



29 September 2017

(17-5224)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION 臺灣通知—化學物質

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU</u> 臺灣
If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Environmental Protection Administration No. 83, Sec 1, Zhonghua Rd. Zhongzheng Dist, Taipei City 10042, Taiwan Tel: (+886 2) 2325-7399 Fax: (+886 2) 2325-3823 Email: chhahsu@epa.gov.tw 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 化學物質
5. Title, number of pages and language(s) of the notified document: Amendments to Regulation of New and Existing Chemical Substances Registration (Draft) (21 page(s), in English; 59 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, "Regulation of New and Existing Chemical Substances Registration and Management", was enacted on 11 December 2014. This proposal aims to update the provisions under the "Regulation of New and Existing Chemical Substances Registration." Major amendments are as follows: <ol style="list-style-type: none">1. Harmonizing the information requirement between the Environmental Protection Administration (EPA) and the Ministry of Labour regarding hazard assessment and exposure assessment;2. Issuing the registration number, instead of the registration document for the approved registration;3. Clarifying the quantity that triggers the obligation of 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 an annual volume of less than 100 kilograms;

4. Clarifying the period of confidentiality of information on 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;
5. Requiring an annual report on new and existing chemical substances registered and approved;
6. Indicating the calculation of the review period, that the review period is calculated anew upon the registrant's supplementation or correction to the registration application;
7. Extending the limit on the time period and the number of times that supplementations and corrections may be made for a registration application, by the EPA taking into account the scientific and technical feasibility;
8. Accepting written appeals with stated reasons for which the registrant may have concerns over the review results;
9. Deleting outdated provisions.

毒性化學物質管理法在 2013 年 11 月 11 日公布修正，依據該法，在 2014 年 11 月 11 日頒布新化學物質及既有化學物質資料登錄及管理辦法。此次更新該辦法之相關條文如下：

1. 調和環境保護局及勞動部關於危害評估和接觸評估的資訊要求。
2. 發給核准登錄者登錄碼取代登錄文件。
3. 明定既有化學物質第一段登錄的數量。製造或輸入既有化學物質年數量達一百公斤以上者，應於六個月內提出既有化學物質第一階段申請登錄。而製造或輸入既有化學物質年數量未達一百公斤者，得自主提出申請登錄。
4. 明定納入既有化學物質清單之新化學物質資訊保密的期間，並確保資訊保密期間和核准登錄效期的一致性。
5. 核准登錄之新化學物質及既有化學物質須提供年度報告。
6. 依據申請人補充和更正申請登錄重新起算審查期。
7. 環保署在科技和技術可行性考量下，延長申請登錄的補充和更正的時間與次數的限制。
8. 登錄人就審查結果有疑義者，得書面敘明理由提出申覆。
9. 刪除過時規定。

7. Objective and rationale, including the nature of urgent problems where applicable: The purpose of this amendment is to align with global trends in chemical substance registration, to meet the essential needs of inter-agency cooperation, to reasonably reduce the costs incurred for 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 and fax numbers and email and website addresses, if available, of other body:

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https://members.wto.org/crnattachments/2017/TBT/TPKM/17_4382_00_e.pdf

https://members.wto.org/crnattachments/2017/TBT/TPKM/17_4382_00_x.pdf