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Fact sheet on the termination of negotiations over an institutional Framework Agreement between Switzerland and the EU

What this means for placing products on the EU single market

Situation today:

The Federal Law on Technical Barriers to Trade (LTBT) aims to avoid and eliminate technical trade barriers to trade. This objective is pursued using three instruments which are all anchored in the LTBT:

- The autonomous harmonisation of Swiss technical regulations with those of the EU.
- The conclusion of international agreements including a legal basis for standardisation and accreditation.
- The autonomous application of the “Cassis-de-Dijon Principle”.

It was on this basis that the Agreement on Mutual Recognition in Relation to Conformity Assessment (MRA) was concluded as one of the Bilateral Agreements with the EU in 1999.

This agreement governs the import country's recognition of the conformity assessment conducted in the exporting country. A conformity assessment examines whether a product meets the applicable regulations and may be introduced to the market. The MRA ensures that the necessary certification processes need only be performed once and that based on this certification the product can be placed on both markets. In addition, thanks to facilitations, it grants Switzerland’s economic operators analogous market access to the EU’s internal market as its competitors from the EU or the EEA in 20 product aereas. Swiss companies benefit from lower costs and reduced workloads as a result.

In future:

Some time ago the European Commission announced that, along with other measures, it would no longer update the MRA as long as no progress is being made on the Institutional Framework Agreement. However, the Federal Council is still aiming to completely update and continue the MRA. Even after its decision to terminate negotiations over the Institutional Agreement the Federal Council emphasised that Switzerland will remain a reliable partner to the EU in future. The Federal Council remains committed to ensure that Switzerland is not discriminated against and, among other things, is not treated differently from other third countries in EU equivalence processes.

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Short term

The **medical devices** sector is affected. In April 2017 the EU adopted a new regulation on medical devices (Medical Devices Regulation 2017/745, MDR) and a regulation on in vitro diagnostic devices (In Vitro Medical Devices Regulation 2017/746, IVDR). The situation in regard to in vitro diagnostic products is currently unchanged as the IVDR is scheduled to be applicable in May 2022 at the earliest. However, the MDR has been applied in its entirety since 26 May 2021. A corresponding update of the MRA section on medical devices is needed in order to maintain the continued equivalence of both legal systems and, in turn, to continue to secure Switzerland's participation in the EU single market in this sector.

As the MRA section on medical devices could not be updated in May 2021 due to the EU's decision, since 26 May 2021 Swiss products which are exported to the EU must fully meet the requirements of the MDR for products from third countries. The facilitations on the MRA do not apply anymore. Among other requirements, these products now need an authorised representative in the EU and product labelling also needs to be adjusted accordingly. For the opposite direction, EU products that are exported to Switzerland must fully meet the requirements of Swiss law for products from third countries. On 19 May 2021 the Federal Council adopted measures to amend the Swiss Medical Devices Ordinance (MedDO) in order to guarantee provision of safe medical products in Switzerland even under these more difficult circumstances.

In addition, the European Commission announced in its communication of 26 May 2021 that, in its view, also products which were certified and introduced to the market in accordance with the old legislation (Medical Devices Directive, MDD), should no longer benefit from the MRA. As such, the European Commission is challenging the validity of the existing MRA. Switzerland, however, puts forth the position that MDD products continue to be covered by the existing MRA. As a result, these products should continue to benefit from the facilitations set forth by the MRA in trade between Switzerland and the EU. As is also mentioned in the European Commission's communication, Switzerland and the EU are currently holding talks to clarify these issues. It will also depend on the European Commission whether and when Switzerland and the EU reach an understanding in this regard.

Medium term

The technical laws of the EU and Switzerland are continually developing. In line with this, the European Commission recently launched a project to revise the Machinery Directive 2006/42/EC. The Swiss authorities will closely monitor this legislation process. They will check in due course whether a corresponding update of the MRA section on machines will be required.

Long term

The Federal Council considers it to be in the shared interest of Switzerland and the EU to safeguard their well-established bilateral cooperation and to systematically maintain the agreements already in force. It therefore wishes to initiate a political dialogue with the EU on continued cooperation.

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What this means for standardisation

For the standards organisation

Nothing is changing for the Swiss Association for Standardization (SNV) as the umbrella organisation and a member of CEN, as well as for Electrosuisse as a member of CENELEC. As a member of CEN and CENELEC from an EFTA member state we have defined rights and duties in the statutes. Significant obligations include the adoption and withdrawal obligation.

For standardisation work

Nothing is changing. As has always been the case, it remains important for Swiss experts engage on the development of European standards. In future, standards will remain an important basis for conformity assessments and interoperability, independent of what contractual relationships may look like.

Swiss companies cannot have a direct influence on European legislation, but they can however influence their concretisation by taking part in the development of harmonised European standards. In future, these standards will also receive the status of a Swiss standard.

For additional information please e-mail info@switec.info