

I. Background

Section 101(a)(2)(C) of the CPSIA (15 U.S.C. 1278a(a)(2)(C)) provides that, as of August 14, 2011, children's products may not contain more than 100 ppm of lead unless the Commission determines that such a limit is not technologically feasible. The Commission may make this determination only after notice and a hearing and after analyzing the public health protections associated with substantially reducing lead in children's products. Section 101(d) of the CPSIA (15 U.S.C. 1278a(d)) provides that a lead limit shall be deemed technologically feasible with regard to a product or product category if:

(1) A product that complies with the limit is commercially available in the product category;

(2) technology to comply with the limit is commercially available to manufacturers or is otherwise available within the common meaning of the term;

(3) industrial strategies or devices have been developed that are capable or will be capable of achieving such a limit by the effective date of the limit and that companies, acting in good faith, are generally capable of adopting; or

(4) alternative practices, best practices, or other operational changes would allow the manufacturer to comply with the limit.

On July 27, 2010, we published a notice in the **Federal Register** (75 FR 43942), requesting comment and seeking information concerning the technological feasibility of meeting the 100 ppm lead content limit for children's products that are not otherwise excluded from the lead content limits under 16 CFR 1500.87 through 1500.91. After initial consideration of the comments and information received in response to the July 27, 2010 notice, we published a notice in the **Federal Register** (76 FR 4641) on January 26, 2011, announcing that we would be conducting a public hearing to receive views from all interested parties about the technological feasibility of meeting the 100 ppm lead content limit for children's products and associated public health considerations. The hearing was held on February 16, 2011. On March 9, 2011, we published another notice in the **Federal Register** (76 FR 12944), reopening the hearing record to allow hearing participants to submit relevant studies and supplementary data in response to additional questions from certain Commissioners.

Participants who submitted comments and hearing testimony regarding the

technological feasibility of meeting the 100 ppm lead content limit and associated public health considerations included consumers, consumer groups, manufacturers, retailers, associations, and laboratories. Comments submitted in this proceeding are available at <http://www.regulations.gov>, under Docket No. CPSC-2010-0080. The video webcast of the hearing, as well as the presentations and written comments from the hearing, are available at the CPSC web site: <http://www.cpsc.gov/webcast/previous.html>. A transcript of the hearing and supplemental information provided by hearing participants are also available at <http://www.regulations.gov>, docket CPSC-2010-0080.

II. Technological Feasibility of 100 ppm

We evaluated the technological feasibility of the 100 ppm lead content limit for children's products based on available technical information, written public comments, public hearing oral comments, and other available information. CPSC staff's analysis regarding the technological feasibility of materials and products to meet the 100 ppm lead content limit is contained in the staff briefing package available on the CPSC Web site at: <http://www.cpsc.gov/library/foia/foia11/brief/lead100tech.pdf> and <http://www.cpsc.gov/library/foia/foia11/brief/100ppmlead.pdf>. We evaluated the technological feasibility of meeting the 100 ppm lead content limit in materials such as plastics, glass, and metals; reviewed the economic impacts of reducing the lead content limit from 300 ppm to 100 ppm; and considered the public comments received in this proceeding, including comments on public health protectiveness, economic burdens, availability of compliant materials, and variability in test results. Based upon this analysis, the staff could not recommend that the Commission make a determination that it is not technologically feasible for a product or product category to meet the 100 ppm lead content limit for children's products under section 101(d) of the CPSIA. No such determination has been made by the Commission. Therefore, all children's products sold, offered for sale, manufactured for sale, distributed in commerce, or imported for sale in the United States must meet the 100 ppm lead content limit beginning August 14, 2011 as statutorily mandated by the CPSIA unless otherwise excluded under 16 CFR 1500.87 through 1500.91. With respect to bicycles and related products and youth motorized recreational vehicles, a stay of enforcement regarding the lead content in certain

parts, including metal components, is currently in effect until December 31, 2011 (76 FR 6765).

Dated: July 18, 2011.

Todd A. Stevenson,
Secretary, Consumer Product Safety
Commission.

[FR Doc. 2011-18510 Filed 7-25-11; 8:45 am]

BILLING CODE 6355-01-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 39 and 140

RIN 3038-AD00

Process for Review of Swaps for Mandatory Clearing

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission or CFTC) is adopting regulations to implement certain provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). These regulations establish the process by which the Commission will review swaps to determine whether the swaps are required to be cleared.

DATES: Effective September 26, 2011.

FOR FURTHER INFORMATION CONTACT: Eileen A. Donovan, Special Counsel, 202-418-5096, edonovan@cftc.gov, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2010, the Commission published proposed regulations to implement certain provisions of the Dodd-Frank Act regarding the mandatory clearing of swaps.¹ The Commission is hereby adopting Regulation 39.5² to establish procedures for: (1) Determining the eligibility of a DCO to clear swaps; (2) the submission of swaps by a DCO to the Commission for a mandatory clearing determination; (3) Commission-initiated reviews of swaps; and (4) staying a clearing requirement.

Section 723(a)(3) of the Dodd-Frank Act provides that "it shall be unlawful for any person to engage in a swap unless that person submits such swap

¹ See 75 FR 67277 (Nov. 2, 2010).

² Commission regulations referred to herein are found at 17 CFR Ch. 1.

for clearing to a derivatives clearing organization [(DCO)] that is registered under [the CEA] or a [DCO] that is exempt from registration under [the CEA] if the swap is required to be cleared.”³ The Commission’s final regulations implement Section 723(a)(3), which also requires the Commission to adopt rules for the review of a swap, or group, category, type, or class of swaps (collectively, “swaps”) to make a determination as to whether the swaps are required to be cleared. The final regulations also implement Section 745(b) of the Dodd-Frank Act, insofar as it directs the Commission to prescribe criteria, conditions, or rules under which the Commission will determine the initial eligibility or the continuing qualification of a DCO to clear swaps.⁴

II. Comments on the Notice of Proposed Rulemaking

The Commission received eighteen comments during the 60-day public comment period following publication of the notice of proposed rulemaking, and eight additional comments during the 30-day reopened public comment period that covered many of the Commission’s rulemakings under the Dodd-Frank Act. The Commission considered each of these comments in formulating the final regulations.⁵

A. Swaps Listed for Clearing by a DCO Prior to the Enactment of the Dodd-Frank Act

Section 723(a)(3) of the Dodd-Frank Act provides that swaps listed for clearing by a DCO as of the date of enactment of the Dodd-Frank Act (referred to hereinafter as “pre-enactment swaps”) shall be considered submitted to the Commission.⁶ Once a swap is submitted to the Commission, the Commission must review it within 90 days to determine whether it is required to be cleared. Accordingly, Section 723(a)(3) required a Commission determination on pre-enactment swaps within 90 days after July 21, 2010, the date of enactment of the Dodd-Frank Act. However, before the deadline was reached, each DCO that was clearing pre-enactment swaps agreed to an extension of the deadline

until after the Commission had adopted the regulations discussed herein.

In its comment letter, the American Federation of State, County and Municipal Employees (AFSCME) recommended that the Commission provide for public notice and comment for pre-enactment swaps in a manner similar to that put forward in the proposed regulations for the swaps that DCOs will submit going forward. CME Group, Inc. (CME) recommended that a DCO not be required to make any submission to the Commission for pre-enactment swaps or for swaps that a DCO cleared before the effective date of the clearing requirement. Sungard Energy & Commodities (Sungard) inquired as to whether pre-enactment swaps being considered submitted means that the DCO is not required to submit the supporting information required in proposed Regulation 39.5(b)(3), that the DCO is automatically eligible to clear the swap, and that the DCO is permitted to continue clearing while the Commission conducts its review.

In response to these comments, the Commission notes its intention to apply the final regulations to all swaps submitted or considered submitted to the Commission, including the pre-enactment swaps. Shortly after the enactment of the Dodd-Frank Act, Commission staff contacted those DCOs identified as clearing swaps and requested that they submit information similar to that which will be required under Regulation 39.5(b)(3). After the final regulations take effect and the Commission has verified that the previously submitted information is accurate and complete, the Commission will post the submissions for public comment as required. The Commission confirms that a DCO that is clearing pre-enactment swaps may continue to clear them and does not have to wait for a determination from the Commission as to whether the swaps are required to be cleared.

B. Eligibility of a DCO To Clear Swaps

Under Regulation 39.5(a), a DCO would be presumed eligible to accept for clearing any swap that is within a group, category, type, or class of swaps that the DCO already clears. This presumption of eligibility would be subject to Commission review, and if the Commission determines that the swap is not within a group, category, type, or class of swaps that the DCO already clears, the DCO would be required to request a determination by the Commission of its eligibility to clear the swap. A DCO that plans to accept for clearing any swap that is *not* within a

group, category, type, or class of swaps that the DCO already clears also would be required to request a determination by the Commission of its eligibility to clear the swap. A swap generally would be considered to be “within a group, category, type, or class of swaps that the DCO already clears” if the terms of the swap are substantially similar to the terms of a swap, group, category, type or class of swaps that the DCO already clears, and clearing the swap will not require any changes to the DCO’s risk management framework.

The Financial Services Roundtable (FSR) commented that a DCO’s authority to clear swaps transactions should not be conditioned on its ability to clear the entire market volume of such swaps transactions, and therefore the reference to mandatory clearing should be deleted from Regulation 39.5(b)(3)(i). As proposed, Regulation 39.5 (b)(3)(i) required the DCO’s submission to the Commission to include “[a] statement that the [DCO] is eligible to accept the swap, or group, category, type or class of swaps for clearing and, if the Commission determines that the swap, or group, category, type, or class of swaps is required to be cleared, the [DCO] will be able to maintain compliance with section 5b(c)(2) of the Act.”⁷ Therefore, as FSR noted, the DCO would be required to have the ability to clear the entire market volume for any swap, or group, category, type or class of swaps that it planned to accept for clearing. In the final regulation, the Commission is maintaining the reference to mandatory clearing but revising Regulation 39.5(b)(3)(i) as follows (added text in italics): “A statement that the [DCO] is eligible to accept the swap, or group, category, type or class of swaps for clearing and *describes the extent to which*, if the Commission were to determine that the swap, or group, category, type, or class of swaps is required to be cleared, the [DCO] will be able to maintain compliance with section 5b(c)(2) of the Act.” The revised regulation would not require the Commission to find a DCO ineligible to clear a swap if the DCO is unable to clear the entire market volume of such swap transactions, but the Commission would take the DCO’s inability to clear the entire market into consideration in determining whether the swap must be cleared.

The International Swaps and Derivatives Association (ISDA) asked the Commission to confirm that it

⁷ Section 5b(c)(2) sets out the core principles with which a DCO must comply to maintain its registration with the Commission.

³ See Section 2(h)(1)(A) of the CEA, 7 U.S.C. 2(h)(1)(A).

⁴ See Section 5c(c)(5)(C)(iii) of the CEA, 7 U.S.C. 7a–2(c)(5)(C)(iii).

⁵ The Commission also reviewed the proposed rule of the Securities and Exchange Commission concerning the process for submissions for review of security-based swaps for mandatory clearing. See 75 FR 82490 (Dec. 30, 2010).

⁶ See Section 2(h)(2)(B)(ii) of the CEA, 7 U.S.C. 2(h)(2)(B)(ii).

intends for a DCO eligibility review to be separate from and precede a swap review, and that the intent is not to commence both reviews simultaneously. LCH.Clearnet Group (LCH) urged the Commission to decouple the determination that a DCO may clear a swap from the determination that a swap should be subject to a mandatory clearing obligation. Similarly, Sungard asked for clarification as to whether a DCO can begin accepting a new swap for clearing once eligibility for clearing is established, independent of the review for mandatory clearing.

The Commission confirms that it intends for a DCO eligibility review to be separate from and precede a review of swaps that the DCO plans to accept for clearing. The Commission also confirms that a DCO may begin accepting a new swap for clearing once the DCO's eligibility for clearing is established and the submission requirements of Regulation 39.5(b) have been met, as discussed further below.

Michael Greenberger recommended that a DCO be required to state with specificity in its written request the sufficiency of its financial resources and its ability to manage the risks associated with clearing the swap. Chris Barnard stated that sufficient evidence indicating that the DCO would be able to maintain compliance with the requirements of section 5b(c)(2) of the CEA, or a CFTC review to determine the DCO's ability, should be required for all DCOs planning to accept swaps for clearing.

The Commission notes that it has proposed separate regulations that will impose new requirements on DCOs, including financial resources and risk management requirements, for maintaining compliance with the core principles applicable to DCOs set out in section 5b(c)(2).⁸ Therefore, even if a DCO is presumed eligible, or determined to be eligible, to accept swaps for clearing, the Commission will be monitoring the DCO's eligibility on an ongoing basis through the requirements of those regulations.

C. A DCO's Notice to Its Members of a Swap Submission

Regulation 39.5(b)(3)(xi) requires a DCO's swap submission to include a "description of the manner in which the

[DCO] has provided notice of the submission to its members and a summary of any opposition to the submission expressed by the members." In the notice of proposed rulemaking, the Commission invited comment on whether the regulation should prescribe a specific manner in which a DCO must provide notice to its members, and whether the regulation should prescribe a specific period of time between the notice to members and the submission to the Commission to allow time for members to make their views on the submission known. Section 723(a)(3) of the Dodd-Frank Act only requires the DCO to provide notice to its members of the submission; it does not require the DCO to provide its members with the opportunity to comment.

The Air Transport Association of America (ATA) requested that the Commission require a DCO to provide in its submission a description of how the DCO has notified market participants of the submission and of any opposition expressed by such market participants. Although the Commission will accept public comment on the DCO's submission, ATA believes by that time the DCO may have made important, and sometimes irreversible, decisions with regard to its proposed clearing offering.

The Alternative Investment Management Association Limited (AIMA) stated that the Commission should require a DCO's members to pass on to their customers all details about a submission by the DCO to the Commission and encourage those customers to provide comments to the Commission.

Better Markets, Inc. suggested requiring a DCO to provide notice to the Commission and the public when considering clearing a new class of swaps, rather than only providing notice when a decision to submit has been made. Better Markets also recommended that the Commission require a DCO to solicit input from customers and the public to enable a full and fair consideration of a submission and to include member comments in support of a submission in addition to comments in opposition. Additionally, Better Markets commented that a DCO should be required to provide notice to the Commission and the public of a decision not to submit a swap for clearing, including comments for and against submission.

The FSR expressed the view that the DCO and its clearing members will be in the best position to determine appropriate notice and voting procedures with respect to these matters.

Freddie Mac recommended that the Commission require DCOs to provide pre-submission notice of any clearing proposal and a meaningful opportunity to comment to all interested stakeholders, rather than merely to the DCO's own members.

Mr. Greenberger suggested that it would be preferable for the regulations to prescribe a specific manner and timeline for notice, so that the notice is given with sufficient time and in the proper manner to gather all of the appropriate objections by DCO members.

IntercontinentalExchange, Inc. (ICE) observed that the requirement that a DCO provide to the Commission a summary of any opposition to a swap submission expressed by its members has the effect of creating two comment periods (including the Commission's 30-day public comment period), thus extending the timeline for a DCO to submit swaps for mandatory clearing. ICE proposed that the Commission adopt a 30-day comment period as sufficient for input from all members and require the DCO to include only a statement of any opposition from the DCO's board as part of its submission.

Mr. Barnard recommended that the Commission change the wording under Regulation 39.5(b)(3)(xi) and require the DCO to provide a summary of "any comments on the submission expressed by the members" rather than just "any opposition to the submission expressed by the members," in order to promote fairness.

In response to these comments, the Commission is replacing the words "opposition to" with the words "views on," revising the text of Regulation 39.5(b)(3)(xi) to read as follows: "A description of the manner in which the [DCO] has provided notice of the submission to its members and a summary of any views on the submission expressed by the members." Further, the Commission clarifies that the regulations do not require a DCO to solicit the views of its members or the public on the submission, because all interested parties will have the opportunity to comment during the Commission's 30-day public comment period. However, if the members do make their views known directly to the DCO, the DCO is required to share a summary of that information with the Commission under Regulation 39.5(b)(3)(xi).

D. Public Comment Process for Swap Submissions

In the notice of proposed rulemaking, the Commission stated that, upon receiving a DCO's swap submission, the

⁸ See 75 FR 63113 (Oct. 14, 2010) (financial resources); 75 FR 63732 (Oct. 18, 2010) (conflicts of interest); 75 FR 77576 (Dec. 13, 2010) (general regulations); 75 FR 78185 (Dec. 15, 2010) (information management); 76 FR 722 (Jan. 6, 2011) (governance); 76 FR 3698 (Jan. 20, 2011) (risk management); and 76 FR 13101 (Mar. 10, 2011) (participant and product eligibility).

Commission would begin its 90-day review by posting the submission on the Commission Web site for a 30-day public comment period, as required by the Dodd-Frank Act. The Commission invited comment regarding the appropriateness and sufficiency of providing notice of the submission on the Commission Web site as compared to publishing notice of the submission in the **Federal Register**.

AFSCME, Americans for Financial Reform, Mr. Greenberger, and Mr. Barnard recommended that the Commission publish submissions both on the Commission Web site and in the **Federal Register** to provide the fullest disclosure possible. ATA supported the Commission's use of its Web site to provide notice of submissions but recommended that, at the time a submission is posted, the Commission send a notification to the same subscribers that receive notifications of **Federal Register** notices. The Commission is accepting the recommendation to publish submissions both on the Commission Web site and in the **Federal Register**. Accepting this recommendation does not require any changes to the text of proposed Regulation 39.5(b)(4), which states that the submission "will be made available to the public and posted on the Commission website." Publication of the submission in the **Federal Register** will make the submission available to the public, and the Commission will have a link to the **Federal Register** notice on its Web site.

In other comments on the public comment process for swap submissions, Freddie Mac recommended that the Commission extend the period for notice and comment beyond 30 days, and ISDA suggested that the Commission extend the public comment period to 45 days. The Commission has decided to keep the comment period at 30 days, the minimum required by the Dodd-Frank Act, because the Commission typically will have just 90 days to review the swap submission. The Commission is concerned that extending the comment period by regulation may not leave sufficient time for the Commission to carefully consider the comments received and conduct a thorough review. Nevertheless, the Commission expects that it will extend the comment period on a case-by-case basis, because the Commission is allowed to extend the 90-day review period if the submitting DCO agrees to an extension.

Finally, the National Milk Producers Federation (NMPF) commented that the regulations would invite DCOs to lay claim to swaps and categories of swaps,

leaving all actual and potential future end users only 30 days to become aware of, and respond to, such claims. The Commission notes that all public comments received on a swap submission, not just the DCO's views, will be considered in making a mandatory clearing determination and, as discussed above, the Commission will allow more than 30 days for comments when possible on a case-by-case basis.

E. Contents of a DCO's Swap Submission

Regulation 39.5(b) sets out the process for DCOs to follow when submitting a swap, or group, category, type or class of swaps to the Commission, including what information a DCO must include in the submission to assist the Commission in its review.

In its comment letter, LCH encouraged the Commission to amend the supporting information requirements under Regulation 39.5(b)(3), such that a DCO is required to include in its submission only that information which is necessary for determining the suitability of a swap for clearing and the eligibility of a DCO to clear that swap. LCH believes that a DCO should not have to provide the information required to support the determination of whether a swap should be subject to a clearing requirement. LCH commented that the determination that a DCO may clear a swap should be separate from, and independent of, any determination that a swap should be subject to mandatory clearing. LCH recommended that certain words be deleted from the text of proposed Regulations 39.5(b)(3)(ii)(A), (C), and (D), and that proposed Regulation 39.5(b)(3)(viii) be deleted, because, in LCH's view, a DCO would not have access to the information required.

Similarly, CME commented that the Commission should limit the breadth of the submission required by a DCO seeking approval to clear a swap to only addressing whether clearing the swap comports with the DCO core principles. CME stated that the Commission's proposed regulations would impose costs and obligations that would effectively undermine the purposes of the Dodd-Frank Act and that, in effect, the Commission is attempting to charge a DCO that wishes to list a new swap with the obligation to collect and analyze massive amounts of information so that the Commission can perform its statutory duty of determining whether the swap should be subject to the mandatory clearing requirement. In a second comment letter, CME expressed concern that the regulations conflate the

"voluntary clearing determination" and the "mandatory clearing determination" for swaps. CME also revised its earlier comments on the information required for the submission and recommended that the Commission delete proposed Regulations 39.5(b)(3)(ii), (vii), (viii), and (x) in their entirety and proposed Regulation 39.5(b)(3)(vi) in part.

In response to LCH and CME's comments, the Commission is deleting proposed Regulations 39.5(b)(3)(vii), (viii), and (x) in their entirety and proposed Regulation 39.5(b)(3)(vi) in part, and renumbering proposed Regulations 39.5(b)(3)(ix) and (xi) as Regulations 39.5(b)(3)(vii) and (viii), respectively, due to the removal of the other provisions. As a result of this revision, a DCO will only be required to submit information to the Commission, such as product specifications and risk management procedures, which a DCO should have gathered and considered in making its own decision to accept a particular swap for clearing. The Commission is also adding Regulation 39.5(b)(3)(ix), which would require a DCO to submit "[a]ny additional information specifically requested by the Commission." This will allow the Commission to request any information not required by Regulation 39.5(b) if needed on a case-by-case basis.

The Commission is declining to delete Regulation 39.5(b)(3)(ii) or revise it in accordance with LCH's comments. Regulation 39.5(b)(3)(ii), as proposed, requires a DCO to submit to the Commission a "statement that includes, but is not limited to, information regarding the swap, or group, category, type, or class of swaps that is sufficient to provide the Commission a reasonable basis to make a quantitative and qualitative assessment of the following factors," and then lists the five factors set out in Section 723(a)(3) of the Dodd-Frank Act that the Commission is required to take into account in reviewing a swap submission. LCH had suggested editing these factors for purposes of the required statement. For example, LCH had suggested editing proposed Regulation 39.5(b)(3)(ii)(A), which reads "[t]he existence of significant outstanding notional exposures, trading liquidity, and adequate pricing data," to read as "[t]he existence of adequate pricing data." The Commission does not believe it is appropriate to change the wording that is used in the Dodd-Frank Act.

Instead, in response to LCH's comments, the Commission is revising the introductory language of Regulation 39.5(b)(3)(ii) to read, in part: "A statement that includes, but is not limited to, information that will assist

the Commission in making a quantitative and qualitative assessment of the following factors * * *.” The Commission believes this change will require a DCO to address each of the five factors only to the extent that the DCO is reasonably able to do so. For example, with regard to the factor in Regulation 39.5(b)(3)(ii)(A) cited above, if LCH is only able to provide information regarding the existence of adequate pricing data, then that is the only information that LCH would be required to provide.

Some DCOs believe that certain swaps that are accepted for clearing may be obviously unsuitable for mandatory clearing and therefore a DCO should only have to submit swaps to the Commission for review at the discretion of the DCO or the Commission. The Dodd-Frank Act, however, does not give either the DCO or the Commission such discretion. As previously noted, a DCO is required to submit to the Commission each swap, or any group, category, type, or class of swaps that it plans to accept for clearing, and the Commission is required to review each submission and determine whether clearing is required. Nevertheless, the Commission would encourage a DCO to use the statement required by Regulation 39.5(b)(3)(ii) to express its views as to whether the swaps being submitted should be subject to a clearing requirement.

The Commission believes it is necessary to clarify that a “voluntary clearing determination” is not required before a DCO may accept swaps for clearing. The Commission had expected that a DCO that wished to accept swaps for clearing would be permitted to do so after meeting the eligibility requirements of Regulation 39.5(a) and the submission requirements of Regulations 39.5(b) and 40.2,⁹ the latter of which applies to DCOs accepting products for clearing by certification. Under Regulation 40.2, if the Commission has received the submission required under that section by the open of business on the business day preceding the product’s acceptance for clearing, then the DCO may begin clearing the product as planned. However, the Commission recognizes that it would be burdensome to require a DCO to comply with two different submission requirements before it could accept swaps for clearing. Accordingly, the Commission has decided to eliminate the provision in Regulation 40.2 concerning DCOs and only require

compliance with Regulation 39.5. The Commission has also added paragraph (b)(4) to Regulation 39.5 to require, like Regulation 40.2, that a DCO’s submission must be received by the Commission by the open of business on the business day preceding the acceptance of the swap, or group, category, type, or class of swaps for clearing. This change clarifies that a DCO, which must be eligible or presumed eligible to clear any swap or group, category, type, or class of swaps that it plans to accept for clearing, may begin clearing such swaps shortly after it has made its submission to the Commission and does not have to wait until the Commission has made a determination on mandatory clearing.

In other comments regarding the DCO’s swap submission, the American Benefits Council (ABC) recommended that the submission be required to include a specific analysis of the costs and burdens of clearing on market participants, and Better Markets proposed that the regulations clearly state that the additional statements and materials the DCO must include with its submission are not intended to increase the number of factors to be taken into account by the Commission in its review beyond the five factors set forth in the Dodd-Frank Act. The Commission believes a better approach to assessing the costs and burdens of clearing on market participants is by requesting public comment on the issue during its reviews of DCO swap submissions. The Commission also believes that the information that a DCO will be required to provide with its submission is clearly intended to aid the Commission in its assessment of the five factors set forth in the Dodd-Frank Act.

F. Group, Category, Type or Class of Swaps

Regulation 39.5(b)(2) encourages a DCO to submit swaps to the Commission by “group, category, type or class of swaps,” language taken from Section 723(a)(3) of the Dodd-Frank Act. Several commenters expressed concern about how “group, category, type or class of swaps” will be defined. The Coalition for Derivatives End-Users expressed concern that these groups or categories could be defined too broadly, without due consideration of the important differences between swaps within these groups or categories. ABC stated its opposition to the Commission adopting any clearing requirement that covers a group, category, type or class of swaps unless the Commission reviews each swap within the group, category, type or class and determines that each swap should be cleared.

How the Commission defines a particular group, category, type or class of swaps for purposes of a clearing requirement will be informed by: (1) How it is defined by the DCO in its submission (for those swaps submitted by a DCO); (2) the comments received by the Commission during the public comment period; (3) the five factors enumerated in the Dodd-Frank Act that the Commission is required to take into account; and (4) the Commission’s own analysis during its review. The Commission will review each swap within a group, category, type or class of swaps to the extent the Commission believes it is necessary to make the proper determination on mandatory clearing.

G. Factors the Commission Must Take Into Account When Reviewing Swaps

Section 723(a)(3) of the Dodd-Frank Act requires the Commission, in reviewing a swap or swaps on its own initiative, or a swap submission, to take into account the following factors, also set out in Regulation 39.5(b)(3)(ii): (1) The existence of significant outstanding notional exposures, trading liquidity, and adequate pricing data; (2) the availability of rule framework, capacity, operational expertise and resources, and credit support infrastructure to clear the contract on terms that are consistent with the material terms and trading conventions on which the contract is then traded; (3) the effect on the mitigation of systemic risk, taking into account the size of the market for such contract and the resources of the DCO available to clear the contract; (4) the effect on competition, including appropriate fees and charges applied to clearing; and (5) the existence of reasonable legal certainty in the event of the insolvency of the relevant DCO or one or more of its clearing members with regard to the treatment of customer and swap counterparty positions, funds, and property.

In a comment letter, AIMA expressed its view that the third factor, the effect on the mitigation of systemic risk, should override other considerations. Better Markets proposed that the regulations make clear that a given level of contract-specific systemic risk avoided by mandatory clearing does not constitute a threshold for a determination by the Commission because the Dodd-Frank Act in no way suggests that only contract types that by themselves pose a risk to the financial system should be cleared.

The Coalition for Derivatives End-Users urged the Commission to give significant weight to a swap’s liquidity in assessing whether that swap should

⁹ The Commission has proposed to amend Regulation 40.2 to implement certain provisions of the Dodd-Frank Act. See 75 FR 67282 (Nov. 2, 2010).

be subject to mandatory clearing and to consider the link between the clearing requirement and the trading requirement. The FSR requested that the Commission consider the changes in the trading market structure being effected by the Dodd-Frank Act and related regulations in evaluating mandatory clearing decisions. The FSR is concerned that a trading system that limits participation will also reduce liquidity in the system because, due to the trading requirements for cleared swaps, counterparties will not have the option to complete trades off-exchange when on-exchange trading is unattractive or unavailable.

ISDA provided detailed comments on each of the five factors and encouraged the Commission to interpret these criteria strictly. Sungard proposed that the Commission apply some form of concentration test in determining whether a swap should be mandated for clearing out of concern that if the market for a swap is too heavily concentrated in the hands of a few market makers on the supply side, or a handful of hedgers or speculators on the demand side, such concentration would hamper discovery of the market clearing price and impose liquidity risk on the DCO.

CME commented that the proposed regulations do not state how the Commission will decide which swaps will be subject to a clearing requirement. CME believes that the Commission is required to make public how it will make this critical determination, because it would allow market participants to anticipate which swaps will be required to be cleared and may incentivize market participants to voluntarily submit those swaps for clearing in advance of any requirement that they be submitted for clearing.

The National Corn Growers Association (NCGA) and Natural Gas Supply Association (NGSA) encouraged the Commission to acknowledge that swaps that are not liquid over their full terms should not be required to be cleared because such swaps do not meet the Dodd-Frank Act's requirement of trading liquidity for swaps to be subject to the mandatory clearing requirement. In particular, NCGA and NGSA suggested that the Commission acknowledge that it will not require illiquid long-term swaps to be split up into various components in order to extract one or more clearable components, since the Dodd-Frank Act provides no authority for such a requirement.

As required by the Dodd-Frank Act, the Commission will take each of the five factors and the information

submitted by the DCO into account when making a mandatory clearing determination, as well as these comments and any comments received during the public comment period that will be a part of each review. The Commission does not believe it would be appropriate to address these comments at this time, as they are beyond the scope of the regulations.

H. Commission-Initiated Reviews of Swaps

Section 723(a)(3) of the Dodd-Frank Act and Regulation 39.5(c) require the Commission, on an ongoing basis, to review swaps that have not been accepted for clearing by a DCO to make a determination as to whether the swaps should be required to be cleared.

AIMA suggested that it may be desirable to have a set frequency of reviews that the Commission must carry out, and that parties other than DCOs be allowed to request that the Commission initiates a review. AIMA recommended the Commission use the same criteria to assess a swap under a Commission-initiated review as it would for a DCO-submitted review. Finally, AIMA opined that there should be no prohibitions placed on trading a swap that would be subject to a mandatory clearing requirement if a DCO existed to clear the contract, and requested greater clarity as to possible solutions the Commission will consider to encourage DCOs to begin clearing a new class of swaps.

The Commission does not think it would be prudent to have a set frequency of Commission-initiated reviews at this time. The Commission anticipates that the initial mandatory clearing determinations would only involve swaps that are either already being cleared or that a DCO wants to clear. Once those determinations are made, the Commission will be in a better position to assess that portion of the swaps market that remains uncleared. The Commission can confirm that it will use the same criteria to assess a swap for both Commission-initiated and DCO-submitted reviews, and encourages all parties to make recommendations as to swaps that would be appropriate for a Commission-initiated review. Finally, the Commission notes that, under Regulation 39.5(c)(3), for any swap that would otherwise be subject to a clearing requirement except that no DCO has accepted it for clearing, the Commission may "take such actions as the Commission determines to be necessary and in the public interest * * *," and it will make such determinations on a case-by-case basis, after taking into

consideration any comments received pursuant to the 30-day public comment period provided for in Regulation 39.5(c)(2).

I. Capital and Margin Requirements for Uncleared Swaps

Regulation 39.5(c)(3)(iii) provides that, if the Commission identifies a swap or group, category, type, or class of swaps that would otherwise be subject to a clearing requirement except that no DCO has accepted it for clearing, the Commission may take such actions as it "determines to be necessary and in the public interest, which may include requiring the retaining of adequate margin or capital by parties to the swap, group, category, type, or class of swaps." This language is taken directly from Section 723(a)(3) of the Dodd-Frank Act.¹⁰

ISDA sought clarification that the Commission's authority is restricted to requiring the retention of adequate margin or capital only for swap transactions that are not otherwise exempt from the clearing requirements. First, the Commission notes that, with respect to swap dealers and major swap participants, it will not impose margin or capital requirements under Regulation 39.5(c)(iii) that differ from final Commission regulations on margin or capital for uncleared swaps.¹¹ Further, the Commission does not foresee that it would take action under Regulation 39.5(c)(3)(iii) to impose margin or capital requirements on any swap counterparty permitted, under final Commission regulations, to exercise the end-user exception to mandatory clearing of swaps.¹²

J. Stay of Clearing Requirement

Under Regulation 39.5(d), after making a determination that a swap or group, category, type, or class of swaps is required to be cleared, the Commission, on application of a counterparty to a swap or on its own initiative, may stay the clearing

¹⁰ Section 731 of the Dodd-Frank Act (Section 4s(e)(1) of the CEA) requires rules imposing capital and margin for bank swap dealers and bank major swap participants to be set jointly by prudential regulators and gives the Commission authority to adopt rules imposing capital and margin for non-bank swap dealers and non-bank major swap participants. The Commission would consult with the prudential regulators before taking action under Regulation 39.5(c)(3)(iii).

¹¹ The Commission has proposed margin and capital requirements for certain swap dealers and major swap participants. See 76 FR 23732 (Apr. 28, 2011) (Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants) and 76 FR 27802 (May 12, 2011) (Capital Requirements of Swap Dealers and Major Swap Participants).

¹² The Commission has proposed requirements governing the end-user exception to mandatory clearing of swaps. See 75 FR 80747 (Dec. 23, 2010).

requirement until it completes a review of the terms of the swap and the clearing arrangement. Upon completion of the review, the Commission could determine, subject to any terms or conditions as the Commission determines to be appropriate, that the swap must be cleared, or that the clearing requirement will not apply but clearing may continue on a non-mandatory basis.

FHLB suggested that the right to request a stay would be more meaningful for market participants if the regulation enumerated certain factors that the Commission will consider in granting such a stay or an exemption from the clearing requirement. FHLB recommended that the Commission consider the following factors: DCO credit risk, lack of relationships with DCO clearing members, and unique/special characteristics of transactions.

The FSR noted that there is no discussion in the Dodd-Frank Act or the notice of proposed rulemaking with respect to the time period for the issuance of the stay after an application has been made and believes a delay in the issuance of such a stay would defeat the purpose of the mechanism, especially in circumstances where complying with a mandatory clearing requirement may not be feasible. The FSR encouraged the Commission to adopt a policy to issue a stay within one business day of any request for a stay, unless the request on its face appears to be frivolous, so as to avoid any lengthy market disruption while the Commission determines whether the stay should be granted. Additionally, because the Commission may stay a mandatory clearing requirement on its own initiative, the FSR recommended that the Commission allow DCOs, DCMs, and SEFs to request a stay, because these entities will be in key positions to identify developing market disturbances related to mandatory clearing.

Mr. Greenberger commented that a counterparty's written request for a stay should be very specific and the involvement of the DCO in aiding the investigation should be substantial.

ISDA suggested that the clearing requirement should be stayed in the following circumstances: In the absence of competition; when there is an unresolved clearing member default at the only DCO then clearing the relevant product; when no DCO has elected to clear the product; or when a product becomes so illiquid as to threaten the DCO's ability to calculate margin or manage defaults.

The Commission does not believe it would be prudent to enumerate the

factors that it would consider in determining whether to stay a clearing requirement. Doing so could potentially limit the Commission's ability to respond to unforeseen or unusual circumstances. Likewise, the Commission is declining to adopt a deadline by which it must respond to a request for a stay. The Commission would respond to such requests in a timely manner and, if any situation developed that would necessitate the immediate staying of a clearing requirement, the Commission would not be required to await a request for a stay in order to take action. Finally, the Commission notes that it would expect to consult with DCOs, DCMs, and SEFs as appropriate before it would stay a clearing requirement.

K. Additional Comments

The Commission received many comments that did not pertain to the aspects of the regulations discussed above. In particular, many of these comments related to the clearing of swaps in general, rather than the process for review of swaps for mandatory clearing.

ABC expressed concern that, if a clearing mandate is too broad, entities could be precluded from customizing swaps to hedge very specific risks. ABC encouraged the Commission to clarify that it would not constitute illegal evasion for an entity to enter into a swap that would be subject to a clearing mandate but for the fact that the swap contains a unique tailored term adopted for a bona fide business or investment reason, even if that term prevented the swap from being accepted for clearing by any DCO.

The Coalition for Derivatives End-Users urged the Commission to avoid regulations that would serve to discourage end-users from using customized transactions, and thereby preserve end-users' ability to enter into transactions that are tailored to meet specific economic and accounting objectives.

The FSR stated that the need to establish appropriate hedges may require financial entities to enter into transactions that are similar to swaps that are subject to a mandatory clearing requirement, but are not themselves eligible for clearing. In such circumstances, the FSR believes the presumption should be that the terms of the swap were determined to support the hedge and not to evade the mandatory clearing requirement. In addition, the FSR encouraged the Commission to provide exemptions from the clearing requirement for any swaps entered into prior to the adoption

of the relevant clearing requirement due to the costs and burdens involved in transitioning swaps into a clearing arrangement, especially where such swaps have terms that differ from the standardized terms established by the DCO for cleared swaps. Lastly, the FSR expressed its belief that the Commission needs to address whether entering into amendments to, and assignments and novations of, existing swap transactions will be considered to be "engaging in a swap," which could require them to be cleared.

Freddie Mac urged that the Commission should clarify that the Dodd-Frank Act requires parties to a swap subject to the clearing requirement to submit a swap for clearing but does not require parties to terminate or unwind swaps that fail to clear. Freddie Mac believes that the uncertainty of whether a swap may be terminated after execution would increase systemic risk and that allowing uncleared swaps subject to mandatory clearing to become OTC swaps would reduce uncertainty and not substantially increase systemic risk.

The Financial Services Agency of the Government of Japan asked the Commission to confirm that, as the Commission phases in the central clearing requirement, it would only be applied if both parties of such swaps are U.S. institutions. If this treatment could not be made permanent, at the very least they would formally request that such a transitional arrangement be made until the end of 2012.

NCGA and NGSF stated that the Commission should clarify in its final rule that, after the mandatory clearing provisions go into effect, a determination that a swap is required to be cleared will not apply retroactively to swaps that are open as of the date of such determination. They believe that retroactive application would impose substantial undue logistical burdens and transactional costs on market participants by requiring them to reexamine their portfolios each time a new determination is made and then arrange with counterparties to have affected swaps transferred for clearing.

NMPF recommended that the process for reviewing swaps for mandatory clearing not be so heavily weighted toward a determination that swaps be mandatorily cleared. NMPF believes that DCOs have an interest in such a determination, and will have the preponderance of input in a 90-day determination process. Thus NMPF believes that weight must be put on the other side for the process to be fair.

In addition to the comments discussed above, the Commission

received multiple comments recommending that the Commission exempt interaffiliate transactions from mandatory clearing, and offering thoughts on how the Commission should implement a clearing requirement. The Commission notes that all of these comments go beyond the limited scope of these regulations, and it will consider how to address them outside of this rulemaking.

L. Effective Date

Upon the effective date of this rule: (1) Any swap or group, category, type, or class of swaps listed for clearing by a DCO shall be considered submitted to the Commission, in accordance with Section 2(h)(2)(B)(ii) of the CEA; (2) the Commission will review the submissions and make the required determinations under Sections 2(h)(2)(B)(iii), (C), and (D); (3) the Commission may initiate its own reviews under Section 2(h)(2)(A); and (4) DCOs shall submit swaps that they plan to accept for clearing under Section 2(h)(2)(B)(i), and the Commission will review the submissions and make the required determinations under Sections 2(h)(2)(B)(iii), (C), and (D).

III. Cost-Benefit Considerations

Section 15(a) of the CEA¹³ requires the Commission to consider the costs and benefits of its action before promulgating a regulation under the CEA. Section 15(a) specifies that costs and benefits shall be evaluated in light of 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. In conducting its analysis, the Commission may, in its discretion, give greater weight to any one of the five enumerated areas and it may determine that, notwithstanding its costs, a particular rule is necessary to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.¹⁴

The Commission invited but did not receive public comments specific to its cost-benefit estimates and considerations within the initial comment period following the publication of the Commission's notice of proposed rulemaking. The

Commission also invited the public "to submit any data or other information that [it] may have quantifying or qualifying the costs and benefits of the proposal with their comment letters." The Commission received no such data or other information. The Commission did, however, receive comments generally discussing the "burden" associated with the submission process proposed in this regulation.

The Commission has considered the costs and the benefits of these final regulations, as amended below, in light of each area of public concern specified in Section 15(a) of the CEA. In this regard, the Commission would like to note that it has discussed the costs and benefits of its regulations throughout the narrative discussion of its regulations above and generally views the cost-benefit considerations of this final rulemaking to be an extension of that discussion. The Commission would also like to note that its Paperwork Reduction Act estimates have informed its analysis of the costs of the final regulations and that any information collection costs have been considered an important component of the overall compliance costs associated with final Regulation 39.5.

Consideration of the five broad areas is set out immediately below, followed by a discussion of the comments received in response to the proposal that relate to the costs and benefits of the regulations. The Commission has determined that the public benefits associated with each of its final regulations promulgated in this release outweigh the costs.

1. Protection of Market Participants and the Public

This regulation provides an orderly framework for determining the eligibility of a DCO to clear swaps that it plans to accept for clearing; for DCOs submitting swaps to the Commission for review; for Commission-initiated reviews of swaps; and for staying a clearing requirement. An orderly framework for such a review and determination reduces uncertainty while collecting relevant information in order to make an informed decision, which protects all market participants.

Maintaining the Commission's prerogative to engage in Commission-initiated reviews may also enhance risk management for the financial system as a whole because it will encourage parties to swap transactions to seek to have their swaps cleared, rather than face the uncertainty of not knowing what action the Commission may take at the conclusion of its review.

Lastly, the notice of proposed rulemaking required DCOs to include various types of information in their submissions, including an analysis of the effect of a clearing requirement on the market "including the potential effect on market liquidity, trading activity, use of swaps by direct and indirect market participants, and any potential market disruption." This final regulation eliminates some of these requirements, thereby transferring the responsibility to collect and analyze this information to the Commission. The Commission has determined that this approach will provide the same benefits to market participants and the public while being less costly for DCOs.

2. Efficiency, Competitiveness, and Financial Integrity of the Markets

The final regulations require a DCO to submit swaps to the Commission "to the extent reasonable and practicable to do so, by group, category, type or class of swaps." The Commission believes this will make the review process more efficient, allowing the Commission to move more swaps into clearing quickly, which in turn will promote clarity in the markets and contribute to their efficiency and integrity.

The final regulations also provide an opportunity for the public to comment on DCO submissions and require DCOs to relay both negative and positive feedback they receive from market participants. To the extent that the feedback summarized by DCOs is complete and accurate or that the public submits feedback directly to the Commission, this provides ample opportunity for broad input into mandatory clearing decisions. This greater transparency and public participation increases the likelihood that all important costs and benefits of mandatory clearing will be identified and weighed by the Commission.

3. Price Discovery

The process outlined in the regulations will move more swaps into clearing, which will facilitate price discovery in the swap markets.

4. Sound Risk Management Procedures

The proposed regulations also required DCOs to obtain independent validation of the scalability of their "risk management policies, systems, and procedures, including the margin methodology, settlement procedures, and default management procedures." The Commission finds that this would increase cost to DCOs and has determined that there is an alternative that will be less costly and will likely achieve similar benefits. Specifically,

¹³ 7 U.S.C. 19(a).

¹⁴ See, e.g., *Fisherman's Doc Co-op., Inc v. Brown*, 75 F.3d 164 (4th Cir. 1996); *Center for Auto Safety v. Peck*, 751 F.2d 1336 (DC Cir. 1985) (noting that an agency has discretion to weigh factors in undertaking cost-benefit analysis).

DCOs will be required to evaluate the scalability of their risk management policies, systems, and procedures to comply with the DCO core principles and additional proposed risk management regulations that may be promulgated.

5. Other Public Interest Considerations

An orderly framework for the review of swaps and determination on mandatory clearing will facilitate moving swaps quickly into clearing, which is likely to reduce risk to the financial system.

Public comments. In its notice of proposed rulemaking, the Commission solicited comment from the public.¹⁵ Comments relating to costs and benefits are summarized below, together with corresponding responses.

The National Milk Producers Federation suggested that small farmers will bear a disproportionate share of the costs associated with mandatory clearing. The subject of this rulemaking is not the costs to small farmers associated with mandatory clearing but the process a DCO must follow in order to submit a swap or group, category, type, or class of swaps to the Commission for a determination as to whether the swap must be cleared. Moreover, the National Milk Producers Federation did not specify how and to what extent this disproportionate cost will manifest itself. In this final regulation, the Commission has determined that an orderly review of swaps, a review mandated by Congress, reduces risk and increases certainty and therefore will reduce costs by making sure such swaps are quickly and properly vetted. Furthermore, the Commission has considered these concerns and believes that they should be addressed as each swap or group, category, type, or class of swaps is considered for mandatory clearing. The regulations create an opportunity for these concerns to be raised by the public for a period of 30 days as each swap submission is being reviewed. If there are particular swaps for which members of the public believe this concern is relevant, they are encouraged to bring that to the Commission's attention during the public comment period and these factors will be weighed as decisions about mandatory clearing are made. In addition, the Commission has proposed separate regulations that create an exception to mandatory clearing for end users, which may address some of these concerns.

CME commented that the information required in the proposed regulations

would be costly for the DCOs to gather and analyze. This concern has been addressed in the final regulations by eliminating the requirements that DCOs submit independent validation of the scalability of their risk management policies, systems, and procedures, and by eliminating the requirement that DCOs conduct an analysis of the effect of a clearing requirement on the market. The final regulations now only require the submission of some of the information that the Commission assumes a DCO would have gathered and considered in making its own decision to accept a particular swap for clearing.

The Coalition for Derivative End-Users, expressed concern that central clearing and required margins for cleared swaps will be expensive for market participants and could be considered an inefficient use of resources. These comments are beyond the scope of this rule, which focuses exclusively on the process for reviewing swaps.

The Coalition for Derivative End-Users also expressed concern that the indirect as well as the direct costs of mandatory clearing should be considered when reviewing swaps. The Commission agrees that it is important to take the full range of costs as well as the benefits into account when considering mandatory clearing of a swap. As previously noted, the regulations establish a public comment process through which those costs and benefits may be raised and given due consideration. If there are any ancillary costs related to mandatory clearing of a specific swap or group, category, type, or class of swaps that the public believes are either unlikely to be recognized or particularly problematic, the Commission encourages comments to that effect. Comments that quantify the referenced costs or that offer specific scenarios are particularly helpful in that regard.

The Coalition for Derivative End-Users further suggested that the high cost to a DCO of submitting a swap to the Commission will put U.S.-based DCOs at a competitive disadvantage to foreign DCOs. The Coalition for Derivative End-Users did not illustrate how and to what extent a U.S.-based DCO will be disadvantaged nor specify to what extent non-U.S.-based DCOs offer the similar functionality, liquidity or risk profiles in comparison to U.S.-based DCOs. However, concerns over the costs of submission have been addressed in the final regulations by reducing the DCO's submission requirements and the attendant costs.

Freddie Mac expressed concern that uncertainty about whether swaps that are rejected for clearing by DCOs have to be unwound could generate losses for organizations using those swaps for hedging purposes. This concern goes beyond the limited scope of these regulations, and the Commission will consider how to address it outside of this rulemaking.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires Federal agencies, in promulgating rules, to consider whether those rules will have a significant economic impact on a substantial number of small entities and, if so, provide a regulatory flexibility analysis respecting the impact.¹⁶ The rules adopted herein will affect DCOs. The Commission has previously established certain definitions of "small entities" to be used by the Commission in evaluating the impact of its rules on small entities in accordance with the RFA.¹⁷ The Commission has previously determined that DCOs are not small entities for the purpose of the RFA.¹⁸ Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that these rules will not have a significant economic impact on a substantial number of small entities. The Chairman made the same certification in the proposed rulemaking,¹⁹ and the Commission did not receive any comments on the RFA in relation to the proposed rulemaking.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA)²⁰ 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 rulemaking imposes new collection of information requirements within the meaning of the PRA. Accordingly, the Commission requested, but the Office of Management and Budget (OMB) has not yet assigned, a control number for the new collection of information. However, OMB has assigned the reference number 201011-3038-002 in the interim. The

¹⁶ 5 U.S.C. 601 *et seq.*

¹⁷ 47 FR 18618 (Apr. 30, 1982).

¹⁸ See 66 FR 45605, 45609 (August 29, 2001).

¹⁹ See 75 FR 67277, 67280 (Nov. 2, 2010).

²⁰ 44 U.S.C. 3501 *et seq.*

¹⁵ See 75 FR 67277, 67278 (Nov. 2, 2010).

Commission has submitted this final rule along with supporting documentation for OMB's review. Responses to this collection of information will be mandatory.

The Commission will protect proprietary information according to the Freedom of Information Act and 17 CFR part 145, "Commission Records and Information." In addition, section 8(a)(1) of the CEA strictly prohibits the Commission, unless specifically authorized by the CEA, from making public "data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers." The Commission is also required to protect certain information contained in a government system of records according to the Privacy Act of 1974, 5 U.S.C. 552a.

1. Information Provided by Reporting Entities/Persons

These regulations require DCOs to collect and submit to the Commission information concerning swaps they plan to accept for clearing. The Commission is adopting these information collection requirements in order to give effect to certain provisions of the Dodd-Frank Act.

Each DCO will determine for itself whether and how often it will accept a new swap or group, category, type, or class of swaps for clearing, which will require a submission of the required information to the Commission. The regulations direct DCOs to submit swaps to the Commission, to the extent reasonable and practicable to do so, by group, category, type, or class of swaps, thereby reducing the number of submissions a DCO would be required to make. The Commission's notice of proposed rulemaking therefore estimated one annual response per respondent. Commission staff estimated that each DCO would expend 40 hours to prepare each filing required under the proposed regulations, which was estimated based on the Commission's prior experience with DCOs and their preparation of filings for the Commission's review. This burden may be reduced under the final regulations, which do not require a DCO to include as much information in its submission as the proposed regulations would have. Commission staff estimated that it would receive filings from up to 12 respondents annually, which assumes that each DCO would make an average of one filing per year. Accordingly, the burden in terms of hours would in the aggregate be 40 hours annually per respondent and 480 hours annually for all respondents.

Commission staff estimated that each respondent could expend up to \$4000 annually, based on an hourly wage rate of \$100, to comply with the proposed regulations. This would result in an aggregated cost of \$48,000 per annum (12 respondents $\times$ \$4,000).

2. Information Collection Comments

The Commission did not receive any comments on the PRA in relation to the proposed rulemaking.

List of Subjects

17 CFR Part 39

Business and industry, Commodity futures, Reporting and recordkeeping requirements.

17 CFR Part 140

Authority delegations (Government agencies), Conflict of interests, Organization and functions (Government agencies).

For the reasons stated in the preamble, amend 17 CFR parts 39 and 140 as follows:

PART 39—DERIVATIVES CLEARING ORGANIZATIONS

■ 1. The authority citation for part 39 is revised to read as follows:

Authority: 7 U.S.C. 7a–1 as amended by Pub. L. 111–203, 124 Stat. 1376.

■ 2. Redesignate § 39.5 as § 39.8 and add new § 39.5 to read as follows:

§ 39.5 Review of swaps for Commission determination on clearing requirement.

(a) *Eligibility to clear swaps.* (1) A derivatives clearing organization shall be presumed eligible to accept for clearing any swap that is within a group, category, type, or class of swaps that the derivatives clearing organization already clears. Such presumption of eligibility, however, is subject to review by the Commission.

(2) A derivatives clearing organization that wishes to accept for clearing any swap that is not within a group, category, type, or class of swaps that the derivatives clearing organization already clears shall request a determination by the Commission of the derivatives clearing organization's eligibility to clear such a swap before accepting the swap for clearing. The request, which shall be filed electronically with the Secretary of the Commission, shall address the derivatives clearing organization's ability, if it accepts the swap for clearing, to maintain compliance with section 5b(c)(2) of the Act, specifically:

(i) The sufficiency of the derivatives clearing organization's financial resources; and

(ii) The derivative clearing organization's ability to manage the risks associated with clearing the swap, especially if the Commission determines that the swap is required to be cleared.

(b) *Swap submissions.* (1) A derivatives clearing organization shall submit to the Commission each swap, or any group, category, type, or class of swaps that it plans to accept for clearing. The derivatives clearing organization making the submission must be eligible under paragraph (a) of this section to accept for clearing the submitted swap, or group, category, type, or class of swaps.

(2) A derivatives clearing organization shall submit swaps to the Commission, to the extent reasonable and practicable to do so, by group, category, type, or class of swaps. The Commission may in its reasonable discretion consolidate multiple submissions from one derivatives clearing organization or subdivide a derivatives clearing organization's submission as appropriate for review.

(3) The submission shall be filed electronically with the Secretary of the Commission and shall include:

(i) A statement that the derivatives clearing organization is eligible to accept the swap, or group, category, type, or class of swaps for clearing and describes the extent to which, if the Commission were to determine that the swap, or group, category, type, or class of swaps is required to be cleared, the derivatives clearing organization will be able to maintain compliance with section 5b(c)(2) of the Act;

(ii) A statement that includes, but is not limited to, information that will assist the Commission in making a quantitative and qualitative assessment of the following factors:

(A) The existence of significant outstanding notional exposures, trading liquidity, and adequate pricing data;

(B) The availability of rule framework, capacity, operational expertise and resources, and credit support infrastructure to clear the contract on terms that are consistent with the material terms and trading conventions on which the contract is then traded;

(C) The effect on the mitigation of systemic risk, taking into account the size of the market for such contract and the resources of the derivatives clearing organization available to clear the contract;

(D) The effect on competition, including appropriate fees and charges applied to clearing; and

(E) The existence of reasonable legal certainty in the event of the insolvency of the relevant derivatives clearing organization or one or more of its

clearing members with regard to the treatment of customer and swap counterparty positions, funds, and property;

(iii) Product specifications, including copies of any standardized legal documentation, generally accepted contract terms, standard practices for managing any life cycle events associated with the swap, and the extent to which the swap is electronically confirmable;

(iv) Participant eligibility standards, if different from the derivatives clearing organization's general participant eligibility standards;

(v) Pricing sources, models, and procedures, demonstrating an ability to obtain sufficient price data to measure credit exposures in a timely and accurate manner, including any agreements with clearing members to provide price data and copies of executed agreements with third-party price vendors, and information about any price reference index used, such as the name of the index, the source that calculates it, the methodology used to calculate the price reference index and how often it is calculated, and when and where it is published publicly;

(vi) Risk management procedures, including measurement and monitoring of credit exposures, initial and variation margin methodology, methodologies for stress testing and back testing, settlement procedures, and default management procedures;

(vii) Applicable rules, manuals, policies, or procedures;

(viii) A description of the manner in which the derivatives clearing organization has provided notice of the submission to its members and a summary of any views on the submission expressed by the members (a copy of the notice to members shall be included with the submission); and

(ix) Any additional information specifically requested by the Commission.

(4) The Commission must have received the submission by the open of business on the business day preceding the acceptance of the swap, or group, category, type, or class of swaps for clearing.

(5) The submission will be made available to the public and posted on the Commission Web site for a 30-day public comment period. A derivatives clearing organization that wishes to request confidential treatment for portions of its submission may do so in accordance with the procedures set out in § 145.9(d) of this chapter.

(6) The Commission will review the submission and determine whether the swap, or group, category, type, or class

of swaps described in the submission is required to be cleared. The Commission will make its determination not later than 90 days after a complete submission has been received, unless the submitting derivatives clearing organization agrees to an extension. The determination of when such submission is complete shall be at the sole discretion of the Commission. In making a determination that a clearing requirement shall apply, the Commission may impose such terms and conditions to the clearing requirement as the Commission determines to be appropriate.

(c) *Commission-initiated reviews.* (1) The Commission, on an ongoing basis, will review swaps that have not been accepted for clearing by a derivatives clearing organization to make a determination as to whether the swaps should be required to be cleared. In undertaking such reviews, the Commission will use information obtained pursuant to Commission regulations from swap data repositories, swap dealers, and major swap participants, and any other available information.

(2) Notice regarding any determination made under paragraph (c)(1) of this section will be made available to the public and posted on the Commission Web site for a 30-day public comment period.

(3) If no derivatives clearing organization has accepted for clearing a particular swap, group, category, type, or class of swaps that the Commission finds would otherwise be subject to a clearing requirement, the Commission will:

(i) Investigate the relevant facts and circumstances;

(ii) Within 30 days of the completion of its investigation, issue a public report containing the results of the investigation; and

(iii) Take such actions as the Commission determines to be necessary and in the public interest, which may include requiring the retaining of adequate margin or capital by parties to the swap, group, category, type, or class of swaps.

(d) *Stay of clearing requirement.* (1) After making a determination that a swap, or group, category, type, or class of swaps is required to be cleared, the Commission, on application of a counterparty to a swap or on its own initiative, may stay the clearing requirement until the Commission completes a review of the terms of the swap, or group, category, type, or class of swaps and the clearing arrangement.

(2) A counterparty to a swap that wishes to apply for a stay of the clearing

requirement for that swap shall submit a written request to the Secretary of the Commission that includes:

(i) The identity and contact information of the counterparty to the swap;

(ii) The terms of the swap subject to the clearing requirement;

(iii) The name of the derivatives clearing organization clearing the swap;

(iv) A description of the clearing arrangement; and

(v) A statement explaining why the swap should not be subject to a clearing requirement.

(3) A derivatives clearing organization that has accepted for clearing a swap, or group, category, type, or class of swaps that is subject to a stay of the clearing requirement shall provide any information requested by the Commission in the course of its review.

(4) The Commission will complete its review not later than 90 days after issuance of the stay, unless the derivatives clearing organization that clears the swap, or group, category, type, or class of swaps agrees to an extension.

(5) Upon completion of its review, the Commission may:

(i) Determine, subject to any terms and conditions as the Commission determines to be appropriate, that the swap, or group, category, type, or class of swaps must be cleared; or

(ii) Determine that the clearing requirement will not apply to the swap, or group, category, type, or class of swaps, but clearing may continue on a non-mandatory basis.

PART 140—ORGANIZATION, FUNCTIONS, AND PROCEDURES OF THE COMMISSION

■ 3. The authority citation for part 140 continues to read as follows:

Authority: 7 U.S.C. 2 and 12a.

■ 4. In § 140.94, revise paragraph (a)(5) and add new paragraph (a)(6) to read as follows:

§ 140.94 Delegation of authority to the Director of the Division of Clearing and Intermediary Oversight.

(a) * * *

(5) All functions reserved to the Commission in § 5.14 of this chapter; and

(6) All functions reserved to the Commission in §§ 39.5(b)(2) and (d)(3) of this chapter.

* * * * *

Issued in Washington, DC, on July 19, 2011, by the Commission.

David A. Stawick,

Secretary of the Commission.

Appendices to Process for Review of Swaps for Mandatory Clearing—Commission Voting Summary and Statements of Commissioners

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

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Dunn, Sommers, Chilton and O'Malia voted in the affirmative; no Commissioner voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler

I support the final rulemaking to establish a process for the review and designation of swaps for mandatory clearing. One of the primary goals of the Dodd-Frank Wall Street Reform and Consumer Protection Act was to lower risk by requiring standardized swaps to be centrally cleared. The final rule is consistent with the congressional requirement that derivatives clearing organizations be eligible to clear swaps and that the public has an opportunity for input before a swap is subject to mandatory clearing.

[FR Doc. 2011-18663 Filed 7-25-11; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 341

[Docket No. FDA-1995-N-0031 (Formerly Docket No. 1995N-0205)]

RIN 0910-AF32

Labeling for Bronchodilators To Treat Asthma; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the final monograph (FM) for over-the-counter (OTC) bronchodilator drug products to add additional warnings (e.g., an "Asthma alert") and to revise the indications, warnings, and directions in the labeling of products

containing the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, epinephrine, epinephrine bitartrate, racephedrine hydrochloride, and racepinephrine hydrochloride. FDA is issuing this final rule after considering data and information submitted in response to the Agency's proposed labeling revisions for these products. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: *Effective Date:* This regulation is effective January 23, 2012.

Compliance Date: The compliance date for all products, regardless of annual sales, is January 23, 2012.

FOR FURTHER INFORMATION CONTACT:

Elaine Abraham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5410, Silver Spring, MD 20993, 301-796-2090.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Changes to the Labeling of OTC Drug Products Used To Treat Asthma
- II. History of the Development of the 1986 Final Monograph
- III. Amendments to the 1986 Final Monograph Proposed by FDA
- IV. FDA's Response to Comments Received About the Proposed Labeling Changes
- V. Additional Consumer-Friendly Changes FDA Made to the Labeling
- VI. FDA's Final Conclusions on Warnings and Other Labeling Information for OTC Bronchodilator Drug Products
 - A. Implementation Date for New Labeling
 - B. Statement About Warnings
- VII. Analysis of Impacts
 - A. Introduction and Summary
 1. Introduction
 2. Summary
 - B. Need for Regulation
 - C. Benefits
 - D. Costs
 1. Relabeling Costs
 2. Switching Costs
 3. Estimated Total Costs
 - E. Summary of Costs and Benefits
 - F. Analysis of Regulatory Alternatives to the Final Rule
 - G. Regulatory Flexibility Analysis
 1. Description and Number of Affected Small Entities
 2. Economic Effect on Small Entities
 3. Additional Flexibility Considered
- VIII. Paperwork Reduction Act of 1995
- IX. Environmental Impact
- X. Federalism
- XI. References

I. Changes to the Labeling of OTC Drug Products Used To Treat Asthma

This rulemaking amends the FM for OTC bronchodilator drug products used to treat asthma. The "Indications," "Warnings" and "Directions" portions of the Drug Facts label are being changed to help consumers better

understand how to use these products and when it is appropriate to seek treatment from a doctor for their asthma. The "Indications" section now recommends use only for temporary relief of mild symptoms of intermittent asthma. Changes to both the "Warnings" and "Directions" sections emphasize that consumers should not exceed the recommended dose or duration of use with these drug products. The "Warnings" section is being changed to make it clearer that consumers whose symptoms worsen or do not improve should see a doctor. The "Indications," "Warnings" and "Directions" portions of the Drug Facts label have also been revised to use language that is more readily understood by the average consumer.

II. History of the Development of the 1986 Final Monograph

In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published an advance notice of proposed rulemaking (ANPR) under 21 CFR 330.10(a)(6) to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. The ANPR included the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel), the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The Panel recommended that ephedrine and epinephrine preparations be placed in Category I (generally recognized as safe and effective or GRASE) for OTC bronchodilator use (41 FR 38312 at 38370 through 38372).

FDA concurred with the Panel's recommendations and subsequently published the proposed rule in the **Federal Register** of October 26, 1982, (47 FR 47520) and the FM for OTC bronchodilator drug products in the **Federal Register** of October 2, 1986, (51 FR 35326). FDA included the following active ingredients in the FM:

- "Ephedrine ingredients" (*i.e.*, ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride)
- "Epinephrine ingredients" (*i.e.*, epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride)

In subsequent rulemaking documents for this category, including this final rule, the term "ephedrine ingredients" refers to the four active ephedrine ingredients, the term "epinephrine ingredients" refers to the three active epinephrine ingredients, and the term "OTC bronchodilator drug products"