



Federal Council revises two ordinances relating to the electrical sector

Changes to legal basis for low voltage products and Ex-products

On 25 November 2015, the Federal Council agreed to amendments to the Ordinance on Electrical Low Voltage Equipment (NEV) and the Ordinance on Equipment and Protective Systems for Use in Potentially Explosive Atmospheres (VGSEB). The revised versions of the NEV and the VGSEB are to enter into effect on 20 April 2016.

The EU has amended directives falling within the scope application of the Mutual Recognition Agreement (MRA)¹ with Switzerland. The NEV and the VGSEB are affected by these changes. The two revised ordinances now bring the technical regulations into line with the statutory basis of the EU regulations, thus ensuring the continued free exchange of goods with the European Economic Area.

The changes to the NEV and the VGSEB are largely formal in nature. Terms that have been recently adopted by the EU are now also to be applied in Swiss law. The few substantive changes, which are also to be applied in Swiss law from the corresponding EU directives, largely relate to the obligations of economic operators (manufacturer, authorised representative, importer and distributor) as well as certain market surveillance activities.

These changes will also see a tightening of mechanisms for market surveillance, in particular an enhancement of the traceability of products made available on the market. In addition, a distinction is now made between 'placing on the market' and 'making available on the market'.

The essential health and safety requirements of the NEV (and of the EU Low Voltage Directive 2014/35/EU²) and the VGSEB (and of the EU 'ATEX' Directive 2014/34/EU³) remain unchanged. Likewise, the changes to scope of application of the two ordinances are only minor and there will be no substantive change to the existing conformity assessment procedures.

Obligations of economic operators

ESTI (the Swiss Federal Inspectorate for Heavy Current Installations) as the public authority responsible for market surveillance is authorised as previously to demand from each economic operator the declaration of conformity, the technical documentation and in particular all other documents and specifications required in connection with its activities as the supervisory authority (see Art. 23 para. 4 NEV and Art. 17 para. 4 VGSEB)⁴.

For their part, the economic operators should note the following (see Art. 4 para. 1 NEV and Art. 4 para. 1 VGSEB):

Manufacturers shall

- ensure conformity of the product and create the associated declaration of conformity and the technical documentation
- enclose the instructions and safety information with the product
- affix the identification label to the product
- affix the name and postal address of the manufacturer to the product
- take the necessary measures if the product is not compliant
- if appropriate, designate an authorised representative (agent)
- support market surveillance

Authorised representatives (agents) shall

- hold the declaration of conformity and the technical documentation ready
- support market surveillance

Importers shall

- ensure conformity of the product as well as the availability of the associated declaration of conformity and the technical documentation
- ensure that the instructions and safety information are enclosed with the product
- ensure that the name and postal address of the manufacturer is affixed to the product
- if necessary, affix the name and postal address of the importer to the product
- support market surveillance

Distributors shall

- verify the conformity of the product
- verify before making available on the market that the required documents, in particular the instructions and safety information are enclosed with the product
- verify that the identification label is affixed to the product
- verify that the name and postal address of the manufacturer and if applicable also the importer is affixed to the product
- support market surveillance

An importer or a distributor is considered to be the manufacturer if it places on the market a low voltage equipment or Ex-product under its own name or under its own trademark or modifies the said product (see Art. 4 para. 3 NEV and Art. 4 para. 3 VGSEB).

This is no obligation to affix a CE mark. If such a mark has been previously affixed to the product in accordance with the EU Low Voltage Directive or the EU 'ATEX' Directive (see Art. 4 para. 2 NEV or Art. 4 para. 2 VGSEB), it may be left in place.

Placing on the market and making available on the market

A distinction is now made between placing on the market and making available on the market. Henceforth, placing on the market is understood as initial placement on the Swiss market. Making



available on the market includes any issue of a low voltage equipment or Ex-product, whether or not against payment for sale or use on the Swiss market. Only a manufacturer or importer can act as the entity who places on the market a product (see Art. 2 para. 1 NEV or Art. 2 para. 1 VGSEB).

Identification

In order to ensure the traceability of products made available on the market, the contact address of the manufacturer and, if applicable, of the importer, must be affixed directly to the low voltage equipment (on the type plate) in addition to the type, batch or serial number, or if it is not feasible to provide these details on the product, they must be provided on its packaging or in the enclosed documents (see Art. 6 NEV).

In the case of Ex-products, the year of construction and, if applicable, the identification number of the notified body, the specific marking of explosion protection and the symbols of the equipment group/category must also be displayed on the product (see Art. 5 VGSEB).

Information to be enclosed

The operating instructions and the required safety information, which as a minimum must be in the official language(s) of the locality in which the product is made available on the market, must be enclosed with the product (see Art. 11 NEV).

In the case of Ex-products, a copy of the (EU) declaration of conformity and in the case of Ex-components a written attestation of conformity must be enclosed with the product (see Art. 10 VGSEB).

Declaration of conformity

The declaration of conformity for low voltage equipment must as a minimum contain the details as specified in Art. 8 para. 4 c NEV, or conformity with EU law is declared according to Annex IV of the EU Low Voltage Directive. In addition, the product model must now be listed with type, batch or serial number. Likewise, the version (EN) or the edition (IEC) must now be stated when specifying the applicable standards.

The declaration of conformity for Ex-products must contain the specifications as per Art. 7 para. 3 VGSEB. If applicable, the name and address of the testing and conformity assessment body, also detailing the assessment performed

and the certificate issued, must be included in the declaration of conformity. In the case of Ex-components, according to Art. 7 para. 4 VGSEB a written attestation of conformity by the manufacturer is sufficient. It must state that the components comply with the specifications of this ordinance and state the characteristics and conditions for their incorporation in equipment or protective systems which fulfil the essential requirements.

Technical documentation

With one notable exception, there is no substantive change to the requirements on the technical documentation. An adequate risk assessment as part of the technical documentation must now be provided by the manufacturer. As hitherto, that technical documentation must be held by each economic operator for presentation to the ESTI on request from the latter (see Art. 12 NEV and Art. 11 VGSEB).

The content and nature of the risk assessment performed is a matter for the manufacturer, subject to the condition that in addition to the application of harmonised standards, it covers risks and all possible hazards resulting from the product. In order to comply with this comprehensive approach, the CENELEC Guide 32⁵ may be applied correspondingly.

Retention periods

The declaration of conformity and the technical documentation must be held for presentation to ESTI at least 10 years after the last placing on the market (i.e. by import or by manufacture of the last production batch). See Art. 9 and Art. 12 para. 4 NEV and Art. 8 and Art. 11 para. 3 VGSEB.

Requirements on the conformity assessment bodies

The new legal framework created by the EU for the marketing of products⁶ define additional requirements on the conformity assessment bodies. These are designed to create a standardised quality level for the performance of conformity assessments. By 20 April 2016, all conformity assessment bodies accredited in the context of the MRA under the EU 'ATEX' Directive must be re-notified to the EU Commission. This re-notification requirement does not apply for conformity assessment bodies under the EU Low Voltage Directive.

Market observation by economic operators

The principle on which ESTI bases its surveillance of whether the products made available on the market comply with the requirements of the ordinance are supplemented by a provision which expressly states the previously implicit obligation of economic operators to comprehensively support the public authority in the implementation of the ordinance. A new aspect is that it is also required that economic operators must provide information about their suppliers and the purchasers of the products (see Art. 23 NEV and Art. 17 VGSEB).

Market surveillance by ESTI is now supplemented by an obligation on economic operators to observe the market (see Art. 24 NEV and Art. 18 VGSEB). The latter must take measures and organise themselves so that they are in a position to react appropriately, if a hazard results from products that they manufacture, place on the market or make available on the market. In the process, they are to work closely with public authorities.

Safety mark

The requirements for the certification of electrical equipment with the voluntary Swiss safety mark  by ESTI have been adopted unchanged in the revised NEV (http://www.esti.admin.ch/en/dienstleistungen_sicherheitszeichen.htm).

Transitional provision

Low voltage equipment and Ex-products that are made available on the market according to the previous ordinance, may from 20 April 2016 continue to be made available on the market if they meet the essential requirements of the existing ordinance and were placed on the market before the entry into effect of the present ordinance (see Art. 30 NEV and Art. 24 VGSEB).

Daniel Otti, Director

¹ Agreement between the Swiss Confederation and the European Community on mutual recognition of conformity assessments (MRA)

² Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast)

³ Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)

⁴ NEV and VGSEB respectively, in the version dated 25.11.2015

⁵ CENELEC GUIDE 32 «Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment», Edition 1, 2014-07

⁶ The so-called «New Legislative Framework» [NLF] Regulation (EC) No. 765/2008