**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**BEFORE THE ADMINISTRATOR**

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| In the Matter of: | ) | |
| | ) | Docket No. FIFRA-03-2015-0248 |
| FMC Corporation, | ) | |
| | ) | RESPONDENT FMC CORPORATION'S |
| Respondent. | ) | PREHEARING EXCHANGE |
| | ) | |

**RESPONDENT FMC CORPORATION'S PREHEARING EXCHANGE**

In accordance with Administrative Law Judge Christine Coughlin's Prehearing Order ("Prehearing Order") dated May 6, 2016, and pursuant to 40 C.F.R. § 22.19(a) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Rules of Practice"), Respondent FMC Corporation ("FMC" or "Respondent") hereby submits its Prehearing Exchange. FMC respectfully reserves the right to supplement this Prehearing Exchange in accordance with the Prehearing Order and 40 C.F.R. § 22.19(f).

## I. WITNESSES THAT FMC EXPECTS TO CALL AT THE HEARING AND A BRIEF NARRATIVE SUMMARY OF EXPECTED TESTIMONY

FMC expects to call the following individuals as witnesses to testify to the matters described generally below and other matters that may be needed in light of Complainant's actual testimony. FMC agrees with Complainant's statement anticipating that the parties will be able to stipulate that the exhibits are what they purport to be and hopefully avoid unnecessary additional testimony of records custodians or other witnesses (whether in person or in written form). To the extent that the parties can stipulate to facts and narrow the issues, the number of witnesses or the length of their testimony may be reduced.

A. Fact Witnesses

FMC expects to call the following individuals to testify as fact witnesses at the hearing. The witnesses' testimony is expected to include the matters generally described below. In addition, each witness is expected to testify to his or her relevant professional experience and educational background.

1. Linda Froelich
Director, FMC Global Sustainability

Ms. Froelich leads FMC's corporate sustainability program. She has served in this position since 2013. Ms. Froelich has been employed by FMC for over 35 years. During her career at FMC, Ms. Froelich has held leadership and management roles in research and development, regulatory affairs and sustainability for FMC's pesticide business. For example, Ms. Froelich managed FMC's North America Registrations and Regulatory group and served as FMC's Product Stewardship Manager for the Agricultural Solutions business unit before assuming her current position.

Ms. Froelich may be called to testify about FMC's commitment to compliance. This may include information about FMC's approach to ensuring compliance with the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and its implementing regulations, the processes FMC has in place to help ensure such compliance, and the steps FMC took when it learned of the matters at issue in this case. She may also testify about FMC's product stewardship program. Finally, Ms. Froelich may testify that to FMC's knowledge, no harm to any person, non-target animal, or the environment resulted from any of the violations alleged by the United States Environmental Protections Agency ("EPA").

2. John Cummings, Ph.D.
Manager, FMC North America Crop Registration Regulatory Affairs

Dr. Cummings is the Manager for North America Registration and Regulatory Affairs for FMC Agricultural Solutions. He has served in this role since joining FMC in 2006. As Registration and Regulatory Affairs Manager, Dr. Cummings is responsible for regulatory compliance of FMC's pesticides in the United States and Canada. From 1997 to 2006, Dr. Cummings served as a pesticide product registration manager for DuPont.

Dr. Cumming may be called to testify about FMC's approach to ensuring compliance with FIFRA and its implementing regulations and the processes FMC has in place to help ensure such compliance.

Dr. Cummings may be called to testify about the regulatory history relating to *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545, including EPA's acceptance of the alternate brand name "Stallion Brand Insecticide."

Dr. Cummings may also testify generally about the documents involved in the advertising allegations, and explain that each included the instruction to "always read and follow the label directions" and the label contained the phrase "Restricted Use Pesticide" and related detailed directions.

In addition, Dr. Cummings may testify that FMC is not aware of any sales to non-certified applicators that resulted from the documents associated with the advertising allegations, and that there are safeguards in place to ensure such sales do not occur.

Dr. Cummings may also be called to testify about other EPA-approved pesticide product names that refer to animals, including horses, and that are not for use on the referenced animals.

Dr. Cummings may also testify about the corrective measures FMC took as soon as it became aware of EPA's allegations and its follow-up stewardship actions. In addition,

Dr. Cummings may discuss the actions FMC has taken since EPA's allegations to help ensure FMC's continued compliance with FIFRA and its implementing regulations. Finally, Dr. Cummings may testify that to FMC's knowledge, no harm to any person, non-target animal, or the environment resulted from any of the violations alleged by EPA.

3. Aaron Locker
Director, FMC North America Crop Marketing

Mr. Locker is FMC's Director of Marketing for the North America Crop business. He has served in this position since 2013. Mr. Locker began his career with FMC as a Product Manager in Marketing in 2006. In 2008, Mr. Locker was promoted to Director of Strategic Account Management before assuming his current role.

Before joining FMC, Mr. Locker worked for Ciba-Geigy in its pesticide business (Ciba-Geigy merged with another company to form Novartis and again later to form Syngenta while Mr. Locher was an employee) and held positions in sales, technical sales, sales management, key account management, sales force automation, program management and channel strategy.

Mr. Locker may be called to testify generally about FMC's development and execution of marketing for FMC Agricultural Solutions in the United States. This may include a discussion of FMC's relationship with outside advertising agencies. Mr. Locker may also testify about FMC marketing efforts that are intended to raise brand and product awareness as contrasted with offers for sale and directions for product use.

Mr. Locker's testimony may also include a discussion about the single graphic at issue in the advertising allegations, and the advertising allegations in general. In this regard, Mr. Locker may testify that each of the materials associated with EPA's advertising allegations instructed the potential recipient to "always read and follow label directions" and the labels contained the phrase "Restricted Use Pesticide" and related detailed directions.

With respect to the direct mailer at issue in this case, Mr. Locker may explain how the lists of intended recipients were created. Mr. Locker may also explain how the number of intended direct-mailer recipients is smaller than EPA alleged in its Complaint.

Mr. Locker may also be called to testify about EPA-approved product names for other pesticides that refer to animals, including horses, and that are not for use on such animals. Mr. Locker may also testify about the different distribution channels for agricultural products on the one hand and animal health products on the other. He may discuss that FMC does not sell its products directly into the animal health marketplace. Mr. Locker may also be called to testify about FMC's sales channels and how as a supplier it interacts with customers.

Mr. Locker's testimony may also address the corrective measures FMC took once it was made aware of EPA's allegations. Finally, Mr. Locker may testify that to FMC's knowledge, no harm to any person, non-target animal, or the environment resulted from any of the violations alleged by EPA.

4. Kevin Kalb
<u>Finance Director, FMC North America</u>

Mr. Kalb is FMC's North America Finance Director and has served in that position since May 2016. In this role, he is responsible for both North America Crop and Global Specialty Solutions. Mr. Kalb began his career at FMC 19 years ago as a Senior Accountant and has since held a series of accounting and finance positions, including Group Accounting Manager, Group Financial Reporting Manager for Agricultural Solutions, and North America Crop Controller.

Mr. Kalb may be called to testify generally about the accounting aspects of production, packaging, labeling, distribution and sales of FMC products. Mr. Kalb may also testify about the sales of *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545 during the time period addressed in the Complaint. Mr. Kalb may also be called to testify about FMC's production schedule for *F9047-*

*2 EC Insecticide*, EPA Reg. No. 279-9545 vis-à-vis the 30-day waiting period for EPA notifications and EPA's communications in this matter. Mr. Kalb may also testify that to FMC's knowledge, no harm to any person, non-target animal, or the environment resulted from any of the violations alleged by EPA.

B. Expert Witnesses

Respondent expects to call the following individuals to testify as expert witnesses at the hearing.

1. Debra F. Edwards, Ph.D.
Former Director, EPA Office of Pesticide Programs

A copy of Dr. Edwards' curriculum vitae is provided as an exhibit in accordance with the Prehearing Order. Dr. Edwards is an expert on EPA pesticide regulation under FIFRA.

Dr. Edwards had a long and distinguished career as a federal pesticide regulator. The majority of Dr. Edwards' career has been spent in leadership positions within EPA. Apart from two years as a United States Peace Corps Volunteer in Guatemala during 1997 to 1999, Dr. Edwards worked continuously at EPA from 1985 to 2010.

From 2007 until her retirement from EPA in February 2010, Dr. Edwards served as the Director of EPA's Office of Pesticide Programs ("OPP"). OPP is the office within EPA responsible for implementing and administering the federal regulation of pesticides in the United States under FIFRA. As Director of OPP, Dr. Edwards was the senior EPA career employee in charge of U.S. pesticide regulation and was responsible for the overall management and direction of all of EPA's pesticide activities. She directed approximately 850 employees and managed a budget of approximately $150 million.

Dr. Edwards' prior EPA positions and responsibilities are provided on her curriculum vitae. Since retiring from EPA, Dr. Edwards has worked as a consultant advising businesses and

government agencies on U.S. and global regulatory compliance and policy issues relating to pesticides, biocides, and food safety.

Dr. Edwards is an expert in EPA's regulation of pesticides, including EPA's evaluation of and decisions about pesticides. This includes among other things, EPA's designation of pesticides as restricted use pesticides ("RUPs"), registrant non-notifications, notifications, and applications for amendment for registrations and EPA's practices with regard to same, including regarding product names, and EPA's regulation of pesticide advertising. Her expertise is from the perspective of a scientist, program manager, and the person who was ultimately responsible for EPA's regulatory oversight over all pesticides and all pesticide determinations under FIFRA.

Dr. Edwards earned her Ph.D. and Masters of Science in Plant Pathology in 1981 and 1978, respectively, from The Ohio State University. Dr. Edwards earned her Bachelors of Science degree in Botany in 1975 from Miami University, graduating Phi Beta Kappa.

Dr. Edwards may be called to testify about EPA's oversight of pesticides generally, its approval processes, and ongoing oversight.

Dr. Edwards may be called to testify about RUPs in general, as well as those containing chlorpyrifos and zeta-cypermethrin as an active ingredient. She also may testify about chlorpyrifos and zeta-cypermethrin regulation more generally.

Dr. Edwards may also be called to testify about practices related to pesticide non-notification, notifications and amendments, including alternate name brand notifications submitted to EPA under Pesticide Registration ("PR") Notice 98-10.

Dr. Edwards may also be called to testify about EPA's oversight of pesticide advertising.

Dr. Edwards may be called to testify about how OPP coordinates with EPA's Office of Enforcement and Compliance Assurance on pesticide matters, and discuss her opinion of the

alleged violations, including putting them into context with EPA's history of FIFRA enforcement and EPA's FIFRA Enforcement Response Policy.

2. Dale Burnett
Former Texas Department of Agriculture
Director of Pesticide Enforcement

A copy of Mr. Burnett's curriculum vitae is provided as an exhibit in accordance with the Prehearing Order.

Mr. Burnett is an expert in the use of RUPs and pesticide applicator certification, expertise he gained through his career as a Texas pesticide regulator, investigator, pesticide applicator certification and training specialist, and enforcement official, as well as his personal experience as a certified pesticide applicator. He is an expert on the federal certification standards for pesticide applicators, as well as the state-based standards and programs.

Mr. Burnett spent 28 years working in Texas state government, 14 of which were with the Texas Department of Agriculture ("TDA"). TDA is the lead state agency for regulating pesticides. TDA investigates alleged violations of the Texas Pesticide Law and its implementing regulations as well as FIFRA in coordination with EPA.

Mr. Burnett served as a TDA pesticide certification and training specialist, investigator and district supervisor, and then as the Director of Pesticide Enforcement. As Director, Mr. Burnett supervised all district and state-wide inspections and investigations, which included oversight of all dealer licensing and applicator certification compliance matters.

In addition to his extensive career at TDA, Mr. Burnett spent 10 years working in supervisory positions at the Texas Commission on Environmental Quality ("TCEQ"), including as Manager, Special Investigations and Chair, Multi-Agency Task Force.

Following his work at TCEQ, Mr. Burnett was for four years the Executive Director of the Texas Structural Pest Control Board, which licenses and regulates pest management professionals who apply pesticides in and around structures.

After retiring from government service, Mr. Burnett established a private consulting firm that provides regulatory support to both government and private entities.

Mr. Burnett received a Bachelor of Science in Agriculture from Texas State University (formerly Southwest Texas University) in 1977.

Mr. Burnett may be called to testify about the federal and state regulatory framework that governs RUP use and certified pesticide applicator training and certification.

Mr. Burnett may be called to testify about the processes an individual must follow before she or he may purchase and apply RUPs. This may include testimony about certification, training requirements, and point-of-sale restrictions and safeguards that prevent non-certified applicators from purchasing RUPs.

Mr. Burnett may also be called to testify about the alleged violations in this case vis-à-vis EPA's approach to the proposed penalty.

3. George Orme
Founder and Managing Director of Strategic Marketing Partners, Inc.

A copy of Mr. Orme's curriculum vitae is provided as an exhibit in accordance with the Prehearing Order.

Mr. Orme is a Marketing expert with over 25 years of experience. Among other things, he is an expert in direct mail and branding. Mr. Orme is a co-author of *The New Direct Marketing*, which is used throughout the United States for teaching marketing in business and graduate schools.

From 1982 to 1986, Mr. Orme was Executive Vice President at BBDO Direct. In that role, Mr. Orme directed client services for that substantial agency and developed direct marketing strategies and programs for large companies. From 1986 to 1987, Mr. Orme was Senior Vice President at Ogilvy and Mather Direct, where he was responsible for all direct marketing programs for specific accounts. Mr. Orme then worked for David Shepard Associates, first as a Senior Consultant from 1987-2009, and then as President from 2009-2015. At David Shepard Associates, Mr. Orme advised major clients on both branding and marketing strategies. Mr. Orme founded Strategic Marketing Partners, Inc. in 2016, where he is currently the Managing Director.

Mr. Orme earned his Bachelor of Science in English from Carroll University.

Mr. Orme may be called to provide a general overview about marketing. Such an overview may include, for instance, a discussion about marketing efforts that are used to raise brand and product awareness, compared to efforts that are intended to be offers for sale. Mr. Orme may also be called to testify about marketing metrics and the efficacy of different types of marketing, both in general and as they relate to this case.

Mr. Orme may be called to testify from a marketing perspective about the nature of the materials involved in the advertising allegations in this case and responses to such documents.

With respect to the direct mailer, Mr. Orme may be called to testify about the lists used to identify potential recipients and their efficacy. He may also testify that the number of intended direct mailer recipients is smaller than EPA alleged in its Complaint.

Mr. Orme may also be called to testify about the process through which companies develop product names, including brand names. Mr. Orme may also discuss factors that influence customer decision making. Mr. Orme may testify about the specific alternate brand

names involved in this case, including among others "Stallion Insecticide" and "Stallion Brand Insecticide."

Mr. Orme may be called to testify about marketing in the pesticide industry in general and by FMC's competitors.

## II. EXHIBITS THAT FMC INTENDS TO INTRODUCE INTO EVIDENCE

FMC intends to introduce the following exhibits. Any overlap between Complainant's and FMC's exhibit lists is noted below.

FMC reserves the right to introduce (i) exhibits Complainant included in its Prehearing Exchange; (ii) additional exhibits to rebut evidence that Complainant presents; and (iii) such other exhibits as may become necessary.

| Exhibit No. | Description | Bates Nos. |
|---|---|---|
| RX 001 | 40 CFR Subpart 152 Subpart I (§§ 152.160 to 152.175) | FMC 000001 – FMC 000008 |
| RX 002 | 40 CFR Part 171 | FMC 000009 – FMC 000025 |
| RX 003 | 7 CFR Part 110 | FMC 000026 – FMC 000036 |
| RX 004 | EPA Pesticide Registration Manual ("Blue Book"), Chapter 7 (Notifications and Minor Formulation Amendments) | FMC 000037 – FMC 000050 |
| RX 005 | EPA Label Review Manual, Chapter 6 (Use Classification) | FMC 000051 – FMC 000055 |
| RX 006 (CX 07) | EPA PR Notice 98-10 | FMC 000056 – FMC 000078 |
| RX 007 (CX 21) | EPA Draft PR Notice 2002-X: False or Misleading Pesticide Product Brand Names | FMC 000079 – FMC 000087 |
| RX 008 | EPA Draft PR Notice 2010-X, False Or Misleading Pesticide Product Brand Names Docket ID EPA-HQ-OPP-2010-0282-0004 | FMC 000088 – FMC 000099 |
| RX 009 (CX 37) | FIFRA Enforcement Response Policy (2009) | FMC 000100 – FMC 000138 |

| Exhibit No. | Description | Bates Nos. |
|---|---|---|
| RX 010 | State Statutes and Regulations Governing RUPs In Relevant Jurisdictions<br><br>Tab A: Idaho<br>Statute: FMC 000140 - FMC 000185<br>Regulations: FMC 000186 - FMC 000356<br>Tab B: Iowa<br>Statute: FMC 000358 - FMC 000410<br>Regulations: FMC 000411 - FMC 000597<br>Tab C: Minnesota<br>Statute: FMC 000599 - FMC 00675<br>Regulations: FMC 000676 - FMC 000683<br>Tab D: Montana<br>Statute: FMC 000685 - FMC 000751<br>Regulations: FMC 000752 - FMC 000904<br>Tab E: Nebraska<br>Statute: FMC 000906 - FMC 000975<br>Regulations: FMC 000976 - FMC 001011<br>Tab F: North Dakota<br>Statute: FMC 001013 - FMC 001055<br>Regulations: FMC 001056 - FMC 001090<br>Tab G: South Dakota<br>Statute: FMC 001092 - FMC 001151<br>Regulations: FMC 001152 - FMC 001216<br>Tab H: Wisconsin<br>Statute: FMC 001218 - FMC 001221<br>Regulations: FMC 001222 - FMC 001324 | FMC 000139 – FMC 001324 |
| RX 011 | Stallion Brand Insecticide Alternate Brand Name Chronology In Context | FMC 001325 – FMC 001327 |
| RX 012 | "Cobra 25 Herbicide" EPA Reg. No. 59639-113 (October 12, 2000) | FMC 001328 – FMC 001346 |
| RX 013 | "Maverick Pro Herbicide" EPA Reg. No. 524-525 (August 2, 2001) | FMC 001347 – FMC 001348 |
| RX 014 | "Mad Dog Plus" EPA Reg. No. 34704-890 (August 14, 2008) | FMC 001349 – FMC 001371 |
| RX 015 | "Colt AS Herbicide" EPA Reg. No. 34704-895 (October 23, 2008) | FMC 001372 – FMC 001380 |
| RX 016 | "Colt + Salvo Herbicide" EPA Reg. No. 34704-1010 (November 28, 2008) | FMC 001381 – FMC 001391 |
| RX 017 | "Colt AS" EPA Reg. No. 34704-1019 (December 18, 2009) | FMC 001392 – FMC 001413 |
| RX 018 | "Cobra Herbicide" EPA Reg. No. 59639-34 (February 5, 2010) | FMC 001414 – FMC 001484 |
| RX 019 | "Wolverine Herbicide" EPA Reg. No. 264-1075 (February 18, 2010) | FMC 001485 – FMC 001497 |
| RX 020 | "Mustang Insecticide" EPA Reg. No. 279-3126 (March 10, 2010) | FMC 001498 – FMC 001523 |
| RX 021 | "Eagle 0.62G" EPA Reg. No. 62719-462 (March 12, 2010) | FMC 001524 – FMC 001522 |
| RX 022 | "Bison" EPA Reg. No. 9779-347 (May 14, 2010) | FMC 001553 – FMC 001571 |
| RX 023 | "Steed Insecticide" (April 15, 2010) | FMC 001572 – FMC 001602 |

| Exhibit No. | Description | Bates Nos. |
|---|---|---|
| RX 024 | "Colt + Sword Herbicide" EPA Reg. No. 34704-1011 (November 24, 2010) | FMC 001603 – FMC 001607 |
| RX 025 | "Python WDG" EPA Reg. No. 62719-277 (December 13, 2010) | FMC 001608 – FMC 001638 |
| RX 026 | "Eagle 0.39G Specialty Fungicide" EPA Reg. No. 62719-461 (December 27, 2010) | FMC 001639 – FMC 001664 |
| RX 027 (CX 09) | Initial Registration Of "F9047-2 EC Insecticide" EPA Reg. No. 279-9545 (January 21, 2011) | FMC 001665 – FMC 001691 |
| RX 028 (CX 10) | FMC Letter To EPA Re Adding Alternate Brand Name "Stallion Insecticide" Under PR Notice 98-10 And Attaching Application For Pesticide, PR Notice 98-10 Certification Statement, One Copy Of Label (January 24, 2011) | FMC 001692 – FMC 001721 |
| RX 029 | "Eagle 20EW" EPA Reg. No. 62719-463 (February 9, 2011) | FMC 001722 – FMC 001747 |
| RX 030 (CX 11 ) | EPA Email To FMC Including Initial Reaction To FMC's PR Notice 98-10 Notification Re "Stallion Insecticide" (April 26, 2011) | FMC 001748 |
| RX 031 (CX 12) | EPA Letter To FMC Stating "Action Requested Does Not Fall Within The Scope of PRN 98-10" (April 28, 2011) | FMC 001749 |
| RX 032 | "Osprey Herbicide" EPA Reg. No. 264-802 (May 4, 2011) | FMC 001750 – FMC 001766 |
| RX 033 | "Parrot 4L" EPA Reg. No. 66222-54 (May 20, 2011) | FMC 001767 – FMC 001797 |
| RX 034 | "Eagle 40WP" EPA Reg. No. 62719-417 (June 24, 2011) | FMC 001798 – FMC 001833 |
| RX 035 | "Blackhawk" EPA Reg. No. 62719-523 (June 30, 2011) | FMC 001834 – FMC 001869 |
| RX 036 | "Maverick Herbicide" EPA Reg. No. 524-500 (July 7, 2011) | FMC 001870 – FMC 001871 |
| RX 037 | "Mustang Maxx Insecticide" EPA Reg. No. 279-3426 (November 30, 2011) | FMC 001872 – FMC 001874 |
| RX 038 (CX 15, letter and Application form only) | FMC Notification To EPA Re Alternate Brand Name "Stallion Insecticide (Not for use on horses)" And Attaching Application, Revised Label, and Copy Of EPA's April 28, 2011 Letter To FMC (March 2, 2012) | FMC 001875 – FMC 001879 |
| RX 039 (CX 17) | EPA Letter To FMC Stating, Among Other Things, That "Stallion Insecticide (Not for use on horses)" Is An Acceptable Alternate Brand Name And Requesting FMC TO Submit Revised Labeling (April 2, 2012) | FMC 001880 – FMC 001881 |
| RX 040 (CX 18, letter without revised labeling) | FMC Letter To EPA Regarding Amendment To Label To Add Alternate Brand Name "Stallion Insecticide (Not for use on horses) (April 13, 2012) | FMC 001882 – FMC 001935 |
| RX 041 (CX 19) | EPA Letter to FMC Approving Amended Label With Alternate Brand Name "Stallion Insecticide (Not for use on horses)" And Enclosing A Stamped Copy of the Label (April 23, 2012) | FMC 001936 – FMC 001961 |
| RX 042 | FMC Letter To EPA Re, Among Other Things, Adding The Alternate Brand Name "Stallion Brand Insecticide" And Attaching Proposed Label (December 20, 2012) | FMC 001962 – FMC 001989 |

| Exhibit No. | Description | Bates Nos. |
|---|---|---|
| RX 043 | EPA Letter To FMC Re Amending Label To, Among Other Things, Add The Alternate Brand Name "Stallion Brand Insecticide" And Attaching Label (December 20, 2012) | FMC 001990 – FMC 002017 |
| RX 044 | "Grizzly® Too Insecticide" EPA Reg. No. 1381-257 (June 23, 2015) | FMC 002018 – FMC 002065 |
| RX 045 | "Lynx EC 1.4" EPA Reg. No. 82074-6 (July 30, 2015) | FMC 002066 – FMC 002083 |
| RX 046 | "Cheetah® Herbicide" EPA Reg. No. 71368-112 (February 2, 2016) | FMC 002084 – FMC 002113 |
| RX 047 | EPA Approval Of F9047-2 EC Insecticide Amendment (EPA Reg. No. 279-9545) (April 26, 2011) | FMC 002114 – FMC 002140 |
| RX 048 | FMC Letter To EPA Re Amended Labeling And Proposed Alternate Brand Name (April 16, 2012) | FMC 002141 – FMC 002143 |
| RX 049 (CX 20) | EPA Letter To FMC Re FMC Stewardship Plan (April 24, 2012) | FMC 002144 |
| RX 050 | EPA Letter Re F9047-2 EC Insecticide Label Changes Under PR Notice 98-10 EPA Reg. No. 279-9545 (July 2, 2014) | FMC 002145 – FMC 002166 |
| RX 051 | FMC Letter To EPA Re Adding Alternate Brand Name "Chariot Insecticide" Under PR Notice 98-10 And Attaching Application For Pesticide, PR Notice 98-10 Certification Statement (September 9, 2011) | FMC 002167 |
| RX 053 | EPA Letter To FMC Stating That Alternate Brand Name "Chariot Insecticide" Is Acceptable (September 26, 2011) | FMC 002195 |
| RX 054 | 2012 Response Rate Report: Performance And Cost Metrics Across Direct Media (Direct Marketing Association 2012) | FMC 002196 – FMC 002250 |
| RX 057 **Contains FMC CBI** | Analysis Showing (1) Majority of Product Produced, Packaged and Labeled After Customary 30-Day Waiting Period And Before EPA Communicated Any Concern About The Alternate Brand Name And (2) Sales Were Made To Not More Than 14 Companies<br><br>Tab A: Spreadsheet Showing Majority Of Product Produced, Packaged and Labeled After Customary 30-Day Waiting Period And Before EPA Communicated Any Concern About Alternate Brand Name<br><br>Tab B: Spreadsheet Showing Relevant Batches Were Produced, Packaged and Labeled Before April 21, 2011<br><br>Tab C: Spreadsheet Showing Sales Were Made To Not More Than 14 Companies From April 29, 2011 Through April 2, 2012 | FMC 002251 – FMC 002260 |
| RX 058 (CX 25 at EPA 0691-0692 [copy]) | Direct Mailer (Farms/Growers) (March 7, 2012) [Physical Object] | FMC 002261 |

| Exhibit No. | Description | Bates Nos. |
|---|---|---|
| RX 059<br>(CX 25 at EPA 0693-0694 [copy]) | Direct Mailer (Retailers) (March 7, 2012) [Physical Object] | FMC 002262 |
| RX 060<br>(CX 25 at EPA 0690) | Stomp Plate | FMC 002263 |
| RX 061<br>**Contains FMC CBI** | Direct Mailer Intended Recipients<br>With Analysis Of Duplicates And Returned Mailers<br><br>Tab A: "Retailer List With Duplicates & Returned Mailers"<br>Key: grey shading = duplicates; blue shading = returned mailers<br>FMC 002265 - FMC 002322<br>Tab B: "Retailer List without Duplicates and Returned Mailers"<br>(FMC 002323 - FMC 002330)<br><br>Tab C: "Grower List With Duplicates And Returned Mailers"<br>Key: grey shading = duplicates; blue shading = returned mailers; yellow = additional duplicates identified after July 21, 2015<br>FMC 002331 - FMC 002513)<br><br>Tab D: "Grower List Without Duplicates And Returned Mailers"<br>FMC 002514 - FMC 002628 | FMC 002264 – FMC 002628 |
| RX 062 | Excerpt From Successful Farming Magazine (Mid-March 2012, Vol. 110, No. 5) | FMC 002629 – FMC 002630 |
| RX 063<br>(CX 31 at EPA 1148, 1 page of this issue) | Progressive Forage Grower (April 1, 2012) | FMC 002631 – FMC 002670 |
| RX 064<br>(CX 31 at EPA 1149, 1 page of this issue) | Progressive Forage Grower (May 15, 2012) | FMC 002671 – FMC 002710 |
| RX 065<br>(CX 31 at EPA 1150, 1 page of this issue) | Progressive Forage Grower (July 1, 2012) | FMC 002711 – FMC 002750 |
| RX 066<br>(CX 32 at EPA 1153, 1 page of this issue) | The Sunflower (March /April 2012) | FMC 002751 – FMC 002778 |
| RX 067<br>(CX 33) | FMC Website Post (September 9, 2012) | FMC 002779 |

| Exhibit No. | Description | Bates Nos. |
|---|---|---|
| RX 068 | Largest Civil and Criminal FIFRA Enforcement Cases And Settlements | FMC 002780 – FMC 002786 |
| RX 069 (CX 24) | EPA Letter To FMC Requesting Information Re FMC-Generated Promotional/Advertising Materials For "Stallion Insecticide" And Sales Records Of Same From January 21, 2011 Through Date Of Letter (June 6, 2013) | FMC 002787 – FMC 002790 |
| RX 070 (CX 25) | FMC's Response To EPA's June 6 Request For Information (July 18, 2013) (documents enclosed on CD not included) | FMC 002791 – FMC 002792 |
| RX 071 (CX 26) | EPA Letter To FMC Providing Opportunity To Show Cause (May 7, 2014) | FMC 002793 – FMC 002797 |
| RX 072 (CX 27) | FMC's Response To EPA's May 7, 2014, Request For Information (July 15, 2014) | FMC 002798 – FMC 002800 |
| RX 073 | Beveridge & Diamond Email To EPA Following Up On August 5, 2014, Telephone Conference And Providing Additional Requested Information (August 19, 2014) | FMC 002801 – FMC 002803 |
| RX 074 CX 28) | EPA Letter To FMC Re FIFRA Request For Information (June 23, 2015) | FMC 002804 – FMC 002807 |
| RX 075 (CX 29) **Contains FMC CBI** | FMC's Response To EPA's June 23, 2015, Request For Information (July 21, 2015) (not including attachments) | FMC 002808 – FMC 002810 |
| RX 076 **Contains FMC CBI** | Beveridge & Diamond Email To EPA Re Direct Mailer Return Information (March 3, 2016) (not including attachment; returned mailers are identified in RX 061, Tabs A and C) | FMC 002811 |
| RX 077 | Dale Burnett Curriculum Vitae | FMC 002812 – FMC 002814 |
| RX 078 | Debra F. Edwards, Ph.D. Curriculum Vitae | FMC 002815 – FMC 002820 |
| RX 079 | George Orme Curriculum Vitae | FMC 002821 – FMC 002823 |

## III. TIME NEEDED FOR HEARING AND TRANSLATION SERVICE NEEDS

FMC estimates that it will need four days to present its direct case. FMC does not require translation services for any of its witnesses.

## IV. DOCUMENTARY SUPPORT FOR DENIALS IN FMC'S ANSWER

In accordance with Section 3(A) of the Prehearing Exchange, FMC intends to introduce the following exhibits in support of FMC's denials in its Answer.

FMC intends to introduce Respondent's Exhibits RX 006 (CX 07) and RX 28 (CX 10) in support of FMC's denials in paragraphs 11 and 77, in which FMC asserts that on January 24, 2011, it submitted a notification under EPA's October 22, 1998, *Pesticide Registration (PR) 98-10: Notifications, Non-Notifications and Minor Formulation Amendments* ("PRN 98-10") notifying EPA that it would be adding "Stallion Insecticide" as an alternate brand name for *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545.

FMC initially denied in part paragraph 12, in which Complainant asserted that on or after January 24, 2011 Respondent began referring to *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545 as *Stallion*™ *Insecticide*, *Stallion*® *Insecticide*, *Stallion Insecticide* and/or *Stallion* in advertising. FMC asserted that the date was too early. In Complainant's subsequent Prehearing Exchange, it indicated the date is February 10, 2011, and FMC does not deny that date.

FMC intends to introduce Respondent's Exhibits RX 058 and RX 060 (CX 25 at EPA 0690) in support of FMC's partial denials in paragraphs 22, 25, 26 and its denial in paragraph 28, in which FMC asserts that it took a single action to cause a single direct mailer to be sent. FMC also asserts the single direct mailer instructed the intended recipient to "always read and follow label directions" and the product label contained the RUP phrase and detailed directions.

FMC intends to introduce Respondent's Exhibits RX 059 and RX 060 (CX 25 at EPA 0690) in support of FMC's partial denials in paragraphs 32, 35, 36 and its denial in paragraph 38, in which FMC asserts that it took a single action to cause a single direct mailer to be sent. FMC also asserts the single direct mailer instructed the intended recipient to "always read and follow label directions" and the product label contained the RUP phrase and detailed directions.

FMC intends to introduce Respondent's Exhibit RX 060 (CX 25 at EPA 0690) in support of FMC's partial denials in paragraphs 41, 44, and 45, in which FMC asserts it took a single action to cause a document to appear in *Progressive Forage Grower* magazine. FMC also asserts the document instructed the potential reader to "always read and follow label directions" and the product label contained the RUP phrase and detailed directions.

FMC initially denied in part paragraph 65, in which Complainant asserted that Respondent caused an article about *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545 to be posted on the PRWeb online news distribution and publicity website. FMC asserted that the date was too early. In its subsequent Prehearing Exchange, Complainant indicated the date is February 10, 2011. FMC does not deny that date.

FMC intends to introduce Respondent's Exhibit RX 006 (CX 07) and RX 38 (CX 15) in support of FMC's denial in paragraphs 81, in which FMC asserts it added the alternate brand name "Stallion Insecticide (not for use on horses)" for *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545 by submitting a notification under Pesticide Registration Notice 98-10.

FMC initially denied paragraph 82 because it could not locate EPA's March 19, 2012 letter. Complainant produced the letter as CX 16.

FMC intends to introduce Respondent's Exhibit RX 057 in support of FMC's partial denial in paragraph 87, in which FMC asserts that from April 29, 2011, through April 2, 2012, it sold *F9047-2 EC Insecticide*, EPA Reg. No. 279-9545 to no more than 14 companies.

## V. SUPPORT FOR FMC'S DEFENSES

### A. The Design "Plate" At Issue Was Intended To Raise Brand Awareness And Neither It Nor the Website Postings Rise To The Level Of Advertising Under FIFRA

At issue in virtually all the advertising allegations is a single design "plate" showing a horseshoe imprint on soil accompanied by the statement "stomp more" insects, which was

developed to raise brand awareness for the product at issue (the "Stomp Plate"). It did not include detailed information on price or any specific offer for sale, nor did it provide any inducements to purchase the product or any way to purchase the product. FIFRA itself contains no definition of advertisement or advertising, nor do EPA's general regulations implementing FIFRA. The general litany of modes of communicating in EPA's RUP regulations similarly contains little information and is so broad as to cover virtually any type of communication.

Under these circumstances and given the overall context here, FMC disagrees that the use of this design plate should be considered advertising under FIFRA. For the same reasons discussed above, FMC also disagrees that the two website documents should be considered advertising. FMC will provide expert testimony to support this defense.

B. Respondent Constructively Met The Requirement To Include RUP Language On Communications At Issue In The Advertising Allegations

Even if use of the Stomp Plate and the website postings are considered advertising under FIFRA, FMC constructively met the requirement to include a statement of the terms of restriction in accordance with FIFRA § 12(a)(2)(E) and 40 C.F.R. § 152.168. All of the communications included language directing the potential audience to "always read and follow label directions" and the actual product labels included the statement "Restricted Use Pesticide" and detailed directions. Even if the Tribunal finds that the Stomp Plate and website postings violated FIFRA or its implementing regulations, FMC asserts that Complainant's proposed approach to counting the unit of violation is arbitrary and capricious. *See infra* § V(D).

C. Complainant's Allegations That Respondent's Product Was Misbranded Are Arbitrary and Capricious

Despite approving a functionally equivalent alternate brand name for this product and similar names for other products, EPA claims that Respondent's product was misbranded. EPA's interpretation is at odds with its own guidance. *See* RX 007 (CX 21) and RX 008. EPA has not carried its burden to demonstrate that FMC's initially proposed alternate brand name of "Stallion Insecticide" was false and misleading compared to the subsequently approved alternate brand name of "Stallion Brand Insecticide." Moreover, EPA previously approved and has maintained approvals for numerous pesticide product brand names that refer to animals, including horses, which are not for use on such animals. *See* RX 012 to 026, RX 029, RX 032 to 037, and RX 044 to 046. As FMC will explain through fact and expert testimony, FMC does not directly sell any products into the separate veterinary marketplace that deals in products for use on animals and the distribution channels for agricultural products and veterinary products are separate. The Agency's allegation is further undermined by EPA's own action in approving "Stallion Brand Insecticide" as an alternate brand name after it rejected "Stallion Insecticide." *See* RX 043.

If the Tribunal agrees with FMC that the name was not false and misleading, there should be no penalty. To the extent that there was any violation, the Complaint's proposed number of violations would lead to a civil penalty that is disproportionate to the actual gravity of the alleged violations. No harm to any non-target animal (or any person or the environment) resulted from any sale or distribution of product with the "Stallion Insecticide" name.

Complainant also fails to take into account that: (1) to the extent the proposed alternate brand name is considered to have been misleading, no more than 14 companies could have been "misled," as they were the only companies that bought the product from FMC during the

period identified by EPA; and (2) because of Complainant's delay beyond the customary 30-day period in responding to FMC's alternate brand name notification, Respondent had already produced, packaged and labeled the majority of the product that Complainant now alleges was misbranded before EPA communicated any concern about the alternate brand name to FMC. *See* RX 057.

D. Complainant's Interpretation Of The Proposed Number Of Alleged Violations Is Arbitrary And Capricious And Not In Accordance With Law

Complainant's interpretation of the proposed number of violations in this case is internally inconsistent, unreasonable, arbitrary and capricious, and not in accordance with law. Not only does Complainant's proposed number of violations disregard FIFRA's mandate to consider the appropriateness of a penalty based on the "gravity of the violation" (7 U.S.C. § 136l(a)(4)), it also ignores the explicit goal of EPA's FIFRA ERP to be fair as between members of the regulated community, who in the agricultural pesticide industry in particular are in direct competition with one another. To the extent Complainant is relying on the FIFRA ERP as the basis for its number of proposed violations, Complainant's interpretation and application of this non-binding policy statement is arbitrary and capricious and would lead to a penalty that is unreasonable and inconsistent with FIFRA and its implementing regulations.

The advertising allegations in this matter largely involve a single design plate that FMC authorized for use in two print documents (one was included in periodicals and the other was included in mailers), and two website posts. Nevertheless, Complainant alleges 12,273 separate acts of advertising based on Respondent's alleged failure to include on the Stomp Plate the statement "Restricted Use Pesticide," even though the design plate included the instruction "always read and follow label directions" and the actual product labels included the statement "Restricted Use Pesticide" and detailed directions as required. The extrapolation

from a single design plate, that did not lead to any harm to any person, non-target animal, or the environment, to over 12,000 separate violations is plainly unfair and would lead to an excessive and unjustified penalty.

As a result of the mailer allegations alone, Complainant proposes 12,267 separate violations. First, there is no evidence that the mailer was actually received or read by any of the intended recipients. FMC will provide expert testimony and documentary evidence about the efficacy of such mailers. *See* RX 054. Nor is there any evidence that any intended recipient who was not a certified applicator actually attempted to purchase the product as a result of the mailer. In any event, a noncertified applicator would not have been able to purchase the product. FIFRA § 12(a)(2)(F) prohibits the sale of an RUP to a noncertified applicator and there are robust procedures in place to prevent such sales. FMC will provide expert testimony on these procedures, supported by federal and state laws. EPA's proposed number of violations for the mailer fails to take into account the regulatory controls that apply to the use, sale and distribution of RUPs, which dramatically reduce the potential for harm to human health or the environment.

Complainant's assessment of the alleged advertising violations is also internally inconsistent and arbitrary and capricious. Complainant alleges one violation for Respondent's decision to "cause[] a testimonial sell sheet . . . to be posted on Respondent's website on the product's webpage in January 2012" but alleges 9,545 separate violations for Respondent's decision to "cause[] direct mailers . . . to be sent to individuals associated with various agricultural farms." Complaint ¶¶ 22, 49. On the one hand, Complainant assesses the unit of violation based on Respondent's decision, *i.e.*, to "cause" the testimonial sell sheet to be posted to its website. On the other hand, however, Complainant proposes to count the unit of

violation not based on Respondent's decision to cause the document to be printed, but instead, based on the number of intended recipients. The more reasonable and appropriate approach between these two approaches is to assess the unit of violation based on Respondent's decision. Even more appropriate would be a single violation tied to the single design plate that excluded the language that appeared in magazines and mailers. In any event, assessing the unit of violation in this case based on intended recipients of mailers would lead to an excessive and unwarranted penalty.

In summary: (i) Complainant's proposed number of advertising violations would lead to a civil penalty that is disproportionate to the actual gravity of the alleged violations and therefore at odds with FIFRA; (ii) no harm to any person, any non-target animal or the environment resulted from any use of the Stomp Plate or other communications; (iii) all communications directed potential readers to "always read and follow label directions," and the labels made clear that the product was an RUP and provided detailed directions for use; and (iv) any penalty should take into account the fairness of the amount vis-à-vis other members of the regulated community of pesticide company competitors.

### E. Complainant's Assessment Of Alleged Violations Is Flawed, Not Supported By Law Or Fact, And Arbitrary And Capricious

Complainant's approach to assessing the alleged violations is inconsistent with EPA's enforcement of FIFRA, without precedent, legally unsupportable, and unreasonable in light of the facts of this case. Complainant's proposed number of advertising violations also is based in part on a misstatement of the factual record. *See* RX 061. EPA has alleged misbranding without taking into account the timing of its response to FMC's notification and its own actions approving similar animal names, which as an equitable matter should preclude action against FMC here. *See* RX 4, RX 012 to 026, RX 029, RX 032 to 037, and RX 044 to 046.

F. Complainant's Interpretation Of Applicable Statutory And Regulatory Provisions Infringes On FMC's Right To Commercial Free Speech Under The First Amendment To The U.S. Constitution

Complainant's incorrect interpretation of FIFRA and its implementing regulations with respect to FMC's selection of "Stallion Insecticide" as an alternate brand name for its product, impermissibly infringes on FMC's right to commercial free speech under the First Amendment. The Supreme Court has explicitly held that the First Amendment protects commercial speech. *See, e.g.*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 561 (1980) ("The First Amendment, as applied to the States through the Fourteenth Amendment, protects commercial speech from unwarranted governmental regulation.").

Respondent's choice of the alternate brand name here was an informed and strategic decision. It should be afforded the protection that the First Amendment guarantees to commercial speech. Complainant lacks knowledge or expertise about branding and marketing and has not justified its arbitrary and capricious decision to curtail FMC's constitutionally protected right to commercial speech in its choice of "Stallion Insecticide" as an alternate brand name. Just as Complainant authorized FMC to use "Mustang Insecticide" (*see* RX 020) as an alternate brand name for a different RUP and other similar names for pesticides that are not registered for use on horses or other animals, it should have allowed FMC to use "Stallion Insecticide" here.

## VI. FMC'S STATEMENT ON PENALTY ASSESSMENT AND EXPLANATION WHY THE PROPOSED PENALTY SHOULD BE ELIMINATED OR REDUCED

A. If The Presiding Officer Determines There Was Non-Compliance In Any Aspect of This Matter The Penalty Should Be Proportionate To The Gravity Of The Matter And Should Take Into Account The Broader Context Of EPA's Enforcement of FIFRA

Complainant has not yet proposed a specific penalty in this matter. *See* 40 C.F.R. § 22.19(a)(4). Complainant bears the burdens of "presentation and persuasion" to show that

the relief it seeks is "appropriate." 40 C.F.R. § 22.27(a). If Complainant were to propose a civil penalty based on the alleged number of violations in the Complaint, the penalty would be orders of magnitude greater than any penalty in the history of FIFRA. To the extent the Presiding Officer determines FMC did not comply with FIFRA, the Presiding Officer should identify a penalty that is proportionate to the gravity of this matter in the broader civil and criminal FIFRA enforcement context.

Assessment of administrative penalties is governed by the Rules of Practice. 40 C.F.R. Part 22. Under those Rules, if the Presiding Officer determines that a violation has occurred and a civil penalty is sought, the Presiding Officer must "determine the amount of the recommended civil penalty based on the evidence in the record and in accordance with any penalty criteria set forth in the Act" (in this case, FIFRA). 40 C.F.R. § 22.27(b). The Presiding Officer must also consider "any civil penalty guidelines issued" under FIFRA. *Id.*

FIFRA requires that the Presiding Officer consider the "appropriateness" of the "penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation." 7 U.S.C. § 136l(a)(4). FIFRA also authorizes EPA to issue a warning, in lieu of a penalty, upon finding that the violation did not cause significant harm to health or the environment. *Id.*

With regard to the civil penalty guidelines, the Rules of Practice direct the Presiding Officer to consider EPA's *FIFRA Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act* (Dec. 2009) ("FIFRA ERP"), although it is "a non-binding agency policy whose application is open to attack" in every proceeding. *In re McLaughlin Gormley King Co.*, 6 E.A.D. 339, 1996 WL 107270 *6 (EAB 1996). Such attacks are so common because "a penalty calculated according to the ERP can be excessive." *In re: 99*

*Cents Only Stores*, Docket No. FIFRA-09-2008-0027, 2010 WL 2787749 at *40 (ALJ June 24, 2010). The Presiding Officer should therefore ensure any "penalty is appropriate in relation to the facts and circumstances of the case at hand." *In re FRM Chem, Inc.*, 12 E.A.D. 739, 2006 WL 1806982 *9 (EAB 2006). Such an approach is consistent with the stated "goal" of the FIFRA ERP "to provide fair and equitable treatment of the regulated community . . . and comparable penalty assessments for comparable violations." FIFRA ERP at 4. Thus, to the extent a penalty is assessed here, Respondent respectfully submits that it should be informed by the totality of the evidence, including the context of FIFRA enforcement matters.

This Tribunal has made clear that significant FIFRA penalties must be "reserved for the most horrific violator, who has committed the most horrific violations such as a respondent with a long history of committing serious FIFRA violations, who then commits other egregious violations, which were knowing and willful, involving a pesticide of the highest toxicity, and/or which caused *actual* serious or widespread harm to human health and the environment." *In re: Rhee Bros., Inc.*, Docket No. FIFRA-03-2005-0028, 2006 WL 2847398 *27 (ALJ Sept. 19, 2006) (emphasis in original).

This case does not warrant such a penalty. To FMC's knowledge, neither the "Stomp Plate," two website postings, nor the allegedly misbranded label resulted in any harm to any person, non-target animal or the environment. There is no evidence to suggest otherwise. Moreover, FMC took corrective actions promptly upon learning of the alleged violations.

In summary, if Complainant were to propose a civil penalty based on the alleged number of violations in the Complaint, the proposed penalty would be excessive, unreasonable, and disproportionate to the totality of the circumstances and the gravity of the alleged violations. Such a penalty would also run afoul of the Eighth Amendment to the U.S.

Constitution, which prohibits the imposition of "excessive fines." *See, e.g., United States v. Bajakajian*, 524 U.S. 321, 334 (1998) ("The touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the [fine] must bear some relationship to the gravity of the offense that it is designed to punish.").

FMC plans to support the above through factual testimony about the underlying facts in this matter and expert testimony putting those facts into context, including a discussion of FIFRA, and EPA's enforcement actions under FIFRA, including the matters in RX 068 and the broader context of FIFRA enforcement generally.

## VII. RESPONDENT'S RESERVATION OF RIGHTS

FMC respectfully reserves the right to supplement this Prehearing Exchange upon reasonable notice to the Presiding Officer and the Complainant. Depending on Complainant's proposed penalty, FMC reserves the right to address the financial impact of the penalty.

Dated: July 8, 2016

Respectfully Submitted,

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