# ATEX EUROPEAN MANDATORY SCHEME AND IECEx INTERNATIONAL VOLUNTARY SCHEME: DO THESE SCHEMES HAVE A FUTURE?

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***Abstract*** - ATEX European Mandatory Scheme and IECEX International Voluntary Scheme have many similarities that will be briefly exposed in this article.

European Union, because of its present expansion, in terms of number of members, tends to offer the manufacturers an increasing number of Notified Bodies.
As such this could not be a problem but a comparison has to be made with similar markets size.

A quick comparison with North America (USA and Canada) shows that three (3) important bodies are acting in the HAZLOC Market. In EU, fifty (50) bodies are, to day, acting in the ATEX Market. One can expect this number to be higher at the date of the publication of this article!

By experience, the larger a group is, the more different the accumulated experiences are (e.g. : some times, different standards leading to different approaches in the interpretations or to very different testing equipment, the more difficult it is to get from this group sufficiently harmonized practices for testing and approval. This create an intrinsic ***risk*** with regards to the quality of the Certificates that may be issued under these circumstances. The target of having harmonised practices is nonetheless expected by manufacturers because it is the basis of a fair treatment.

As first Chairman of the ExNB Group (ATEX Notified Bodies Group) I can confirm that harmonisation of practices and interpretations were already a daily challenge and during this period one should note that the number of NBs was “only” 22.

The main consequence is that a *de facto* situation of unfair competition between the manufacturers and of uneven quality of the certificates may arise.

An other risk, is, generated by the process itself of granting the right to be a Notified Body as set out in the Annexe XI of Directive 94/9/EC.

This, combined to the fact that, the number of NBs, within less than 4 years, has reached 50, EU is probably facing a serious risk of decreasing the quality of its Ex Certification.

Comparatively the IECEx Scheme has some specific features :

The process of entering in the IECEx Scheme is different and probably more demanding.

The Factory assessment provisioned in the IECEx corresponds to the most onerous module provisioned in the Directive (see Annex IV).

The present number of Certifications Bodies and Testing bodies (21) is still relatively limited.

The combination of these points create a more favourable situation.

Therefore an IECEx Certificate issued by one of its member is expected to be reliable.

This may certainly remain true if the number of IECEx ACB increases in a controlled manner preserving the possibility of harmonised practices

The conditions whereby the two Schemes could remain credible in the short term will be briefly reviewed.

If these conditions are met, they will contribute to consequently secure the future of each Schemes, bearing in mind that it is the interest of end users, regulatory authorities and manufacturers to, respectively, buy, accept and sell **safe Ex product**.

*Index Terms* – ATEX, Mandatory Testing and Approval Scheme, Directive 94/9/EC, Notified Bodies, Voluntary Testing and Approval Scheme IECEx, Future.

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## I. INTRODUCTION

Ex product are serious matters and involve such liabilities that it is widely accepted that they should not be treated exactly as normal product.

Regulators, Authorities, Insurance companies, Manufacturers and Users agree on that.

Various Schemes (Regional, International) aim at addressing the testing and approval process of Ex product.

These Schemes are supposed to bring an appropriate answer to the safety issues.

One of the scheme is *mandatory* in EU : The ATEX Scheme and one is *voluntary* and is the IECEx Scheme.

## II. PRESENTATION OF TWO SCHEMES

### II-1 EU ATEX Scheme.

**Context**

This Scheme is based on Directive 94/9/EC that set principles and general rules for testing and approval process of Ex product. This document transposed and voted by the member state is said to be legally binding.

This document spells out the **E**ssential **H**ealth and **S**afety **R**equirements (**EHSR**) that apply to Ex product.

It refers to Harmonised Standards (CENELEC, CEN …, Standards published at the OJEC) as the recommended tools to demonstrate compliance to EHSR.

Depending on the intended use, it defines three categories of product (CAT1, CAT2, CAT3). For the two first, a Type Certification by a **N**otified **B**ody **(**NB**)** is mandatory.

It defines, for product that are submitted to Type Certification, the principle of factory assessment through Annex IV or VII that applies respectively to CAT1 or CAT2 product.

*It defines, in Annex XI, the minimum criteria to be taken into account by individual member states for the NBs.*

By so doing the Directive is supposed to contribute to guarantee :

the *safety* of Ex product before accessing the EU Market

and

the *free circulation* of those Ex product in EU.

In most of the case, the safety relies mainly through the use of the relevant **H**armonised **S**tandards (**HS**).

These standards are defined initially through a voting process made by all the EU National Committees and reflect the *consensus* reached at an European level.

These HS are the common basis for all NBs, although it still exists interpretation issues.

Any product put on the EU Market can be challenged through the surveillance organised by the authorities.

This surveillance is primarily directed to Manufacturers and is not used to assess the selection of NBs. It named Market surveillance.

It is a fact that, this market surveillance is not implemented in the same way and certainly not with the same intensity throughout the EU.

Regarding the minimum criteria of Annex XI, one can observe that there is no reference made to additional document that would develop, for the member states, the detailed process to reach the decision to notify a NB.

Therefore there is no official detailed common approach and, it is a fact, there is no verification by a common body that such a process has been ever done, how and to which extent.

One possible result is that the selection and designation of NBs are conducted through processes that may differ significantly from a member state to another.

This phenomenon may just be amplified by the expansion of the EU leading to more Notified Bodies.

This in turn may lead to some difficulty to actually achieve the expectations of the Directive 94/9/EC

**Decrease of Ex product lines.**

It should be stressed that on a global basis, the testing and approval market, in EU (before and with expansion), is, slowly but clearly shrinking for various reasons :

Decrease of Ex lines of product through companies mergin. Leading, often, to lines harmonisation and reduction;

Difficulties to innovate (illustrated by the frequency of some exhibition changed from 1 year up to 3 years, see Explorisk);

Unfortunately, closing of companies.

**Multiplication of Notified Body.**

In the same time, the multiplication of Notified Bodies, is to be noted.

Three causes can be identified :

- Sometime, this multiplication is resulting from the request of some National Manufacturers Union put to their own member state, hopping to mainly reduce their lead time to market and subsequently hopping also to reduce the cost for getting a product tested and approved.

- Sometime, it is the result of the perception by some of new business opportunities. Although some competence may lack.

- And of course, it results from the expansion of the EU that brings new Notified Bodies.

It should be noted that, as a foreseeable result from the application of ANNEX XI of Directive 94/9/EC, the EU Commission has little power to actually regulate the process for becoming a Notified Body.

Resulting from the application of this annex, the selection and the designation of a notified body is the *privilege* of each individual member state.

**Threat on Safety**

The threat on safety lies in the relation between the actual market size for testing and approval of Ex product and the number of body "authorized" to perform this task.

**Why an expected decrease in quality of testing and approval?**

It is not surprising to expect that if there are too many bodies competing for a too small a market, the quality of testing and approval is bound to decrease.

The lead time of NBs might be reduced to such an extent that it might well become incompatible with the normal time requested by a standard.

This may first affect non subsidised companies, but may also affect subsidised companies because the general trend is to limit, today, human and equipment investment due to reduced expenses at level of state.

And because of such a number of bodies, by experience, no sufficiently harmonized practices can be really expected.

So "similar" services may be provided without the guarantee that the expected safety level for Ex certified product is, actually, met.

The (amazing?!) increase in NBs raises questions in relation to the mechanism whereby they are selected and then "Authorized".

It may, also, raise questions on a *de facto* absence of a global approach concerning the acceptable number of Notified bodies at the level of EU. This global approach being conducted in close coordination with all members states. The aim being to maintain the expected quality level.

One can just regret that for the moment being, in EU, no reflexion is being conducted on the possible necessity of this global assessment procedure of NBs. Would it be available and would the application of the procedure be verified by an appropriate entity, it would certainly contribute to ensure an appropriate equal level in terms of testing, approval and or auditing capability

It should be noted that this type of assessment is done, in good faith, according to each member state own procedures.

These procedures are not officially known and therefore are not yet harmonized through all the various member states. Bearing in mind that the Annex XI sets out minimum criteria only, but does not set out an actual detailed process nor provisions for a common verification of this process.

This situation is known to the member states.

Some of them through the Standing Committee, chaired by the Commission, tries with its support to
recommend minimum rules.

So far, no modification of the Directive has been recommended on this important issue. The relevant process for amending a Directive being difficult and long, may be a guide could be drafted and adopted by the member states.

**II-2 IECEx Scheme**

**Context**

The IECEx Scheme is not regional, it is international.

The founding principles are described in the IECEx 01 document.

The principle is that a "country" represented usually by its National Committee declares adherence to these founding principles. This adhesion is voluntary and results from a consensus within the country.

Once the country is a member, the process of accepting a Certification body and a Testing body belonging to this country starts.

These two entities are respectively ruled by the ISO Guide 65 and the ISO 17025.

This is a difference with the Notified Bodies where this distinction is not mandatory and somehow recent.

It means that the body doing the testing focuses all its energy to provide reliable results and that the body in charge of the certification is the body that conducts the process of evaluation (Test reports, drawings, manufacturer documentation, inspection of the product,…) and makes the certification recommendation and endorses it then the Certificate is issued.

The standards that are used are the relevant IEC standards that are very close to the relevant EN standards.

**Decrease of Ex product lines.**

The same phenomenon is observed at international scale for the very same reasons exposed above.

**Multiplication of Certification and Testing Body?**

The same observation **can not** be made, at this stage for three reasons :

- One is due to the fact it is a voluntary Scheme.
- Therefore a country must adhere first and pay a membership.
- A Certification and Testing Body of this country may not wish to participate to the scheme. For instance, because a membership is required by each Certification and Testing body, although it may not be yet accepted to operate the scheme.
- Or because the Certification and Testing Body does not wish to be submitted to the acceptation process.

Clearly the process of entering in the IECEx Scheme is demanding and is based on the **peer assessment process.**

**Peer Assessment**

An IECEx assessment team is composed, at minimum of two experienced auditors in the Ex field.

The rule of composing such a team imposes assessors coming from different continents.

The Certification Body and the testing body are assessed each for their specificity.

The assessment is concerned by the capability of the bodies that are assessed, in terms of Ex knowledge, organization, the existence of most of Ex testing tools, the confidentiality provisions, the actual accreditations e.g . : against ISO 65, ISO 17025, the actual experience of Ex testing.

Note : The assessment team will in the future certainly be composed, at least, of one or two experts from the IECEx assessment pool plus an
expert of an organisation dedicated to formal assessment like ILAC.

The lead assessor with the help of its assessors formulates corrective actions that have to be solved before a recommendation for acceptance can be presented to the Management Committee.

This approach allows to end up with bodies very close in terms of capability and practice.

There is also a provision whereby the Certification and testing body is to be regularly assessed to be maintained.

Al in all, this favours the minimum of harmonisation that is needed to reach the same quality level for the Certificate.

The points exposed above, also explains why the number of players is still limited.

This is a very positive point that contributes at its level to the quality of the IECEx Certificate.

Another positive points is the fact that an IECEx Certificate can only be issued if an **Ex T**est **R**eport **(ExTR)** has been produced (similar to the EC Type Examination Certificate in the ATEX scheme) and if a positive Quality Assessment Report **(QAR)** of the factory producing the Ex product has been produced. The interesting point is that whatever the product ,the QAR is based on a document that is identical to the reference document used when CAT 1 product are concerned (Annex IV requirements ) what ever the intended use .

The reference documents for the ATEX Scheme is the EN 13980 used in conjunction with Annex IV (CAT1 product) and with Annex VI(CAT 2 product).

**EN 13980 and OD IECEx 005**

Both document are, purposely, structured around the ISO 9001-2000.

ISO 9001-2000 is a Quality Management System based on Process Approach

A process is made of any linked activities managed in order to enable the transformation of inputs in outputs. Often output from one process directly forms the input to the next.

5 Processes have been identified :

Management Responsibility
Quality Management System
Resource Management
Product Realization

ISO9001-2000 requirements are complementary to requirements for product. It may be useful to remind that ISO 9001-2000 results from the merging of former ISO 9001-1994, ISO 9002-1994 and ISO 9003-1994.

IECEx OD 005 and EN-13980 last editions
set out IECEx and Ex EU Schemes requirements for manufacturers Quality Systems.

Both IECEx OD 005 and EN 13980
relates to Ex products and their production.

Within the 5 processes identified in
ISO 9001-2000, emphasis is deliberately given to
Product and Production parameters that may affect the integrity of an Ex Product

Therefore the use of ISO 9001-2000 structure
gives a quality frame that is normally not assessed if the manufacturer holds a valid ISO 9001-2000 certificate issued by a recognized body.

This approach brings the following benefit :

It is an opportunity to deal with *actual* manufacturing in relation with actual Ex features of the manufactured product.

If ISO 9001-2000 is good for the Manufacturer's

Image, it helps, in fact, meeting some of their customer expectations by improving the global company processes.

If ISO 9001-2000 focuses mainly on processes (organization), both IECEx OD 005 and EN 13980 focuse on actual Content of processes more than on processes themselves.

Therefore IECEx OD 005 and EN 13980 focuse on improved control of changes in production in relation to Ex features.

Therefore IECEx OD 005 and EN 13980 clearly contribute to maintain safety of produced Ex product over time.

IECEx OD 005 and EN 13980, when properly conducted, contribute to decrease the liability of the manufacturer.

Differences with ISO 9001-2000 have to be stressed :

IECEx OD 005 and EN 13980 IECEx OD 005 have **23** additional requirements to embrace the "good" manufacturing practices appropriate to Ex.

**The assessment under the two documents are product, production and technology oriented.**

The fact that the IECEx Scheme has chosen the most onerous approach is an additional asset in favor of the quality of the IECEx Certificates.

## III. CONCLUSIONS

If no appropriate actions are taken, one may fear that the credibility of the European Scheme that is mandatory, is threatened by the increasing number of Notified Body authorized to operate in a quasi stable market.

To remain credible some important changes have to be brought by the member states regarding the designation of a NB and their continuous acceptance. The notified bodies may also contribute by recommending systematically Annex IV whenever annex VII is authorised.

To remain credible, the IECEx Scheme, that is voluntary, shall make sure not to follow the same trend, in term of number of player. For that purpose it should think on how to improve its present rules to control efficiently the number of IECEx members in order to develop the best harmonized practices in relation to Ex safety requirements.

This article has briefly reviewed the conditions whereby the two Schemes could remain credible in the short term and consequently secure their own future bearing in mind that it is the interest of end users, regulatory authorities and manufacturers to, respectively, buy, accept and sell safe Ex product.

## IV. Nomenclature

*Scheme* All the rules pertaining to a process, here a Testing and Approval Process conducted by a third Party
*Third Party* A body which is not a manufacturer or a client of these manufacturer. It can be private or state owned.
*EU* European Union (includes also EFTA)
*EFTA* European Free Trade Association
*NB* Notified Bodies
*ACB* Certification Body within the IECEx Scheme

## V. REFERENCES


Directive 94/9/EC
Guideline to Directive 94/9/EC
ExNB Group decisions Sheet available on

http://europa.eu.int/comm/enterprise/atex/indexinfor.htm

Public Information available from www.IECEx.com

IECEx 01 and IECEx (Rules of Procedure) 02 last edition


## VI. VITA

Michel Brénon between 1975 and 1978 teaches Chemical Engineering at Compiègne University and is in charge of research on hydrodynamic of fluidized bed.
In 1983, he is Head of Applied Research at Good-Year Chemicals Division Technical Center.
In 1994, he is Process and Instrumentation Manager in a subsidiary of Groupe Bertin that designs specific equipment for the Chemical and Pharmaceutical industry.
In Sept 1994, he joins LCIE and is in charge of the ATEX Dpt.
He is now the Director for Certification of BV/LCIE.
From 1996 to 1998 for the IEC TC 31, he iss Secretary of the SC 31 D. From 1997 to 2001, he is the first Chairman of the ExNB Group. He is, at the moment, Officer of the Management Committee of the IECEX Scheme and Secretary of the ExTAG.