

procedures and tests identified as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(3) *Contacting the Manufacturer:* As of the effective date of this AD, except as specified in paragraph (j) of this AD for the use of an alternative method to check the PFR for CFDS messages, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(4) *Previously Approved AMOCs:* AMOCs approved previously for the AD 2011-13-11 and AD 2013-16-09 are approved as AMOCs for the corresponding provisions of this AD.

#### (cc) Special Flight Permits

Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the airplane can be modified (if the operator elects to do so), provided the MLG remains extended and locked, and that no MLG recycle is done.

#### (dd) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014-0221, dated September 30, 2014, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov/#!documentDetail;D=FAA-2014-0529-0003>.

(2) For Airbus service information identified in this AD, contact Airbus, Airworthiness Office—ELAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email [account.airworth-eas@airbus.com](mailto:account.airworth-eas@airbus.com); Internet <http://www.airbus.com>.

(3) For General Electric service information identified in this AD, contact GE Aviation, Customer Support Center, 1 Neumann Way, Cincinnati, OH 45215; phone: 513-552-3272; email: [cs.techpubs@ge.com](mailto:cs.techpubs@ge.com); Internet: <http://www.geaviation.com>.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on August 21, 2015.

**Kevin Hull,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## COMMODITY FUTURES TRADING COMMISSION

### 17 CFR Part 23

RIN 3038-AE17

#### Proposal To Amend the Definition of “Material Terms” for Purposes of Swap Portfolio Reconciliation

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Commodity Futures Trading Commission (“Commission” or “CFTC”) proposes to amend a provision of the Commission’s regulations in connection with the material terms for which counterparties must resolve discrepancies when engaging in portfolio reconciliation.

**DATES:** Comments must be received on or before November 23, 2015.

**ADDRESSES:** You may submit comments, identified by RIN 3038-AE17, and Proposal to Amend the Definition of “Material Terms” for Purposes of Swap Portfolio Reconciliation by any of the following methods:

- The agency’s Web site, at <http://comments.cftc.gov>. Follow the instructions for submitting comments through the Web site.

- Mail: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

- *Hand Delivery/Courier:* Same as Mail above.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission’s regulations.<sup>1</sup>

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission

<sup>1</sup> 17 CFR 145.9. Commission regulations referred to herein are found at 17 CFR Chapter I.

from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

#### FOR FURTHER INFORMATION CONTACT:

Frank N. Fisanich, Chief Counsel, 202-418-5949, [ffisanich@cftc.gov](mailto:ffisanich@cftc.gov); Katherine S. Driscoll, Associate Chief Counsel, 202-418-5544, [kdriscoll@cftc.gov](mailto:kdriscoll@cftc.gov); Gregory Scopino, Special Counsel, 202-418-5175, [gscopino@cftc.gov](mailto:gscopino@cftc.gov), Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On September 11, 2012, the Commission published in the **Federal Register** final rules § 23.500 through § 23.505<sup>2</sup> establishing requirements for the timely and accurate confirmation of swaps, the reconciliation and compression of swap portfolios, and documentation of swap trading relationships between swap dealers (“SDs”),<sup>3</sup> major swap participants (“MSPs”),<sup>4</sup> and their counterparties. These regulations were promulgated by the Commission pursuant to the authority granted under Sections 4s(h)(1)(D), 4s(h)(3)(D), and 4s(i) of the Commodity Exchange Act (the “CEA”),<sup>5</sup>

<sup>2</sup> Confirmation, Portfolio Reconciliation, Portfolio Compression, and Swap Trading Relationship Documentation Requirements for Swap Dealers and Major Swap Participants, 77 FR 55904 (Sept. 11, 2012) (hereinafter, “Portfolio Reconciliation Final Rule”).

<sup>3</sup> Generally, an SD is any person who, in addition to transacting in a notional amount of swaps in excess of specified de minimis thresholds, holds itself out as a dealer in swaps, makes a market in swaps, regularly enters into swaps with counterparties as an ordinary course of business for its own account, or engages in any activity causing it to be commonly known in the trade as a dealer or market maker in swaps. See 7 U.S.C. 1a(49); 17 CFR 1.3(ggg).

<sup>4</sup> Generally, an MSP is any non-dealer that maintains a substantial position in swaps for any of the specified major swap categories, whose outstanding swaps create substantial counterparty exposure that could have serious adverse effects on the financial stability of the United States banking system or financial markets, or any financial entity that is highly leveraged relative to the amount of capital such entity holds and that is not subject to capital requirements established by an appropriate Federal banking agency and maintains a substantial position in outstanding swaps in any major swap category. See 7 U.S.C. 1a(33); 17 CFR 1.3(hhh).

<sup>5</sup> 7 U.S.C. 6s(h)(1)(D), 6s(h)(3)(D) and 6s(i).

as amended by Section 731 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”),<sup>6</sup> which, among other things, directed the Commission to prescribe regulations for the timely and accurate confirmation, processing, netting, documentation and valuation of all swaps entered into by SDs and MSPs,<sup>7</sup> and the Commission’s general rulemaking authority under Section 8a(5) of the CEA.<sup>8</sup>

Under § 23.502,<sup>9</sup> SDs and MSPs must reconcile their swap portfolios with one another and provide non-SD and non-MSP counterparties with regular opportunities for portfolio reconciliation.<sup>10</sup> Section 23.500(i)<sup>11</sup> defines the term, “portfolio reconciliation,” as “any process by which the two parties to one or more swaps: (1) Exchange the terms of all swaps in the swap portfolio between the counterparties; (2) exchange each counterparty’s valuation of each swap in the swap portfolio between the counterparties as of the close of business on the immediately preceding business day; and (3) resolve any discrepancy in material terms and valuations.” Section 23.500(g) defines “material terms” to mean “all terms of a swap required to be reported in accordance with part 45 of this chapter.”<sup>12</sup> Thus, portfolio reconciliation seeks to enable “the swap market to operate efficiently and to reduce systemic risk”<sup>13</sup> by requiring

counterparties periodically to (1) exchange the terms of their mutual swaps, and (2) locate and resolve discrepancies in material terms of mutual swaps. In particular, the Commission recognized that “portfolio reconciliation [would] facilitate the identification and resolution of discrepancies between the counterparties with regard to valuations of collateral held as margin.”<sup>14</sup> The Commission also has described portfolio reconciliation, generally, as follows:

Portfolio reconciliation is a post-execution processing and risk management technique that is designed to (i) identify and resolve discrepancies between the counterparties with regard to the terms of a swap either immediately after execution or during the life of the swap; (ii) ensure effective confirmation of terms of the swap; and (iii) identify and resolve discrepancies between the counterparties regarding the valuation of the swap.<sup>15</sup>

In adopting § 23.502, the Commission intended to require that SDs, MSPs, and their counterparties engage in portfolio reconciliation at regular intervals. Explaining the rationale for § 23.502, the Commission noted that portfolio reconciliation can identify and reduce overall risk “[b]y identifying and managing mismatches in key economic terms and valuation for individual transactions across an entire portfolio.”<sup>16</sup> Portfolio reconciliation is not required for cleared swaps where a derivatives clearing organization (“DCO”) holds the definitive record of the trades and determines binding daily valuations for the swaps.<sup>17</sup>

## II. Proposed Regulation

In 2013, the International Swaps and Derivatives Association, Inc. (“ISDA”) requested interpretive guidance from Commission staff that would permit certain swap data elements to be excluded from portfolio reconciliation as required under § 23.502.<sup>18</sup> Specifically, ISDA requested that “the terms” of a swap that counterparties must exchange during portfolio reconciliation exercises be limited to the “material terms” of a swap, and that

“material terms” have the same meaning as “primary economic terms” in § 45.1. ISDA further asked that the following data fields (hereinafter referred to as the “No-Action Excluded Data Fields”) be excluded from the definition of “material terms” for purposes of compliance with § 23.502:

1. An indication that the swap will be allocated;
2. If the swap will be allocated, or is a post-allocation swap, the legal entity identifier<sup>19</sup> of the agent;
3. An indication that the swap is a post-allocation swap;
4. If the swap is a post-allocation swap, the unique swap identifier;<sup>20</sup>
5. Block trade indicator;
6. Execution timestamp;
7. Timestamp for submission to swap data repository (“SDR”);<sup>21</sup>
8. Clearing indicator;
9. Clearing venue;
10. If the swap will not be cleared, an indication of whether the clearing requirement exception in CEA Section 2(h)(7)<sup>22</sup> has been elected; and
11. The identity of the counterparty electing the clearing requirement exception in CEA Section 2(h)(7).<sup>23</sup>

ISDA contended generally that the definition of “material terms” in § 23.500(g) is too broad to guide market participants in the construction of a reconciliation process, and with regard to the No-Action Excluded Data Fields specifically, ISDA argued that these fields are not relevant to the portfolio reconciliation process because they pertain to the circumstances

<sup>6</sup> Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (July 21, 2010).

<sup>7</sup> Portfolio Reconciliation Final Rule, 77 FR at 55926 (“[P]ortfolio reconciliation involves both confirmation and valuation and serves as a mechanism to ensure accurate documentation.”).

<sup>8</sup> 7 U.S.C. 12a(5).

<sup>9</sup> 17 CFR 23.502.

<sup>10</sup> 17 CFR 23.502; see Portfolio Reconciliation Final Rule, 77 FR at 55926.

<sup>11</sup> 17 CFR 23.500(i).

<sup>12</sup> 17 CFR 23.500(g). Part 45 of the Commission regulations govern swap data recordkeeping and reporting requirements. The swap terms that must be reported under part 45 are found in appendix 1 to part 45. See 17 CFR part 45, App. 1; see also 17 CFR 45.1 (defining “primary economic terms” as “all of the terms of a swap matched or affirmed by the counterparties in verifying the swap,” including “at a minimum each of the terms included in the most recent **Federal Register** release by the Commission listing minimum primary economic terms for swaps in the swap asset class in question” and stating that the current list of minimum primary economic terms is in appendix 1); Swap Data Recordkeeping and Reporting Requirements, 77 FR 2197 (Jan. 13, 2012) (promulgating the list of primary economic terms). Examples of primary economic terms include the price of the swap, payment frequency, type of contract (e.g., a “vanilla option” or “complex exotic option”), execution timestamp, and, if the swap is a multi-asset class swap, the primary and secondary asset classes. 17 CFR part 45, App. 1.

<sup>13</sup> Portfolio Reconciliation Final Rule, 77 FR at 55926.

<sup>14</sup> *Id.* In response to comments that industry practice was only to resolve swap terms that lead to material collateral disputes, the Commission, in promulgating the final § 23.502, emphasized the importance of both (1) resolving disputes related to the material terms of swaps and (2) resolving valuation disputes impacting margin payments. *Id.* at 55926–27, 55929–31.

<sup>15</sup> Portfolio Reconciliation Final Rule, 77 FR at 55926.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.* at 55927.

<sup>18</sup> See CFTC Staff Letter No. 13–31 (June 26, 2013), available at <http://www.cftc.gov/ucm/groups/public/@lrllettergeneral/documents/letter/13-31.pdf>.

<sup>19</sup> A legal entity identifier is “a 20-digit, alphanumeric code, to uniquely identify legally distinct entities that engage in financial transactions.” See Legal Entity Identifier Regulatory Oversight Committee, <http://www.leiroc.org/>; 17 CFR 45.6.

<sup>20</sup> A unique swap identifier is a unique identifier assigned to all swap transactions which identifies the transaction (the swap and its counterparties) uniquely throughout the duration of the swap’s existence. See 17 CFR 45.5.

<sup>21</sup> A swap data repository is any person that collects and maintains information or records with respect to transactions or positions in, or the terms and conditions of, swaps entered into by third parties for the purpose of providing a centralized recordkeeping facility for swaps. 7 U.S.C. 1a(48); 17 CFR 1.3(qqqq).

<sup>22</sup> Generally speaking, Section 2(h)(1)(A) of the CEA establishes a clearing requirement for swaps, providing that “[i]t shall be unlawful for any person to engage in a swap unless that person submits such swap for clearing to a derivatives clearing organization that is registered under [the CEA] or a derivatives clearing organization that is exempt from registration under [the CEA] if the swap is required to be cleared.” 7 U.S.C. 2(h)(1)(A). CEA Section 2(h)(7), however, provides for several limited exceptions to the clearing requirement of Section 2(h)(1)(A). *Id.* at 2(h)(7); see also End-User Exception to the Clearing Requirement for Swaps, 77 FR 42560, 42560–61 (July 19, 2012).

<sup>23</sup> CFTC Staff Letter No. 13–31 at 2–3.

surrounding entry into a transaction, and whether a transaction was intended to be cleared, and are not relevant to ongoing rights and obligations under swaps in a swap portfolio existing bilaterally between an SD and a counterparty.

After considering ISDA's request, the Commission's Division of Swap Dealer and Intermediary Oversight (the "Division") provided SDs and MSPs with no-action relief on June 26, 2013, pursuant to CFTC Staff Letter 13-31.<sup>24</sup> In such letter, the Division chose not to interpret the reference to "the terms" of a swap in § 23.500(i)(1) as meaning the "material terms" or to define "material terms" to mean the "primary economic terms" of a swap minus the No-Action Excluded Data Fields. Rather, the Division merely stated that it would not recommend an enforcement action against an SD or MSP that omits the No-Action Excluded Data Fields from the portfolio reconciliation process required under § 23.502.<sup>25</sup> Thus, it appears that following the issuance of CFTC Staff Letter 13-31, an SD that chose to take advantage of the relief could consider the No-Action Excluded Data Fields not to be terms of a swap required to be exchanged with a counterparty in a portfolio reconciliation exercise.

Against this background, the Commission is now proposing to amend the definition of "material terms" in § 23.500(g) to specifically exclude a modified version of the No-Action Excluded Data Fields. As amended, § 23.500(g) would exclude the following data fields from the definition of "material terms" (hereinafter referred to as the "Proposed Excluded Data Fields"):

1. An indication that the swap will be allocated;
2. If the swap will be allocated, or is a post-allocation swap, the legal entity identifier<sup>26</sup> of the agent;
3. An indication that the swap is a post-allocation swap;
4. If the swap is a post-allocation swap, the unique swap identifier;<sup>27</sup>
5. Block trade indicator;
6. With respect to a cleared swap, the execution timestamp;
7. With respect to a cleared swap, the timestamp for submission to SDR;

8. Clearing indicator; and

9. Clearing venue.

The Proposed Excluded Data Fields modify the No-Action Excluded Data Fields by: (1) Amending the execution timestamp data field to be specific to cleared swaps; (2) amending the timestamp for submission to an SDR data field to be specific to cleared swaps; (3) removing the data field containing an indication of whether the clearing requirement exception in CEA Section 2(h)(7) has been elected with respect to an uncleared swap; and (4) removing the data field containing the identity of the counterparty electing the clearing requirement exception in CEA Section 2(h)(7). The Commission is proposing to retain these data fields for uncleared swaps as "material terms" because a discrepancy in this information in the records of the counterparties could mean that the related information is erroneous in the records of an SDR, which could have an impact on the Commission's regulatory mission.

The time of execution of an uncleared swap and the time of submission to an SDR is of regulatory value to the Commission for purposes of determining the compliance of SDs and MSPs with Commission regulations.<sup>28</sup> Similarly, the identity of a counterparty electing the end-user exception to clearing is important to the Commission's enforcement of the clearing requirement and its monitoring of systemic risk in the OTC markets under its jurisdiction. Thus, the Commission believes it is reasonable to require SDs, MSPs, and their counterparties to resolve any discrepancy in these data fields and, if necessary, correct the information reported to an SDR.<sup>29</sup>

The Commission intends that, if and when the proposed amendment to the definition of "material terms" is adopted, it will direct the Division to withdraw the no-action relief provided pursuant to CFTC Letter 13-31. Accordingly, under this proposal, the Commission is maintaining the status quo of § 23.502 in that SDs and MSPs and their counterparties would be required to exchange "the terms" of a swap as required under § 23.500(i)(1)

and would have to resolve discrepancies in "material terms" of swaps pursuant to § 23.502(a)(4) and (b)(4). However, "material terms" would not include the Proposed Excluded Data Fields. This requirement differs from what may be the current practice of SDs and MSPs that have chosen to take advantage of the relief provided in CFTC Staff Letter 13-31. Such SDs and MSPs may be omitting the No-Action Excluded Data Fields from the portfolio reconciliation process altogether and not exchanging such terms at all, or if exchanging them, choosing not to resolve discrepancies that may be discovered. If the Commission's proposal is adopted, such SDs and MSPs would be required to resume exchanging the terms included in the Proposed Excluded Data Fields, although they could continue the practice of choosing not to resolve discrepancies in such terms. In addition, SDs and MSPs would have to resolve discrepancies in execution and SDR submission timestamps for cleared swaps, and discrepancies in the identities of counterparties electing the end-user exception from clearing, which may not be the practice for SDs and MSPs that have been relying on CFTC Staff Letter 13-31.

It is the intention of the Commission's proposal to alleviate the burden of resolving discrepancies in terms of a swap that are not relevant to the ongoing rights and obligations of the parties and the valuation of the swap, or to the Commission's regulatory mission. However, with respect to at least some of the No-Action Excluded Data Fields and the corresponding information that is included in the Proposed Excluded Data Fields, the Commission questions whether such data is actually required to be included in any ongoing portfolio reconciliation exercise. For example, the "clearing indicator" and "clearing venue" items included in the Proposed Excluded Data Fields pertain to a swap only until it is extinguished when accepted for clearing by a DCO.<sup>30</sup> When extinguished, the original swap would no longer be subject to portfolio reconciliation,<sup>31</sup> and, as explained

<sup>30</sup> See 17 CFR 23.504(b)(6) (" . . . upon acceptance of a swap by a derivatives clearing organization: (i) The original swap is extinguished; (ii) The original swap is replaced by equal and opposite swaps with the derivatives clearing organization; and (iii) All terms of the swap shall conform to the product specifications of the cleared swap established under the derivative clearing organization's rules.").

<sup>31</sup> The Commission notes that portfolio reconciliation only applies to swaps currently in effect between an SD or MSP and a particular counterparty, not to expired or terminated swaps. See Definition of "swap portfolio," 17 CFR 23.500(k).

<sup>24</sup> See *id.*

<sup>25</sup> *Id.* at 3.

<sup>26</sup> A legal entity identifier is "a 20-digit, alpha-numeric code, to uniquely identify legally distinct entities that engage in financial transactions." See Legal Entity Identifier Regulatory Oversight Committee, <http://www.lei.org/>; 17 CFR 45.6.

<sup>27</sup> A unique swap identifier is a unique identifier assigned to all swap transactions which identifies the transaction (the swap and its counterparties) uniquely throughout the duration of the swap's existence. See 17 CFR 45.5.

<sup>28</sup> For example, among other things, the time of execution of a swap between an SD and a counterparty may be relevant to determining the SD's compliance with the deadlines for confirmation of the swap set forth in § 23.501. Likewise, the time of execution and the time of reporting to an SDR may be relevant to determining the SD's compliance with the reporting deadlines set forth in part 45 of the Commission's regulations.

<sup>29</sup> Reporting counterparties are required to correct errors and omissions in data previously reported to an SDR pursuant to § 45.14.

above, portfolio reconciliation is not required for cleared swaps.<sup>32</sup> As noted below, the Commission seeks comment on whether such terms should be included in the Proposed Excluded Data Fields.

Finally, the Commission notes that it is not proposing an amendment to § 23.500(i)(1) that would exclude the Proposed Excluded Data Fields from portfolio reconciliation altogether. Thus the Commission is not proposing to change the existing requirement under § 23.502 that parties must exchange terms of all swaps in a mutual portfolio, but need only resolve discrepancies over material terms and valuations. As stated above, the Commission recognizes that the proposed amendment would not have the same effect as the no-action relief provided by the Division in CFTC Staff Letter 13–31. Nevertheless, the Commission has determined that it would be premature to propose to codify the staff relief without considering comments from the public on the nature of the post-Dodd-Frank-Act portfolio reconciliation process and how the Proposed Excluded Data Fields relate to that process.

### III. Request for Comment

To ensure that the proposed rule would, if adopted, achieve its stated purpose, the Commission requests comment generally on all aspects of the proposed rule. Specifically, the Commission requests comment on the following:

- Should the Commission amend its regulations to provide relief identical to that granted in CFTC Letter No. 13–31? Alternatively, should the Commission amend § 23.500(i)(1) so that counterparties only have to exchange the “material terms” (which would not include the Proposed Excluded Data Fields) of swaps? Or, lastly, should the Commission adopt its current proposal which is to only remove the Proposed Excluded Data Fields from the definition of “material terms” that counterparties must resolve for discrepancies pursuant to § 23.500(i)(3)?
- Should the Commission’s Proposed Excluded Data Fields not include the execution and SDR submission timestamps for uncleared swaps? Please explain why or why not.
- Should the Commission’s Proposed Excluded Data Fields include an indication of the election of the clearing exception in CEA Section 2(h)(7) and/or the identity of the counterparty electing such clearing requirement exception? Please explain why or why not.

<sup>32</sup> Portfolio Reconciliation Final Rule, 77 FR at 55927.

• Are there other items in the Proposed Excluded Data Fields that may have material regulatory value to the Commission or that may be relevant to the ongoing rights and obligations of the parties and the valuation of the swap and, thus, should not be included in the Proposed Excluded Data Fields? Please explain why or why not.

• Is each of the Proposed Excluded Data Fields actually required to be included in any ongoing portfolio reconciliation exercise, and, if not, should any such term be removed from the list of Proposed Excluded Data Fields? Please explain why or why not.

• Should any other “material term” as defined in § 23.500(g) be included in the list of Proposed Excluded Data Fields? Please explain why or why not.

• Should the Commission amend § 23.500(g) so that the term, “material terms,” is defined as all terms of a swap required to be reported in accordance with part 45 of the Commission regulations other than the Proposed Excluded Data Fields, as proposed? Please explain why or why not.

• To what extent does the proposed amendment facilitate (or fail to facilitate) the policy objectives of portfolio reconciliation? Feel free to reference specific terms listed in the Proposed Excluded Data Fields in your answer.

• Where are the cost savings realized by not having to resolve discrepancies in the Proposed Excluded Data Fields? If any other alternative approach should be considered, what cost savings would be realized by such alternative approach? Commenters are encouraged to quantify these cost savings.

### IV. Related Matters

#### A. Regulatory Flexibility Act.

The Regulatory Flexibility Act<sup>33</sup> requires that agencies consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis reflecting the impact. For purposes of resolving any discrepancy in material terms and valuations, the proposed regulation would amend the definition in § 23.500(g) of the Commission regulations so that the term “material terms” (which is used in § 23.500(i)(3)) is defined as all terms of a swap required to be reported in accordance with part 45 of the Commission’s regulations other than the Proposed Excluded Data Fields. As noted above, clause (3) of the definition of “portfolio

reconciliation” in § 23.500(i) requires the parties to resolve any discrepancy in “material terms” and valuations. As a result of the proposed change to the definition of “material terms” in § 23.500(g) of the Commission regulations, SDs and MSPs would not need to include the Proposed Excluded Data Fields<sup>34</sup> in any resolution of discrepancies of material terms or valuations when engaging in portfolio reconciliation. The Commission has previously determined that SDs and MSPs are not small entities for purposes of the Regulatory Flexibility Act.<sup>35</sup> Furthermore, any financial end users that may be indirectly<sup>36</sup> impacted by the proposed rule are likely to be eligible contract participants, and, as such, they would not be small entities.<sup>37</sup>

Thus, for the reasons stated above, the Commission preliminarily believes that the proposal will not have a significant economic impact on a substantial number of small entities. Accordingly, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the proposed regulations in this **Federal Register** release would not have a significant economic impact on a substantial number of small entities.

#### B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (“PRA”)<sup>38</sup> imposes certain requirements on Federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information, as defined by the PRA. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. This proposed rulemaking would result in an amendment to existing collection of information OMB Control Number 3038–0068 with respect to the collection of information entitled “Confirmation, Portfolio Reconciliation, and Portfolio Compression Requirements for Swap Dealers and

<sup>34</sup> See section II above for a list of “Proposed Excluded Data Fields” and proposed § 23.500(g) of the Commission regulations.

<sup>35</sup> Policy Statement and Establishment of Definitions of “Small Entities” for Purposes of the Regulatory Flexibility Act, 47 FR 18618, 18619 (Apr. 30, 1982).

<sup>36</sup> The Regulatory Flexibility Act focuses on direct impact to small entities and not on indirect impacts on these businesses, which may be tenuous and difficult to discern. See *Mid-Tex Elec. Coop., Inc. v. FERC*, 773 F.2d 327, 340 (D.C. Cir. 1985); *Am. Trucking Assns. v. EPA*, 175 F.3d 1027, 1043 (D.C. Cir. 1998).

<sup>37</sup> See *Opting Out of Segregation*, 66 FR 20740, 20743 (Apr. 25, 2001).

<sup>38</sup> 44 U.S.C. 3501 *et seq.*

<sup>33</sup> 5 U.S.C. 601 *et seq.*

Major Swap Participants.”<sup>39</sup> The Commission is therefore submitting this proposal to the Office of Management and Budget (OMB) for review. The Commission previously discussed, for purposes of the PRA, the burden<sup>40</sup> that the regulation mandating, *inter alia*, portfolio reconciliation would impose on market participants.<sup>41</sup> In particular, the Commission estimated the burden to be 1,282.5 hours for each SD and MSP, and the aggregate burden for registrants—based on a then-projected 125 registrants—was 160,312.5 burden hours.<sup>42</sup> Since the Commission finalized the rules for SDs and MSPs, 104 entities have provisionally registered as SDs and two entities have provisionally registered as MSPs, for a total of 106 registrants.<sup>43</sup> Accordingly, based on the original estimate of 1,282.5 burden hours for each SD and MSP, the aggregate burden for all registrants is estimated at 135,945 burden hours.

The proposed regulation would amend the definition in § 23.500(g) of the Commission regulations so that the term “material terms” (which is used in § 23.500(i)(3)) is defined as all terms of a swap required to be reported in accordance with part 45 of the Commission’s regulations other than the Proposed Excluded Data Fields.<sup>44</sup> As noted above, clause (3) of the definition of “portfolio reconciliation” in § 23.500(i) requires the parties to resolve any discrepancy in “material terms” and valuations. The proposed change would clarify that SDs and MSPs would not need to include the Proposed Excluded Data Fields in any resolution of discrepancies of material terms or valuations.

As discussed above, the rule change proposed herein would reduce the number of “material terms” that counterparties would need to resolve for discrepancies in portfolio reconciliation

exercises, but would not eliminate the portfolio reconciliation requirement itself. However, the Commission believes that the changes proposed to the regulatory definition of “material terms” described herein would reduce the time burden for portfolio reconciliation by one burden hour for each SD and MSP, which would reduce the annual burden to 1,281.5 hours per SD and MSP. The Commission believes that the proposed rule would result in one hour of less work for computer programmers for SDs and MSPs because the programmers who have to match the needed data fields from two different databases would have fewer data fields to obtain and resolve for discrepancies. Given that there are 106 provisionally registered SDs and MSPs, the proposed rule, if adopted, would result in an aggregate burden of 135,839 burden hours. The Commission welcomes comments about the potential impact that this proposal would have on the time and cost burden associated with portfolio reconciliation.

#### 1. Information Collection Comments

The Commission invites the public and other Federal agencies to comment on any aspect of the reporting burdens discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission’s estimate of the burden of the proposed collection of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (4) mitigate the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Comments may be submitted directly to the Office of Information and Regulatory Affairs, by fax at (202) 395–6566 or by email at

[OIRASubmissions@omb.eop.gov](mailto:OIRASubmissions@omb.eop.gov). Please provide the Commission with a copy of submitted comments so that all comments can be summarized and addressed in the final rule preamble. Refer to the **ADDRESSES** section of this notice of proposed rulemaking for comment submission instructions to the Commission. A copy of the supporting statement for the collection of information discussed above may be obtained by visiting <http://reginfo.gov/>. OMB is required to make a decision concerning the collection of information

between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

#### C. Considerations of Costs and Benefits

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing an order. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the section 15(a) factors.

#### 1. Background

The Commission believes that, while portfolio reconciliation generally helps counterparties to manage risk by facilitating the resolution of discrepancies in material terms of swaps, forcing entities to resolve discrepancies in the Proposed Excluded Data Fields does not improve the management of risks in swaps portfolios. By eliminating the need to resolve discrepancies over material swap terms that remain constant (and that do not impact the valuation of the swap or the payment obligations of the counterparties) and thereby reducing the number of data fields that parties must resolve for differences in portfolio reconciliation exercises, the Commission believes this proposal will slightly decrease the costs that its regulations impose on SDs and MSPs (and their counterparties) without a concomitant reduction in the benefits obtained from portfolio reconciliation exercises under the existing regulatory framework, as described below.

#### 2. Costs

The Commission believes this proposal will slightly decrease the costs that its regulations impose on SDs and MSPs (and their counterparties) because it would eliminate the need to verify and resolve discrepancies in swap terms that remain constant (or that do not impact the valuation of swaps or the payment obligations of the counterparties) and thereby reduce the number of data fields requiring particular attention in portfolio

<sup>39</sup> See OMB Control No. 3038–0068, <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0068>.

<sup>40</sup> “For purposes of the PRA, the term ‘burden’ means the ‘time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal Agency.’” Portfolio Reconciliation Final Rule, 77 FR at 55959.

<sup>41</sup> Portfolio Reconciliation Final Rule, 77 FR at 55958–60.

<sup>42</sup> Portfolio Reconciliation Final Rule, 77 FR at 55959.

<sup>43</sup> Provisionally Registered Swap Dealers as of June 17, 2015, <http://www.cftc.gov/LawRegulation/DoddFrankAct/registerswapdealer>; Provisionally Registered Major Swap Participants as of March 1, 2013, <http://www.cftc.gov/LawRegulation/DoddFrankAct/registermajorswappart>.

<sup>44</sup> As noted earlier, the proposed rule is amending the definition of the term “material terms” at § 23.500(g) to exclude nine data fields that would not be considered “material terms” in the definition of the term “portfolio reconciliation” of § 23.500(i)(3).

reconciliation exercises.<sup>45</sup> As mentioned previously, the Commission believes that this change will reduce the annual burden hours for each SD and MSP by one hour, resulting in a total of 1,281.5 hours, which leads to an aggregate number, based on 106 registrants, of 135,839 burden hours. The Commission previously estimated that, assuming 1,282.5 annual burden hours per SD and MSP, the financial cost of its regulations on each SD and MSP would be \$128,250.<sup>46</sup> Therefore, based on those prior estimates, a one-hour reduction in the annual burden hours for each SD and MSP would result in a financial cost of \$128,150 per registrant. Accordingly, the Commission estimates that, if the proposed rule is adopted, the aggregate financial burden of its regulations on SDs and MSPs would be \$13,583,900.<sup>47</sup>

The Commission does not believe the proposed regulation would increase the Commission's costs or impair the Commission's ability to oversee and regulate the swaps markets. Portfolio reconciliation is designed to enable counterparties to understand the current status or value of swap terms. As mentioned above, the Commission is proposing to amend the definition of "material terms" in § 23.500(g) so as to exclude the Proposed Excluded Data Fields because it preliminarily agrees with market participants that the Proposed Excluded Data Fields are not material to the ongoing rights and obligations of the counterparties to a swap. Because the Commission's proposal would only remove terms from the discrepancy resolution process for material terms, as opposed to the general portfolio reconciliation process or swaps reporting requirements, it will not negatively impact the amount of information available to the Commission about swaps. While the Commission believes that this proposal would reduce SDs', MSPs', or their counterparties' costs of complying with Commission regulations (because it would reduce the number of terms that counterparties must periodically resolve for discrepancies during portfolio reconciliations), the Commission seeks specific comment on the following, and encourages commenters to provide

<sup>45</sup> The Commission notes the existence of CFTC Staff Letter No. 13-31 and that the Proposal, if finalized, could increase the burden for SDs, MSPs, and their counterparties relying on the relief in that letter.

<sup>46</sup> Portfolio Reconciliation Final Rule, 77 FR at 55959.

<sup>47</sup> The Commission had estimated that, if 125 entities had registered as SDs and MSPs, the aggregate burden would be \$16,031,250. *Id.*

quantitative information in their comments where practical):

- How will the proposed regulation affect the costs of portfolio reconciliation for swap counterparties? Is the Commission's estimate of cost reductions that would result from the proposed rule a reasonable estimate of cost savings that would be realized from adopting the proposal?
- Will the proposed regulation make the portfolio reconciliation process more or less expensive? How so?
- How would the proposed rule affect the ongoing costs of compliance with Commission regulations?
- Are there other costs that the Commission should consider?

Commenters are strongly encouraged to include quantitative information in their comment on this rulemaking where practical.

### 3. Benefits

The Commission believes that this proposal would benefit SDs, MSPs, and their counterparties because it will not require them to expend the resources necessary to resolve discrepancies over swap terms that are included in the Proposed Excluded Data Fields in accordance with tight regulatory timeframes.<sup>48</sup> The Commission requests comment on all aspects of its preliminary consideration of benefits and encourages commenters to provide quantitative information where practical. Has the Commission accurately identified the benefits of this proposed regulation? Are there other benefits to the Commission, market participants, and/or the public that may result from the adoption of the proposed regulation that the Commission should consider?

### 4. Section 15(a)

Section 15(a) of the CEA requires the Commission to consider the effects of its actions in light of the following five factors:

#### a. Protection of Market Participants and the Public

The Commission believes that, notwithstanding its proposal to remove the Proposed Excluded Data Fields from the list of material terms that counterparties must periodically scrutinize to resolve any discrepancies, its regulations will continue to protect market participants and the public. The

<sup>48</sup> See § 23.502(a)(4) requiring SDs and MSPs to resolve discrepancies in material terms immediately with counterparties that are also SDs or MSPs. See also § 23.502(b)(4) (requiring SDs and MSPs to resolve discrepancies in material terms and valuations in a timely fashion with counterparties that are not SDs or MSPs).

Commission, however, welcomes comment as to how market participants and the public may be protected or harmed by the proposed regulation.

#### b. Efficiency, Competitiveness, and Financial Integrity of Markets

The Commission believes that its proposal, which will ensure that the parties resolving discrepancies in material terms and valuations in portfolio reconciliation exercises need not concern themselves with terms in the Proposed Excluded Data Fields may increase resource allocation efficiency of market participants engaging in reconciliation exercises without increasing the risk of harm to the financial integrity of markets.

The Commission seeks comment as to how the proposed regulation may promote or hinder the efficiency, competitiveness, and financial integrity of markets.

#### c. Price Discovery

The Commission has not identified an impact on price discovery as a result of the proposed regulation, but seeks comment as to any potential impact. Will the proposed regulation impact, positively or negatively, the price discovery process?

#### d. Sound Risk Management

The Commission believes that its proposal is consistent with sound risk management practices because the proposed regulatory change would not impair an entity's ability to conduct portfolio reconciliations. The Commission solicits comments on whether market participants believe the proposal will impact, positively or negatively, the risk management procedures or actions of SDs, MSPs, or their counterparties.

#### e. Other Public Interest Considerations

The Commission has not identified any other public interest considerations, but welcomes comment on whether this proposal would promote public confidence in the integrity of derivatives markets by ensuring meaningful regulation and oversight of all SDs and MSPs. Will this proposal impact, positively or negatively, any heretofore unidentified matter of interest to the public?

### List of Subjects in 17 CFR Part 23

Authority delegations (Government agencies), Commodity futures, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures

Trading Commission proposes to amend 17 CFR part 23 as set forth below:

## PART 23—SWAP DEALERS AND MAJOR SWAP PARTICIPANTS

■ 1. The authority citation for part 23 continues to read as follows:

**Authority:** 7 U.S.C. 1a, 2, 6, 6a, 6b, 6b–1, 6c, 6p, 6r, 6s, 6t, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21.

■ 2. Revise § 23.500(g) to read as follows:

### § 23.500 Definitions.

\* \* \* \* \*

(g) *Material terms* means all terms of a swap required to be reported in accordance with part 45 of this chapter other than the following:

(1) An indication that the swap will be allocated;

(2) If the swap will be allocated, or is a post-allocation swap, the legal entity identifier of the agent;

(3) An indication that the swap is a post-allocation swap;

(4) If the swap is a post-allocation swap, the unique swap identifier;

(5) Block trade indicator;

(6) With respect to a cleared swap, execution timestamp;

(7) With respect to a cleared swap, timestamp for submission to a swap data repository;

(8) Clearing indicator; and

(9) Clearing venue.

\* \* \* \* \*

Issued in Washington, DC, on September 17, 2015, by the Commission.

**Christopher J. Kirkpatrick,**  
*Secretary of the Commission.*

**Note:** The following appendices will not appear in the Code of Federal Regulations.

## Appendices to Proposal To Amend the Definition of “Material Terms” for Purposes of Swap Portfolio Reconciliation—Commission Voting Summary, Chairman’s Statement, and Commissioner’s Statement

### Appendix 1—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

### Appendix 2—Statement of Chairman Timothy G. Massad

I support issuing this proposal to amend the definition of “material terms” for purposes of portfolio reconciliation performed by swap dealers and major swap participants.

The proposed amendment would replace an existing “no-action” letter issued during the implementation of the Dodd-Frank Act. This gives greater certainty to affected registrants and furthers the Commission’s

ongoing process of simplifying, fine-tuning, and harmonizing our rules.

The proposal not only seeks comment on the technical aspects of reconciling specific data fields excluded under the staff no-action letter, but also seeks answers to important questions regarding the experience of swap dealers and major swap participants in complying with the portfolio reconciliation requirement more generally. Further, it seeks comment on the relationship of portfolio reconciliation to the integrity of data reported to swap data repositories.

The feedback of knowledgeable market participants on this proposal will allow the Commission to further its goal of continuously improving our recordkeeping, reporting, and data quality rules and practices. I encourage all market participants to join in this effort by examining the proposal and providing detailed comments. I look forward to reviewing them.

### Appendix 3—Statement of Commissioner J. Christopher Giancarlo

In its rush to implement the Dodd-Frank Act over the past few years, the Commission issued multiple rules that proved to be confusing, impracticable or unworkable, which in turn necessitated the unprecedented issuance of no-action relief, either due to unrealistic compliance deadlines, problematic elements of the rules or both. I trust that today’s proposal from the Commission signals that the epoch of heedless rule production is drawing to a close.

The Commission is seeking comment on a proposed rule that would codify a modified version of no-action relief issued in 2013 (the “No-Action Relief”) by the Division of Swap Dealer and Intermediary Oversight (“DSIO”) pursuant to a request for an interpretive letter from the International Swaps and Derivatives Association (“ISDA”). The No-Action Relief allows Swap Dealers (“SDs”) and Major Swap Participants (“MSPs”) to treat certain Part 45 data fields as non-material for purposes of portfolio reconciliation under Commission Regulation 23.502.<sup>1</sup>

I commend the Chairman and DSIO staff for taking steps to replace the No-Action Relief with a rulemaking subject to a cost-benefit analysis and the notice and comment requirements of the Administrative Procedure Act. Reasonable people understood at the height of the Dodd-Frank rulemaking frenzy that the Commission would and could not get everything right. That is why actions like today’s rule proposal are necessary and appropriate.

I urge the CFTC staff to continue down the path of bringing to the Commission for consideration amendments to flawed Dodd-Frank rulesets. It is appropriate as a matter of good government that we replace the hundreds of no-action, exemptive and interpretive letters, guidance, advisories and other communications, both written and unwritten, issued without a Commission vote in the wake of the Dodd-Frank Act with proper administrative rulemakings.

I support issuing for public comment the proposed amendments to the definition of

“material terms” for purposes of portfolio reconciliation. As the public reviews this rule change and formulates comments, I would like to draw its attention to several aspects of the proposal. Commission Regulation 23.502 requires SDs and MSPs to engage in portfolio reconciliation once each day, week or calendar quarter, depending on the size of the swap portfolio, and to resolve immediately any discrepancy in a material term. It is unclear why the Commission needs a daily, weekly, or quarterly reconciliation of data fields that will not change over time once established. In particular, I note that the proposed rule would continue to treat as material terms the execution timestamp and timestamp for submission to a swap data repository for uncleared swaps, an indication of whether the clearing requirement exception in section 2(h)(7) of the Commodity Exchange Act has been elected and the identity of the counterparty electing the clearing requirement exception. I am aware of the staff’s concern that a discrepancy in these terms could negatively impact the Commission’s regulatory mission, but question whether these terms will ever need to be reconciled after an initial verification.

On the other hand, I also question what additional burden will be placed on market participants by including these terms in the portfolio reconciliation process. I note that in its request for an interpretive letter ISDA stated that requiring reconciliation of data fields that are not relevant to the ongoing rights and obligations of the parties to a swap unnecessarily adds to the costs and complexity associated with implementing and managing the portfolio reconciliation process.<sup>2</sup> It would be most helpful if parties affected by the rule would submit detailed comments regarding these costs.

It is also unclear why the Commission is proposing to retain the requirement that SDs and MSPs exchange non-material terms throughout the life of a swap as part of a portfolio reconciliation exercise. Commission Regulation 23.500(i) defines portfolio reconciliation as the process by which two parties to one or more swaps: (1) Exchange “terms” (meaning all terms) of all swaps between the counterparties; (2) exchange each counterparty’s valuation of each swap as of the close of business on the immediately preceding business day; and (3) resolve any discrepancy in “material” terms and valuations. I note that ISDA requested that the Commission narrow the definition of “terms” in Rule 23.500(i)(1) to mean “material terms,” but the Commission is not proposing to do so. Thus, counterparties will be required to exchange all terms of each swap on a daily, weekly, or quarterly basis throughout the life of a swap, but will be required to reconcile only “material terms.” As with treating the terms relating to timestamps and the clearing exception as “material terms” discussed above, I question the utility of including non-material terms that are not required to be reconciled as part of the portfolio reconciliation process. It would be most helpful if parties affected by

<sup>1</sup> See CFTC Letter No. 13–31 (June 26, 2013).

<sup>2</sup> See ISDA Request for Interpretive Letter—Part 23 dated May 31, 2013.

the rule would submit detailed comments weighing the burdens against benefits of continuing to include such non-material terms.

I look forward to thoughtful comments on all aspects of the proposal.

[FR Doc. 2015-24021 Filed 9-21-15; 8:45 am]

BILLING CODE 6351-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, 211, 225, 500, 507, and 579

[Docket No. FDA-2015-N-001]

RIN 0910-AG10 and 0910-AG36

#### The Food and Drug Administration Food Safety Modernization Act: Final Rules To Establish Requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal Food; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing a public meeting entitled “FDA Food Safety Modernization Act: Final Rules to Establish Requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human and Animal Food.” The public meeting will provide interested persons an opportunity to discuss the final rules for current good manufacturing practice, hazard analysis, and risk-based preventive controls for human and animal food (the preventive controls final rules) and FDA’s comprehensive planning effort for the next phase of the FDA Food Safety Modernization Act (FSMA) implementation, which involves putting in place the new public health prevention measures and the risk-based industry oversight framework that is at the core of FSMA. The purpose of the public meeting is to brief stakeholders and interested persons on the key components of the preventive controls final rules, respond to questions, and discuss the next phase of FSMA implementation with respect to human and animal food preventive controls requirements.

**DATES:** See section III, “How to Participate in the Public Meeting” in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the

public meeting, closing dates for advance registration, and requesting special accommodations due to disability.

**ADDRESSES:** See section III, “How to Participate in the Public Meeting” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** For questions about registering for the meeting or to register by phone: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: [ctreece@planningprofessionals.com](mailto:ctreece@planningprofessionals.com).

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: [Juanita.yates@fda.hhs.gov](mailto:Juanita.yates@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring preventive controls for human food and animal food, setting standards for produce safety, and requiring importers to perform certain activities to help ensure that the food they bring into the United States is produced in a manner consistent with U.S. standards.

FSMA was the first major legislative reform of FDA’s food safety authorities in more than 70 years. In the **Federal Register** of January 16, 2013 (78 FR 3646), we proposed to amend our regulations for Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food to modernize it and to add requirements for domestic and foreign facilities that are required to register under the FD&C Act to establish and implement hazard analysis and risk-based preventive controls for human food. We also proposed to revise certain definitions in our current regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided by the FD&C Act for “farms.” In the **Federal Register** of October 29, 2013 (78

FR 64735), we proposed regulations for domestic and foreign facilities that are required to register under the FD&C Act to establish requirements for current good manufacturing practice in manufacturing, processing, packing, and holding of animal food. We proposed to require that certain facilities establish and implement hazard analysis and risk-based preventive controls for food for animals to provide greater assurance that animal food is safe and will not cause illness or injury to animals or humans.

Based on input we received from public comments, in the **Federal Register** of September 29, 2014 (79 FR 58476 and 79 FR 58524), we proposed to amend our 2013 proposed rules for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human and Animal Food and reopened the comment period only with respect to specific issues identified in supplemental proposed rules.

In the **Federal Register** of September 17, 2015 (80 FR 55908), we issued a final rule to establish the requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. In the **Federal Register** of September 17, 2015 (80 FR 56170), we issued a final rule to establish requirements for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals. The preventive controls final rules apply to human and animal food and require domestic and foreign facilities that are required to register under the FD&C Act to have written plans that identify hazards, specify the preventive controls that will be put in place to significantly minimize or prevent those hazards, include procedures to monitor the implementation of the preventive controls, and include corrective action procedures for use when preventive controls are not properly implemented. We also revised certain definitions in the regulation for Registration of Food Facilities to clarify the scope of the exemption from registration requirements provided for “farms” and, in so doing, to clarify which domestic and foreign facilities are subject to the requirements for hazard analysis and risk-based preventive controls for food. The preventive controls final rules and related fact sheets are available on FDA’s FSMA Web page located at <http://www.fda.gov/FSMA>.