

February 9, 2011

Table of Comparison of 2012 CDR v 2006 IUR Definitions

In forming 40 CFR 711, EPA sought to simplify the definition section and remove unnecessary duplication of regulatory terms. Note that applicable statutory definitions from TSCA section 3 are not included in the following list.

2006 IUR: The regulations governing the 2006 IUR were chiefly located in 40 CFR 710 Subpart C. The primary definition section was in 710.43, which had the following introduction:

In addition to the definitions in §704.3 of this chapter and §710.3, the following definitions also apply to subpart C of this part:

2012 CDR: The regulations governing the 2012 CDR are chiefly located in 40 CFR 711. The primary definition section is in 711.3, which has the following introduction:

The definitions in this section and the definitions in TSCA section 3 apply to this part. In addition, the definitions in 40 CFR 704.3 also apply to this part, except the definitions *manufacture* and *manufacturer* in 40 CFR 704.3.

Comparison of 2006 IUR Definitions and 2012 CDR Definitions

Term	Definition used for 2012 CDR (40 CFR 704.3 and 40 CFR 711.3)	Definition(s) used for 2006 IUR (40 CFR 710.43, 40 CFR 710.3, and 40 CFR 704.3)	Comment
<i>Article</i>	Uses the 704.3 definition.	<p>704.3 – A manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design.</p> <p>710.3 - A manufactured item: (1) Which is formed to a specific shape or design during manufacture, (2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in §710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.</p>	
<i>Byproduct</i>	Uses the 704.3 definition.	<p>704.3 – A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).</p> <p>710.3 - A chemical substance produced without separate commercial intent during the manufacture or processing of another chemical substance(s) or mixture(s).</p>	
<i>CDX or Central Data Exchange</i>	EPA's centralized electronic document receiving system, or its successors.		New definition
<i>Commercial use</i>	The use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.	710.43 - The use of a chemical substance or mixture in a commercial enterprise providing saleable goods or services (e.g., dry cleaning establishment, painting contractor).	Revised to make more consistent with definitions collaboratively developed with Canada.

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<i>Consumer use</i>	The use of a chemical substance or a mixture containing a chemical substance (including as part of an article) when sold to or made available to consumers for their use.	710.43 - The use of a chemical substance that is directly, or as part of a mixture, sold to or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in or around recreational areas.	Revised to make more consistent with definitions collaboratively developed with Canada.
<i>e-CDRweb</i>	The electronic, web-based tool provided by EPA for the completion and submission of the CDR data.		New definition
<i>EPA</i>	Uses the 704.3 definition.	704.3 – The United States Environmental Protection Agency 710.3 - The U.S. Environmental Protection Agency	
<i>Importer</i>	Uses the 704.3 definition with the following technical correction: 704.3 – (1) any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States, and includes: (i) The person primarily liable for the payment of any duties on the merchandise, or (ii) An authorized agent acting on his behalf. (2) Importer also includes, as appropriate: (i) The consignee. (ii) The importer of record. (iii) The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 CFR 141.20. (iv) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144. (3) For the purposes of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.	704.3 – (1) Any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the United States, and includes: (i) The person primarily liable for the payment of any duties on the merchandise, or (ii) An authorized agent acting on his behalf (as defined in 19 CFR 1.11). (2) Importer also includes, as appropriate: (i) The consignee. (ii) The importer of record. (iii) The actual owner if an actual owner's declaration and superseding bond have been filed in accordance with 19 CFR 141.20. (iv) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR part 144. (3) For the purposes of this definition, the customs territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia. 710.3 - Any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the U.S. and includes: (1) The person primarily liable for the payment of any duties on the merchandise, or (2) An authorized agent acting on his/her behalf (as defined in 19 CFR 1.11).	

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<i>Impurity</i>	Uses the 704.3 definition.	704.3 – a chemical substance which is unintentionally present with another chemical substance. 710.3 - a chemical substance which is unintentionally present with another chemical substance.	
<i>Industrial function</i>	The intended physical or chemical characteristic for which a chemical substance or mixture is consumed as a reactant; incorporated into a formulation, mixture, reaction product, or article; repackaged; or used.		New definition
<i>Industrial use</i>	Identical to the 710.43 definition.	710.43 – Use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.	
<i>Intended for use by children</i>	Identical to the 710.43 definition.	710.43 – The chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers “yes” to at least one of the following questions for the product into which the submitter’s chemical substance or mixture is incorporated: (1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger? (2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger? (3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?	

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<i>Intermediate</i>	Uses the 704.3 definition.	<p>704.3 – Any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions</p> <p>710.3 - Any chemical substance:</p> <p>(1) Which is intentionally removed from the equipment in which it is manufactured, and</p> <p>(2) Which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).</p> <p>Note: The <i>equipment in which it was manufactured</i> includes the reaction vessel in which the chemical substance was manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical substance may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.</p>	
<i>Known to or reasonably ascertainable by</i>	Uses the 704.3 definition.	<p>704.3 – All information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.</p> <p>710.43 - All information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.</p>	

Comparison of 2006 IUR Definitions and 2012 CDR Definitions

Term	Definition used for 2012 CDR (40 CFR 704.3 and 40 CFR 711.3)	Definition(s) used for 2006 IUR (40 CFR 710.43, 40 CFR 710.3, and 40 CFR 704.3)	Comment
<i>Manufacture</i>	To manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is: (1) Produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production	704.3 - To manufacture for commercial purposes. 710.3 - To manufacture, produce, or import for commercial purposes	Revised <i>manufacture</i> to include certain elements from the 704.3 and 720.3 definitions for <i>manufacturer</i> , specifically: <ul style="list-style-type: none"> • extraction of a component chemical substance and • contract (toll) manufacturing. <p>The Agency is also adding a simple definition for the term <i>manufacturer</i> (See below).</p> <p>Note that EPA also added a paragraph (c) to the regulation at 40 CFR 711.22 to clarify the reporting relationship between the contracting company and the toll manufacturer. The contracting company and the toll manufacturer should confer with each other to avoid duplicate reporting, and both the contracting company and the toll manufacturer are liable if no report is made.</p>

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<i>Manufacture “for commercial purposes”</i>	Uses the 704.3 definition.	<p>704.3 – (1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes among other things, such “manufacture” of any amount of a chemical substance or mixture:</p> <ul style="list-style-type: none"> (i) For commercial distribution, including for test marketing. (ii) For use by the manufacturer, including use for product research and development, or as an intermediate. <p>(2) Manufacture for commercial purposes also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.</p> <p>710.3 - To manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, for example, the manufacture or import of any amount of a chemical substance or mixture:</p> <ul style="list-style-type: none"> (1) For commercial distribution, including for test marketing, or (2) For use by the manufacturer, including use for product research and development, or as an intermediate. 	

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<i>Manufacturer</i>	A person who manufactures a chemical substance.	704.3 - A person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance.	Added new definition to avoid confusion with the 704.3 definition for manufacturer. Part of the 704.3 definition was used in the new 711 definition for <i>manufacture</i> . See discussion, above.
<i>Master Inventory File</i>	EPA's comprehensive list of chemical substances which constitutes the TSCA Inventory compiled under section 8(b). It includes chemical substances reported under 40 CFR part 710 and substances reported under 40 CFR part 720 for which a Notice of Commencement of Manufacture or Import has been received under 40 CFR 720.120.	710.43 - EPA's comprehensive list of chemical substances which constitute the Chemical Substances Inventory compiled under section 8(b) of the Act. It includes substances reported under subpart A of this part and substances reported under part 720 of this chapter for which a Notice of Commencement of Manufacture or Import has been received under §720.120 of this chapter.	Slight, non-substantive change from 710.43 definition.
<i>Non-isolated intermediate</i>	Uses the 704.3 definition.	<p>704.3 – Any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture. Mechanical or gravity transfer through a closed system is not considered to be intentional removal, but storage or transfer to shipping containers “isolates” the substance by removing it from process equipment in which it is manufactured.</p> <p>710.3 - Any intermediate that is not intentionally removed from the equipment in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.</p>	

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<i>Person</i>	Uses the 704.3 definition.	<p>704.3 – Any individual, firm, company, corporation, joint venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.</p> <p>710.3 - Any natural or juridical person including any individual, corporation, partnership, or association, any State or political subdivision thereof, or any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.</p>	
<i>Principal reporting year</i>	The latest complete calendar year preceding the submission period.	710.43 - <i>Reporting year</i> means the calendar year in which information to be reported to EPA during an IUR submission period is generated, i.e., calendar year 2005 and the calendar year at 5-year intervals thereafter.	Revised to reflect new reporting requirements.
<i>Process</i>	Uses the 704.3 definition.	<p>704.3 – To process for commercial purposes</p> <p>710.3 - The preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce:</p> <p>(1) In the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or</p> <p>(2) As part of a mixture or article containing the chemical substance or mixture.</p>	

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<i>Process for commercial purposes</i>	Uses the 704.3 definition.	704.3 – The preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes. 710.3 - To process: (1) For distribution in commerce, including for test marketing purposes, or (2) For use as an intermediate.	
<i>Processor</i>	Uses the 704.3 definition.	704.3 – Any person who processes a chemical substance or mixture. 710.3 - Any person who processes a chemical substance or mixture.	
<i>Readily obtainable information</i>	N/A	710.43 - Information which is known by management and supervisory employees of the submitter company who are responsible for manufacturing, processing, distributing, technical services, and marketing of the reportable chemical substance. Extensive file searches are not required.	This reporting standard is no longer in use.
<i>Reasonably likely to be exposed</i>	Identical to the 710.43 definition.	710.43 –An exposure to a chemical substance which, under foreseeable conditions of manufacture (including import), processing, distribution in commerce, or use of the chemical substance, is more likely to occur than not to occur. Such exposures would normally include, but would not be limited to, activities such as charging reactor vessels, drumming, bulk loading, cleaning equipment, maintenance operations, materials handling and transfers, and analytical operations. Covered exposures include exposures through any route of entry (inhalation, ingestion, skin contact, absorption, etc.), but excludes accidental or theoretical exposures.	

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<i>Repackaging</i>	Identical to the 710.43 definition.	710.43 – The physical transfer of a chemical substance or mixture, as is, from one container to another container or containers in preparation for distribution of the chemical substance or mixture in commerce.	
<i>Reportable chemical substance</i>	A chemical substance described in §711.5.	710.43 - Chemical substance described in §710.45.	To reflect a reference update.
<i>Site</i>	<p>A contiguous property unit. Property divided only by a public right-of-way shall be considered one site. More than one plant may be located on a single site.</p> <p>(1) For chemical substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured.</p> <p>(2) The site for an importer who imports a chemical substance described in §711.5 is the U. S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.</p> <p>(3) For portable manufacturing units sent out to different locations from a single distribution center, the distribution center shall be considered the site.</p>	<p>704.3 - A contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one plant on a single site. The site for a person who imports a substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction and may in some cases be the organization's headquarters office in the United States.</p> <p>710.3 - A contiguous property unit. Property divided only by a public right-of-way will be considered one site. There may be more than one manufacturing plant on a single site. For the purposes of imported chemical substances, the site will be the business address of the importer.</p>	Revised definition to clarify that the importer's site must be a U.S. address, to accommodate manufacturing under contract, and to accommodate portable manufacturing units.
<i>Site-limited</i>	Identical to the 710.43 definition.	710.43 – A chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited. Although a site-limited chemical substance is not distributed for commercial purposes outside the site at which it is manufactured and processed, the chemical substance is considered to have been manufactured and processed for commercial purposes.	Definition retained because it is used by other parts of the regulatory text, even though the CDR will no longer ask companies to identify if the substance is site limited.

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<i>Small quantities for research and development</i>	Uses the 704.3 definition.	<p>704.3 – (or “small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product”) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.</p> <p>710.3 - <i>Small quantities for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product</i> (hereinafter sometimes shortened to <i>small quantities for research and development</i>) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that:</p> <p>(1) Are no greater than reasonably necessary for such purposes, and</p> <p>(2) After the publication of the revised inventory, are used by or directly under the supervision of a technically qualified individual(s).</p> <p>Note: Any chemical substances manufactured, imported, or processed in quantities less than 1,000 lbs. (454 kg) annually will be presumed to be manufactured, imported, or processed for research and development purposes. No person may report for the inventory any chemical substance in such quantities unless that person can certify that the substance was not manufactured, imported, or processed solely in small quantities for research and development, as defined in this section.</p>	
<i>Submission period</i>	The period in which manufacturing, processing, and use data are submitted to EPA.	710.43 - The period in which the information generated during the reporting year is submitted to EPA.	Revised definition

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<i>Test marketing</i>	Uses the 704.3 definition	<p>704.3 – the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, article containing that chemical substance or mixture, or a mixture containing that substance, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.</p> <p>710.3 - The distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.</p>	
<i>Use</i>	Identical to the 710.43 definition.	710.43 – Any utilization of a chemical substance or mixture that is not otherwise covered by the terms manufacture or process. Relabeling or redistributing a container holding a chemical substance or mixture where no repackaging of the chemical substance or mixture occurs does not constitute use or processing of the chemical substance or mixture.	