



# Revised regime for 'new' chemicals in China

China is overhauling its existing regime for the notification of new chemical substances to make it more like the EU's regime.

The regime only applies to novel substances – ie those not already listed on China's chemicals inventory – so it will not immediately have a direct effect on all companies in the sector. However, this is unlikely to mark the end of China's efforts to strengthen its chemical safety regime and regulatory trends in such an important market will no doubt be watched with interest by all chemical companies

This briefing examines the new proposals and the challenges they pose, and offers practical suggestions on preparing for compliance.

## Key points

- China is consulting on new measures to overhaul its existing regime for the notification of new chemical substances. If adopted in the current form, the new rules would come into force in October 2010.
- The new rules would apply only to 'new' chemical substances – ie chemicals other than the approximately 45,000 substances currently listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). Substances listed on IECSC would continue to enjoy lighter touch regulation.
- The proposed new regime draws on many elements of the EU's chemicals regulatory framework, REACH<sup>1</sup>, and has been dubbed 'China REACH'. The similarities relate to risk assessment, risk management and data submission. It would expand on China's existing registration regime for new chemical substances by increasing the volume and complexity of data that must be supplied to the authorities before import or production. The manufacture, import or use of a new chemical substance that had not been properly registered would be expressly prohibited.
- It appears from the current legislative draft that data to support product registration may be submitted only by Chinese-registered entities. If so, non-Chinese companies wishing to export innovative products to China, or to have them manufactured there, would have to rely on local agents or affiliates. Moreover, it would be mandatory under the regime to use Chinese testing laboratories to generate certain of this data.

As with any other sharing of product data with a third party, steps will need to be taken to protect confidentiality.

- Financial penalties for breach of the new regime would not, on their face, be significant. However, the practical costs of non-compliance – eg an inability to produce, import or use a particular product – might be more substantial, and the relevant authorities can also require corrective action to be taken in case of breach.
- Compliance with the new regime may be challenging for those whose products fall within its scope. We have set out suggestions on how to prepare at the end of this briefing.

## In detail: the new proposals

On 21 May 2009, China's Ministry of Environmental Protection launched an internal, inter-ministries consultation on a proposal (the 2009 Measures) to replace its existing Measures on Environmental Management of New Chemical Substances, which date from 2003 (the 2003 Measures). The proposed new regime has been dubbed 'China REACH'.

The 2009 Measures would, like the 2003 Measures, apply only to substances that are not listed on IECSC. There were 45,290 substances listed on IECSC, as at December 2008, and these are and would remain subject to piecemeal regulation<sup>2</sup>.

<sup>2</sup> There are specific occupational health and safety rules governing the marketing and use of hazardous and toxic chemicals, but no generally applicable rules. Managerial and enforcement responsibilities are shared between a plethora of district, provincial and state entities.

<sup>1</sup> REACH is the EU's chemicals regulatory framework, put in place by Regulation 1907/2006/EC on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

Already, under the 2003 Measures, manufacturers and importers of new chemical substances must obtain a 'registration certificate' prior to manufacture/import. They do so by notifying toxicological and other data to the Chemical Registration Centre (the CRC) of the Ministry of Environmental Protection. The 2009 Measures would not change this basic structure, but would significantly increase the burden on industry in terms of data production and ongoing risk management obligations.

The main features of the new regime are set out below.

- Under the 2009 Measures, the CRC must be notified, and a registration certificate obtained, before a new chemical substance may be manufactured in China or imported into China. The manufacture, import or use of a new chemical substance that has not been so registered is expressly prohibited. For example, a valid registration certificate will need to be provided to the General Administration of Customs before any import is permitted (*Article 5*).
- On notification of a new chemical substance manufactured or imported at over 1 tonne per year, the manufacturer or importer must provide:
  - the appropriate notification form;
  - a test report detailing the substance's physico-chemical properties and its toxicity and eco-toxicity;
  - an environmental risk assessment report (covering a variety of areas, including exposure scenarios, control measures, pollution prevention control and waste disposal);
  - recommendations on classification and labelling; and
  - a chemical safety data sheet.
- The level of data required will increase depending on the annual tonnage band of the substance in question (1-10, 10-100, 100-1000 or 1000+ tonnes). This principle is described as 'the higher the volume, the more information required' (*Article 8*).
- Less onerous requirements apply in the case of new chemical substances, which:
  - are manufactured/imported at under 1 tonne a year;
  - are low-volume intermediates for export;
  - are polymers containing less than 2 per cent monomers and which are 'of low concern' (a term which is not defined in the 2009 Measures); or

- fall into defined categories of low-volume substances for scientific research or for technical research and product development.

However, while the contents of the notification dossier may be reduced (in some cases, substantially so) for new chemical substances of this sort, notification is still required for all such chemicals (*Article 8*).

- On the wording of the current draft, certain fast-track notifications may only be made by an entity registered in China (*Article 10*). However, it is unclear, based on the current draft, whether this requirement in fact applies to all notifications – in other words, whether only China-based companies can notify. If so, this would be similar to the situation under REACH, except that REACH, unlike the 2009 Measures, expressly provides for the appointment of 'only representatives' by non-EU manufacturers.
- However, it is clear on the wording of the current draft that the eco-toxicological test report included in the notification dossier (where required) must 'include testing data using Chinese target organisms within the territory of the People's Republic of China' (*Article 8*).<sup>3</sup> Use of Chinese laboratories will therefore be mandatory in most cases.
- Notifications may be submitted jointly with other applicants. Applicants may also rely on data already submitted to support the registration of the same new chemical substance, but only with the agreement of the prior applicant (*Article 10*).
- The CRC will consider any notification submitted to it and will classify the substance in question in one of three ways: as a general chemical substance, a hazardous chemical substance or as a chemical substance of environmental concern. If it is satisfied that the information supplied to it meets the statutory requirements, the CRC will issue a registration certificate. However, it is not permitted to register a chemical substance of environmental concern unless the application has been accompanied by the appropriate risk control measures (*Article 13*).
- Registrants and end users of new chemical substances are required to adopt various risk management measures covering hazard and exposure in the areas of labelling and packaging, transportation and

<sup>3</sup> However, data testing more generally may be carried out by both accredited overseas and Chinese laboratories (*Article 11*).

disposal. Stricter risk management obligations and supply chain information obligations will apply in the case of substances classified as hazardous or of environmental concern (*Articles 7 and 19-21*).

- There are also various post-registration reporting and record-keeping requirements. For example, a ‘first-time activity report’ must be submitted to the CRC within 30 days of the first production or transfer of a registered substance. In the case of new chemical substances of environmental concern, registrants must file similar reports each time they transfer such substances to other market actors, and processors and users must file such reports within 30 days of their first processing or use of such a substance (*Article 23*). This permits the Ministry of Environmental Protection to issue ‘administrative control notices’ to local Environmental Protection Bureaus, which will set conditions for the processing or use of substances classified as hazardous and of environmental concern (*Article 26*).
- Enforcement is by the Ministry of Environmental Protection and local Bureaus (*Articles 35-37*). All such regulators may impose financial penalties of between RMB10,000 (approx €1,050) to RMB30,000 (approx €3,150) and require corrective measures be taken for violation of specified requirements under the 2009 Measures. These include failing to notify new chemical substances before production/import, failing to disclose relevant information during the notification process, providing false data to the CRC and failing to comply with an administrative control notice.
- Private prosecutions by companies and members of the public are also foreseen (*Article 29*). It is possible that this may become a tool for competitive regulation – ie taking legal action to sanction competitors’ failure to comply with the law.

## What does this mean for the international chemicals industry?

Since the EU first began debating REACH, there has been speculation that other countries would be forced by the globalised nature of the chemicals industry to introduce similar controls. In the US, the bill to introduce the Kid-Safe Chemicals Act of 2008, which would have required (among other things) manufacturers of existing chemical substances to provide all reasonably available

information not previously submitted concerning those substances to the Environmental Protection Agency, ran out of time. However, similar legislation may well be introduced into the current session of Congress. As regards the major Asian economies, the authors of a recent study noted that legislators were ‘trying to fill the regulatory gap they see between REACH and their own chemical regulatory systems’. They predicted that ‘China may follow at a slower pace. Not because China is not willing to do so, but because its existing chemical control system has a complex structure governed by multiple Ministries’ and its scientific and testing infrastructure might require development.<sup>4</sup>

Although to describe the 2009 Measures as ‘China REACH’ is probably to overstate the case, they do represent a significant step towards introducing a REACH-style regime in China. By this, we mean that they are intended to bolster the 2003 Measures by introducing REACH-style data submission requirements and ongoing risk management obligations, while continuing to apply only to non IECSC-listed chemicals.<sup>5</sup> They are unlikely to mark the end of China’s efforts to strengthen its chemical safety regime, particularly since they are administered by the new Ministry of Environmental Protection – a powerful ‘super-ministry’ created in 2008 from the State Environmental Protection Administration. Regulatory trends in such an important market will no doubt be watched with interest by all chemical companies.

The 2009 Measures will of course be of particular interest to businesses that export innovative chemical substances, or preparations containing such substances, to China or that manufacture them there (either themselves or under licence). This might include those involved in nanotechnology development, since, unlike REACH, a notification will still need to be made in the case of new chemical substances manufactured/imported at under 1 tonne per year (although, as noted, there are reduced data submission requirements in these cases).

As well as the practical challenges involved in generating the datasets required to support notification/registration,

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<sup>4</sup> ‘REACHing Asia: Recent Trends in Chemical Regulations of China, Japan and Korea’, DaeYoung Park, Me-Young Song, Kwi-Ho Lee, Duk-Chan Yoon, Xiong Cong, Social Science Research Network Working Paper Series, 18 April 2008 (last revised 26 June 2008). An electronic copy of this study is available at <http://ssrn.com/abstract=1121404>.

<sup>5</sup> REACH, by contrast, applies to both existing and new substances, although existing substances listed on the EU inventory (EINECS) benefit from extended deadlines for registration if duly pre-registered.

the proposed measures raise concerns from the perspective of commercial confidentiality. If, ultimately, it remains the case that notifications may only be filed by Chinese-registered entities, foreign exporters with no affiliates in the territory are likely to have to appoint an agent in China for these purposes. In addition, the need for eco-toxicological test reports to include China-generated test data means that sensitive product information may also have to be shared with testing houses there. As with any instance in which sensitive information is shared with a third party, businesses would be advised to ensure that robust arrangements are in place to protect confidentiality.

In the short to medium term, there may also be questions as to the capacity of China's existing technical infrastructure to support the services required of it by the measures.

Possibilities for influencing the legislative text appear limited. The current consultation is scheduled to close on 28 June 2009 and is in any event only open to designated government authorities and to certain trade associations (the China Petroleum and Chemical Industry Association, the Chinese Chemical Society, the Association of International Chemical Manufacturers and the European Chamber of Commerce in China). Since the 2009 Measures are currently scheduled to come into force on 15 October 2010, businesses that may be affected should start planning for compliance now (see our suggestions, below).

Finally, it is currently unclear how a number of elements of the proposed regime will function in practice. Key issues include how joint notification or cost-sharing between a notifying party and a previous registrant of the same substance will operate; how 'administrative control notices' served by the relevant local regulators may affect a business's ability freely to market its products; and, more generally, the impact of the designation of a new chemical substance as hazardous or of environmental concern. The Ministry of Environmental Protection is expected to update its existing Guidance for New Substance Notification after the draft measures come into effect, and other elements of the regime should become more certain with time. We will continue to monitor the situation closely and will provide further updates in future, if there are significant developments to report.

### Preparing for compliance

- Establish whether any products that you are planning to bring to market in, say, the next five years are likely to be caught by the new regime. In other words: do you plan to export any new product to China, or produce any new product there, that contains substances that are not listed on IECSC? If so, are you planning to do so after the 2009 Measures come into force?
- Consider whether it might be possible to accelerate your plans, in order to be able to notify under the less onerous current regime.
- Consider whether your products might fall within one of the categories for which less onerous obligations will apply under the 2009 Measures.
- For products that will require a full notification dossier, work out what the data requirements are likely to be (on the basis of the applicable guidance) and consider your strategy for gathering the necessary data and presenting it in due course. It may be possible to repackage existing data that is being or has been generated in the context of, for example, REACH registration. Previous experience suggests that managing registration effectively will involve bringing together a number of different perspectives from across the organisation – production, quality/environmental/health and safety, legal etc.
- Establish needs for testing by third party laboratories, in China or elsewhere.
- Consider your current arrangements in China. Do you have an existing affiliate who could manage notification and registration for you, as required? If not, is there a natural candidate who might act as an agent for you?
- Formal contractual arrangements, compliant with local legal requirements, ought to be put in place with any Chinese testing laboratory or third party importer, not least to protect business-sensitive information.

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