c-LEcta
A KERRY® COMPANY

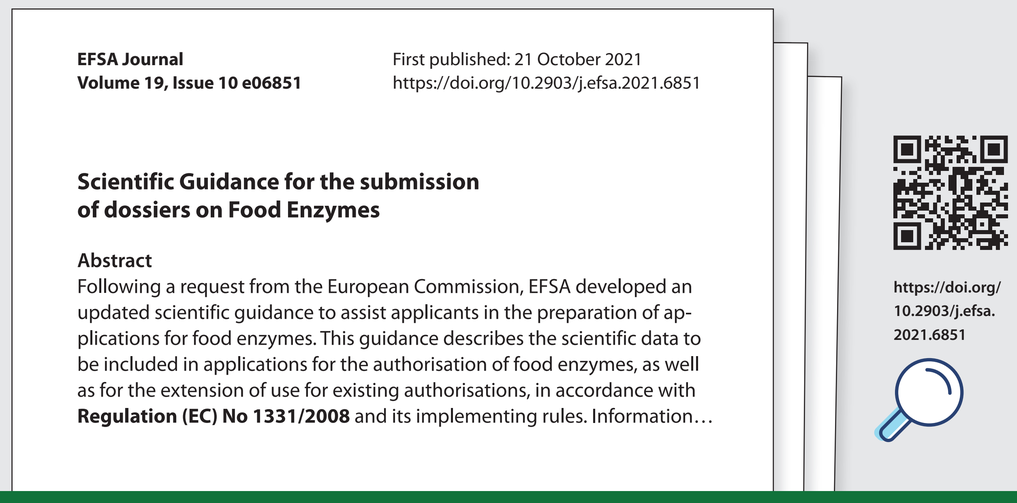
Ensure absence of DNA in Food Enzymes with NuCLEANase®!

Introduction

The EFSA guidance on dossiers for food enzymes describes the scientific data to be included in applications for the authorization of food enzymes in the European Union to fulfil **Regulation (EC) No 1331/2008** and its implementing rules. Based on the submitted data, EFSA will assess the safety of food enzymes and conclude whether they present a risk to human health under the proposed conditions of use.
One of the aspects that will be assessed during the risk assessment is, among others, testing for DNA of the production strain. This is mandatory for food enzymes using GM production strains or non-GM production strains carrying acquired AMR (anti-microbial resistance) genes. The **risk** associated to acquired AMR genes is considered **absent** if an applicant can demonstrate the absence of DNA and viable cells of the production strain.

NuCLEANase® is a highly active food-grade endonuclease, which **reduces all forms of nucleic acids to smaller nucleotides**, enabling manufacturers of food and feed enzymes to meet the regulatory requirements for the absence of DNA.

Scientific Guidance by EFSA for the submission of Food Enzyme Dossiers



EFSA guidance is valid for new and extension of existing applications.

Verification of Absence of DNA

Among other requirements the **EFSA Scientific Guidance** provides guidance for the scientific verification of absence of DNA when using GM production strains or using non-GM production strains carrying acquired AMR genes.

In summary:

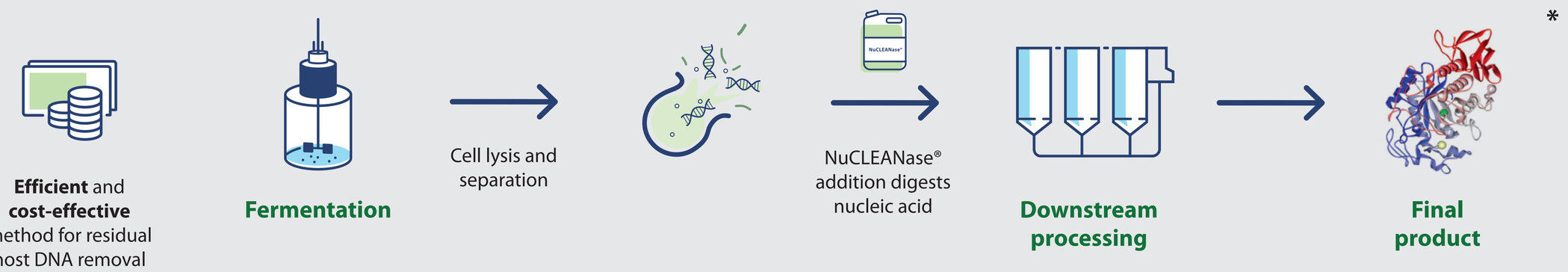
- **Verification of absence of DNA** from the microbial host with a LOD of **10 ng per gram** of product.
- Fermentatively obtained molecules with their production hosts, must not add to the pool of antimicrobial resistant (AMR) genes, thus being obligatory to also show absence of acquired **AMR genes** in the final product.

For the final food enzyme, absence of DNA and acquired AMR genes must be demonstrated in accordance with EFSA requirements.

NuCLEANase® – For Enzymatic Removal of Unwanted DNA

Unwanted DNA from Food Enzyme products can be removed in the manufacturing process with NuCLEANase®, an Endonuclease that catalyzes the hydrolysis of phosphodiester bonds between nucleotides, leaving short fragments with a length of 2 to 5 bases. The enzyme is active under a broad range of conditions so it can be used at different stages in the manufacturing process.

NuCLEANase® is an easy to implement solution for the removal of DNA from fermentative food and feed products.

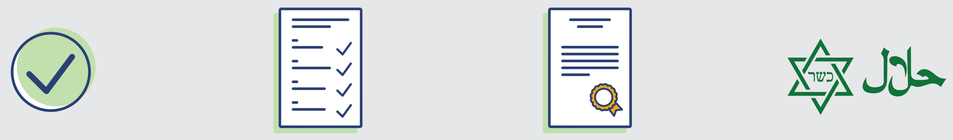


Exemplary standard fermentation process for intracellularly produced products.

NuCLEANase® helps to increase the overall process efficiency by reducing DNA related viscosity increases.

Benefits

The production of NuCLEANase® makes use of a QPS production strain from *Bacillus sp* and is free of antibiotics and animal derived raw materials.



Supports **production under regulatory compliance** (e.g., EFSA)

Improved purification and **process efficiency**

GRAS notification

Kosher and **halal-certified**

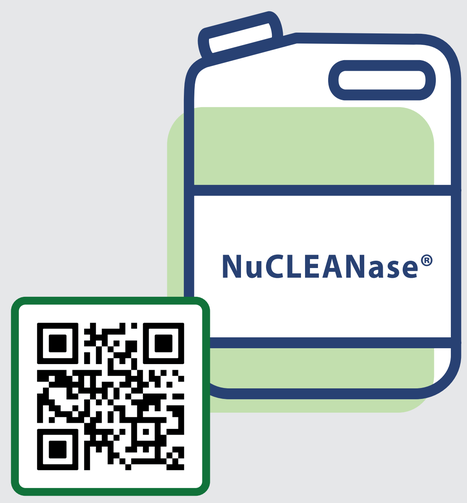
Highly active – Cleaves all forms of DNA and RNA to 2-5 oligonucleotides

Order & Test

NuCLEANase® now!

Get your free sample!
New customers can request a free 10 mL sample for first lab trials.

More Information:
www.NuCLEANase.com



NuCLEANase® – Cleans your product from unwanted DNA

Poster NuCLEANase | October 2024