ENVIRONMENTAL LEGISLATION APPLICABLE TO INDUSTRIAL AND MEDICAL GAS OPERATIONS WITHIN THE EU

Doc 108/20

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Prepared by WG-5 Environment

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Amendments to 108/14

Section	Change
	Editorial to align style with EIGA style manual
4.2	Update from ISO 14001
Appendix 1	Update to latest directives, regulations, decisions
Appendix 2	Update to latest directives, regulations, decisions
Appendix 3	Update to latest directives, regulations, decisions
Appendix 4	Update to latest directives, regulations, decisions
Appendix 5	Update to latest directives, regulations, decisions
Appendix 6	Update to latest directives, regulations, decisions
Appendix 7	Update to latest directives, regulations, decisions
Appendix 8	Update to latest directives, regulations, decisions

NOTE Technical changes from the previous edition are underlined

1 Introduction

This publication is confined to discussion of environmental legislation that originate from the European Union. Whilst there is a wide variety of environmental legislation in each member state, the main driving force comes from the EU with over 400 legislative instruments put in place since 2001.

2 Scope and purpose

2.1 Scope

This publication provides guidance on European legislation concerning the main environmental aspects relevant to the industrial and medical gas industry. In all cases the relevant national legislation should be consulted for specific implementation in each country or region.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Environmental aspect

Elements of an organisation's activities, products or services that can interact with the environment. For example, use of energy or transportation of products.

3.2.2 Environmental impact

Any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organization's environmental aspects as per ISO 14001, *Environmental Management Systems – Requirements with Guidance for Use*, [1]. [1] For example, the contamination of water with hazardous substances or the reduction of air emissions.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.

4 Environmental legislation relevant to the industrial gases industry

4.1 General environmental aspects and impacts and links to other EIGA publications

This publication covers in detail the legislation concerning industrial gas operations. There are a series of EIGA publications that provide more general details on environmental aspects, legislation for the gas industry and good operational, environmental practices. A list of these publications is provided in Appendix 1.

4.2 Background

Each company and site shall be aware of the relevant environmental legislation so that they can comply.

In addition, ISO 14001 and the European Eco-Management and Audit scheme (EMAS) requires that the organisation has identified applicable legal requirements (and voluntary initiatives such as Responsible Care®) [1, 2].

ISO 14001 states in clause 6.1.2 [1]:

"Within the defined scope of the environmental management system, the organization shall determine the environmental aspects of its activities, products and services that it can control and those that it can influence, and their associated environmental impacts, considering a life cycle perspective".

4.3 EU legislation

4.3.1 Principles of EU legislation

The purpose of legislation is usually harmonisation of the laws to promote free trade and movement of goods under Articles 27 and 28 of the consolidated version of the Treaty on the Functioning of the European Union, but this cannot be done at the expense of the environment [3]. There are also community measures dealing with specific environmental issues under Article 191 [3]. The legislation sets policy and introduces common standards for the protection of the environment. The implementation is therefore up to the member states. International agreements and conventions such as Montreal and Kyoto protocols, Basel Convention etc. also influence EU legislation [4, 5, 6].

The EU Commission sets the long-term plans for legislation and strategy. Prior to the formal publication of legislation, the Commission produces discussion documents (green and white papers) to get feedback from industry and other stakeholders (non-governmental organisations, consumer groups etc.), and conducts public consultations.

4.3.2 Strategy and action programmes

The EU legislative programme is organised around strategic action programmes. These define the actions to be taken or the principles to be applied in a 5 to 7 year time period.

Typical principles of the action programmes include:

- polluter pays;
- integration of environmental considerations into other policy areas;
- prevention is better than cure;
- no transfer across media, i.e. air, water, land; and
- sustainable development.

4.3.3 The legislative process

The legislative process is:

1. The Commission proposes legislation. It is a non-elected body made up of nominated representatives from the member states. Major departments involved with environmental legislation are DG Environment and DG Climate.

2. The European Parliament is an elected body with committees that give opinions on the Commission's proposals, and in some cases, for example environmental issues, they have the power to veto commission proposals under the powers of co decision in the Amsterdam treaty.

3. The Council of Ministers is made up of member states' representatives and has a veto on some issues such as taxation.

4. The European Court of Justice decides on points of EU law, though these normally come via the judicial process in each member state.

4.3.4 Types of EU legislation

There are three main types of EU legislation:

- Directives are addressed to member states who shall implement them in their own legislation for them to have effect. Directives set the objectives and are binding as to the result to be achieved. Member states are thus required to interpret the directives and give then the force of law in their own jurisdictions. Member states can go over and above the requirements of a directive for reasons of enhancing environmental protection.

- Regulations are effective immediately in the member states with no implementing legislation necessary, for example the regulation on ozone depleting substances.

- Decisions are also effective immediately, and are mostly administrative in nature, for example the waste list.

In addition, the commission can adopt delegated acts.

A delegated act is a non-legislative act of general application adopted by the Commission to supplement or amend certain non-essential elements of a basic legislative act (EU regulation or directive) (Article 290 of the Treaty on the Functioning of the European Union) [3].

For example:

- under the Regulation (EU) 528/2012 *concerning the making available on the market and use of biocidal products*, adapt the definition of nanomaterial; specify the scientific criteria for determining endocrine-disrupting properties [7];

- under the Seveso III directive (Directive 2012/18/EU *on the control of major-accident hazards involving dangerous substances*), adapt Annex II (minimum data to be considered in the safety report) and IV (criteria for the notification of a major accident to the commission) to technical progress [8]; and

- under the Industrial Emissions Directive (Directive 2010/75/EU *on industrial emissions*), set the date from which continuous measurement of emissions of heavy metals, dioxins and furans into the air are to be carried out [9].

4.3.5 Scope of legislation

Many of the regulations are written with a wide remit without an understanding of how they could affect specialised sectors such as industrial gases. This can lead to anomalies that need to be addressed at

the appropriate point in the legislative process. The decisions on environmental issues are taken at many different levels.

4.3.6 Local and national legislation

EU legislation is implemented in national and local regulations. A timeframe is established to implement each directive so it is possible for them to be implemented with different interpretations and at different times in each member state.

4.4 Compliance with new and existing legislation

4.4.1 Tracking new EU legislation

The EIGA office receives publications from the Commission (the Official Journal) directly and also has information from working group experts, other trade associations (such as CEFIC, UNICE see 4.4.4.1), EIGA members and associations, publications and monitoring services. This information is passed to the relevant working group, which decides if action is needed to produce guidance for the members and tracks the progress. The working group process is described in the EIGA Doc 901, *Working Group Expert Guide* [10].

4.4.2 Consulting on new EU legislation

Input into legislation is possible at various steps in the process. The original drafting is usually done by the Commission and contact can be made with the officials involved or via other trade associations. However, it is sometimes difficult to identify how the more general framework legislation will be interpreted.

Often the framework legislation is developed further at EU level with standards, annexes or other documents. These are developed in conjunction with experts from member states, so the input from national associations or other EIGA members in those countries is a crucial part of the process. Standards organisations such as CEN (see 4.4.4.2) and ISO (see 4.4.4.3) are usually not involved, which can make these publications more difficult to influence.

The legislation is then transposed into national and local regulations in the member states. This can lead to different interpretations that also can be fed back into the European documents. Again, input from, and communication with, EIGA members in these countries can be critical.

4.4.3 Tracking information at each site or company

To identify and satisfy the relevant legal requirements and / or ISO 14001, each company and site needs to establish a process to manage the legal information from EIGA and other sources [1]. This should include regular communication of the requirements to relevant employees (for example from bulletins, newsletters and electronic information) and updates to relevant standards, procedures and training. It is important that any unexpected interpretation or European legislation that differs from the EIGA interpretation is communicated back to EIGA.

4.4.4 Sources of information

4.4.4.1 Trade associations and non-government organisations

EIGA	European Industrial Gases Association	www.eiga.eu
CEFIC	The European Chemical Industry Council	www.cefic.org
BUSINESSEUROPE		www.businesseurope.eu
WBCSD	World Business Council for Sustainable Development	www.wbcsd.org

UNESDA	Union of European Soft Drinks Associations	www.unesda.org
EUROFER	European Steel Association	www.eurofer.org
Fuels Europe	Refining and marketing industry in Europe	www.fuelseurope.eu
AEGPL	European Liquefied Petroleum Gas Association	www.aegpl.eu
ECMA	European Cylinder Makers Association	www.ecma.info

4.4.4.2 European law and standardisation

Euro-Lex	EU law and other public EU documents, Official Journal of the EU	www.europa.eu
EEA	European Environment Agency	www.eea.europa.eu
EIPPCB	European IPPC Bureau	eippcb.jrc.ec.europa.eu
CEN	European Committee for Standardisation	www.cen.eu

4.4.4.3 International law and standardisation

OECD	Organisation for Economic Co-operation and Development	www.oecd.org
UNEP	United Nations Environment Programme	www.unep.org
ISO	International Organization for Standardization	www.iso.org

4.5 European Union environmental legislation applicable to industrial gas operations

The attached tables in Appendices 2 to 8 provide a summary of the main European environmental legislation that could impact industrial gas operations. More details are provided in publication EIGA Doc 106, *Environmental Issues Guide* [11]. The legislation included in these tables is that which has a direct or possible indirect impact on EIGA members. Legislation with no obvious impact (for example, noise levels for sub-sonic aircraft) does not appear on the list.

5 References

Unless otherwise specified, the latest edition shall apply.

[1] ISO 14001, *Environmental Management Systems – Requirements with guidance for use*, www.iso.org.

[2] European Union Eco-Management and Audit scheme (EMAS), www.ec.europa.eu/environment/emas.

[3] Treaty on the Functioning of the European Union, www.europa.eu.

[4] The Montreal Protocol, www.unenvironment.org.

[5] The Kyoto Protocol, www.unfccc.int.

[6] The Basel Convention, www.basel.int.

[7] Regulation (EU) 528/2012 *concerning the making available on the market and use of biocidal products*, www.europa.eu.

[8] Directive 2012/18/EU *on the control of major-accident hazards involving dangerous substances*, www.europa.eu.

[9] Directive 2010/75/EU *on industrial emissions*, www.europa.eu.

[10] EIGA Doc 901, *Working Group Expert Guide*, www.eiga.eu.

[11] EIGA Doc 106, *Environmental Issues Guide*, www.eiga.eu.

[12] EIGA TB20, *Baseline Reports for Industrial Emissions Directive Sites*, www.eiga.eu.

[13] EIGA Doc 192, *Fluorinated Gases Management*, www.eiga.eu.

[14] EIGA Doc 85, *Noise Management*, www.eiga.eu.

[15] EIGA Doc 60, *Seveso Documents - Guidance on Applicability, Assessment and Legal Documents for Demonstrating Compliance of Industrial Gases Facilities with Seveso Directive(s)*, www.eiga.eu.

NOTE For European Union Directives, Regulations and Treaties referenced in Appendices 2 to 8 please see www.europa.eu.

Appendix 1 EIGA Document Links to ISO 14001

EIGA Doc	Title of EIGA document	ISO 14001 sections	Clause
107	*Guidelines on Environmental Management Systems*	Determining the scope of the environmental management system	4.3
		Environmental Policy	5.2
		Planning	6
		Environmental objectives and planning to achieve them	6.2
		Operational planning and control	8.1
		Organisational roles, responsibilities and authorities	5.3
		Competence	7.2
		Communication	7.4
		Documented information	7.5
		Control of documented information	7.5.3
		Emergency Preparedness and response	8.2
		Performance evaluation	9
		Monitoring and measurement analysis and evaluation	9.1
		Evaluation of compliance	9.1.2
		Non-conformity and corrective action	10.2
		Management review	9.3
106	*Environmental issues guide*	Environmental aspects	6.1.2
108	*Environmental Legislation guide*	Compliance obligations	6.1.3
30	*Disposal of Gases*	Operational planning and control	8.1
85	*Noise Management for the industrial gas industry*	Operational planning and control	8.1
88	*Good Environmental Management Practices for the industrial gas industry*	Operational planning and control	8.1
109	*Environmental Impacts of Acetylene plants*	Operational planning and control	8.1
84	*Calculation of Air Emissions from Acetylene Plants*	Operational planning and control	8.1
05	*Guidelines for the management of waste acetylene cylinders*	Operational planning and control	8.1
94	*Environmental Impacts of Air Separation Units*	Operational planning and control	8.1
110	*Environmental Impacts of Cylinder Filling Plants*	Operational planning and control	8.1
117	*Environmental Impacts of Customer Installations*	Operational planning and control	8.1
111	*Environmental Impacts of Carbon Dioxide and Dry Ice Production*	Operational planning and control	8.1
122	*Environmental. Impacts of Hydrogen Plants*	Operational planning and control	8.1
112	*Environ. Impacts of Nitrous Oxide Plants*	Operational planning and control	8.1
113	*Environmental Impacts of Transportation of Gases*	Operational planning and control	8.1
137	*Decommissioning*	Operational planning and control	8.1
135	*Environmental auditing guide*	Internal audit programme	9.2.2

Appendix 2 Legislation – Permits

Number	Type	Description	Impact on gas industry
2003/87/EC	Directive	EU Emissions trading scheme	HYCO and energy plants (boilers COGEN) need to have GHG permits and surrender allowances, ASUs not covered
2008/1/EC	Directive	Integrated Pollution Prevention and Control Directive (replaces 96/61/EC)	Acetylene and Hydrogen plants N_20 plants, speciality gas production and organometallics, ASUs excluded. See EIGA Doc 106 [11]
2010/75/EU	Directive	Industrial Emissions Directive (IED) (replaces 96/61/EC)	Included: Acetylene and Hydrogen plants, N_2O plants, speciality gas production and organometallics, CO and CO_2 plants and cylinder painting or cleaning activities of more than 2 tonnes of VOC per year. Excluded: ASU, cylinder filling. EIGA Doc 106 and EIGA TB 20, *Baseline Reports for Industrial Emissions Directive Sites* [12]
2014/52/EU	Directive	Environmental Impact Directive on the assessment of the effects of certain public and private projects on the environment (replaces 2011/92/EU)	Very large-scale projects may require this as part of getting the permit, large groundwater abstractions for ASU may need assessment

Appendix 3 Legislation – Environmental management

Number	Type	Description	Impact on gas industry
401/2009	Regulation	On the European Environmental Agency	None
97/265/EC	Decision	Adoption of ISO 14001 as recognised standard for EMAS	None, adoption of ISO 14001 as recognised standard for EMAS
2001/42/EC	Directive	Assessment of the effects of certain plans and programmes on the environment (replaces 96/511/EC)	None
2004/35/CE	Directive	On environmental liability with regard to the prevention and remedying of environmental damage	Sets framework for liability for environmental damage
2007/747/EC	Decision	Recognition of accreditation procedures for EMAS	None for information only
2009/1221	Regulation	Allowing voluntary participation by companies in the industrial sector in a community eco-management and audit scheme (replaces 761/2001)	None, voluntary scheme
2010/75/EU	Directive	Industrial Emissions Directive (IED) (replaces 96/61/EC)	Included: Acetylene and Hydrogen plants, N_20 plants, speciality gas production and organometallics, CO and CO_2 plants and cylinder painting or cleaning activities of more than 2 tonnes of VOC per year. Excluded: ASU, Cylinder filling. See EIGA Doc 106 [11]
2011/92/EU	Directive	On the assessment of the effects of certain public and private projects on the environment (replaces 85/337/EEC)	Very large-scale projects may require this as part of getting the permit, large groundwater abstractions for ASU may need asses

Appendix 4 Legislation – Waste

Number	Type	Description	Impact on Gases Industry
86/278/EEC	Directive	On the protection of the environment and in particular of the soil, when sewage sludge is used in agriculture	Impacts the use of lime as a soil conditioner, as contains reference standards
94/62/EC	Directive	On packaging and packaging waste	See EIGA Doc 106 [11]
COM/96/191	Resolution	Identification and marking of Packaging Material, daughter directive to packaging waste 94/3/EC	None as the system is voluntary
96/59/EC	Directive	on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (replaces directive 76/403)	Transformers and capacitors containing PCBs (>50 ppm) need to be identified and plans to remove, see EIGA Doc 106 [11]
97/640/EC	Regulation	Convention on the control of trans-boundary movements of hazardous wastes and their disposal (Basel Convention)	Waste shipments shall comply, see EIGA Doc 106 [11].
99/31/EC	Directive	On the landfill of waste	Restrictions on landfilling of acetylene cylinders will be extended to all countries. Lime ponds may be classified as landfill
2000/532/EC	Decision	Establishing a list of wastes (combined hazardous and non-hazardous)	Revised with hazardous waste list incorporated. See EIGA Doc 106 [11].
2003/33/EC	Decision	On establishing criteria and procedures for the acceptance of waste at Landfill	Restrictions on landfilling of acetylene cylinders will be extended to all countries.
2006/66	Directive	On batteries and accumulators containing certain dangerous substances (replaces 91/157/EEC)	None
2006/117/Euratom	Directive	On the supervision and control of shipments of radioactive waste between Member States and into and out of the Community	None
1013/2006	Regulation	On shipments of waste within, into and out of the European Community	Waste shipments shall comply, see EIGA Doc 106 [11]

Number	Type	Description	Impact on Gases Industry
1418/2007	Regulation	Decision on control procedure for waste shipments to certain non-OECD countries (replaces 2007/801)	Waste shipments shall comply, see EIGA Doc 106 [11]
2008/98/EC	Directive	Replaces directive on hazardous waste 91/689/EEC, directive on the disposal of waste oils 75/439/EEC and 2006/12/EC waste directive	See EIGA Doc 106 [11]
2010/75/EU	Directive	Industrial Emissions Directive (IED) (replaces 96/61/EC)	Included: Acetylene and Hydrogen plants, N_2O plants, speciality gas production and organometallics, CO and CO_2 plants and cylinder painting or cleaning activities of more than 2 tonnes of VOC per year. Excluded: ASU, cylinder filling. See EIGA Doc 106 [11]
2012/19/EU	Directive	Directive on Waste Electrical and Electronic Equipment (replaces 2008/34/EC)	Users of electronic equipment may pay more for disposal in addition there shall be means of take back.

Appendix 5 Legislation – Air

Number	Type	Description	Impact on Gases Industry
87/217/EEC	Directive	On the prevention and reduction of environmental pollution by asbestos	See EIGA Doc 106 [11]
94/63/EC	Directive	On the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from term	None
2001/81/EC	Directive	Directive on national emission ceilings for certain atmospheric pollutants	Large HYCO plants >50 MWh may be impacted. Tightening of permit conditions (NO_X emissions) especially for new plant
2008/50/EC	Directive	Directive on ambient air quality and cleaner air for Europe (Replaces 96/62/EC)	Indirect, this directive establishes the policy framework within which limit values for air pollutants are set.
2009/1005	Regulation	On substances that deplete the ozone layer (replaces 2037/2000)	Further restrictions on the use of HCFCs, Halons and CFCs see EIGA Doc 106 [11]
2010/75/EU	Directive	On industrial emissions (integrated pollution prevention and control) (replaces 1999/13/EC)	Included: Acetylene and Hydrogen plants, N_2O plants, speciality gas production and organometallics, CO and CO_2 plants and cylinder painting or cleaning activities of more than 2 tonnes of VOC per year. Excluded: ASU, cylinder filling. Will affect some tank painting or cleaning operations where large volumes of paint and solvent are used See EIGA Doc 106 [11]
517/2014	Regulation	On fluorinated greenhouse gases (Replaces 842/2006)	Gas industry is user of F-gases in stationary applications such as refrigeration equipment, air conditioning and heat pump equipment, including their circuits, as well as fire protection equipment. See EIGA Doc 192, *Fluorinated Gases Management* [13].

Appendix 6 Legislation – Water

Number	Type	Description	Impact on Gases Industry
91/271/EEC	Directive	Concerning urban wastewater treatment	As standards are tightened, discharge consents will also get more stringent
COM/96/315	Proposal	Action Programme on integrated groundwater protection and Management	May effect abstractions for ASUs
98/83/EC	Directive	On the quality of water for human consumption	None
2000/60/EC	Directive	Water framework directive. Proposal for establishing a framework for community action in the field of water policy,	May impact cooling water discharge (Copper limits).
2006/7/EC	Directive	Concerning the management of bathing water quality (replaces 76/160/EEC)	Wastewater discharges shall conform
2008/105/EC	Directive	On environmental quality standards in the field of water policy	Wastewater discharges shall conform
2010/75/EU	Directive	On industrial emissions (integrated pollution prevention and control)	See EIGA Doc 106 [11]

Appendix 7 Legislation – Noise

Number	Type	Description	Impact on Gases Industry
2000/14/EC	Directive	On the approximation of the laws of the member states relating to the noise emission in the environment by equipment for use outdoors	Purchased equipment needs to meet the required noise standard. See EIGA Doc 85, *Noise management* [14]
2002/49/EC	Directive	This directive defines a common approach intended to avoid, prevent or reduce the harmful effects of exposure to environmental noise	Could lead to more restrictive noise limits for facilities; see EIGA Doc 85 [14]
2003/10/EC	Directive	Regarding the exposure of workers to the risks arising from physical agents (noise)	See EIGA Doc 85 [14]

Appendix 8 Legislation – Hazardous substances

Number	Type	Description	Impact on Gases Industry
96/59/EC	Directive	On the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)	Transformers and capacitors containing PCBs (>50 ppm) need to be identified and plans to remove, see Doc 106 [11]
98/24/EC	Directive	On the protection of the health and safety of workers from the risks related to chemical agents at work	Safety Advisory Council
2006/66/EC	Directive	On batteries and accumulators containing certain dangerous substances (replaces 91/157/EEC)	None
1907/2006	Regulation	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Obligation for registration, SDS, restrictions.
1272/2008	Regulation	Classification, labelling and packaging of substances and mixtures, (CLP) (amending 1907/2006)	Classification, labelling and packaging of gases
2012/18/EU	Directive	Control of major accident hazards involving dangerous substances (replaces 96/82/EC)	See EIGA Doc 60, *Prevention of major accidents. Guidance on Compliance with the Seveso II Directive* [15]
2017/2398	Directive	On the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Replaces 2004/37/EC)	Safety Advisory Council