

Appendices:

2. Appendix to the milk product questionnaire-Equivalent Breakdown Table of Good Manufacturing Practice, part GB 12693-2010

## Description materials equivalent to relevant good manufacturing practices for milk products in China

Please fill in the right hand column of the following table listing the provisions of the exporting country's national legislation and/or other standards used for manufacturers intending to export dairy products to the PRC. If not already covered in this table, please provide a copy of the exporting country's relevant national laws, regulations and administrative provisions.

| Chinese National Manufacture Standard                        |   | Exporting country's national legislation and/or other standards  |
|--|---|--|
| Good manufacturing practice for milk products (GB12693-2010) |   |  |
| Scope  | 1 | <p>Federal Act on Food and Utility Articles [LMG]<br/> <b>Art. 2</b> Scope of application<br/> <sup>1</sup> This Act applies to:</p> <ul style="list-style-type: none"> <li>a. the manufacture, processing, storage, transport and offering of foodstuffs and utility articles;</li> <li>b. the labelling and advertising of foodstuffs and utility articles;</li> <li>c. the import, transit and export of foodstuffs and utility articles.</li> </ul> <p><sup>2</sup> This Act also applies to agricultural production to the extent that it is for the manufacture of foodstuffs.<br/> <sup>3</sup> The same provisions apply to imported foodstuffs, provided this is not contradictory to international agreements.</p> <p>Foodstuffs and Utility Articles Ordinance [LGV]<br/> <b>Art. 1</b> Subject matter and scope of application<br/> <sup>1</sup> This Ordinance regulates:</p> <ul style="list-style-type: none"> <li>a. the manufacture, processing, treatment, storage, transport, labelling, advertising and offering of foodstuffs and utility articles;</li> <li>b. the hygienic handling of foodstuffs and utility articles;</li> <li>c. the self-supervision and official controls of foodstuffs and utility articles, namely the sampling, the evaluation basis and analysis methods, their entry in the Swiss Food Manual, and the requirements to be satisfied by persons charged with controlling foodstuffs;</li> <li>d. the import, transit and export of foodstuffs and utility articles;</li> </ul> |

|  |          |   |
|--|----------|---|
|  |          | <p><b>Hygiene Ordinance [HyV]</b><br/> <b>Art. 1</b> Subject matter and scope of application<br/> 1 This Ordinance:<br/> a. establishes the general hygiene provisions applicable to handling foodstuffs and utility articles;<br/> b. sets out the personal hygiene requirements to be satisfied by the employees of food businesses and their training and education in respect of hygiene matters;<br/> c. specifies the thermal processes and processing hygiene;<br/> d. establishes special hygiene provisions applicable to certain foodstuffs of animal origin;<br/> e.2 establishes the microbiological criteria for foodstuffs and utility articles.</p> <p><b>Ordinance on Hygiene in Milk Production [VHyMP]</b><br/> <b>Art. 1</b><br/> This Ordinance applies to:<br/> a. animal husbandry facilities in which milk is collected for the supply of food;<br/> b. the transport of milk.</p> <p><b>Ordinance on the Disposal of Animal By-products [VTNP]</b><br/> <b>Art. 2</b> Subject matter and scope of application<br/> 1 This Ordinance regulates the disposal of animal by-products.</p> |
| <p>Location and Plant Environments</p> | <p>4</p> | <p><b>Foodstuffs and Utility Articles Ordinance [LGV]</b><br/> <b>Art. 12</b> Reporting requirements<br/> 1 Whoever manufactures, processes, treats, stores, transports, offers, imports or exports foodstuffs must report their operations to the competent cantonal enforcement authority.<br/> 2 This shall not apply to the occasional offering on a small scale of food products at bazaars, school events and similar venues.<br/> 3 Any significant changes taking place within the firm or its closure must also be reported.</p> <p><b>Art. 13</b> Licensing requirements applicable to firms<br/> 1 Firms which manufacture, process, handle, store or offer foodstuffs of animal origin are subject to an</p>  |

|  |  |
|--|--|
|  | <p>operating licence issued by the competent cantonal enforcement authority.</p> <p>2 The following do not require an operating licence:</p> <p>a. Firms which operate only in primary production;</p> <p>b. Firms which engage only in transport operations;</p> <p>c.32 Firms which only store foodstuffs of animal origin for which no temperature control is required;</p> <p>d.33 Retailers which only offer foodstuffs of animal origin directly to consumers;</p> <p>e.34 Retailers which offer foodstuffs of animal origin to other food businesses where they only store or transport these foodstuffs beforehand;</p> <p>f.35 Retailers which offer foodstuffs of animal origin to other retailers, where this represents a secondary activity at the local level of limited scope;</p> <p>g. Firms which only manufacture, process, treat, store or offer foodstuffs that contain both products of plant origin as well as meat products, gelatine, collagen, treated stomachs, treated bladders and treated intestines, crackling (pork rind), rendered animal fats, processed fishery products, dairy products or egg products;</p> <p>h. Firms which only manufacture, process, treat, store or offer apiculture products.</p> <p>3 Before the competent cantonal enforcement authority issues an operating licence it will conduct an on-site inspection.</p> <p>4 It will issue an operating licence where the relevant food law requirements applicable to the respective operation have been satisfied.</p> <p>5 The licensed firm will receive an authorisation number. This is a component part of the firm's identification mark.</p> <p>6 Where the control authority detects serious non-compliance during an official inspection, it may suspend the operating licence or revoke it entirely.</p> <p>7 Where modifications are made in a licensed firm which might affect food hygiene this must be reported to the competent cantonal enforcement authority.</p> <p><b>Art. 56</b> Regular and risk-based controls</p> <p>1 Official controls are conducted by the competent authorities. They serve to verify compliance with food laws and provisions relating to animal health and animal welfare.</p> <p>2 The controls are to be conducted regularly and with the appropriate frequency. As a rule, they are</p> |
|--|--|

|                           |          |   |
|---------------------------|----------|---|
|                           |          | <p>conducted without any advance notification.</p> <p>3 They are conducted on a risk basis; the following is to be taken into account:</p> <ol style="list-style-type: none"> <li>a. The established risks which are associated with foodstuffs, food businesses, the use of foodstuffs or with processes, materials, substances, activities or processes which may have an impact on food safety;</li> <li>b. The conduct to date of the responsible persons with regard to compliance with food laws;</li> <li>c. The reliability of self-supervisions previously conducted;</li> <li>d. The size of the firm;</li> <li>e. Information which might point to a violation of food laws;</li> <li>f. Any guarantees provided by the competent authorities of the country of origin;</li> <li>g. The potential for deception in advertising.</li> </ol>   |
| <p>Plant and Workshop</p> | <p>5</p> | <p><b>Hygiene Ordinance [HyV]</b></p> <p><b>Art. 7</b> General provisions applicable to food businesses</p> <ol style="list-style-type: none"> <li>1 The premises and facilities of food businesses must be clean and always be well maintained.</li> <li>2 The layout, design, construction, siting and size of premises and facilities must permit the following requirements to be satisfied: <ol style="list-style-type: none"> <li>a. They must be capable of being maintained in appropriate condition, cleaned and disinfected; air-borne contamination must be capable of being avoided or restricted to a minimum. They must provide for adequate working space to allow for the hygienic performance of all operations.</li> <li>b. The accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces must be capable of being prevented.</li> <li>c. Good food hygiene practices must be ensured which also includes protection against contamination.</li> <li>d. Where necessary, suitable temperature-controlled handling and storage conditions of sufficient capacity must be provided for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.</li> <li>e. Drainage facilities must be adequate for the purpose intended and designed and constructed to avoid any risk of contamination of foodstuffs. Where drainage channels are fully or partially open, they must be so designed to ensure that waste does not flow from a contaminated area into a clean area, in particular not into an area where foods likely to present a high risk to the final consumer are handled.</li> <li>f. Food-handling areas must have adequate natural or artificial lighting.</li> </ol> </li> </ol> |

|  |   |
|--|---|
|  | <p>g. Premises and installations must be kept free of vermin, rodents and other pests. Where necessary, suitable pest control procedures are to be employed.</p> <p>h. Cleaning agents and disinfectants may not be stored in areas where food is handled.</p> <p><b>Art. 8</b> Special provisions applicable to premises</p> <p>1 In areas where food is prepared, treated or processed, the design and layout must permit good food hygiene practices, including protection against cross-contamination between and during operations.</p> <p>2 These areas must satisfy the following requirements in particular:</p> <p>a. The floor surfaces must be maintained in a sound condition and be easy to clean and, if necessary, disinfect. They must be impervious, non-absorbent and washable and be made of non-toxic materials. Where necessary, they must allow adequate surface drainage. The responsible person must be able to prove to the competent cantonal enforcement authority that any other materials which might be used are suitable.</p> <p>b. The wall surfaces must be maintained in a sound condition and be easy to clean and, if necessary, disinfect. They must be impervious, non-absorbent and washable and be made of non-toxic materials, and feature a smooth surface up to a height appropriate for the respective operations. The responsible person must be able to prove to the competent cantonal enforcement authority that any other materials which might be used are suitable.</p> <p>c. Ceilings, directly visible interior surfaces of the roof and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to minimise condensation, the growth of undesirable mould and the shedding of particles.</p> <p>d. Windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must, where necessary, be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in the contamination of foodstuffs, they must remain closed and fixed during production, processing or treatment processes.</p> <p>e. Doors must be easy to clean and, if necessary, disinfect. They must possess a smooth and water-repellent surface. The responsible person must be able to prove to the competent cantonal enforcement authority that any other materials which might be used are suitable.</p> <p>f. Surfaces in food-handling areas and in particular those which come into contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, easy to disinfect. They must</p> |
|--|---|

|            |     |  |
|------------|-----|--|
|            |     | <p>be made of corrosion-resistant, smooth, washable and non-toxic materials. The responsible person must be able to prove to the competent cantonal enforcement authority that any other materials which might be used are suitable.</p> <p>3 Where necessary, adequate facilities are to be provided for the cleaning, disinfecting and storage of working utensils and equipment. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.</p> <p><b>Ordinance on Hygiene in Milk Production [VHyMP]</b></p> <p><b>Art. 17</b> Cleaning areas</p> <p>Areas in which containers, milking equipment and dairy equipment are cleaned must feature:</p> <ol style="list-style-type: none"> <li>a. washable, acid-resistant walls and floors;</li> <li>b. hot and cold water;</li> <li>c. drains fitted with a trap;</li> <li>d. good lighting and ventilation.</li> </ol> <p><b>Art. 23</b> Facilities, containers and dairy equipment</p> <ol style="list-style-type: none"> <li>1 Areas in which milk is stored, treated and refrigerated must be situated and equipped so that contamination of milk is avoided to the maximum extent possible.</li> <li>2 Containers and dairy equipment must also be designed so that contamination of milk is avoided to the maximum extent possible.</li> <li>3 Containers and dairy equipment may only be used for milking, for the treatment, refrigeration and storage of milk and for the transport of milk as well as for the return of these items for reuse, however, not for storing whey or skimmed milk.</li> </ol> <p>Swiss Guide on Good Manufacturing Practice for milk processing:<sup>1</sup><br/>SOP 04.01-04.04</p> |
| Facilities | 5.3 | Hygiene Ordinance [HyV]  |

<sup>1</sup> Swiss Guide on Good Manufacturing Practice for milk processing: Leitlinie für eine gute Verfahrenspraxis für die gewerbliche Milchverarbeitung, fromarte

|  |   |
|--|---|
|  | <p><b>Art. 10</b> Sanitary conveniences</p> <ol style="list-style-type: none"> <li>1 In food businesses, an adequate number of flush lavatories must be available and connected to an effective drainage system. They may not open directly into areas in which food is handled.</li> <li>2 A sufficient number of washbasins for cleaning hands must be located at suitable sites and be provided with hot and cold running water and materials for hygienically cleaning hands and drying them.</li> <li>3 All sanitary conveniences must be provided with adequate natural or mechanical ventilation.</li> </ol> <p><b>Art. 17</b> Water supply</p> <ol style="list-style-type: none"> <li>1 Food businesses must provide for potable water in sufficient quantity as specified by the Ordinance of the Federal Department of Home Affairs (FDHA) of 23 November 2005<sup>14</sup> on Potable, Spring and Mineral Water.</li> <li>2 This potable water must be used whenever necessary to ensure that foodstuffs are not contaminated.</li> <li>3 Water which is recycled either for use in processing or as an ingredient must not present a risk of contamination to food by microbiological, chemical or physical hazards, and must be of the same standard as potable water.</li> <li>4 Ice which comes into contact with food or which may contaminate food is to be made from potable water.<br/>The ice is to be made, handled and stored under conditions which protect it from contamination.</li> <li>5 Steam which comes into direct contact with food may not contain any hazardous substances nor may it contaminate the food.</li> <li>6 Where non-potable water is used for fire control, steam production, refrigeration and other similar purposes, it must circulate in a separate system and be identified as such.<br/>Non-potable water may not connect with, or allow reflux into, potable water systems.</li> </ol> <p>See also Hygiene Ordinance [Hyv], Art. 7 e:</p> <p>e. Drainage facilities must be adequate for the purpose intended and designed and constructed to avoid any risk of contamination of foodstuffs. Where drainage channels are fully or partially open, they must be so designed to ensure that waste does not flow from a contaminated area into a clean area, in particular not into an area where foods likely to present a high risk to the final consumer are handled.</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing:</p> |
|--|---|

|   |         |  |
|---|---------|--|
|   |         | SOP 04.01-04.04  |
| Ventilation facilities  | 5.3.5   | <p>Hygiene Ordinance [HyV]<br/> <b>Art. 11</b> Ventilation</p> <ol style="list-style-type: none"> <li>1 Food-handling areas in food businesses must have adequate natural or artificial ventilation.</li> <li>2 Mechanical airflow from a contaminated area to a clean area is to be avoided.</li> <li>3 Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.</li> </ol> <p>Swiss Guide on Good Manufacturing Practice for milk processing:<br/> SOP 04.02, point 4.3:<br/> Areas in hygiene zones 1 and 2 must have adequate ventilation and if necessary must be equipped with installations to control air humidity.</p>   |
| Lighting facilities   | 5.3.6   | <p>Hygiene Ordinance [HyV], Art. 7 f.<br/> f. Food-handling areas must have adequate natural or artificial lighting.</p>   |
| Plant should have adequate natural lighting or artificial lighting inside. The lighting coefficient for the workshop shall not be lower than Standard IV; the mixed illumination shall not be lower than 540 lx for the work area of quality monitoring and control, not less than 220 lx for the work area of processing, and not less than 110 lx for other areas, except for the areas sensitive to light. The light source shall not cause any change in the color of foodstuffs. | 5.3.6.1 | <p>Hygiene Ordinance [HyV], Art. 7 f:<br/> f. Food-handling areas must have adequate natural or artificial lighting.</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing:<br/> SOP 04.02, point 4:<br/> An adequate natural or artificial lighting shall enable proper manufacturing conditions and the evaluation of the quality and cleanliness.</p>   |
| Equipment   | 6       | <p>Hygiene Ordinance [HyV]<br/> <b>Art. 14</b> Equipment</p> <ol style="list-style-type: none"> <li>1 The following provisions apply to vessels, apparatus, implements and other objects and equipment which come into contact with food (Equipment): <ol style="list-style-type: none"> <li>a. It must be thoroughly cleaned regularly to avoid any contamination and, where necessary, disinfected. This does not apply to non-returnable containers and packaging.</li> <li>b. It must be constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination.</li> <li>c. The equipment must be installed in such a manner so as to allow it to be adequately cleaned along</li> </ol> </li> </ol> |

|                    |   |  |
|--------------------|---|--|
|                    |   | <p>with the surrounding area.</p> <p>d. Where necessary, it must be fitted with appropriate control devices.</p> <p>2 Where chemical additives have to be used to prevent the corrosion of equipment and containers, they are to be used in accordance with good practice.</p> <p><b>Ordinance on Hygiene in Milk Production [VHyMP]</b></p> <p><b>Art. 16</b> General principles</p> <p>1 The surfaces of materials which come into contact with milk must:</p> <p>a. be made of non-toxic material which does not negatively affect the milk;</p> <p>b. have smooth, corrosion-resistant surfaces;</p> <p>c. be readily accessible;</p> <p>d. be easy to clean and, if necessary, disinfect;</p> <p>e. be maintained in a sound condition.</p> <p>2 The surfaces must be cleaned and, where necessary, disinfected after use.</p> <p>3 After each use, or after a series of uses where the period of time between emptying and refilling is very short, but in any event at least once per day, the containers and tanks used for the transport of milk must be cleaned and disinfected before re-use.</p> <p><b>Swiss Guide on Good Manufacturing Practice for milk processing:</b><br/>SOP 04.05</p> |
| Hygiene Management | 7 | <p><b>Federal Act on Food and Utility Articles (LMG)</b></p> <p><b>Art. 15</b> Hygiene</p> <p>1 Anyone who manufactures, processes, stores, transports or offers foodstuffs must ensure that they:</p> <p>a. are stored in clean, tidy conditions;</p> <p>b. are stored, transported or offered in such a way that they cannot be affected by substances that present a risk to health, or be adversely affected in any other way;</p> <p>c. only come into direct or indirect contact with containers, packaging materials,</p>   |

|  |   |
|--|---|
|  | <p>facilities, tools and other similar products that are clean and in good condition;</p> <p>d. are stored only on premises and transported only in vehicles that are clean, sufficiently large and equipped for organised storage;</p> <p>e. are, as far as possible, not affected by pests and parasites.</p> <p><sup>2</sup> Persons who excrete pathogens that may present a risk to the health of consumers must take special precautions when handling foodstuffs.</p> <p><sup>3</sup> The Federal Council shall enact regulations on the hygienic handling of foodstuffs.</p> <p><sup>4</sup> If it is necessary for the purposes of the Act, the Federal Council may by means of an Ordinance require persons supplying or offering food or drinks for immediate consumption to undergo training in the field of hygiene.</p> <p><b>Art. 23 Self-supervision</b></p> <p><sup>1</sup> Anyone who manufactures, processes, offers, imports or exports foodstuffs, additives or utility articles must ensure in the course of his activities that the goods are in conformity with legal requirements. He must analyse them or have them analysed according to "Good Manufacturing Practice".</p> <p><sup>2</sup> Official inspection does not imply a dispensation from the obligation to carry out self-supervision.</p> <p><sup>2bis</sup> Anyone who discovers that foodstuffs or utility articles that he introduces, manufactures, processes, handles, supplies or offers may constitute a health risk must ensure that consumers come to no harm. If the foodstuffs or utility articles are no longer under the direct control of the person in question, that person must notify the enforcement authorities in question immediately and cooperate with them.<sup>17</sup></p> <p><sup>3</sup> The Federal Council shall regulate the conditions under which analysis may be dispensed with in individual cases.</p> <p><sup>4</sup> Owners and purchasers of animals for slaughter must notify the official veterinarian or official expert assistant if there are health concerns concerning an animal or if an animal has been treated with therapeutic products.</p> <p><sup>5</sup> The Federal Council may issue the documentation relating to self-supervision.</p> |
|--|---|

|  |  |
|--|--|
|  | <p><b>Foodstuffs and Utility Articles Ordinance [LGV]</b></p> <p><b>Art. 47</b> Hygiene</p> <p>1 The responsible person must ensure that:</p> <ol style="list-style-type: none"> <li>a. Foodstuffs and utility articles are not degraded by micro-organisms, foreign matter or in another manner;</li> <li>b. A foodstuff is fit for human consumption taking into account its intended use.</li> </ol> <p>2 The responsible person must take all the actions and precautions necessary to control hazards posed to humans.</p> <p>3 The vessels, apparatus, implements, packaging materials, conveyances etc. used in food handling and in food production and the premises designated for storage and sale must be kept clean and in a good condition.</p> <p><b>Self-supervision</b></p> <p><b>Art. 49</b> General principles</p> <p>1 The responsible person, as part of his or her duties, must ensure that the legal requirements applicable to foodstuffs and utility articles have been satisfied at all levels of production, processing and distribution, and in particular those provisions relating to health protection, protection against deception, and the hygienic handling of foodstuffs and utility articles.</p> <p>2 In order to comply with the requirements according to Paragraph 1, the responsible person is obligated to engage in self-supervision.</p> <p>3 Key self-supervision tools include in particular:</p> <ol style="list-style-type: none"> <li>a. The use of good practices (Good Hygiene Practice, Good Manufacturing Practice);</li> <li>b. The use of procedures based on the principles of the HACCP concept (Art. 51);</li> <li>c. Traceability;</li> <li>d. The sampling and analysis of foodstuffs and utility articles.</li> </ol> <p><b>Art. 50</b> Traceability</p> <p>1 Foodstuffs, animals intended for food manufacture and all substances which may be expected to be processed into a foodstuff must be traceable through all stages of manufacturing, processing and</p> |
|--|--|

|  |  |
|--|--|
|  | <p>distribution.</p> <p>2 Whoever trades with products according to Paragraph 1 must be able to provide the following information to the competent cantonal enforcement authority:</p> <ol style="list-style-type: none"> <li>a. From whom the products were obtained; and</li> <li>b. To whom they were supplied; this shall not apply to the direct sale to consumers.</li> </ol> <p>2bis Whoever trades in foodstuffs of animal origin, sprouts or seeds for the generation of sprouts must also ensure that the food business to which the products are supplied and the competent enforcement authority, should it so request, is supplied with the following information:</p> <ol style="list-style-type: none"> <li>a. An exact description of the product;</li> <li>b. The volume or quantity of the product;</li> <li>c. The name and address of the food business by which the product was shipped;</li> <li>d. The name and address of the previous owner by whom the product was shipped, where the owner is not a food business;</li> <li>e. The name and address of the food business to which the product was shipped;</li> <li>f. The name and address of the new owner to whom the product was shipped, where the owner is not a food business;</li> <li>g. A reference number to identify the lot, batch or consignment;</li> <li>h. The shipping date.</li> </ol> <p>2ter The information according to Paragraphs 2 and 2bis must be kept on file at minimum until it can be assumed that the product has been consumed.</p> <p>3 An importer who imports products from a country which does not implement a similar system of traceability shall be responsible for ensuring that the origin of the products is traceable to the extent that a food safety hazard can be precluded. The extent of responsibility shall be in line with the potential hazard posed by the product.</p> <p><b>Art. 51 Hazard Analysis and Critical Control Points (HACCP)</b></p> <ol style="list-style-type: none"> <li>1 Whoever manufactures, processes, treats, stores, transports or markets foodstuffs must develop and apply one or more procedures based on HACCP principles to ensure the on-going monitoring of specific biological, chemical and physical hazards. This shall be without prejudice to Article 53.</li> <li>2 Such a procedure must include the following elements:</li> </ol> |
|--|--|

|  |   |
|--|---|
|  | <ul style="list-style-type: none"> <li>a. Identifying and assessing any hazards that must be prevented, eliminated or reduced to acceptable levels (Hazard Analysis, HA);</li> <li>b. Identifying the critical control points at the process levels at which control is essential to bring a hazard under control, i.e. to prevent or eliminate a hazard or to reduce it to an acceptable level (Critical Control Point(s), CCP);</li> <li>c. Establishing guide values at the aforementioned process levels which distinguish acceptable values from unacceptable values for the prevention, elimination or reduction of identified hazards;</li> <li>d. Establishing and implementing an effective system for monitoring procedures at critical control points;</li> <li>e. Establishing corrective actions when monitoring indicates that a critical control point is no longer under control;</li> <li>f. Establishing a review procedure to determine compliance with the provisions according to Subparagraphs a–e; reviews are to be conducted regularly, in any event whenever a change in the production process is likely to negatively affect the safety of the foodstuffs produced;</li> <li>g. Creating documents and keeping records which show that the provisions according to Subparagraphs a–f have been satisfied; the documents and records must be commensurate with the nature and size of the food business; they must be kept up to date at all times and be archived for an appropriate period of time.</li> </ul> <p>3 The HACCP concept must be appropriately applied in a manner commensurate with the safety risk posed and the production scale.</p> <p>4 The FDHA may appropriately ease the requirements applicable to retailers.</p> <p>5 Paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> <li>a. Primary production;</li> <li>b. Producers who exclusively offer small quantities of primary products produced by them to consumers directly or by way of local retailers.</li> </ul> <p><b>Art. 52</b> Guides to good practice</p> <p>1 The food business sectors may establish guidelines for good practice based on HACCP principles. These must be submitted to the Federal Food Safety and Veterinary Office (FSVO) for approval by same.</p> <p>2 The following applies to these guidelines:</p> <ul style="list-style-type: none"> <li>a. They must be suitable for the correct implementation of the provisions of this section and other food</li> </ul> |
|--|---|

|  |   |
|--|---|
|  | <p>hygiene provisions;</p> <p>b. They must take account of the relevant codes of practice of the Codex Alimentarius; and</p> <p>c. Affected groups must have been consulted.</p> <p><b>Art. 53</b> Evidence of good practice</p> <p>The responsible person must be able to prove to the competent cantonal enforcement authority that:</p> <p>a. A procedure complying with HACCP is applied; or</p> <p>b. Where guidelines for good practice are present which have been approved by the FSVO, these guidelines are applied to ensure good practice.</p> <p><b>Art. 54</b> Marketing of foodstuffs or utility articles which are hazardous to health</p> <p>1 Where the responsible person establishes or has reason to suspect that foodstuffs or utility articles imported, manufactured, processed, treated or marketed by his or her firm pose or may pose a hazard to health, and where the respective foodstuffs or utility articles are no longer under the firm's direct control, the responsible person must do the following immediately:</p> <p>a. Inform the competent cantonal enforcement authority;</p> <p>b. Take the requisite actions to withdraw the products from the market (Withdrawal); and</p> <p>c. Where the products might have already reached consumers: recall the products (Recall) and effectively and accurately inform consumers of the reason for the recall.</p> <p>2 Where the responsible person has knowledge that or has reason to suspect that food-borne outbreaks are associated with his or her food business, he or she must ensure that samples of suspicious foods or strains of isolated pathogens are preserved and made available to the enforcement authorities as required.</p> <p>3 The responsible person must cooperate with the enforcement authorities.</p> <p><b>Art. 55</b> Documentation of self-supervision</p> <p>1 All self-supervision actions are to be documented in writing or by way of an equivalent procedure.</p> <p>2 The FDHA may regulate the nature and manner of self-supervision and the details of documentation.</p> <p><b>Hygiene Ordinance [HyV]</b></p> <p><b>Art. 58a</b> Obligations of the responsible person</p> |
|--|---|

|  |   |
|--|---|
|  | <p>1 In conducting self-supervision, the responsible person must take all actions required to ensure that:</p> <ol style="list-style-type: none"> <li>a. The process hygiene criteria applicable to raw ingredients and foodstuffs which are under his or her control have been satisfied;</li> <li>b. The food safety criteria applicable throughout the shelf-life of products have been satisfied under reasonably foreseeable conditions applicable to distribution, storage and use.</li> </ol> <p>2 In validating or reviewing the proper functioning of his or her HACCP-based procedure or other hygiene control measures the responsible person must conduct, where appropriate, analyses applying the microbiological criteria according to Annexes 1–3.</p> <p><b>Art. 16 Waste</b></p> <ol style="list-style-type: none"> <li>1 Food waste, non-edible by-products and other refuse are to be removed as quickly as possible from areas in which foods are handled.</li> <li>2 It is to be stored in closable containers. They must be suitable for being maintained in a sound condition, be easy to clean and, if necessary, easy to disinfect.</li> <li>3 Food waste, non-edible by-products and other refuse are to be temporarily stored and disposed of in a suitable manner.</li> <li>4 Refuse stores are to be designed and managed in such a way so as to enable them to be kept clean and free of animals and pests. If necessary, they are to be refrigerated.</li> <li>5 Waste is to be disposed of in a hygienic manner. It may not be permitted to contaminate foodstuffs whether directly or indirectly.</li> <li>6 The responsible person must be able to prove to the competent cantonal enforcement authority that any other container types or disposal systems which might be used are equally suitable.</li> </ol> <p>See also Hygiene Ordinance [HyV], Art. 7 g and 8 [above]</p> <p>Ordinance on the Disposal of Animal By-products [VTNP]</p> <p><b>Art. 20 Labelling and accompanying documents</b></p> <ol style="list-style-type: none"> <li>1 Animal by-products must be labelled so that it is clear what category they belong to, save for operations not subject to a reporting requirement (Art. 10 para. 2).</li> <li>2 Transports of animal by-products must include an accompanying document or a ruling issued by the meat inspectorate as provided in Annex 4 Section 3. This shall not apply to transports associated with</li> </ol> |
|--|---|

|                                       |     |  |
|---------------------------------------|-----|--|
|                                       |     | <p>operations not subject to a reporting requirement (Art. 10 para. 2) as well as to transports of food waste.</p> <p>3 The requirements according to Paragraphs 1 and 2 shall apply to derived products:</p> <ol style="list-style-type: none"> <li>a. Transports to the site of final incineration or disposal, where they are comprised of Category 1 starting materials;</li> <li>b. Transports to the plant in which they are to be processed to feed or fertiliser;</li> <li>c. Until they have been processed according to Annex 5, where they are designated for the manufacture of technical products.</li> </ol> <p>4 The accompanying documents are to be issued by the consignor of the animal by-products.</p> <p>5 The accompanying documents are to be retained on file for three years. The competent federal and cantonal control authorities shall have the right to inspect these documents at any time.</p> <p>6 The requirements pertaining to labelling and the accompanying documents are contained Annex 4 Sections 1 and 3.</p> <p><b>Art. 38</b> Infrastructure of the cantons</p> <p>1 Every canton must ensure that</p> <ol style="list-style-type: none"> <li>a. An appropriate infrastructure is in place for the collection and temporary storage of animal by-products.</li> </ol> <p>Swiss Guide on Good Manufacturing Practice for milk processing:<br/>SOP 12.01-12.03, 13.01-13.02</p> |
| Human Health and Hygiene Requirements | 7.4 | <p>Hygiene Ordinance [HyV]</p> <p><b>Art. 21</b> Personal hygiene</p> <ol style="list-style-type: none"> <li>1 Persons who work in a food business must be mindful of personal hygiene and cleanliness when handling foodstuffs.</li> <li>2 Work clothing or, as necessary, protective clothing must be appropriate and clean.</li> <li>3 Food businesses must provide for the requisite changing facilities and facilities for tending to personal hygiene.</li> <li>4 The responsible person must ensure that personnel complies with the proper hygiene with regard to their hands, body and clothing.</li> </ol>   |

|  |   |  |
|--|---|--|
|  |   | <p><b>Art. 22 Sick or injured persons</b></p> <p>1 Persons who are suffering from an acute food-borne disease are prohibited from entering food-handling areas.</p> <p>2 Persons who still excrete pathogens after recovering or who exhibit an infected wound, skin injury or similar are prohibited from entering food-handling areas, unless it is ensured by way of suitable hygiene measures that direct or indirect contamination of food is precluded.</p> <p>3 Persons who are affected by a food-borne disease or who work in a food business or come into contact with food must report illnesses and symptoms immediately to the responsible person and, where possible, their causes.</p> <p>4 Where food-borne diseases occur simultaneously in more than one person in a food business, the responsible person must report this to the competent cantonal enforcement authority.</p> <p><b>Art. 23 Training and monitoring</b></p> <p>1 The responsible person must ensure that food handlers are supervised and are instructed and/or trained in food hygiene matters commensurate with their work activity.</p> <p>2 The responsible person must ensure that members of the food business which are responsible for the development and application of the HACCP plan have received adequate training in all matters relating to the application of the HACCP plan.</p> <p><b>Art. 24 Access by external persons</b></p> <p>The responsible person must control access by persons from outside the firm (e.g. visitors) to the food-handling areas and must establish the requisite hygiene measures to be taken.</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing:<br/>SOP 03.01</p> |
| Requirements for Raw Materials and Packing Materials | 8 | <p>Ordinance on Hygiene</p> <p>Ordinance on Hygiene in Milk Production [VHyMP]</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing<br/>SOP 08.09</p>   |

|   |            |   |
|---|------------|---|
| <p>Requirements for Purchasing, Acceptance Check of Raw Materials and Packaging Materials</p> | <p>8.2</p> | <p><b>Ordinance on Hygiene</b></p> <p><b>Art. 18</b> Raw materials, ingredients and foodstuffs</p> <p>1 The responsible person may not accept raw materials or ingredients if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances to such an extent that the final product would be unfit for human consumption, even after normal sorting and/or hygienic preparatory or processing procedures were to be applied.</p> <p>2 Raw, non-consumable foodstuffs are to be stored separately of consumable, ready-to-eat foodstuffs. During processing and preparation (washing, set-up, etc.) suitable precautions are to be taken to prevent cross-contamination.</p> <p>3 Raw materials and ingredients kept on hand in a food business are to be stored in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p> <p>4 All food must be protected against any contamination likely to render the food unfit for human consumption during manufacture, processing, treatment, storage, packaging, offering and transport.</p> <p>5 Hazardous or inedible substances are to be adequately labelled and stored in separate and secure containers.</p> <p><b>Ordinance on Hygiene in Milk Production [VHyMP]</b></p> <p><b>Requirements to be satisfied by milk</b></p> <p><b>Art. 8</b> Hygiene requirements to be satisfied by milk</p> <p>1 Only milk of the highest quality whose content is unaltered and which comes from animals in a good general state of health may be supplied.</p> <p>2 The milk must comply with the following requirements, whereby methodological spread is taken into account:</p> <p><b>Cow's milk</b></p> <p>Criterion, requirement</p> <p>Microbial count at 30°C (per ml) &lt; 80,000</p> <p>Somatic cell count (per ml) &lt; 350,000</p> <p>Inhibitors: not detectable</p> |
|---|------------|---|

|  |  |
|--|--|
|  | <p>1 Geometric mean calculated per month for at least two samples per calendar month</p> <p>2 Geometric mean calculated per month for at least two samples per calendar month</p> <p><b>Milk from other animals</b></p> <p>Criterion, requirement</p> <p>Microbial count at 30°C (per ml) &lt; 1,500,000 or &lt; 500,000, where the milk is intended for the manufacture of products made with raw milk without undergoing heat treatment</p> <p>Inhibitors: not detectable</p> <p>3 In every month in which milk is produced the milk must be analysed at least twice to determine whether it satisfies the requirements according to Paragraph 2.</p> <p><b>Art. 9</b> Milk which does not satisfy requirements</p> <p>Where milk does not satisfy the requirements of Article 8, the testing laboratories must notify the competent authority. The producers must take the requisite remedial measures.</p> <p><b>Art. 10</b> Where the supply of milk is prohibited</p> <p>1 The supply of the following milk is prohibited:</p> <ol style="list-style-type: none"> <li>a. Milk from animals to which substances or products have been administered that are prohibited or are not licensed or are not approved for the respective treatments;</li> <li>b. Milk from animals which have been treated with drugs or other substances or products that have an adverse effect on milk or require that a withdrawal period be observed for milk deliveries as long as the animals are undergoing treatment or the withdrawal period has not lapsed;</li> <li>c. Milk from animals which exhibit signs of a disease communicable to humans through milk, in particular tuberculosis or brucellosis; the same shall apply to animals in which such a disease is suspected;</li> <li>d. Milk from animals which suffer from a disease that can have a negative effect on milk such as infections or enteritis with diarrhoea and fever, acetonæmia, ovarian cysts, or infections of the genital tract with discharge;</li> <li>e. Milk from udders with a recognisable inflammation and milk from udders testing positive in the Schalm test (California Mastitis Test, CMT);</li> <li>f. Milk from animals with open suppurating wounds on or in the vicinity of the udder or other wounds which may have a negative effect on the milk;</li> </ol> |
|--|--|

|  |       |   |
|--|-------|---|
|  |       | <p>g. Milk obtained within the first eight days of the onset of lactation;</p> <p>h. Milk from animals which are milked less than twice a day;</p> <p>i. Milk from cows that produce less than two liters of milk per day;</p> <p>j. Milk which is not fit for the intended use;</p> <p>k. Milk from pre-milk and foremilk.</p> <p>2 Animals likely to transfer residues to the milk as the result of undergoing medical treatment must be clearly identified.</p> <p>3 Milk from animals showing clinical signs of udder disease may not be used for human consumption unless this has been approved by a veterinarian.</p> <p>4 Colostrum as defined in Article 66a of the Ordinance of the Federal Department of Home Affairs (FDHA) of 23 November 2005 on Foodstuffs of Animal Origin which was obtained no later than five days subsequent to birth may be marketed. Colostrum must be collected separately from the other milk and must be labelled accordingly. Mixing colostrum with milk is prohibited. The hygiene requirements applicable to the production of milk apply equally to colostrum.</p> |
| Requirements for Transportation and Storage of Raw Materials and Packaging Materials | 8.3   | <p>Hygiene Ordinance [HyV]</p> <p><b>Art. 20</b> Wrapping and packaging of foodstuffs</p> <p>1 Wrapping and packaging materials may not pose a source of contamination to food. When using metal or glass in particular, it must be ensured that the receptacle is clean and not damaged.</p> <p>2 Wrapping and packaging materials must be stored so that they cannot be contaminated.</p> <p>3 Wrapping and packaging materials that are reused for foods must be easy to clean and, if necessary, disinfect.</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing<br/>SOP 08.09</p>   |
| Transportation and storage of raw milk   | 8.3.2 | <p>Hygiene Ordinance [HyV]</p> <p><b>Art. 46</b> Handling of raw milk after milking</p> <p>1 During the transport of raw milk from the production holding, the refrigeration chain may not be interrupted. Upon reaching the destination the temperature of the milk may not exceed 10°C.</p> <p>2 Departure from this temperature is permitted where the milk is collected or processed within two hours of milking.</p>   |

|  |                |  |
|--|----------------|--|
|  |                | <p><b>Art. 48</b> Milk-processing establishments</p> <p>1 Upon being accepted in a processing establishment raw milk must be quickly cooled to a temperature not exceeding 6°C and be maintained at this temperature until it is processed.</p> <p>2 The milk may be kept at a higher temperature, provided that:</p> <p>a. Processing begins immediately after milking, or within four hours of acceptance at the processing establishment; or</p> <p>b. This is necessary for technological reasons and food safety is ensured at all times.</p> <p>3 In establishments in which dairy products are manufactured, a suitable process must be employed to ensure that the following tolerance values have been satisfied immediately prior to heat treatment:</p> <p>a. For raw milk: a microbial count not exceeding 300,000 per ml at 30°C;</p> <p>b.37 For heat-treated milk used for the manufacture of dairy products: a microbial count not exceeding 100,000 per ml at 30°C;</p> <p>c. For cream: a microbial count not exceeding 300,000 per ml at 30°C.</p> <p>4 The values according to Paragraph 3 must be verified applying the reference methods of the Swiss Foodstuffs Manual.</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing<br/>SOP 08.01-08.06</p> |
| <p>Raw milk shall be, within 2 hours after milking, cooled down to 0°C~4°C and transported in normal temperature lorry. The lorry shall maintain completed certificate and record.</p> | <p>8.3.2.2</p> | <p><b>Hygiene Ordinance [HyV]</b></p> <p><b>Art. 46</b> Handling of raw milk after milking</p> <p>1 During the transport of raw milk from the production holding, the refrigeration chain may not be interrupted. Upon reaching the destination the temperature of the milk may not exceed 10°C.</p> <p>2 Departure from this temperature is permitted where the milk is collected or processed within two hours of milking.</p> <p><b>Art. 48</b> Milk-processing establishments</p> <p>1 Upon being accepted in a processing establishment raw milk must be quickly cooled to a temperature not exceeding 6°C and be maintained at this temperature until it is processed.</p> <p>2 The milk may be kept at a higher temperature, provided that:</p> <p>a. Processing begins immediately after milking, or within four hours of acceptance at the processing</p>   |

establishment; or

b. This is necessary for technological reasons and food safety is ensured at all times.

3 In establishments in which dairy products are manufactured, a suitable process must be employed to ensure that the following tolerance values have been satisfied immediately prior to heat treatment:

a. For raw milk: a microbial count not exceeding 300,000 per ml at 30°C;

b.37 For heat-treated milk used for the manufacture of dairy products: a microbial count not exceeding 100,000 per ml at 30°C;

c. For cream: a microbial count not exceeding 300,000 per ml at 30°C.

4 The values according to Paragraph 3 must be verified applying the reference methods of the Swiss Foodstuffs Manual.

#### Ordinance on Hygiene in Milk Production [VHyMP]

##### Art. 14 Refrigeration and storage of milk

1 Immediately after milking the milk must be brought to a clean place which is designed and equipped to preclude contamination.

2 Where milk is collected twice a day, it must be effectively precooled using running cold water.

3 Where the milk is collected once a day it must be cooled directly subsequent to milking to a temperature of 8°C or lower within two hours and be stored at this temperature.

4 Where the milk is collected every other a day it must be cooled down further to a temperature of 6°C or lower and be stored at this temperature.

5 The producer must conduct regular checks of the chilling time and storage temperature. During refrigeration and storage no fat deterioration may occur which degrades quality.

6 The first milk-yield may be stored for a maximum of 48 hours until it is transported to the processing establishment.

7 The milk producer may establish other refrigeration temperatures for the production of cheese. However, the storage temperature may not exceed 18°C. Where the storage temperature exceeds 8°C processing must be done no later than 24 hours of the first milking. Food safety is to be ensured at all times.

##### Art. 15 Transport of milk

|                                   |     |  |
|-----------------------------------|-----|--|
|                                   |     | <p>1 Milk is to be transported to the processing establishment hygienically and with due care.</p> <p>2 During transportation the refrigeration chain may not be interrupted; upon reaching its destination the temperature of the milk may not exceed 10°C.</p> <p>Swiss Guide on Good Manufacturing Practice for milk processing<br/>SOP 08.01-08.06</p>   |
| Food Safety Control in Production | 9   | <p>Hygiene Ordinance [HyV]<br/>See also Swiss Guide on Good Manufacturing Practice for milk processing</p>   |
| Microbial Contamination Control   | 9.1 | <p>Hygiene Ordinance [HyV]<br/><b>Art. 25</b> Refrigeration</p> <p>1 Raw materials, ingredients, intermediate products and finished, ready-to-eat food likely to support the development of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which prevent this to the maximum extent possible.</p> <p>2 Refrigeration temperatures are to be selected so that food safety is ensured at all times. Upon offering to the consumer or upon reaching the use-by date the limits and tolerance values for micro-organisms established in Annexes 1 and 2 in particular must be satisfied.</p> <p>3 The refrigeration chain may not be interrupted. Limited periods outside temperature control are permitted to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that this does not result in a risk to consumer health.</p> <p><b>Art. 58a</b> Obligations of the responsible person</p> <p>1 In conducting self-supervision, the responsible person must take all actions required to ensure that:</p> <p>a. The process hygiene criteria applicable to raw ingredients and foodstuffs which are under his or her control have been satisfied;</p> <p>b. The food safety criteria applicable throughout the shelf-life of products have been satisfied under reasonably foreseeable conditions applicable to distribution, storage and use.</p> <p>2 In validating or reviewing the proper functioning of his or her HACCP-based procedure or other hygiene control measures the responsible person must conduct, where appropriate, analyses applying the microbiological criteria according to Annexes 1–3.</p> |

|  |         |  |
|--|---------|--|
|  |         | See also Hygiene Ordinance [HyV], Art. 46 and 48 [above]   |
| Atmospheric cleanness in production area   | 9.1.3   | See general requirements for plant and workshop [above]<br>See also Swiss Guide on Good Manufacturing Practice for milk processing   |
| Determine as per natural settlement method specified in GB/T 18204.1, the total plate count (TPC) in the air of the clean work area shall be controlled within 30cfu/dish. | 9.1.3.2 | Hygiene Ordinance [HyV]<br><b>Art. 58d</b> Sampling of processing areas and equipment<br>1 Samples shall be taken from processing areas and equipment used in food production, when such sampling is necessary for ensuring that the criteria are met. In that sampling the ISO standard 18593 shall be used as a reference method.<br><br>See also Swiss Guide on Good Manufacturing Practice for milk processing<br>SOP 14.04  |
| Testing of Products  | 10      | Hygiene Ordinance [HyV]<br><b>Art. 3</b> Duty of care<br>1 The responsible person must ensure compliance with the hygiene provisions of this Ordinance during all stages of production, processing and distribution of food.<br>2 The responsible person must ensure<br>a. compliance with the temperature requirements applicable to food and end-to-end maintenance of the refrigeration chain;<br>b.8 compliance with the microbiological criteria established in Annexes 1–3.<br><br>See also Art. 49 of the Foodstuffs and Utility Articles Ordinance [LGV] [above]<br>See also Swiss Guide on Good Manufacturing Practice for milk processing<br>SOP 14.05 |
| Product Storage and Transportation   | 11      | Hygiene Ordinance [HyV]<br><b>Art. 13</b> Transport<br>1 Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning or disinfection.<br>2 Where a risk is posed of foodstuffs being contaminated by other transported goods, conveyances  |

|  |   |
|--|---|
|  | <p>and/or containers must be used which are reserved exclusively for the transport of foodstuffs.</p> <p>3 Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there must be, where necessary, effective separation of products.</p> <p>4 In the case of liquid, granulate and powdered foodstuff products carried in bulk, transport must take place in conveyances and/or containers which are reserved exclusively for the transport of foodstuffs. Such conveyances and/or containers must be marked in a clearly visible and indelible fashion, in one of Switzerland's official languages, to show that they are used exclusively for the transport of foodstuffs.</p> <p>5 Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.</p> <p>6 Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.</p> <p>7 Conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at a specific temperature. They must be designed to allow foodstuffs to be maintained at appropriate temperatures and permit these temperatures to be monitored during transport.</p> <p><b>Art. 18</b> Raw materials, ingredients and foodstuffs</p> <p>1 The responsible person may not accept raw materials or ingredients if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances to such an extent that the final product would be unfit for human consumption, even after normal sorting and/or hygienic preparatory or processing procedures were to be applied.</p> <p>2 Raw, non-consumable foodstuffs are to be stored separately of consumable, ready-to-eat foodstuffs. During processing and preparation (washing, set-up, etc.) suitable precautions are to be taken to prevent cross-contamination.</p> <p>3 Raw materials and ingredients kept on hand in a food business are to be stored in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p> <p>4 All food must be protected against any contamination likely to render the food unfit for human consumption during manufacture, processing, treatment, storage, packaging, offering and transport.</p> |
|--|---|

|  |           |  |
|--|-----------|--|
|  |           | <p>5 Hazardous or inedible substances are to be adequately labelled and stored in separate and secure containers.</p> <p>See also Swiss Guide on Good Manufacturing Practice for milk processing<br/>SOP 11.03, SOP 08.01-08.09</p>  |
| <p>Product Traceability and Recall</p> | <p>12</p> | <p><b>Federal Act on Food and Utility Articles (LMG)</b><br/><b>Art. 23a</b> Traceability</p> <p>1 Foodstuffs, animals intended for food manufacture and all substances pertaining thereto or which may be expected to be processed into a foodstuff must be traceable through all stages of manufacturing, processing and distribution.</p> <p>2 Systems and processes must be put in place so that the authorities can, at their request, be notified of any necessary information.</p> <p><b>Foodstuffs and Utility Articles Ordinance [LGV], Art. 50:</b><br/><b>Art. 50</b> Traceability</p> <p>1 Foodstuffs, animals intended for food manufacture and all substances which may be expected to be processed into a foodstuff must be traceable through all stages of manufacturing, processing and distribution.</p> <p>2 Whoever trades with products according to Paragraph 1 must be able to provide the following information to the competent cantonal enforcement authority:</p> <p>a. From whom the products were obtained; and</p> <p>b. To whom they were supplied; this shall not apply to the direct sale to consumers.</p> <p>2bis Whoever trades in foodstuffs of animal origin, sprouts or seeds for the generation of sprouts must also ensure that the food business to which the products are supplied and the competent enforcement authority, should it so request, is supplied with the following information:</p> <p>a. An exact description of the product;</p> <p>b. The volume or quantity of the product;</p> <p>c. The name and address of the food business by which the product was shipped;</p> <p>d. The name and address of the previous owner by whom the product was shipped, where the owner is not a food business;</p> <p>e. The name and address of the food business to which the product was shipped;</p> |

|  |  |
|--|--|
|  | <p>f. The name and address of the new owner to whom the product was shipped, where the owner is not a food business;</p> <p>g. A reference number to identify the lot, batch or consignment;</p> <p>h. The shipping date.</p> <p>2ter The information according to Paragraphs 2 and 2bis must be kept on file at minimum until it can be assumed that the product has been consumed.</p> <p>3 An importer who imports products from a country which does not implement a similar system of traceability shall be responsible for ensuring that the origin of the products is traceable to the extent that a food safety hazard can be precluded. The extent of responsibility shall be in line with the potential hazard posed by the product.</p> <p><b>Art. 54</b> Marketing of foodstuffs or utility articles which are hazardous to health</p> <p>1 Where the responsible person establishes or has reason to suspect that foodstuffs or utility articles imported, manufactured, processed, treated or marketed by his or her firm pose or may pose a hazard to health, and where the respective foodstuffs or utility articles are no longer under the firm's direct control, the responsible person must do the following immediately:</p> <p>a. Inform the competent cantonal enforcement authority;</p> <p>b. Take the requisite actions to withdraw the products from the market (Withdrawal); and</p> <p>c. Where the products might have already reached consumers: recall the products (Recall) and effectively and accurately inform consumers of the reason for the recall.</p> <p>2 Where the responsible person has knowledge that or has reason to suspect that food-borne outbreaks are associated with his or her food business, he or she must ensure that samples of suspicious foods or strains of isolated pathogens are preserved and made available to the enforcement authorities as required.</p> <p>3 The responsible person must cooperate with the enforcement authorities.</p> <p>See also Swiss Guide on Good Manufacturing Practice for milk processing<br/>SOP 06.01-06.04</p> <p>See also Guideline for Implementation, Art. 54 of the Foodstuffs and Utility Articles</p> |
|--|--|

|                                       |    |   |
|---------------------------------------|----|---|
|                                       |    | Ordinance [LGV]   |
| Training                              | 13 | See Hygiene Ordinance [HyV], Art. 23<br>See also Swiss Guide on Good Manufacturing Practice for milk processing<br>SOP 03.01-03.04  |
| Management Organization and Personnel | 14 | <p>Foodstuffs and Utility Articles Ordinance [LGV]:</p> <p><b>Art. 49</b> General principles</p> <p>1 The responsible person, as part of his or her duties, must ensure that the legal requirements applicable to foodstuffs and utility articles have been satisfied at all levels of production, processing and distribution, and in particular those provisions relating to health protection, protection against deception, and the hygienic handling of foodstuffs and utility articles.</p> <p>2 In order to comply with the requirements according to Paragraph 1, the responsible person is obligated to engage in self-supervision.</p> <p>3 Key self-supervision tools include in particular:</p> <p>a. The use of good practices (Good Hygiene Practice, Good Manufacturing Practice);</p> <p>b. The use of procedures based on the principles of the HACCP concept (Art. 51);</p> <p>c. Traceability;</p> <p>d. The sampling and analysis of foodstuffs and utility articles.</p> <p><b>Art. 50</b> Traceability</p> <p>1 Foodstuffs, animals intended for food manufacture and all substances which may be expected to be processed into a foodstuff must be traceable through all stages of manufacturing, processing and distribution.</p> <p>2 Whoever trades with products according to Paragraph 1 must be able to provide the following information to the competent cantonal enforcement authority:</p> <p>a. From whom the products were obtained; and</p> <p>b. To whom they were supplied; this shall not apply to the direct sale to consumers.</p> <p>2bis Whoever trades in foodstuffs of animal origin, sprouts or seeds for the generation of sprouts must also ensure that the food business to which the products are supplied and the competent enforcement authority, should it so request, is supplied with the following information:</p> |

|  |  |
|--|--|
|  | <p>a. An exact description of the product;</p> <p>b. The volume or quantity of the product;</p> <p>c. The name and address of the food business by which the product was shipped;</p> <p>d. The name and address of the previous owner by whom the product was shipped, where the owner is not a food business;</p> <p>e. The name and address of the food business to which the product was shipped;</p> <p>f. The name and address of the new owner to whom the product was shipped, where the owner is not a food business;</p> <p>g. A reference number to identify the lot, batch or consignment;</p> <p>h. The shipping date.</p> <p>2ter The information according to Paragraphs 2 and 2bis must be kept on file at minimum until it can be assumed that the product has been consumed.</p> <p>3 An importer who imports products from a country which does not implement a similar system of traceability shall be responsible for ensuring that the origin of the products is traceable to the extent that a food safety hazard can be precluded. The extent of responsibility shall be in line with the potential hazard posed by the product.</p> <p><b>Art. 51 Hazard Analysis and Critical Control Points (HACCP)</b></p> <p>1 Whoever manufactures, processes, treats, stores, transports or markets foodstuffs must develop and apply one or more procedures based on HACCP principles to ensure the on-going monitoring of specific biological, chemical and physical hazards. This shall be without prejudice to Article 53.</p> <p>2 Such a procedure must include the following elements:</p> <p>a. Identifying and assessing any hazards that must be prevented, eliminated or reduced to acceptable levels (Hazard Analysis, HA);</p> <p>b. Identifying the critical control points at the process levels at which control is essential to bring a hazard under control, i.e. to prevent or eliminate a hazard or to reduce it to an acceptable level (Critical Control Point(s), CCP);</p> <p>c. Establishing guide values at the aforementioned process levels which distinguish acceptable values from unacceptable values for the prevention, elimination or reduction of identified hazards;</p> <p>d. Establishing and implementing an effective system for monitoring procedures at critical control points;</p> |
|--|--|

|  |   |
|--|---|
|  | <p>e. Establishing corrective actions when monitoring indicates that a critical control point is no longer under control;</p> <p>f. Establishing a review procedure to determine compliance with the provisions according to Subparagraphs a–e; reviews are to be conducted regularly, in any event whenever a change in the production process is likely to negatively affect the safety of the foodstuffs produced;</p> <p>g. Creating documents and keeping records which show that the provisions according to Subparagraphs a–f have been satisfied; the documents and records must be commensurate with the nature and size of the food business; they must be kept up to date at all times and be archived for an appropriate period of time.</p> <p>3 The HACCP concept must be appropriately applied in a manner commensurate with the safety risk posed and the production scale.</p> <p>4 The FDHA may appropriately ease the requirements applicable to retailers.</p> <p>5 Paragraph 1 shall not apply to:</p> <p>a. Primary production;</p> <p>b. Producers who exclusively offer small quantities of primary products produced by them to consumers directly or by way of local retailers.</p> <p><b>Art. 52</b> Guides to good practice</p> <p>1 The food business sectors may establish guidelines for good practice based on HACCP principles. These must be submitted to the Federal Food Safety and Veterinary Office (FSVO) for approval by same.</p> <p>2 The following applies to these guidelines:</p> <p>a. They must be suitable for the correct implementation of the provisions of this section and other food hygiene provisions;</p> <p>b. They must take account of the relevant codes of practice of the Codex Alimentarius; and</p> <p>c. Affected groups must have been consulted.</p> <p><b>Art. 53</b> Evidence of good practice</p> <p>The responsible person must be able to prove to the competent cantonal enforcement authority that:</p> <p>a. A procedure complying with HACCP is applied; or</p> <p>b. Where guidelines for good practice are present which have been approved by the FSVO, these</p> |
|--|---|

|  |            |  |
|--|------------|--|
|  |            | <p>guidelines are applied to ensure good practice.</p> <p>See also Swiss Guide on Good Manufacturing Practice for milk processing SOP 02.01</p>  |
| Management of Records and Documents          | 15         | <p>Foodstuffs and Utility Articles Ordinance [LGV]:</p> <p><b>Art. 55</b> Documentation of self-supervision</p> <p>1 All self-supervision actions are to be documented in writing or by way of an equivalent procedure.</p> <p>2 The FDHA may regulate the nature and manner of self-supervision and the details of documentation.</p> |
| Requirements for Computer System Application | Appendix A | See Foodstuffs and Utility Articles Ordinance [LGV], Art. 49 – 55 [above]  |
|  |            |  |
|  |            |  |

## Attachment: List of regulations and standards

| SR/RS       | Name of regulation   | Documents<br>(German)   |
|-------------|--|---|
| 916.40      | Tierseuchengesetz vom 1. Juli 1966 (TSG)<br><i>Animal Health Act of 1 July 1966</i>  | <br>916.40.de.pdf        |
| 916.401     | Tierseuchenverordnung vom 27. Juni 1995 (TSV)<br><i>Animal Health Ordinance of 27 June 1995</i>  | <br>916.401.de.pdf       |
| 916.402     | Verordnung vom 16. November 2011 über die Aus-, Weiter- und Fortbildung der Personen im öffentlichen Veterinärdienst<br><i>Ordinance of 16 November 2011 on training, further education and continuing education of persons in the public veterinary service</i> | <br>916.402.de.pdf       |
| 916.404.1   | Verordnung vom 26. Oktober 2011 über die Tierverkehr-Datenbank (TVD-Verordnung)<br><i>Ordinance of 23 November 2005 on the animal movements database</i>   | <br>916.404.1.de.pdf     |
| 916.407     | Verordnung vom 10. November 2004 über die Ausrichtung von Beiträgen an die Kosten der Entsorgung von tierischen Nebenprodukten<br><i>Ordinance of 10 November 2004 on the payment of contributions to the cost of disposing of animal by-products</i>            | <br>916.407.de.pdf     |
| 916.441.22  | Verordnung vom 25. Mai 2011 über die Entsorgung von tierischen Nebenprodukten (VTNP)<br><i>Ordinance of 25 May 2011 on the disposal of animal by-products</i>  | <br>916.441.22.de.pdf  |
| 916.443.10  | Verordnung vom 18. April 2007 über die Ein-, Durch- und Ausfuhr von Tieren und Tierprodukten (EDAV)<br><i>Ordinance of 18 April 2007 on the import, transit and export of animals and animal products</i>  | <br>916.443.10.de.pdf  |
| 916.443.106 | Verordnung des EDI vom 16. Mai 2007 über die Kontrolle der Ein- und Durchfuhr von Tieren und Tierprodukten (EDAV-Kontrollverordnung)<br><i>Ordinance of the EAER dated 16 May 2007 on the control of imports and transits of animals and animal products</i>     | <br>916.443.106.de.pdf |

## Attachment: List of regulations and standards

| SR/RS      | Name of regulation   | Documents<br>(German)  |
|------------|--|--|
| 916.443.13 | Verordnung vom 27. August 2008 über die Ein- und Durchfuhr von Tierprodukten aus Drittstaaten im Luftverkehr (EDTpV)<br><br><i>Ordinance of 27 August 2008 on the import and transit of animal products from third countries by air</i>  | <br>916.443.13.de.pdf   |
| 916.307    | Verordnung vom 26. Oktober 2011 über die Produktion und das Inverkehrbringen von Futtermitteln (Futtermittel-Verordnung, FMV)<br><br><i>Ordinance of 26 October 2011 on the production and marketing of feed</i>   | <br>916.307.de.pdf      |
| 812.212.27 | Verordnung vom 18. August 2004 über die Tierarzneimittel (TAMV)<br><br><i>Ordinance of 18 August 2004 on veterinary medicines</i>  | <br>812.212.27.de.pdf   |
| 817.0      | Bundesgesetz vom 9. Oktober 1992 über Lebensmittel und Gebrauchsgegenstände (Lebensmittelgesetz, LMG)<br><br><i>Federal act of 9 October 1992 on food and utility articles</i>   | <br>817.0.pdf           |
| 817.02     | Lebensmittel- und Gebrauchsgegenständeverordnung vom 23. November 2005 (LGV)<br><br><i>Ordinance of 23 November 2005 on food and utility articles</i>  | <br>817.02.de.pdf     |
| 817.042    | Verordnung vom 9. November 2011 über die Ausbildung und die Prüfung der mit dem Vollzug der Lebensmittelgesetzgebung betrauten Personen (Verordnung über die Vollzugspersonen im Lebensmittelbereich, VVPLM)<br><br><i>Ordinance of 9 November 2011 on implementing persons in the food sector</i> | <br>817.042.de.pdf    |
| 817.022.31 | Verordnung des EDI vom 22. Juni 2007 über die in Lebensmitteln zulässigen Zusatzstoffe (Zusatzstoffverordnung, ZuV)<br><br><i>Ordinance of the FDHA of 22 June 2007 on the additives permitted in foods</i>  | <br>817.022.31.de.pdf |
| 817.021.23 | Verordnung des EDI vom 26. Juni 1995 über Fremd- und Inhaltsstoffe in Lebensmitteln (Fremd- und Inhaltsstoffverordnung, FIV)<br><br><i>Ordinance of the FDHA of 26 June 1995 on residues and ingredients in foods</i>  | <br>817.021.23.de.pdf |

## Attachment: List of regulations and standards

| SR/RS         | Name of regulation  | Documents<br>(German)   |
|---------------|---|---|
| 817.022.108   | Verordnung des EDI vom 23. November 2005 über Lebensmittel tierischer Herkunft<br><br><i>Ordinance of the FDHA of 23 November 2005 on food of animal origin</i>   | <br>817.022.108.de.pdf     |
| 817.022.21    | Verordnung des EDI vom 23. November 2005 über die Kennzeichnung und Anpreisung von Lebensmitteln (LKV)<br><br><i>Ordinance of the FDHA of 23 November 2005 on the labelling and advertising of foods</i>  | <br>817.022.21.de.pdf      |
| 817.024.1     | Hygieneverordnung des EDI vom 23. November 2005 (HyV)<br><br><i>Hygiene ordinance of the FDHA of 23 November 2005</i>   | <br>817.024.1.de.pdf       |
| 817.025.21    | Verordnung des EDI vom 23. November 2005 über den Vollzug der Lebensmittel-gesetzgebung<br><br><i>Ordinance of the FDHA dated 23 November 2005 on the implementation of food legislation</i>  | <br>817.025.21.de.pdf      |
| 916.020       | Verordnung vom 23. November 2005 über die Primärproduktion (VPrP)<br><br><i>Ordinance of 23 November 2005 on primary production</i>   | <br>916.020.de.pdf       |
| 916.020.1     | Verordnung des WBF vom 23. November 2005 über die Hygiene bei der Primär-produktion (VHyPrP)<br><br><i>Ordinance of 23 November 2005 on hygiene in primary production</i>   | <br>916.020.1.de.pdf     |
| 910.15        | Verordnung vom 26. Oktober 2011 über die Koordination der Kontrollen auf Landwirtschaftsbetrieben (Kontrollkoordinationsverordnung, VKKL)<br><br><i>Ordinance of 26 October 2011 on the coordination of controls at agricultural establishments</i> | <br>910.15.de.pdf        |
| 916.351.0     | Milchprüfungsverordnung (MiPV)<br><br><i>Milk testing ordinance of 20 October 2010</i>  | <br>916.351.0.de.pdf     |
| 916.351.021.1 | Verordnung des EDI vom 23. November 2005 über die Hygiene bei der Milchproduktion (VHyMP)<br><br><i>Ordinance of the EAER dated 23 November 2005 on hygiene in milk production</i>  | <br>916.351.021.1.de.pdf |

## Attachment: List of regulations and standards

| SR/RS       | Name of regulation  | Documents (German)   |
|-------------|---|--|
| 916.161     | Verordnung vom 12. Mai 2010 über das Inverkehrbringen von Pflanzenschutzmitteln (Pflanzenschutzmittelverordnung, PSMV)<br><br><i>Ordinance of 18 May 2005 on the commercialisation of crop protection agents</i>                    | <br>916.161.de.pdf                          |
| 817.024.2   | Verordnung vom 11. Mai 2009 über die hygienische Milchverarbeitung in Sömmerungsbetrieben<br><br><i>Ordinance of the FDHA of 11 May 2009 on hygienic milk processing on Alpine pasturing farms</i>                                  | <br>817.024.2.pdf                           |
| 817.022.102 | Verordnung des EDI vom 23. November 2005 über Trink-, Quell- und Mineralwasser<br><br><i>Ordinance of the FDHA of 23 November 2005 on potable, spring and mineral water</i>   | <br>817.022.102.de.pdf                      |
| 817.022.104 | Verordnung des EDI über Speziallebensmittel vom 23. November 2005<br><br><i>Ordinance of the FDHA of 23 November 2005 on special food</i>   | <br>817.022.104.de.pdf                     |
|             | Technische Weisung über die amtlichen Kontrollen in der Primärproduktion in Tierhaltungen (Hygiene in der tierischen Primärproduktion, Milchhygiene, Tierarzneimittel, Tiergesundheit und Tierverkehr sowie Tierschutz bei Fischen) | <br>2013_01_10_TW_Kontrollen+inkl+allen+K |
|             | Kontrollhandbuch für die amtstierärztlichen Kontrollen in Betrieben mit Nutztierhaltung   | <br>Kontrollhandbuch+2010.pdf             |
|             | Technische Weisung für die Durchführung der Milchprüfung  | <br>Technische+Weisung+für+die+Durchführ  |
|             | Technische Weisung für die Verfügung und die Aufhebung der Milchliefer Sperre bei der Qualitätskontrolle der Milch  | <br>Technische+Weisung+Verfügung+und+At   |
|             | Technische Weisung Kontrollen der hygienischen Milchproduktion  | <br>techn_weisung_vhymp_v1_vis_hwy[1].p   |
|             | Kontrollhandbuch für die Kontrollen der hygienischen Milchproduktion  | <br>Kontrollhandbuch_vhymp_v1[1].pdf      |

## Attachment: List of regulations and standards

| SR/RS | Name of regulation   | Documents (German)   |
|-------|--|--|
|       | Vorlage zu Kontrollbericht Hygiene bei der Milchproduktion   | <br>VHyMP_Kontrollberic<br>ht_v1(1).xlsx          |
|       | Bestimmung der Kontrollfrequenz von Lebensmittelbetrieben  | <br>Risiko+Konzept+VKC<br>S-D_V130517.pdf         |
|       | Weisung Nr. 7: Zur Umsetzung der Artikel 12 und 13 der Lebensmittel- und Gebrauchsgegenständeverordnung (Melde- und Bewilligungspflicht)   | <br>Weisung nr. 7 zur<br>Umsetzung der Artike     |
|       | Leitfaden Inspektion von bewilligungspflichtigen Betrieben, nach Artikel 13 der Lebensmittel- und Gebrauchsgegenständeverordnung   | <br>Leitfaden+Anhang+<br>DE.pdf                   |
|       | Leitfaden Pflicht zur Rücknahme / zum Rückruf und zur Information der Behörden bei der Feststellung oder dem Grund zur Annahme der erfolgten Abgabe gesundheitsgefährdender Lebensmittel oder Gebrauchsgegenstände nach Artikel 54 LGV | <br>Art_54_D+Leitfaden<br>[1].pdf                 |
|       | Leitfaden Raster zur Erstellung von Leitlinien für eine gute Verfahrenspraxis nach Artikel 52 der Lebensmittel- und Gebrauchsgegenständeverordnung   | <br>Leitfaden+Umsetzun<br>g+Art.+52+LGV[1].p    |
|       | MANCP 2013: Multi-annual national control plan 2010-2014   | <br>NKP+2013+English<br>(1).pdf                 |
|       | Information für die Lebensmittelvollzugsbehörden zur Umsetzung von Bestimmungen im Bereich tierischer Lebensmittel   | <br>Information_Lebens<br>mittelvollzugsbehoerd |
|       | Information über den Umgang mit positiven Befunden in der amtlichen Milchprüfung beim Einsatz von Antibiotika, insbesondere Mastiplan  | <br>2012_10_01_Mastipl<br>an+Infoschreiben[1].  |
|       | Leitlinie Milchverarbeitung<br><i>Swiss Guide on Good Manufacturing Practice for milk processing</i>   | Only available<br>on-site  |