15 January 2016

FAQ on Cassis de Dijon

Since 2010, products that are lawfully marketed in the EU and the EEA can in principle also be marketed in Switzerland.

Being particularly sensitive products, however, foods are subject to special regulations: foods that are produced according to the technical regulations of the EU or an EU/EEA Member State, are lawfully marketed there and do not conform to the Swiss Foods Act are subject to approval. If the food concerned does not pose a risk to the health and safety of consumers, and the product information requirements are met, the approval (general ruling) is granted. This then applies also to homogeneous foodstuffs.

1. Do all European foodstuffs now have uncontrolled access to the Swiss market since 1 July 2010?
No. In line with the Cassis de Dijon principle, approved and imported foodstuffs must comply with the safety standards of the EU or the EU/EEA Member State concerned. The FSVO requires evidence of this compliance. If there are any safety concerns, the application is rejected. A negative decision is taken in an individual ruling and communicated to the applicant.

2. What foodstuffs fall under the Cassis de Dijon principle?
Foodstuffs from the EU/EEA that do not meet Swiss regulations basically fall under the Cassis de Dijon principle. For these products, approval must be obtained from the Federal Food Safety and Veterinary Office (FSVO). This is granted in the form of a general ruling and then applies to homogeneous foodstuffs. If an imported food meets Swiss regulations, it can be imported as before without the Cassis de Dijon approval (e.g. pasta from Italy).

3. When does the FSVO grant approval for foodstuffs that do not conform to the technical requirements of Switzerland?
The approval is granted in the form of a general ruling when there is an assurance that the food concerned does not pose any kind of risk to health and the contents are consistent with the details given in the product information.

4. Are Swiss safety and quality levels jeopardized by EU imports?
The safety level for foods is as high in the EU as it is in Switzerland; in certain areas, EU requirements are even higher. Switzerland’s food law has been harmonized with European law for some time in order to remove trade barriers and establish the same standards. But some typical Swiss quality requirements with regard to the composition of foods will certainly have less importance in future as a result of the new regulations.
5. Which Swiss regulations will be retained?
The Federal Council and Parliament have defined a number of requirements which Switzerland plans to retain. These include, for example, the declaration of alcohol content in alcopops, declaration of the country of production, labelling requirements for GMO products and the declaration of unauthorized cage housing for hens.
In all these cases, Swiss regulations must be observed as before and therefore do not fall under the Cassis de Dijon principle.

6. Switzerland has some quality regulations of its own. Will they remain in place?
There are 20 ordinances in Switzerland on the composition of foods, e.g. on the fat content required in cream or ice cream in order for the products to be described as cream or ice cream. While a specified fat content of 8% applies to ice cream in Switzerland, an importer can now apply for approval to sell ice cream according to the Greek standard with a fat content of only 3%.
In the approval process, the FSVO primarily reviews the safety of a product. Restrictions are only foreseen in cases of essential public interest where health, environment or consumer protection might be at risk.

7. What will become of Switzerland’s environmental and animal welfare standards?
The possibility for Swiss manufacturers to produce according to the requirements of an EU/EEA Member State is limited to product requirements (requirements that must be met by an end product when it is placed on the market). By contrast, so-called process standards, which relate to the manufacture of a product (e.g. regulations on water protection, air pollution control or animal welfare), continue to apply for Swiss producers.

8. How do products have to be labelled in future?
As a rule, products must be labelled in at least one official language. This means that, for imports from Austria, France, Germany and Italy (apart from some exceptions), no language adjustments should be necessary. The country of production must be indicated on prepacked food. This requirement, which is stricter than that of the EU, remains in place.

9. Who checks whether unlawful products enter the Swiss market?
The organization for food controls in Switzerland remains unchanged. Together with the customs authority, the FSVO is responsible for food checks at the border. The cantons (cantonal chemists) continue to be responsible for within Switzerland.

10. What has to be submitted for approval under Article 16c Technical Barriers to Trade Act (TBA)?
The application form, which is available for download at www.cassis.admin.ch, has to be completely carefully in an official Swiss language or in English. All additional documents required can be submitted in an official language or in English as enclosures together with the application form. The applicant must furnish proof that the product meets the technical requirements of the European Union (EU) or a Member State of the EU or of the European Economic Area (EEA). In addition, the applicant must furnish evidence that the product is lawfully marketed in the EU Member State concerned. The packaging sample with label must be submitted in its original form or in colour printed or electronic form.

11. How long does an approval procedure last according to Article 16c Technical Barriers to Trade Act (TBA)?
The FSVO decides on approval within two months of receiving the application. If an application is incomplete, the two-month period for reviewing the application is suspended until the additional documents required have been submitted. If the missing documents are not submitted on time, the FSVO will not assess the application.
12. For how long is a general ruling valid?
General rulings are issued for an unlimited period. But it must be borne in mind that, if the technical regulations are changed, the food must always conform to the new technical regulations (Art. 10 Para. 1 of the Cassis de Dijon Ordinance (CdDO)). If there is a change in the technical regulations that is relevant to the manufacture of the foods, then the food has to conform to the new technical regulations at the latest when the period of transition provided for in the foreign legislation expires. An adjustment of the food to the changed technical regulations does not require a new approval. However, if the technical regulations on which the general ruling is based are changed in such a way that public interest as set forth in Article 4 Paragraph 4a-e TBA is jeopardized, then the FSVO revokes the general ruling (Art. 10 Para. 2 CdDO).

13. Can all Swiss producers manufacturer According to European requirements?
To prevent discrimination against companies in Switzerland, Swiss producers may manufacture their domestic products according to the regulations of the EU or an EU/EEA Member State provided that

- the food conforms to the description in the general ruling and
- to the technical regulations on which the general ruling is based; and
- the Swiss regulations on worker protection and animal welfare are observed during manufacture (Art. 9 b Para. 1 to 3 CdDO).

14. How is the “confidentiality” of the submitted data, e.g. of the formulation, guaranteed?
While the application must contain details on the composition and the essential specifications of the food, this is understood to involve the list of ingredients, not the formulation. If data are submitted with the application for approval that constitute business or manufacturing secrets, these are protected by official secrecy in accordance with Article 22 of the Federal Personnel Act and Article 320 of the criminal code.

15. According to Article 16d Paragraph 2 TBA, the general ruling automatically applies to homogeneous foodstuffs. What is understood by the term “homogeneous”?
“Homogeneity” is described in Article 9 of the ordinance (CdDO), where a distinction is drawn between homogeneous foods from the EU/EEA on the one hand (Art. 9a) and homogeneous foods from Switzerland on the other (Art. 9b).

The general ruling will refer in each case to a generic description of a product. It is basically irrelevant by whom the product in question is manufactured or under what trade name it is marketed.

For foods from the EU/EEA to be homogeneous, three criteria must be met (Art. 9a):

- Firstly, a food to be declared homogeneous must conform to the description used in the general ruling to identify the food (Paragraph 1), regardless of the designation on the food in question. As long as a food conforms to this description, the requirement of homogeneity is met, even if the food shows a designation that does not conform to the Swiss designation applicable to the food in question, or if the food does not show the composition specified in Swiss legislation.
- Secondly, homogeneity refers to the technical regulations on which the general ruling is based (Paragraph 2), i.e. the technical regulations according to which the product has been manufactured (e.g. the technical regulations of the EU or a certain EU/EEA Member State).
- Thirdly, the same food in this EU or EU/EEA Member State must be lawfully on the market.

If a general ruling has been granted for a certain food that has been manufactured according to the technical regulations of EU Member State A, then this general ruling is valid for all foods to which this description applies and which have been manufactured according to the regulations of Member State A and are lawfully on the market there. The general ruling cannot be referred to, however, by manufacturers or importers of foods that have been manufactured according to the technical regulations of a different EU Member State.
Producers in Switzerland may also invoke a general ruling (Art. 9b). If a general ruling exists for a food manufactured according to the requirements of the EU or an EU/EEA Member State, the domestic Swiss producer is also permitted to produce corresponding foods according to these regulations and market them in Switzerland. See question 6.

16. Will the standard duty of disclosure for special foodstuffs be relaxed with the introduction of the Cassis de Dijon principle?

No. According to Article 2 b Paragraph 10 CdDO, food supplements and supplementary nutrition do not fall under the Cassis de Dijon principle. Infant formula and FSMPs (foods for special medical purposes; described by the EU as foods for specific nutritional purposes) will remain subject to a duty of notification and disclosure to the FSVO in accordance with Articles 17b and 20a of the ordinance on special foods.

17. Is the Cassis de Dijon principle applicable to cosmetic products?

The Cassis de Dijon principle is applicable to cosmetic products. If the imported cosmetic products do not conform to Swiss food law, the distributor may still market the products on the Swiss market - on condition that they comply with the provisions of the Technical Barriers with Trade Act (TBA). According to Article 16e Paragraph 2 TBA, it is permissible (by derogation from Swiss regulations) for the warning and safety notices, including the instructions on cosmetic products relevant to personal safety, to be compiled only in the official language or languages of the place where the products are placed on the market.

18. How can information be obtained on the foods approved by the FSVO according to Article 16c TBA? Is there a list of all general rulings and, if so, where can it be found? Are the rejections (decrees) also published?

All the general rulings issued are published in the federal gazette. General rulings that have been legally finalized are announced in the federal gazette and included in the lists as set forth in Article 31 Paragraph 2 b TBA. The FSVO informs the cantonal enforcement body responsible and the SECO about the approval and its legal force. A list of all general rulings issued can be found at www.cassis.admin.ch under “General rulings issued”.

If an application is refused for any reason in an individual ruling, the applicant and the SECO are informed of the decision, which can be found on www.cassis.admin.ch under “Rejected applications”.
19. Which Swiss regulations does Switzerland plan to remain despite the application of the Cassis de Dijon principle?

In principle, protection of health, protection against fraud and legal certainty must be guaranteed with all products. Products exempted from the Cassis de Dijon principle are those that are subject to regulatory approval or an import ban (Art. 16a Para. 2 TBA). There are also exceptions for various product groups to which the Cassis de Dijon principle would be applicable. In the case of foods, for example, there is an obligation to declare the origin of foodstuffs and raw materials, to declare allergens and to declare cage eggs. The requirements are set forth in the regulations (Art. 16a Para. 2 TBA and Art. 2 and 19 CdDO).

20. What safety risks could there be in the case of foods?

Food risks include not only microbiological, but also chemical risks, i.e. nutritional and toxicological risks. Chemical risks involve contamination with heavy metals, radioactive elements or other organic forms of contamination, e.g. with dioxins. In particular they involve contaminants that enter the food during the production process.