

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:)
)
Bayer CropScience LP and) FIFRA-HQ-2016-0001
Nichino America, Inc.,)
)
)
)
Petitioners.)
_____)

JOINT MOTION TO CONFORM TRANSCRIPT

As directed by Judge Biro at the May 10, 2016 hearing, Petitioners Bayer CropScience LP and Nichino America, Inc. and Respondent Environmental Protection Agency hereby submit a Joint Motion to Conform the Transcript for the May 10, 2016 hearing requesting that the Court Reporter make the following corrections to conform the Transcript to the testimony as delivered. The Parties have discussed and reached agreement on these corrections. Counsel for Respondent has authorized counsel for Petitioners to file this motion as a joint motion on behalf of all parties.

Page No.	Line No.	Original	Corrected
1	N/A	The ARBITRATION	The HEARING
1	N/A	SUSAN L. BIRO / Arbitrator	SUSAN L. BIRO / Administrative Law Judge ¹
4	4	Bayer Crop LP	Bayer CropScience LP
5	4	Lee Hall,	Lee Hall, both of Bayer
5	6	for the Nichino	for Nichino
6	11	four certain additional	four conditional

¹ Note that “Arbitrator Biro” should be changed to “Judge Biro” throughout the transcript.

Page No.	Line No.	Original	Corrected
6	13	°6(b)	§ 6(b) ²
6	17	Orders of Substance	orders of substance
6	18	Petitioner’s Objection	Petitioners’ Objection
6	19	Ruling	Rulings
6	21	Objections	objection
7	2	we don’t have to	you don’t have to
7	10-11	this condition of the withdrawal	existing stocks
7	17-18	to read over these statements	to make opening statements
8	1	do know you through the background	do know the background
9	2	risks of concerns.	risks of concern.
9	5	FIFRA °3(c)(7)(c)	FIFRA § 3(c)(7)(C)
9	20	voluntarily cancellation request	voluntary cancellation request
10	11	with have affirmed	which have affirmed
10	19	by registrant’s	by registrants’
11	1	the registrant’s	the registrants’
11	21	today on	today in
12	13	standards.	standard.
12	18	Voluntarily	Voluntary
13	16	first time that FIFRA °6(b)	first time that a FIFRA § 6(e)
13	17-18	under FIFRA. The registrants	under FIFRA. The registrants ³
14	2	The fact and expert testimony	The fact and expert testimony ⁴

² The degree symbol should be changed to a section symbol (with a space between the section symbol and the number) throughout the transcript.

³ Start new paragraph with “The registrants....”

⁴ Start new paragraph with “The fact and expert testimony....”

Page No.	Line No.	Original	Corrected
14	8	registration standard,	registration standard;
14	8	the environment, and, fourth,	the environment; and fourth,
14	19	in the Tribunal's	and the Tribunal's
15	11	data to engage	data, and to engage
16	2	Congress established §6(b) hearings	Congress established § 6(e) hearings
17	4	which is of itself	which is itself
17	10	limits at EPA's	limits on EPA's
17	15	review discussion	review, discussion
18	4	so much power of the	so much power over the
18	8	Miss	Ms.
18	10	Miss	Ms.
18	14	included	excluded
19	16	Susan Torgus Lewis	Susan Torregrosa Lewis
20	18	20106	200106
20	21	CSPD	CSPD
22	19	which of course if given to us we reserve the	which it advised us it reserved the
22	22	If you	If EPA
23	1	indicate --	indicates --
26	13	data pollen	data call-in
26	16	registrants	registrants'
27	15	I'd love to ask you	I'd like to ask you
28	22	registrant's Exhibits	registrants' Exhibits
30	18	Respondent's Exhibit,	Respondent's Exhibit 6,
31	3	2008 B Public	2008 BEAD Public
32	19	that PBNX	that's PBNX
34	18-19	page 2 and the large numbers are 200095.	page 2 in the large numbers, 200095 in the small.

Page No.	Line No.	Original	Corrected
35	7-8	Environmental Impacts Division	Environmental Fate and Effects Division
37	12	the registrar	the registrant
40	5	Bayer suggested to deleting	Bayer suggested deleting
40	11	you viewed the data	review of the data
41	2-3	provisions that included	provisions included
41	10	part six	paragraph 6
42	8	he worked at this	he worked there at this
42	16	The one --	The one week, yes.
43	4	that was in EPA's --	that was in EPA's draft.
43	8	20062 to 20065	200062 to 200065
43	13	20063 to 20064	200063 to 200064
44	4-5	additional data supporting information	additional data and supporting information
44	9	form 8(b)	from 8(b)
44	14	20064	200064
45	12	Exhibit RD10	Exhibit RE10
45	19	Maryann Johnson	Marion Johnson
46	9	for 2008	from 2008
46	12-13	for 2008	from 2008
46	22	safety of infants	safety to infants
47	3	that at risk assessment	that HED risk assessment
47	11-12	they probably would have been up to date for this new system of assessments	it probably would have been updated for these new uses
47	16	RD5	RE5
47	18	RD5	RE5
47	19-20	recordation cancel of currently registered provide flubendiamide	recommendation to cancel all currently registered flubendiamide products

Page No.	Line No.	Original	Corrected
48	4	RD5	RE5
48	14	referring there to the Effects Division?	referring there to the Environmental Fate and Effects Division
48	16	And what about the --	And what about BEAD?
48	17-18	RE? We used their report and they refute the document and edit.	BEAD? We used their report and they reviewed the document and edited it.
48	22	brief you in it?	weigh in on it?
49	2	OCSS SPT Management	OCSPP Management
49	5	December 2016 meeting	December 16 meeting
50	12	registrations would cause	registration would cause
51	10	RD5	RE5
51	18	RD4	RE4
52	7	existing facts	existing stocks
52	17	on basis	on the basis
53	2	the amount flubendiamide	the amount of flubendiamide
54	12	existing stocks for those proposal	existing stocks for the proposal
55	3	tend not to hide	tend not to buy
56	18-19	Production can continue now our firm can keep running	Production can continue now, or can keep running,
57	14	entertaining	entering
57-58	22-1	In my testimony, I anticipated we put the matter quickly	In my testimony, I anticipated we would act quickly
58	12	7 1/2 years	7 1/2 years
59	3-4	have that before so	have that before January so
59	17-18	That's probably more of a team if it's been registered for a model.	There's probably more time if it's been registered for a while.
60	11	"6(b)."	section 6(e)."
61	10	your council	your counsel

Page No.	Line No.	Original	Corrected
61	14	its	it's
61	21	the Rodenticide posture	the Rodenticide cluster
62	8	registrations were misbranding	registrations were misbranded
62	12-13	And the record then has challenged that option in the report.	And Reckitt Benckiser then challenged that option in court.
62	15	the report found	the court found
62	20	prior to the delay	part of the delay
62-63	22-1	a different option as the first option as the first option	a different option as the first option
63	22	to keep us all under	to cancel under
64	1	°6(b)	§ 6(e)
64	6-7	In this particular action, the record then has an action.	In this particular action the Agency took action in response to the registrants' letter.
64	8-9	There was the issue of timing. 2005 versus 2012 was an intent to cancel.	There was the issue of timing in EPA's other 2008 decision versus its 2013 notice of intent to cancel.
64	12	one FIFRA °6(b).	one FIFRA § 6(b) hearing.
64	15-17	all the documents that we entered into the record and I think you know what the documents are.	all the documents that we can enter into the record and can state what the documents are.
64	17	EPA produced their list as well.	EPA has its copies as well.
65	4	Registry Notice	Register Notice
65	6	Six	For 6
65	7	Registry Notice	Register Notice
65	7	documents under face	documents on their face
65	9	FIFRA °3(b)(c)(7)	FIFRA § 3(c)(7)
65	10	reference	registrations were
65	13	She did not appear to the registrants withdrawn	She did not appear as the registrants withdrew
65	17	the registration marks which show the numbers	the registration letters which show the numbers

Page No.	Line No.	Original	Corrected
65	18	You	We
66	10	taking a lot of time	saving a lot of time
66	19	BAILIFF	MR. WRIGHT
67	7	Federal Registry Notice	Federal Register Notice
67	12	this joint case caption.	this case caption
68	2	Not that we see the volunteer cancellation	Note that because we have not seen the voluntary cancellation
68	8	are going to be reviewed	you reviewed
68	9	the registrant's request	the registrants' request
68	15	look at if	look at it if
69	3	mark the PBNX 127	mark this as PBNX 127
69	7	the registrant's motion	the registrants' motion
69	8	full decision	full opposition
71	9	There were	There was
71	15-16	the director was	the other directors were
73	21	my colleague	my manager
75	3	PBN1977	PBN1911
75	5	options neither raise	options either raise
75	19	my question	my questions
76	16	1910	PBN1910
77	5	read the paragraph that please begins	please read the paragraph that begins
78	18	Dr. Edwards) Edwards	Dr. Edwards
79	4	in 2000	in 2008
80	12	biological analysis division	Biological and Economic Analysis Division
80	13	wouldn't be expensive	wouldn't be extensive
80	22	what stops	what stocks
83	20	the agency's	the agency's,

Page No.	Line No.	Original	Corrected
85	9	says released for shipment	says release for shipment
87	17	you asked the question	you were asked the question
88	13	registered for about two products	registered for about two years
88	15	instant data	incident data
90	2	in any time limited	many time limited
91	22	the science	the scientists
92	22	Pesticide Pollution	Pollution Prevention
93	16	SSI programs	OPP programs
94	5	or clarification	for clarification
94	10	is record	is in the record
95	6	petitioner's	petitioners'
95	15	Exhibits 10, 13	Exhibits 10, 12, 13
96	7-12	If you'd like Yes, Your Honor.	Delete these duplicate lines, which already are included in lines 1-6.
96	21	the Registrant's first witness	the Registrants' first witness
97	18	124 to 126 is	124 to 126 are
98	10	You'll put that on	Yes, we'll put that on
99	7	the registrant's exhibits, the petitioner's	the registrants' exhibits, the petitioners'
99	16	that you are very happy with the statement we	that this is a true and correct copy of the statement you
99	21	Petitioner Exhibits	Petitioners' Exhibits
101	13	registration commission	Registration Division
103	9	page --	page 200012
103	10	PALS	conditions
103	20-22	They'll be a constant – they're still being – that could be submitted to EPA.	They're continuing – they're still being conducted – that could be submitted to EPA
104	5	studies that were	studies that are

Page No.	Line No.	Original	Corrected
104	7	ones that were	ones that are
106	6-8	this isn't predicated	this is predicated
106	20	real water monitoring data	real world water monitoring data
107	11	it's a typical	it's not a typical
109	5-6	did not have issue with registration about that provision	would not have issued the registration without that provision
109	7	based on emails	based on the emails
109	14	on this	like this
110	3	would have a	would have had no
110	20	the condition	a condition
111	10-11	like our other groups	like our other products
111	12	non-conditional	unconditional
113	3-4	It was all or nothing? When this is far enough and you take	It was all or nothing. EPA has gone as far as it would and you take
113	10	registrant's registration	registrants' registration
114	9	you just answered your question	I just sustained your objection.
114	14	Approved.	Proceed.
114	22	Under (e)	Under (b)
115	1	all of data	all of the data
116	14	the party	the parties
117	20	judge's	Judge's
119	15	known unknown	known unknowns
120	2	these aquatic	these benthic aquatic
120	11	based on the	based on if the
121	8-9	But, clearly, the science has demonstrated	But clearly if the science had demonstrated
121	12-13	long-term cancellation.	long-term registration.
122	16-17	the power strip	the buffer strip
123	20-21	it's necessary to.	it's necessary for stewardship.

Page No.	Line No.	Original	Corrected
125	5	its metabolife	its metabolite
125	7-8	over time, it's the	over time, as the
125	10	they're looking at real world data,	they're not looking at real world data
125	12	its specs	it expects it
125	18	we're still a little bit concerned	we're still below levels of concern
127	2	EPA didn't think	EPA indicated
127	8	they're	we're
127	11-12	science opinion of EPA, they're assessing us in decision endpoint	science division of EPA, they're assessing us using a decision endpoint
127	13	discussions was	discussions and was
128	4-5	it was a scientific	it was not scientific
130	2	BAILIFF	MR. WRIGHT
130	3	11:32 p.m.	11:32 a.m.
131	10-11	I would like to very well call	I would like to call
131	21	the petitioner's	the petitioners'
132	5	we have Bayer CropScience and Nichino America	on behalf of Bayer CropScience and Nichino America
133	2	Petitioner's Exhibit	Petitioners' Exhibit
133	14	a non-standard existing stock	a standard existing stock
133	18-19	and the lab cleared the channel with 18 to 24 months	they have been allowed to clear the channel within 18 to 24 months
133	21	proceed to approve the diagram	proceed to cancellation
134	1-4	a determination that if the product is to be cancelled that at that point a reasonable standard of procedures would apply.	a determination that the product is to be cancelled, at that point a reasonable standard procedure would apply.
134	6-7	and you did not inquire for permission	when you did not comply with the condition
134	11	existing stock's treatment	existing stocks treatment

Page No.	Line No.	Original	Corrected
135	19	your admission	your position
136	3	allowed to for those products	allowed to sell those products
137	19	and made the products	that made the products
137	20	to end user	to end users
138	1	an involuntary	a voluntary
138	13	we were either	where we are either
138	18	experience from a standard procedure	experience, a standard procedure
139	8	I'm going to get a hold of Jeffrey Johnson.	I would like to call Jeffrey Johnson.
139	21-22	And for record, this is the fourth binder, PBNX 118?	And for the record, this is the fourth binder, PBNX 118? [Question for court reporter: Is there a question and/or answer missing between this and the prior line?]
140	4	And what was this?	And what is this?
140	16	PBNX 118 in evidence	PBNX 118 into evidence
141	12	involvement with Nichino of said products?	involvement in the initial registration of Nichino's products?
141	17	a parent company	our parent company
141	21	have new compound	have a new compound
142	1	registration process, and I work with our national	registration process, and I work with our management
142	5-6	How often did you get a record of the developmental studies?	How often do you meet with EPA regulatory officials on pesticide matters?
142	16	EPA to related	EPA related
142	19	those discussion	those discussions
142	21	parent company, Nohyaku	parent company, Nihon Nohyaku
143	9	involvement or	involvement in
144	10	termination	determination

Page No.	Line No.	Original	Corrected
144	21	I was aware only that it was	I was aware only that it was a
145	6	may be jeopardy	may be in jeopardy
146	7	I believe the regulatory – yes.	I believe the regulatory people were – yes.
147	4	expected to accept the provision for	pressured to accept the provision for
147	10	would not issue	would not have issued
147	15-16	it was accepted for registration	it accepted the registration
147	19	January 24th	January 29th
147	20	about the	to cancel the
148	21	based on	was based on
148/ 149	22/ 1	would not have a registration before that time limit	would not have gotten a registration but for that commitment
149	4	that clarify what you mean by commitment	that counsel clarify what you mean by commitment
150	13	after where says	after where it says
150	17	look at,	look at, is
151	7	paragraph, the EPA abruptly shifting course and	paragraph, the EPA abruptly shifted course and
152	9	degridates	degradates
152	11	I not a scientist	I'm not a scientist
154	3	with pesticide applications	with pesticide applicants
155	3	like, EPA	like EPA
155	16	losses incurred	licensing program
155	22	losses incurred	licensing program
156	8-9	losses incurred	licensing program
156	21	losses incurred	licensing program
157	1	When you use the word --	[Question for court reporter: Is the remainder of the question missing?]

Page No.	Line No.	Original	Corrected
157	10	we have to be transparent, and we learn by law,	we have to be transparent, and we have to by law,
157	18	to civil action	to bring action
157/ 158	22/ 1	if the condition were not believable	if the condition were not legal
159	13	we felt it was the appropriate thing to do at the	we felt that it was not the appropriate thing to do at the
159	20	EPA need	EPA needed
160	14	program operated under fair	program should operate in a fair
161	15	You asked for the voluntary cancellation request	We asked for the voluntary cancellation request
164	16	status is when	status is of
165	2	and pulled away from any stocks to be used, all	and permitted any stocks to be used, all
165	12	status is in a pesticide product	status is of a pesticide product
165	20	sold in a sense	sold under any circumstances
166	21	would be able produce	would be able to produce
167	1	and they requested	had they requested
167	13	narrowly scoped, and you give him, Counsel, a lot	narrow in scope, and we have given Counsel a lot
168	13	the shipment	for shipment
168	15	and they complied	had they complied
169	17	if Bayer and Nichino had honored	if Bayer or Nichino had honored
170	1	that this is getting very narrow spoken testimony	that this is very narrow direct testimony
170	2	I don't think it should be up to his imagination.	I don't think he should be asked about his imagination.
171	20	come up maybe five times in the question. It's	come up maybe five times in the questions. It's
172	4-5	This is Nichino's present	This is Nichino's president
173	2	existing stocks provision which will be kick in	an existing stocks provision which will kick in

Page No.	Line No.	Original	Corrected
173	6-7	I think I do, but I think it's inappropriate, but I think it was more of a	I think I do, and I think it's inappropriate, because I think it is more of a
173	9	we're doing in legal	we're doing is legal
174	12	everything back and we would have to just waste	everything back and we would have to do hazardous waste
174	21	28th, and I became aware of the more difficult	28th, and I then became aware of the more difficult
175	19-20	a formulation of flubendiamide and the focus of it	a formulation of flubendiamide and buprofezin
176	9-10	Dana Sargent's provided registrants concerned	Dana Sargent's letter described registrants' concerns
178	4-5	Is that word "ignored" in this place, is that a word to dissociate the scientific	Is that word "ignored" in those places, is that a word you associate with scientific
179	8	That's correct. They're a	That's correct. They're our
180	3	I'm not a scientist, I go through my experience in	I'm not a scientist, I speak from my experience in
180	4	managing over top that area	managing over top of that area
181	9	you can go with and try to address all the	you can get and try to address all the
182	3	primarily Bayer and Nihon Nohyaku market the	primarily Bayer and Nihon Nohyaku that market the
182	19	This is not totally available information in the general course.	This is not publicly available information in the general course.
183	6	we had to agree to it.	we import the active ingredient.
183	18-19	3rd-party contract normally	third-party contract formulator.
185	10	In your letter	In their letter
187	12-13	but we were in discussions about litigation	but we were in discussions about mitigation
187	14	things for use label	things for the end use label
188	17	So the tremendous compound	So it's a tremendous compound.

Page No.	Line No.	Original	Corrected
189	12	environmentally very good human tox,	environmentally very good, human tox,
189	13	aquatic tox, except for this one vented organism	aquatic tox, except for this one benthic organism
191	5	determining this pesticide	to terminate this pesticide
191	9	persistent pesticide and had to take	persistent pesticide and have to take
192	8	address the question posed that we though touched	address the question posed that we thought touched
193	4	through each general area.	through Nichino America.
193	7	It would not have paid by back by then.	It would not have paid us back yet.
196	18	ARBITRATION	HEARING

Dated: May 16, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 16th day of May, 2016, a true and correct copy of the foregoing Joint Motion to Conform Transcript was filed electronically using the EPA OALJ e-filing system; and served in the following manner to the below addressees:

Electronically Using EPA OALJ e-filing system:

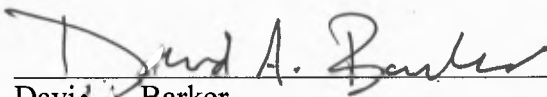
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