

reimbursement of research and development costs, maintenance costs, or user fees.

(n) For purposes of this section, rights to, or obligations of, research and development cost reimbursement, maintenance cost reimbursement, or user fees cannot be transferred from any individual or entity unless specifically approved in writing by the Board.

(o) Applicants requesting reimbursement for research and development costs, maintenance costs, or user fees, may present their request in person to the Board prior to consideration for approval.

(p) Index-based weather plans of insurance are not eligible for reimbursement from FCIC for maintenance costs or research and development costs. Submitters of approved index-based weather plans of insurance may collect user fees from other approved insurance providers in accordance with Procedures Handbook 17050—Approved Procedures for Submission of Index-based Weather Plans of Insurance.

§ 400.713 Non-reinsured supplemental (NRS) policy.

(a) Unless otherwise specified by FCIC, any NRS policy that covers the same agricultural commodity as any policy reinsured by FCIC under the Act must be provided to RMA to ensure it does not shift any loss under the FCIC reinsured policy. Failure to provide such NRS policy or endorsement to RMA prior to its issuance shall result in the denial of reinsurance, A&O subsidy and risk subsidy on the underlying FCIC reinsured policy for which such NRS policy was sold.

(b) Three hard copies, and an electronic copy in a format approved by RMA, of the new or revised NRS policy and related materials must be submitted at least 150 days prior to the first sales closing date applicable to the NRS policy. At a minimum, examples that demonstrate how liability and indemnities are determined under differing scenarios must be included.

(1) Hard copies of the NRS must be sent to the Deputy Administrator for Product Management (or successor), USDA/Risk Management Agency, Beacon Facility Mail Stop 0812, 9240 Troost Ave., Kansas City, MO 64131-3055.

(2) Electronic copies of the NRS must be sent to the Deputy Administrator for Product Management (or successor) at DeputyAdministrator@rma.usda.gov.

(c) RMA will review the NRS policy. If any of the conditions found in paragraphs (c)(1) through (5) of this section are found to occur, FCIC will

deny reinsurance, A&O subsidy and risk subsidy on the underlying FCIC reinsured policy for which such NRS policy was sold.

(1) If the NRS policy materially increases or shifts risk to the underlying policy or plan of insurance reinsured by FCIC.

(i) An NRS policy will be considered to materially increase or shift risk to the underlying policy or plan of insurance reinsured by FCIC if it creates an incentive for moral hazard such as a financial incentive to increase the number or size of losses or, allows for aggregate indemnities in excess of the expected value of the insured commodity.

(ii) The NRS must include language that clearly states no indemnity will be paid in excess of the initial value of the insured commodity.

(2) The NRS reduces or limits the rights of the insured with respect to the underlying policy or plan of insurance reinsured by FCIC. An NRS policy will be considered to reduce or limit the rights of the insured with respect to the underlying policy or plan of insurance if it alters the terms or conditions of the underlying policy or otherwise preempts procedures issued by FCIC.

(3) The NRS disrupts the marketplace. An NRS policy will be considered to disrupt the marketplace if it encourages planting more acres of the insured commodity in excess of normal market demand, adversely affects the sales or administration of reinsured policies, undermines producers' confidence in the Federal crop insurance program, or harms public perception of the Federal crop insurance program.

(4) The NRS is an impermissible rebate. An NRS may be considered to be an impermissible rebate if FCIC determines that the premium rates charged are insufficient to cover the expected losses and a reasonable reserve or it offers other benefits that are generally provided at a cost.

(5) The NRS policy is conditioned upon or provides incentive for the purchase of the underlying policy or plan of insurance reinsured by FCIC with a specific agent or approved insurance provider.

(d) RMA will respond not less than 60 days before the first sales closing date or provide notice why RMA is unable to respond within the time frame allotted.

(e) NRS policies reviewed by RMA will not need to be submitted for a five year period unless a change is made to the NRS or the underlying policy or the loss ratio for the NRS policy exceeds 2.0. Once any changes are made to either policy or the five year period has

concluded, the NRS must be resubmitted for review.

Signed in Washington, DC, on February 13, 2015.

Brandon Willis,
Manager, Federal Crop Insurance Corporation.

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 15, 17, 19, 32, 37, 38, 140, and 150

RIN 3038-AD99; 3038-AD82

Position Limits for Derivatives and Aggregation of Positions

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking; provision of Table 11a; and reopening of comment periods.

SUMMARY: On December 12, 2013, the Commodity Futures Trading Commission (“Commission”) published in the **Federal Register** a notice of proposed rulemaking (the “Position Limits Proposal”) to establish speculative position limits for 28 exempt and agricultural commodity futures and options contracts and the physical commodity swaps that are economically equivalent to such contracts. On November 15, 2013, the Commission published in the **Federal Register** a notice of proposed rulemaking (the “Aggregation Proposal”) to amend existing regulations setting out the Commission’s policy for aggregation under its position limits regime. The Commission’s Energy and Environmental Markets Advisory Committee has scheduled a public meeting to be held on February 26, 2015, which will consider, among other matters, exemptions for bona fide hedging positions. In conjunction with the meeting of the Commission’s Energy and Environmental Markets Advisory Committee, the Commission will post an agenda and associated materials, if any, on the Commission’s Web site; additionally, access to a video webcast of the meeting will be added to the Web site. In addition, and in connection with the meeting, the Commission is providing counts of the unique persons over percentages of the 28 proposed position limit levels (currently provided in Table 11 of the Position Limits Proposal based on counts from the period of January 1, 2011, to December 31, 2012 period) in a new table, Table

11a, based on counts from the period of January 1, 2013, to December 31, 2014. To provide commenters with a sufficient period of time to respond to questions raised and points made at the Energy and Environmental Markets Committee meeting, as well as to provide an opportunity to comment on Table 11a, the Commission will reopen the comment periods for an additional 30 days. The Commission is providing notice that comments may be made on the issues addressed at the meeting or in the associated materials posted to the Commission's Web site, as they pertain to energy commodities. Furthermore, comments may be made on Table 11a, showing counts of the unique persons over percentages of the 28 proposed position limit levels based on counts from the period of January 1, 2013, to December 31, 2014.

DATES: The comment periods for the Aggregation Proposal published November 15, 2013, at 78 FR 68946, and for the Position Limits Proposal published December 12, 2013, at 78 FR 75680, will reopen on February 26, 2015, and will close on March 28, 2015.

ADDRESSES: You may submit comments, identified by RIN 3038-AD99 for the Position Limits Proposal or RIN 3038-AD82 for the Aggregation Proposal, by any of the following methods:

- *Agency Web site:* <http://comments.cftc.gov>;
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581;
- *Hand Delivery/Courier:* Same as Mail, above; or
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow instructions for submitting comments.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted under § 145.9 of the Commission's regulations (17 CFR 145.9).

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may

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

FOR FURTHER INFORMATION CONTACT:

Stephen Sherrod, Senior Economist, Division of Market Oversight, (202) 418-5452, ssherrod@cftc.gov; or Riva Spear Adriance, Senior Special Counsel, Division of Market Oversight, (202) 418-5494, radriance@cftc.gov; Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission has long established and enforced speculative position limits for futures and options contracts on various agricultural commodities as authorized by the Commodity Exchange Act ("CEA").¹ The part 150 position limits regime² generally includes three components: (1) the level of the limits, which set a threshold that restricts the number of speculative positions that a person may hold in the spot-month, individual month, and all months combined,³ (2) exemptions for positions that constitute bona fide hedging transactions and certain other types of transactions,⁴ and (3) rules to determine which accounts and positions a person must aggregate for the purpose of determining compliance with the position limit levels.⁵ The Position Limits Proposal generally sets out proposed changes to the first and second components of the position limits regime and would establish speculative position limits for 28 exempt and agricultural commodity futures and option contracts, and physical commodity swaps that are "economically equivalent" to such contracts (as such term is used in CEA section 4a(a)(5)).⁶ The Aggregation Proposal generally sets out proposed changes to the third component of the position limits regime.⁷

¹ 7 U.S.C. 1 *et seq.*

² See 17 CFR part 150. Part 150 of the Commission's regulations establishes federal position limits on futures and option contracts in nine enumerated agricultural commodities.

³ See 17 CFR 150.2.

⁴ See 17 CFR 150.3.

⁵ See 17 CFR 150.4.

⁶ See Position Limits for Derivatives, 78 FR 75680 (Dec. 12, 2013).

⁷ See Aggregation of Positions, 78 FR 68946 (Nov. 15, 2013).

The Commission published the Position Limits Proposal and the Aggregation Proposal separately because it believes that the proposed amendments regarding aggregation of positions could be appropriate regardless of whether the Position Limits Proposal is finalized.⁸ If the Aggregation Proposal is finalized first, the modifications would apply to the current position limits regime for futures and option contracts on nine enumerated agricultural commodities. If the Position Limits Proposal is subsequently finalized, the modifications in the Aggregation Proposal would apply to the position limits regime for 28 exempt and agricultural commodity futures and options contracts and the physical commodity swaps that are economically equivalent to such contracts.

In order to provide interested parties with an opportunity to comment on the Aggregation Proposal during the comment period on the Position Limits Proposal, the Commission extended the comment period for the Aggregation Proposal to February 10, 2014, the same end date as the comment period for the Position Limits Proposal.⁹

Subsequent to publication of the Position Limits Proposal and the Aggregation Proposal, the Commission directed staff to schedule a June 19, 2014, public roundtable to consider certain issues regarding position limits for physical commodity derivatives. The roundtable focused on hedges of a physical commodity by a commercial enterprise, including gross hedging, cross-commodity hedging, anticipatory hedging, and the process for obtaining a non-enumerated exemption. Discussion included the setting of spot month limits in physical-delivery and cash-settled contracts and a conditional spot-month limit exemption. Further, the roundtable included discussion of: The aggregation exemption for certain ownership interests of greater than 50 percent in an owned entity; and aggregation based on substantially identical trading strategies. As well, the Commission invited comment on whether to provide parity for wheat contracts in non-spot month limits. In conjunction with the roundtable, staff questions regarding these topics were posted on the Commission's Web site.

To provide commenters with a sufficient period of time to respond to questions raised and points made at the roundtable, the Commission published a document in the **Federal Register** on May 29, 2014 (79 FR 30762), reopening

⁸ See *id.* at 68947.

⁹ See 79 FR 2394 (Jan. 14, 2014).

the comment periods for the Position Limit Proposal and the Aggregation Proposal for three weeks, from June 12, 2014 to July 3, 2014. The Commission published a document in the **Federal Register** on July 3, 2014 (79 FR 37973), further extending the comment periods to August 4, 2014.

The Commission’s Agricultural Advisory Committee met on December 9, 2014. The agenda adopted for the meeting included consideration, among other matters, of two issues associated with the Position Limits rulemaking: Deliverable supply and exemptions for bona fide hedging positions. In conjunction with the meeting of the Commission’s Agricultural Advisory Committee, the Commission posted questions and presentation materials on the Commission’s Web site; additionally, access to a video webcast of the meeting was added to the Web site.¹⁰ To provide interested persons with a sufficient period of time to respond to questions raised and points made at the Agricultural Advisory Committee meeting, the Commission reopened both the Position Limit Proposal and the Aggregation Proposal for an additional 45-day comment period.¹¹

Comment letters received on the Position Limits Proposal are available at <http://comments.cftc.gov/PublicComments/>

[CommentList.aspx?id=1436](http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1436). Comment letters received on the Aggregation Proposal are available at <http://comments.cftc.gov/PublicComments/CommentList.aspx?id=1427>.

II. Reopening of Comment Period

The Commission’s Energy and Environmental Markets Advisory Committee has scheduled a meeting on February 26, 2015. The agenda adopted for the meeting includes consideration of exemptions for bona fide hedging positions. In conjunction with the meeting of the Commission’s Energy and Environmental Markets Advisory Committee, the Commission will post associated materials on the Commission’s Web site; additionally, access to a video webcast of the meeting will be added to the Web site. To provide interested persons with a sufficient period of time to respond to questions raised and points made at the Energy and Environmental Markets Advisory Committee meeting, the Commission is reopening both the Position Limit Proposal and the Aggregation Proposal for an additional 30-day comment period. The Commission is providing notice that, in addition to commenting on the agenda issues, comments may be made on the issues addressed at the meeting or in associated materials posted to the Commission’s Web site, as they pertain

to energy commodities, including hedges of a physical commodity by a commercial enterprise, as pertains to energy commodities.

In addition, and in connection with the Energy and Environmental Markets Advisory Committee meeting, the Commission is providing counts of the unique persons exceeding the 28 proposed position limit levels (currently provided in Table 11 of the Positions Limits Proposal based on counts from the period of January 1, 2011, to December 31, 2012 period¹²) by certain specified percentages in a new table, Table 11a, based on counts from the period of January 1, 2013, to December 31, 2014. As was the case with Table 11, to provide the public with additional information regarding the number of large position holders in the past two calendar years, Table 11a provides counts of unique persons over 60, 80, 100, and 500 percent of the levels of the position limits proposed for 28 core referenced futures products.¹³ Note that the 500 percent line is omitted from Table 11a for contracts where no person held a position over that level. The Commission notes that in addition to commenting on the agenda issues and on the issues addressed at the meeting or in associated materials posted to the Commission’s Web site, as they pertain to energy commodities, comments may be made on Table 11a.

TABLE 11a—UNIQUE PERSONS OVER PERCENTAGES OF PROPOSED POSITION LIMIT LEVELS, JANUARY 1, 2013, TO DECEMBER 31, 2014

Commodity type/core referenced futures contract	Percent of level	Unique persons over level			
		Spot month (physical-delivery)	Spot month (cash-settled)	Single month	All months
Legacy Agricultural					
CBOT Corn (C)	60	206	—	12	25
	80	147	—	4	7
	100	49	—	(*)	5
	500	4	—	—	—
CBOT Oats (O)	60	(*)	—	11	12
	80	(*)	—	6	8
	100	—	—	(*)	5
CBOT Soybeans (S)	60	127	—	14	18
	80	90	—	9	11
	100	31	—	6	9
	500	9	—	—	—
CBOT Soybean Meal (SM)	60	53	—	42	54
	80	31	—	12	19

¹⁰ Questions, presentation materials, and a video webcast have been made available at http://www.cftc.gov/PressRoom/Events/opaevent_aac120914.

¹¹ See 79 FR 71973 (Dec. 4, 2014). The Commission also provided notice and clarification that, in addition to commenting on the agenda issues noted in the December 4, 2014, **Federal Register** release providing notice of the reopened comment period, comments could be made on the issues addressed at the meeting or in associated

materials posted to the Commission’s Web site, as they pertained to agricultural commodities, including hedges of a physical commodity by a commercial enterprise; and the process for estimating deliverable supplies used in the setting of spot month limits, as each pertained to agricultural commodities. See also 80 FR 200 (Jan. 5, 2015).

¹² See 78 FR 75680 at 75731 (Dec. 12, 2013).

¹³ As is the case for Table 11, the Commission notes that Table 11a is presented using the

proposed initial limit levels, without regard to alternatives presented in the proposed rule. See 78 FR at 75839 for the proposed initial limit levels for the spot month. The Commission also proposed alternatives methods for setting initial levels for the spot month. See FR at 75727–8. The proposed initial limit levels for the non-spot months are found at 78 FR 76787 (Dec. 19, 2013). The Commission also proposed an alternative method to establish higher initial limit levels in the non-spot months. See FR 78 at 75734.

TABLE 11a—UNIQUE PERSONS OVER PERCENTAGES OF PROPOSED POSITION LIMIT LEVELS, JANUARY 1, 2013, TO DECEMBER 31, 2014—Continued

Commodity type/core referenced futures contract	Percent of level	Unique persons over level			
		Spot month (physical-delivery)	Spot month (cash-settled)	Single month	All months
CBOT Soybean Oil (SO)	100	16	—	6	11
	500	(*)	—	—	—
	60	82	—	31	38
	80	51	—	10	18
	100	18	—	5	11
CBOT Wheat (W)	500	(*)	—	—	—
	60	39	—	35	33
	80	30	—	12	17
	100	10	—	8	11
	500	(*)	—	—	—
ICE Cotton No. 2 (CT)	60	16	—	15	22
	80	10	—	10	14
	100	7	—	8	10
	500	4	—	—	—
KCBT Hard Winter Wheat (KW)	60	17	—	32	39
	80	7	—	16	27
	100	(*)	—	12	12
	60	7	—	33	36
MGEX Hard Red Spring Wheat (MWE)	80	4	—	20	29
	100	(*)	—	15	21
	100	(*)	—	—	—
Other Agricultural					
CBOT Rough Rice (RR)	60	9	—	6	5
	80	7	—	4	4
	100	(*)	—	(*)	(*)
CME Milk Class III (DA)	60	NA	5	(*)	26
	80	NA	4	—	15
	100	NA	(*)	—	10
CME Feeder Cattle (FC)	60	NA	113	8	14
	80	NA	70	(*)	8
	100	NA	28	—	5
CME Lean Hog (LH)	60	NA	98	19	34
	80	NA	74	8	24
	100	NA	45	(*)	14
CME Live Cattle (LC)	60	51	—	14	29
	80	7	—	7	16
	100	5	—	(*)	8
ICUS Cocoa (CC)	60	4	—	47	42
	80	4	—	38	30
	100	(*)	—	21	21
ICE Coffee C (KC)	60	14	—	30	32
	80	10	—	13	16
	100	6	—	8	11
ICE FCOJ-A (OJ)	500	(*)	—	—	—
	60	5	—	7	7
	80	5	—	4	4
	100	5	—	4	4
ICE Sugar No. 11 (SB)	60	55	—	41	39
	80	42	—	31	29
	100	16	—	21	22
	500	(*)	—	—	—
ICE Sugar No. 16 (SF)	60	5	—	6	13
	80	5	—	6	11
	100	4	—	5	11
Energy					
NYMEX Henry Hub Natural Gas (NG)	60	187	236	(*)	7
	80	142	205	(*)	(*)
	100	83	187	—	(*)
	500	(*)	46	—	—
NYMEX Light Sweet Crude Oil (CL)	60	135	100	(*)	12
	80	95	87	(*)	7
	100	44	65	—	(*)
	500	—	—	—	—
NYMEX NY Harbor ULSD (HO)	60	76	68	13	16

TABLE 11a—UNIQUE PERSONS OVER PERCENTAGES OF PROPOSED POSITION LIMIT LEVELS, JANUARY 1, 2013, TO DECEMBER 31, 2014—Continued

Commodity type/core referenced futures contract	Percent of level	Unique persons over level			
		Spot month (physical-delivery)	Spot month (cash-settled)	Single month	All months
NYMEX RBOB Gasoline (RB)	80	49	63	7	9
	100	31	44	(*)	6
	500	—	5	—	—
	60	97	57	26	30
	80	67	52	15	17
	100	36	37	11	12
	500	—	(*)	—	—
Metals					
COMEX Copper (HG)	60	12	—	61	62
	80	9	—	37	40
	100	4	—	29	30
COMEX Gold (GC)	60	13	—	22	24
	80	9	—	14	14
	100	5	—	10	11
COMEX Silver (SI)	60	9	—	34	32
	80	4	—	20	21
	100	(*)	—	16	16
NYMEX Palladium (PA)	60	9	—	12	13
	80	5	—	9	5
	100	(*)	—	4	4
NYMEX Platinum (PL)	60	11	—	29	29
	80	7	—	18	18
	100	(*)	—	9	9

Legend:
 * means fewer than 4 unique owners exceeded the level.
 — means no unique owner exceeded the level.
 NA means not applicable.¹⁴

Both comment periods will reopen on February 26, 2015, and will close on March 28, 2015.

Issued in Washington, DC, on February 19, 2015, by the Commission.

Christopher J. Kirkpatrick,
Secretary of the Commission.

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

Appendix to Position Limits for Derivatives and Aggregation of Positions Reopening of Comment Periods—Commission Voting Summary

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

[FR Doc. 2015-03834 Filed 2-24-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket Nos. FDA-2003-N-0196 (Formerly 2003N-0233), FDA-1978-N-0018 (Formerly 1978N-0038 and 78N-0038), and FDA-1996-N-0006 (Formerly 96N-0277)]

Over-the-Counter Sunscreen Drug Products—Regulatory Status of Enzacamene

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a proposed sunscreen order (proposed order) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Sunscreen Innovation Act (SIA). The proposed order announces FDA's tentative determination that enzacamene is not generally recognized as safe and effective (GRASE) and is misbranded when used in over-the-counter (OTC) sunscreen products

because the currently available data are insufficient to classify it as GRASE and not misbranded, and additional information is needed to allow us to determine otherwise.

DATES: Submit either electronic or written comments on this proposed order by April 13, 2015. Sponsors may submit written requests for a meeting with FDA to discuss this proposed order by March 27, 2015. See section VI for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

¹⁴ Table notes: (1) Aggregation exemptions were not used in computing the counts of unique persons; (2) the position data was for futures, futures options and swaps that are significant price discovery contracts (SPDCs).