

Corporate News

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c-LEcta: European dossiers submitted for approval of new enzymes in the food industry

- Successful submission of two registration dossiers for food enzymes in Europe.
- Dossiers were prepared in exclusive collaboration with a partner in the food industry.
- Evaluation to take place as part of the uniform approval procedure for "Food Improvement Agents," which is also to be applied to enzymes from 2023 on.
- c-LEcta is thus positioning itself even more strongly as an expert partner not only in the development of enzymes, but also for their approval.

Leipzig, May 26, 2021 – c-LEcta, a global biotechnology company with technology leadership in enzyme engineering and bioprocess development, has submitted dossiers for two newly developed enzymes in the food sector. The evaluation by EFSA (European Food Safety Agency) and the EU Commission is based on the harmonized EU approval procedure for food improvement agents (food enzymes, food additives and food flavors). The enzyme dossiers submitted by c-LEcta for products in the target market of the food industry complement the company's offering to its customers, who thus no longer have to worry separately about approvals for the use of the enzymes.

The two dossiers were submitted as part of an exclusive collaboration with an industry partner in the food sector for two food enzymes. Both enzymes are used to produce a natural sugar, for example, that can replace lactose, which has recently become unpopular with consumers, in industrially processed foods. With the help of the c-LEcta enzymes and the process developed by the cooperation partner, this sugar can be extracted from readily available sugar beets on a large scale.

"This is a typical case of enzymes making something entirely new and valuable possible. We are proud of this and, in cooperation with our partner, we are safeguarding this development result for the future. Thanks to our expertise in both new product development and regulatory matters, we can also provide our partners and customers with comprehensive support at this point," explained Paula Pescador, responsible for enzyme dossiers at c-LEcta.

As part of the implementation of the FIAP (Food Improvement Agents Package), a new approval procedure was introduced for enzymes used in the production of food. This is intended to create a harmonized regulatory system for food enzymes throughout the European Union. Following evaluation by the European Food Safety Authority (EFSA), the EU Commission will draw up a positive list of enzymes approved in the EU for use in the food



industry in the future. So-called enzyme dossiers have to be submitted for inclusion in this list, demonstrating the safety and technical necessity of the enzymes. The first publication of the new list is planned for 2023. From that date on, food manufacturers will only be allowed to use the enzymes listed. To provide customers with planning security, c-LEcta is therefore ensuring the necessary submission of enzyme dossiers so that the enzymes can already be included in the list when it is first published.

"The EU enzyme approval is of course a new process that everyone in the industry has to get used to. However, for us at c-LEcta, this is not a problem thanks to our in-house expertise and flexibility. On the other hand, the European positive list also offers us a simplification for the approval of new products for the food industry. Of course, we will continue to handle this in such a way that we submit these dossiers for all our products for the food industry. For us, this is a natural part of the service we provide to our customers," concluded Dr. Marc Struhalla, founder and CEO of c-LEcta.

About c-LEcta

c-LEcta is a world-leading biotechnology company with a focus on enzyme engineering and application in regulated markets like the food and pharma industries. The company is based in Leipzig, Germany, and has established itself as a leading player in the realization of high-value biotech products, either in the form of in-house developments or in close cooperation with industry. The company currently employs more than 100 people.

c-LEcta delivers cost-efficient and sustainable production processes which open new markets and allow for better penetration of existing markets. The company is characterized by fast and efficient development of best-in-class biotech solutions and a rapid and successful market introduction and commercialization of the resulting products. This enables c-LEcta to leverage the unique potential of its core technologies. c-LEcta has a proven track record of more than ten successfully commercialized high-value industrial biotech products.

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