

Federal Court of Australia District Registry: Victoria

Division: General

No: VID243/2020

#### **KELVIN MCNICKLE** Applicant

HUNTSMAN CHEMICAL COMPANY AUSTRALIA PTY LTD (ACN 004 146 338) and others named in the schedule Respondent

## ORDER

**JUDGE:** JUSTICE LEE

**DATE OF ORDER:** 26 April 2023

WHERE MADE: Sydney

# THE COURT ORDERS THAT:

#### Initial Trial

- 1. Order 41 of the Orders dated 10 May 2021 be vacated.
- Pursuant to ss 33ZF and 37P(2) of the *Federal Court of Australia Act 1976* (Cth) and r 30.01 of the *Federal Court Rules 2011* (Cth), the proceeding be listed for an initial trial (Initial Trial) of the common questions at Annexure 1 of these Orders (Initial Trial Common Questions) in accordance with the trial plan at Annexure 2.

#### **Submissions Template**

- Order 20(a) of the Orders dated 10 May 2021 and Order 17 of the Orders dated 23 March 2022 be vacated.
- 4. By 25 May 2023, the parties' junior counsel briefed to appear at the hearing confer and attempt to agree on and produce:
  - (a) a template for the opening submissions (Submissions Template), which document, when completed, will:
    - (i) provide an overview of each party's case in summary form (**Part A**); and



- (ii) identify that party's summary contentions in relation to each of the Initial Trial Common Questions (**Part B**);
- (b) the Agreed and Non-Contentious Background Facts document referred to in Order 6 of the Orders of 12 October 2020.
- 5. By 23 June 2023, the parties provide to the Associate to Justice Lee:
  - (a) the agreed documents prepared in accordance with Order 4; or
  - (b) in the event the parties are unable to reach agreement as to the contents of any of the documents to be prepared in accordance with Order 4, one version of the draft document with the extent of the disagreement identified in mark-up.
- 6. By 23 June 2023, the parties provide to the Assessor a copy of the Initial Trial Common Questions and the Agreed and Non-Contentious Background Facts document prepared in accordance with Order 4(a) and (b).

#### Witnesses to be called and lists of documents to be tendered at Initial Trial

- 7. By 25 May 2023, each party provide to the other:
  - (a) the names of the witnesses proposed to be called by that party at the Initial Trial;
  - (b) notice of any witness required for cross-examination; and
  - (c) the order in which those witnesses are likely to be called.
- 8. By 16 June 2023, Mr McNickle serve an index of all documents that, as presently advised, he proposes to tender at the hearing of the Initial Trial.
- 9. By 23 July 2023, the respondents serve an index of any document not included in Mr McNickle's index that they, as presently advised, propose to tender at the hearing of the Initial Trial.

#### **Opening submissions**

 By 1 August 2023, Mr McNickle file and serve his opening submissions (and provide a Microsoft Word version of those submissions by email to the Associate to Justice Lee).



- By 21 August 2023, the respondents file and serve their opening submissions (and provide a Microsoft Word version of those submissions by email to the Associate to Justice Lee).
- 12. By 28 August 2023, Mr McNickle provide his reply to the opening submissions of the respondents, by way of including, in a revised opening submission, any material in reply and file and serve his revised opening submissions (and provide a Microsoft Word version of those submissions by email to the Associate to Justice Lee).
- 13. The submissions filed by the parties in accordance with these Orders are to follow the Submissions Template, are to refer to any authorised report of any cases referred to or cited (or in the absence of an authorised report, any unauthorised report and the medium neutral citation), contain hyperlinks to the extent they refer to documents to be tendered, and are not to include footnotes.

#### **Court Book**

- 14. By 17 August 2023, each party notify the other party of the objections the notifying party has to material contained in Parts C, D, E and F of the Court Book and, in respect of each objection, the grounds of the objection. The requirement for Mr McNickle to notify the respondents of objections to the material contained in Part D of the Court Book be limited only to those lay witnesses who the respondents propose to be called to give evidence at the Initial Trial pursuant to Order 7 above.
- 15. By 24 August 2023, junior counsel briefed by each party confer and endeavour to resolve all objections notified pursuant to Order 14 above.
- 16. By 25 August 2023, the parties serve upon each other and the e-Trial Provider an electronic index of their respective documents, including the lists of documents served pursuant to Orders 9 and 10 above, and any additional documents they intend to rely upon at the hearing of the Initial Trial.
- 17. By 29 August 2023, the parties deliver to the Associate to Justice Lee a Court Book which:
  - (a) *as Part A* contains the final version only of the pleadings or points of claim or responses to points of claim relied upon by the parties, any particulars not



included in the pleadings to be relied upon, and the final versions of the Agreed Background Facts and the Initial Trial Common Questions;

- (b) *as Part B* contains the final versions of the Opening Submissions of each party;
- (c) *as Part C* contains an electronic copy only of the documents for tender notified by each party (being only documents to which a party proposes to refer to in submissions);
- (d) *as Part D* contains any of the lay affidavit material and outlines of evidence proposed to be relied upon by any party (without any annexures or exhibits);
- (e) *as Part E* contains any of the expert affidavit and report material proposed to be relied upon by any party (without any annexures or exhibits); and
- (f) *as Part F* contains the Joint Reports.
- 18. The hard copy aspects of the Court Book are to contain double-sided printing and, to the extent filed Court documents are reproduced, the Notice of Filing form is to be reproduced at the end of the relevant Court document.

#### Objections

19. By 12 noon on 1 September 2023, Mr McNickle file and serve a Consolidated List of Objections that contains a list of those objections prepared pursuant to Order 14 above that are pressed and, in respect of each such objection, the grounds of the objection and the response to those grounds provided by the counter-party.

Date that entry is stamped: 4 May 2023

Sia Lagos Registrar



#### Schedule

No: VID243/2020

Federal Court of Australia District Registry: Victoria Division: General

Interested Person	AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY
Second Respondent	MONSANTO AUSTRALIA PTY LTD (ACN 006 725 560)
Third Respondent	MONSANTO COMPANY
Fourth Respondent	PHARMACIA LLC

# CROSS CLAIM

Cross-Claimant HUNTSMAN CHEMICAL COMPANY AUSTRALIA PTY LTD (ACN 004 146 338)



#### Annexure 1

# **Initial Trial Common Questions**

#	Proposed common questions raised by [26]-[30]
1.	Throughout the period July 1976 until 4 July 2022 (the Relevant Period), were:
	(a) glyphosate; and/or
	(b) glyphosate based formulations (GBFs)—
	carcinogenic to humans?
2.	Throughout the Relevant Period, were:
	(a) Roundup Herbicide; and/or
	(b) Roundup Biactive—
	carcinogenic to humans?
3.	Throughout the Relevant Period, if Roundup Herbicide and or Roundup Biactive contacted the skin, did any surfactants present increase absorption in the bloodstream by reason of the factors identified in 4FASOC [29]?
4.	Throughout the Relevant Period, did or could use of and/or exposure to:
	(a) Roundup Herbicide;
	(b) Roundup Biactive;
	(c) glyphosate; and/or
	(d) GBFs—
	(i) increase an individual's risk of developing NHL; and/or
	(ii) cause an individual to develop NHL?
5.	If use of or exposure to Roundup Herbicide or Roundup Biactive can cause NHL in humans, would use in accordance with the Labels, Safety Data Sheets and Safety Directions detailed in paragraphs 52 to 60 of the Statement of Agreed Background Facts (which paragraphs are at Annexure 3 of this order) amount to a use or exposure that is capable of causing NHL by reason of that use?



## Annexure 2

#### Trial Plan

	Activity	Time estimate
1.	Opening addresses and objections to the admissibility of expert evidence	2 days
2.	Expert evidence on causation	<b>23.5 days</b> (6 sitting weeks)
2.1	Conclave A: Cancer Biology (Causation of NHL)	2.5 days
	Prof Flecknoe-Brown (Applicant)	
	Prof Prince (Respondents)	
2.2	Conclave B: Cancer Biology (Hallmarks of Cancer and Key Characteristics of Human Carcinogens)	2.5 days
	Prof Smith (Applicant)	
	Prof Prince (Respondents)	
2.3	Conclave C: Epidemiology Concerning Glyphosate	2.5 days
	Prof Checkoway (Applicant)	
	Prof Harris (Respondents)	
2.4	Conclave D: Epidemiology/Biostatistics + AHS data	2.5 days
	Prof Gordon (Applicant)	
	Prof Harris (Respondents)	
2.5	Conclave E: Biostatistics (Statistical Analysis of Epidemiology Studies)	2 days
	Prof Gordon (Applicant)	
	Dr Crump (Respondents)	
2.6	Conclave F: Exposure and Absorption	2 days
	Dr Sawyer (Applicant)	
	Dr Driver (Respondents)	
2.7	Conclave G: Mechanistic Toxicology	2.5 days
	Prof Smith (Applicant)	
	Dr Juberg (Respondents)	
2.8	Conclave H: Animal Studies A (Toxicological	2.5 days



	Activity	Time estimate
	Analysis of Results of Animal Studies)	
	Dr Bayard (Applicant)	
	Dr Juberg (Respondents)	
2.9	Conclave I: Animal Studies B (Relevance of Animal Studies and Bioassays to Humans)	2 days
	Dr Bayard (Applicant)	
	Prof Prince (Respondents)	
2.10	Conclave J: Animal Studies C (Statistical Analysis of Results of Animal Studies)	2.5 days
	Dr Bayard (Applicant)	
	Dr Crump (Respondents)	
3.	Objections to lay evidence	1 day
4.	Respondents' lay evidence	3 days
	Break	(at least) 7 days
5.	Applicant/Respondents' closing submissions and replies	2 days



#### Annexure 3

# Labels and Safety Directions Detailed In Paragraphs [52] to [60] of the Statement of Agreed Background Facts

#### K. Labels and warnings

- 52. Information concerning the safe use of Roundup Herbicide and Roundup Biactive was communicated by the Respondents to consumers in Australia during the Relevant Period by two primary means:
  - a. the product label including the "Directions for Use" booklet, both affixed to the container of the products; and
  - b. the safety data sheets.

#### Labels

53. Following application by Monsanto Australia (Old) and/or Monsanto Australia (New) to the Registrar of Pesticides NSW, the following labels (as further described in the table below) were approved by the Registrar of Pesticides NSW for Roundup Herbicide between 3 November 1987 and 2 September 1993:

No.	Date	Label approved number	Description	Document ID
1.	3 November 1987	MON-2-L27	Registrar of Pesticides NSW registered label (250 ml)	MAL.900.010.0836
2.	1 August 1989	MON-2-L33	Registrar of Pesticides NSW registered label and label booklet (400 litres)	MAL.001.025.1893
3.	6 November 1989	MON-2-L34	Registrar of Pesticides NSW registered label (250ml)	MAL.900.010.1017
4.	14 October 1992	MON-2-L32	Registrar of Pesticides NSW approved label booklet	MAL.900.004.0361



No.	Date	Label approved number	Description	Document ID
5.	2 September 1993	MON-2-L36	Registrar of Pesticides NSW approved label and label booklet (5 litres)	MAL.001.025.1959

54. Following application by Monsanto Australia (Old), the following labels (as further described in the table below) were approved by the Department of Agriculture VIC, Registrar of Pesticides NSW, Public Health and Medical Services WA, Department of Primary Industries QLD and Division of Public Health Tasmania for Roundup Herbicide between December 1978 and January 1985:

No.	Date	Label approved number	Description and jurisdiction	Document ID
1.	7 December 1978	193/78 (Label Serial Number)	Department of Agriculture VIC registered label and label booklet (360 g/L, 20 litres) <sup>1</sup>	MAL.900.003.0443 at _ 04500455, _0550 (Approval), _05510555 (Approved Form)
2.	25 January 1985	MON-2-L17, MON-2-L18, MON-2-L19, MON-2-L20, MON-2-L21, MON-2-L22	Registrar of Pesticides NSW registered label and label booklet (360 g/L)	MAL.900.001.0669 at _08630883, _0856 (Approval)

55. Following application by Monsanto Australia (New), the following labels (as described in the table below) were approved by the National Registration Authority (**NRA**) for Roundup Herbicide between 1995 and 1998:

<sup>&</sup>lt;sup>1</sup> This glyphosate label was also approved in other jurisdictions, see approval letter of 8 November 1978 by Public Health and Medical Services WA registered label (360 g/L) (MAL.900.003.0443 at \_0568); approval letter of 14 November 1978 by Department of Primary Industries QLD (MAL.900.003.0443 at \_0572); approval letter of 20 November 1978 by Division of Public Health Tasmania (MAL.900.003.0443 at \_0575) and approval letter of 22 December 1978 by Registrar of Pesticides NSW (MAL.900.003.0443 at 0567).



No.	Date	Label approved number	Description	Document ID
1.	10 November 1995	31393/0001 3193/0695 3193/0495 3193/0498	NRA approved 31393/0001 label booklet cover for (1 litre) NRA approved 3193/0695 label (1 litre) NRA approved 3193/0495 label (5, 20, 200, 400 litres) NRA approved 3193/0498 label (5, 20, 200, 400 litres)	MAL.900.007.0211
2.	10 November 1995	31393/1	NRA approved back label (5, 20, 200, 400 litres) NRA approved label booklet (1 litre) NRA approved label (5 litres) NRA approved label (110 litres) NRA approved labels (1 litre)	MAL.900.007.0230, MAL.900.007.0251, MAL.900.007.0215, MAL.900.007.0232, MAL.900.007.0253
3.	29 May 1996	3193/02	NRA approved label booklet front covers (1 litre), NRA approved label (5 litres), NRA approved label (20 litres)	MAL.900.007.0488, MAL.900.007.0489, MAL.900.007.0486
4.	29 May 1996	31393/03	NRA approved labels and a label booklet (1, 5, 20, 110, 200 and 400 litres)	MAL.001.025.2003
5.	5 November 1996	31393/04	NRA approved labels and a label booklet (1, 55, 110, 115, 200 and 400 litres)	MAL.001.025.2095 at [.2120] to [.2139]
6.	15 April 1998	31393/0498	NRA approved label (1 litre), NRA approved label (20 litres), NRA approved front label (20 litres) and back label (5, 20, 200 and 400 litres)	MAL.900.007.0433, MAL.900.006.8274, MAL.900.007.0432



- 56. The Public Chemical Registration Information System Search database, which records approvals under the Agvet Code following applications by Monsanto Australia (New) records approvals of the following labels for Roundup Herbicide and Roundup Biactive between 1995 and 2018:
  - a. Roundup Herbicide:

No.	Roundup Herbicide (Product No.: 31393)	Document ID
1.	1 - 1995-11-10	MAL.900.007.0211
2.	02 - 1996-05-29	MAL.001.025.1999
3.	03 - 1996-05-29	MAL.001.025.2003
4.	04 - 1996-11-05	MAL.001.025.2095
5.	0498 - 1998-04-15	MAL.001.025.2156
6.	0402 - 2002-05-07	This label is relevantly in the same form as MAL.001.025.2156
7.	0502 - 2002-06-13	This label is relevantly in the same form as MAL.001.025.2156
8.	1002 - 2002-10-29	This label is relevantly in the same form as MAL.001.025.2156
9.	1102 - 2002-12-03	This label is relevantly in the same form as MAL.001.025.2156
10.	506 - 2006-08-30	MAL.001.021.9150,
		MAL.001.021.9152,
		MAL.001.021.9154,
		MAL.001.021.9155,
		MAL.001.021.9157
11.	0410 - 2010-02-24	MAL.001.017.4589
12.	52085 - 2011-03-25	KMN.001.001.0266
13.	53452 - 2011-05-18	MAL.001.025.2324



No.	Roundup Herbicide (Product No.: 31393)	Document ID
14.	54214 - 2011-10-14	MAL.001.017.4504
15.	107956 - 2016-10-21	MAL.001.014.0388
16.	112339 - 2017-11-02	MAL.001.026.0803

#### b. Roundup Biactive:

	Roundup Biactive (Product No.: 48518)	Document ID
1.	01 - 1996-05-29	MAL.001.025.2075
2.	0897 - 1997-08-19	MAL.001.025.2140
3.	0100 - 2000-01-18	MAL.001.025.2173
4.	0502 - 2002-06-17	This label is relevantly in the same form as MAL.001.025.2173
5.	1102 - 2002-12-03	MAL.001.021.9168
6.	52081 - 2011-03-25	MAL.001.025.2212
7.	58484 - 2013-04-18	MAL.001.025.2229
8.	101447 - 2015-04-28	MAL.001.025.2272

- 57. Copies of product labels and 'Directions for Use' produced by the Respondents for Roundup Herbicide identified in the far right column of the tables at paragraphs 53, 54, 55 and 56(a) above and the safety data sheets for Roundup Herbicide identified in the far right column of the table at paragraph 59 below are at Annexure A.
- 58. Copies of product labels and 'Directions for Use' produced by the Respondents for Roundup Biactive identified in the far right column of the table at 56(b) above and the safety data sheets for Roundup Biactive identified in far right column of the table at paragraph of the table at paragraph 60 below are at Annexure B.



# Safety data sheets

The following Roundup Herbicide safety data sheets were published during the 59. **Relevant Period:** 

No.	Date	Published by	Document ID
1.	February 1987	Monsanto Australia Limited	MAL.903.016.0048
2.	30 April 1989	Monsanto Australia Limited	MAL.916.013.0022
3.	23 August 1993	Monsanto Australia Limited	MAL.934.025.0017
4.	22 January 1997	Monsanto Australia Limited	MAL.001.025.2338
5.	10 January 2000	Monsanto Australia Limited	MAL.001.025.2205
6.	June 2004	Nufarm Australia Limited, in accordance with information provided by Monsanto Australia Limited <sup>2</sup>	MAL.007.019.9179
7.	April 2009	Nufarm Australia Limited, in accordance with information provided by Monsanto Australia Limited	MAL.001.017.4606
8.	February 2012	Nufarm Australia Limited, in accordance with information provided by Monsanto Australia Limited	MAL.004.180.1615
9.	April 2013	Sinochem International Australia Pty Ltd, in accordance with information provided by Monsanto Company (New). <sup>3</sup>	MAL.001.014.0601
10.	29 April 2013	Sinochem International Australia Pty Ltd, in accordance with information provided by Monsanto Company (New).	MAL.001.025.2345
11.	13 October 2015	Scotts Australia Pty Ltd, in accordance with information provided by Monsanto Australia Limited and Monsanto Company (New). <sup>4</sup>	MAL.001.026.1142

<sup>&</sup>lt;sup>2</sup> Cl 6.2

<sup>&</sup>lt;sup>3</sup> Supply and Distribution Agreement between Monsanto Company (New) and Sinochem dated 1 March 2013, e.g t cl 13.5, 13.8 and 13.10 and 14.2.

<sup>&</sup>lt;sup>4</sup> Cl 2.4(c), 4.4



No.	Date	Published by	Document ID
12.	14 October 2016	Sinochem International Australia Pty Ltd, in accordance with information provided by Monsanto Company (New).	MAL.001.014.0571

60. The following Roundup Biactive safety data sheets were published during the Relevant Period:

No.	Date	Published by	Document ID
1.	29 May 1996	Monsanto Australia Limited	KMN.001.002.0001
2.	27 June 1996	Monsanto Australia Limited	MAL.001.015.8535
3.	22 April 1997	Monsanto Australia Limited	MAL.001.025.2297
4.	8 January 2000	Monsanto Australia Limited	MAL.001.025.2194
5.	November 2008	Nufarm Australia Limited, in accordance with information provided by Monsanto Australia Limited	MAL.001.015.9307
6.	February 2012	Nufarm Australia Limited, in accordance with information provided by Monsanto Australia Limited	MAL.001.015.9265
7.	13 February 2012	Monsanto Australia Limited	MAL.001.015.9293
8.	April 2013	Sinochem International Australia Pty Ltd, in accordance with information provided by Monsanto Company (New)	MAL.001.015.9278
9.	29 April 2013	Sinochem International Australia Pty Ltd, in accordance with information provided by Monsanto Company (New)	MAL.001.025.2288
10.	14 October 2016	Sinochem International Australia Pty Ltd, in accordance with information provided by Monsanto Company (New)	MAL.001.015.9258