STC | 中国资讯速递

1. The China Version of the "REACH Restricted Chemicals" Standard was Implemented on 1 June 2021

On 1 June 2021, the China version of the "REACH Restricted Chemicals" GB/T 39498-2020 "Guidelines for the Use and Control of Key Chemicals in Consumer Products" was officially implemented.

Recently, the recalls reports from European Union and the United States towards China consumer products have shown that more than half of the recalled consumer products were caused by chemical hazards. Lack of relevant standards for chemical safety and hazards in China may be one of the reasons. To enter the global market and improve the quality of consumer products, it is critical to establish guidelines for consumer products safety and restrictions for chemical usage that suit for the current Chinese industries and markets and lead for industrial development.

The guidelines only focus on consumer products, their components and packaging, such as toys, textiles, leather goods, jewelry, electrical and electronic products, inks, coating paints, cleaning supplies, etc. However, it is not eligible to other medicines, cosmetics, food and industrial products. For details, please email hkstc@stc.group.

Source: http://www.dianqizazhi.com/2021/05/18/42550.html

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2021 年 6 月 1 日中国版“REACH 限制物质”标准正式实施

2021 年 6 月 1 日，“中国版 REACH 限制物质”GB/T 39498-2020《消费品中重点化学物质使用控制指南》正式实施。

近年来欧盟、美国对中国消费品的召回通报信息显示，半数以上的产品召回是由于化学危害而导致。而造成此现象的根本原因是中国缺乏相关化学安全危害因素的标准。为加快中国产品走出战略的实施，提升中国消费品品质，亟需制定符合中国产业和行业现状，并引领产业发展的消费品安全化学危害限制要求标准。

本次标准只针对消费品、其组件及包装，例如玩具、纺织品、皮革制品、首饰品、电子电器产品、油墨、涂料、清洗剂等，不适合其他医药、化妆品、食品和工业用品。如有意咨询，欢迎电邮 hkstc@stc.group 查询。

资料来源 http://www.dianqizazhi.com/2021/05/18/42550.html

2. Notice on the 2021 Guangdong’s Cosmetic Products Supervision and Random Inspection Results

According to the 2021 cosmetic products supervision and random inspection (5th phase by the Guangdong Administration for Market Regulation), it involved 214 batches of cosmetic samples in the province. As a result, 212 batches of samples were qualified while 2 batches were failed. Excessive lead amounts and total bacterial counts were found in the failed

batches. Compared to the last Guangdong cosmetics sampling inspection (4th phase), 340 batches of samples were qualified while 24 batches were unqualified. It demonstrated a reduction in the failure rate.

STC (Dongguan) has successfully passed the assessment for cosmetics and information management system from the National Medical Products Administration since 2019. It became one of the designated testing and inspection organizations for cosmetic products registration and recordation. STC can conduct inspection of the recordation of China produced non-special-purpose cosmetics. Please contact hkstc@stc.group for details.

Source: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/hzhpchjgg/hzhpcjdf/gdhzhpss/20210602020139327.html

广东省 2021 年化妆品产品监督抽检抽查情况通告

根据广东省市场监督局 2021 年化妆品监督抽检工作安排(第五期) ,本期涉及全省 214 批次化妆品的抽样检验信息，经检验合格样品 212 批次，不合格样品 2 批次。不合格原因为铅和细菌落总数超限值。上一次 2021 年第四期的广东省化妆品抽样中，抽查情况为合格样品 340 批，不合格样品 24 批，产品不合格率有所降低。

东莞标检产品检测有限公司（东莞标检）于 2019 年 11 月 20 日通过国家药监局化妆品和备案信息管理系统审核，成为化妆品注册和备案检验检测机构之一，具备承担国产非特殊用途化妆品备案检验工作的资质。如厂家需要进一步了解有关测试和备案业务，可电邮 hkstc@stc.group 查询。

资料来源 https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/hzhpchjgg/hzhpcjdf/gdhzhpss/20210602020139327.html

3. China State Administration for Market Regulation Issued the Implementation Rules for Supervisory Spot Checks on Product Quality for 62 Types of Products

To enhance the scientificity and standardization of the China national supervision and inspection on product quality, the China State Administration for Market Regulation compiled and issued the implementation rules for Supervisory Spot Checks on Product Quality for 62 Types of Products included Toys and other products in accordance with "Interim Measures for the Administration of Supervisory Spot Checks on Product Quality" (Order No. 18 of the China State Administration for Market Regulation). Local supervisory spot checks could refer to the implementation rules. At the same time, the old rules have been abolished.

STC is an accredited testing laboratory of China Metrology Accreditation (CMA) and is able to issue testing reports for domestic market access. In addition, STC's toys and children's products labortory and electrical and electronic products laboratory are the designated CCC testing laboratories, which can provide comprehensive CCC testing and certification services. For more information, please contact hkstc@stc.group.

Source: https://www.cqn.com.cn/ms/content/2021-05/14/content_8692419.htm

国家市场监管总局发布玩具等 62 种产品质量国抽实施细则

为提升产品质量国家监督抽查工作的科学性、规范性，依照《产品质量监督抽查管理暂行办

法》（市场监管总局令第 18 号），市场监管总局组织编制了玩具等 62 种产品质量国家监督抽查实施细则，现予发布。各地在开展监督抽查工作时可参照执行。旧版产品质量国家监督抽查实施细则同时废止。

STC 实验室获得中国 CMA 资质认定，提供内销市场市场准入的检测报告，玩具和电子电器更是国家强制性产品认证指定实验室，承担 CCC 认证检测任务。详情可电邮 hkstc@stc.group 与 STC 实验室联系。

资料来源 https://www.cqn.com.cn/ms/content/2021-05/14/content_8692419.htm

4. The Revised "Regulation on the Supervision and Administration of Medical Devices" Came into Force on 1 June 2021

The " Regulation on the Supervision and Administration of Medical Devices" was revised and adopted at the 119th executive meeting of the China State Council on 21 December 2020 and came into force on 1 June 2021. The revised Regulation stipulated the reformation requirements for the evaluation and approval system of medical products and medical devices, reinforced corporate responsibilities, continued to deepen the "Decentralization-Control-Service" reform, and stimulated market innovation. The classification administration of medical devices are divided into three classes according to their risk levels. Class I will be subjected to product recordation administration while Class II and Class III shall be

subjected to product registration administration. The Regulation adopted the globally recognized concept of "registrants and recordation entities", which corresponded to the concept of license holders. Additionally, a clause for urgent use of medical devices has been added to the Regulation in respond to any particularly serious public health emergencies.

As a Good Laboratory Practice (GLP) medical device testing laboratory in China certified by the Organization for Economic Co-operation and Development (OECD), STC provides internationally recognized medical device testing services such as biocompatibility and EMC testing. For inquiry, please email hkstc@stc.group.

Source: http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm

新的《医疗器械监督管理条例》于 2021 年 6 月 1 日起施行

《医疗器械监督管理条例》已经在 2020 年 12 月 21 日国务院第 119 次常务会议修订通过，现于 2021 年 6 月 1 日正式施行。其主要是落实药品医疗器械审评审批制度改革要求，夯实企业主体责任以及继续推进“放管服”改革，释放市场创新活力。医疗器械实行分类管理，第一类实行备案，第二类、第三类需要取得上市许可，《条例》使用了国际通用的“注册人、备案人”概念，对应上市许可持有人概念。另外,也加入了紧急使用制度条款,以便应对突发公共卫生事件。

STC 医疗器械实验室已经获得经济合作与发展组织(OECD)成员的 GLP 认可。为客户提供国际认可的医疗器械检测服务，例如生物兼容性测试及医疗器械产品 EMC 测试。如需进一步了解测试和认证，可电邮 hkstc@stc.group。

资料来源 http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm