



DESIGN AND OPERATION OF ON-SITE NITROGEN GENERATORS FOR FOOD USE

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Amendments to 194/15

Section	Change
3.2.11	New definitions added
3.2.12	New definitions added
5.1	New sub-sections added
6.1	New sub-sections added
6.2	New sub-sections added
6.3	New sub-sections added
6.4	New sub-sections added

NOTE Technical changes from the previous edition are marked with a line in the left margin.

1 Introduction

This publication provides specific guidelines for on-site nitrogen generators for food use.

An on-site nitrogen generator separates nitrogen from air for use directly at the user location delivered by pipeline. In terms of gas flow rates, on-site nitrogen generators range from a few litres per minute up to many tons per hour.

In the course of discussions with customers and authorities, requests are often made for compliance certificates related to nitrogen specifications, hazard analysis and critical control point (HACCP) studies, materials of construction and consumable materials for those on-site gas production units: pressure swing adsorption (PSA), membrane air separation system and cryogenic air separation system that are dedicated for food use.

On-site nitrogen generators for food use, for example for modified atmosphere packaging (MAP) or inerting applications, are installed at customer sites by either gas companies or equipment suppliers and can be operated by either gas companies or food companies.

Nitrogen generators which use PSA and membrane technologies have potential hazards that shall be recognised and addressed in view of the applicable food laws.

The nitrogen produced from an on-site generator is used in many food applications as a processing aid (without purity limit) or additive (E941 as per Regulation 2012/231/EC *laying down specific purity criteria on food additives other than colours and sweeteners*) [1].¹ Typical applications include but are not limited to: atmosphere protection of liquid and solid foodstuffs; tank blanketing; liquids mixing; liquid pressure transfer; modified atmosphere packaging; injection in liquid for container pressurisation; decarbonation; deoxygenation; beverage dispensing; and aerosol propulsion.

NOTE No purity criteria are set under European Union (EU) law for the use of gas as a processing aid. However, national legislation can require a purity alignment with those criteria applied to food additives.

2 Scope and purpose

2.1 Scope

The design and operation of on-site nitrogen generators by industrial gas companies for food use.

2.2 Purpose

This publication is intended as a guide for on-site nitrogen generators for food use regarding:

- identification of potential hazards (biological, chemical and physical types) during the equipment design and its operation according to Hazard Analysis and Critical Control Point (HACCP) procedures;
- description of appropriate design, operation, maintenance and modification;
- recommendations concerning traceability, production lots, registration parameters, product analysis; and
- assurance for operators and authorities of the quality and compliance of the gas produced with an on-site nitrogen generator.

¹ References are shown by bracketed numbers and are listed in order of appearance in the reference section.

On-site generators producing nitrogen as a processing aid are not subject to the same legal requirements as food. In this publication the requirements for food gases are indicated with a “shall”, for processing aids it may be read as “should” as the legal requirements do not apply to processing aids.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Asphyxiation

Effect on the body of inadequate oxygen, usually resulting in loss of consciousness and/or death.

3.2.2 Batch

A discrete, defined quantity whose characteristics can be proven, for example it could be a number of cylinders filled on the same manifold at the same time, an isolated bulk storage tank or tanker or a period of continuous production.

3.2.3 Critical control point (CCP)

A step where a control shall be applied and which is essential to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

3.2.4 Cryogenic air separation generator

Equipment for the production of high purity nitrogen by means of a cryogenic process.

3.2.5 Cryogenic liquid

Liquid that is extremely cold at a temperature that is lower than $-90\text{ }^{\circ}\text{C}$.

3.2.6 Fail safe

Causing a component or machine to revert to a safe condition in the event of breakdown or malfunction.

3.2.7 Food additive

Any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may reasonably be expected to result, in it or its by-products becoming directly or indirectly a component of such foods as per Regulation (EC) No 1333/2008 *on food additives* [2].

3.2.8 Food business operator

The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control as per Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety Directive 1333/2008/EC* [3].

3.2.9 Food defence

The efforts to protect food from acts of intentional adulteration.

3.2.10 Food or foodstuff

Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans as per Regulation (EC) No 178/2002 [3].

3.2.11 Food fraud

The act of purposely altering, misrepresenting, mis-labelling, substituting or tampering with any food product at any point along the supply chain.

3.2.12 Food gas

For the purposes of this publication, food gases are defined as food intended to be used as an additive or ingredient.

3.2.13 Food grade lubricant

Synthetic lubricant conforming to ISO 21469, *Safety of machinery. Lubricants with incidental product contact. Hygiene requirements* [4].

3.2.14 Food traceability

Ability to trace and follow a food through all stages of production, processing and distribution. This requires food business operators to know from whom they have received food and to whom they supply it. The principal purpose of the traceability requirement is to enable efficient and rapid withdrawal from the market of any food that may be injurious to the consumer's health.

3.2.15 Good manufacturing practices (GMP)

Safety conditions for operating the supply chain in order not to introduce contamination.

3.2.16 Hazard analysis and critical control points (HACCP)

Method to identify, evaluate, and control hazards which are significant for food safety.

3.2.17 Labelling

Distinctive mark of the on-site nitrogen generator for food use.

3.2.18 Modified atmosphere packaging (MAP)

Application exchanging the air in contact with food with a gas or a gas mixture to increase the shelf-life of food.

3.2.19 Membrane

Polymer material that acts like a filter to separate components such as nitrogen from oxygen in air.

3.2.20 Non-conforming product

Product which does not meet the relevant company specifications nor has other unspecified impurities which are suspected or known to be at levels that might, when used in contact with foods, be injurious to health (company specifications are assumed to comply with legislative specifications).

3.2.21 On-site nitrogen generator

Equipment for the production of nitrogen from air at the customer site; the equipment usually supplies the nitrogen to a distribution pipework system.

3.2.22 Oxygen-deficient atmosphere / nitrogen-enriched atmosphere

Air in which the oxygen concentration by volume is less than 19.5%, also known as nitrogen-enriched atmosphere.

3.2.23 Oxygen-enriched atmosphere

Air in which the oxygen concentration by volume exceeds 23.5%; also known as an oxygen enriched atmosphere.

3.2.24 Prerequisite programmes procedure (PRP)

Basic food safety conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

3.2.25 Operational prerequisite programme (OPRP)

PRP identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards and / or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment.

3.2.26 Pressure relief device

Device designed to protect a vessel or piping from reaching pressures higher or lower (vacuum) than its design limits in order to avoid the failure of the pipe or vessel.

NOTE As these devices can have significant flow when activated, the discharge should be directed towards a safe area.

3.2.27 Pressure swing adsorption (PSA)

Family of generators that separates one gas from another by passing a feed gas over a bed of adsorbent material at one pressure and cleaning the waste product off the adsorbent material at another pressure, hence the term pressure swing.

3.2.28 Processing aid

Any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, and

which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product as per Directive 1333/2008/EC [2].

3.2.29 Safe area

Location where exhaust gases can be discharged safely causing no harm to personnel or property. A safe area is also a place where surrounding materials are compatible with the exhaust gas.

3.2.30 Safety permits (permit to work)

Procedural documents highlighting specific safety considerations that are issued to allow work to commence in a specific location.

3.2.31 Standard operating procedure (SOP)

Formal method of management to control the supply chain system operation and maintenance, in order to supply safe product.

4 Production process

4.1 Nitrogen quality

For any food use, on-site generated nitrogen shall comply with the general principles described in the EIGA Doc 125, *Guide to the Use of Gases in Foods* [5].

In the case where on-site generated nitrogen is used as a food additive, such as in the modified atmosphere packaging (MAP) application, nitrogen should comply with minimum purity criteria for E941 additive described in EIGA Doc 126, *Minimum Specifications for Food Gases Applications* [1, 6]:

- nitrogen $\geq 99\%$ vol

NOTE 99% including other inert gases such as noble gases (argon mainly).

- oxygen $\leq 1\%$ vol
- water $\leq 0.05\%$ vol

Impurities:

- carbon monoxide ≤ 10 ppmv
- methane and other hydrocarbons (as methane) ≤ 100 ppmv
- nitrogen monoxide and nitrogen dioxide ≤ 10 ppmv

In the case where on-site generated nitrogen is used as a processing aid / propellant, in accordance with the user's specifications, the on-site generator can be designed to produce different nitrogen assay values (typically between 90% and 99% nitrogen, with the balance predominantly noble gases and oxygen).

NOTE Propellant in this case refers to the use of nitrogen as a carrier gas for beverage dispensing.

At least one continuously online residual oxygen analyser shall be installed in the generated nitrogen gas stream to ensure the end-user's product quality and traceability requirements. Consideration should be given to the installation of an online residual moisture analyser. In any event the process and its environment shall be subject to a food safety risk assessment.