



China New Chemical Substance Notification FAQ

《新化学物质环境管理办法》（7 号令）
常见问题解答

Chemical Registration Center of Ministry
of Environmental Protection (CRC-MEP)

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Q1: For APIs that haven't obtained registration approval from CFDA, are they subject to China new chemical substance notification (China NCSN, a.k.a China REACH) if belong to new chemical substances?

A1: Yes. They should be notified.

Q2: If a DL- XX acid has been listed on the IECSC, does its L-XX acid or D-XX acid need to complete notification?

A2: If its L-body acid or D-body acid is not listed on IECSC, they need to comply with China NCSN respectively.

Q3: If the liquid crystal, used in the production of LCD TV panel, PC monitors and mobile phone monitors, belongs to new chemical substances, is it required to be notified?

A3: Yes, it is the duty of manufacturer or importer to notify.

Q4: Is it necessary to make sure the additive components (e.g. antioxidants, heat stabilizers, nucleating transparent agents, slipping agents and anti-block agents, etc.) to be used in polymers are listed on IECSC prior to manufacture or importation?

A4: If any chemical substance contained in the additives is not listed on IECSC, namely belonging to new chemical substances, the substance should be notified according to the MEP Order 7.

Q5: If a substance exists in the form of preparation and the preparation medium contains another new chemical substance (not notified under China NCSN), how to deal with the notification of the substance?

A5: All new chemical substances contained in the preparation should be notified.

Q6: Could the natural substances extracted by some organic solvents like alcohols be exempt for the obligation of notification?

A6: According to provisions on page 8 of the New Chemical Substance Notification Guidance Document (herein as "Guidance Document"), only natural substances extracted by water could be exempt.

Q7: Does enzyme protein fall into the category of living matters under natural substances? Polypeptides (like gramicidin), mucopolysaccharides (like keratin sulfate) and other biological macromolecules can be exempted or not?

A7: As stated on page 8 of the Guidance Document, living matters under the category of natural

substances can be exempt. However, if they are produced or processed by the industrial approach, China new chemical substance notification is still required.

Q8: A domestic company plans to import a cosmetic ingredient listed on the MoH approved IECIC inventory. However, the substance is identified as a new chemical following IECSC enquiry. Should the company notify for this substance under China NCSN?

A8: Yes, the new chemical substance should be notified. As stated in Article 2 of MEP Order 7 and the page 7 of the Guidance Document, cosmetic ingredients and intermediates not listed on IECSC should be notified in compliance with MEP Order 7.

Q9: Catalyst A is the reaction mixture of Substance B (active constituent) and Substance C. A and B are both new chemicals. If a company is intended to import a product D which is a new chemical on its own and contains A, which substance should be notified?

A9: All the new substances contained in the product should be notified.

Q10: Substance A is a food additive composed by the preparation of three constituents B, C and D. Constituents B, C and D are all food additives. Are the three constituents required to be notified?

A10: According to provisions on page 7 of the Guidance Document, food additives do not need notification on their own but if the ingredients or intermediates contained in a food additive belong to new chemicals, they need notification. Therefore if B, C and D are identified as food additives with adequate scientific justification, they shall be exempted from the notification, no matter they are new or not.

Q11: A group of substances are identified as by-products in areas outside of China. Their concentration percentage exceeds 10% and they do not meet the criteria of impurities defined in MEP Order 7. Could they be exempt from China NCSN?

A11: These substances should be notified according to MEP Order 7 and the Guidance Document.

Q12: A synthetic new substance P will generate impurity Q in percentage of 5% and impurity R in percentage of 20% as a result of side reaction. None of P, Q and R is listed on IECSC. It is technically workable to isolate Q and R from P, but due to cost considerations, the company currently sells this product in the form of a non-isolated mixture, with P at 75%, Q 5% and R 20%. How should the company deal with the notification in this case?

A12: According to page 8 of the Guidance Document, both P and R should be notified. Yet Q could be exempt as it can be considered impurity below 10% in concentration.

Q13: During the synthetic process of new chemical substance X, impurities Y and Z are generated in respective percentage of 12% and 13% as a result of side reaction. None of X, Y and Z is listed on IECSC. It is technically workable to isolate Y and Z from X, but due to cost considerations, the company now sells this product in the form of a non-isolated mixture, with X at 75%, Y 12% and Z 13%. How should the company deal with the notification in this case?