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Autor(en): **Laulund, Esben**

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Safety criteria of microorganisms as food additives: the starter culture producers' view*

Esben Laulund, Food Cultures & Enzymes, Research, Development & Application, CHR. HANSEN A/S, Denmark

Introduction

CHR. HANSEN A/S has produced and supplied commercial starter cultures almost since the company was established in 1874 and it is today the world-leading supplier of starter cultures primarily based on lactic acid bacteria (LAB) to the dairy and food industry worldwide. The business strategy of CHR. HANSEN A/S is to be the focused ingredients specialist within the starter cultures for dairy, meat and wine products, cultures for human and animal health and nutrition, dairy enzymes, natural colours and flavours. The market segments in focus are dairy products, meat & prepared foods, food & beverage, human health and nutrition and animal health and nutrition industries.

As the world-leading supplier of starter cultures CHR. HANSEN A/S has a strong interest in the safety aspect and legal criteria of starter cultures. It is of great importance to secure that consumers and customers have a high confidence in the use of the starter cultures applied in the food industry and microbial cultures intended for human and animal health and nutrition.

In order to comply with the demands from the consumers and customers CHR. HANSEN A/S therefore actively follows and welcomes the regulatory initiatives regarding starter cultures that are taken within the European Union as well as on international and national level worldwide.

Discussion

Present regulation with regard to starter cultures within the European Union

Regulatory conditions for starter cultures for the food industry have so far not been regulated at a common European Union level and the official European Union

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regulatory status of starter culture is still unclear as to whether they should be regarded as processing aid, food additives or food ingredients (1).

A few EU countries have, however, in this relation a national regulation for approving starter cultures. In Denmark a notification procedure has been in operation since 1973 when the first Danish horizontal legislation concerning food additives entered into force (2). The Danish regulation for starter cultures states that every microorganism in a starter culture has to be notified to the Danish Veterinary and Food Administration before being approved for production and commercial sale (3). In principle the Danish notification of starter cultures is based on approval of the microorganism on a strain level. The documentation requirements for a notification include an identification of the strain, a description of the intended use as well as a specification of the commercial product. In most cases the authorities accept that the notification system is on a species level rather than on a strain level. It is therefore not necessary to notify new strains of well-known cultures as long as the specifications of the cultures do not deviate from comparable, previously accepted starter cultures and the application is not changed. The approved use of *Penicillium roqueforti* in cheese can illustrate this. The isolation of a white mutant of *P. roqueforti* will not require CHR. HANSEN A/S to notify the new strain. However, a change in application of *P. roqueforti* from cheese making to say meat fermentation will require a new notification.

Starter cultures combined of several species need to have the individual species notified separately.

The Danish notification procedure also requires a characterisation of the particular species with possible reference to a standard culture in a type culture collection. At request, documentation shall be provided concerning the culture if it has any unwanted toxicological or antibiotic properties.

There is not a French approval system for starter cultures but the French Food Safety Agency has in 2002 (4) issued guidelines on the evaluation of starter cultures. The guidelines are generally more detailed than the Danish notification system and include some of the considerations made on European level for microbial cultures used as feed additives.

The principles of the internal market make it impossible for other Member States to block for approved products unless it is possible to document that the original approval was issued on insufficient grounds. Given that no other Member States have an approval procedure for starter cultures the Danish notification procedure automatically secures access for an approved starter culture to all national markets in the European Union.

Table 1 below shows the overview of the number of different species for different food product applications CHR. HANSEN A/S has had notified at the Danish Veterinary and Food Administration since 1973 (2).

Table 1

Species notified in Denmark by CHR. HANSEN A/S since 1973:

- ▼ Species included in cultures produced for food application notified to the Danish Veterinary & Food Administration. Procedure implemented in 1973.

| | |
|-----------|-----------------------------|
| ► Dairy: | 35 species within 16 genera |
| ► Meat: | 13 species within 6 genera |
| ► Wine: | 3 species within 3 genera |
| ► Bread: | 8 species within 1 genus |
| ► Egg: | 4 species within 3 genera |
| ► Others: | 2 species within 1 genus |

New regulatory initiatives within the European Union

The Scientific Committee on Animal Nutrition (SCAN) set up by the EU commission took in their position paper from July 2002 "Safety Assessment and Regulatory Aspects of Micro-organisms in Feed and Food Application" (5) the initiative to propose a new EU approval system for starter culture for food applications similar to the current approval system for cultures for animal health and nutrition. The proposition from SCAN was to set up an approval system based on the principles of "Qualified Presumption of Safety" (QPS), where the presumption being defined as a belief or assumption based on reasonable evidence. One primary background of the proposal by SCAN was to deal with the safety aspects in relation to transmissible antibiotic resistance markers or other virulent factors occurring in certain lactic acid bacteria.

This initiative taken by SCAN led to the working paper from the European Commission "On a generic approach to the safety assessment of micro-organisms used in feed/food and feed/food production" (6) where the principles for the QPS systems were further defined including the establishment of a decision tree approach when evaluating a given micro organism.

In the European Union the initiative is as of 2004 handed over to the newly established European Food Safety Authority (EFSA) to evaluate the introduction of a QPS system.

To set up the provisions in the proposed QPS system a Colloquium will be held during December 2004 with representatives from national food administrations and the food industry. The objective of the colloquium is to have an open scientific debate on the QPS approach and to explore options how to develop the concept of QPS into a proposal for the regulatory community that is based on sound scientific principles (7). Issues that will be discussed include the information needed to assess

hazards and risk. Furthermore how to provide the information to presume safety of a microorganism and finally to define the extent of the QPS approach.

The official content of the QPS system for starter cultures for food production and the format in which it will be implemented within the European Union will await the outcome and recommendations of the EFSA Colloquium in December 2004.

Parallel to the regulatory initiatives taken by the EU commission the European Food and Feed Culture Association (EFFCA) organising the commercial European starter culture producers together with the International Dairy Federation (IDF) have taken the initiative to prepare an "Inventory of Micro-organisms with a Documented History of Use in Food" (8). This inventory contains currently a description of over 100 species within 19 genera of bacteria, 4 genera of moulds and 8 genera of yeast, which have all been applied in commercial starter cultures for the production of food products. The inventory does not contain any information on starter cultures, which have been applied by the use of the back-slopping technique where culture material from the previous production is inoculated to the next production of a food product. The back-slopping technique is today primarily applied by small food factories for geographical defined food products.

The purpose of this inventory was to document towards the official governmental food administrative bodies that commercial starter cultures for food production have had a long history of use with no adverse effects on human health, implying that any new regulatory initiatives for approval of starter cultures taken by international or national food administrations need to build on this history and avoid any provisions that may unnecessarily jeopardize the consumers' trust in the currently applied starter cultures for food production.

CHR. HANSEN A/S initiatives in relation to starter cultures

Given the strong initiatives within the European Union as to the establishment of a common system for regulating the approval procedure for commercial starter cultures CHR. HANSEN A/S has taken the proactive approach to be in the forefront of the expected regulatory environment for commercial starter cultures.

The initiatives taken by CHR. HANSEN A/S are based on two principles:

- 1) The development of new starter cultures shall be based on a combination of defined and characterised single strains.
- 2) New starter cultures are introduced as direct inoculation cultures, e.g. they require no re-activation before use in the production of the food product.

The new starter culture development at CHR. HANSEN A/S is based on fully defined and characterised single strains to secure that there is a complete knowledge of the genetic profile of strains in a given starter culture.

The first step in the development procedure is a characterisation of a strain, which includes complete documentation and history of origin of the culture isolate.

Today CHR. HANSEN A/S bases the new product development on wild type strains and classical strain improvement techniques. CHR. HANSEN A/S has a culture collection covering over 9000 deposits sampled and characterised since 1950. Furthermore new culture materials are primarily supplied via collaboration agreements with research institutions and universities world-wide in due alignment with international rules and regulations (9). Isolation of pure single strains is done using high throughput robots.

CHR. HANSEN A/S does not base the current development of new starter cultures on modern gene-transfer techniques. CHR. HANSEN A/S possesses the necessary technology to perform such a development procedure, however, due to the lack of acceptance from especially European consumers no starter cultures based on this technique have been commercially released.

The second step is to determine the taxonomy and genotype of each isolate on both species and strain level using internationally recognised 16s RNA and DNA profiling techniques, respectively (10).

The third step is to describe the antibiotic susceptibility profile of a candidate strain. This is done by determination of the minimal inhibitory concentration (MIC) for the respective antibiotics and compare the MICs to the microbiological breakpoints set up by SCAN (11). Only strains that pass these criteria will be included in the new product development of starter cultures.

The microbiological breakpoints from SCAN were originally intended for feed cultures for animal use. The outcome of the ACE-ART project within the 6. Framework Programme within the EU commission is therefore awaited (12). The ACE-ART project should provide a more solid assessment of the antibiotic resistance mechanisms of starter cultures in relation to the human food chain.

After the above-mentioned parameters of a strain have been clarified, the next step in the development process involves a fully technological characterisation of the strain with regard to the requirements needed to work in the production of the intended food product.

The technological evaluation includes determination of several specific properties, among others the following:

- Acidification activity and profile in the food product (milk, meat, wine etc.)

- Flavour and aroma production capability and profile

- Texture via production of exo-polysaccharides

- Bacteriophage sensitivity pattern

Micro-array techniques may be applied to identify the presence and regulation of certain genes related to the properties of a given strain.

Figure 1 shows the steps involved in the screening procedure for new starter cultures for food.

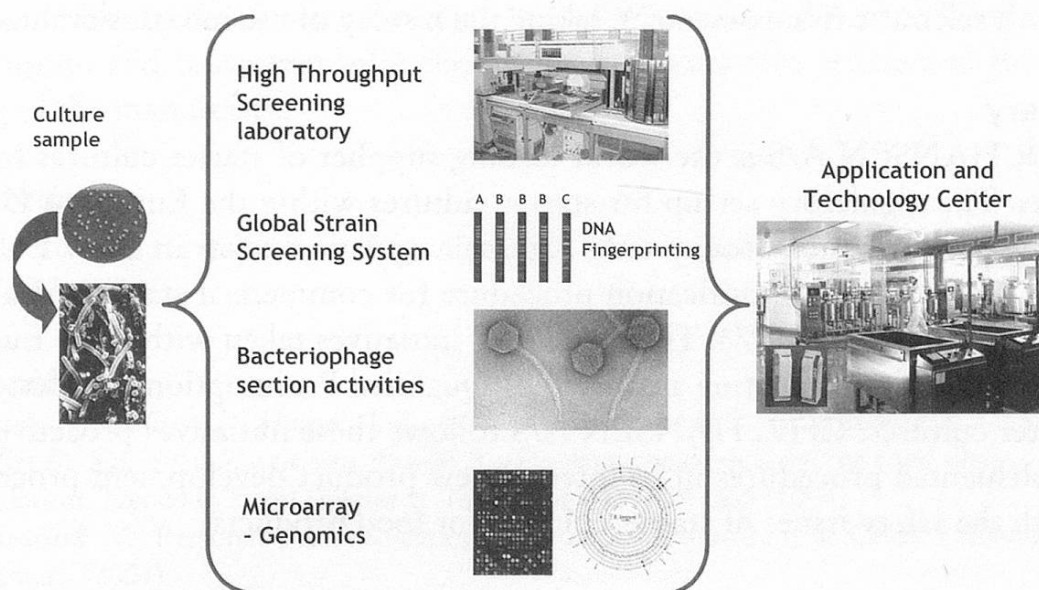


Figure 1 Screening procedure for new food cultures

Finally the identified strain is tested and optimised for fermentation, concentration, stability and reproducibility during the production process at CHR. HANSEN A/S.

The CHR. HANSEN A/S production processes of starter cultures are described and documented according to ISO standards. The handling processes of propagating the inoculation material for a given starter culture are very much in focus to secure that the properties of a particular strain or culture remain identical to the original specifications.

New starter cultures from CHR. HANSEN A/S are primarily introduced as direct inoculation cultures (**DVS®** or **EASY-SET®**). The direct inoculation form provides the user with several benefits with regard to convenience in use, defined specifications as to technological properties and with guaranties as to freedom from undesirable contaminations or cross-contaminations.

Conclusions

CHR. HANSEN A/S acknowledges that the safety of starter cultures applied for food production is a key issue for consumer acceptance.

CHR. HANSEN A/S has in this relation taken a proactive approach and has internal procedures that secure full documentation of history of origin and taxonomy of the isolated strain. Evaluation of the antibiotic resistance profile is required before the isolate is approved for inclusion in the product development where relevant technological properties are determinate. The production of starter cultures follows ISO certified processes.

CHR. HANSEN A/S welcomes the initiatives taken within the European Union to establish a clear regulation regarding starter cultures for food, including provisions regarding the safety issues.

The coming regulatory provisions within the European Union must, however, be based on a scientific risk assessment, taking the history of use into this evaluation.

Summary

CHR HANSEN A/S is the world-leading supplier of starter cultures for food products. The regulatory set-up for starter cultures within the European Union is currently under revision. Today only national regulation exists in a few EU countries, e.g. in Denmark a notification procedure for commercial starter cultures has been in operation since 1973. The regulatory initiatives taken within the European Union focus on implementing a concept of Qualified Presumption of Safety (QPS) for starter cultures. CHR. HANSEN A/S follows these initiatives proactively and has implemented procedures in its internal new product development process that deal with the safety issues of starter cultures for food products.

Zusammenfassung

CHR HANSEN A/S ist der weltweit führende Lieferant von Starterkulturen für Nahrungsmittel. Die Vorschriften für Starterkulturen innerhalb der Europäischen Union werden zurzeit überarbeitet. Derzeit bestehen nur nationale Regelungen in einigen EU-Ländern, in Dänemark zum Beispiel ist ein Ankündigungsverfahren für kommerzielle Starterkulturen seit 1973 in Kraft. Die regelnden Initiativen, die innerhalb der Europäischen Union ergriffen wurden, konzentrieren sich auf das Einführen eines Konzepts der «Qualified Presumption of Safety» (QPS) («Qualifizierte Annahme der Sicherheit») für Starterkulturen. CHR. HANSEN A/S folgt dieser Initiative proaktiv und hat Verfahren in seinem internen neuen Produktentwicklungs-Prozess eingeführt, die sich mit den Sicherheitsfragen zu Starterkulturen für Nahrungsmittel beschäftigen.

Résumé

CHR HANSEN A/S est leader mondial dans la fourniture de ferments pour les produits alimentaires. La mise en place d'une réglementation pour les ferments au sein de l'union européenne est actuellement en cours de révision. Aujourd'hui, une réglementation nationale existe uniquement dans quelques pays d'EU, par exemple au Danemark où une procédure de notification pour les ferments commerciaux est en fonction depuis 1973. Les initiatives de normalisation dans l'union européenne se concentrent sur la mise en application d'un concept de présomption qualifiée de la sûreté (QPS) pour les ferments. CHR. HANSEN A/S suit cette initiative proactivement et a mis en application des procédures dans son nouveau processus interne de développement de produits nouveaux qui traite les questions de sûreté des ferments pour les produits alimentaires.

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Key words

starter cultures, regulation, safety, qualified presumption of safety (QPS), CHR. HANSEN A/S

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Corresponding author: Esben Laulund, Food Cultures & Enzymes, Research, Development & Application, CHR. HANSEN A/S, Bøge Alle 10–12, 2970 Hørsholm Denmark, E-mail: esben.laulund@dk.chr-hansen.com