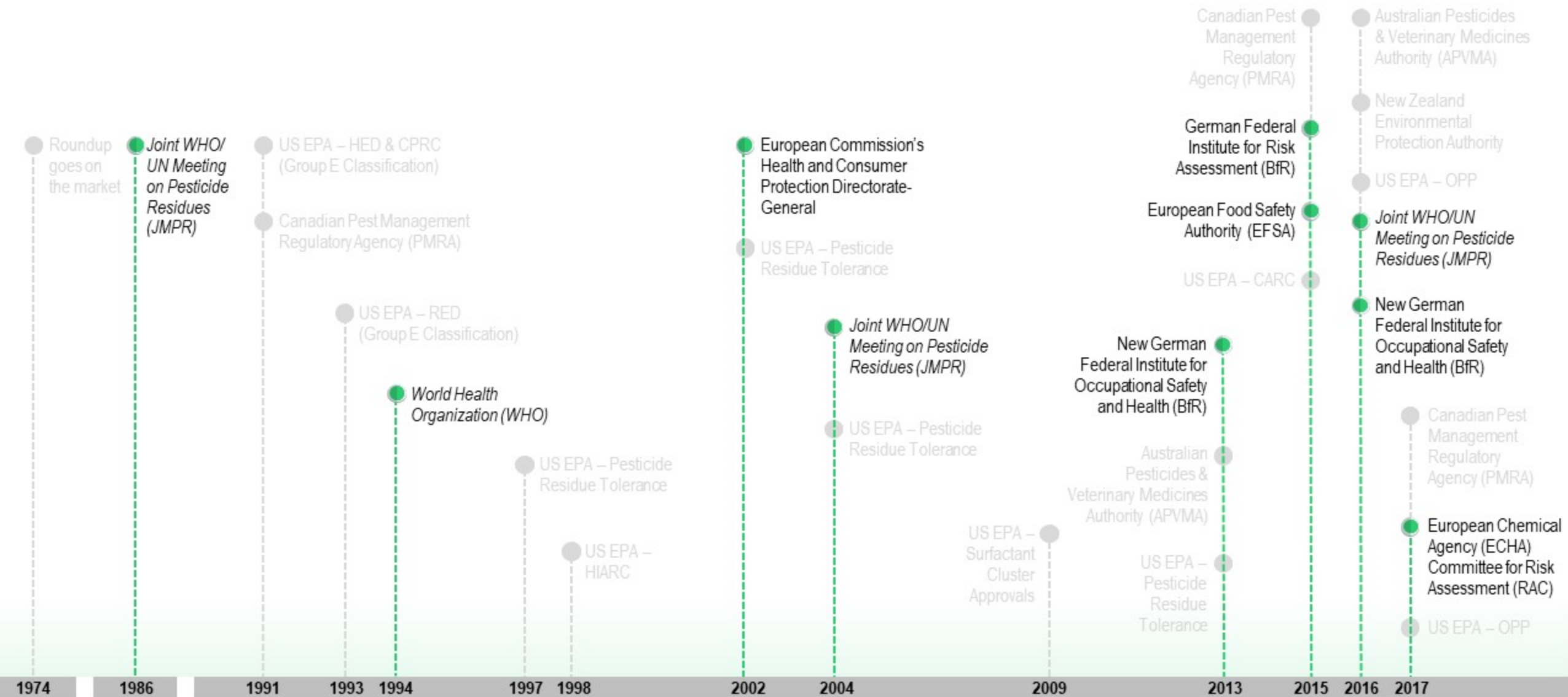
support this cancer descriptor. **The strongest support is for "not likely to be carcinogenic to humans"** at doses relevant to human health risk assessment.

Defendant's Exhibit 2482_0001
Case No: CDC-16-050128

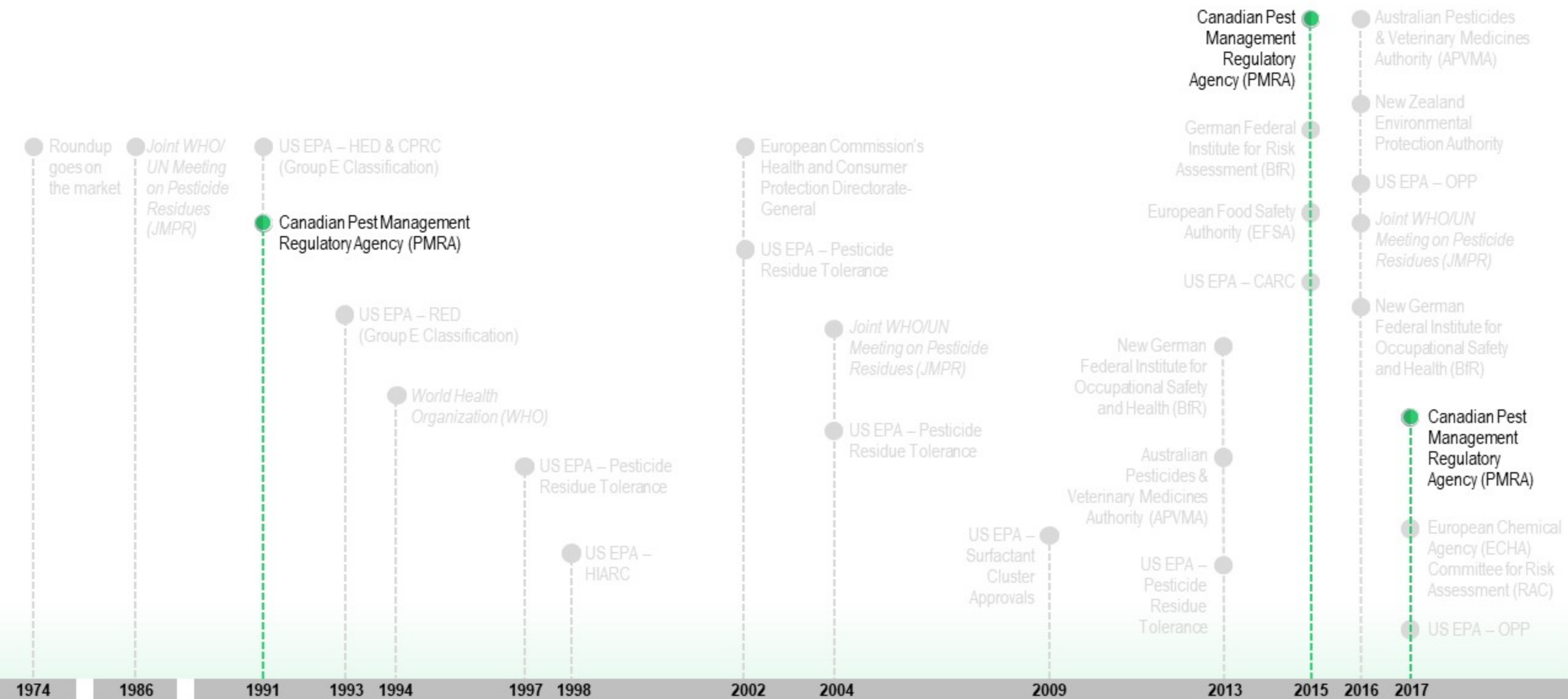
Defendant's Exhibit 2482_0001

Def. Ex. 2482_0141

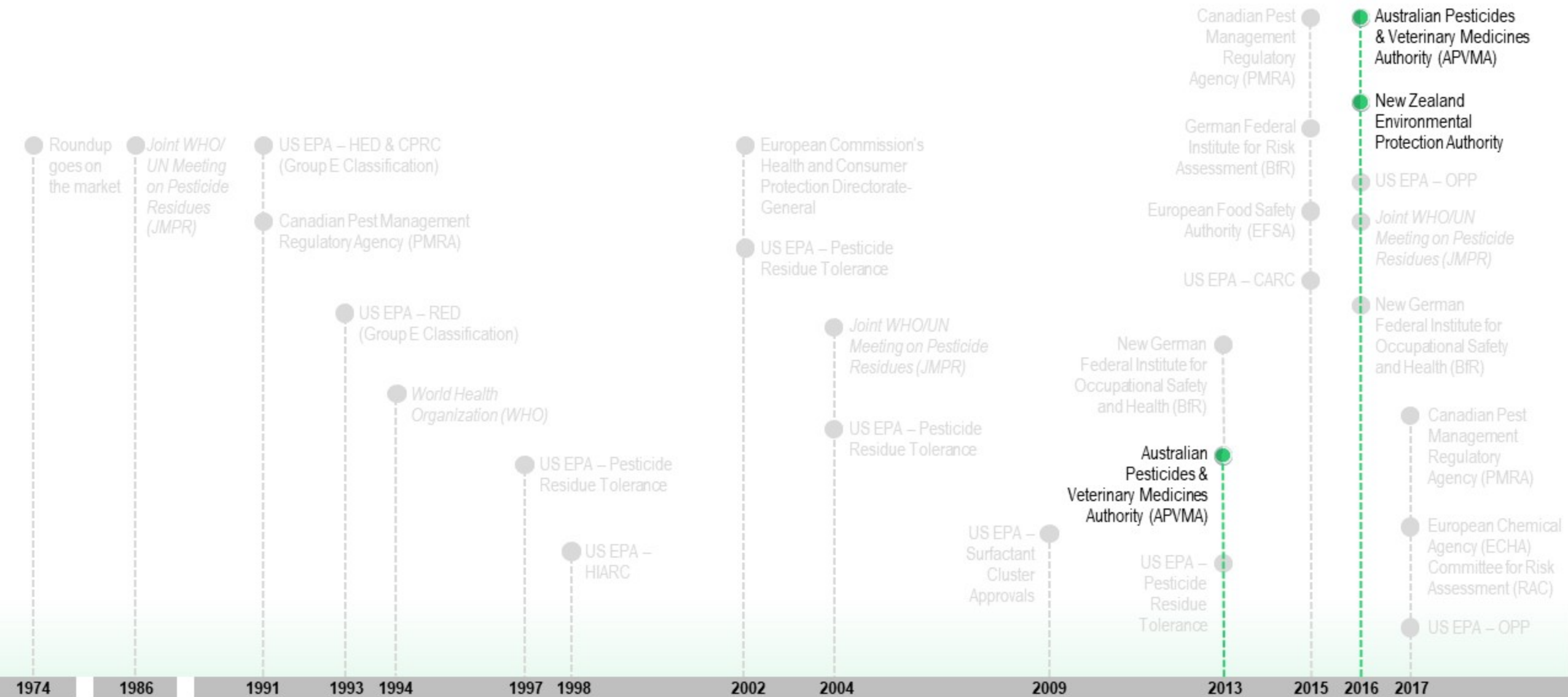
European Regulators: Selected Events



Canadian Regulators: Selected Events



Other International Regulators: Selected Events



IARC: Hazard versus Risk

WORLD HEALTH ORGANIZATION
INTERNATIONAL AGENCY FOR RESEARCH ON CANCER



IARC Monographs on the Evaluation of the
Carcinogenic Risk of Chemicals

A cancer 'hazard' is an agent that is capable of causing cancer under some circumstances, while a cancer 'risk' is an estimate of the carcinogenic effects expected from exposure to a cancer hazard. The *Monographs* are an exercise in evaluating cancer hazards, despite the historical presence of the word 'risks' in the title. The distinction between hazard and risk is important, and the *Monographs* identify cancer hazards even when risks are very low at current exposure levels, because new uses or unforeseen exposures could engender risks that are significantly higher.

LYON, FRANCE
2006



Defendant's Exhibit 2635_0001

Def. Ex. 2635_0004

IARC's Screening Assessment



EXECUTIVE DIRECTOR

13 January 2016
Ref: BU/2016/001 - out-15124233

Prof. Christopher J. Portier
Senior Contributing Scientist
Environmental Defense Fund
1875 Connecticut Ave NW, Ste 600
Washington, DC 20009
United States of America

Subject: Op
and

Dear Professor

First of all, I wo
2015 which yo
Andriukaitis re
directly to yo
share my respo

I would first li
regarding the re
Union and the tr

Enclosed is also
raised in your let
animal carcinoge
IARC monograph

I would like to
debated issue, y
evaluation to de
we avoid confus
who depend on

IARC assessment as a possible first step in a full assessment

As the WHO states on its website in the Preamble to the IARC Monographs, IARC evaluations can represent a first step in carcinogen risk assessment to be considered – if available – by national and international authorities such as EFSA when carrying out their own assessments.

I agree that IARC carries out an important role in the screening assessment of the carcinogenic potential of agents. However, we should not compare this first screening assessment with the more comprehensive hazard assessment done by authorities such as EFSA, which are designed to support the regulatory process for pesticides in close cooperation with the Member States in the EU.

European Food Safety Authority • Via Carlo Magno 1A • 43126 Parma • ITALY
Tel. +39 0521 036 200 • Fax +39 0521 036 0200 • www.efsa.europa.eu



Defendant's Exhibit 2747_0001

I agree that IARC carries out an important role in the screening assessment of the carcinogenic potential of agents. However, we should not compare this first screening assessment with the more comprehensive hazard assessment done by authorities such as EFSA, which are designed to support the regulatory process for pesticides in close cooperation with the Member States in the EU.

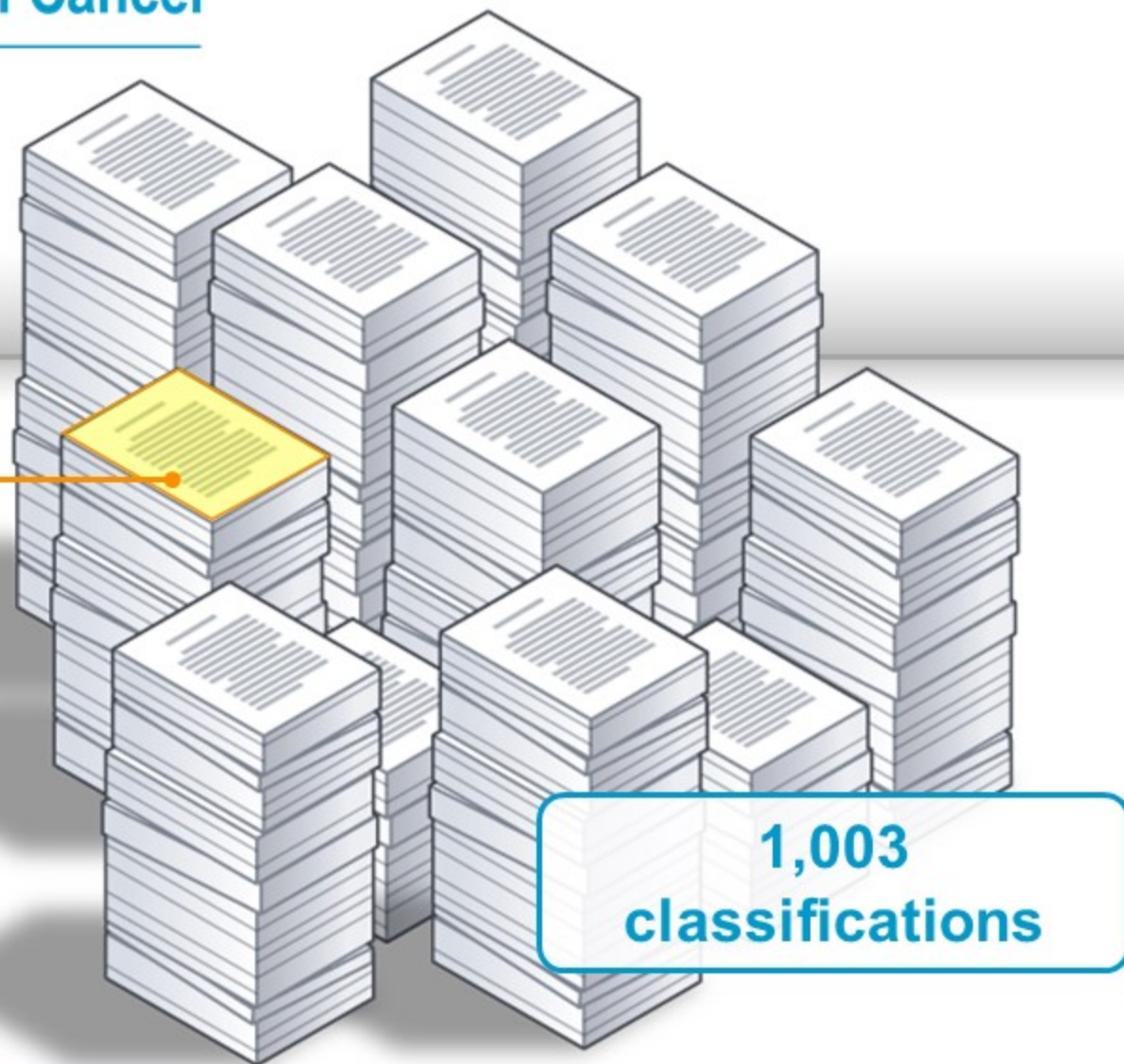
Def. Ex. 2747_0001

IARC: Only One “Probably Not Carcinogenic” Classification

International Agency for Research on Cancer



**Only 1 classified as
“probably not carcinogenic”**



IARC: Probable Carcinogens



**Very Hot
Beverages
(coffee, tea)**



**Night-Shift
Workers**



































































































**Emissions from
Combustion of
Biomass (wood)**



Glyphosate Studies Considered by EPA

	1970s	1980s	1990s	2000s	2010s
Rodent Carcinogenicity Studies		Lankas (1981) Knezevich and Hogan (1983)	Stout and Ruecker (1990) Atkinson (1993a) Atkinson (1993b) Suresh (1996) Excel (1997) Enemoto (1997) Sugimoto (1997)	Chruscielska (2000) Kumar (2001) Brammer (2001) Wood (2009a) Wood (2009b)	
Cell Testing					
Ames Tests	Flowers and Kier (1978) Shirasu (1978)	Majeska (1982a) Wilderman and Nazar (1982) Moriya (1983) Majeska (1985a)	Jensen (1991a) NTP (1992) Suresh (1993a) Akanuma (1995) Thompson (1996) Callander (1996) Callander (1999)	Chruscielska (2000) Ranzani (2000) Sokolowski (2007a) Sokolowski (2007b) Sokolowski (2007c) Ribeiro do Val (2007) Miyaji (2008) Sokolowski (2009a) Sokolowski (2009b) Flugge (2009a)	Flugge (2010b) Sokolowski (2010) Schreib (2010) Wallner (2010)
In Vitro Mammalian Gene Mutation Assays		Li (1983a) Majeska (1985b)	Jensen (1991b) Clay (1996)		
In Vitro Tests for Chromosomal Abnormalities and Micronuclei Induction in Mammals		Majeska (1985c)	Matsumoto (1995) Wright (1996) Fox (1998) Lioi (1998a) Lioi (1998b)	Piesova (2004) Piesova (2005) Sivikova (2006) Mladinic (2009a) Mladinic (2009b) Manas (2009)	Koller (2012) Roustan (2014)
In Vivo Tests for Chromosomal Aberrations and Micronuclei Induction in Mammals		Rodwell (1980) Majeska (1982c) Li (1983b) Majeska (1987)	Jensen (1991c) NTP (1992) Suresh (1992) Rank (1993) Suresh (1993b) Suresh (1994) Fox & Mackay (1996) Zaocaria (1996) Bolognesi (1997) Jones (1999) Marques (1999)	Chruscielska (2000) Gava (2000) Honarvar (2005) Durward (2008) Zoriki Hosomi (2007) Honarvar (2008) Costa (2008) Manas (2009) Flugge (2009b)	
Assays for Detecting Primary DNA Damage	Shirasu (1978)	Majeska (1982b) Li and Long (1988)	Bolognesi (1997) Peluso (1998) Lioi (1998a) Lioi (1998b)	Sivikova (2008) Manas (2009) Mladinic (2009a)	Koller (2012) Manas (2013) Alvarez-Moya (2014)

Glyphosate Studies Considered by Working Group 112

	1970s	1980s	1990s	2000s	2010s
Rodent Carcinogenicity Studies		 Lankas (1981)  Knezevich and Hogan (1983)	 Stout and Ruecker (1990)  Atkinson (1993a)  Atkinson (1993b)  Suresh (1996)  Excel (1997)  Enemoto (1997)  Sugimoto (1997)	 Chruscielska (2000)  Kumar (2001)  Brammer (2001)  Wood (2009a)  Wood (2009b)	
Cell Testing					
Ames Tests	 Flowers and Kier (1978)  Shirasu (1978)	 Majeska (1982a)  Wilderman and Nazar (1982)  Moriya (1983)  Majeska (1985a)	 Jensen (1991a)  NTP (1992)  Suresh (1993a)  Akanuma (1995)  Thompson (1996)  Callander (1996)  Callander (1999)	 Chruscielska (2000)  Ranzani (2000)  Sokolowski (2007a)  Sokolowski (2007b)  Sokolowski (2007c)  Ribeiro do Val (2007)  Miyaji (2008)  Sokolowski (2009a)  Sokolowski (2009b)  Flugge (2009a)	 Flugge (2010b)  Sokolowski (2010)  Schreib (2010)  Wallner (2010)
In Vitro Mammalian Gene Mutation Assays		 Li (1983a)  Majeska (1985b)	 Jensen (1991b)  Clay (1998)		
In Vitro Tests for Chromosomal Abnormalities and Micronuclei Induction in Mammals		 Majeska (1985c)	 Matsumoto (1995)  Wright (1996)  Fox (1998)  Lioi (1998a)  Lioi (1998b)	 Piesova (2004)  Piesova (2005)  Sivikova (2006)  Mladinic (2009a)  Mladinic (2009b)  Manas (2009)	 Koller (2012)  Roustan (2014)
In Vivo Tests for Chromosomal Aberrations and Micronuclei Induction in Mammals		 Rodwell (1980)  Majeska (1982c)  Li (1983b)  Majeska (1987)	 Jensen (1991c)  NTP (1992)  Suresh (1992)  Rank (1993)  Suresh (1993b)  Suresh (1994)  Fox & Mackay (1996)  Zaocaria (1996)  Bolognesi (1997)  Jones (1999)  Marques (1999)	 Chruscielska (2000)  Gava (2000)  Honarvar (2005)  Durward (2008)  Zoriki Hosomi (2007)  Honarvar (2008)  Costa (2008)  Manas (2009)  Flugge (2009b)	
Assays for Detecting Primary DNA Damage	 Shirasu (1978)	 Majeska (1982b)  Li and Long (1988)	 Bolognesi (1997)  Peluso (1998)  Lioi (1998a)  Lioi (1998b)	 Sivikova (2008)  Manas (2009)  Mladinic (2009a)	 Koller (2012)  Manas (2013)  Alvarez-Moya (2014)

Journal of the National Cancer Institute Study (2018)



JNCI Natl Cancer Inst (2018) 110(5): djz333

doi:10.1093/jnci/djz333
First published online November 9, 2017
Article



ARTICLE

Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Gabriella Andreotti, Stella Koutros, Jonathan N. Hofmann, Dale P. Sandler, Jay H. Lubin, Charles F. Lynch, Catherine C. Lerro, Anneclaire J. De Roos, Christine G. Parks, Michael C. Alavanja, Debra T. Silverman, Laura E. Beane Freeman

Affiliations of authors: Occupational and Environmental Epidemiology Branch (JA, BC, JNL, CCL, DTF, DSB), Biostatistics Branch (JNL) and Division of Occupational and Environmental Epidemiology Branch (JNL), Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda (Bethesda) of Health, Department of Health and Human Services, Bethesda, MD; Epidemiology Branch, National Institute of Environmental Health Sciences, National Institute of Health, Department of Health and Human Services, Research Triangle Park, NC (JNL, CCL); Department of Epidemiology, University of Iowa, Iowa City, IA (JNL); Iowa State University, Ames, IA (JNL); Department of Environmental and Occupational Health, DePaul University, Chicago, IL (JNL); School of Public Health, University of Michigan, Ann Arbor, MI (JNL)

Correspondence to: Laura E. Beane Freeman, PhD, NIH, NCI, Division of Cancer Epidemiology and Genetics, Bethesda, MD 20892 (e-mail: beane@nih.gov).

Abstract

Background: Glyphosate is the most used herbicide in the world. In 2015, the International Agency for Research on Cancer (IARC) classified glyphosate as a probable carcinogen based on strong mechanistic evidence and previous evaluations in the Agricultural Health Study (AHS) showing associations with glyphosate use and cancer. **Methods:** The AHS is a prospective cohort study of the previous evaluation of glyphosate use and cancer. Lifetime days and intensity-weighted days (LIDW) were calculated for each herbicide use interval (UI) using Poisson regression models. **Results:** Among 54 251 applicators, 44 in unadjusted analyses, glyphosate was associated with the highest exposure group (HR = 2.44, 95% CI = 0.94 to 6.36) for AMI. **Conclusions:** In this large, prospective cohort study, we found a statistically significant association between glyphosate use and lymphoid malignancies overall, in the highest exposed group that required

Glyphosate Use and Cancer Incidence in the Agricultural Health Study

Glyphosate was introduced as a broad-spectrum herbicide in 1974, and it quickly became one of the most heavily used herbicides worldwide. With the introduction of genetically

engineered glyphosate-tolerant crops, glyphosate use increased dramatically in the late-1990s and 2000s. In addition to agricultural use, glyphosate is one of the most common residential

Received: August 15, 2017; Revised: September 26, 2017; Accepted: October 6, 2017

Published by Oxford University Press 2017. This work is written by US Government employees and is in the public domain in the US.

503

Downloaded from <https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djz333/5071111> by National Library of Medicine user on 21 June 2018

Defendant's Exhibit 2052_0001



Def. Ex. 2052_0001

Post-IARC EPA Glyphosate Issue Paper



Glyphosate Issue Paper:

Evaluation of

EPA's Office
Sept

Overall, there is remarkable consistency in the database for glyphosate across multiple lines of evidence. For NHL, observed associations in epidemiological studies were non-statistically significant and were of relatively small magnitude. Chance and/or bias cannot be excluded as an explanation for the observed associations. For all other cancer types, there were no associations found; however, only one or two studies were available for evaluation of most cancer types. Across species, strain, and laboratory, tumor incidence was not increased at doses <500 mg/kg/day, except the testicular tumors which were only seen in one study. Observed tumors were not reproduced in other studies, including those conducted using the same strain at similar or higher doses. The genotoxicity studies demonstrate that glyphosate is not directly mutagenic or genotoxic *in vivo*.

Def. Ex. 2482_0131

Dewayne Johnson v.
Monsanto Company
Defendant's Exhibit 2482
Case No: CGC-16-550128

Defendant's Exhibit 2482_0001

Post-IARC EPA Glyphosate Issue Paper



Glyphosate Issue Paper:

Evaluation of

EPA's Office of
Sept

Overall, there is remarkable consistency in the database for glyphosate across multiple lines of evidence. For NHL, observed associations in epidemiological studies were non-statistically significant and were of relatively small magnitude. Chance and/or bias cannot be excluded as an explanation for the observed associations. For all other cancer types, there were no associations found; however, only one or two studies were available for evaluation of most cancer types. Across species, strain, and laboratory, tumor incidence was not increased at doses <500 mg/kg/day, except the testicular tumors which were only seen in one study. Observed tumors were not reproduced in other studies, including those conducted using the same strain at similar or higher doses. The genotoxicity studies demonstrate that glyphosate is not directly mutagenic or genotoxic *in vivo*.

Def. Ex. 2482_0131

Dewayne Johnson v.
Monsanto Company
Defendant's Exhibit 2482
Case No: CGC-16-550128

Defendant's Exhibit 2482_0001

Post-IARC EPA Glyphosate Issue Paper



Glyphosate Issue Paper:

Evaluation of

EPA's Office
Sept

Overall, there is remarkable consistency in the database for glyphosate across multiple lines of evidence. For NHL, observed associations in epidemiological studies were non-statistically significant and were of relatively small magnitude. Chance and/or bias cannot be excluded as an explanation for the observed associations. For all other cancer types, there were no associations found; however, only one or two studies were available for evaluation of most cancer types.

Across species, strain, and laboratory, tumor incidence was not increased at doses <500 mg/kg/day, except the testicular tumors which were only seen in one study. Observed tumors were not reproduced in other studies, including those conducted using the same strain at similar or higher doses. The genotoxicity studies demonstrate that glyphosate is not directly mutagenic or genotoxic *in vivo*.

Def. Ex. 2482_0131

Dewayne Johnson v.
Monsanto Company
Defendant's Exhibit 2482
Case No: CDC-16-550128

Defendant's Exhibit 2482_0001

Post-IARC EPA Glyphosate Issue Paper



Glyphosate Issue Paper:

Evaluation of

EPA's Office
Sept

Overall, there is remarkable consistency in the database for glyphosate across multiple lines of evidence. For NHL, observed associations in epidemiological studies were non-statistically significant and were of relatively small magnitude. Chance and/or bias cannot be excluded as an explanation for the observed associations. For all other cancer types, there were no associations found; however, only one or two studies were available for evaluation of most cancer types. Across species, strain, and laboratory, tumor incidence was not increased at doses <500 mg/kg/day, except the testicular tumors which were only seen in one study. Observed tumors were not reproduced in other studies, including those conducted using the same strain at similar or higher doses. The genotoxicity studies demonstrate that glyphosate is not directly mutagenic or genotoxic *in vivo*.

Def. Ex. 2482_0131

Dewayne Johnson v.
Monsanto Company
Defendant's Exhibit 2482
Case No: CDC-16-550128

Defendant's Exhibit 2482_0001

Post-IARC ECHA Conclusion



2017
European Chemical
Agency (ECHA)
Committee for Risk
Assessment (RAC)



ECHA's Committee for Risk Assessment (RAC) agrees to maintain the current harmonised classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects. RAC 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.

Further information

Video: Recording of RAC press briefing (15 March 2017)

<https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>

Dewayne Johnson v.
Monsanto Company
Defendant's Exhibit 2559
Case No. 1:07-cv-00229

1/3

Defendant's Exhibit 2559_0001

Def. Ex. 2559_0001

Post-IARC European Food Safety Authority



EFSA Journal 2015;13(11):4902

Conclusion on the

are identified. Following a second mandate from the European Commission to consider the findings from the International Agency for Research on Cancer (IARC) regarding the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products in the on-going peer review of the active substance, EFSA concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.

Def. Ex. 2323_0001

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) assessments carried out by its experts on the active substance glyphosate (EU No 1141/2010) in 2015. Conclusions were reached on the potential carcinogenicity of glyphosate in the context of its use on emerged annual, perennial and woody crops, including vegetables, bulb vegetables, root vegetables and fresh herbs, leeks, asparagus, orchard crops and vine, before desiccation in cereals and oilseed crops. Missing information on the potential carcinogenicity of glyphosate is identified. Following a second mandate from the European Commission to consider the findings from the International Agency for Research on Cancer (IARC) regarding the potential carcinogenicity of glyphosate or glyphosate-containing plant protection products in the on-going peer review of the active substance, EFSA concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.

© European Food Safety Authority

KEY WORDS

glyphosate, peer review,

substance and considered in a weight of evidence all available information. In contrast to the IARC evaluation, the EU peer review experts, with only one exception, concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation).

Def. Ex. 2323_0002

Defendant's Exhibit 2323_0001

¹ On request from the European Commission, October 2015.

² Correspondence: pesticides@efsa.europa.eu

Suggested citation: EFSA (2015) The assessment of the active substance glyphosate. EFSA Journal 13(11):4902. Available online: www.efsa.europa.eu

© European Food Safety Authority

Post-IARC WHO Agency



Food and Agriculture Organization
of the United Nations



World Health
Organization

JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

exclude the possibility that it is carcinogenic in mice at very high doses. In view of the absence of carcinogenic potential in rodents at human-relevant doses and the absence of genotoxicity by the oral route in mammals, and considering the epidemiological evidence from occupational exposures, the Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet. The Meeting reaffirmed the group ADI for the sum of glyphosate and its metabolites

Edited version
report of the M
disseminated on

A Joint Meeting of the Experts on Pesticide Residues (WHO) Core Assessment Group (Switzerland), followed the agenda by the JMPR to evaluate these compounds in full assessments.

The following extracts of are provided to make them

More info

http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/

Summary Report from the May 2016 Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

Dwayne Johnson v.
Monsanto Company
Defendant's Exhibit 2665
Exhibit No. 000000000000000000

Defendant's Exhibit 2665_0001

Def. Ex. 2665_0002

EPA and IARC: Low Dermal Absorption

Glyphosate Issue Paper:
Evaluation of Carcinogenic Potential

EPA's Office of Pesticide Programs
September 12, 2016



its low vapor pressure, inhalation exposure to glyphosate is expected to be minimal. **Dermal penetration has also been shown to be relatively low for human skin (<1%)** indicating dermal exposure will only contribute slightly to a systemic biological dose. Furthermore, in route-

Def. Ex. 2482_0015



For example, when an aqueous solution of 1% glyphosate was applied in an in-vitro human skin model, **only 1.4% of the applied dose was absorbed through the skin.** Glyphosate is typically formulated as an isopropylamine salt, and is dissolved in a water-based vehicle, while the

Def. Ex. 3131_0371

Scientific Literature

Acquavella (2016) Def. Ex. 2020

Gllyphosate epidemiology expert panel review: a weight of evidence systematic review of the relationship between glyphosate exposure and non-Hodgkin's lymphoma in multiple populations

John Acquavella, David Soto, Lisa Soto, Tom Soto, and Douglas J. Soto

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Brusick (2016) Def. Ex. 2114

Genotoxicity expert panel review: weight of evidence evaluation of the genotoxicity of glyphosate, glyphosate-based formulations, and aminopyridinylglyphosate acid

David Brusick, Andrew Soto, Lisa Soto, Tom Soto, and Douglas J. Soto

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Solomon (2016) Def. Ex. 3010

Glyphosate in the general population and in applications: a critical review of studies on exposures

Mark A. Solomon

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Williams (2016) (review) Def. Ex. 3109

Gllyphosate rodent carcinogenicity bioassay expert panel review

Casey M. Williams, John Soto, Lisa Soto, Tom Soto, and Douglas J. Soto

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Williams (2016)(summary) Def. Ex. 3108

A review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment

Casey M. Williams, John Soto, Lisa Soto, Tom Soto, and Douglas J. Soto

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Kier & Kirkland (2013) Def. Ex. 2679

Review of genotoxicity studies of glyphosate and glyphosate-based formulations

Larry G. Kier and David J. Kirkland

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Greim (2015) Def. Ex. 2570

Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies

Heinz G. Greim, David Soto, Lisa Soto, Tom Soto, and Douglas J. Soto

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Williams (2000) Def. Ex. 3110

Safety Evaluation and Risk Assessment of the Herbicide Roundup® and its Active Ingredients, Glyphosate, for Humans

Casey M. Williams, John Soto, Lisa Soto, Tom Soto, and Douglas J. Soto

Table of contents

- Introduction
- Background
- Methods
- Results
- Conclusions

Acquavella (2016)

Acquavella
(2016) Def. Ex. 2020



Williams
(2016)(summary) Def. Ex. 3108



Declaration of interest

The employment affiliation of the authors is as shown on the cover page. However, it should be recognized that each individual participated in the review process and preparation of this paper as an independent professional and not as a representative of their employer. This expert panel evaluation was organized and conducted by Intertek Scientific & Regulatory Consultancy. Funding for this evaluation was provided by **Monsanto** Company, which is a primary producer of glyphosate and products containing this active ingredient. The authors had sole responsibility for the content of the paper, and the interpretations and opinions expressed in the paper are those of the authors.

JA worked for **Monsanto** from 1989 through 2004 and is a consultant on a legal case unrelated to glyphosate that involves a former **Monsanto** industrial chemical plant. DG serves on a scientific advisory board to Dow Agro Sciences, which markets pesticides including glyphosate, and has consulted on behalf of Bayer Corp. on litigation matters concerning glyphosate and leukemia. GM has no additional declarations. TS has received consultancy fees and travel grants from **Monsanto** Europe SA/NV as a member of the European Glyphosate Toxicology Advisory Panel and participated in the IARC Monograph Meeting for volume 112, as an Observer for the **Monsanto** Company. In addition, TS has consulted for **Monsanto** on litigation matters involving glyphosate. DW has consulted on litigation matters concerning **Monsanto** that did not involve glyphosate.

This article is part of a supplement, sponsored and supported by Intertek Scientific & Regulatory Consultancy. Funding for the sponsorship of this supplement was provided to Intertek by the **Monsanto** Company, which is a primary producer of glyphosate and products containing this active ingredient.

Williams
(2016) (review) Def. Ex. 3109



Williams
(2000) Def. Ex. 3110



Def. Ex. 2020_0014

Williams (2000)

Acquavella
(2016) Def. Ex. 2020

Brusick
(2016) Def. Ex. 2114

Solomon
(2016) Def. Ex. 3010

Williams
(2016) (review) Def. Ex. 3109

ACKNOWLEDGMENTS

The authors acknowledge the assistance of individuals who participated in the preparation of this document. First, we are grateful to those who gathered and made available the large amount of information used to write the manuscript for this document. Second, we thank the toxicologists and other scientists at **Monsanto** who made significant contributions to the development of exposure assessments and through many other discussions. The authors were given complete access to toxicological information contained in the great number of laboratory studies and archival material at **Monsanto** in St. Louis, Missouri, and elsewhere. **Key personnel at Monsanto who provided scientific support were William F. Heydens, Donna R. Farmer, Marian S. Bleeke, Stephen J. Wratten, and Katherine H. Carr.** We also acknowledge the participation and assistance of Douglass W. Bryant and Cantox Health Sciences International for scientific and logistical support in the preparation of the final manuscript.

Williams
(2016)(summary) Def.

Williams
(2000) Def. Ex. 3110

Def. Ex. 3110_0044



EFSA Statement regarding the EU assessment of glyphosate and the so-called "Monsanto papers"

Background

On 29 May 2017, EFSA received a request from the European Commission to produce a statement concerning the EU assessment of glyphosate following allegations made in the so-called "Monsanto papers". The requestor asked EFSA to provide responses to the following points:

- What impact the allegations about Monsanto ghostwriting scientific review articles would have on the overall EU assessment of glyphosate, if they were confirmed;
- The role of the scientific review articles in question, including the type of publication, amount of available information, transparency of industry support for

There is no information contained within the "Monsanto papers" or that EFSA is otherwise aware of that indicates that industry attempted to falsify or manipulate the findings and raw data of the regulatory guideline studies used in the glyphosate assessment. If new information were to become available in the future that gave EFSA

The EU legislative framework governing the authorisation of pesticides was adopted by the European Parliament and the Council in 2009 and is Regulation (EC) No. 1107/2009. Commission Regulation (EU) No 1141/2010 lays down the detailed rules for the procedure of the renewal of the approval of a second group of active substances (AJR II) of which glyphosate was part. The Regulations (EC) No 1197/2009 and (EU) No 1141/2010 contain provisions regarding the information applicants must provide in their dossier to the regulatory authorities involved in carrying out the risk assessment.

Regarding publications from the open scientific literature, Article 8(5) of Regulation (EC) No. 1107/2009 requires applicants to submit scientific peer-reviewed open literature on the active substance and its metabolites dealing with side-effects on health, the environment and non-target species published within the last 10 years before the date of submission of the dossier.

According to Article 8(5) of Regulation (EC) No. 1107/2009, the search of the scientific peer-reviewed open literature has to be conducted "as determined by EFSA".



European Food Safety Authority • Via Carlo Magno 1A • 43126 Parma • ITALY
Tel. +39 0521 036 111 • Fax +39 0521 036 110 • www.efsa.europa.eu

Defendant's Exhibit 2322_0001

Def. Ex. 2322_0004

Ranger Pro Label



Keep out of reach of children.

CAUTION!

CAUSES EYE IRRITATION.

Avoid contact with eyes or clothing.

FIRST AID: Call a poison control center or doctor for treatment advice.

IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses if present after the first 5 minutes then continue rinsing eye.

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- You may also contact (314) 694-4000, collect day or night, for emergency medical treatment information.

- This product is identified as **Ranger PRO[®]** herbicide, EPA Registration No. 524-517.

ATTENTION:
This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale in your area.
- It is your responsibility to follow all federal, state and local laws and regulations regarding the use of pesticides.
- Unless using any pesticide, be sure the intended use is approved by your state or locality.
- Your state or locality may require additional precautions and restrictions for use of this product that are not included here.
- Monsanto does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information found on the product label. Be sure to read the EPA approved labeling on all of the items of use and read and follow all label directions.
- You should not have a copy of a similar product on the premises, instructions for use or other information you find here.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.



Ranger PRO herbicide is a complete broad spectrum post-emergent herbicide for use on lawns, lawns, and ornamental wood plant.

Complete Directions for Use

Avoid Contact with Herbicide with Plants, Animals, Fishes, Birds, and Insects

Read the entire label before using this product. Use only according to label directions.

Not all products listed in this label are registered for use in California. Check the registration status of each product in California before using.

Read the LABEL OF ALL WEEDS AND PLANTS (LAWNS) before use of this label before applying this product. There are no restrictions on use of this product.

THIS IS AN EMBROIDERED PRODUCT. MONSANTO'S DOES NOT ACCEPT ANY LIABILITY FOR REPRODUCTION OF THIS INFORMATION. CONTACT MONSANTO'S FOR REPRODUCTION INFORMATION.

1.0 INGREDIENTS

ACTIVE INGREDIENTS:
*Glyphosate, N-(phosphonomethyl)glycine
in the form of its isopropylamine salt..... 4.0%
OTHER INGREDIENTS (including surfactants)..... 96.0%
TOTAL..... 100.0%

*Contains 488 grams per liter or 1 pound per 8.33 gallons of the active ingredient glyphosate in the form of its isopropylamine salt. Equivalent to 230 grams per liter or 2 pounds per 8.33 gallons of the salt, glyphosate.

This product is registered by EPA. Patent Nos. 5,183,016, 5,183,017, 5,183,018, 5,183,019, 5,183,020, 5,183,021, 5,183,022, 5,183,023, 5,183,024, 5,183,025, 5,183,026, 5,183,027, 5,183,028, 5,183,029, 5,183,030, 5,183,031, 5,183,032, 5,183,033, 5,183,034, 5,183,035, 5,183,036, 5,183,037, 5,183,038, 5,183,039, 5,183,040, 5,183,041, 5,183,042, 5,183,043, 5,183,044, 5,183,045, 5,183,046, 5,183,047, 5,183,048, 5,183,049, 5,183,050, 5,183,051, 5,183,052, 5,183,053, 5,183,054, 5,183,055, 5,183,056, 5,183,057, 5,183,058, 5,183,059, 5,183,060, 5,183,061, 5,183,062, 5,183,063, 5,183,064, 5,183,065, 5,183,066, 5,183,067, 5,183,068, 5,183,069, 5,183,070, 5,183,071, 5,183,072, 5,183,073, 5,183,074, 5,183,075, 5,183,076, 5,183,077, 5,183,078, 5,183,079, 5,183,080, 5,183,081, 5,183,082, 5,183,083, 5,183,084, 5,183,085, 5,183,086, 5,183,087, 5,183,088, 5,183,089, 5,183,090, 5,183,091, 5,183,092, 5,183,093, 5,183,094, 5,183,095, 5,183,096, 5,183,097, 5,183,098, 5,183,099, 5,183,100, 5,183,101, 5,183,102, 5,183,103, 5,183,104, 5,183,105, 5,183,106, 5,183,107, 5,183,108, 5,183,109, 5,183,110, 5,183,111, 5,183,112, 5,183,113, 5,183,114, 5,183,115, 5,183,116, 5,183,117, 5,183,118, 5,183,119, 5,183,120, 5,183,121, 5,183,122, 5,183,123, 5,183,124, 5,183,125, 5,183,126, 5,183,127, 5,183,128, 5,183,129, 5,183,130, 5,183,131, 5,183,132, 5,183,133, 5,183,134, 5,183,135, 5,183,136, 5,183,137, 5,183,138, 5,183,139, 5,183,140, 5,183,141, 5,183,142, 5,183,143, 5,183,144, 5,183,145, 5,183,146, 5,183,147, 5,183,148, 5,183,149, 5,183,150, 5,183,151, 5,183,152, 5,183,153, 5,183,154, 5,183,155, 5,183,156, 5,183,157, 5,183,158, 5,183,159, 5,183,160, 5,183,161, 5,183,162, 5,183,163, 5,183,164, 5,183,165, 5,183,166, 5,183,167, 5,183,168, 5,183,169, 5,183,170, 5,183,171, 5,183,172, 5,183,173, 5,183,174, 5,183,175, 5,183,176, 5,183,177, 5,183,178, 5,183,179, 5,183,180, 5,183,181, 5,183,182, 5,183,183, 5,183,184, 5,183,185, 5,183,186, 5,183,187, 5,183,188, 5,183,189, 5,183,190, 5,183,191, 5,183,192, 5,183,193, 5,183,194, 5,183,195, 5,183,196, 5,183,197, 5,183,198, 5,183,199, 5,183,200, 5,183,201, 5,183,202, 5,183,203, 5,183,204, 5,183,205, 5,183,206, 5,183,207, 5,183,208, 5,183,209, 5,183,210, 5,183,211, 5,183,212, 5,183,213, 5,183,214, 5,183,215, 5,183,216, 5,183,217, 5,183,218, 5,183,219, 5,183,220, 5,183,221, 5,183,222, 5,183,223, 5,183,224, 5,183,225, 5,183,226, 5,183,227, 5,183,228, 5,183,229, 5,183,230, 5,183,231, 5,183,232, 5,183,233, 5,183,234, 5,183,235, 5,183,236, 5,183,237, 5,183,238, 5,183,239, 5,183,240, 5,183,241, 5,183,242, 5,183,243, 5,183,244, 5,183,245, 5,183,246, 5,183,247, 5,183,248, 5,183,249, 5,183,250, 5,183,251, 5,183,252, 5,183,253, 5,183,254, 5,183,255, 5,183,256, 5,183,257, 5,183,258, 5,183,259, 5,183,260, 5,183,261, 5,183,262, 5,183,263, 5,183,264, 5,183,265, 5,183,266, 5,183,267, 5,183,268, 5,183,269, 5,183,270, 5,183,271, 5,183,272, 5,183,273, 5,183,274, 5,183,275, 5,183,276, 5,183,277, 5,183,278, 5,183,279, 5,183,280, 5,183,281, 5,183,282, 5,183,283, 5,183,284, 5,183,285, 5,183,286, 5,183,287, 5,183,288, 5,183,289, 5,183,290, 5,183,291, 5,183,292, 5,183,293, 5,183,294, 5,183,295, 5,183,296, 5,183,297, 5,183,298, 5,183,299, 5,183,300, 5,183,301, 5,183,302, 5,183,303, 5,183,304, 5,183,305, 5,183,306, 5,183,307, 5,183,308, 5,183,309, 5,183,310, 5,183,311, 5,183,312, 5,183,313, 5,183,314, 5,183,315, 5,183,316, 5,183,317, 5,183,318, 5,183,319, 5,183,320, 5,183,321, 5,183,322, 5,183,323, 5,183,324, 5,183,325, 5,183,326, 5,183,327, 5,183,328, 5,183,329, 5,183,330, 5,183,331, 5,183,332, 5,183,333, 5,183,334, 5,183,335, 5,183,336, 5,183,337, 5,183,338, 5,183,339, 5,183,340, 5,183,341, 5,183,342, 5,183,343, 5,183,344, 5,183,345, 5,183,346, 5,183,347, 5,183,348, 5,183,349, 5,183,350, 5,183,351, 5,183,352, 5,183,353, 5,183,354, 5,183,355, 5,183,356, 5,183,357, 5,183,358, 5,183,359, 5,183,360, 5,183,361, 5,183,362, 5,183,363, 5,183,364, 5,183,365, 5,183,366, 5,183,367, 5,183,368, 5,183,369, 5,183,370, 5,183,371, 5,183,372, 5,183,373, 5,183,374, 5,183,375, 5,183,376, 5,183,377, 5,183,378, 5,183,379, 5,183,380, 5,183,381, 5,183,382, 5,183,383, 5,183,384, 5,183,385, 5,183,386, 5,183,387, 5,183,388, 5,183,389, 5,183,390, 5,183,391, 5,183,392, 5,183,393, 5,183,394, 5,183,395, 5,183,396, 5,183,397, 5,183,398, 5,183,399, 5,183,400, 5,183,401, 5,183,402, 5,183,403, 5,183,404, 5,183,405, 5,183,406, 5,183,407, 5,183,408, 5,183,409, 5,183,410, 5,183,411, 5,183,412, 5,183,413, 5,183,414, 5,183,415, 5,183,416, 5,183,417, 5,183,418, 5,183,419, 5,183,420, 5,183,421, 5,183,422, 5,183,423, 5,183,424, 5,183,425, 5,183,426, 5,183,427, 5,183,428, 5,183,429, 5,183,430, 5,183,431, 5,183,432, 5,183,433, 5,183,434, 5,183,435, 5,183,436, 5,183,437, 5,183,438, 5,183,439, 5,183,440, 5,183,441, 5,183,442, 5,183,443, 5,183,444, 5,183,445, 5,183,446, 5,183,447, 5,183,448, 5,183,449, 5,183,450, 5,183,451, 5,183,452, 5,183,453, 5,183,454, 5,183,455, 5,183,456, 5,183,457, 5,183,458, 5,183,459, 5,183,460, 5,183,461, 5,183,462, 5,183,463, 5,183,464, 5,183,465, 5,183,466, 5,183,467, 5,183,468, 5,183,469, 5,183,470, 5,183,471, 5,183,472, 5,183,473, 5,183,474, 5,183,475, 5,183,476, 5,183,477, 5,183,478, 5,183,479, 5,183,480, 5,183,481, 5,183,482, 5,183,483, 5,183,484, 5,183,485, 5,183,486, 5,183,487, 5,183,488, 5,183,489, 5,183,490, 5,183,491, 5,183,492, 5,183,493, 5,183,494, 5,183,495, 5,183,496, 5,183,497, 5,183,498, 5,183,499, 5,183,500, 5,183,501, 5,183,502, 5,183,503, 5,183,504, 5,183,505, 5,183,506, 5,183,507, 5,183,508, 5,183,509, 5,183,510, 5,183,511, 5,183,512, 5,183,513, 5,183,514, 5,183,515, 5,183,516, 5,183,517, 5,183,518, 5,183,519, 5,183,520, 5,183,521, 5,183,522, 5,183,523, 5,183,524, 5,183,525, 5,183,526, 5,183,527, 5,183,528, 5,183,529, 5,183,530, 5,183,531, 5,183,532, 5,183,533, 5,183,534, 5,183,535, 5,183,536, 5,183,537, 5,183,538, 5,183,539, 5,183,540, 5,183,541, 5,183,542, 5,183,543, 5,183,544, 5,183,545, 5,183,546, 5,183,547, 5,183,548, 5,183,549, 5,183,550, 5,183,551, 5,183,552, 5,183,553, 5,183,554, 5,183,555, 5,183,556, 5,183,557, 5,183,558, 5,183,559, 5,183,560, 5,183,561, 5,183,562, 5,183,563, 5,183,564, 5,183,565, 5,183,566, 5,183,567, 5,183,568, 5,183,569, 5,183,570, 5,183,571, 5,183,572, 5,183,573, 5,183,574, 5,183,575, 5,183,576, 5,183,577, 5,183,578, 5,183,579, 5,183,580, 5,183,581, 5,183,582, 5,183,583, 5,183,584, 5,183,585, 5,183,586, 5,183,587, 5,183,588, 5,183,589, 5,183,590, 5,183,591, 5,183,592, 5,183,593, 5,183,594, 5,183,595, 5,183,596, 5,183,597, 5,183,598, 5,183,599, 5,183,600, 5,183,601, 5,183,602, 5,183,603, 5,183,604, 5,183,605, 5,183,606, 5,183,607, 5,183,608, 5,183,609, 5,183,610, 5,183,611, 5,183,612, 5,183,613, 5,183,614, 5,183,615, 5,183,616, 5,183,617, 5,183,618, 5,183,619, 5,183,620, 5,183,621, 5,183,622, 5,183,623, 5,183,624, 5,183,625, 5,183,626, 5,183,627, 5,183,628, 5,183,629, 5,183,630, 5,183,631, 5,183,632, 5,183,633, 5,183,634, 5,183,635, 5,183,636, 5,183,637, 5,183,638, 5,183,639, 5,183,640, 5,183,641, 5,183,642, 5,183,643, 5,183,644, 5,183,645, 5,183,646, 5,183,647, 5,183,648, 5,183,649, 5,183,650, 5,183,651, 5,183,652, 5,183,653, 5,183,654, 5,183,655, 5,183,656, 5,183,657, 5,183,658, 5,183,659, 5,183,660, 5,183,661, 5,183,662, 5,183,663, 5,183,664, 5,183,665, 5,183,666, 5,183,667, 5,183,668, 5,183,669, 5,183,670, 5,183,671, 5,183,672, 5,183,673, 5,183,674, 5,183,675, 5,183,676, 5,183,677, 5,183,678, 5,183,679, 5,183,680, 5,183,681, 5,183,682, 5,183,683, 5,183,684, 5,183,685, 5,183,686, 5,183,687, 5,183,688, 5,183,689, 5,183,690, 5,183,691, 5,183,692, 5,183,693, 5,183,694, 5,183,695, 5,183,696, 5,183,697, 5,183,698, 5,183,699, 5,183,700, 5,183,701, 5,183,702, 5,183,703, 5,183,704, 5,183,705, 5,183,706, 5,183,707, 5,183,708, 5,183,709, 5,183,710, 5,183,711, 5,183,712, 5,183,713, 5,183,714, 5,183,715, 5,183,716, 5,183,717, 5,183,718, 5,183,719, 5,183,720, 5,183,721, 5,183,722, 5,183,723, 5,183,724, 5,183,725, 5,183,726, 5,183,727, 5,183,728, 5,183,729, 5,183,730, 5,183,731, 5,183,732, 5,183,733, 5,183,734, 5,183,735, 5,183,736, 5,183,737, 5,183,738, 5,183,739, 5,183,740, 5,183,741, 5,183,742, 5,183,743, 5,183,744, 5,183,745, 5,183,746, 5,183,747, 5,183,748, 5,183,749, 5,183,750, 5,183,751, 5,183,752, 5,183,753, 5,183,754, 5,183,755, 5,183,756, 5,183,757, 5,183,758, 5,183,759, 5,183,760, 5,183,761, 5,183,762, 5,183,763, 5,183,764, 5,183,765, 5,183,766, 5,183,767, 5,183,768, 5,183,769, 5,183,770, 5,183,771, 5,183,772, 5,183,773, 5,183,774, 5,183,775, 5,183,776, 5,183,777, 5,183,778, 5,183,779, 5,183,780, 5,183,781, 5,183,782, 5,183,783, 5,183,784, 5,183,785, 5,183,786, 5,183,787, 5,183,788, 5,183,789, 5,183,790, 5,183,791, 5,183,792, 5,183,793, 5,183,794, 5,183,795, 5,183,796, 5,183,797, 5,183,798, 5,183,799, 5,183,800, 5,183,801, 5,183,802, 5,183,803, 5,183,804, 5,183,805, 5,183,806, 5,183,807, 5,183,808, 5,183,809, 5,183,810, 5,183,811, 5,183,812, 5,183,813, 5,183,814, 5,183,815, 5,183,816, 5,183,817, 5,183,818, 5,183,819, 5,183,820, 5,183,821, 5,183,822, 5,183,823, 5,183,824, 5,183,825, 5,183,826, 5,183,827, 5,183,828, 5,183,829, 5,183,830, 5,183,831, 5,183,832, 5,183,833, 5,183,834, 5,183,835, 5,183,836, 5,183,837, 5,183,838, 5,183,839, 5,183,840, 5,183,841, 5,183,842, 5,183,843, 5,183,844, 5,183,845, 5,183,846, 5,183,847, 5,183,848, 5,183,849, 5,183,850, 5,183,851, 5,183,852, 5,183,853, 5,183,854, 5,183,855, 5,183,856, 5,183,857, 5,183,858, 5,183,859, 5,183,860, 5,183,861, 5,183,862, 5,183,863, 5,183,864, 5,183,865, 5,183,866, 5,183,867, 5,183,868, 5,183,869, 5,183,870, 5,183,871, 5,183,872, 5,183,873, 5,183,874, 5,183,875, 5,183,876, 5,183,877, 5,183,878, 5,183,879, 5,183,880, 5,183,881, 5,183,882, 5,183,883, 5,183,884, 5,183,885, 5,183,886, 5,183,887, 5,183,888, 5,183,889, 5,183,890, 5,183,891, 5,183,892, 5,183,893, 5,183,894, 5,183,895, 5,183,896, 5,183,897, 5,183,898, 5,183,899, 5,183,900, 5,183,901, 5,183,902, 5,183,903, 5,183,904, 5,183,905, 5,183,906, 5,183,907, 5,183,908, 5,183,909, 5,183,910, 5,183,911, 5,183,912, 5,183,913, 5,183,914, 5,183,915, 5,183,916, 5,183,917, 5,183,918, 5,183,919, 5,183,920, 5,183,921, 5,183,922, 5,183,923, 5,183,924, 5,183,925, 5,183,926, 5,183,927, 5,183,928, 5,183,929, 5,183,930, 5,183,931, 5,183,932, 5,183,933, 5,183,934, 5,183,935, 5,183,936, 5,183,937, 5,183,938, 5,183,939, 5,183,940, 5,183,941, 5,183,942, 5,183,943, 5,183,944, 5,183,945, 5,183,946, 5,183,947, 5,183,948, 5,183,949, 5,183,950, 5,183,951, 5,183,952, 5,183,953, 5,183,954, 5,183,955, 5,183,956, 5,183,957, 5,183,958, 5,183,959, 5,183,960, 5,183,961, 5,183,962, 5,183,963, 5,183,964, 5,183,965, 5,183,966, 5,183,967, 5,183,968, 5,183,969, 5,183,970, 5,183,971, 5,183,972, 5,183,973, 5,183,974, 5,183,975, 5,183,976, 5,183,977, 5,183,978, 5,183,979, 5,183,980, 5,183,981, 5,183,982, 5,183,983, 5,183,984, 5,183,

Ranger Pro Label



ATTENTION:
This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale in your area.
- It is your responsibility to follow all federal, state and local laws and regulations regarding the use of pesticides.
- Unless using any pesticide, be sure the intended use is approved by your state or locality.
- Your state or locality may require additional precautions and restrictions for use of this product that are not included here.
- Manufacturer does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information on the actual product.
- You should not base a purchase of a pesticide product on the completeness, instructions for use or other information on this label.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.



Ranger PRO Herbicide is a complete broad spectrum post-emergence herbicide for use on lawns, lawns, and ornamental wood plantings.

Complete Directions for Use

10/19/15

10/19/15

AVOID CONTACT OF HERBICIDE WITH PLANTS, STEMS, EXPOSED WOODWORK, BRICKS OR FRUIT OF CROPS, OR SUSCEPTIBLE PLANTS AND TREES, BECAUSE SEVERE BURNING OR DESTRUCTION IS LIKELY TO OCCUR.

Read the entire label before using this product.
Use only according to label instructions.

Not all products listed in this label are registered for use in California. Check the registration status of each product in CA before using.

Read the LABEL OF ALL HERBICIDE AND FERTILIZER ADDENDAS at the end of the label before using. There are no restrictions on their use.

THIS IS AN OXADIAZINONE HERBICIDE. DO NOT MIX WITH AND DO NOT REFRIGERATE. IF FOR REFRIGERATION, SEE ORIGINAL CONTAINER LABEL FOR RECOMMENDATIONS.

1.0 INGREDIENTS

ACTIVE INGREDIENTS:

*Glyphosate, 5-(3-chlorophenyl)-4-hydroxy-2,4,6-trioxo-1,3,5-triazine 2,2,2-trifluoroethyl ester 4.0%
OTHER INGREDIENTS (including surfactants) 96.0%
TOTAL 100.0%

*Contains 480 grams per liter or 1 pound per 0.83 gallons of the active ingredient glyphosate in the form of its isopropylamine salt. Contains 0.250 grams per liter or 0.25 pounds per 0.83 gallons of the inert ingredients.

This product is produced by D.E. Shaw Inc., 5140 S.W. 5th St., Ocala, FL 34474, U.S.A. © 2015. All rights reserved. No other parties are approved or authorized.

2.0 IMPORTANT PHONE NUMBERS

FOR PRODUCT INFORMATION OR ASSISTANCE IN USING THIS PRODUCT, CALL TOLL-FREE: 1-800-332-3811.

IN CASE OF AN EMERGENCY INVOLVING THIS PRODUCT, OR FOR RESCUE, ASSISTANCE, CALL CHEMICAL EMERGENCY: 24-HOUR 1-800-424-9000.

3.0 PRECAUTIONARY STATEMENTS

3.1 Hazards to Humans and Domestic Animals

Keep out of reach of children.
CAUTION!
DANGER TO FISH AND AQUATIC LIFE.
Avoid contact with eyes or clothing.

FIRST AID: Call a poison control center or doctor for treatment advice.
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 minutes. Remove contact lenses if present after the first rinse, but not if removal increases the irritation.
IF ON SKIN: Wash thoroughly with soap and water. Remove contaminated clothing or shoes if they are wet with this product. Do not reuse.

• Rinse the product container and label with water when using a pump sprayer, or pump for treatment.
• Do not use equipment that creates mist or spray when using this product.
• This product is not for use on lawns or ornamental plants.

ENVIRONMENTAL HAZARDS: This product is considered to be a moderate to high acute aquatic toxicant. However, because of the product's low volatility and low water solubility, it will not be transported by wind or water to sensitive areas. Do not apply to water bodies or wetlands. Do not apply to areas where birds, bees, butterflies, or other beneficial insects are present. Do not apply to areas where fish, shellfish, or other aquatic life are present.

Personal Protective Equipment (PPE): Apply herbicide and other herbicides from a long-sleeved shirt and pants. Follow manufacturer's instructions for cleaning or disposing of PPE. Wash thoroughly before reuse. Do not eat, drink, or use tobacco products while wearing this product. Do not use equipment that creates mist or spray when using this product. Do not use equipment that creates mist or spray when using this product. Do not use equipment that creates mist or spray when using this product.

When handling use a closed system, enclosed cab or enclosure in a well-ventilated area. Do not breathe dust or spray. Do not use equipment that creates mist or spray when using this product. Do not use equipment that creates mist or spray when using this product.

Use Safety Precautions:
• Do not drink from containers that have been used for this product.
• Wash hands before eating, drinking, chewing gum, using tobacco products, or using the toilet.
• Remove clothing immediately if pesticide gets inside. Do not put on clean clothing.

3.2 Environmental Hazards

Do not apply directly to water, to areas where water is on or runs over the soil, or to areas where water is on or runs over the soil. Do not contaminate water, streams, or irrigation or drainage equipment with this product.

3.3 Physical or Chemical Hazards

This product is not a flammable liquid or solid. It is not a gas, vapor, or dust. It is not a highly flammable liquid or solid. It is not a highly flammable liquid or solid. It is not a highly flammable liquid or solid. It is not a highly flammable liquid or solid.

Do not mix with other pesticides or fertilizers. Do not mix with other pesticides or fertilizers. Do not mix with other pesticides or fertilizers. Do not mix with other pesticides or fertilizers.

Importance of droplet size

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see the Wind, Temperature and Humidity, and Temperature Inversion sections of this label).

Wind

Drift potential is lowest between wind speeds of 2 to 10 miles per hour. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application must be avoided below 2 miles per hour due to variable wind direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator must be familiar with local wind patterns and how they affect drift.

Dewayne Johnson v. Monsanto Company
Defendant's Exhibit 2947
Case No. CFC-16-00131

Defendant's Exhibit 2947_0001

Def. Ex. 2947_0004

Ranger Pro Label



ATTENTION:
This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale in your area.
- It is your responsibility to follow all federal, state and local laws and regulations regarding the use of pesticides.
- Unless using any pesticide, be sure the intended use is approved by your state or locality.
- Your state or locality may require additional precautions and restrictions for use of this product that are not included here.
- Monsanto does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information found on the product label. Be sure to read the full approved labeling and all the terms of use and restrictions and follow all label directions.
- You should not have a copy of a pesticide product on the premises, instructions for use or other information you find here.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.



Ranger PRO herbicide is a complete broad spectrum post-emergence professional herbicide for use on lawns, turf and ornamental weed control.

Complete Directions for Use

EPH Reg. No. 208-017 2008-1

AVOID CONTACT OF HERBICIDE WITH FOLIAGE, STEMS, EXPOSED ROOTS AND WOODS OF TREES, OR VISIBLE PLANTS AND TREES, BECAUSE OF SEVERE INJURY OR DESTRUCTION OF TREES TO WHICH.

Read the entire label before using this product. Use only according to label instructions. Not all products listed in this label are registered for use in California. Check the registration status of each product in California before using. Read the LABEL OF WEEDKILLER (LAWN CARE) at the end of the label before buying or using. There are no restrictions on use of this product. THIS IS AN OUTDOOR PRODUCT. MONSANTO DOES NOT ADVISE AND HAS NOT REGISTERED IT FOR REFORMULATION, SET, REFORMAL, CONTAINER LABEL, FOR REPACKAGING OR FOR OTHER USES.

1.0 INGREDIENTS

ACTIVE INGREDIENTS:
*Glyphosate, 5-(3-chlorophenyl)-4-hydroxyisobutylamine 4.0%
OTHER INGREDIENTS (including surfactants) 96.0%
TOTAL 100.0%

*Contains 480 grams per liter or 1 pound per 0.5 gallon of the active ingredient glyphosate in the form of its isopropylamine salt. Contains 250 grams per liter or 1 pound per 0.5 gallon of the active ingredient.

This product is produced by D.S. Brand Inc., 15400 Old, S. 700 St., Olathe, KS 66061, U.S.A. © 2008, D.S. Brand Inc. For more information, see the product label.

2.0 IMPORTANT PHONE NUMBERS

FOR PRODUCT INFORMATION OR ASSISTANCE IN USING THIS PRODUCT, CALL TOLL-FREE, 1-800-332-3033.
IN CASE OF AN EMERGENCY INVOLVING THIS PRODUCT, OR FOR TECHNICAL ASSISTANCE, CALL COLLECT, 800-969-4949.

3.0 PRECAUTIONARY STATEMENTS

3.1 Hazards to Humans and Domestic Animals

Keep out of reach of children.

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

CAUTION

Personal Protective Equipment (PPE)

Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining Personal Protective Equipment. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Dewayne Johnson v.
Monsanto Company
Defendant's Exhibit 2947
Case No. CFC-16-080131

Defendant's Exhibit 2947_0001

Def. Ex. 2947_0001

Ranger Pro Label



ATTENTION:
This specimen label is provided for general information only.

- This pesticide product may not yet be available or approved for sale in your area.
- It is your responsibility to follow all Federal, state and local laws and regulations regarding the use of pesticides.
- Unless using any pesticide, be sure the intended use is approved by your state or locality.
- Your state or locality may require additional precautions and restrictions for use of this product that are not included here.
- Monsanto does not guarantee the completeness or accuracy of this specimen label. The information found in this label may differ from the information found on the product label.
- You should read the label on the actual product on the occasion, instructions for use and other information you find there.
- Always follow the precautions and instructions for use on the label of the pesticide you are using.



Ranger PRO herbicide is a complete broad spectrum postemergence herbicide for use on lawns, turf, and ornamentals.

Complete Directions for Use

EPA Reg. No. 294-017

AVOID CONTACT OF HERBICIDE WITH FOLIAGE, STEMS, EXPOSED ROOT-NODES, BUDS OR FRUIT OF DESIRED PLANTS AND TREES, BECAUSE SEVERE INJURY OR DESTRUCTION IS LIKELY TO OCCUR.

Read the entire label before using the product.
Use only according to label instructions.

Not all products listed in this label are registered for use in California. Check the registration status of each product in CA before using.

Read the LABEL OF APPLICATOR (A.I.) LABEL (T) information at the end of the label before using. There are no restrictions noted in this document.

THIS IS AN OXYGEN-SENSITIVE PRODUCT. DO NOT BURN AND HAS NOT BEEN TESTED FOR REFORMULATION SET. NORMAL CONTAINER LABEL FOR REFORMULATION IS A WARNING.

1.0 INGREDIENTS

ACTIVE INGREDIENTS:
*Glyphosate, N-(phosphonmethyl)glycine
in the form of its isopropylamine salt 4.0%
OTHER INGREDIENTS (including surfactants) 96.0%
TOTALS 100.0%

*Contains 488 grams per liter or 1 pound per 8.3 gallons of the active ingredient glyphosate in the form of its isopropylamine salt. Equivalent to 230 grams per liter or 2 pounds per 8.3 gallons of the acid glyphosate.

This product is produced by D.E. Shaw Inc., 5400 21st St., St. Louis, MO 63112. U.S. EPA Reg. No. 294-017. For more product information, call 1-800-441-4000.

2.0 IMPORTANT PHONE NUMBERS

FOR PRODUCT INFORMATION OR ASSISTANCE IN USING THIS PRODUCT, CALL TOLL-FREE, 1-800-342-3833.

IN CASE OF AN EMERGENCY INVOLVING THIS PRODUCT, OR FOR REGIONS, ASSISTANCE, CALL COLLECT, 1-800-441-4000.

3.0 PRECAUTIONARY STATEMENTS

3.1 Hazards to Humans and Domestic Animals

Keep out of reach of children.
CAUTION!

Prevent contact with eyes, nose, mouth, skin, hair, or clothing.
Do not eat, drink, or use tobacco while using this product.
Do not get clothing or work clothes wet with this product.
Do not use near children or livestock.
Do not use in areas where people or animals are likely to be present.
Do not use in areas where people or animals are likely to be present.
Do not use in areas where people or animals are likely to be present.
Do not use in areas where people or animals are likely to be present.

Do not use in areas where people or animals are likely to be present.

Do not use in areas where people or animals are likely to be present.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Dewey Johnson v.
Monsanto Company
Defendant's Exhibit 2947
Case No. CPC-16-000131

Defendant's Exhibit 2947_0001

Def. Ex. 2947_0001

Mr. Johnson's Personal Protective Equipment



Tyvek Suit

Chemical resistant gloves



Sweatshirt
with hoodie

Mask



Goggles



Chemical resistant boots

Mr. Johnson's Backpack Sprayer



PX-0126

Dilution of Ranger Pro



Non-Hodgkin Lymphomas

B-cell neoplasms

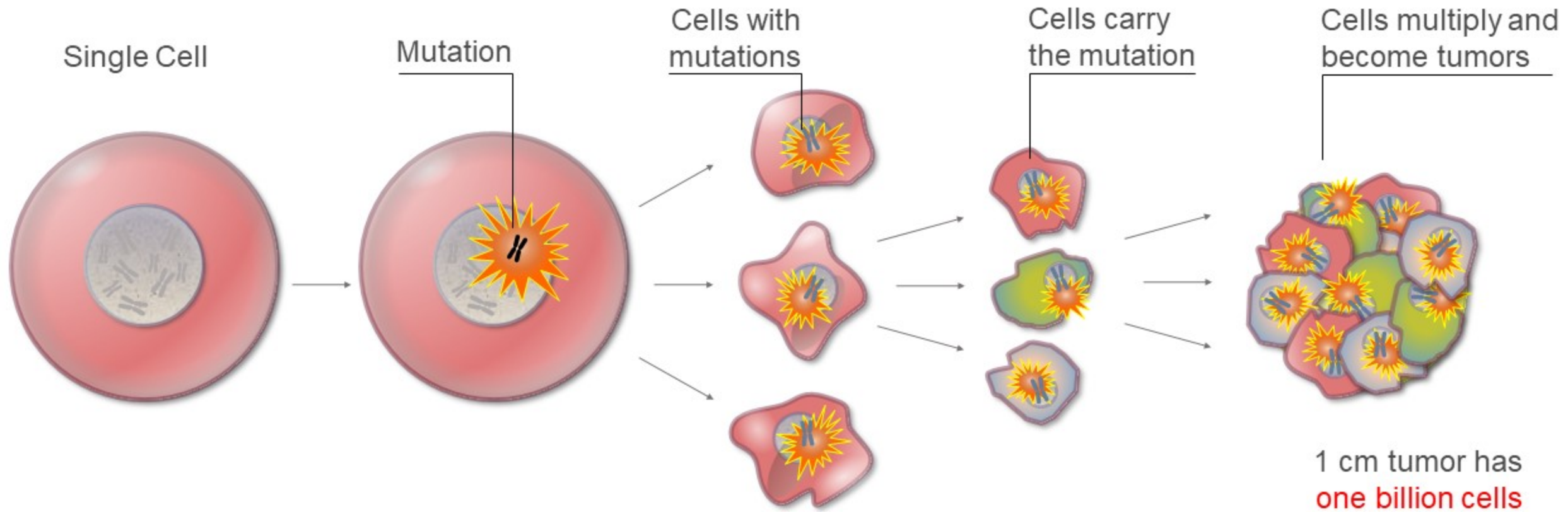
- Precursor B-cell lymphoblastic leukemia/lymphoma, NOS
- Precursor B-cell lymphoblastic leukemia/lymphoma, with recurrent genetic abnormalities
- Chronic lymphocytic leukemia/small lymphocytic lymphoma
- Prolymphocytic leukemia, B-cell
- Mantle cell lymphoma
- Lymphoplasmacytic lymphoma
- Waldenstrom macroglobulinemia
- Diffuse large B-cell lymphoma, NOS
- Primary DLBCL of the CNS
- Primary cutaneous DLBCL, leg type
- T-cell/histiocyte rich large B-cell lymphoma
- Intravascular large B-cell lymphoma
- ALK positive large B-cell lymphoma
- Plasmablastic lymphoma
- Large B-cell (plasmablastic) lymphoma arising from HHV-8 associated multicentric Castlemans disease
- Primary effusion lymphoma
- Primary mediastinal (thymic) large B-cell lymphoma
- Burkitt lymphoma/leukemia
- Splenic marginal zone lymphoma
- Extranodal marginal zone lymphoma
- Nodal marginal zone lymphoma
- Primary cutaneous follicle center lymphoma
- Follicular lymphoma NOS
- Hairy cell leukemia
- Hairy cell leukemia variant
- Solitary plasmacytoma of bone
- Extravascular plasmacytoma
- Plasma cell myeloma/leukemia
- Heavy chain diseases
- B-cell lymphoid neoplasms, NOS

T and NK neoplasms

- Precursor T/NK-cell lymphoblastic leukemia/lymphoma, NOS
- Sezary syndrome
- Peripheral T/NK-cell lymphoma, NOS
- Angioimmunoblastic T/NK-cell lymphoma
- Subcutaneous panniculitis-like T-cell lymphoma
- Anaplastic large cell lymphoma ALK-positive
- Hepatosplenic T-cell lymphoma
- Enteropathy-associated T-cell lymphoma
- Primary cutaneous gamma-delta T-cell lymphoma
- Primary cutaneous T-cell lymphoma, NOS
- Mycosis fungoides
- T-cell lymphoproliferative disease
- T-cell lymphoma, type (T-LGL)
- Primary cutaneous CD30 + lymphoproliferative disorders
- T/NK-cell, lymphoid neoplasms, NOS

• Mycosis fungoides

Cancer Has a Latency Period



Latency Period

The time between being **exposed** to something that can cause cancer **and having symptoms**.

Mr. Johnson's Timeline

● **January 20, 1972**
Mr. Johnson
was born

● **June 2012**
Promoted to
Integrated
Pest Manager
at BUSD

1970s

1980s

1990s

2000s

2010s

● **Start of
Mr. Johnson's cancer**
*(according to Plaintiff's
experts)*

Mr. Johnson's Treating Doctors



Dr. Richard Hoppe
Oncologist
Stanford University



Dr. Youn Kim
Oncologist
Stanford University



Dr. Laura Pincus
Dermatopathologist
UCSF



Dr. Thach-Giao Truong
Oncologist
Kaiser Permanente