



**THE EXPORT OF DAIRY AND DAIRY PRODUCTS TO THE EUROPEAN UNION (EU)**

Dairy products to the EU

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# Introduction

Disclaimer: This report has been constructed based on the information gathered from European Union law with the purpose of providing information regarding the export of dairy and dairy products to the European Union (EU). Much of the information is summarised and one should refer to the relevant references for detailed information.

The European Union (EU) has certain requirements for non-EU countries to comply with in order to export food of animal origin, such as diary and dairy products in this situation. Food imported into the EU must meet the same laws and regulations as food produced in the EU. It must be safe and contain no prohibited ingredients, and all labelling and packaging must be informative and truthful.

An important aspect of food safety - in the context of animal-derived food - is the control of residues. These residues present in foodstuffs can be:

• Intentionally added (i.e. food additives, or the illegal addition for adulterant purposes);

• Present as residues from defined uses (e.g. pesticides and veterinary drugs); or

• Contaminants (formed during production, processing, storage - or stemming from the environment).

Chemical residues can be harmful to consumers and can cause chronic toxicological adverse effects, allergic reactions and resistance problems if substances are applied incorrectly e.g. at levels higher than permitted by food safety legislation.

Specific legislation protects consumers from exposure to potentially harmful residues of veterinary medicines, pesticides and environmental contaminants in food of animal origin (Directive 96/23/EC)

Regulation (EU) No 605/2010 lays down the public and animal health conditions and certification requirements for the introduction into the European Union of consignments of raw milk, dairy products, colostrum and colostrum-based product as well as the list of third countries from which the introduction into the European Union of such consignments is authorised.

# The Health Certificate

South Africa needs to use the Health certificate for dairy products for human consumption from third countries or parts thereof authorised in column C of Annex I to Regulation (EU) No 605/2010 intended for importation into the European Union.

Animal Health Attestation a (iii) of the health certificate states the dairy product needs to be obtained from animals subject to regular veterinary inspections to ensure that they satisfy the animal health conditions laid down in:

* Chapter I of section IX of Annex III to Regulation (EC) No 853/2004

AND

* Directive 2002/99/EC

# Monitoring of Residues and Substances in Food Producing Animals

Point 1 (d)of Chapter I of section IX of Annex III to Regulation (EC) No 853/2004; raw milk and colostrum must come from animals: to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

EU countries implement residue monitoring plans for the detection of illegal use of substances in animal production and the misuse of authorised veterinary medicines. They must also take appropriate action to minimise the occurrence of such residues in food.

Directive 96/23/EC outlines the relevant requirements (Articles 29 and 30). Article 29 (1) states that a non-EU country should submit a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I of the above mentioned council directive. Guarantees must have an effect at least equivalent to those in the Directive and meet the requirements of:

* Article 4 and specify the particulars in Article 7 of the Directive
* Article 11(2) of Directive 96/22/EC.

The monitoring of residues and substances should actively take place on four different levels complying to the sampling methodologies explained in Annex III and IV to Council Directive 96/23/EC namely;

* The animals
* Feedingstuffs
* Drinking water
* Primary animal products

EU countries cannot import (Article 11 (2), Directive 96/22/EC):

* animals (and/or products derived from them) to which stilbenes, thyrostats and oestradiol have been administered for *any* purpose or
* animals (and/or products derived thereof) to which certain steroid hormones and beta-agonists have been administered for growth promotion.

South Africa currently authorises the use of hormones and beta agonists for growth promotion. The EU would require that a “split system” is put in place guaranteeing that animals and their products have not been treated with these substances at any time during their rearing. This necessitates monitoring and sampling of the four above mentioned levels.

South Africa is currently unable to meet the requirements set out for the monitoring of residues and substances due to the following reasons;

* South Africa has a deficient plan to monitor residues and substances according to EU standards.
* Inadequate risk assessment and analysis of residues and substances.
* South Africa only has one EU approved laboratory (ARC -Onderstepoort Veterinary Institute) in Pretoria to monitor residues.
* The EU requires a complete ban on the use of oestradiol 17 β in food-producing animals (Article 11b of Directive 96/22/EC). (A “split system” can be placed)
* Resources are maybe wasted by monitoring residues in milk not required by the EU regulations due to the lack of risk assesments.
* Lack of resources to fund a residue monitoring plan.

# How to open the trade route

The Residue Control Programme and more specifically the Export Residue Control programme, is the responsibility of the Department of Agriculture, Forestry and Fisheries (DAFF) who is mandated to give assurance to the EU that animals and animal products produced in South Africa comply with the rules/requirements laid down by the importing country. (Burger 2013)

The first step in South Africa’s eligibility to export food of animal origin to the EU is the Commission’s approval of the country’s residue monitoring plan for those commodities. An approved residue monitoring plan is one of the pre-requisites for export to the EU. The EU animal and public health conditions must also be satisfied.

The initial plan must include:

• Details on the structure of South Africa’s competent authority i.e. the central public body drawing up the residues monitoring plan and co-ordinating the departments involved in implementing the plan, plus information on their structure and resources;

• A description of the legislative framework covering the rules on the use of veterinary medicines, authorisation and/or prohibition procedures etc. In particular, the authorisation/use/prohibition of hormones and beta-agonists for growth promotion must be described. If hormones and beta-agonists for growth promotion are authorised, details of the split system(s) in place must be provided and should include the specific programme requirements, advance approval and certification procedures, record-keeping requirements, identification systems for segregation and traceability of the animals produced under the programme and the food products derived from them.

 • A list of approved laboratories for residue testing and their accreditation status;

 • Details on measures to be taken in the event of a non-compliant (positive) result.

South Africa should test for those substances which are likely to be used or misused in their livestock production systems. They should justify their choice of tested substances with a documented risk-based approach. If there are substance-subgroups in Group B in Annex I to Directive 96/23/EC not included in the residue monitoring plan, the absence of testing would have to be justified and supported with documentary evidence accompanying the plan which could include:

• A register of all authorised therapeutic medicines and their class e.g. antibiotics, anthelmintics, etc. for use in each species of food-producing animals.

• Historical residue monitoring data justifying decisions not to include specific Group B substances or substance groups in the monitoring plan etc.

• Toxicological data or preferably, an assessment of the chemical risk of individual substances, the use patterns of these substances in each (export) livestock sector, the likelihood of potentially harmful residues occurring and the relative risk of consumer exposure.

Importantly samples need to be taken across the various production stages – these samples can be taken at farm level or at the processing plant – as long as it is possible to trace back to the farm of origin in the event of a non-compliant result. Sampling levels and frequencies are laid down in Directive 96/23/EC and Decision 97/747/EC.

The Commission’s evaluation assesses whether the regulatory systems for the control of residues, authorisation of veterinary medicines etc. and the plan offer guarantees at least equivalent to those in EU legislation.

# Triangular Trade

Triangular trade is a concept in which South Africa import milk from the EU or EU approved countries. The milk can then be processed in EU approved establishments with the intention of exporting the final product back into the EU. This ensures that the milk used satisfies the EU standards.

The EU will currently not accept any of these products as South Africa is not listed in section IX (dairy products) of third country establishments.

DAFF could make a special request to the EU in order for triangular trade to occur.

# Additional requirements for export to the EU

1. The treatment of milk intended for use in dairy and dairy products

South Africa (ZA) is currently listed in column C of Annex I to Regulation (EU) No 605/2010. This implies that the EU shall authorise the importation of consignments of dairy products derived from raw milk of cows, ewes, goats and buffaloes provided that such dairy products have undergone, or been produced from raw milk which has undergone, a heat treatment involving:

(a) A sterilisation process, to achieve an F 0 value equal to or greater than three;

(b) An ultra high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time;

(c)

(i) A high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds applied twice to milk with a pH equal to or greater than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment; or

(ii) A treatment with an equivalent pasteurisation effect to point (i) achieving, where applicable, a negative reaction to an alkaline phosphatase test, applied immediately after the heat treatment;

(d) A HTST treatment of milk with a pH below 7.0; or

(e) A HTST treatment combined with another physical treatment by either:

(i) Lowering the pH below 6 for one hour, or

(ii) Additional heating equal to or greater than 72 °C, combined with desiccation.

(Article 4 to Regulation (EU) No 605/2010)

1. Food business operators producing or, as appropriate, collecting raw milk and colostrum

Operators must ensure compliance with the requirements laid down in Chapter I-V of Section IX, Annex III to Regulation (EC) No 853/2004.

* CHAPTER I: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS
* CHAPTER II: HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS
* CHAPTER III: WRAPPING AND PACKAGING
* CHAPTER IV: LABELLING
* CHAPTER V: IDENTIFICATION MARKING
1. Public Health Attestation

The dairy products need to be produced in accordance with the following relevant provisions of;

* Regulations (EC) No 178/2002
* Regulations (EC) No 852/2004
* Regulations (EC) No 853/2004
* Regulations (EC) No 854/2004

# Conclusion

South Africa will only be able to export diary and diary based products to the EU once DAFF has implemented a residue monitoring plan for residues and substances set in Directive 96/23/EC.

“Split systems” need to be placed on farms guaranteeing that animals, their feedstuffs, their drinking water and their products have not been treated with illegal substances.

Triangular trade may be a possibility once DAFF and the EU come to an agreement regarding the matter.

# References

1. Burger, J. 2013, Controlling residues in animal-derived food, Milk Essay, Page 4-5, Volume 4 Number 1
2. DG Health and Food Safety. (n.d). Imports of food of animal origin from non-EU countries [Brochure] Retrieved from https://ec.europa.eu/food/sites/food/files/safety/docs/cs\_vet-med-residues\_animal-imports-non-eu\_brochure\_en.pdf