

except airplanes on which Airbus Modification 35869 has been embodied in production.

(1) Airbus Model A318-111, -112, -121, and -122 airplanes.

(2) Airbus Model A319-111, -112, -113, -114, -115, -131, -132, and -133 airplanes.

(3) Airbus Model A320-211, -212, -214, -231, -232, and -233 airplanes.

(4) Airbus Model A321-111, -112, -131, -211, -212, -213, -231, and -232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Reason

This AD was prompted by a report of cracks found during maintenance inspections on certain lugs of the 10VU rack side fittings in the cockpit. We are issuing this AD to prevent reading difficulties of flight-critical information displayed to the flightcrew during a critical phase of flight, such as an approach or takeoff, which could result in loss of airplane control at an altitude insufficient for recovery.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections and Repair

At the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD: Do a detailed inspection for cracking of the lugs on the 10VU rack side fittings in the cockpit, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-92-1087, Revision 02, dated November 25, 2014. If any crack is found, before further flight, repair in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-92-1087, Revision 02, dated November 25, 2014. Repeat the inspection thereafter at intervals not to exceed 20,000 flight cycles or 40,000 flight hours, whichever occurs first. Repair of the 10VU rack lugs does not terminate the repetitive inspections required by this paragraph.

(1) Before the accumulation of 30,000 total flight cycles or 60,000 total flight hours, whichever occurs first since the airplane's first flight.

(2) Within 24 months after the effective date of this AD.

(h) Reporting Requirement

Submit a report of any findings (positive and negative) of any inspection required by paragraph (g) of this AD to Airbus Service Bulletin Reporting Online Application on Airbus World (<https://w3.airbus.com/>), at the applicable time specified in paragraph (h)(1) or (h)(2) of this AD. Where Figure A-FRAAA—Sheet 02, titled "Inspection Report," of Airbus Service Bulletin A320-92-1087, Revision 02, dated November 25, 2014, specifies sending removed lugs to Airbus for investigation, this AD does not include that requirement. The form contained in Figure A-FRAAA—Sheet 02, titled "Inspection Report," of Airbus Service Bulletin A320-92-1087, Revision 02, dated

November 25, 2014, may be used to meet this reporting requirement.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 90 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 90 days after the effective date of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1405; fax 425-227-1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer*: 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 the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements*: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(4) *Required for Compliance (RC)*: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those

procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) Airworthiness Directive 2015-0170, dated August 18, 2015, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-8132.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Service Bulletin A320-92-1087, Revision 02, dated November 25, 2014.

(ii) Reserved.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 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; Internet <http://www.airbus.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.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on September 14, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Order Establishing De Minimis Threshold Phase-In Termination Date

AGENCY: Commodity Futures Trading Commission.

ACTION: Order.

SUMMARY: With respect to the *de minimis* exception to the swap dealer definition, the Commodity Futures Trading Commission (“Commission” or “CFTC”) is issuing an order (“Order”), pursuant to the applicable Commission regulation, to establish December 31, 2018 as the *de minimis* threshold phase-in termination date.

DATES: Issued October 13, 2016.

FOR FURTHER INFORMATION CONTACT:

Eileen T. Flaherty, Director, 202–418–5326, eflaherty@cftc.gov; Erik Remmler, Deputy Director, 202–418–7630, eremmler@cftc.gov; Lauren Bennett, Special Counsel, 202–418–5290, lbennett@cftc.gov; Margo Dey, Special Counsel, 202–418–5276, mdey@cftc.gov; or Rajal Patel, Special Counsel, 202–418–5261, rpatel@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

A. Statutory and Regulatory Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”)¹ directed the CFTC and the U.S. Securities and Exchange Commission (“SEC” and together with the CFTC, “Commissions”) to jointly further define the term “swap dealer” and to include therein a *de minimis* exception.² The CFTC’s further definition of swap dealer is provided in Regulation 1.3(ggg). The *de minimis* exception therein provides that a person shall not be deemed to be a swap dealer unless its swap dealing activity exceeds an aggregate gross notional amount threshold of \$3 billion (measured over the prior 12-month period), subject to a phase-in period during which the gross notional amount threshold is set at \$8 billion.³ Absent further action by the Commission, the phase-in period would

terminate on December 31, 2017, at which time the *de minimis* threshold would decrease to \$3 billion.⁴ This would require firms to start tracking their swap activity beginning January 1, 2017 to determine whether their dealing activity over the course of that year would require them to register as swap dealers.

When the \$3 billion *de minimis* exception was established, the Commissions explained that the information then available regarding certain portions of the swap market was limited in certain respects, and that they expected that the implementation of swap data reporting may enable reassessment of the *de minimis* exception.⁵ Accordingly, the Commission adopted Regulation 1.3(ggg)(4), which directed CFTC staff to issue a report, after a specified period of time, on topics relating to the *de minimis* exception “as appropriate, based on the availability of data and information.”⁶ Regulation 1.3(ggg)(4) further provides that after giving due consideration to the report and any associated public comment, the Commission may issue an order to establish a termination date for the phase-in period or propose through rulemaking modifications to the *de minimis* exception.

B. Staff Reports

Staff issued for public comment a preliminary report concerning the *de minimis* exception on November 18, 2015 (“Preliminary Report”).⁷ After consideration of the public comments received, and further data analysis, staff issued the Swap Dealer *De Minimis* Exception Final Staff Report⁸ on August 15, 2016 (“Final Report,” and together with the Preliminary Report, “Staff Reports”). The Staff Reports analyzed the available swap data⁹ in conjunction with relevant policy considerations to assess alternative *de minimis* threshold

levels and other potential changes to the *de minimis* exception.

C. Swap Data Analysis

As discussed in the Staff Reports, the lack of certain metrics needed for evaluating different *de minimis* thresholds, as well as data validity issues, limited the analysis of the potential impact of changes to the current *de minimis* exception.¹⁰ The Final Report further noted that, notwithstanding these data issues, the quality of the swap data that is reported to the Commission appears to be continually improving, and that the Commission is taking additional steps to enhance swap data quality.¹¹

The data analysis in the Staff Reports provided some insights into the effectiveness of the *de minimis* exception as currently implemented. Staff analyzed the number of swap transactions involving at least one registered swap dealer, which is indicative of the extent to which swaps are subject to swap dealer regulation at the current \$8 billion threshold. Data reviewed for the Final Report indicated that approximately 96% of all reported swap transactions involved at least one registered swap dealer. When considering individual swap asset classes, approximately 98% or more of swaps in each asset class, other than the Non-Financial Commodity asset class, involved at least one registered swap dealer. Approximately 89% of Non-Financial Commodity swaps involved a registered swap dealer.¹²

However, as discussed above, the data available was not sufficient to assess whether, and to what extent, specific changes to the *de minimis* threshold levels would increase or decrease the coverage of swaps by swap dealer regulation. In particular, the Staff Reports noted that reliable notional amount data was not available for Non-Financial Commodity, Equity, and FX Derivative swaps.

The Commission also notes that it has not yet adopted a regulation on capital requirements for swap dealers, which is a significant component of swap dealer registration. The Commission believes it

¹ Public Law 111–203, 124 Stat. 1376 (2010). The text of the Dodd-Frank Act can be accessed on the Commission’s Web site, at www.cftc.gov.

² See Dodd-Frank Act sections 712(d) and 721. The definition of “swap dealer” can be found in section 1a(49) of the Commodity Exchange Act and as further defined in Regulation 1.3(ggg). 7 U.S.C. 1a(49) and 17 CFR 1.3(ggg). The Commodity Exchange Act is at 7 U.S.C. 1, *et seq.* (2014), and is accessible on the Commission’s Web site, at www.cftc.gov.

³ See 17 CFR 1.3(ggg)(4). See also Further Definition of “Swap Dealer,” “Security-Based Swap Dealer,” “Major Swap Participant,” “Major Security-Based Swap Participant” and “Eligible Contract Participant,” 77 FR 30596 (May 23, 2012).

This Order does not impact the *de minimis* threshold for swaps with “special entities” as defined in the Commodity Exchange Act, section 4s(h)(2)(C), 7 U.S.C. 6s(h)(2)(C).

⁴ See 17 CFR 1.3(ggg)(4)(ii)(D).

⁵ See 77 FR at 30634, 30640.

⁶ SEC Regulation 240.3a71–2A similarly directs SEC staff to prepare a report on the security-based swap dealer *de minimis* exception. 17 CFR 240.3a71–2A.

⁷ Swap Dealer *De Minimis* Exception Preliminary Report (Nov. 18, 2015), available at http://www.cftc.gov/idc/groups/public/@swaps/documents/file/dfreport_sddeminis_1115.pdf.

⁸ Swap Dealer *De Minimis* Exception Final Staff Report (August 15, 2016), available at http://www.cftc.gov/idc/groups/public/@swaps/documents/file/dfreport_sddeminis081516.pdf.

⁹ The data analysis broke down the data into the following asset classes: Interest rate swaps (“IRS”); credit default swaps (“CDS”); non-financial commodity (“Non-Financial Commodity”) swaps; equity (“Equity”) swaps; and foreign exchange derivatives (“FX Derivatives”).

¹⁰ See Preliminary Report at 12–21; Final Report at 4–6, 19–20. For example, the data reported does not indicate whether either counterparty to a swap is acting as a dealer, and there are difficulties in calculating the notional amounts for certain types of swaps in a uniform manner useful for data analysis.

¹¹ See Final Report at 18–19. For example, in June 2016, the Commission finalized amendments related to the reporting of cleared swaps. See Amendments to Swap Data Recordkeeping and Reporting Requirements for Cleared Swaps, 81 FR 41736 (June 27, 2016).

¹² See Final Report at 22.

is prudent to finalize the capital rule before addressing the *de minimis* threshold. In addition, the swap dealer requirements regarding margin for uncleared swaps, another important component of swap dealer registration, are currently being implemented. The Commission believes that a year's delay would allow it to finalize the swap dealer capital rule and assess the implementation of margin requirements for uncleared swaps. Having information on these aspects associated with swap dealer registration would be helpful in further assessing the impact of changing the *de minimis* threshold.

Accordingly, the Commission believes that it is prudent to extend the phase-in period by one year, which may provide additional time for more information to become available to reassess the *de minimis* exception. Adopting this Order at this time also provides clarity to market participants regarding when they would need to begin preparing for a change to the *de minimis* exception.

II. Conclusion and Order

For the reasons discussed above, and pursuant to its authority under Regulation 1.3(ggg)(4)(ii)(C)(1), the Commission is establishing December 31, 2018 as the termination date for the *de minimis* threshold phase-in period. The Commission notes that prior to the termination of the phase-in period, the Commission may take further action regarding the *de minimis* threshold by rule amendment, order, or other appropriate action.¹³

III. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act ("PRA")¹⁴ imposes certain requirements on Federal agencies in connection with their conducting or sponsoring any collection of information as defined by the PRA. This Order does not impose any new recordkeeping or information collection requirements, or other collections of information that require approval of the Office of Management and Budget under the PRA.

B. Cost-Benefit Considerations

Section 15(a) of the Commodity Exchange Act ("CEA") requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders.¹⁵ Section 15(a) further specifies that the costs and

benefits shall be evaluated in light of five broad areas of market and public concern: (i) Protection of market participants and the public; (ii) efficiency, competitiveness, and financial integrity of futures markets; (iii) price discovery; (iv) sound risk management practices; and (v) other public interest considerations. In this section, the Commission considers the costs and benefits resulting from its determinations with respect to the section 15(a) factors.

1. Background

As discussed above, Regulation 1.3(ggg)(4)(i) provides an exception from the swap dealer definition for persons who engage in a *de minimis* amount of swap dealing activity. Currently, under Regulation 1.3(ggg)(4)(i), a person shall not be deemed to be a swap dealer unless its swap dealing activity exceeds an aggregate gross notional amount threshold of \$3 billion (measured over the prior 12-month period), subject to a phase-in period during which the gross notional amount threshold is set at \$8 billion.¹⁶ The phase-in period would have terminated on December 31, 2017, and the *de minimis* threshold would have decreased to \$3 billion, absent this Order.¹⁷ This would have required firms to start tracking their swap activity beginning January 1, 2017 to determine whether their dealing activity over the course of that year would require them to register as swap dealers.

The \$3 billion threshold, which, absent this Order, would be effective on December 31, 2017, sets the baseline for the Commission's consideration of the costs and benefits of this Order.¹⁸ Accordingly, the Commission considers the costs and benefits that will result from an extended phase-in period.

2. General Cost and Benefit Considerations

There are several policy objectives underlying swap dealer regulation and the *de minimis* exception to swap dealer registration. The primary policy objectives of swap dealer regulation include the reduction of systemic risk, increased counterparty protections, and market efficiency, orderliness, and transparency.¹⁹ Registered swap dealers are subject to a broad range of requirements, including, *inter alia*, registration, internal and external business conduct standards, reporting,

recordkeeping, risk management, posting and collecting margin, and chief compliance officer designation and responsibilities. As noted in the Regulation 1.3(ggg) adopting release, generally, the lower the *de minimis* threshold, the greater the number of entities that are subject to these requirements, which could decrease systemic risk, increase counterparty protections, and promote swap market efficiency, orderliness, and transparency.²⁰

The Commission also considers policy objectives furthered by a *de minimis* exception, which include regulatory certainty, allowing limited ancillary dealing, encouraging new participants to enter the swap dealing market, and regulatory efficiency.²¹ Generally, the higher the *de minimis* threshold, the greater the number of entities that are able to engage in dealing activity without being required to register, which could increase competition and liquidity in the swap market.²² In addition, because competitive markets may be more efficient, a higher *de minimis* threshold might improve swap market efficiency. Further, the Commission notes that it has been suggested that a higher threshold could allow the Commission to expend its resources on entities with larger swap dealing activities warranting more oversight. An alternative view is that the *de minimis* threshold should be set based on policy independent of consideration of the Commission's resources.

Extending the phase-in period by one year will delay realization of the policy benefits associated with the \$3 billion *de minimis* threshold, but will also extend the policy benefits associated with a higher *de minimis* threshold. The additional time to adjust to the \$3 billion *de minimis* threshold also would potentially increase regulatory certainty for some market participants. Given that the *de minimis* exception is subject to a 12-month look-back, extending the phase-in period to December 31, 2018 would allow entities that would potentially have to register as swap dealers additional time to adjust their activities and prepare for the compliance obligations related to swap dealer registration.

3. Section 15(a)

Section 15(a) of the CEA requires the Commission to consider the effects of its

¹⁶ 17 CFR 1.3(ggg)(4)(i). See generally 77 FR at 30626–35. See also note 3, *supra*.

¹⁷ 17 CFR 1.3(ggg)(4).

¹⁸ See 77 FR at 30702–14 (discussing the cost-benefit considerations with regard to the final swap dealer definition).

¹⁹ *Id.* at 30628–30, 30707–08.

²⁰ *Id.* at 30628–30, 30703, 30707–08.

²¹ *Id.* at 30628–30, 30707–08.

²² Alternatively, the Commission notes that a lower *de minimis* threshold may lead to potential changes in market behavior, including, for example, product innovation.

¹³ See 17 CFR 1.3(ggg)(4)(v).

¹⁴ 44 U.S.C. 3501 *et seq.*

¹⁵ 7 U.S.C. 19(a).

actions in light of the following five factors. This Order will delay the potential costs and benefits discussed below by one year.

(i) Protection of Market Participants and the Public

Providing regulatory protections for swap counterparties who may be less experienced or knowledgeable about the swap products offered by swap dealers (particularly end-users who use swaps for hedging or investment purposes) is a fundamental policy goal advanced by the regulation of swap dealers. The Commission recognizes that the \$3 billion *de minimis* threshold may result in more entities being required to register as swap dealers compared to an \$8 billion threshold, thereby extending counterparty protections to a greater number of market participants. Further, swap dealer regulation is intended to reduce systemic risk in the swap market. Pursuant to the Dodd-Frank Act, the Commission has proposed or adopted regulations for swap dealers—including margin and risk management requirements—designed to mitigate the potential systemic risk inherent in the swap market. Therefore, the Commission recognizes that a lower *de minimis* threshold may result in more entities being required to register as swap dealers, thereby potentially further reducing systemic risk.

(ii) Efficiency, Competitiveness, and Financial Integrity of Markets

Other goals of swap dealer regulation are swap market transparency, orderliness, and efficiency. These benefits are achieved through regulations requiring, for example, swap dealers to keep trading records and report trades, provide counterparty disclosures about swap risks and pricing, and undertake portfolio reconciliation and compression exercises. Accordingly, the Commission notes that a lower *de minimis* threshold may have a positive effect on the efficiency and integrity of the markets.

However, the Commission also recognizes that the efficiency and competitiveness of the swap market may be negatively impacted if the *de minimis* threshold is set too low by potentially increasing barriers to entry that may stifle competition and reduce swap market efficiency. For example, if entities choose to reduce or cease their swap dealing activities so that they would not need to register if the *de minimis* threshold decreases to \$3 billion, the number or availability of market makers for swaps may be reduced, which could lead to increased

costs for potential counterparties and end-users.

(iii) Price Discovery

The Commission preliminarily believes that a \$3 billion *de minimis* threshold may discourage participation of new swap dealers and ancillary dealing. If there are fewer entities engaged in dealing, there may be a negative effect on price discovery.

(iv) Sound Risk Management

The Commission notes that a \$3 billion *de minimis* threshold could lead to better risk management practices because a greater number of entities would be required by regulation to: (i) Develop and implement detailed risk management programs; (ii) adhere to business conduct standards that reduce operational and other risks; and (iii) satisfy margin requirements for uncleared swaps.

(v) Other Public Interest Considerations

The Commission has not identified any other public purpose considerations for this Order.

C. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the objectives of the CEA, in issuing any order or adopting any Commission rule or regulation. The Commission does not anticipate that the Order discussed herein will result in anti-competitive behavior.

IV. Order

In light of the foregoing, *it is ordered*, pursuant to the Commission's authority under Regulation 1.3(ggg)(4)(ii)(C)(1), that the *de minimis* threshold phase-in termination date shall be December 31, 2018. Absent further action by the Commission, the phase-in period would terminate on December 31, 2018, at which time the *de minimis* threshold will be \$3 billion.

The Commission retains the authority to condition further, modify, suspend, terminate, or otherwise restrict any of the terms of the Order provided herein, in its discretion.

Issued in Washington, DC, on October 13, 2016, by the Commission.

Christopher J. Kirkpatrick,
Secretary of the Commission.

Appendices To Order Establishing *De Minimis* Threshold Phase-In Termination Date Pursuant to Commission Regulation 1.3(ggg)(4)(ii)(C)(1)—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 thank my fellow Commissioners for unanimously supporting this order, which extends the phase-in of the *de minimis* threshold for swap dealing by one year.

The *de minimis* threshold determines when an entity's swap dealing activity requires registration with the CFTC. Registration triggers capital and margin requirements as well as other responsibilities, such as disclosure, recordkeeping, and documentation requirements. In 2012, the CFTC set the threshold initially at \$8 billion in notional amount of swap dealing activity over the course of a year, and provided that it would fall to \$3 billion at the end of 2017.

This registration requirement is a pillar of the framework for swap regulation mandated by the Dodd-Frank Act. Congress required this framework because excessive risk related to over-the-counter derivatives contributed to the intensity of the worst financial crisis since the Great Depression, one which resulted in millions of American families losing their jobs, their homes and their savings. At the same time, Congress recognized that derivatives play an important role in enabling businesses to hedge risk. Therefore, getting this framework right is very important.

There are now more than 100 swap dealers provisionally registered with the CFTC, which include most of the largest global banking entities. Absent our action today, the threshold would have dropped from \$8 billion to \$3 billion at the end of 2017. That means firms would have been required to start determining whether their activity exceeds that lower threshold just a few months from now—in January of next year. Pushing back this date is a sensible and responsible step for several reasons.

First, our staff has completed the study required by the rule on the threshold. They estimated that lowering the threshold would not increase significantly the percentage of interest rate swaps (IRS) and credit default swaps (CDS) covered by swap dealer regulation, but it would require many additional firms to register. This might include some smaller banks whose swap activity is related to their commercial lending

business. At the same time, the study notes that the data has certain shortcomings, particularly when it comes to nonfinancial commodity swaps. This market is very different than the IRS and CDS markets, and I know there is much concern about the threshold with respect to it. This delay will allow us to consider all these issues further.

In addition, I believe it makes sense to adopt a rule setting capital requirements for swap dealers before addressing the threshold. This rule, which is required by Dodd-Frank, is one of the most important in our regulation of swap dealers, and I am hoping the Commission can act on a reproposal of it soon. This one-year delay will also allow us to more fully assess how the new margin requirements are working.

These are just some of the reasons we have taken this action. I thank the CFTC staff for their hard work on this order and on this issue generally. And I again thank my fellow Commissioners for their support.

Appendix 3—Concurring Statement of Commissioner Sharon Y. Bowen

While we might disagree on the details of today's order, I think we can all agree on one thing: Today's action is very important to how the swaps industry operates and our system of financial regulation functions. If we do not accurately and appropriately set the mandatory level of trading for swap dealer registration, our entire regulatory regime for the swaps market will be weakened.

I know that a great deal has been said about the subject of the *de minimis* threshold, and I expect that just about everyone reviewing today's decision to extend the current phase-in of the \$3 billion threshold by one year is all-too familiar with its substance. Yet, given the amount of prior actions that the Commission has taken on this topic, I think we cannot fully consider how to view today's action without first reviewing how we got here. Following the 2008 financial crisis, which was exacerbated by the absence of regulation of the swaps market, Congress passed the Dodd-Frank Wall Street Reform and Consumer Protection Act. Among the many things in that Act were a raft of robust regulatory requirements on the swaps market, including mandatory clearing, a system of data reporting, and a mandate to trade many products on Swap Execution Facilities (SEFs).

Some of the most significant new regulatory requirements were crafted for what we now call swap dealers, those entities which had significant involvement in the swaps market.¹ For instance, along with

major swap participants, swap dealers were at the heart of our new regulation regarding margin for uncleared swaps and the related cross-border rulemaking. Swap dealers will similarly be substantially impacted by our upcoming rule proposal on capital.

Who has to register as a swap dealer is therefore one of the linchpins of the entire swaps regulatory regime. If the level of swap dealing activity is not sufficient to capture entities that should be registered as swap dealers, then many of our other rules, including margin and capital, will not apply to these entities, and the markets may not be adequately protected. On the other hand, if the level of swap dealing activity is too low, many entities, that do not pose a meaningful risk to the financial system, will be required to register as swap dealers, thereby unnecessarily burdening markets.

It was with this concern in mind that Congress required that we create a threshold for swap dealer registration. Dodd-Frank requires that the Commission shall exempt from designation as a swap dealer an entity that engages in a *de minimis* quantity of swap dealing in connection with transactions with or on behalf of its customers. The Commission shall promulgate regulations to establish factors with respect to the making of this determination to exempt.² We are thus required to give entities an exemption from swap dealer registration if the quantity of their swap transactions falls below a certain level.

As required, the Commission set that level in 2012. As part of a rulemaking released in May 2012, the Commission set the level of the *de minimis* exemption at \$3 billion, with a temporary phase-in level of \$8 billion during the first few years.³ The Commission also agreed to release a report within the next few years as more data from the various industry participants involved in the swaps market was reported to the CFTC.⁴ The Commission further committed, once nine months had passed after the report was published "and after giving due consideration to the report and any associated public comment," to give itself three options for how to deal with the threshold.⁵ First, we could terminate the phase-in period and have the threshold immediately drop to \$3 billion. Second, if we decided it was "necessary or appropriate in the public interest" to propose a new threshold limit, we could do so via our typical rulemaking authority.⁶ Third, if we failed to pursue either the first or second options before a date certain—December 31, 2017, the phase-in period would automatically and immediately end, and the threshold would simply be \$3 billion.⁷

to enter into a swap with a customer in connection with originating a loan with that customer.

² Dodd-Frank section 721(49)(D).

³ See Further Definition of "Swap Dealer," "Security-Based Swap Dealer," "Major Swap Participant," "Major Security-Based Swap Participant," and "Eligible Contract Participant," 77 FR 30596 (May 23, 2012), available at: <http://www.cftc.gov/idc/groups/public/@lfederalregister/documents/file/2012-10562a.pdf>.

⁴ *Id.* at 30756.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

We have now published our final staff report on the *de minimis* threshold and the nine month period of considering whether to change the threshold has formally begun. I am grateful for the staff for all their hard work and appreciate that it has not been an easy undertaking. I am also grateful to market participants and the public for the comments and opinions that they have provided on the first and final drafts of the report. That said, it is clear from the report that our staff does not have sufficient data to make a fully informed decision.

Today, the Commission is augmenting our efforts to get better data on this issue by extending the phase-in period of the threshold by one year. Because of the Commission's action, the threshold will continue to be at \$8 billion until December 31, 2018. At that point, absent additional action by the Commission, the phase-in period will end and the threshold will be \$3 billion.

I support this initiative to get additional data on this subject, and I do not support changing the threshold at this time. But I wish to make something clear: We need to see hard data backing up the opinions we will receive during this delay about why we should not just allow the threshold to be \$3 billion as established in the rule. I know that there is a great deal of disagreement about this issue, and I do not think we will be able to reach a consensus unless we have real economic analysis and evidence to back up people's comments. If you believe the threshold should be changed to \$8 billion, or some other amount, because of market conditions, please, provide us with supporting data. Or, if you believe that the threshold should be even lower, as low as the \$150 million threshold that was once contemplated, please provide us with supporting data. If we stay focused on hard, economic analysis and an objective view about the state of the market, the final determination of the threshold will be more understandable and transparent. Given the years of existing discussion and analysis and the established process the Commission has created, we would do both a disservice to the industry and to the public to change the threshold now absent strong evidence for doing so.

I am sympathetic to the concerns that there may be onerous impacts on the market just because of this threshold. We know that cleared swaps are safer than uncleared swaps, which is why we have tried to encourage increased clearing of swaps. As such, I think there is some merit to modifying the threshold in the future by exempting cleared swaps from being counted in calculations of whether a firm is above it. If market participants or observers have strong thoughts on this idea or other ways that we might help make the \$3 billion threshold less arduous, I encourage you to reach out to my office and my staff.

I believe we should receive empirical data that can justify where the threshold number needs to be. I therefore expect that, near the start of 2017, we will start to collect additional data from market participants regarding those portions of the swaps market for which we still lack full and detailed

¹ See Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank), section 721(49)(A), available at: http://www.cftc.gov/idc/groups/public/@swaps/documents/file/hr4173_enrolledbill.pdf. That provision states that the term "swap dealer" means any person who 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 the person to be commonly known in the trade as a dealer or market maker in swaps, with the proviso that, in no event shall an insured depository institution be considered to be a swap dealer to the extent it offers

information. Absent that, I will have no basis from which to change the phase-in or move the threshold to something other than \$3 billion.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2016-N-2829]

Medical Devices; Physical Medicine Devices; Classification of the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components' classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 18, 2016. The classification was applicable on May 9, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2640, Silver Spring, MD, 20993-0002, 301-796-6476, Michael.Hoffmann@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in

commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the

FD&C Act, FDA issued an order on May 18, 2012, classifying the DEKA Arm System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II.

On June 15, 2012, DEKA Integrated Solutions Corporation submitted a request for classification of the DEKA Arm System under section 513(f)(2) of the FD&C Act. In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 9, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 890.3450.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components will need to comply with the special controls named in this final order. The device is assigned the generic name upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, and it is identified as a prescription device intended for medical purposes, and intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously