

NOTE: For figure 4, time starts at the moment cabin altitude exceeds 8,000 feet during depressurization. If depressurization analysis shows that the cabin altitude limit of this curve is exceeded, the following alternate limitations apply: After depressurization, the maximum cabin altitude exceedence is limited to 40,000 feet. The maximum time the cabin altitude may exceed 25,000 feet is 2 minutes; time starting when the cabin altitude exceeds 25,000 feet and ending when it returns to 25,000 feet.

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Issued in Renton, Washington, on October 5, 1995.
Gary L. Killion,
Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service,
ANM–100.
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DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 799

RIN 0694-AB33

[Docket No. 950928239-5239-01]

Correcting Amendments; General Software Note, Commerce Control List Interpretations 24, 25, and 26

AGENCY: Bureau of Export Administration, Commerce. **ACTION:** Final rule; correcting amendments.

SUMMARY: This final rule makes two corrections to the Export Administration Regulations. First, this rule amends the General Software Note to correctly reflect that Country, Groups S and Z, Iran, and Syria are not eligible to receive exports of mass-marketed software under General License GTDR without written assurance (also referred to as General License GTDU). This is not a regulatory change, but a correction to the Code of Federal Regulations, which erroneously omitted the appropriate amendatory language regarding Country Groups S and Z, Iran and Syria after it was published in the Federal Register on September 14, 1992 (57 FR 41854).

Second, this rule removes Commerce Control List interpretations Nos. 24, 25, and 26. BXA intended to remove these interpretations on July 15, 1992. However, due to a typographical error, this change was inadvertently omitted from the Export Administration Regulations.

EFFECTIVE DATE: This rule is effective October 17, 1995.

FOR FURTHER INFORMATION CONTACT:

Nancy Crowe, Office of Exporter Services, Regulatory Policy Division, Bureau of Export Administration, Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

This final rule makes two corrections to the Export Administration Regulations (EAR) (15 CFR Parts 730–799). First, this rule amends the General Software Note found in Supplement No. 2 to § 799.1 of the EAR to correctly reflect that Country Groups S and Z, Iran, and Syria are not eligible to receive exports of mass-marketed software under General License GTDR without written assurances (also referred to as General License GTDU). This is not a regulatory change.

The amendatory language concerning Country Groups S and Z, Iran and Syria was originally published in the Federal Register on September 14, 1992 (57 FR 41854), along with corresponding language in § 779.4(a) of the EAR. The amendments to § 779.4(a) and the General Software Note were included in the loose-leaf version of the EAR, but the amendment to the General Software Note was inadvertently omitted from the CFR.

Supplement No. 2 to § 799.1 was removed and reserved in error in the January 1, 1995, version of the CFR. On July 18, 1995, a CFR correction was published in the Federal Register (60 FR 36638) to reinstate Supplement No. 2 to § 799.1. However, the July 1995 correction did not include the amendatory language regarding Country Groups S and Z, Iran and Syria that was published in 1992. This final rule corrects the text of Supplement No. 2 to § 799.1 in Title 15 of the CFR to reflect the language originally published in the Federal Register on September 14, 1992.

This rule also removes interpretations Nos. 24, 25, and 26 from Supplement No. 1 to § 799.2. BXA intended to remove these interpretations on July 15, 1992 (57 FR 31309). However, due to a typographical error, this change was inadvertently omitted from the EAR.

Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the EAR in Executive Order 12924 of August 19, 1994, and Notice of August 15, 1995 (60 FR 42767).

Rulemaking Requirements

Notwithstanding any other provision of law, no person is 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 currently valid OMB Control number.

- 1. This final rule has been determined to be not significant for purposes of Executive Order 12866.
- 2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694–0005 and 0694–0007.
- This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.
- 4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be

given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a foreign and military affairs function of the United States. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Therefore, this regulation is issued in final form.

List of Subjects in 15 CFR Part 799

Exports, Reporting and recordkeeping requirements.

Accordingly, Part 799 the Export Administration Regulations (15 CFR Parts 730–799) is amended, as follows:

1. The authority citation for 15 CFR Part 799 continues to read as follows:

Authority: 50 U.S.C. App. 5, as amended; Pub. L. 264, 59 Stat. 619 (22 U.S.C. 287c), as amended; Pub. L. 90-351, 82 Stat. 197 (18 U.S.C. 2510 et seq.), as amended; sec. 101, Pub. L. 93-153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94-163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94-258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95-223, 91 Stat. 1626 (50 U.S.C. 1701 et seq.); Pub. L. 95-242, 92 Stat. 120 (22 U.S.C. 3201 et seq. and 42 U.S.C. 2139a); sec. 208, Pub. L. 95-372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. App. 2401 et seq.), as amended; sec. 125, Pub. L. 99-64, 99 Stat. 156 (46 U.S.C. 466c); Pub. L. 102-484, 106 Stat. 2575 (22 U.S.C. 6004); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12851 of June 11, 1993 (58 FR 33181, June 15, 1993); E.O. 12867 of September 30, 1993 (58 FR 51747, October 4, 1993); E.O 12918 of May 26, 1994 (59 FR 28205, May 31, 1994); E.O. 12924 of August 19, 1994 (59 FR 43437 of August 23, 1994); E.O. 12938 of November 14, 1994 (59 FR 59099 of November 16, 1994), and Notice of August 15, 1995 (60 FR 42767).

PART 799—[AMENDED]

2. Supplement No. 2 to Section 799.1 is amended by revising the introductory text of the second note to read as follows:

Supplement No. 2—General Technology and Software Notes

* * * * *

2. General Software Note. General License GTDR, without written assurance, is available to all destinations, except Country Groups S and Z, Iran, and Syria, for release of software that is generally available to the public by being:

* * * * *

Supplement No. 1 to § 799.2 [Amended]

3. In Supplement No. 1 to § 799.2 (Interpretations), interpretations Nos. 24, 25, and 26 are removed.

Dated: October 12, 1995.

Sue E. Eckert.

Assistant Secretary for Export

Administration.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements; Exemption of Certain Iron Containing Dietary Supplement Powders

AGENCY: Consumer Product Safety

Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations to exempt from childresistant packaging requirements those dietary supplement powders that have no more than the equivalent of 0.12 percent weight-to-weight elemental iron. The Commission issues this exemption because there are no known poisoning incidents with these products, and the dry powdered form deters children from ingesting them in harmful amounts.

DATES: The exemption is effective on October 17, 1995.

FOR FURTHER INFORMATION CONTACT:

Michael Bogumill, Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400 ext. 1368.

SUPPLEMENTARY INFORMATION:

A. Background

In 1978, the Consumer Product Safety Commission ("the Commission") required child-resistant packaging ("CRP") for drugs and dietary supplements that contain iron. 16 CFR 1700.14(a) (12) and (13). The Commission issued these rules under the Poison Prevention Packaging Act ("PPPA"), 15 U.S.C. 1471–1476, which authorizes the Commission to require CRP to protect children under 5 years of

age from poisoning hazards posed by harmful household substances.

Specifically, CRP is required for dietary supplements "that contain an equivalent of 250 milligrams or more of elemental iron, from any source, in a single package in concentrations of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent or more on a weight-to-weight basis for nonliquids." 16 CFR 1700.14(a)(13). This requirement does not apply if iron is present only as a colorant. *Id.*

On May 11, 1994, Nutritech, Inc. ("Nutritech"), petitioned the Commission to exempt unflavored, unsweetened iron powders from CRP requirements for dietary supplements containing iron. Nutritech manufactures an unsweetened, unflavored vitamin, mineral, and amino acid powder intended to be mixed with fruit juice. The petitioner stated several reasons why CRP is unnecessary for this dietary supplement. (1) ¹ The Commission published a notice in the Federal Register on August 4, 1994, soliciting comments on the petition, 59 FR 39747, and received no responses.

B. Proposed Rule and Comment

On April 7, 1995, the Commission published a notice granting Nutritech's petition to initiate rulemaking and proposing to exempt certain powdered iron-containing dietary supplements from CRP requirements. 60 FR 17660. The Commission proposed that the exemption would apply to dietary supplement powders, both flavored and unflavored, with no more than the equivalent of 0.12 percent w/w elemental iron.

In response to the proposed rule, the Commission received one comment. The comment, submitted on behalf of an organization called SI Metric, objected that the proposed regulation did not use proper SI metric terminology. The Commission has considered the comment and has made some changes in the preamble to ensure that measurements are presented in metric terminology. However, the Commission declines to make some changes suggested by the commenter—for example, using the term mass rather than weight. The Commission also believes that its expression of the percentage of concentration of iron for liquids and non-liquids as weight-tovolume ("w/v") or weight-to-weight ("w/w") measurements is appropriate. Based on the United States Pharmacopeia guidelines, the percent

w/v refers to the number of grams of a constituent in 100 milliliters of solution, and the percent w/w is the number of grams of a constituent in 100 grams of solution or mixture. The Commission believes that its use of terminology is consistent with use throughout the Federal government. Moreover, the terminology is consistent with other regulations under the PPPA.

C. Toxicity Data

The minimum toxic and lethal doses of iron are not well defined. Generally, doses of elemental iron from 20 to 60 milligrams per kilogram of body weight ("mg/kg") may produce mild symptoms of poisoning, 60 mg/kg is the minimal dose for serious toxicity, and approximately 180 to 250 mg/kg is considered a lethal dose. However, fatalities of young children have been reported at lower doses. (2)(3)

According to the relevant scientific and medical literature, where information on the formulation was available, the majority of pediatric poisoning incidents involved solid iron—in the form of tablets or capsules—with the remaining cases involving liquid preparations. Among the reported ingestion incidents, fatalities and serious cases of toxicity usually involve ingestion of adult preparations (such as prenatal vitamins) that contain 60 mg or more of elemental iron per tablet. The literature search did not identify a single case of pediatric poisoning involving powdered iron formulations. (2)(3)(5)

When the Food and Drug Administration ("FDA") published proposed labeling and packaging requirements for iron-containing dietary supplements and drugs, 59 FR 51030 (October 6, 1994), it decided to limit the proposed rules to products in solid oral dosage forms (capsules and tablets) and not include liquid or powder products.

The Commission's own 1994 study of pediatric iron poisonings and fatalities found that the majority of serious outcomes involved products in solid or capsule forms. The report showed that all 36 of the in-depth investigations of iron ingestion deaths of children under 5 years old occurring between 1986 and 1993 involved solid capsule or tablet formulations. In 1993, 57 hospital emergency room cases documented through NEISS involved ingestion of iron capsules or tablets by children under 5 years old, and one involved liquid iron. As noted, there were no known pediatric poisonings that involved powdered formulations. This study was based on data from the Commission's National Electronic Injury

 $^{^{1}}$ Numbers in parentheses identify documents listed at the end of this notice.