

4 April 2018

Original: English

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Committee on Technical Barriers to Trade

NOTIFICATION 臺灣 修正通知-化學品

Revision

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU

If applicable, name of local government involved (Articles 3.2 and 7.2):

2. Agency responsible:

Environmental Protection Administration

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Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:

- 3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [X], 5.7.1 [], other:
- 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Chemical substances
- 5. Title, number of pages and language(s) of the notified document: Amendments to Regulations of New and Existing Chemical Substances Registration (Draft) (32 page(s), in English; 67 page(s), in Chinese)
- 6. Description of content: The Toxic Chemical Substances Control Act (TCSCA) was amended and promulgated on 11 December 2013. Pursuant to TCSCA, the subordinate implementing law "Regulations of New and Existing Chemical Substances Registration and Management" were enacted on 11 December 2014. This proposal aims to update the provisions under the "Regulations of New and Existing Chemical Substances Registration." Major amendments include the following: 毒性化學物質管理法(TCSCA)已於 2013 年 12 月 11 日 修訂及公布。依據 TCSCA,新化學物質及既有化學物質資料登錄辦法於 2014 年 12 月 11 日頒布。本 提案旨在更新新化學物質及既有化學物質登錄之條文。主要修正如下:
 - 1. Clarifying the scope of application of the Regulations. The Regulations shall not apply to Toxic Chemical Substances, as defined by TCSCA. 說明本法規適用範圍。TCSCA 規範的毒性化學物質不適用本辦法。
 - 2. Harmonizing the information requirement between the EPA and the Ministry of Labour regarding hazard assessment and exposure assessment; 調和環境保護署和勞動部間對於危害評估和暴露評估資訊的需求。
 - 3. Issuing the registration number, instead of the registration document for the

registration approved; 發給登錄碼,取代登錄批准的登錄文件。

- 4. Clarifying the quantity that triggers the obligation for the existing chemical substance phase 1 registration. For an existing chemical substance manufactured or imported in the annual volume of 100 kilograms or more, the phase 1 registration must be made within 6 months. Also a voluntary phase 1 registration may be made for the existing chemical substance manufactured or imported in the annual volume less than 100 kilograms. 說明觸動既有化學物質第一階段義務之數量。製造或進口既有化學物質年數量達一百公斤或以上者,應於 6 個月內辦理第一階段之登錄。製造或進口既有化學物質年數量未達一百公斤者得自主辦理第一階段登錄。
- 5. Designating the first stage of 106 chemical substances subject to the standard registration of existing chemical substances. 指定 106 種化學物質應完成既有化學物質標準登錄。
- 6. Clarifying the period of the information confidentiality of chemical substances included in the inventory of existing chemical substances, and ensuring consistency in the period of the information confidentiality and the validity of registration approval; 闡明化學物質保密資訊期限,包括在既有化學物質清單中,確保保密資訊期間的一致性害批准登錄的有效性。
- 7. Requiring an annual report of the new and existing chemical substance registered and approved. For the chemical substance registered and approved, an annual report shall be completed from April to September each year; 要求經核准登錄之新化學物質及既有化學物質提出年度報告。年度報告為每年四月到九月。
- 8. Indicating the calculation of the review period, so that the review period is calculated anew upon the registrant's supplementation or modification of the registration application; 指示審查期的計算,依據登錄者補正或更正登錄申請資料重新計算審查期。
- 9. Extending the limit on the time period and the number of times that a supplementation and correction may be made for a registration application, by taking into account the scientific and technical feasibility assessed by the EPA.經環境保護署評估科學和技術上的可行性,延長補正和更正的時間和次數限制。
- 10. Accepting written appeal with stated reasons for which the registrant may have concerns over the review result. 接受關於登錄者對審查結果有疑義的書面申覆。
- 11. Deleting outdated provisions.刪除過時條文。
- 7. Objective and rationale, including the nature of urgent problems where applicable: The purpose of these amendments are to reflect the global trends in chemical substance registration mechanisms, to meet the essential need of inter-agency cooperation, to reasonably reduce the costs incurred from chemical risk assessment and governmental administration, as well as to achieve the goal of environmental and human health protection.
- 8. Relevant documents: Toxic Chemical Substances Control Act (TCSCA)
- 9. Proposed date of adoption: To be determined

Proposed date of entry into force: To be determined

10. **Final date for comments**: 60 days from notification

11. Texts available from: National enquiry point [X] or address, telephone or fax numbers and email and website addresses, if available, of other body:

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