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APIC Position Paper

APICs position on the use of recycled solvents in production of APIs: a risk-based practice to foster

The use of recycled solvents in API production is one of the most important opportunities to lower the environmental footprint of APIs without negatively impacting product quality. Naturally, it requires a science and risk-based approach specific to each facility and the chemistry associated with each API processing.

In current ICH Q7 and current EMA Guideline on the chemistry of active substances, the use of recovered solvents in API processing is acceptable, provided that specifications for intended use and appropriate procedures are in place.

However, APIC does observe a more risk-averse trend/approach to solvent recycling in new or draft regulations, limiting or eliminating the risk-based use of recycled solvents.

APIC believes that we should foster the risk-based approach of the current guidelines and allow and stimulate a broader use of recycled solvents.

- Contributing most to the environmental footprint of APIs are the organic solvents that are vital in synthesis and purifications in the synthesis routes. The use of these solvents comes with a large footprint as it uses fossil resources and energy in the production and transportation of the solvents, and in high levels of waste after usage. After all, in general large volumes of organic solvents are required for API production.
- The use of recycled solvents in API production – regardless of possible solvent purification steps - with a risk-based approach, present an excellent opportunity to reduce usage of fresh solvents – reducing usage of (fossil) resources, transportation, and costs – and solvent waste and thus it is one of the most important opportunities to lower the environmental footprint of APIs without negatively impacting product quality.
- State-of-the art technology for solvent recycling and purification, such as distillation or membrane separation, accompanied by a proper quality framework, yields solvents with a high quality, equaling the quality of fresh solvents. Appropriate release specifications combined with a risk assessment on cross-contamination and impurities such as nitrosamines must be in place in order to ensure the quality of the recycled solvents.

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- Recycled solvents can be used either in the same product step or steps in the same API-route or in steps of different API-routes. Depending on the application the quality specifications of the recycled solvent may be tailored, provided it is justified.
- Our industry already proves that it is possible. Within APIC we know several examples where recycled solvents are used, and sometimes have been used for decades, in the production of APIs, both in a single production step, multi-product use and even final purifications. In all cases, a solid justification is in place which is challenged on a regular basis by inspectors and authorities.
- APIC will work on Guidance in a How-to-document with definitions of recycled solvents, best practices in industry, pre-requisites for the use of recycled solvents and guidance for a justification or risk-assessment, suggesting regulatory flexibility where scientific justification is in place.
- In conclusion, APIC acknowledges that the recycling of used solvent from API processing may require specialized regeneration processes and quality control in order to robustly produce solvent of sufficient quality for use in future API processing. The How-to document will be authored as an industry best practice guidance to share technical knowledge and propose an acceptable approach to create a solvent regeneration program that meets regulatory requirements and expectations, while providing regulatory flexibility where possible. The industry has proven that a risk-controlled approach combined with justified quality requirements is capable of producing solvent meeting quality standards for general use.
- The use of recycled solvents supports long-term goals held by the industry including reduction of fossil fuels leading to a reduced carbon footprint, future sustainability of the industry and overall impact to the environment. Additionally, it helps to protect the global supply chain threatened by tariffs, export restrictions, and cyclic solvent supply disruptions. These aspects impact the general population as well as the very patients we serve.

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