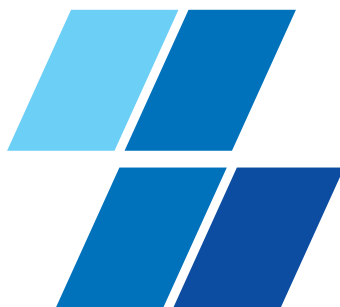


HACCP CONCEPT OF THE SUGAR INDUSTRY



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FOREWORD

In 1996/1997, as part of the implementation of European hygiene law, the companies of the German sugar industry agreed on a common concept for good hygiene practices and laid down the principles for the implementation of an HACCP concept.

This common agreement on good hygiene practices is documented in the Hygiene Concept of the Sugar Industry, while this document deals with the practical implementation of HACCP principles.

Both concepts have been updated to reflect the amendments made to the European hygiene law and the repealing of Directive 93/43/EEC by Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.

The development of company-specific HACCP concepts has long been a requirement of European hygiene law. Companies themselves are responsible for their implementation, which can only take place on-site. The HACCP concept should be integrated into existing quality management systems as a part of companies' quality management systems.

As sugar products and production processes are comparable, the common identification and evaluation of potential risks is possible, at least to a certain extent.

This common basis for an HACCP concept, the methods used in hazard identification and the appropriate expertises are documented in this concept, which forms an integral part of company-specific HACCP documentation.

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1. EXPLANATIONS FOR THE DEVELOPMENT OF AN HACCP CONCEPT

1.1 INTRODUCTION

The HACCP concept (**H**azard **A**nalysis and **C**ritical **C**ontrol **P**oint) is an internationally-recognised tool for ensuring food safety. It enables potential consumer risks caused by food consumption to be identified and controlled using preventive measures. A prerequisite for the introduction and maintenance of an HACCP concept are measures of the good hygiene practices (GHP), which are described in the Hygiene Concept of the Sugar Industry.

1.2 PRINCIPLES FOR THE DEVELOPMENT OF HACCP CONCEPTS

The HACCP concept is based on the seven principles of the Codex Alimentarius as laid down in Article 5 of the Regulation (EC) 852/2004 on the hygiene of foodstuffs:

- a) **Identifying any hazards** that must be prevented, eliminated or reduced to acceptable levels;
- b) **Identifying the critical control points (CCP)** at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
- c) **Establishing critical limits** at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- d) Establishing and implementing effective **monitoring procedures** at critical control points;
- e) **Establishing corrective actions** when monitoring indicates that a critical control point is not under control;
- f) Establishing **procedures**, which shall be carried out regularly, **to verify** that the measures outlined in subparagraphs (a) to (e) are working effectively;
- g) Establishing **documents and records** commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

The HACCP concept must be regularly reviewed to ensure that it is always up to date. The HACCP concept must be updated according to reflect any changes to the product or the manufacturing process as well as new scientific discoveries concerning potential risks.

2. DEVELOPMENT OF AN HACCP CONCEPT FOR THE WHITE SUGAR PRODUCTION PROCESS

The development of an HACCP concept involves the following steps:

2.1 DEFINITION OF THE SCOPE

The scope of the HACCP concept covers the production and storage of white sugar as well as its transportation while it falls within the area of responsibility of the companies.

2.2 HACCP TEAM

The HACCP team is formed of specialists from the areas of production, quality assurance, food law and development. The team members have appropriate training and knowledge of the application of HACCP principles in practice. The HACCP team should report directly to the company's management.

2.3 PRODUCT DESCRIPTION

The product description contains such information as

- Product characteristics,
- Product composition,
- Storage requirements,
- Placing on the market.

2.4 PROCESS DESCRIPTION

The basic steps in the sugar production process are represented in a flow diagram (Appendix, Fig. 1).

2.5 IDENTIFICATION OF POTENTIAL HAZARDS

The production process is systematically analysed and all hazards are identified using the flow diagram. The term "hazard" is used to describe a potential adverse health effect for the consumer, which may be of a biological, chemical or physical nature.

2.6 IDENTIFICATION OF CRITICAL CONTROL POINTS (CCPs)

A CCP is a point, process or procedure for which control measures can be applied and which is essential to prevent or eliminate a health hazard posed by a finished product or to reduce it to an acceptable level. CCPs are defined with the help of a decision tree (Appendix, Fig. 2).

2.7 ESTABLISHING CRITICAL LIMITS

Control conditions and their critical limits are set for each CCP in order to control it.

2.8 MONITORING PROCEDURE

Monitoring measures are defined in order to ensure that the defined process conditions and control measures are adhered to.

2.9 ESTABLISHING CORRECTIVE ACTIONS

Corrective actions are established for use in cases when a CCP is no longer under control. These actions stipulate what should be done with the product produced during this period and how the CCP should be brought back under control.

2.10 VERIFICATION PROCEDURE

This is a procedure which is used to confirm the effectiveness of the HACCP concept.

This could involve:

- Product monitoring,
- Checking of measures for monitoring CCPs,
- Internal audits,
- Factory tours / site visits,
- Evaluation of complaints.

2.11 DOCUMENTATION

All the actions involved in the introduction, implementation and verification of the HACCP concept are documented and preserved for an appropriate period of time.

3. IDENTIFICATION AND ASSESSMENT OF POTENTIAL HAZARDS

White sugar is produced in four main steps: juice extraction, juice purification, juice thickening and crystallisation. The aim of the sugar production process is to isolate the sucrose in the sugar beet and to create a product with a defined, high level of purity. The purity of the white sugar produced is at least 99.7 %. Since it was first developed more than 150 years ago, sugar production has proceeded along the same, though with the time more sophisticated, process. This means that the process steps used for the production of white sugar are comparable in all factories of the German sugar industry.

For this reason, there is a large amount of data available about both the finished product and the production process, which enables a common and well-founded assessment of potential hazards as relevant for the HACCP concept.

The following biological, chemical and physical hazards have been identified:

- Pesticides,
- Heavy metals,
- Pathogenic microorganisms and their spores,
- Processing aids,
- Foreign bodies.

Food allergens can also pose a health hazard, in that they can trigger intolerance reactions. These intolerance reactions are the result of an antigen-antibody-reaction, which is usually triggered by proteins contained in food-stuffs. As carbohydrates do not function as antigens, white sugar has no allergenic potential*.

The following joint expertises evaluate the potential risks mentioned above can result in a health hazard for the consumer. This evaluation is the basis for the companies of the sugar industry to decide the extent to which these potential hazards must be controlled using an HACCP concept.

In addition to the knowledge and practical experiences, this evaluation also takes into account the results of scientific research performed over the past few decades.

In some cases, local conditions and guidelines differ so greatly that no joint evaluation is possible and the companies themselves must evaluate the risks. This applies both to the prevention of contamination by foreign bodies and to the use of processing aids, which concerns company-specific knowledge.

* Koletzko B., Kohlenhydrate in der Ernährung, Aktuelle Ernährungsmedizin 2006; 31, Suppl. 1: p. 1-3.

4. EXPERTISE ON THE ASSESSMENT OF POTENTIAL HEALTH HAZARDS CAUSED BY PESTICIDE RESIDUES IN SUGAR

4.1 INTRODUCTION

The use of pesticides in sugar beet cultivation is one of a range of agricultural measures which contribute to ensuring stable yields. This expertise will examine and evaluate whether or not the use of these substances is relevant for the product safety of sugar, i. e. whether it could pose a risk to consumer health.

The approval and monitoring of the use and safety of pesticides in Germany is the responsibility of the Federal Office of Consumer Protection and Food Safety (BVL).

Approval of a pesticide is granted after comprehensive preliminary tests have been carried out in accordance with the German Plant Protection Act and associated regulations [1-3], which take into account consumer health protection requirements and consumption patterns. These tests involve defining the maximum residue levels and Acceptable Daily Intake (ADI) values. To achieve this end, information is exchanged with the Federal Biological Research Centre (BBA), the Federal Institute for Risk Assessment (BfR), the Federal Environment Agency (UBA) and the relevant departments of the BVL. The results of their findings are consolidated by the

BVL. Once the primary investigation has been completed, the expert committee is heard. The final decision rests with the BVL, which specifies the pesticide quantities which can be used for treating seeds and field, the waiting periods between the last pesticide usage and harvest, the distances which must be observed between areas where pesticides are used and the nearest water as well as the persons authorised to use pesticides.

4.2 ENSURING CONSUMER HEALTH THROUGH MAXIMUM RESIDUE LEVELS

The basis for protecting consumer health is the toxicological assessment of a pesticide, which in Germany is carried out by the BfR. As a rule, long-term animal experimentation is used to determine a "*no observed adverse effect level*" (NOAEL) in mg per kilogram of animal weight. This level is then used to derive an ADI value in mg per kilogram of body weight, taking into account the differences in animal and human metabolism. Strict evaluation criteria ensure that even lifelong exposure to the ADI should have no adverse health effects.

Using the average consumption quantities of plant-based foodstuffs as a baseline, maximum consumption levels can be calculated for theoretical residues. The definition of usage quantities, waiting times and maximum residue levels in the Maximum Residue Level Regulation (RHmV) [4] ensures that estimated consumption does not exceed the ADI.

While the RHmV stipulates maximum levels for a wide variety of foodstuffs and active substances, it does not define measurement tolerances. These can be considerable, depending on the active substance, analysis method, sample quality and the laboratory involved. When analysing residues in foodstuffs using the usual methods, a 60 % scatter region can be assumed. This value is based on the evaluation of numerous round-robin tests and is also taken into account when defining the maximum residue levels in the RHmV. This ensures that no health hazard is posed, even when the maximum level is reached or exceeded beyond the scatter limit of the analysis method involved [5].

According to § 2 Para. 2 of the RHmV, the maximum levels set for sugar beets also apply to the sugar produced from them, taking into account appropriate concentration factors. If no maximum value for sugar beets has been set for a particular active substance, the value

specified under "all plant-based foodstuffs" or "other plant-based foodstuffs" should be used.

At European level, the coming into force of Regulation (EC) No. 396/2005 on the Maximum Residue Levels of Pesticides [6] on 5th April 2005 set the framework for the harmonisation of the permitted maximum residue levels for pesticides in EU member states. Specific maximum residue levels should also be set for sugar beets in the appendices to Regulation (EC) No. 396/2005. Until then, national legislation will continue to apply.

Also according to European law, future maximum pesticide residue levels will only be set after consultation with the European Food Safety Authority (EFSA) (Recital 6 Regulation (EC) No. 396/2005).

4.3 ANALYSIS DATA

Scientific research on residue levels in sugar beets, intermediate products from sugar production and in sugar has been carried out and published.

The pesticide contents in sugar were either below the analytical detection limit or extremely low. This applies to compounds with widely diverse chemical and physical properties [7-10].

The values fall far below those defined in the RHmV for sugar, which already do not admit any health risk. Normally no pesticides are detected.

As part of their duty of care, companies carry out regular monitoring which confirms these results. Health-relevant residue levels in sugar can thus be ruled out.

4.4 CONCLUSION

If the maximum residue levels defined in the RHmV are adhered to, the ADI values defined using the results of the toxicological assessment will not be exceeded. As a rule, sugar generally contains no pesticides or only traces which are far below the defined maximum levels.

Thus, the use of pesticides in sugar beet production does not result in a health risk for sugar consumption.

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5. EXPERTISE ON THE ASSESSMENT OF POTENTIAL HEALTH HAZARDS CAUSED BY ARSENIC, LEAD, CADMIUM AND MERCURY IN SUGAR

5.1 INTRODUCTION

This expertise determines whether or not the levels of heavy metals (lead, cadmium and mercury) as well as the semi-metal arsenic in sugar pose a health hazard.

Generally, the term “heavy metals” is used to describe those elements which have a density greater than 3.5 to 5 g/cm³, such as lead, cadmium, chrome, cobalt, iron, copper, manganese, mercury, selenium and zinc.

Some heavy metals are essential trace elements or micronutrients used for metabolic activity in humans, animals and microorganisms, while others have toxic effects, even in lower concentrations in their elemental form and often also when they occur as metallorganic compounds [1].

5.2 HEAVY METALS IN FOODSTUFFS

The contamination of foodstuffs through lead, cadmium, mercury and arsenic is largely the result of contamination of air, soil and water by these substances. Measures for environmental protection have helped to reduce this level of pollution.

Lead is primarily released into the environment with industrial emissions and can then land on plants as a result of dust and precipitation. Lead in drinking

water may be associated with old buildings which still contain lead piping [2, 3].

High cadmium concentrations are frequently found in vegetables, edible mushrooms, linseeds, peanuts, sunflower seeds and the intestines of animals slaughtered for consumption [3, 4].

Organically-bound mercury (e. g. methylmercury) is found primarily in fish and mussels [4].

Higher concentrations of arsenic are found above all in organic compounds, particularly in marine fish and molluscs, and to a lesser extent in freshwater fish and rice. The largest concentration is thus caused by the arsenic compounds found in water and the marine food chain [4].

Since 1972, substances which enter foodstuffs as a result of environmental factors and which tend to accumulate in the body have been monitored using PTWI (*Provisional Tolerable Weekly Intake*) values. These values are published by the *Joint FAO/WHO Expert Committee on Food Additives* (JECFA) and represent the tolerable weekly consumption level for humans. It is far below the dose at which toxicological effects can be assessed and, in this respect, is based on the precautionary principle [5]. The PTWI value for

lead is given as 25 µg per kilogram of body weight, for cadmium as 7 µg per kilogram of body weight, for mercury as 5 µg per kilogram of body weight (total mercury) or 1.6 µg per kilogram of body weight (methylmercury) and for inorganic arsenic as 15 µg per kilogram of body weight [4].

The results of the national food monitoring programme carried out between 1995 and 2002 show that the PTWI values are exhausted by a value of 50 %, meaning that the heavy metal load among the population with normal consumption habits lies considerably below the PTWI values. The food monitoring programme is a systematic analysis and observation scheme which has been carried out jointly by the Federal Government and the Länder since 1995 and which involves testing representative samples of foodstuffs in Germany for undesirable substances. The basis for the annual monitoring is a plan drawn up by both the Federal Government and the Länder, which specifies details of the foods to be tested and the substances to be tested for [4].

5.3 DATA COLLECTION AND ASSESSMENT OF HEAVY METAL CONTENTS IN SUGAR - DEVELOPMENT IN GERMANY

The systematic logging and evaluation of environmental chemicals in foodstuffs began in the mid 1970s with the work of the German Central Body for the Identification and Assessment of Environmental Chemicals of the German Federal Health Office (ZEBS).

The ZEBS analyses of the heavy metal content in food were prompted by incidents chiefly in Japan in which people became ill after eating food contaminated with heavy metals, as well as by events which took place in Germany in 1972 in which cattle kept near a lead and zinc works were poisoned by a fault in the filter system.

Until then, in Germany, there were neither epidemiological nor case-based findings to suspect that lead, cadmium or mercury could be potential causes of disease in commercially-available foodstuffs [6].

It was against this backdrop that the ZEBS issued the first recommended values for the amount of arsenic, lead, cadmium and mercury in individual foodstuffs in 1976 [7].

These guidance values '76 were orientation values on which to base analyses of the level of contamination in foodstuffs. They were exclusively the result of observing the actual situation and included values for sugar.

In the updated guidance values '79, which took improved assessment methods as well as toxicological considerations into account and which were already considered by the German Federal Health Office (BGA) to have a certain binding character for the food industry and control, sugar is not listed. As the guidance values '79 reflected toxicological evaluations, sugar was obviously no longer considered a relevant product group [8].

This assessment was confirmed by comprehensive tests carried out on different types of sugar for lead and cadmium, which were published by the ZEBS in 1989 with the following result: "All types of sugar and sugar products can be considered to be low-contaminated foods where lead and cadmium are concerned. The results of these tests do not require the definition of recommended values for sugar in order to eliminate peak concentrations." [9].

Until 1997, the recommended values for toxins in foodstuffs were published by the BGA and its successor, the Federal Institute for Consumer Health and Veterinary Medicine (BgVV). It was subsequently decided not to revise the national recommended values because of new EU regulations [10].

5.4 EU REGULATION ON MAXIMUM CONTAMINANT LEVELS

The 1993 passing of Regulation (EEC) No. 315/93 laying down Community procedures for contaminants in food laid the legislative basis for the definition of maximum levels of individual contaminants in foodstuffs [11].

A contaminant means any substance not intentionally added to food, but which is nonetheless present, whether

as a result of environmental contamination (environmental contaminant) or as a residue in the course of the extraction, manufacture, processing, preparation, treatment, packaging, transportation or storage processes.

When Regulation (EC) No. 466/2001 setting maximum levels for certain contaminants in foodstuffs was adopted, maximum EU levels for lead and cadmium in various foodstuffs and the current maximum permitted levels of mercury in fishery products were listed in this regulation for the first time. There are currently no maximum values for arsenic [12].

The regulation does not define maximum levels for sugar. This can be interpreted to the effect that the occurrence of lead, cadmium, mercury and arsenic in sugar does not significantly contribute to the ingestion of heavy metals in food. This tallies with the results of the assessment of the *Scientific Committee on Food* (SCF) in its 1992 and 1995 statements [13] as well as in the March 2004 SCOOP Report (*report on tasks for scientific cooperation*) prepared by the EU Commission on the "assessment of the dietary exposure to arsenic, cadmium, lead and mercury of the population of the EU Member States" [14].

5.5 CODEX ALIMENTARIUS

Since 1969, the international standards of the Codex Alimentarius have specified the maximum levels of lead and arsenic in the different types of sugar [15], whereby the maximum level of 2 mg/kg for lead was reduced to 0.5 mg/kg as part of the 1996 revision of the product standards [16]. In 1999, these maximum levels were removed from the *Codex Standard for Sugars* by the *Codex Committee on Sugars* [17, 18].

The Codex's horizontal approach "*General Standard for Contaminants and Toxins in Foods*" (GSC), which places the maximum levels for individual foodstuffs in a wider context, defines maximum levels of contaminants only for those foodstuffs which contribute significantly to the overall consumption of contaminants. In this context, the maximum levels of lead for sugars listed in the Codex commodity standards were not transferred to the "*Proposed Draft Maximum Levels for Lead*" [19] in 1995. The reason given for this was that due to their low lead content sugars do not contribute significantly to the overall intake of lead via foodstuffs [20].

5.6 ANALYSIS DATA

Monitoring carried out regularly by companies of the sugar industry as part of their duty of care show that the levels of lead, cadmium and mercury, as well as arsenic, found in sugar are all below the determination limits.

This confirms the figures for the heavy metal content of white sugar published in the literature [9, 21-24].

5.7 CONCLUSION

The data shows that the health risk posed to the consumer by lead, cadmium, mercury and arsenic in sugar can generally be ruled out. This is particularly borne out by the fact that no maximum values for heavy metals in sugar have been set, neither by the Codex nor at European level. Regular monitoring carried out as part of the food industry's legal duty of care further confirms this assessment.

5.8 LITERATURE

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6. EXPERTISE ON THE EVALUATION OF THE IMPACT ON HEALTH CAUSED BY THE OCCURRENCE OF PATHOGENIC MICROORGANISMS IN SUGAR

6.1 INTRODUCTION

Microorganisms are omnipresent in nature and consequently also in foodstuffs. Of the multitude of microorganisms which can occur in foods, only a few are actually pathogenic for humans. If these foodborne pathogenic microorganisms or their spores are ingested with food, they may, under certain conditions, cause illness, above all in the gastrointestinal tract.

This expertise evaluates the likelihood of the occurrence of these pathogenic microorganisms and their spores occurring in sugar and their relevance for consumer health.

6.2 CAUSES OF A POSSIBLE CONTAMINATION

Microorganisms are ubiquitous in the environment and, therefore, also on agricultural products such as sugar beet and any attached soil. For this reason, it cannot be eliminated that in addition to other microorganisms also foodborne pathogenic microorganisms enter the sugar production process from the raw materials.

The rest of the sugar production process takes place in closed systems, meaning that there is no opportunity for contamination by microorganisms from the environment. The transport of sugar takes

place in covered systems to a great extent. Accordingly there is limited opportunity for contamination by environmental microorganisms, but it cannot be entirely ruled out; however, these environmental organisms are primarily spores and microorganisms which are considered irrelevant for food safety [1].

While contamination of sugar by pathogenic spores through either direct or indirect human contact cannot be entirely ruled out, the risk of this type of contamination is considered relatively low; this is also reflected in the fact that sugar is not one of those foodstuffs for which provisions are laid down in the German Infection Protection Act.

6.3 PREREQUISITES FOR DISEASE CAUSED BY MICROORGANISMS

Foodborne pathogenic microorganisms are divided into vegetative pathogenic microorganisms (which can cause illness either by triggering an infection or by releasing a toxin) and the spores of pathogenic microorganisms (which germinate to form toxins which then pass into foodstuffs and cause illness).

In order for food consumption to trigger disease in humans, a certain number of microorganisms or microorganism toxins must be ingested. The minimum infectious dose of food borne pathogenic

microorganisms in food is around 100,000 germs, for some infectious foodborne pathogenic microorganisms, the minimum infectious dose is 100 to 1,000 germs [2, 3]. Here it must be taken into account restrictively that illness caused by ingesting the minimum dose usually only occurs in patients with weakened disposition.

For organisms which act as pathogens by excreting toxins, the conditions must first support the formation of an effective dose of toxin.

As well as supporting the amount of germs required to produce an effective dose of toxin – in the majority of cases, approx. 100,000 germs/g – the foodstuff itself must also support germinative activity [2].

6.4 ASPECTS OF CONSUMER PROTECTION

Sugar is regarded as one of the world's safest foodstuffs. Until now, therefore, there has been no reason to define microbiological threshold values for foodborne pathogenic microorganisms in sugar.

6.5 INFLUENCING THE MICROORGANISM LOAD

Any evaluation of the microbial risk posed by a foodstuff must take into account both the production process and the product attributes, which have an influence on the ability of microorganisms and microorganism spores to survive and multiply.

Thermal treatment is one of the most important influences on a substance's microbiological load. Temperatures of at least 60 °C are required to destroy vegetative microorganisms [2, 4]. The D-value is a measure of the effectiveness of microorganism destruction. The D-value gives the number of minutes for which a constant temperature must be maintained in order to reduce the number of germs by 90 %; exposure times of 12 D are mathematically equivalent to sterilisation. D-values for the most resistant of foodborne pathogenic microorganisms are 2 min/65 °C for vegetative organisms and as much as 20 min/100 °C or 2 min/130 °C for spores [5].

The pH values and a_w (water activity) values of the environment in which the microorganisms are contained can also be growth-inhibiting factors. Foodborne pathogenic microorganisms grow, multiply and metabolise at pH values of between 4 and 10. Microorganisms cannot grow and metabolise (and produce toxins) at values outside these levels. As far as the available amount of free water is concerned, a_w -values of at least 0.86 are required for foodborne pathogenic microorganisms to grow. At lower a_w values, no growth and no metabolic activity or toxin formation can take place.

6.6 ASPECTS OF THE SUGAR PRODUCTION PROCESS WHICH INFLUENCE THE MICROBIOLOGICAL LOAD

Producing sugar from sugar beet involves various different processing steps, which affect the microbiological load. These include primarily temperature treatment and pH regulation, both of which are necessary for the technical processes. The production steps and the prevailing conditions are shown in the following table:

Process Step	Temperature [°C]	pH	Exposure Time [min]
Extraction	60 – 70	4 – 6.5	60 – 90
Liming	80	> 12	≥ 15
Carbonatation I	≥ 80	≥ 10.5	> 8
Carbonatation II	> 90	> 8.5	> 8
Evaporation	> 125 100-125	> 8.4 > 8.4	> 5 > 25

The sugar production process thus involves the following minimum residence times in closed systems at temperatures of more than:

Temperature [°C]	Residence Time [min]
> 60	120
> 80	60
> 100	30
> 125	5

The (at some points) high pH values during the individual processing steps have a synergistic effect on destroying the microorganisms and spores in the course of the sugar production process.

6.7 CONDITIONS FOR THE SURVIVAL OF MICROORGANISMS IN SUGAR

Sugar consists of at least 99.7 % sucrose. At a residual moisture content of less than 0.1 %, the a_w value of sugar lies below the limit at which food pathogenic bacteria can grow or produce toxins [2, 6, 7].

Serial tests in which sugar was deliberately contaminated with salmonella showed that no trace of the injected bacteria was found in the sugar solution (10 g in 40 ml tryptone solution) after 18 hours [8]. These tests prove that high sugar concentrations not only inhibit the growth of introduced microorganisms (in this case salmonellae), but can actually destroy them.

6.8 ASSESSING THE MICROBIOLOGICAL RISK OF SUGAR

The temperatures used during the sugar production process cover the D-values even for the most resistant vegetative foodborne pathogenic microorganisms. With a total residence time of 60 minutes at temperatures of more than 80 °C, sterilisation conditions for vegetative pathogenic organisms are greatly exceeded ($12 D_{65} = 24$ min). Furthermore, the temperatures of more than 100 °C reached during the evaporation phase are sufficient to destroy more resistant pathogenic spores (D_{120} in most cases < 1 min) [2, 5].

Under these technical conditions, it can therefore be assumed that any vegetative foodborne pathogenic microorganisms are completely destroyed. For this reason, the thick juice, the intermediate

product which forms the basis for the sugar crystallisation process, is an almost entirely germ-free product.

In crystallised sugar, microorganisms which have entered the sugar after the crystallisation process are unable to reproduce. This is because the sugar's high purity level means that the nitrogen sources required for microorganism growth are lacking, and a_w values below the growth threshold prevent both multiplying of microorganisms and forming of toxins.

In view of the above, therefore, it would be impossible for any potential contamination with pathogenic food organisms to create a microorganism load which would pose a health risk during sugar consumption. This is backed up by the fact that:

- Sugar has been regarded as one of the microbiologically safest foods, and there has, therefore, been no reason to define maximum threshold values for foodborne pathogenic microorganisms in sugar;
- The total germ counts found in sugar – as shown by the microbiological analyses carried out during the quality control process – are around one-tenth of those proposed as an evaluation criterion for individual foodborne pathogenic microorganisms in other foodstuffs [9].

6.9 CONCLUSION

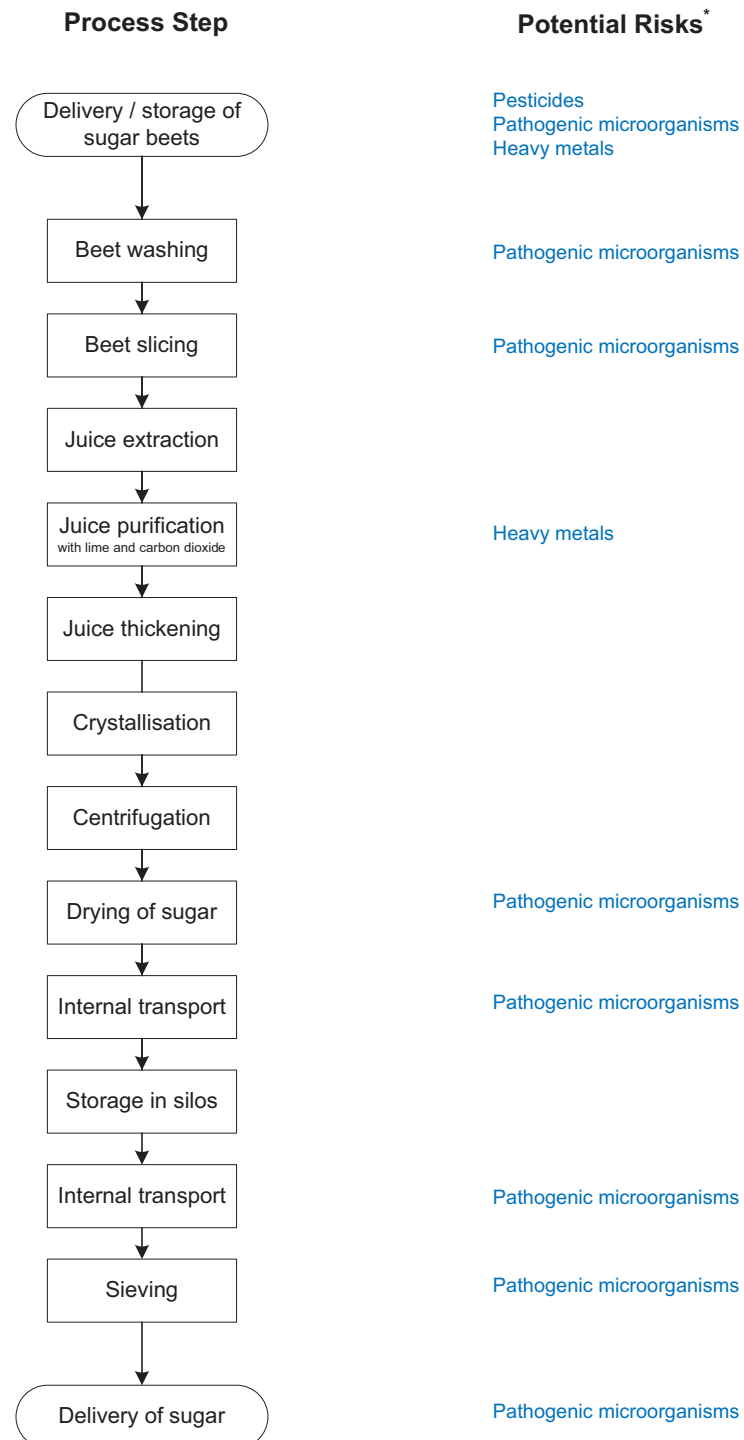
Due to the technical requirements of the sugar production process, the product-specific properties of sugar and the tendency exhibited by vegetative pathogenic microorganisms to die off in sugar solutions during testing, the contamination of sugar by vegetative pathogenic microorganisms and their spores in food is not a relevant consumer health hazard. Monitoring carried out by companies as part of their duty of care and of general quality control serve to confirm this assessment.

6.10 LITERATURE

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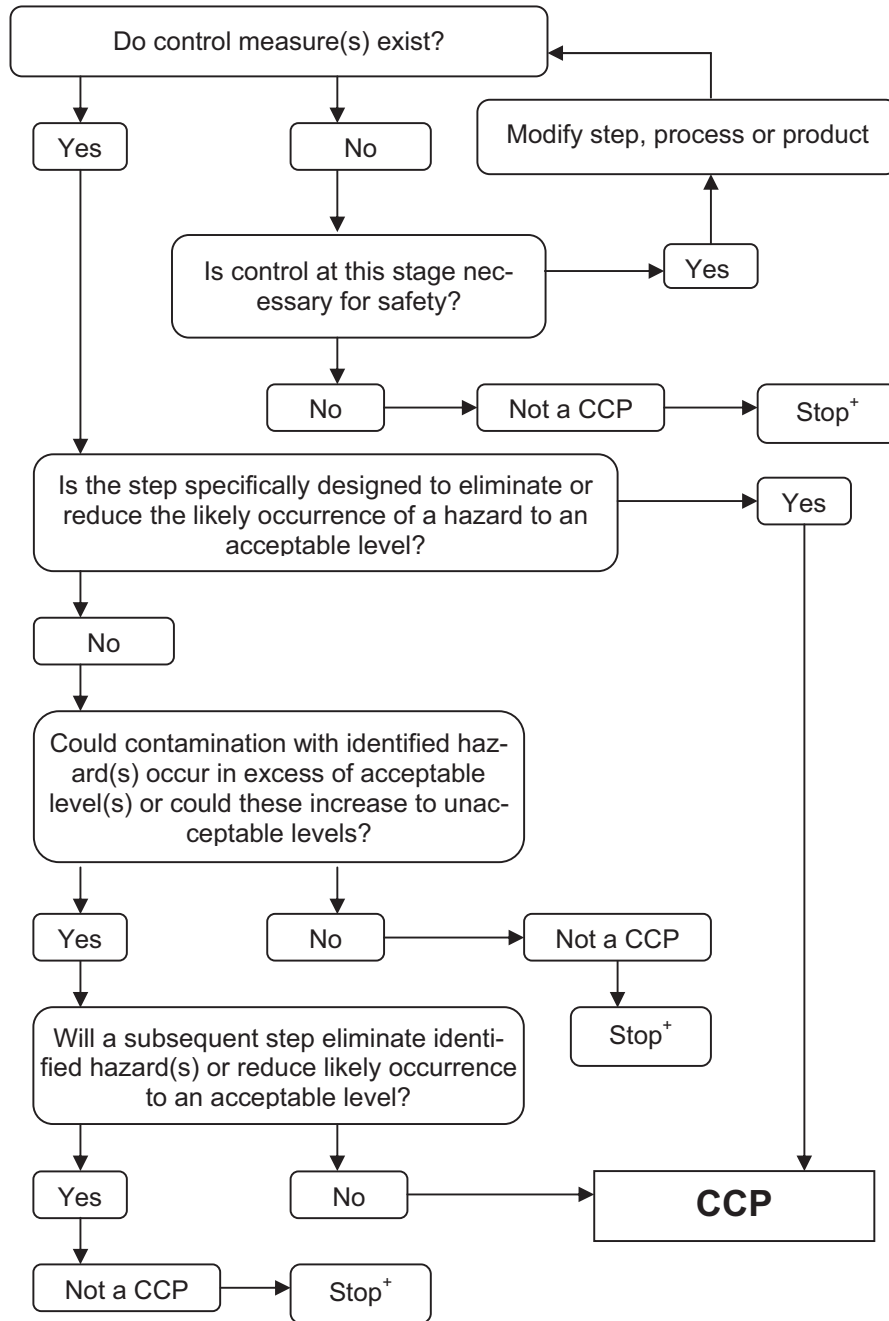
7. APPENDIX

Fig. 1: The Sugar Production Process and Potential Risks



* Conditions at the individual companies and production plants must be taken into account when determining the process steps in which foreign bodies can enter the product or which are relevant with regard to residues from processing aids.

Fig. 2: Decision Tree*



*Stop = Proceed to the next identified hazard in the process described.

* Codex General Principles of Food Hygiene, CAC/RCP1-1969, Rev. 4-2003.

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