

既有化學物質增補提報作業要點

Direction for Supplementary Existing Chemical Substance Nomination

(04/18/2012)

(Tentative Translation 04/2012)

(In case of discrepancies in interpretation, the Traditional Chinese text shall prevail)

Rules
<p>1. The Council of Labor Affairs (hereafter referred as the CLA), Executive Yuan, established this Direction to continuously update and maintain national existing chemical substance inventory and enhance national chemical management.</p>
<p>2. Definitions</p> <p>(1) Nominator: The company or organization who imports, or manufactures, handles, uses or sells chemicals domestically, or agent company or organization who is entrusted to do the nomination in accordance with this Direction.</p> <p>(2) Coordinator: The Register Office who is appointed to manage the nomination program by the CLA.</p> <p>(3) Supplementary Existing Chemical Substance Nomination Tools: The computer program appointed by the CLA for Supplementary Existing Chemical Substance Nomination.</p> <p>(4) Chemical Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;</p> <p>(5) Substances which Occurred in Nature: Substances occurring in nature are substances that are unprocessed, processed only by manual, gravitational, or mechanical means, or by dissolution in water, or by flotation, or by heating solely to remove water, or are extracted from air by any means, without chemical change in the substance.</p> <p>(6) Mixture: Mixture means a mixture or a solution composed of two or more substances in which they do not react.</p> <p>(7) Manufactured Article: means a manufactured item formed to a specific shape or design during manufacture, and the final use of which is entirely or partially determined by the specified shape or design, and during normal usage, will not release chemical substances.</p> <p>(8) Polymers: Polymer means a chemical substance consisting of:</p> <ol style="list-style-type: none"> Molecules characterized by the sequence of one or more types of monomers units; monomer unit means the reactive form of monomer chemicals in polymers. Greater than 50% by weight of molecules having three or more monomer units that are covalently bound to one or more other monomer units or reactants; Less than 50% by weight of molecules of the same molecular weight; and Molecules distributed over a range of molecular weights wherein differences in the

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<p>molecular weights are primarily attributable to differences in the number of monomer units.</p> <p>(9) Intermediate: Intermediate is a chemical substance produced and consumed in the course of the manufacture of another chemical substance.</p> <p>(10) Impurity: An impurity is an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present along with the final substance it was not intentionally added, nor does it enhance the commercial value of that substance.</p> <p>(11) Incidental Reaction Products: Incidental reaction products are substances produced when a substance undergoes a chemical reaction that is consequent to the use to which the substance is put or that results from storage or from environmental factors.</p> <p>(12) Chemical Substances Under Customs Supervision: A chemical substance under customs supervision, which is in temporary storage or placed in harbor's designated area or warehouse, container freight station, bonded warehouse, logistics center and free trade zone, with a provision to re-exportation or in transit.</p> <p>(13) Generic Name: it means to mask the name of a chemical substance to disguise the full identity, while retaining the generic molecular structure.</p> <p>(14) 2% Rule: There is no need to nominate (if the polymer has been nominated) while using other monomers or reactants at 2% (w/w) or less without changing the chemical identity. In other words, if the weight of monomer or reactant charged to the reaction is 2 % (w/w) or less, the monomer or reactant is not considered part of the chemical identity of the polymer, unless indicated by the nominator. According to the weight percentage for monomer or reactant mentioned in the 2% Rule defined above, the nominator can opt for</p> <ol style="list-style-type: none"> the calculation of amounts added (charged) to the reaction vessel: the weight percent of a monomer or a reactant is determined by its weight charged to the reaction vessel, expressed as a percentage of the weight of the polymer after the polymer's isolation from the reaction vessel. Or chemical analysis or theoretical calculation: it needs to determine the actual amount added into compound in the chemical combined form (incorporated) with the polymers through chemical analysis or theoretical calculation. Analytical data records or appropriate theoretical calculations must be kept. When this approach is used. <p>(15) National Existing Chemical Substance Inventory (draft): The chemical substance inventory received and compiled by the CLA in accordance with the "Direction for Existing Chemical Substance Nomination."</p>

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<p>3. Chemical substances imported to or manufactured, handled, used, or sold in Taiwan during January 1, 1993 and December 31, 2011, and are NOT listed in the National Existing Chemical Substance Inventory (draft) as existing chemical substances can be nominated pursuant to this Direction.</p>
<p>4. Exemptions</p> <p>When the chemical substance meets one of the following conditions, it is exempted from the nomination:</p> <ol style="list-style-type: none"> (1) A substance or a polymer occurred in nature without physical and chemical process. (2) A polymer that is applicable to the 2 % Rule. (3) Chemical substances accompanied in the machines and equipments for test-run purpose. (4) Inseparable intermediates from the chemical reaction in the reaction vessel or production process. (5) Mixture. But the chemical substances in the mixture need to be nominated. (6) Manufactured articles. (7) Chemical substances under customs supervision. (8) Chemical substances for national defense purpose. (9) Incidental reaction products or impurities without intended commercial purpose. (10) Wastes.
<p>5. Nomination Content</p> <p>Nominator must use the Supplementary Existing Chemical Substance Nomination Tools provided by the Coordinator to submit the following information:</p> <ol style="list-style-type: none"> (1) The basic information of the Nominator. (2) Chemical Abstracts Service Registry Number, CAS No. (3) Chinese/English/ Other names (synonym) of substances. (4) Annually average tonnage (the average amount for the three years prior to the nomination).
<p>6. Procedures</p> <ol style="list-style-type: none"> (1) After completed the information entry using Supplementary Existing Chemical Substance Nomination Tools and attached supplementary existing chemical substance supporting documents, nominator should submit the electronic file by email to ecncla@mail.cla.gov.tw, and also mail the print-out hardcopy with signature to the Coordinator. (2) While checking the integrity of the submission, the Coordinator may request the

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<p>Nominator to fill, correct and resubmit if required.</p> <p>(3) The Nominator needs to correct and resubmit within 30 days upon receiving of each request for correction. The procedure allows no more than one time of correction. If the correction procedure cannot be fulfilled in time, such nomination application will be cancelled automatically.</p> <p>(4) The Nominator is responsible for keeping copies of both electronic and paper file submissions.</p> <p>(5) Upon the receiving of both electronic and paper file submissions, the Coordinator will issue a notice. After the confirmation of the data, another notice will be issued as the proof of completing the nomination.</p>
<p>7. Data Protection</p> <p>Information submitted by the Nominator using the Supplementary Existing Chemical Substance Nomination Tools is subject to data protection of the following two categories:</p> <p>(1) Basic information of the Nominator and the annually average tonnage are protected automatically.</p> <p>(2) If the Nominator wants to further protect the information of Chemical Abstracts Service Registry Number and Chinese/English Names of Chemical Substances, the Nominator must apply for data protection and provide the preferred generic names for approval process using application forms provided. The application is subject to Conditions of Applying for Data Protection prescribed. After a review procedure, a protection period of five year term will be granted for not making public the information mentioned hereby. Instead, the approved generic name and serial number will be used as the identity of the nominated chemical substance as assigned. Within six months prior to its expiration date of the first granted five year term of data protection, Nominator is entitled to apply for another five years term of data protection. Only one time of extension is allowed.</p>
<p>8. Conditions of Applying for Data Protection</p> <p>The Nominator who wants to apply for data protection specified above must meet All the conditions prescribed below:</p> <p>(1) The requested data for protection contains Nominator's confidential business information.</p> <p>(2) The Nominator has taken action and will maintain the confidentiality of such information.</p> <p>(3) The data has not been accessed by the third party through reasonable and legal approaches unless authorized by the Nominator.</p> <p>The Coordinator reserves the right not to grant the application of data protection if the conditions prescribed above are not fully met.</p>

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<p>9. The CLA and the Coordinator are entitled to request the Nominator to provide document(s) or explanation to prove the Nomination Content. A written notice will be issued to cancel the nomination, if any Nomination Content is found to be fraudulent, or the information has not been corrected and resubmitted in time as specified.</p>
<p>10. If the Nominator has questions regarding the result of nomination, a written appeal must be filed detailing reasons to the Coordinator for reassessment within 30 days upon receiving the written notice of result. This application for reassessment is limited to one time only. Should the Coordinator fail to deal with the relevant issues, the case will be transferred to the CLA for further evaluation.</p>
<p>11. Deadline The Supplementary Existing Chemical Substance Nomination period is from June 1, 2012 to August 31, 2012.</p>

The Coordinator: National Chemical Substance Register Office (NCSR)

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