EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Industrial Transformation and Advanced Value Chains
Advanced Engineering and Manufacturing Systems

GUIDANCE DOCUMENT ON THE ATEX DIRECTIVE TRANSITION FROM 94/9/EC TO 2014/34/EU

The new **ATEX Directive 2014/34/EU**[1] is the result of the alignment of the previous ATEX Directive 94/9/EC to the "New Legislative Framework" (NLF)[2], in particular to Decision No 768/2008/EC[3], as well as to the provisions of the Treaty on the Functioning of the European Union (TFEU) after the Treaty of Lisbon.

Being the result of an alignment and a recast, the main changes in the new Directive 2014/34/EU with respect to the previous Directive 94/9/EC are quite limited, and do not concern the most substantial characteristics of the act that remain the same: scope, essential health and safety requirements, categorization and conformity assessment procedures. The main changes are the following:

- *Reference number*: according to the model YYYY / No / UE
- *Definitions*: horizontal additions from the NLF
- *Economic operators* (manufacturers, authorised representatives, importers, distributors) *and their obligations*: more detailed descriptions from the NLF
- *Harmonised standards and presumption of conformity*: reference to Regulation (EU) No 1025/2012 on European Standardisation[4]
- *CE marking*: reference to Regulation (EC) No 765/2008[5]
- *Notified bodies*: more detailed requirements and procedures from the NLF

[1] 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) (OJ L 96, 29.3.2014, p. 309)

[2] See http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

[3] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82)

[4] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12)

[5] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30)

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: BREY 10/160 - Tel. direct line +32 229-95941 - Fax +32 229-66273

Mario.GABRIELLI-COSSELLU@ec.europa.eu – GROW-DIR-ATEX@ec.europa.eu

- *Market surveillance and safeguard procedure*: reinforced activities and new simplified procedures (also related to the "Product safety and market surveillance package"[6])
- *ATEX committee and implementing acts*: reference to Regulation (EU) No 182/2011[7] ("Comitology") concerning Commission Implementing Decisions on formal objections against harmonised standards, safeguard clauses against products and challenges on the competence of notified bodies
- *EU declaration of conformity*: more detailed contents, and a model, from the NLF
- *EU-type examination certificate*: conditions for validity and date of expiry from the NLF

The new ATEX Directive 2014/34/EU is applicable from **20 April 2016**.

This document includes a list of "Frequently Asked Questions and Answers" on the transition to the ATEX Directive 2014/34/EU, which covers both "horizontal" and "sectorial" questions, this is to say, those common to all the EU legislation aligned to the "New Legislative Framework"[8] and those specifically related to Directive 2014/34/EU. It reflects the result of ongoing discussions, notably at the workshop on the transition to the new ATEX Directive 2014/34/EU held on 30th September 2015. It should be noted that this document is preliminary, pending the revision of the Blue Guide and the new ATEX Guidelines. Upon finalisation of the revised Blue Guide (planned for end of 2015) and the ATEX Guidelines (planned for the first quarter of 2016) the latter documents have to be considered as the main references for the interpretation of horizontal issues related to the New Legislative Framework and the ATEX Directive respectively.

A list of reference documents for guidance is provided at the end of the document.

[6] See http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm

[7] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13)

[8] *Pyrotechnic Articles* Directive 2013/29/EU (applicable 1 July 2015); *Civil Explosives* Directive 2014/28/EU, *Simple Pressure Vessels* Directive 2014/29/EU, *Electromagnetic Compatibility* Directive 2014/30/EU, *Non-automatic Weighing Instruments* Directive 2014/31/EU, *Measuring Instruments* Directive 2014/32/EU, *Lifts* Directive 2014/33/EU, *ATEX* Directive 2014/34/EU, *Low Voltage* Directive 2014/35/EU (applicable 20 April 2016); *Radio Equipment* Directive 2014/53/EU (applicable 13 June 2016); *Pressure Equipment* Directive 2014/68/EU (applicable 19 July 2016) and *Marine Equipment* Directive 2014/90/EU (applicable 18 September 2016). See http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

FREQUENTLY ASKED QUESTIONS AND ANSWERS ON THE TRANSITION TO THE ATEX DIRECTIVE 2014/34/EU

TOPIC	QUESTION	ANSWER
Scope ***Article 1(1) and (2)***	Is there any change in the scope from Directive 94/9/EC to Directive 2014/34/EU?	No. When compared with the previous Directive 94/9/EC, in the new Directive 2014/34/EU the scope has not changed. The new Directive is the result of the alignment to the reference provisions of the New Legislative Framework, in particular Decision No 768/2008/EC and Regulation (EC) No 765/2008. The term "product" is introduced in Article 1(1) including (a) equipment and protective systems, (b) safety-, controlling- and regulating devices, and (c) components, now explicitly listed in the scope. The list of exclusions from the scope in Article 1(2) remains the same.
Manufacturer ***Article 2(12)***	Who is a manufacturer – can an operator/user also be a manufacturer?	The definition of manufacturer requires the act of making a product available on the market. Users and operators do not make products available on the market, so they are usually not considered to be manufacturers. However, according to Article 2(12) of the ATEX Directive 2014/34/EU, any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its own name or trademark or uses it for its own purposes, is a manufacturer. This means that an operator/user who produces a product for his own use becomes a manufacturer. In this case he has to meet all the related obligations and requirements of the Directive, including the necessary conformity assessment procedures. This also applies to products that were originally not put on the market for the use in potentially explosive atmospheres and which have been modified by an operator/user in a way that they can now be used in hazardous areas. This represents a substantial modification of the products and the resulting "new" products fall under the scope of Directive 2014/34/EU. The same applies to products where due to modifications, the integrity of type of protection is concerned, and thus a re-evaluation is necessary. As in these cases a product will not be put on the market, the criterion of initial putting into service of the product applies here.

TOPIC	QUESTION	ANSWER
		See also § 3.1. "Manufacturer" in the "Blue Guide"
Other economic operators	Can following operators be considered as "economic operators" similar to importers or distributors? - "Agent" which is a person inside the EU that promotes goods via a homepage or somewhere else and is paid when people order the goods and after requests the manufacturer outside the EU to send directly the batch of products or one single product to the customer - "Fulfilment houses" which put just the EU citizen address label and send the goods	"Economic operators" are defined in Article 2(16) of the ATEX Directive 2014/34/EU as "the manufacturer, the authorised representative, the importer and the distributor". The common element to all these actors is that they make products available on the market. New distribution modes (in particular in electronic commerce) have developed and there are new types of actors, like agents or fulfilment houses. It is often not entirely clear whether they can be considered to be importers or distributors according to the relevant definitions. The particular role as economic operators that certain actors will play will have to be decided according to their specific activities. For example, a "fulfilment house" generally goes beyond a purely logistic role and plays an essential role in the distribution chain, and it should be considered as a distributor. The subject is still under consideration in the Commission and further guidance might be provided on that issue. *See also § 3. "The actors in the product supply chain and their obligations" in the "Blue Guide"*
Making available on the market / Placing on the market ***Article 2(10) and (11)*** ***Articles 5, 6, 7, 8***	Which is the difference between "making available on the market" and "placing on the market" in the framework of Directive 2014/34/EU (e.g. in Article 5 "making available on the market" is mentioned, but for the same activity when the responsibilities of economic operators are covered – e.g. Articles 6, 7 and 8 – "placing on the market" is mentioned)?	"Making available on the market" is the overall concept. Any transfer between economic operators of a product is considered as making available. "Placing on the market" is a specific case of making available, namely it is the first time that the product is introduced on the market. It is important because at that moment the EU legislation applies. Any subsequent transfer is a "making available". The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market. When a manufacturer or an importer supplies a product to a distributor or an end-user for the first time, that operation is labelled in legal terms as placing on the market. Any subsequent operation, for instance, from a distributor to another or to an end-user is defined as making available. It should be noted the difference between "making available on the market" in

TOPIC	QUESTION	ANSWER
		Article 5, as the general concept referred to free movement in the EU internal market in any moment, and "placing on the market" in Articles 6, 7 and 8, referred to the first time that the product is introduced on the EU market. As regards the case of products manufactured for the manufacturer's own use the product is not placed on the market: in this case the legislation applies at the moment of putting into service. *See also §§ 2.2. "Making available" and 2.3. "Placing on the market" of the "Blue Guide"*
	Which kinds of obligations are related to selling products through the internet?	EU harmonisation legislation applies to all form of supply, including distance selling and selling through electronic means (as the internet): in any case, products intended to be made available on the EU market must be in conformity with the applicable legislation. A product offered in a catalogue or by means of electronic commerce has to comply with EU harmonisation legislation when the catalogue or website directs its offer to the EU market and includes an ordering and shipping system. Products offered for sale online by sellers based outside the EU are considered to be placed on the EU market if sales are specifically targeted at EU consumers or businesses. *See also § 2.1. "Product coverage" of the "Blue Guide"*
	In many cases products can be marketed through the internet or other distance/electronic means but the product is not physically in the EU. Placing on the market requires the products to be physically in the EU territory?	
Obligations of manufacturers: **Type, batch or serial number** ***Article 6(5)***	Does this Article mean that a product specification is required, but not necessarily a serial number? Would there be a way to specify the sequential serial number using a barcode?	The important point is that the numbering must allow making a clear link to the relevant documentation that demonstrates the conformity of the specific type of product, in particular for ATEX the EU declaration of conformity or the attestation of conformity. A barcode can be used if this can reasonably be considered by a manufacturer as an appropriate way enabling the manufacturer and authorities to identify and trace his products and to make the link to the relevant documentation. Depending on the product, it is up to the manufacturer to decide whether the identification element should allow the identification of each single product or just the relevant batch or type. But manufacturers should be aware that when

TOPIC	QUESTION	ANSWER
		public authorities in charge of market surveillance recall products and it is not possible to distinguish between batches or serial numbers, all products of that brand must be removed from the market. The ATEX Directive allows placing the information on the packaging or in a document accompanying the product if the size or nature of the product does not allow it. Of course if the information is not visible at a first sight, it must be easily and safely accessible. *See also § 4.2.2.3. "Identification element" of the "Blue Guide"*
Name and address on the product ***Article 6(7)***	If lack of space, would be possible to indicate the name and address within the product?	The manufacturer must indicate his (1) name, (2) registered trade name or trade mark and (3) a single contact postal address at which he can be contacted, on the product or, when not possible because of the size or physical characteristics of the product, on its packaging and/or on the accompanying documentation. If the information is put inside the product, it must be easily accessible by the Market Surveillance Authorities without damaging the product or the need for disassembling it with specific tools. *See also §§ 3.1. "Manufacturer" and 4.2.2.1. "The requirement to indicate name and address of the manufacturer" of the "Blue Guide"*
	Must the information refer to the local distributor or the economic operator placing the product on the EU market?	The information is related to the economic operator that places the product on the market i.e. the manufacturer or importer, not the distributor.

TOPIC	QUESTION	ANSWER
	In the case that a company is based in a third country and in an EU country, is it necessary to put the information of both places as manufacturer and importer?	For imported products, it is required to indicate the name and address of the manufacturer and of the importer, as a basic traceability requirement for market surveillance. But, if both, manufacturer and importer, belong to the same group or company and if the company based in the EU takes the full manufacturer's responsibility, the indication of the branch based in the EU will suffice to comply with the requirements. *See also § 4.2.2. "Traceability provisions" of the "Blue Guide"*
	The postal address in which the manufacturer can be contacted, must be the one of the manufacturer?	Not necessarily. The postal address must be "at which [the manufacturer] can be contacted": this is not necessarily the address where the manufacturer is actually established. This address can for example be the one of the authorised representative or of the customer services. *See also § 4.2.2.1. "The requirement to indicate name and address for manufacturers" of the "Blue Guide"*
	How to implement the requirement that the contact details shall be in a language easily understood?	The address does not have to be translated. The characters of the language must allow identifying the origin and the name of the company. This is not possible with certain alphabets.
	What elements are needed to constitute an address? Does it always need a street name, house no. etc.?	The address must be specific enough for a letter to arrive in the right place. Not all addresses are composed of street names and/or house numbers.
Instructions and safety information ***Article 6(8)***	What can be considered as manufacturer's documentation within the ATEX Directive?	The documents that are required to accompany the product include the instructions and safety information to be drawn up and provided by the manufacturer to the end-user of the product. One single document can include both instructions and safety information. It includes also a copy of the EU declaration of conformity or the attestation of conformity, which have to accompany each ATEX product, as per Article 6(2).

TOPIC	QUESTION	ANSWER
	As the ATEX Directive covers health and safety matters only, may any mandatory documentation relate to safety only?	The documentation (instructions and safety information) must include all the necessary information for the safe use of the product, to enable the end-users to assemble, install, operate, store, maintain, repair, and dispose of it. It is for the manufacturer to determine the relevant information which should be included in the instructions and safety information for a particular product.
	Should each product sold in a bulk contain the instructions and safety information?	In principle, every individual product must be accompanied by the instructions and safety information but it does not mean that the full instructions must be given in paper. In some specific cases, where several identical products are bundled in a packaging for use in one application (e.g. installation equipment), it is sufficient to accompany the shipping unit with one set of instructions. If another economic operator along the distribution chain dismantles the bundle and sells the products individually, he should ensure that each product individually sold is accompanied by the necessary instructions and safety information. This item will also be clarified in the revised "Blue Guide". *See also § 3.1. "Manufacturer" of the "Blue Guide"*
	According to Directive 2014/34/EU, is it necessary to attach instructions to a component?	According to Article 6(8) the manufacturer shall ensure that the product is accompanied by instructions and safety information: the term "product" includes also components, so in principle ATEX components should be accompanied by instructions, too. Taking into consideration that components are often very small items supplied in a wide range of batch sizes and package quantities, an alternative means of satisfying the information obligation is to attach the instructions to delivery documentation or to the smallest additional packaging. The topics that shall be included in the instructions for equipment according to Directive 2014/34/EU are specified in Annex II point 1.0.6. This point is only valid for equipment and so it is not applicable to components. The content of the instructions for ATEX components has to be adapted accordingly: they shall describe the substantial properties of the component

TOPIC	QUESTION	ANSWER
		and illustrate how the component has to be installed into the product according to the intended use.
Products not in conformity with the Directive ***Article 6(9)***	The ATEX Directive 2014/34/EU requires that where the product presents a risk, manufacturers shall immediately inform the competent national authorities. Which is the threshold of "unacceptable risk" above which authorities have to be informed?	The "acceptable level of risk" for a product is determined by the compliance with the essential health and safety requirements. The EHSRs of the ATEX Directive have not been changed and therefore the previous thresholds for assessing the risks would continue to apply.
Provision of information and documentation ***Articles 6(10), 8(9) and 9(5)***	May "a competent national authority" in any Member State or EEA country contact an economical operator (manufacturer, importer, distributor) for information and documentation directly without any involvement of the local national authorities, or not?	The Directive makes reference to "a competent national authority", that could be any of the countries of the EU and the EEA in which EU legislation applies. Any competent market surveillance authority can and is recommended to contact directly the economic operator even if he is based in a different Member State. The information of local national authorities in direct contacts between any national/EEA authority and economic operators, is advisable, for a matter of transparency and good co-operation. If the authority needs information to complete the compliance evaluation and the economic operators does not provide the information requested, then the first authority can request the assistance of the local national authority. The legal basis for this type of mutual assistance is set out in Article 24(2) of Regulation (EC) 765/2008. If the economic operator does not voluntary take corrective action, the competent national authority will adopt corrective measures concerning its country and notify them as appropriate via ICSMS/RAPEX Rapid Alert System. The market surveillance authorities of the other Member States will take follow up measures in the context of the safeguard clause procedure and in particular the local national authority will contact the manufacturer/EU importer and requests corrective action in relation to all relevant products. *See also §§ 7.4. "Safeguard mechanisms for Member States" and 7.5. "Cooperation and exchange of information between the Member States and the European Commission" of the "Blue Guide"*

TOPIC	QUESTION	ANSWER
Obligations of importers: **Ensuring the manufacturer's requirements** ***Article 8(2)***	How do we interpret "Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure… has been carried out by the manufacturer"? Does it mean that the importers must have a copy of the EU declaration of conformity or the attestation of conformity and the related technical documentation?	The importer needs to have a copy of the EU declaration of conformity and has to keep it for 10 years after a product has been placed on the market. The importer has to ensure that the technical documentation can be made available to the competent national authority upon request. Even if there is no explicit obligation, the importer is advised to require formal assurance in writing from the manufacturer that the documents will be made available when requested by the market surveillance authority. What is important is that the authorities receive the documentation and that at importer's request the manufacturer provides the information to Member States. The importer has to make sure that the manufacturer has carried out the appropriate conformity assessment procedure for the product. Therefore, the importer must check whether the manufacturer has fulfilled his requirements, but it does not have to carry out a "new" conformity assessment of the product. In addition to that, the importers has a due diligence obligation with regard to the conformity of the product. If he disposes of further information that should reasonably make him believe that the product is not in compliance he should not place the product on the market. The manufacturer retains the overall responsibility for compliance; such responsibility cannot be transferred to the importer. *See also § 3.3. "Importer" of the "Blue Guide"*
	What exactly are the "required documents" that are mentioned in this paragraph?	The "required documents" that the importer needs to make sure that are present are the ones which have to accompany the product, as described in each EU legislation. In the ATEX Directive it is the EU declaration of conformity or the attestation of conformity which must accompany the product, and the instructions and safety information.
Language of instructions and safety information	Can the product be imported with instructions only in English created by the manufacturer, and can the importer himself create a translation of the instructions that will accompany the product	The manufacturer, the importer and the distributor have the obligation to ensure that the product to be placed on the EU market is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. It is for each economic operator which makes available the product in a

TOPIC	QUESTION	ANSWER
Article 8(4)	when is placed on the EU market?	Member State, to ensure that all the languages are available. Nothing prevents economic operators from reaching contractual agreements on the manner in which they are translated.
	What happens if the product is placed on a national market for which the manufacturer has not foreseen a translation?	A manufacturer has a certain set of languages where he intends to ship the product but if it goes somewhere else, importer and distributor must ensure that instructions are translated in the relevant language. It depends on how economic operators are organised by contractual arrangements.
	What happens with "bad" translations?	According to Article 6(8), instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible. Therefore, "bad" (inaccurate, incomplete, etc.) translations cannot be accepted and the product should be considered non-compliant.
Obligations of distributors ***Article 9(2)***	What exactly are the "required documents" that are mentioned in this paragraph?	The "required documents" that the distributor needs to make sure that are present are the ones which have to accompany the product, as described in each EU legislation. In the ATEX Directive it is the EU declaration of conformity or the attestation of conformity which must accompany the product, and the instructions and safety information.
	How do the distributors check whether the requirements were met except for the CE marking and the instructions for use and safety information?	The distributor must not carry out any specific additional checks apart from those explicitly mentioned in Article 9. He also has to check that the manufacturer and importer have indicated their name, registered trade name or trade mark and the address at which they can be contacted on the product, or, when not possible because of the size or physical characteristics of the products, on its packaging and/or accompanying documentation, and that the product bears a type, batch or serial number or other element allowing its identification. The distributor must be able to identify the person (e.g. manufacturer or his authorised representative, the importer or another distributor) who has provided him with the product in order to assist the market surveillance authority in its efforts to obtain the EU declaration of conformity or the attestation of conformity and the necessary parts of the technical

TOPIC	QUESTION	ANSWER
		documentation. Market surveillance authorities have the possibility to address their request for the technical documentation directly to the distributor. The latter, is however not expected to be in possession of the relevant documentation. In addition to that, the distributor also has a due diligence obligation with regard to the conformity of the product. If he disposes of further information that should reasonably make him believe that the product is not in compliance he should not make the product available on the market. *See also section 3.4. "Distributor" of the "Blue Guide"*
Provision of information and documentation ***Article 9(5)***	What is a "reasonable period" for distributors to provide the necessary documents, taking into account the fact that even the smallest distributor should provide the information?	There is not specific time limit in the directive for a "reasonable period". This period has to be assessed by the authorities on a case-by-case basis, taking into account the level of urgency/seriousness of risk and the efforts for the economic operator to follow-up the request. A default period could be e.g. 10 working days, but giving the possibility to shorten it or extend depending of the case. Member States are free to fix a default period in their national laws, but there should always be a possibility to shorten or prolong that period.
Harmonised standards ***Article 12***	Are new lists of references of ATEX harmonised standards to be published on the OJEU in the date of applicability of the new Directive? What would happen if new harmonised standards are not published in such date?	The Commission will not amend the existing standardisation mandates (M/BC/CEN/92/46 and others) for the new ATEX Directive 2014/34/EU: according to Article 43, references to the repealed Directive shall be construed as references to the new Directive. Therefore, there is no need to change reference numbers contained in harmonised standards: any reference to the previous Directive 94/9/EC should be read as a reference to the new Directive 2014/34/EU. In particular, as the legal provisions supported by a harmonised standard (the essential health and safety requirements) have not been changed, Annex Z referencing to the repealed Directive can be read as referencing to the new Directive as given in the new Directive itself. Consequently, standards harmonised under the previous Directive 94/9/EC continue to confer presumption of conformity with the essential health and safety requirements of the new Directive 2014/34/EU Directive because the EHSRs remain the same. There is in principle no need to revise the standards

TOPIC	QUESTION	ANSWER
		to make changes in Annex Z only: revision of standards by CEN and CENELEC can follow the normal revision cycle (approx. 5 years) in order to adequately follow the state of the art and/or to answer to specific needs. In any case, for the sake of clarity and transparency, the first list of references of harmonised standards under Directive 2014/34/EU will be published on the OJEU in time for its applicability, at the same time of the last list under Directive 94/9/EC (probably in February-March 2016). The contents of the last list under Directive 94/9/EC will be the identical to the first list under Directive 2014/34/EU.
EU declaration of conformity ***Article 14***	From which date a manufacturer has to mention the new ATEX Directive for his EU declaration of conformity?	Before 20 April 2016 all the EC declarations of conformity for ATEX products placed on the EU market for the first time must be in line with Directive 94/9/EC. According to Article 41 products that are already in the distribution chain (including stockpiles: see Recital 49), before 20 April 2016, can continue to be distributed with the EC declaration of conformity referring to Directive 94/9/EC, as they have already been lawfully placed on the EU market. Declarations of conformity (EC or EU) remain valid according to the legislation in force when the product is placed on the EU market (= made available on the EU market for the first time). There is no need to change legislative references in documents accompanying the product. For products placed on the EU market as of 20 April 2016 (or, in the case of products manufactured for own use, put into service), the EU declaration of conformity must be in accordance with the new ATEX Directive 2014/34/EU. As the ATEX Directive requires the product to be accompanied by the declaration of conformity, it is difficult for manufacturers to ensure that the declaration is exchanged from one day to the next. In order to facilitate the transition to the new ATEX Directive 2014/34/EU, the EU declaration of conformity can already today (when conformity still has to be declared to the old Directive 94/9/EC) indicate the following: "*The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 94/9/EC (until April 19th, 2016) and Directive 2014/34/EU (from April 20th, 2016)*".

TOPIC	QUESTION	ANSWER
	How old a declaration of conformity can be, when placing a product on the market?	If the product remains the same and no changes in the state of the art (as from the harmonised standards, if available) took place, the same declaration of conformity can continue to be used.
	Is it necessary to change the declaration of conformity when the referred harmonised standards change?	It would depend on the kind of changes in the new harmonised standard superseding the previous one, as indicated by the relevant European Standardisation Organisation (CEN, CENELEC) in the standard itself. For "substantial" changes, related to the state of the art, re-assessment of the product will be necessary; for "formal" or "non-substantial" changes, an update of the declaration of conformity will be enough. The important issue to consider is that the previous standard has lost the presumption of conformity, so conformity is no longer "presumed" but has to be demonstrated, in particular in the technical documentation.
Structure and contents of the EU declaration of conformity ***Article 14(2)***	Which information must be included in the EU declaration of conformity?	If a manufacturer produces an EU declaration of conformity that follows strictly the model set out in Annex X to Directive 2014/34/EU, as a minimum, he will completely fulfil the requirements of the EU declaration of conformity. The elements specified in Annexes III to IX do not add any additional requirement. In any case, additional information can be included.
	Annex X requires "References to the relevant harmonised standards used" when other directives (for instance 2014/30/EU, Annex IV) require "References to the relevant harmonized standards used, *including the date of the standard*". Does it mean that for the ATEX Directive it is not mandatory to mention the date of the standards used?	The reference of the harmonised standard should be indicated in a precise, complete and clearly defined way; this implies that the version and/or date of the relevant standard should be specified. Therefore, it can be necessary to include the date if the version cannot be identified in a different manner (e.g. year of adoption). This is especially useful when two versions of the same standard are providing for presumption of conformity at the same time, during the transitional period between the publication of the reference of the superseding standard on the OJEU and the date of cessation of presumption of conformity of the superseded standard.
	Is the translation of the EU declaration of conformity the manufacturer's responsibility when he markets the equipment under his name	EU harmonisation legislation does not specify who has the obligation to translate. There can be a contractual arrangement between the manufacturer and the importer about who does the translation.

TOPIC	QUESTION	ANSWER
	or trade mark? Can the importer translate the declaration before he places the product on the market or can the distributor translate it before making it available on the market and provide the translation together with the EU declaration of conformity of the manufacturer which is for example in English?	In any case, in Annex X to the new ATEX Directive 2014/34/EU there is a compulsory, more detailed model of the EU declaration of conformity, which is already translated in all the EU official languages.
	Must the translations of the EU declaration of conformity be signed by the manufacturer?	The EU declaration of conformity must be signed by the manufacturer (by an individual working for the manufacturer) or his authorised representative, and the employee's function shall also be indicated. If the translation of the EU declaration of conformity is not signed by the manufacturer, a copy of the original EU declaration of conformity signed by the manufacturer must also accompany the product, together with the translated version. *See also section 4.4. "EU declaration of conformity" of the "Blue Guide"*
Products subject to more than on EU legislation ***Article 14(3)***	Is it necessary to draw up several EU declarations of conformity when more than one Directive is applicable to an ATEX product?	No. On the contrary, a single EU declaration of conformity is required whenever a product is covered by several pieces of EU harmonisation legislation (directives or regulations) requiring an EU declaration of conformity; such single declaration must refer to all of legislation applicable to the product and the related essential requirements. For this reason, if the ATEX Directive applies to a product as well, its reference should be included in the single or "global" EU declaration of conformity which must accompany the product. This should be checked by the importer or distributor. The single EU declaration of conformity can be one-page document listing the different directives or a dossier made up of relevant individual declarations of conformity (see recital 24). *See also § 4.4. "EU declaration of conformity" of the "Blue Guide"*
Products presenting a risk	What is the purpose of Article 35 which describes the procedure for dealing with products	The procedure described in Article 35 has different possible developments, towards the same result: ensuring that only compliant products are placed on

TOPIC	QUESTION	ANSWER
at national level ***Article 35***	presenting a risk at national level?	the EU market. If upon request of the market surveillance authority the economic operator agrees to take the necessary corrective action (voluntary measures by the operator), the procedure ends here. In this case, if the market surveillance authority considers that the risk goes beyond its national territory, the authority will inform the Commission and the other Member States of the results of the evaluation and the actions the economic operator intends to take. However, if the economic operator does not take corrective action as requested, the market surveillance authority shall take appropriate measures against the product (compulsory measures). In this case, the national authorities notify the measure to the Commission and to the other Member States, who have the possibility to object to it during a 3-month period. If no objection is raised, the measure is deemed to be justified. In this case all Member States are obliged to take appropriate action against the product on their territories. If objections are raised, the Commission needs to take a decision to determine whether the measure should be considered as justified or not (the Union safeguard procedure in Article 36). The purpose is that restrictive measures against the product are not an unjustified restriction of the free movement of goods. Additionally, it is an information-sharing tool between market surveillance authorities: this exchange of information, although non-compulsory in the phase of voluntary corrective actions, is also expected to be submitted by the market surveillance authorities to the other Member States.
Three months' time to raise objections ***Article 35(7)***	How to compute the "three months'" time to raise objections by a Member State or the Commission against a measure taken by a Member State?	It is three calendar months, to be calculated according to the general provisions of Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, and in particular Article 3. For example: if a notification comes in on 15 September 2016, the day of notification does not count and the three months' time will end on 16 December 2016, 24:00h.
Compliant	What is the meaning of Article 37, especially	The procedure of Article 37 has to be seen as exceptional case. In principle the

TOPIC	QUESTION	ANSWER
products which present a risk ***Article 37***	with respect to Article 35?	essential requirements of the ATEX Directive 2014/34/EU are performance based and technology neutral. However, the directive takes into account the state of the art when it was drafted. It is possible that with the evolution of time, new technologies and the state of the art, the essential requirements do not cover all risks, in particular related to new products. This is the case foreseen in Article 37. In this case a product may formally comply with the essential requirements but nevertheless present a risk. Authorities must have to possibility to take restrictive measures against the product and this procedure allows them to do so. The difference to the "normal" safeguard procedure is that Article 37 deals with "compliant products", while Article 35 deals with products presenting a risk for not complying with the applicable requirements.
Formal non-compliance ***Article 38(1)***	Is the lack of CE marking, or the incorrect drafting of the EU declaration of conformity; a formal non-compliance?	Unless there are reasons to believe that the product presents a risk, there are cases where non-compliance with a number of administrative or formal requirements are defined as formal non-compliance by Article 38 of Directive 2014/34/EU. The lack of CE marking or the incorrect drafting of the EU declaration of conformity are expressly mentioned in Article 38(1)(c) and (f) respectively but it is rarely just a formal non-compliance: it could be related to more substantial safety issues. In any case, this Article 38 does not affect Article 35 (products presenting a risk). The CE marking, the EU declaration of conformity and the technical files can be defined as the cornerstone to place ATEX products on the EU market. *See also § 7.3.6. "Corrective measures - Bans - Withdrawal - Recalls" in the "Blue Guide"*
	Is the lack of the indication of the year of construction on a component, a formal non-compliance?	The requirement to mark the "year of construction" is set up in section 1.0.5. "Marking" of Annex II to Directive 2014/34/EU, for equipment and protective systems but not for components. So in principle the lack of such information on the component should not be regarded as formal non-compliance according to Article 38(1)(c).
Article 38(2)	How much should the national authorities wait	It depends on each case but always considering the proportionality principle in

TOPIC	QUESTION	ANSWER
	for the non-compliance to continue before taking the appropriate measures to restrict or prohibit the product being made available on the market?	actions taken by national market surveillance authorities vis-à-vis economic operators, for non-compliances which "persist", during some time.
Transitional and final provisions ***Articles 41, 42, 43, 44***	What are the implications of the dates of publication, adoption, entry into force, transposition and applicability?	The most important date is 20 April 2016, the date of applicability, from which Member States have to apply the provisions of the new Directive 2014/34/EU, according to Articles 41 and 44. Until that date, the previous Directive 94/9/EC remains applicable. There are some points in the new Directive that can be already applied because they have not changed. Furthermore, the EU declaration of conformity must refer to the previous Directive 94/9/EC until 19 April 2016 but the new model can be used. The transposition date (19 April 2016) is the date by which Member States must have transposed the relevant provisions of the new ATEX Directive 2014/34/EU, according to Article 42. The adoption date (26 February 2014) is when the text was adopted by the European Parliament and the Council, and has no practical implications, as the date of publication on the OJEU (29 March 2014) and the correlated date of entry into force (18 April 2014, 21st day following the publication).
	Are references to 94/4/EC to be regarded as references to 2014/34/EU also in "private documents", i.e. documentation which is handed over from the manufacturer to the customer?	This provision is related to EU legal texts and the transpositions of such legislation. It does not specifically target private documents, as these are subject to national contractual law. It is however not valid for documents which are required from manufacturers under the ATEX directive (e.g. declaration of conformity, technical documentation), they have to explicitly refer to the new Directive 2014/34/EU.
Transitional provisions for Member States	Which are the main tasks for Member States during the transposition period?	Member States must adopt and publish, by 19 April 2016, the national legal provisions acts (laws, regulations, administrative provisions) to transpose the relevant provisions of the new ATEX Directive 2014/34/EU, necessary to comply with them as by 20 April 2016. At the same time, Member States must communicate to the Commission the text of the main provisions of national law which they adopt.

TOPIC	QUESTION	ANSWER
Transitional provisions for notified bodies	Which are the main tasks for national notifying authorities and for notified bodies during the transposition period?	Member States must appoint notifying authorities at the national level and the national notifying authorities must re-notify their conformity assessment bodies (notified bodies) before 20 April 2016, through the new devoted space in the Commission's NANDO database. The new ATEX Directive gives an opportunity to reinforce the competence, monitoring, information and co-operation activities of notifying authorities and notified bodies, according to the relevant provisions of the Directive (Articles 17 to 33). It is important that Member States transpose the new ATEX Directive or the parts relevant for the notification into national legislation as soon as possible and in any event well ahead April 2016, in order to ensure that notifying procedures are completed in time, and notified bodies under the new ATEX Directive can start operating as of 20 April 2016.
	Will certificates issued in accordance with Directive 94/9/EC still be valid after 20 April 2016?	Yes. According to Article 41(2) of Directive 2014/34/EU, certificates issued under Directive 94/9/EC (in particular EC-type examination certificates or quality assurance certificates issued by notified bodies) until 19 April 2016 will remain valid under Directive 2014/34/EU until their fixed expiration date. Certificates issued according to Directive 94/9/EC can still be used for EU declarations of conformity according to Directive 2014/34/EU.
	Will addenda (supplements) to certificates be possible, such as EC-type examination certificates and quality assurance certificates issued according to Directive 94/9/EC?	Yes. Even after 20 April 2016 addenda (supplements) to "old" certificates will be possible, such as EC-type examination certificates and quality assurance certificates issued according to Directive 94/9/EC. However, these addenda need Directive 2014/34/EU as a reference base and therefore can only be issued by notified bodies under the new ATEX Directive 2014/34/EU.
	When can notified bodies issue certificates according to Directive 2014/34/EU?	Notified bodies can issue certificates in accordance with the new ATEX Directive 2014/34/EU only from 20 April 2016: no certificate under Directive should be issued before 20 April 2016. Only bodies notified under Directive 2014/34/EU can issue certificates under the new Directive. For practical purposes, bodies notified under the new ATEX Directive
	Can a notified body issue certificates according to the new ATEX Directive 2014/34/EU before 20 April 2016 with a validity date from 20 April	

TOPIC	QUESTION	ANSWER
	2016?	2014/34/EU can start the preparatory work before that date.
	Would it be possible to maintain the reference number of an EC-type examination certificate issued under Directive 94/9/EC when it would be converted into an EU-type examination under Directive 2014/34/EU?	According to Article 41(2), certificates issued under Directive 94/9/EC remain valid under Directive 2014/34/EU, so there is no need to "convert" certificates. The numbering of certificates is under the autonomy of the notified body, the Directive does not specify anything in this respect. If the practice of a notified body is to "re-issue" the whole certificate instead of issuing addendums, the certificate can continue carrying the same number and refer to the new Directive. In any case, the reference number of a certificate must allow to clearly identify it with respect to the approved type, according to Annex III(6).
Transitional provisions for manufacturers	Can a manufacturer issue an EU declaration of conformity according to the new ATEX Directive 2014/34/EU before 20 April 2016 with a validity date from 20 April 2016?	There is no "transition period" in Articles 41, 42 and 43, or a "period of overlapping" of Directives 94/9/EC and 2014/34/EU. Before 20 April 2016 all the EC declarations of conformity for ATEX products placed on the EU market must be in line with Directive 94/9/EC. EU declarations of conformity and certificates must be in accordance to the new Directive 2014/34/EU as of 20 April 2016 for ATEX products placed on the EU market or put into service for the first time as by that date. In order to facilitate the transition to the new ATEX Directive 2014/34/EU, the EU declaration of conformity can indicate the following: "*The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 94/9/EC (until April 19th, 2016) and Directive 2014/34/EU (from April 20th, 2016)*".
Classification of equipment-groups into categories ***Annex I*** **Essential health and safety requirements**	Does the new ATEX Directive 2014/34/EU affect the classification of equipment-groups into categories or the essential health and safety and health requirements for equipment and protective systems intended for use in hazardous areas?	No. When compared with the previous Directive 94/9/EC, in the new Directive 2014/34/EU the classification of equipment-groups into categories and the essential health and safety requirements for equipment and protective systems intended for use in potentially explosive atmospheres have not changed. The new Directive is the result of the alignment to the reference provisions of the New Legislative Framework, in particular Decision No 768/2008/EC and Regulation (EC) No 765/2008. So, Annex I "Criteria determining the classification of equipment-groups into categories" was not changed, neither was Annex II "Essential health and safety

TOPIC	QUESTION	ANSWER
Annex II		requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres".
EU-type certificates ***Annex III(6), (7) and (8)***	Is it necessary to limit the period of validity for EU-type examination certificates under Directive 2014/34/EU, for instance 5 years?	The new ATEX Directive 2014/34/EU includes, in points 6, 7 and 8 of Annex III, some references to validity (conditions for, if any, and expiry) of EU-type examination certificates. Such references were not present in the previous Directive 94/9/EC and come from Decision No 768/2008/EC (Article 4(5)(e) and Annex II, Module B). In this sense, in the Directive does not impose an obligation on establishing a period of validity for EU-type examination certificates but foresees the possibility to do so when this is deemed appropriate. The situation remains as it is under the current ATEX Directive 94/9/EC. *See also § 4.1.2.6. "Revision of harmonised standards" in the "Blue Guide"*
	If no date of expiry of the validity of the certificate is given, does it mean that records (a copy of the EU-type examination certificate, its annexes and additions, the technical file etc.) shall be kept indefinitely by notified bodies?	Yes. The obligations for notified bodies concerning the referred documents remain for the whole validity period of the certificate, in order to ensure the proper traceability.
Technical documentation - Risk analysis ***Annex III(3)(c), Annex VIII(2), Annex IX(2.1)***	The new "Blue Guide" § 4.3. "Technical documentation" explains that no additional risk assessment must be carried out and no additional documentation must be created, if harmonized standards are met, that were created on the basis of a risk analysis. How can we know whether a standard is developed on the basis of a risk analysis? In particular, point 2 of Annex VIII "Internal production control" to Directive 2014/34/EU requires from the manufacturer to include an adequate analysis and assessment of the risk(s) in	This statement presupposes a good evaluation of the risks of the product and match between the risks analyses and risks covered by the harmonised standards. Any conformity assessment procedure requires the manufacturer to start a risk analysis of the specific risks of the product to address them in order to comply with the essential health and safety requirements because not all products present the same risks which has to be distinguished from the analysis referred to in the Blue Guide §4.3, namely how to appropriately address the identified risks. The way to address these risks can be done in several ways, such as with the harmonised standards. *See also the diagram at § 4.1.2.2. "Role of harmonised standards" of the "Blue*

TOPIC	QUESTION	ANSWER
	the technical documentation without providing any further details. What should be the form and requirements of the risk analysis and how the risk evaluation should be realized?	*Guide"*
	Will a risk analysis and a risk assessment carried out by the manufacturer also be necessary with Directive 2014/34/EU?	Yes: Directive 2014/34/EU does not provide for a modification to the previous procedure. In fact, Annex III(3)(c), Annex VIII(2) and Annex IX(2.1) to Directive 2014/34/EU explicitly state that the technical documentation shall include an adequate risk analysis and risk assessment. These shall cover all risks, also those being non-typical for explosion protection, including e.g. risks caused by voltage, noise or movable parts (see Annex II point 1.2.7 of Directive 2014/34/EU). Additionally, further EU harmonization legislation applicable to the product has to be considered. The reason is that the ATEX Directive does not cover all risks that may emerge from any product within the scope. The application of a harmonized standard can simplify risk analysis and risk assessment. *See also § 4.1.1. "Definition of essential requirements" of the "Blue Guide"*
Unit verification - Retention of documentation by the notified body ***Annex IX***	This conformity assessment procedure does not require any retention of record by the notified body. Does it mean that no record is formally requested to be available for surveillance authorities from the NB?	Even not explicitly indicated, the notified body should keep the appropriate documentation supporting the certificate of conformity issued according to point 4 of Annex IX, within the general obligation to inform and co-operate with the national markets surveillance authorities and the other notified bodies. *See also § 5.2.2. "Roles and responsibilities" of the "Blue Guide"*

References for guidance

- The "Blue Guide" on the implementation of EU product rules (version 1.1 - 15/7/2015)

- "CERTIF" documents (non-binding interpretative documents issued by the European Commission):
  - CERTIF doc. 2008-002 - Differences between Conformity assessment modules as laid down in new approach (Decision 93/465/EEC - old modules) and as laid down in the new legal framework (Decision 768/2008/EC - new modules)
  - CERTIF 2009–03 - Orientations for selecting and implementing the modules (as laid down in Decision 768/2008 of the new legal framework) – SMES specificities
  - CERTIF 2009–04 - Introduction to conformity assessment and conformity assessment procedures of the new legal framework (as laid down in Decision 768/2008 of the new legal framework)
  - CERTIF 2009-08 - Using standards to assess the competence of conformity assessment bodies in the context of the New Legislative Framework
  - CERTIF 2010-05 Rev1 - Overview of market surveillance procedures (including safeguard clause mechanism) in the area of harmonised products
  - CERTIF doc 2010-06 - Notifications of Notified Bodies in NANDO – requirements of Regulation 765/2008 and Decision 768/2008
  - CERTIF 2012-06 REV1 – Notified Bodies - The use of the notified bodies number for activities not required by EU legislation
  - CERTIF 2013-04 REV2 – Ensuring continuous competence of notified bodies
  - CERTIF 2013-07 – Time frames for notification of NBs following the entry into force of the Alignment Package
  - CERTIF 2013-08 – NANDO procedure for notification of notified bodies that are not accredited by a national accreditation body
  - CERTIF 2013-11 REV1 – Time frames for notification of NBs following the entry into force of the Alignment Package
  - CERTIF Guidance papers on accreditation (July 2014)
  - CERTIF 2015-01 REV2– The functioning of NANDO with regard to providing accurate information, objection periods, notification procedures and notified bodies groups

- ATEX 2014/34/EU Guidelines (in preparation; will be available on the ATEX website on EUROPA)