

Environmental Protection

Environmental Protection Series (XI) –An Interpretation of the Revised Measures for the Registration of the Environmental Management of New Chemical Substances and the New Challenges for Corporate Compliance

Foreword

On April 29, 2020, the Ministry of Ecology and Environment ("MEE") issued the revised 'Measures for the Registration of the Environmental Management of New Chemical Substances' (Order of the Ministry of Ecology and Environment No.12, hereinafter referred to as "**Order No.12**"). The measures will come into force on January 1, 2021. This revision, based on the previous 'Measures for the Environmental Management of New Chemical Substances' (Order of the Ministry of Environmental Protection No.7, hereinafter referred to as "**Order No.7**") that were issued in 2010, make significant revisions to some situations and problems that have arisen during the implementation of Order No. 7 over the past 10 years. This circular will highlight some of the key changes in Order No. 12. Based on these key changes, relevant industrial enterprises and trading companies should be reminded of the compliance issues requiring special attention with respect to the environmental management of new chemical substances.

I. What Are the Key Changes in Order No.12?

We have summarized some material and/or material changes to Order No.12 from the current Order No. 7 as follows:

1. The application's scope has been limited.

Overall, "one application" and "two non-applications" have been added. The "one application" applies to products that are administered by other laws (such as medicine, pesticide and food additives) and are intended to be used for other industrial purposes; while "two non-applications" refer to those new chemical substances that are (i) stored in customs special supervision areas and are then exported without any processing and are therefore not applicable; and (ii) newly-added fertilizer and radioactive substances in the special substance area that are also not applicable.

2. The original seven types of declarations has been reduced to three types.

Order No. 12 has changed the two circumstances of scientific research record filing and simple declaration (where the annual production or import volume is lower than one ton) under Order No. 7 to **record** filing and simplifies the application materials (such as the cancellation of the test report on eco- toxicological properties). The level one declaration (the annual production or import volume ranges from one ton to 10 ton) in the regular declaration shall be changed to a simple registration with the relevant procedures and requirements simplified (such as the cancellation of the requirement of submitting a risk

assessment report and the cancellation of the assessment step by an expert committee). The level two to level four declarations in the regular declaration (the annual production or import volume is more than 10 tons) shall be changed to a normal registration.

3. The methods to report activities related to the production, importation, processing and utilization of new chemicals have been simplified. Firstly, Order No. 12 has deleted the requirement for the reporting of each activity and the reporting of activities with a five year duration, and retained the requirements for the reporting of the first activity and the annual report; secondly, the deadline for the submission of the report of the first activity shall be extended to within 60 days from the date of the first manufacturing or importing and transferring, to the processing user (30 days under Order No. 7); finally, it is specified that only the chemical substances required for the submission of annual reports in the normal registration certificate are required to submit a report of the actual activities of the new chemical substance for the preceding year, prior to 30 April each year (before 1 February each year in Order No. 7).

4. It is specified that a recording system for new chemical activity shall be established. Order No. 12 prescribes that researchers, producers, importers, processors and users of new chemicals shall establish a recording system for activities involving the new chemicals. This is to faithfully record the time, quantity and purpose of the activities involving the new chemicals and undertake environmental risk control measures and environmental management requirements, among others.

5. The legal liability of enterprises has been strengthened. This mainly manifests in: (i) the illegal circumstances of enterprises have increased. The Draft for Comment explicitly stipulates that circumstances such as a failure by enterprises to fulfill information disclosures, record filing or the environmental management

requirements set out in the Inventory of Existing Chemical Substances of China (the "**Inventory**"), shall be listed as matters to be punished. Secondly, the consequences for violation are more serious. Order No.12 clarifies that a fine ranging from CNY 10, 000 to CNY 30, 000 will be imposed on an offender in the case of a false declaration or production or import without the registration certificate or record-filing. It further clarifies that an offender will be subject to joint disciplinary actions for dishonesty and will not be allowed to apply for the registration of new chemicals within one year (we note that the Ministry of Ecology and Environment promulgated the Regulations on Environmental Risk Assessment and Control of Chemical Substances (Draft for Comment) (Huan Ban Solids Han [2019] No.18) on January 8, 2019. If such regulations are formally adopted, future legal liabilities may be substantially increased). In addition, Order No. 12 has deleted the requirements for the registration of new chemicals as a condition for the examination and approval of environmental impact assessment documents for construction projects, manufacturing, processing or using such new chemicals.

6. The management requirements for highly-hazardous chemical substances have increased. Order No. 12 adds the definition of "highly-hazardous chemicals" and the related regulatory requirements. Highly-hazardous substances shall be subject to higher requirements in the registration of new chemical substances and the daily management thereof. For example, the analysis material on the social and economic benefits shall be provided at the time of registration, and the environmental management for the new uses shall be conducted after they are included in the inventory.

II. What are the key compliance issues that enterprises should pay special attention to under Order No. 12?

1. Enterprises should strengthen their compliance management. Enterprises should attach great importance to their own responsibility for the environmental risk control of any new chemical substances. They should complete in a timely manner all the types of registration required for new chemical substances, and carry out the manufacture, import, processing and use of new chemical substances pursuant to the provisions on the registration certificates. They need to pay attention to record-filing, strengthen the lifecycle management of new chemical substances, and in particular, establish a recording system for the activities involving the new chemical substances. Enterprises and businesses should implement compliance requirements in aspects such as record and data preservation, information disclosure, targeted environmental risk control measures and environmental management.

2. Enterprises should strengthen supplier reviews. When selecting suppliers, especially testing institutions, an enterprise shall, in addition to understanding the relevant qualifications and capabilities of their institutions and personnel, comprehensively check the compliance situation of the institutions and the responsible personnel during the most recent three year time period (in accordance with Order No. 12, where a testing institution issues a false test report that provides test data for the application for new chemical substances, the department of ecology and environment shall not accept any test report issued thereby or by the relevant responsible persons within three years).

III. Conclusion and Suggestions

On the one hand, the revision reflects the

legislative trend of "streamlining administration, delegating power, strengthening regulations and improving services", lowering the requirements for new low-level chemicals and simplifying the procedures; on the other hand, the management of enterprises during and after registration has been strengthened. Enterprises should always value and protect their social credit, and strive to do a good job in risk prevention and control and risk management in the whole life cycle of new chemicals, so as to avoid or reduce unnecessary punishment and/or losses. We will also pay close attention to the subsequent supporting regulations (relating to declaration data requirements, hazard assessments, environmental risk assessments, socio-economic benefit analysis and registration of environmental management for new purposes) and the legislative processes related to Order No. 12 and share our observations in a timely manner. If you have any specific questions, please feel free to contact us via email: ecoenvpro@junhe.com.

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环境保护法律热点问题

环保专题系列（十一） - 《新化学物质环境管理登记办法》修订亮点解读及企业合规新挑战

前言

2020年4月29日,生态环境部发布了其审议通过的修订后的《新化学物质环境管理登记办法》(生态环境部12号令,以下简称“12号令”),该办法将自2021年1月1日起施行。本次修订在2010年版的《新化学物质环境管理办法》(环境保护部令7号,以下简称“7号令”)的基础上,针对7号令实施近十年过程中出现的一些新情况、新问题,作出了诸多重大修改。本文将梳理12号令的重点变化,并基于此提示相关工业企业或贸易公司在新化学物质环境管理方面需要重点关注的合规事项。

一、12号令的重点变化有哪些?

我们将12号令相对于现行7号令的一些实质或重大变化归纳如下:

1. **适用范围有所限缩。**整体而言,新增了“一种适用”和“两种不适用”。“一种适用”为:由其他法律管理的产品(如医药、农药、食品添加剂等)拟改变为其他工业用途的适用。“两种不适用”为:进口后在海关特殊监管区内存放且未经任何加工即全部出口的新化学物质不适用;此外,不适用的特殊物质中新增肥料和放射性物质。

2. **申报类型由七种简化为三种。**12号令将7号令下的科学研究备案和简易申报的两种情形(年生产量或进口量为1吨以下)均改为备案,且申请材料有所简化(如生态毒理学特性测试报告被取消);常规申报中的一级申报(年生产或进口量为1-10吨)改为简易登记,同时简化了相关程序和要

求(如取消提交风险评估报告的要求、取消专家委员会评审环节);常规申报中的二级到四级(年生产量或进口量为10吨以上)申报改为常规登记。

3. **简化新化学物质生产、进口和加工使用活动的报告方式。**首先,12号令删除了每次活动报告和五年活动报告的相关要求,保留了首次活动报告和年度报告要求;其次,将提交首次活动报告的时限延长至首次生产或者进口并向加工使用者转移之日起60日(7号令为30日)内;最后,明确只有常规登记证上规定了提交年度报告要求的化学物质,申请人才需于每年4月30日前(7号令为每年2月1日前)提交上一年度的新化学物质实际活动报告。

4. **明确应建立新化学物质活动情况记录制度。**12号令规定,新化学物质的研究者、生产者、进口者和加工使用者应当建立新化学物质活动情况记录制度,如实记录新化学物质活动时间、数量、用途,以及落实环境风险控制措施和环境管理要求等情况。

5. **企业法律责任加强。**这主要体现在:首先,企业的违法情形增加。明确将企业未履行信息公开、记录存档、未落实《中国现有化学物质名录》(以下简称“《名录》”)列明的环境管理要求等情形列为处罚事项。其次,违法的后果更加严重。12号令对于虚假申报、未取得登记证/备案生产或者进口等违法情形除了明确将被处以1-3万元的罚款,还明确了情节严重的依规开展失信联合惩戒,并且一年内不再受理其新化学物质登记申请(我们注意到,生态环境部于2019年1月8日颁布了《化学物质环境风

险评估与管控条例（征求意见稿）》（环办固体函〔2019〕18号），如该条例正式通过，将来的法律责任可能会实质性加大。此外，12号令删除了将新化学物质登记作为审批生产或者加工使用该新化学物质建设项目环境影响评价文件的条件的要求。

6. 新增高危害化学物质管理要求。12号令新增了“高危害化学物质”的概念及相关监管要求。高危害物质在办理新化学物质登记以及日常管理中，均有更高的要求，比如在登记时要提供社会经济效益分析材料，列入《名录》后还要实施新用途环境管理等。

二、12号令下企业应关注的合规重点事项有哪些？

1、企业应加强合规管理。企业应高度重视其自身对新化学物质环境风险控制的主体责任，及时办理新化学物质的各类登记，并按照登记证/备案的规定进行生产、进口或者加工使用并加强新化学物质的全生命周期管理，尤其是建立新化学物质活动情况记录制度，落实记录和资料保存、信息公开、有针对性的环境风险控制措施和环境管理等方面的合规要求。

2、企业应加强供应商审核。企业在选择供应商，特别是测试机构时，除了解其机构和人员的相关资质和能力外，还应全面了解机构和具体负责人员近三年的执业合规情况（根据12号令，测试机构

为新化学物质申请提供测试数据的测试机构出具虚假报告的，生态环境部门将在三年内不接受其出具，或者相关责任人员出具，的测试报告）。

三、结语建议

本次修订一方面体现了“放管服”和简政放权的立法趋势，对于低量级新化学物质的管理要求降低、程序也更加简化；另一方面，又加强了企业事中事后的管理。企业应始终坚守底线，珍惜自己的社会信用，做好新化学物质全生命周期的风险防控和风险管理，以避免或减少给自身带来不必要的处罚/损失。

我们也会持续关注后续配套规定（涉及申报数据要求、危害评估、环境风险评估、社会经济效益分析和新用途环境管理登记等）以及与12号令密切相关立法进程，并及时分享我们的一些观察。如您有任何具体的问题，欢迎邮件联系我们：ecoenvpro@junhe.com。

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