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Biotechnologically produced chitosan for nanoscale products. A legal analysis.

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Highlights

- Regulatory aspects of conventionally versus biotechnologically produced chitosan.
- Similar, yet different chitosans require new authorisations.
- Nanomaterial related requirements create an extra burden for market introduction.
- Knowledge gap exists for nanomaterials on hazard and exposure for the risk assessment.

Abstract

Conventionally, chitosans are derived from shrimp and other crustacean shells. Biotechnology offers an alternative route to produce chitosans and more importantly, specific chitosan structures tailored to the needs of a diversity of industries. However, for biotech chitosans and products thereof to be commercialised, legislation should not create a burden. Here, the requirements of the EU regulatory framework have been analysed for the entire chain from research to development and production of several potential applications including nanomaterials. The animal or biotechnological origin leads to specific requirements in production of the raw material. No EU legislation dedicated to nanomaterials has been adopted. Instead, products are governed under the respective existing product legislation subject to extra requirements for safety assessment. While a knowledge gap exists on hazards related to nanomaterials in general, there is a need to establish realistic regulatory study designs to assess the safety of specific products. Furthermore, as many of the existing chitosan applications are not considered nanomaterials, it would be discriminatory to treat biotechnology derived products differently.

Abbreviations

DA, degree of acetylation; DP, degree of polymerisation; GMO, genetically modified organism; PA, pattern of acetylation

Keywords: chitosan; nanomaterial; biotechnology; regulatory analysis**Introduction**

Chitosans are derived from chitin, the structural element in the exoskeleton of crustaceans. They are mixtures of polysaccharides with a varying degree of polymerisation (DP), degree of acetylation (DA), and pattern of acetylation (PA). Biotechnology offers an alternative production method with the advantage of producing pre-defined molecules with fixed DP, DA and PA. The European FP7 project Nano3Bio [1] explores biotechnological production routes of well-defined chitosans with known structures and functionalities.

Complementary to the scientific and technical aspects, a regulatory analysis was conducted in order to determine if the legal requirements are different for biotechnologically produced chitosans when compared to the chitosan mixtures produced in the conventional way, as well as the possible impact