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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/2117

of 21 November 2017

establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of large volume organic chemicals

(notified under document C(2017) 7469)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) ([1]), and in particular Article 13(5) thereof,

Whereas:

(1) Best available techniques (BAT) conclusions are the reference for setting permit conditions for installations covered by Chapter II of Directive 2010/75/EU and competent authorities should set emission limit values which ensure that, under normal operating conditions, emissions do not exceed the emission levels associated with the best available techniques as laid down in the BAT conclusions.

(2) The forum composed of representatives of Member States, the industries concerned and non-governmental organisations promoting environmental protection, established by Commission Decision of 16 May 2011 ([2]), provided the Commission on 5 April 2017 with its opinion on the proposed content of the BAT reference document for the production of large volume organic chemicals. That opinion is publicly available.

(3) The BAT conclusions set out in the Annex to this Decision are the key element of that BAT reference document.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 75(1) of Directive 2010/75/EU,

HAS ADOPTED THIS DECISION:

Article 1

The best available techniques (BAT) conclusions for the production of large volume organic chemicals, as set out in the Annex, are adopted.

([1]) OJ L 334, 17.12.2010, p. 17.
([2]) Commission Decision of 16 May 2011 establishing a forum for the exchange of information pursuant to Article 13 of the Directive 2010/75/EU on industrial emissions (OJ C 146, 17.5.2011, p. 3).

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 21 November 2017.

For the Commission
Karmenu VELLA
Member of the Commission

ANNEX

BEST AVAILABLE TECHNIQUES (BAT) CONCLUSIONS FOR THE PRODUCTION OF LARGE VOLUME ORGANIC CHEMICALS

SCOPE

These BAT conclusions concern the production of the following organic chemicals, as specified in Section 4.1 of Annex I to Directive 2010/75/EU:

(a) simple hydrocarbons (linear or cyclic, saturated or unsaturated, aliphatic or aromatic);

(b) oxygen-containing hydrocarbons such as alcohols, aldehydes, ketones, carboxylic acids, esters and mixtures of esters, acetates, ethers, peroxides and epoxy resins;

(c) sulphurous hydrocarbons;

(d) nitrogenous hydrocarbons such as amines, amides, nitrous compounds, nitro compounds or nitrate compounds, nitriles, cyanates, isocyanates;

(e) phosphorus-containing hydrocarbons;

(f) halogenic hydrocarbons;

(g) organometallic compounds;

(k) surface-active agents and surfactants.

These BAT conclusions also cover the production of hydrogen peroxide as specified in Section 4.2(e) of Annex I to Directive 2010/75/EU.

These BAT conclusions cover combustion of fuels in process furnaces/heaters, where this is part of the abovementioned activities.

These BAT conclusions cover production of the aforementioned chemicals in continuous processes where the total production capacity of those chemicals exceeds 20 kt/year.

These BAT conclusions do not address the following:

— combustion of fuels other than in a process furnace/heater or a thermal/catalytic oxidiser; this may be covered by the BAT conclusions for Large Combustion Plants (LCP);

— incineration of waste; this may be covered by the BAT conclusions for Waste Incineration (WI);

— ethanol production taking place on an installation covered by the activity description in Section 6.4(b)(ii) of Annex I to Directive 2010/75/EU or covered as a directly associated activity to such an installation; this may be covered by the BAT conclusions for Food, Drink and Milk Industries (FDM).

Other BAT conclusions which are complementary for the activities covered by these BAT conclusions include:

— Common Waste Water/Waste Gas Treatment/Management Systems in the Chemical Sector (CWW);

— Common Waste Gas Treatment in the Chemical Sector (WGC).

Other BAT conclusions and reference documents which may be of relevance for the activities covered by these BAT conclusions are the following:

— Economics and Cross-media Effects (ECM);

— Emissions from Storage (EFS);

— Energy Efficiency (ENE);

— Industrial Cooling Systems (ICS);

— Large Combustion Plants (LCP);

— Refining of Mineral Oil and Gas (REF);

— Monitoring of Emissions to Air and Water from IED installations (ROM);

— Waste Incineration (WI);

— Waste Treatment (WT).

GENERAL CONSIDERATIONS

Best Available Techniques

The techniques listed and described in these BAT conclusions are neither prescriptive nor exhaustive. Other techniques may be used that ensure at least an equivalent level of environmental protection.

Unless otherwise stated, the BAT conclusions are generally applicable.

Averaging periods and reference conditions for emissions to air

Unless stated otherwise, the emission levels associated with the best available techniques (BAT-AELs) for emissions to air given in these BAT conclusions refer to values of concentration, expressed as mass of emitted substance per volume of waste gas under standard conditions (dry gas at a temperature of 273,15 K, and a pressure of 101,3 kPa), and expressed in the unit mg/Nm^3.

Unless stated otherwise, the averaging periods associated with the BAT-AELs for emissions to air are defined as follows.

Type of measurement	Averaging period	Definition
Continuous	Daily average	Average over a period of 1 day based on valid hourly or half-hourly averages
Periodic	Average over the sampling period	Average of three consecutive measurements of at least 30 minutes each (1) (2)

(1) For any parameter where, due to sampling or analytical limitations, 30-minute sampling is inappropriate, a suitable sampling period is employed.
(2) For PCDD/F, a sampling period of 6 to 8 hours is used.

Where BAT-AELs refer to specific emission loads, expressed as load of emitted substance per unit of production output, the average specific emission loads l_s are calculated using Equation 1:

Equation 1: $$l_s = \frac{1}{n}\sum_{i=1}^{n}\frac{c_i q_i}{p_i}$$

where:

n = number of measurement periods;

c_i = average concentration of the substance during i^{th} measurement period;

q_i = average flow rate during i^{th} measurement period;

p_i = production output during i^{th} measurement period.

Reference oxygen level

For process furnaces/heaters, the reference oxygen level of the waste gases (O_R) is 3 vol-%.

Conversion to reference oxygen level

The emission concentration at the reference oxygen level is calculated using Equation 2:

Equation 2: $$E_R = \frac{21 - O_R}{21 - O_M} \times E_M$$

where:

E_R = emission concentration at the reference oxygen level O_R;

O_R = reference oxygen level in vol-%;

E_M = measured emission concentration;

O_M = measured oxygen level in vol-%.

Averaging periods for emissions to water

Unless stated otherwise, the averaging periods associated with the environmental performance levels associated with the best available techniques (BAT-AEPLs) for emissions to water expressed in concentrations are defined as follows.

Averaging period	Definition
Average of values obtained during one month	Flow-weighted average value from 24-hour flow-proportional composite samples obtained during 1 month under normal operating conditions (1)
Average of values obtained during one year	Flow-weighted average value from 24-hour flow-proportional composite samples obtained during 1 year under normal operating conditions (1)

(1) Time-proportional composite samples can be used provided that sufficient flow stability can be demonstrated.

Flow-weighted average concentrations of the parameter (c_w) are calculated using Equation 3:

Equation 3: $$c_w = \sum_{i=1}^{n} c_i q_i / \sum_{i=1}^{n} q_i$$

where:

n = number of measurement periods;

c_i = average concentration of the parameter during i^{th} measurement period;

q_i = average flow rate during i^{th} measurement period.

Where BAT-AEPLs refer to specific emission loads, expressed as load of emitted substance per unit of production output, the average specific emission loads are calculated using Equation 1.

Acronyms and definitions

For the purposes of these BAT conclusions, the following acronyms and definitions apply.

Term used	Definition
BAT-AEPL	Environmental performance level associated with BAT, as described in Commission Implementing Decision 2012/119/EU (1). BAT-AEPLs include emission levels associated with the best available techniques (BAT-AELs) as defined in Article 3(13) of Directive 2010/75/EU
BTX	Collective term for benzene, toluene and ortho-/meta-/para-xylene or mixtures thereof
CO	Carbon monoxide

Term used	Definition
Combustion unit	Any technical apparatus in which fuels are oxidised in order to use the heat thus generated. Combustion units include boilers, engines, turbines and process furnaces/heaters, but do not include waste gas treatment units (e.g. a thermal/catalytic oxidiser used for the abatement of organic compounds)
Continuous measurement	Measurement using an 'automated measuring system' permanently installed on site
Continuous process	A process in which the raw materials are fed continuously into the reactor with the reaction products then fed into connected downstream separation and/or recovery units
Copper	The sum of copper and its compounds, in dissolved or particulate form, expressed as Cu
DNT	Dinitrotoluene
EB	Ethylbenzene
EDC	Ethylene dichloride
EG	Ethylene glycols
EO	Ethylene oxide
Ethanolamines	Collective term for monoethanolamine, diethanolamine and triethanolamine, or mixtures thereof
Ethylene glycols	Collective term for monoethylene glycol, diethylene glycol and triethylene glycol, or mixtures thereof
Existing plant	A plant that is not a new plant
Existing unit	A unit that is not a new unit
Flue-gas	The exhaust gas exiting a combustion unit
I-TEQ	International toxic equivalent – derived by using the international toxic equivalence factors, as defined in Annex VI, part 2 to Directive 2010/75/EU
Lower olefins	Collective term for ethylene, propylene, butylene and butadiene, or mixtures thereof
Major plant upgrade	A major change in the design or technology of a plant with major adjustments or replacements of the process and/or abatement units and associated equipment
MDA	Methylene diphenyl diamine
MDI	Methylene diphenyl diisocyanate
MDI plant	Plant for the production of MDI from MDA via phosgenation
New plant	A plant first permitted on the site of the installation following the publication of these BAT conclusions or a complete replacement of a plant following the publication of these BAT conclusions
New unit	A unit first permitted following the publication of these BAT conclusions or a complete replacement of a unit following the publication of these BAT conclusions

Term used	Definition
NO_X precursors	Nitrogen-containing compounds (e.g. ammonia, nitrous gases and nitrogen-containing organic compounds) in the input to a thermal treatment that lead to NO_X emissions. Elementary nitrogen is not included
PCDD/F	Polychlorinated dibenzo-dioxins and -furans
Periodic measurement	Measurement at specified time intervals using manual or automated methods
Process furnace/heater	Process furnaces or heaters are: — combustion units whose flue-gases are used for the thermal treatment of objects or feed material through direct contact, e.g. in drying processes or chemical reactors; or — combustion units whose radiant and/or conductive heat is transferred to objects or feed material through a solid wall without using an intermediary heat transfer fluid, e.g. furnaces or reactors heating a process stream used in the (petro-)chemical industry such as steam cracker furnaces. It should be noted that, as a consequence of the application of good energy recovery practices, some of the process furnaces/heaters may have an associated steam/electricity generation system. This is considered to be an integral design feature of the process furnace/heater that cannot be considered in isolation.
Process off-gas	The gas leaving a process which is further treated for recovery and/or abatement
NO_X	The sum of nitrogen monoxide (NO) and nitrogen dioxide (NO_2), expressed as NO_2
Residues	Substances or objects generated by the activities covered by the scope of this document, as waste or by-products
RTO	Regenerative thermal oxidiser
SCR	Selective catalytic reduction
SMPO	Styrene monomer and propylene oxide
SNCR	Selective non-catalytic reduction
SRU	Sulphur recovery unit
TDA	Toluene diamine
TDI	Toluene diisocyanate
TDI plant	Plant for the production of TDI from TDA via phosgenation
TOC	Total organic carbon, expressed as C; includes all organic compounds (in water)
Total suspended solids (TSS)	Mass concentration of all suspended solids, measured via filtration through glass fibre filters and gravimetry
TVOC	Total volatile organic carbon; total volatile organic compounds which are measured by a flame ionisation detector (FID) and expressed as total carbon
Unit	A segment/subpart of a plant in which a specific process or operation is carried out (e.g. reactor, scrubber, distillation column). Units can be new units or existing units

Term used	Definition
Valid hourly or half-hourly average	An hourly (or half-hourly) average is considered valid when there is no maintenance or malfunction of the automated measuring system
VCM	Vinyl chloride monomer
VOCs	Volatile organic compounds as defined in Article 3(45) of Directive 2010/75/EU

([1]) Commission Implementing Decision 2012/119/EU of 10 February 2012 laying down rules concerning guidance on the collection of data and on the drawing up of BAT reference documents and on their quality assurance referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions (OJ L 63, 2.3.2012, p. 1).

1. GENERAL BAT CONCLUSIONS

The sector-specific BAT conclusions included in Sections 2 to 11 apply in addition to the general BAT conclusions given in this section.

1.1. Monitoring of emissions to air

BAT 1: BAT is to monitor channelled emissions to air from process furnaces/heaters in accordance with EN standards and with at least the minimum frequency given in the table below. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.

Substance/Parameter	Standard(s) ([1])	Total rated thermal input (MW_{th}) ([2])	Minimum monitoring frequency ([3])	Monitoring associated with
CO	Generic EN standards	≥ 50	Continuous	Table 2.1, Table 10.1
	EN 15058	10 to < 50	Once every 3 months ([4])	
Dust ([5])	Generic EN standards and EN 13284-2	≥ 50	Continuous	BAT 5
	EN 13284-1	10 to < 50	Once every 3 months ([4])	
NH_3 ([6])	Generic EN standards	≥ 50	Continuous	BAT 7, Table 2.1
	No EN standard available	10 to < 50	Once every 3 months ([4])	
NO_X	Generic EN standards	≥ 50	Continuous	BAT 4, Table 2.1, Table 10.1
	EN 14792	10 to < 50	Once every 3 months ([4])	
SO_2 ([7])	Generic EN standards	≥ 50	Continuous	BAT 6
	EN 14791	10 to < 50	Once every 3 months ([4])	

([1]) Generic EN standards for continuous measurements are EN 15267-1, -2, and -3, and EN 14181. EN standards for periodic measurements are given in the table.
([2]) Refers to the total rated thermal input of all process furnaces/heaters connected to the stack where emissions occur.
([3]) In the case of process furnaces/heaters with a total rated thermal input of less than 100 MW_{th} operated less than 500 hours per year, the monitoring frequency may be reduced to at least once every year.
([4]) The minimum monitoring frequency for periodic measurements may be reduced to once every 6 months, if the emission levels are proven to be sufficiently stable.
([5]) Monitoring of dust does not apply when combusting exclusively gaseous fuels.
([6]) Monitoring of NH_3 only applies when SCR or SNCR is used.
([7]) In the case of process furnaces/heaters combusting gaseous fuels and/or oil with a known sulphur content and where no flue-gas desulphurisation is carried out, continuous monitoring can be replaced either by periodic monitoring with a minimum frequency of once every 3 months or by calculation ensuring the provision of data of an equivalent scientific quality.

BAT 2: BAT is to monitor channelled emissions to air other than from process furnaces/heaters in accordance with EN standards and with at least the minimum frequency given in the table below. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.

Substance/Parameter	Processes/Sources	Standard(s)	Minimum monitoring frequency	Monitoring associated with
Benzene	Waste gas from the cumene oxidation unit in phenol production (1)	No EN standard available	Once every month (2)	BAT 57
	All other processes/sources (3)			BAT 10
Cl_2	TDI/MDI (1)	No EN standard available	Once every month (2)	BAT 66
	EDC/VCM			BAT 76
CO	Thermal oxidiser	EN 15058	Once every month (2)	BAT 13
	Lower olefins (decoking)	No EN standard available (4)	Once every year or once during decoking, if decoking is less frequent	BAT 20
	EDC/VCM (decoking)			BAT 78
Dust	Lower olefins (decoking)	No EN standard available (5)	Once every year or once during decoking, if decoking is less frequent	BAT 20
	EDC/VCM (decoking)			BAT 78
	All other processes/sources (3)	EN 13284-1	Once every month (2)	BAT 11
EDC	EDC/VCM	No EN standard available	Once every month (2)	BAT 76
Ethylene oxide	Ethylene oxide and ethylene glycols	No EN standard available	Once every month (2)	BAT 52
Formaldehyde	Formaldehyde	No EN standard available	Once every month (2)	BAT 45
Gaseous chlorides, expressed as HCl	TDI/MDI (1)	EN 1911	Once every month (2)	BAT 66
	EDC/VCM			BAT 76
	All other processes/sources (3)			BAT 12
NH_3	Use of SCR or SNCR	No EN standard available	Once every month (2)	BAT 7
NO_X	Thermal oxidiser	EN 14792	Once every month (2)	BAT 13
PCDD/F	TDI/MDI (6)	EN 1948-1, -2, and -3	Once every 6 months (2)	BAT 67
PCDD/F	EDC/VCM			BAT 77

Substance/Parameter	Processes/Sources	Standard(s)	Minimum monitoring frequency	Monitoring associated with
SO_2	All processes/sources (3)	EN 14791	Once every month (2)	BAT 12
Tetrachloromethane	TDI/MDI (1)	No EN standard available	Once every month (2)	BAT 66
TVOC	TDI/MDI	EN 12619	Once every month (2)	BAT 66
	EO (desorption of CO_2 from scrubbing medium)		Once every 6 months (2)	BAT 51
	Formaldehyde		Once every month (2)	BAT 45
	Waste gas from the cumene oxidation unit in phenol production	EN 12619	Once every month (2)	BAT 57
	Waste gas from other sources in phenol production when not combined with other waste gas streams		Once every year	
	Waste gas from the oxidation unit in hydrogen peroxide production		Once every month (2)	BAT 86
	EDC/VCM		Once every month (2)	BAT 76
	All other processes/sources (3)		Once every month (2)	BAT 10
VCM	EDC/VCM	No EN standard available	Once every month (2)	BAT 76

(1) The monitoring applies where the pollutant is present in the waste gas based on the inventory of waste gas streams specified by the CWW BAT conclusions.
(2) The minimum monitoring frequency for periodic measurements may be reduced to once every year, if the emission levels are proven to be sufficiently stable.
(3) All (other) processes/sources where the pollutant is present in the waste gas based on the inventory of waste gas streams specified by the CWW BAT conclusions.
(4) EN 15058 and the sampling period need adaptation so that the measured values are representative of the whole decoking cycle.
(5) EN 13284-1 and the sampling period need adaptation so that the measured values are representative of the whole decoking cycle.
(6) The monitoring applies where the chlorine and/or chlorinated compounds are present in the waste gas and thermal treatment is applied

1.2. **Emissions to air**

1.2.1. *Emissions to air from process furnaces/heaters*

BAT 3: In order to reduce emissions to air of CO and unburnt substances from process furnaces/heaters, BAT is to ensure an optimised combustion.

Optimised combustion is achieved by good design and operation of the equipment which includes optimisation of the temperature and residence time in the combustion zone, efficient mixing of the fuel and combustion air, and combustion control. Combustion control is based on the continuous monitoring and automated control of appropriate combustion parameters (e.g. O_2, CO, fuel to air ratio, and unburnt substances).

BAT 4: In order to reduce NO_X emissions to air from process furnaces/heaters, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Choice of fuel	See Section 12.3. This includes switching from liquid to gaseous fuels, taking into account the overall hydrocarbon balance	The switch from liquid to gaseous fuels may be restricted by the design of the burners in the case of existing plants
b.	Staged combustion	Staged combustion burners achieve lower NO_X emissions by staging the injection of either air or fuel in the near burner region. The division of fuel or air reduces the oxygen concentration in the primary burner combustion zone, thereby lowering the peak flame temperature and reducing thermal NO_X formation	Applicability may be restricted by space availability when upgrading small process furnaces, thus limiting the retrofit of fuel/air staging without reducing capacity For existing EDC crackers, the applicability may be restricted by the design of the process furnace
c.	Flue-gas recirculation (external)	Recirculation of part of the flue-gas to the combustion chamber to replace part of the fresh combustion air, with the effect of reducing the oxygen content and therefore cooling the temperature of the flame	For existing process furnaces/heaters, the applicability may be restricted by their design. Not applicable to existing EDC crackers
d.	Flue-gas recirculation (internal)	Recirculation of part of the flue-gas within the combustion chamber to replace part of the fresh combustion air, with the effect of reducing the oxygen content and therefore reducing the temperature of the flame	For existing process furnaces/heaters, the applicability may be restricted by their design
e.	Low-NO_X burner (LNB) or ultra-low-NO_X burner (ULNB)	See Section 12.3	For existing process furnaces/heaters, the applicability may be restricted by their design
f.	Use of inert diluents	'Inert' diluents, e.g. steam, water, nitrogen, are used (either by being premixed with the fuel prior to its combustion or directly injected into the combustion chamber) to reduce the temperature of the flame. Steam injection may increase CO emissions	Generally applicable
g.	Selective catalytic reduction (SCR)	See Section 12.1	Applicability to existing process furnaces/heaters may be restricted by space availability
h.	Selective non-catalytic reduction (SNCR)	See Section 12.1	Applicability to existing process furnaces/heaters may be restricted by the temperature window (900–1 050 °C) and the residence time needed for the reaction. Not applicable to EDC crackers

BAT-associated emission levels (BAT-AELs): See Table 2.1 and Table 10.1.

BAT 5: In order to prevent or reduce dust emissions to air from process furnaces/heaters, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Choice of fuel	See Section 12.3. This includes switching from liquid to gaseous fuels, taking into account the overall hydrocarbon balance	The switch from liquid to gaseous fuels may be restricted by the design of the burners in the case of existing plants
b.	Atomisation of liquid fuels	Use of high pressure to reduce the droplet size of liquid fuel. Current optimal burner design generally includes steam atomisation	Generally applicable
c.	Fabric, ceramic or metal filter	See Section 12.1	Not applicable when only combusting gaseous fuels

BAT 6: In order to prevent or reduce SO_2 emissions to air from process furnaces/heaters, BAT is to use one or both of the techniques given below.

Technique		Description	Applicability
a.	Choice of fuel	See Section 12.3. This includes switching from liquid to gaseous fuels, taking into account the overall hydrocarbon balance	The switch from liquid to gaseous fuels may be restricted by the design of the burners in the case of existing plants
b.	Caustic scrubbing	See Section 12.1	Applicability may be restricted by space availability

1.2.2. *Emissions to air from the use of SCR or SNCR*

BAT 7: In order to reduce emissions to air of ammonia which is used in selective catalytic reduction (SCR) or selective non-catalytic reduction (SNCR) for the abatement of NO_X emissions, BAT is to optimise the design and/or operation of SCR or SNCR (e.g. optimised reagent to NO_X ratio, homogeneous reagent distribution and optimum size of the reagent drops).

BAT-associated emission levels (BAT-AELs) for emissions from a lower olefins cracker furnace when SCR or SNCR is used: Table 2.1.

1.2.3. *Emissions to air from other processes/sources*

1.2.3.1. Techniques to reduce emissions from other processes/sources

BAT 8: In order to reduce the load of pollutants sent to the final waste gas treatment, and to increase resource efficiency, BAT is to use an appropriate combination of the techniques given below for process off-gas streams.

Technique		Description	Applicability
a.	Recovery and use of excess or generated hydrogen	Recovery and use of excess hydrogen or hydrogen generated from chemical reactions (e.g. for hydrogenation reactions). Recovery techniques such as pressure swing adsorption or membrane separation may be used to increase the hydrogen content	Applicability may be restricted where the energy demand for recovery is excessive due to the low hydrogen content or when there is no demand for hydrogen

Technique		Description	Applicability
b.	Recovery and use of organic solvents and unreacted organic raw materials	Recovery techniques such as compression, condensation, cryogenic condensation, membrane separation and adsorption may be used. The choice of technique may be influenced by safety considerations, e.g. presence of other substances or contaminants	Applicability may be restricted where the energy demand for recovery is excessive due to the low organic content
c.	Use of spent air	The large volume of spent air from oxidation reactions is treated and used as low-purity nitrogen	Only applicable where there are available uses for low-purity nitrogen which do not compromise process safety
d.	Recovery of HCl by wet scrubbing for subsequent use	Gaseous HCl is absorbed in water using a wet scrubber, which may be followed by purification (e.g. using adsorption) and/or concentration (e.g. using distillation) (see Section 12.1 for the technique descriptions). The recovered HCl is then used (e.g. as acid or to produce chlorine)	Applicability may be restricted in the case of low HCl loads
e.	Recovery of H_2S by regenerative amine scrubbing for subsequent use	Regenerative amine scrubbing is used for recovering H_2S from process off-gas streams and from the acidic off-gases of sour water stripping units. H_2S is then typically converted to elemental sulphur in a sulphur recovery unit in a refinery (Claus process).	Only applicable if a refinery is located nearby
f.	Techniques to reduce solids and/or liquids entrainment	See Section 12.1	Generally applicable

BAT 9: In order to reduce the load of pollutants sent to the final waste gas treatment, and to increase energy efficiency, BAT is to send process off-gas streams with a sufficient calorific value to a combustion unit. BAT 8a and 8b have priority over sending process off-gas streams to a combustion unit.

Applicability:

Sending process off-gas streams to a combustion unit may be restricted due to the presence of contaminants or due to safety considerations.

BAT 10: In order to reduce channelled emissions of organic compounds to air, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Condensation	See Section 12.1. The technique is generally used in combination with further abatement techniques	Generally applicable

Technique		Description	Applicability
b.	Adsorption	See Section 12.1	Generally applicable
c.	Wet scrubbing	See Section 12.1	Only applicable to VOCs that can be absorbed in aqueous solutions
d.	Catalytic oxidiser	See Section 12.1	Applicability may be restricted by the presence of catalyst poisons
e.	Thermal oxidiser	See Section 12.1. Instead of a thermal oxidiser, an incinerator for the combined treatment of liquid waste and waste gas may be used	Generally applicable

BAT 11: In order to reduce channelled dust emissions to air, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Cyclone	See Section 12.1. The technique is used in combination with further abatement techniques	Generally applicable
b.	Electrostatic precipitator	See Section 12.1	For existing units, the applicability may be restricted by space availability or safety considerations
c.	Fabric filter	See Section 12.1	Generally applicable
d.	Two-stage dust filter	See Section 12.1	
e.	Ceramic/metal filter	See Section 12.1	
f.	Wet dust scrubbing	See Section 12.1	

BAT 12: In order to reduce emissions to air of sulphur dioxide and other acid gases (e.g. HCl), BAT is to use wet scrubbing.

Description:

For the description of wet scrubbing, see Section 12.1

1.2.3.2. Techniques to reduce emissions from a thermal oxidiser

BAT 13: In order to reduce emissions to air of NO_X, CO, and SO_2 from a thermal oxidiser, BAT is to use an appropriate combination of the techniques given below.

Technique		Description	Main pollutant targeted	Applicability
a.	Removal of high levels of NO_X precursors from the process off-gas streams	Remove (if possible, for reuse) high levels of NO_X precursors prior to thermal treatment, e.g. by scrubbing, condensation or adsorption	NO_X	Generally applicable

Technique		Description	Main pollutant targeted	Applicability
b.	Choice of support fuel	See Section 12.3	NO_X, SO_2	Generally applicable
c.	Low-NO_X burner (LNB)	See Section 12.1	NO_X	Applicability to existing units may be restricted by design and/or operational constraints
d.	Regenerative thermal oxidiser (RTO)	See Section 12.1	NO_X	Applicability to existing units may be restricted by design and/or operational constraints
e.	Combustion optimisation	Design and operational techniques used to maximise the removal of organic compounds, while minimising emissions to air of CO and NO_X (e.g. by controlling combustion parameters such as temperature and residence time)	CO, NO_X	Generally applicable
f.	Selective catalytic reduction (SCR)	See Section 12.1	NO_X	Applicability to existing units may be restricted by space availability
g.	Selective non-catalytic reduction (SNCR)	See Section 12.1	NO_X	Applicability to existing units may be restricted by the residence time needed for the reaction

1.3. **Emissions to water**

BAT 14: In order to reduce the waste water volume, the pollutant loads discharged to a suitable final treatment (typically biological treatment), and emissions to water, BAT is to use an integrated waste water management and treatment strategy that includes an appropriate combination of process-integrated techniques, techniques to recover pollutants at source, and pretreatment techniques, based on the information provided by the inventory of waste water streams specified in the CWW BAT conclusions.

1.4. **Resource efficiency**

BAT 15: In order to increase resource efficiency when using catalysts, BAT is to use a combination of the techniques given below.

Technique		Description
a.	Catalyst selection	Select the catalyst to achieve the optimal balance between the following factors: — catalyst activity;

Technique		Description
		— catalyst selectivity; — catalyst lifetime (e.g. vulnerability to catalyst poisons); — use of less toxic metals.
b.	Catalyst protection	Techniques used upstream of the catalyst to protect it from poisons (e.g. raw material pretreatment)
c.	Process optimisation	Control of reactor conditions (e.g. temperature, pressure) to achieve the optimal balance between conversion efficiency and catalyst lifetime
d.	Monitoring of catalyst performance	Monitoring of the conversion efficiency to detect the onset of catalyst decay using suitable parameters (e.g. the heat of reaction and the CO_2 formation in the case of partial oxidation reactions)

BAT 16: In order to increase resource efficiency, BAT is to recover and reuse organic solvents.

Description:

Organic solvents used in processes (e.g. chemical reactions) or operations (e.g. extraction) are recovered using appropriate techniques (e.g. distillation or liquid phase separation), purified if necessary (e.g. using distillation, adsorption, stripping or filtration) and returned to the process or operation. The amount recovered and reused is process-specific.

1.5. **Residues**

BAT 17: In order to prevent or, where that is not practicable, to reduce the amount of waste being sent for disposal, BAT is to use an appropriate combination of the techniques given below.

Technique		Description	Applicability
Techniques to prevent or reduce the generation of waste			
a.	Addition of inhibitors to distillation systems	Selection (and optimisation of dosage) of polymerisation inhibitors that prevent or reduce the generation of residues (e.g. gums or tars). The optimisation of dosage may need to take into account that it can lead to higher nitrogen and/or sulphur content in the residues which could interfere with their use as a fuel	Generally applicable
b.	Minimisation of high-boiling residue formation in distillation systems	Techniques that reduce temperatures and residence times (e.g. packing instead of trays to reduce the pressure drop and thus the temperature; vacuum instead of atmospheric pressure to reduce the temperature)	Only applicable to new distillation units or major plant upgrades

	Technique	Description	Applicability
Techniques to recover materials for reuse or recycling			
c.	Material recovery (e.g. by distillation, cracking)	Materials (i.e. raw materials, products, and by-products) are recovered from residues by isolation (e.g. distillation) or conversion (e.g. thermal/catalytic cracking, gasification, hydrogenation)	Only applicable where there are available uses for these recovered materials
d.	Catalyst and adsorbent regeneration	Regeneration of catalysts and adsorbents, e.g. using thermal or chemical treatment	Applicability may be restricted where regeneration results in significant cross-media effects.
Techniques to recover energy			
e.	Use of residues as a fuel	Some organic residues, e.g. tar, can be used as fuels in a combustion unit	Applicability may be restricted by the presence of certain substances in the residues, making them unsuitable to use in a combustion unit and requiring disposal

1.6. **Other than normal operating conditions**

BAT 18: In order to prevent or reduce emissions from equipment malfunctions, BAT is to use all of the techniques given below.

	Technique	Description	Applicability
a.	Identification of critical equipment	Equipment critical to the protection of the environment ('critical equipment') is identified on the basis of a risk assessment (e.g. using a Failure Mode and Effects Analysis)	Generally applicable
b.	Asset reliability programme for critical equipment	A structured programme to maximise equipment availability and performance which includes standard operating procedures, preventive maintenance (e.g. against corrosion), monitoring, recording of incidents, and continuous improvements	Generally applicable
c.	Back-up systems for critical equipment	Build and maintain back-up systems, e.g. vent gas systems, abatement units	Not applicable if appropriate equipment availability can be demonstrated using technique b.

BAT 19: In order to prevent or reduce emissions to air and water occurring during other than normal operating conditions, BAT is to implement measures commensurate with the relevance of potential pollutant releases for:

(i) start-up and shutdown operations;

(ii) other circumstances (e.g. regular and extraordinary maintenance work and cleaning operations of the units and/or of the waste gas treatment system) including those that could affect the proper functioning of the installation.

2. BAT CONCLUSIONS FOR LOWER OLEFINS PRODUCTION

The BAT conclusions in this section apply to the production of lower olefins using the steam cracking process, and apply in addition to the general BAT conclusions given in Section 1.

2.1. Emissions to air

2.1.1. *BAT-AELs for emissions to air from a lower olefins cracker furnace*

Table 2.1

BAT-AELs for emissions to air of NO_X and NH_3 from a lower olefins cracker furnace

Parameter	BAT-AELs ([1]) ([2]) ([3]) (daily average or average over the sampling period) (mg/Nm^3, at 3 vol-% O_2)	
	New furnace	Existing furnace
NO_X	60–100	70–200
NH_3	< 5–15 ([4])	

([1]) Where the flue gases of two or more furnaces are discharged through a common stack, the BAT-AEL applies to the combined discharge from the stack.
([2]) The BAT-AELs do not apply during decoking operations.
([3]) No BAT-AEL applies for CO. As an indication, the CO emission level will generally be 10–50 mg/Nm^3 expressed as a daily average or an average over the sampling period.
([4]) The BAT-AEL only applies when SCR or SNCR are used.

The associated monitoring is in BAT 1.

2.1.2. *Techniques to reduce emissions from decoking*

BAT 20: In order to reduce emissions to air of dust and CO from the decoking of the cracker tubes, BAT is to use an appropriate combination of the techniques to reduce the frequency of decoking given below and one or a combination of the abatement techniques given below.

	Technique	Description	Applicability
Techniques to reduce the frequency of decoking			
a.	Tube materials that retard coke formation	Nickel present at the surface of the tubes catalyses coke formation. Employing materials that have lower nickel levels, or coating the interior tube surface with an inert material, can therefore retard the rate of coke build-up	Only applicable to new units or major plant upgrades
b.	Doping of the raw material feed with sulphur compounds	As nickel sulphides do not catalyse coke formation, doping the feed with sulphur compounds when they are not already present at the desired level can also help retard the build-up of coke, as this will promote the passivation of the tube surface	Generally applicable

Technique		Description	Applicability
c.	Optimisation of thermal decoking	Optimisation of operating conditions, i.e. airflow, temperature and steam content across the decoking cycle, to maximise coke removal	Generally applicable

Abatement techniques

d.	Wet dust scrubbing	See Section 12.1	Generally applicable
e.	Dry cyclone	See Section 12.1	Generally applicable
f.	Combustion of decoking waste gas in process furnace/heater	The decoking waste gas stream is passed through the process furnace/heater during decoking where the coke particles (and CO) are further combusted	Applicability for existing plants may be restricted by the design of the pipework systems or fire-duty restrictions

2.2. **Emissions to water**

BAT 21: In order to prevent or reduce the amount of organic compounds and waste water discharged to waste water treatment, BAT is to maximise the recovery of hydrocarbons from the quench water of the primary fractionation stage and reuse the quench water in the dilution steam generation system.

Description:

The technique consists of ensuring an effective separation of organic and aqueous phases. The recovered hydrocarbons are recycled to the cracker or used as raw materials in other chemical processes. Organic recovery can be enhanced, e.g. through the use of steam or gas stripping, or the use of a reboiler. Treated quench water is reused within the dilution steam generation system. A quench water purge stream is discharged to downstream final waste water treatment to prevent the build-up of salts in the system.

BAT 22: In order to reduce the organic load discharged to waste water treatment from the spent caustic scrubber liquor originating from the removal of H_2S from the cracked gases, BAT is to use stripping.

Description:

For the description of stripping see Section 12.2. The stripping of scrubber liquors is carried out using a gaseous stream, which is then combusted (e.g. in the cracker furnace).

BAT 23: In order to prevent or reduce the amount of sulphides discharged to waste water treatment from the spent caustic scrubber liquor originating from the removal of acid gases from the cracked gases, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Use of low-sulphur raw materials in the cracker feed	Use of raw materials that have a low sulphur content or have been desulphurised	Applicability may be restricted by a need for sulphur doping to reduce coke build-up
b.	Maximisation of the use of amine scrubbing for the removal of acid gases	The scrubbing of the cracked gases with a regenerative (amine) solvent to remove acid gases, mainly H_2S, to reduce the load on the downstream caustic scrubber	Not applicable if the lower olefin cracker is located far away from an SRU. Applicability for existing plants may be restricted by the capacity of the SRU

Technique		Description	Applicability
c.	Oxidation	Oxidation of sulphides present in the spent scrubbing liquor to sulphates, e.g. using air at elevated pressure and temperature (i.e. wet air oxidation) or an oxidising agent such as hydrogen peroxide	Generally applicable

3. BAT CONCLUSIONS FOR AROMATICS PRODUCTION

The BAT conclusions in this section apply to the production of benzene, toluene, ortho-, meta- and para-xylene (commonly known as BTX aromatics) and cyclohexane from the pygas by-product of steam crackers and from reformate/naphtha produced in catalytic reformers; and apply in addition to the general BAT conclusions given in Section 1.

3.1. **Emissions to air**

BAT 24: In order to reduce the organic load from process off-gases sent to the final waste gas treatment and to increase resource efficiency, BAT is to recover organic materials by using BAT 8b. or, where that is not practicable, to recover energy from these process off-gases (see also BAT 9).

BAT 25: In order to reduce emissions to air of dust and organic compounds from the regeneration of hydrogenation catalyst, BAT is to send the process off-gas from catalyst regeneration to a suitable treatment system.

Description:

The process off-gas is sent to wet or dry dust abatement devices to remove dust and then to a combustion unit or a thermal oxidiser to remove organic compounds in order to avoid direct emissions to air or flaring. The use of decoking drums alone is not sufficient.

3.2. **Emissions to water**

BAT 26: In order to reduce the amount of organic compounds and waste water discharged from aromatic extraction units to waste water treatment, BAT is either to use dry solvents or to use a closed system for the recovery and reuse of water when wet solvents are used.

BAT 27: In order to reduce the waste water volume and the organic load discharged to waste water treatment, BAT is to use an appropriate combination of the techniques given below.

Technique		Description	Applicability
a.	Water-free vacuum generation	Use mechanical pumping systems in a closed circuit procedure, discharging only a small amount of water as blowdown, or use dry-running pumps. In some cases, wastewater-free vacuum generation can be achieved by use of the product as a barrier liquid in a mechanical vacuum pump, or by use of a gas stream from the production process	Generally applicable

Technique		Description	Applicability
b.	Source segregation of aqueous effluents	Aqueous effluents from aromatics plants are segregated from waste water from other sources in order to facilitate the recovery of raw materials or products	For existing plants, the applicability may be restricted by site-specific drainage systems
c.	Liquid phase separation with recovery of hydrocarbons	Separation of organic and aqueous phases with appropriate design and operation (e.g. sufficient residence time, phase boundary detection and control) to prevent any entrainment of undissolved organic material	Generally applicable
d	Stripping with recovery of hydrocarbons	See Section 12.2. Stripping can be used on individual or combined streams	Applicability may be restricted when the concentration of hydrocarbons is low
e.	Reuse of water	With further treatment of some waste water streams, water from stripping can be used as process water or as boiler feed water, replacing other sources of water	Generally applicable

3.3. **Resource efficiency**

BAT 28: In order to use resources efficiently, BAT is to maximise the use of co-produced hydrogen, e.g. from dealkylation reactions, as a chemical reagent or fuel by using BAT 8a. or, where that is not practicable, to recover energy from these process vents (see BAT 9).

3.4. **Energy efficiency**

BAT 29: In order to use energy efficiently when using distillation, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Distillation optimisation	For each distillation column, the number of trays, reflux ratio, feed location and, for extractive distillations, the solvents to feed ratio are optimised	Applicability to existing units may be restricted by design, space availability and/or operational constraints
b.	Recovery of heat from column overhead gaseous stream	Reuse condensation heat from the toluene and the xylene distillation column to supply heat elsewhere in the installation	

Technique		Description	Applicability
c.	Single extractive distillation column	In a conventional extractive distillation system, the separation would require a sequence of two separation steps (i.e. main distillation column with side column or stripper). In a single extractive distillation column, the separation of the solvent is carried out in a smaller distillation column that is incorporated into the column shell of the first column	Only applicable to new plants or major plant upgrades. Applicability may be restricted for smaller capacity units as operability may be constrained by combining a number of operations into one piece of equipment
d.	Distillation column with a dividing wall	In a conventional distillation system, the separation of a three-component mixture into its pure fractions requires a direct sequence of at least two distillation columns (or main columns with side columns). With a dividing wall column, separation can be carried out in just one piece of apparatus	
e.	Thermally coupled distillation	If distillation is carried out in two columns, energy flows in both columns can be coupled. The steam from the top of the first column is fed to a heat exchanger at the base of the second column	Only applicable to new plants or major plant upgrades. Applicability depends on the set-up of the distillation columns and process conditions, e.g. working pressure

3.5. **Residues**

BAT 30: In order to prevent or reduce the amount of spent clay being sent for disposal, BAT is to use one or both of the techniques given below.

Technique		Description	Applicability
a.	Selective hydrogenation of reformate or pygas	Reduce the olefin content of reformate or pygas by hydrogenation. With fully hydrogenated raw materials, clay treaters have longer operating cycles	Only applicable to plants using raw materials with a high olefin content
b.	Clay material selection	Use a clay that lasts as long as possible for its given conditions (i.e. having surface/structural properties that increase the operating cycle length), or use a synthetic material that has the same function as the clay but that can be regenerated	Generally applicable

4. BAT CONCLUSIONS FOR ETHYLBENZENE AND STYRENE MONOMER PRODUCTION

The BAT conclusions in this section apply to the production of ethlybenzene using either the zeolite or $AlCl_3$ catalysed alkylation process; and the production of styrene monomer either by ethylbenzene dehydrogenation or co-production with propylene oxide; and apply in addition to the general BAT conclusions given in Section 1.

4.1. **Process selection**

BAT 31: In order to prevent or reduce emissions to air of organic compounds and acid gases, the generation of waste water and the amount of waste being sent for disposal from the alkylation of benzene with ethylene, BAT for new plants and major plant upgrades is to use the zeolite catalyst process.

4.2. **Emissions to air**

BAT 32: In order to reduce the load of HCl sent to the final waste gas treatment from the alkylation unit in the $AlCl_3$-catalysed ethylbenzene production process, BAT is to use caustic scrubbing.

Description:

For the description of caustic scrubbing, see Section 12.1.

Applicability:

Only applicable to existing plants using the $AlCl_3$ catalysed ethylbenzene production process.

BAT 33: In order to reduce the load of dust and HCl sent to the final waste gas treatment from catalyst replacement operations in the $AlCl_3$-catalysed ethylbenzene production process, BAT is to use wet scrubbing and then use the spent scrubbing liquor as wash water in the post-alkylation reactor wash section.

Description:

For the description of wet scrubbing, see Section 12.1.

BAT 34: In order to reduce the organic load sent to the final waste gas treatment from the oxidation unit in the SMPO production process, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Techniques to reduce liquids entrainment	See Section 12.1	Generally applicable
b.	Condensation	See Section 12.1	Generally applicable
c.	Adsorption	See Section 12.1	Generally applicable
d.	Scrubbing	See Section 12.1. Scrubbing is carried out with a suitable solvent (e.g. the cool, recirculated ethylbenzene) to absorb ethylbenzene, which is recycled to the reactor	For existing plants, the use of the recirculated ethylbenzene stream may be restricted by the plant design

BAT 35: In order to reduce emissions of organic compounds to air from the acetophenone hydrogenation unit in the SMPO production process, during other than normal operating conditions (such as start-up events), BAT is to send the process off-gas to a suitable treatment system.

4.3. **Emissions to water**

BAT 36: In order to reduce waste water generation from ethylbenzene dehydrogenation and to maximise the recovery of organic compounds, BAT is to use an appropriate combination of the techniques given below.

Technique		Description	Applicability
a.	Optimised liquid phase separation	Separation of organic and aqueous phases with appropriate design and operation (e.g. sufficient residence time, phase boundary detection and control) to prevent any entrainment of undissolved organic material	Generally applicable
b.	Steam stripping	See Section 12.2	Generally applicable
c.	Adsorption	See Section 12.2	Generally applicable
d.	Reuse of water	Condensates from the reaction can be used as process water or as boiler feed after steam stripping (see technique b.) and adsorption (see technique c.)	Generally applicable

BAT 37: In order to reduce emissions to water of organic peroxides from the oxidation unit in the SMPO production process and to protect the downstream biological waste water treatment plant, BAT is to pretreat waste water containing organic peroxides using hydrolysis before it is combined with other waste water streams and discharged to the final biological treatment.

Description:

For the description of hydrolysis see Section 12.2.

4.4. **Resource efficiency**

BAT 38: In order to recover organic compounds from ethylbenzene dehydrogenation prior to the recovery of hydrogen (see BAT 39), BAT is to use one or both of the techniques given below.

Technique		Description	Applicability
a.	Condensation	See Section 12.1	Generally applicable
b.	Scrubbing	See Section 12.1. The absorbent consists of commercial organic solvents (or tar from ethylbenzene plants) (see BAT 42b). VOCs are recovered by stripping of the scrubber liquor	

BAT 39: In order to increase resource efficiency, BAT is to recover the co-produced hydrogen from ethylbenzene dehydrogenation, and to use it either as a chemical reagent or to combust the dehydrogenation off-gas as a fuel (e.g. in the steam superheater).

BAT 40: In order to increase the resource efficiency of the acetophenone hydrogenation unit in the SMPO production process, BAT is to minimise excess hydrogen or to recycle hydrogen by using BAT 8a. If BAT 8a is not applicable, BAT is to recover energy (see BAT 9).

4.5. **Residues**

BAT 41: In order to reduce the amount of waste being sent for disposal from spent catalyst neutralisation in the $AlCl_3$-catalysed ethylbenzene production process, BAT is to recover residual organic compounds by stripping and then concentrate the aqueous phase to give a usable $AlCl_3$ by-product.

Description:

Steam stripping is first used to remove VOCs, then the spent catalyst solution is concentrated by evaporation to give a usable $AlCl_3$ by-product. The vapour phase is condensed to give a HCl solution that is recycled into the process.

BAT 42: In order to prevent or reduce the amount of waste tar being sent for disposal from the distillation unit of ethylbenzene production, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Material recovery (e.g. by distillation, cracking)	See BAT 17c	Only applicable where there are available uses for these recovered materials
b.	Use of tar as an absorbent for scrubbing	See section 12.1. Use the tar as an absorbent in the scrubbers used in styrene monomer production by ethylbenzene dehydrogenation, instead of commercial organic solvents (see BAT 38b). The extent to which tar can be used depends on the scrubber capacity	Generally applicable
c.	Use of tar as a fuel	See BAT 17e	Generally applicable

BAT 43: In order to reduce the generation of coke (which is both a catalyst poison and a waste) from units producing styrene by ethylbenzene dehydrogenation, BAT is to operate at the lowest possible pressure that is safe and practicable.

BAT 44: In order to reduce the amount of organic residues being sent for disposal from styrene monomer production including its co-production with propylene oxide, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Addition of inhibitors to distillation systems	See BAT 17a	Generally applicable
b.	Minimisation of high-boiling residue formation in distillation systems	See BAT 17b	Only applicable to new distillation units or major plant upgrades
c.	Use of residues as a fuel	See BAT 17e	Generally applicable

5. BAT CONCLUSIONS FOR FORMALDEHYDE PRODUCTION

The BAT conclusions in this section apply in addition to the general BAT conclusions given in Section 1.

5.1. **Emissions to air**

BAT 45: In order to reduce emissions of organic compounds to air from formaldehyde production and to use energy efficiently, BAT is to use one of the techniques given below.

Technique		Description	Applicability
a.	Send the waste gas stream to a combustion unit	See BAT 9	Only applicable to the silver process
b.	Catalytic oxidiser with energy recovery	See Section 12.1. Energy is recovered as steam	Only applicable to the metal oxide process. The ability to recover energy may be restricted in small stand-alone plants
c.	Thermal oxidiser with energy recovery	See Section 12.1. Energy is recovered as steam	Only applicable to the silver process

Table 5.1

BAT-AELs for emissions of TVOC and formaldehyde to air from formaldehyde production

Parameter	BAT-AEL (daily average or average over the sampling period) (mg/Nm^3, no correction for oxygen content)
TVOC	< 5–30 [1]
Formaldehyde	2–5

[1] The lower end of the range is achieved when using a thermal oxidiser in the silver process.

The associated monitoring is in BAT 2.

5.2. **Emissions to water**

BAT 46: In order to prevent or reduce waste water generation (e.g. from cleaning, spills and condensates) and the organic load discharged to further waste water treatment, BAT is to use one or both of the techniques given below.

Technique		Description	Applicability
a.	Reuse of water	Aqueous streams (e.g. from cleaning, spills and condensates) are recirculated into the process mainly to adjust the formaldehyde product concentration. The extent to which water can be reused depends on the desired formaldehyde concentration	Generally applicable
b.	Chemical pretreatment	Conversion of formaldehyde into other substances which are less toxic, e.g. by addition of sodium sulphite or by oxidation	Only applicable to effluents which, due to their formaldehyde content, could have a negative effect on the downstream biological waste water treatment

5.3. **Residues**

BAT 47: In order to reduce the amount of paraformaldehyde-containing waste being sent for disposal, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Minimisation of paraformaldehyde generation	The formation of paraformaldehyde is minimised by improved heating, insulation and flow circulation	Generally applicable
b.	Material recovery	Paraformaldehyde is recovered by dissolution in hot water where it undergoes hydrolysis and depolymerisation to give a formaldehyde solution, or is reused directly in other processes	Not applicable when the recovered paraformaldehyde cannot be used due to its contamination
c.	Use of residues as a fuel	Paraformaldehyde is recovered and used as a fuel	Only applicable when technique b. cannot be applied

6. BAT CONCLUSIONS FOR ETHYLENE OXIDE AND ETHYLENE GLYCOLS PRODUCTION

The BAT conclusions in this section apply in addition to the general BAT conclusions given in Section 1.

6.1. **Process selection**

BAT 48: In order to reduce the consumption of ethylene and emissions to air of organic compounds and CO_2, BAT for new plants and major plant upgrades is to use oxygen instead of air for the direct oxidation of ethylene to ethylene oxide.

6.2. **Emissions to air**

BAT 49: In order to recover ethylene and energy and to reduce emissions of organic compounds to air from the EO plant, BAT is to use both of the techniques given below.

Technique		Description	Applicability
Techniques to recover organic material for reuse or recycling			
a.	Use of pressure swing adsorption or membrane separation to recover ethylene from the inerts purge	With the pressure swing adsorption technique, the target gas (in this case ethylene) molecules are adsorbed on a solid (e.g. molecular sieve) at high pressure, and subsequently desorbed in more concentrated form at lower pressure for reuse or recycling. For membrane separation, see Section 12.1	Applicability may be restricted when the energy demand is excessive due to a low ethylene mass flow
Energy recovery techniques			
b.	Send the inerts purge stream to a combustion unit	See BAT 9	Generally applicable

BAT 50: In order to reduce the consumption of ethylene and oxygen and to reduce CO_2 emissions to air from the EO unit, BAT is to use a combination of the techniques in BAT 15 and to use inhibitors.

Description:

The addition of small amounts of an organochlorine inhibitor (such as ethylchloride or dichloroethane) to the reactor feed in order to reduce the proportion of ethylene that is fully oxidised to carbon dioxide. Suitable parameters for the monitoring of catalyst performance include the heat of reaction and the CO_2 formation per tonne of ethylene feed.

BAT 51: In order to reduce emissions of organic compounds to air from the desorption of CO_2 from the scrubbing medium used in the EO plant, BAT is to use a combination of the techniques given below.

	Technique	Description	Applicability
Process-integrated techniques			
a.	Staged CO_2 desorption	The technique consists of conducting the depressurisation necessary to liberate the carbon dioxide from the absorption medium in two steps rather than one. This allows an initial hydrocarbon-rich stream to be isolated for potential recirculation, leaving a relatively clean carbon dioxide stream for further treatment.	Only applicable to new plants or major plant upgrades
Abatement techniques			
b.	Catalytic oxidiser	See Section 12.1	Generally applicable
c.	Thermal oxidiser	See Section 12.1	Generally applicable

Table 6.1

BAT-AEL for emissions of organic compounds to air from the desorption of CO_2 from the scrubbing medium used in the EO plant

Parameter	BAT-AEL
TVOC	1–10 g/t of EO produced (1) (2) (3)

(1) The BAT-AEL is expressed as an average of values obtained during 1 year.
(2) In the case of significant methane content in the emission, methane monitored according to EN ISO 25140 or EN ISO 25139 is subtracted from the result.
(3) EO produced is defined as the sum of EO produced for sale and as an intermediate.

The associated monitoring is in BAT 2.

BAT 52: In order to reduce EO emissions to air, BAT is to use wet scrubbing for waste gas streams containing EO.

Description:

For the description of wet scrubbing, see Section 12.1. Scrubbing with water to remove EO from waste gas streams before direct release or before further abatement of organic compounds.

BAT 53: In order to prevent or reduce emissions of organic compounds to air from cooling of the EO absorbent in the EO recovery unit, BAT is to use one of the techniques given below.

Technique		Description	Applicability
a.	Indirect cooling	Use indirect cooling systems (with heat exchangers) instead of open cooling systems	Only applicable to new plants or major plant upgrades
b.	Complete EO removal by stripping	Maintain appropriate operating conditions and use online monitoring of the EO stripper operation to ensure that all EO is stripped out; and provide adequate protection systems to avoid EO emissions during other than normal operating conditions	Only applicable when technique a. cannot be applied

6.3. **Emissions to water**

BAT 54: In order to reduce the waste water volume and to reduce the organic load discharged from the product purification to final waste water treatment, BAT is to use one or both of the techniques given below.

Technique		Description	Applicability
a.	Use of the purge from the EO plant in the EG plant	The purge streams from the EO plant are sent to the EG process and not discharged as waste water. The extent to which the purge can be reused in the EG process depends on EG product quality considerations.	Generally applicable
b.	Distillation	Distillation is a technique used to separate compounds with different boiling points by partial evaporation and recondensation. The technique is used in EO and EG plants to concentrate aqueous streams to recover glycols or enable their disposal (e.g. by incineration, instead of their discharge as waste water) and to enable the partial reuse/recycling of water.	Only applicable to new plants or major plant upgrades

6.4. **Residues**

BAT 55: In order to reduce the amount of organic waste being sent for disposal from the EO and EG plant, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
a.	Hydrolysis reaction optimisation	Optimisation of the water to EO ratio to both achieve lower co-production of heavier glycols and avoid excessive energy demand for the dewatering of glycols. The optimum ratio depends on the target output of di- and triethylene glycols	Generally applicable
b.	Isolation of by-products at EO plants for use	For EO plants, the concentrated organic fraction obtained after the dewatering of the liquid effluent from EO recovery is distilled to give valuable short-chain glycols and a heavier residue	Only applicable to new plants or major plant upgrades
c.	Isolation of by-products at EG plants for use	For EG plants, the longer chain glycols fraction can either be used as such or further fractionated to yield valuable glycols	Generally applicable

7. BAT CONCLUSIONS FOR PHENOL PRODUCTION

The BAT conclusions in this section apply to the production of phenol from cumene, and apply in addition to the general BAT conclusions given in Section 1.

7.1. **Emissions to air**

BAT 56: In order to recover raw materials and to reduce the organic load sent from the cumene oxidation unit to the final waste gas treatment, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
Process-integrated techniques			
a.	Techniques to reduce liquids entrainment	See Section 12.1	Generally applicable
Techniques to recover organic material for reuse			
b.	Condensation	See Section 12.1	Generally applicable
c.	Adsorption (regenerative)	See Section 12.1	Generally applicable

BAT 57: In order to reduce emissions of organic compounds to air, BAT is to use technique d given below for waste gas from the cumene oxidation unit. For any other individual or combined waste gas streams, BAT is to use one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Send the waste gas stream to a combustion unit	See BAT 9	Only applicable where there are available uses for the waste gas as gaseous fuel
b.	Adsorption	See Section 12.1	Generally applicable
c.	Thermal oxidiser	See Section 12.1	Generally applicable
d.	Regenerative thermal oxidiser (RTO)	See Section 12.1	Generally applicable

Table 7.1

BAT-AELs for emissions of TVOC and benzene to air from the production of phenol

Parameter	Source	BAT-AEL (daily average or average over the sampling period) (mg/Nm^3, no correction for oxygen content)	Conditions
Benzene	Cumene oxidation unit	< 1	The BAT-AEL applies if the emission exceeds 1 g/h
TVOC		5–30	—

The associated monitoring is in BAT 2.

7.2. **Emissions to water**

BAT 58: In order to reduce emissions to water of organic peroxides from the oxidation unit and, if necessary, to protect the downstream biological waste water treatment plant, BAT is to pretreat waste water containing organic peroxides using hydrolysis before it is combined with other waste water streams and discharged to the final biological treatment.

Description:

For the description of hydrolysis, see Section 12.2. Waste water (mainly from the condensers and the adsorber regeneration, after phase separation) is treated thermally (at temperatures above 100 °C and a high pH) or catalytically to decompose organic peroxides to non-ecotoxic and more readily biodegradable compounds.

Table 7.2

BAT-AEPL for organic peroxides at the outlet of the peroxides decomposition unit

Parameter	BAT-AEPL (average value from at least three spot samples taken at intervals of at least half an hour)	Associated monitoring
Total organic peroxides, expressed as cumene hydroperoxide	< 100 mg/l	No EN standard available. The minimum monitoring frequency is once every day and may be reduced to four times per year if adequate performance of the hydrolysis is demonstrated by controlling the process parameters (e.g. pH, temperature and residence time)

BAT 59: In order to reduce the organic load discharged from the cleavage unit and the distillation unit to further waste water treatment, BAT is to recover phenol and other organic compounds (e.g. acetone) using extraction followed by stripping.

Description:

Recovery of phenol from phenol-containing waste water streams by adjustment of the pH to < 7, followed by extraction with a suitable solvent and stripping of the waste water to remove residual solvent and other low-boiling compounds (e.g. acetone). For the description of the treatment techniques, see Section 12.2.

7.3. **Residues**

BAT 60: In order to prevent or reduce the amount of tar being sent for disposal from phenol purification, BAT is to use one or both of the techniques given below.

	Technique	Description	Applicability
a.	Material recovery (e.g. by distillation, cracking)	See BAT 17c. Use distillation to recover cumene, α-methylstyrene phenol, etc.	Generally applicable
b.	Use of tar as a fuel	See BAT 17e.	Generally applicable

8. BAT CONCLUSIONS FOR ETHANOLAMINES PRODUCTION

The BAT conclusions in this section apply in addition to the general BAT conclusions given in Section 1.

8.1. **Emissions to air**

BAT 61: In order to reduce ammonia emissions to air and to reduce the consumption of ammonia from the aqueous ethanolamines production process, BAT is to use a multistage wet scrubbing system.

Description:

For the description of wet scrubbing, see Section 12.1. Unreacted ammonia is recovered from the off-gas of the ammonia stripper and also from the evaporation unit by wet scrubbing in at least two stages followed by ammonia recycling into the process.

8.2. **Emissions to water**

BAT 62: In order to prevent or reduce emissions of organic compounds to air and emissions to water of organic substances from the vacuum systems, BAT is to use one or a combination of the techniques given below.

	Technique	Description	Applicability
a.	Water-free vacuum generation	Use of dry-running pumps, e.g. positive displacement pumps	Applicability to existing plants may be restricted by design and/or operational constraints
b.	Use of water ring vacuum pumps with recirculation of the ring water	The water used as the sealant liquid of the pump is recirculated to the pump casing via a closed loop with only small purges, so that waste water generation is minimised	Only applicable when technique a. cannot be applied. Not applicable for triethanolamine distillation

Technique		Description	Applicability
c.	Reuse of aqueous streams from vacuum systems in the process	Return aqueous streams from water ring pumps or steam ejectors to the process for recovery of organic material and reuse of the water. The extent to which water can be reused in the process is restricted by the water demand of the process	Only applicable when technique a. cannot be applied
d.	Condensation of organic compounds (amines) upstream of vacuum systems	See Section 12.1	Generally applicable

8.3. **Raw material consumption**

BAT 63: In order to use ethylene oxide efficiently, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
a.	Use of excess ammonia	Maintaining a high level of ammonia in the reaction mixture is an effective way of ensuring that all the ethylene oxide is converted into products	Generally applicable
b.	Optimisation of the water content in the reaction	Water is used to accelerate the main reactions without changing the product distribution and without significant side reactions with ethylene oxide to glycols	Only applicable for the aqueous process
c.	Optimise the process operating conditions	Determine and maintain the optimum operating conditions (e.g. temperature, pressure, residence time) to maximise the conversion of ethylene oxide to the desired mix of mono-, di-, triethanolamines	Generally applicable

9. BAT CONCLUSIONS FOR TOLUENE DIISOCYANATE (TDI) AND METHYLENE DIPHENYL DIISOCYANATE (MDI) PRODUCTION

The BAT conclusions in this section cover the production of:

— dinitrotoluene (DNT) from toluene;

— toluene diamine (TDA) from DNT;

— TDI from TDA;

— methylene diphenyl diamine (MDA) from aniline;

— MDI from MDA;

and apply in addition to the general BAT conclusions given in Section 1.

9.1. **Emissions to air**

BAT 64: In order to reduce the load of organic compounds, NO_X, NO_X precursors and SO_X sent to the final waste gas treatment (see BAT 66) from DNT, TDA and MDA plants, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
a.	Condensation	See Section 12.1	Generally applicable
b.	Wet scrubbing	See Section 12.1. In many cases, scrubbing efficiency is enhanced by the chemical reaction of the absorbed pollutant (partial oxidation of NO_X with recovery of nitric acid, removal of acids with caustic solution, removal of amines with acidic solutions, reaction of aniline with formaldehyde in caustic solution)	
c.	Thermal reduction	See Section 12.1	Applicability to existing units may be restricted by space availability
d.	Catalytic reduction	See Section 12.1	

BAT 65: In order to reduce the load of HCl and phosgene sent to the final waste gas treatment and to increase resource efficiency, BAT is to recover HCl and phosgene from the process off-gas streams of TDI and/or MDI plants by using an appropriate combination of the techniques given below.

Technique		Description	Applicability
a.	Absorption of HCl by wet scrubbing	See BAT 8d.	Generally applicable
b.	Absorption of phosgene by scrubbing	See Section 12.1. The excess phosgene is absorbed using an organic solvent and returned to the process	Generally applicable
c.	HCl/phosgene condensation	See Section 12.1	Generally applicable

BAT 66: In order to reduce emissions to air of organic compounds (including chlorinated hydrocarbons), HCl and chlorine, BAT is to treat combined waste gas streams using a thermal oxidiser followed by caustic scrubbing.

Description:

The individual waste gas streams from DNT, TDA, TDI, MDA and MDI plants are combined to one or several waste gas streams for treatment. (See Section 12.1 for the descriptions of thermal oxidiser and scrubbing.) Instead of a thermal oxidiser, an incinerator may be used for the combined treatment of liquid waste and the waste gas. Caustic scrubbing is wet scrubbing with caustic added to improve the HCl and chlorine removal efficiency.

Table 9.1

BAT-AELs for emissions of TVOC, tetrachloromethane, Cl_2, HCl and PCDD/F to air from the TDI/MDI process

Parameter	BAT-AEL (mg/Nm³, no correction for oxygen content)
TVOC	1–5 (1) (2)
Tetrachloromethane	≤ 0,5 g/t MDI produced (3) ≤ 0,7 g/t TDI produced (3)

Parameter	BAT-AEL (mg/Nm³, no correction for oxygen content)
Cl_2	< 1 (2) (4)
HCl	2–10 (2)
PCDD/F	0,025–0,08 ng I-TEQ/Nm³ (2)

(1) The BAT-AEL only applies to combined waste gas streams with flow rates of > 1 000 Nm³/h.
(2) The BAT-AEL is expressed as a daily average or an average over the sampling period.
(3) The BAT-AEL is expressed as an average of values obtained during 1 year. TDI and/or MDI produced refers to the product without residues, in the sense used to define the capacity of the plant.
(4) In the case of NO_X values above 100 mg/Nm³ in the sample, the BAT-AEL may be higher and up to 3 mg/Nm³ due to analytical interferences.

The associated monitoring is in BAT 2.

BAT 67: In order to reduce emissions to air of PCDD/F from a thermal oxidiser (see Section 12.1) treating process off-gas streams containing chlorine and/or chlorinated compounds, BAT is to use technique a, if necessary followed by technique b, given below.

Technique		Description	Applicability
a.	Rapid quenching	Rapid cooling of exhaust gases to prevent the *de novo* synthesis of PCDD/F	Generally applicable
b.	Activated carbon injection	Removal of PCDD/F by adsorption onto activated carbon that is injected into the exhaust gas, followed by dust abatement	

BAT-associated emission levels (BAT-AELs): See Table 9.1.

9.2. Emissions to water

BAT 68: BAT is to monitor emissions to water with at least the frequency given below and in accordance with EN standards. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.

Substance/Parameter	Plant	Sampling point	Standard(s)	Minimum monitoring frequency	Monitoring associated with
TOC	DNT plant	Outlet of the pretreatment unit	EN 1484	Once every week (1)	BAT 70
	MDI and/or TDI plant	Outlet of the plant		Once every month	BAT 72
Aniline	MDA plant	Outlet of the final waste water treatment	No EN standard available	Once every month	BAT 14
Chlorinated solvents	MDI and/or TDI plant		Various EN standards available (e.g. EN ISO 15680)		BAT 14

(1) In the case of discontinuous waste water discharges, the minimum monitoring frequency is once per discharge.

BAT 69: In order to reduce the load of nitrite, nitrate and organic compounds discharged from the DNT plant to waste water treatment, BAT is to recover raw materials, to reduce the waste water volume and to reuse water by using an appropriate combination of the techniques given below.

Technique		Description	Applicability
a.	Use of highly concentrated nitric acid	Use highly concentrated HNO_3 (e.g. about 99 %) to increase the process efficiency and to reduce the waste water volume and the load of pollutants	Applicability to existing units may be restricted by design and/or operational constraints
b.	Optimised regeneration and recovery of spent acid	Perform the regeneration of the spent acid from the nitration reaction in such a way that water and the organic content are also recovered for reuse, by using an appropriate combination of evaporation/distillation, stripping and condensation	Applicability to existing units may be restricted by design and/or operational constraints
c.	Reuse of process water to wash DNT	Reuse process water from the spent acid recovery unit and the nitration unit to wash DNT	Applicability to existing units may be restricted by design and/or operational constraints
d.	Reuse of water from the first washing step in the process	Nitric and sulphuric acid are extracted from the organic phase using water. The acidified water is returned to the process, for direct reuse or further processing to recover materials	Generally applicable
e.	Multiple use and recirculation of water	Reuse water from washing, rinsing and equipment cleaning e.g. in the counter-current multistep washing of the organic phase	Generally applicable

BAT-associated waste water volume: See Table 9.2.

BAT 70: In order to reduce the load of poorly biodegradable organic compounds discharged from the DNT plant to further waste water treatment, BAT is to pretreat the waste water using one or both of the techniques given below.

Technique		Description	Applicability
a.	Extraction	See Section 12.2	Generally applicable
b.	Chemical oxidation	See Section 12.2	

Table 9.2

BAT-AEPLs for discharge from the DNT plant at the outlet of the pretreatment unit to further waste water treatment

Parameter	BAT-AEPL (average of values obtained during 1 month)
TOC	< 1 kg/t DNT produced
Specific waste water volume	< 1 m^3/t DNT produced

The associated monitoring for TOC is in BAT 68.

BAT 71: In order to reduce waste water generation and the organic load discharged from the TDA plant to waste water treatment, BAT is to use a combination of techniques a., b. and c. and then to use technique d. as given below.

Technique		Description	Applicability
a.	Evaporation	See Section 12.2	Generally applicable
b.	Stripping	See Section 12.2	
c.	Extraction	See Section 12.2	
d.	Reuse of water	Reuse of water (e.g. from condensates or from scrubbing) in the process or in other processes (e.g. in a DNT plant). The extent to which water can be reused at existing plants may be restricted by technical constraints	Generally applicable

Table 9.3

BAT-AEPL for discharge from the TDA plant to waste water treatment

Parameter	BAT-AEPL (average of values obtained during 1 month)
Specific waste water volume	< 1 m^3/t TDA produced

BAT 72: In order to prevent or reduce the organic load discharged from MDI and/or TDI plants to final waste water treatment, BAT is to recover solvents and reuse water by optimising the design and operation of the plant.

Table 9.4

BAT-AEPL for discharge to waste water treatment from a TDI or MDI plant

Parameter	BAT-AEPL (average of values obtained during 1 year)
TOC	< 0,5 kg/t product (TDI or MDI) [1]

[1] The BAT-AEPL refers to the product without residues, in the sense used to define the capacity of the plant.

The associated monitoring is in BAT 68.

BAT 73: In order to reduce the organic load discharged from a MDA plant to further waste water treatment, BAT is to recover organic material using one or a combination of the techniques given below.

Technique		Description	Applicability
a.	Evaporation	See Section 12.2. Used to facilitate extraction (see technique b)	Generally applicable
b.	Extraction	See Section 12.2. Used to recover/remove MDA	Generally applicable
c.	Steam stripping	See Section 12.2. Used to recover/remove aniline and methanol	For methanol, the applicability depends on the assessment of alternative options as part of the waste water management and treatment strategy
d.	Distillation	See Section 12.2. Used to recover/remove aniline and methanol	

9.3. **Residues**

BAT 74: In order to reduce the amount of organic residues being sent for disposal from the TDI plant, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
Techniques to prevent or reduce the generation of waste			
a.	Minimisation of high-boiling residue formation in distillation systems	See BAT 17b.	Only applicable to new distillation units or major plant upgrades
Techniques to recover organic material for reuse or recycling			
b.	Increased recovery of TDI by evaporation or further distillation	Residues from distillation are additionally processed to recover the maximum amount of TDI contained therein, e.g. using a thin film evaporator or other short-path distillation units followed by a dryer.	Only applicable to new distillation units or major plant upgrades
c.	Recovery of TDA by chemical reaction	Tars are processed to recover TDA by chemical reaction (e.g. hydrolysis).	Only applicable to new plants or major plant upgrades

10. BAT CONCLUSIONS FOR ETHYLENE DICHLORIDE AND VINYL CHLORIDE MONOMER PRODUCTION

The BAT conclusions in this section apply in addition to the general BAT conclusions given in Section 1.

10.1. **Emissions to air**

10.1.1. *BAT-AEL for emissions to air from an EDC cracker furnace*

Table 10.1

BAT-AELs for emissions to air of NO_X from an EDC cracker furnace

Parameter	BAT-AELs (1) (2) (3) (daily average or average over the sampling period) (mg/Nm^3, at 3 vol-% O_2)
NO_x	50–100

(1) Where the flue-gases of two or more furnaces are discharged through a common stack, the BAT-AEL applies to the combined discharge from the stack.
(2) The BAT-AELs do not apply during decoking operations.
(3) No BAT-AEL applies for CO. As an indication, the CO emission level will generally be 5–35 mg/Nm^3 expressed as a daily average or an average over the sampling period.

The associated monitoring is in BAT 1.

10.1.2. *Techniques and BAT-AEL for emissions to air from other sources*

BAT 75: In order to reduce the organic load sent to the final waste gas treatment and to reduce raw material consumption, BAT is to use all of the techniques given below.

Technique		Description	Applicability
Process-integrated techniques			
a.	Control of feed quality	Control the quality of the feed to minimise the formation of residues (e.g. propane and acetylene content of ethylene; bromine content of chlorine; acetylene content of hydrogen chloride)	Generally applicable
b.	Use of oxygen instead of air for oxychlorination		Only applicable to new oxychlorination plants or major oxychlorination plant upgrades
Techniques to recover organic material			
c.	Condensation using chilled water or refrigerants	Use condensation (see Section 12.1) with chilled water or refrigerants such as ammonia or propylene to recover organic compounds from individual vent gas streams before sending them to final treatment	Generally applicable

BAT 76: In order to reduce emissions to air of organic compounds (including halogenated compounds), HCl and Cl_2, BAT is to treat the combined waste gas streams from EDC and/or VCM production by using a thermal oxidiser followed by two-stage wet scrubbing.

Description:

For the description of thermal oxidiser, wet and caustic scrubbing, see Section 12.1. Thermal oxidation can be carried out in a liquid waste incineration plant. In this case, the oxidation temperature exceeds 1 100 °C with a minimum residence time of 2 seconds, with subsequent rapid cooling of exhaust gases to prevent the *de novo* synthesis of PCDD/F.

Scrubbing is carried out in two stages: Wet scrubbing with water and, typically, recovery of hydrochloric acid, followed by wet scrubbing with caustic.

Table 10.2

BAT-AELs for emissions of TVOC, the sum of EDC and VCM, Cl_2, HCl and PCDD/F to air from the production of EDC/VCM

Parameter	BAT-AEL (daily average or average over the sampling period) (mg/Nm^3, at 11 vol-% O_2)
TVOC	0,5–5
Sum of EDC and VCM	< 1
Cl_2	< 1–4
HCl	2–10
PCDD/F	0,025–0,08 ng I-TEQ/Nm^3

The associated monitoring is in BAT 2.

BAT 77: In order to reduce emissions to air of PCDD/F from a thermal oxidiser (see Section 12.1) treating process off-gas streams containing chlorine and/or chlorinated compounds, BAT is to use technique a, if necessary followed by technique b, given below.

Technique		Description	Applicability
a.	Rapid quenching	Rapid cooling of exhaust gases to prevent the *de novo* synthesis of PCDD/F	Generally applicable
b.	Activated carbon injection	Removal of PCDD/F by adsorption onto activated carbon that is injected into the exhaust gas, followed by dust abatement	

BAT-associated emission levels (BAT-AELs): See Table 10.2.

BAT 78: In order to reduce emissions to air of dust and CO from the decoking of the cracker tubes, BAT is to use one of the techniques to reduce the frequency of decoking given below and one or a combination of the abatement techniques given below.

Technique		Description	Applicability
Techniques to reduce the frequency of decoking			
a.	Optimisation of thermal decoking	Optimisation of operating conditions, i.e. airflow, temperature and steam content across the decoking cycle, to maximise coke removal	Generally applicable

Technique		Description	Applicability
b.	Optimisation of mechanical decoking	Optimise mechanical decoking (e.g. sand jetting) to maximise coke removal as dust	Generally applicable
Abatement techniques			
c.	Wet dust scrubbing	See Section 12.1	Only applicable to thermal decoking
d.	Cyclone	See Section 12.1	Generally applicable
e.	Fabric filter	See Section 12.1	Generally applicable

10.2. **Emissions to water**

BAT 79: BAT is to monitor emissions to water with at least the frequency given below and in accordance with EN standards. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.

Substance/Parameter	Plant	Sampling point	Standard(s)	Minimum monitoring frequency	Monitoring associated with
EDC	All plants	Outlet of the waste water stripper	EN ISO 10301	Once every day	BAT 80
VCM					
Copper	Oxy-chlorination plant using the fluidised-bed design	Outlet of the pretreatment for solids removal	Various EN standards available, e.g. EN ISO 11885, EN ISO 15586, EN ISO 17294-2	Once every day (1)	BAT 81
PCDD/F			No EN standard available	Once every 3 months	
Total suspended solids (TSS)			EN 872	Once every day (1)	
Copper	Oxy-chlorination plant using the fluidised-bed design	Outlet of the final waste water treatment	Various EN standards available, e.g. EN ISO 11885, EN ISO 15586, EN ISO 17294-2	Once every month	BAT 14 and BAT 81
EDC	All plants		EN ISO 10301	Once every month	BAT 14 and BAT 80
PCDD/F			No EN standard available	Once every 3 months	BAT 14 and BAT 81

(1) The minimum monitoring frequency may be reduced to once every month if adequate performance of the solids and copper removal is controlled by frequent monitoring of other parameters (e.g. by continuous measurement of turbidity).

BAT 80: In order to reduce the load of chlorinated compounds discharged to further waste water treatment and to reduce emissions to air from the waste water collection and treatment system, BAT is to use hydrolysis and stripping as close as possible to the source.

Description:

For the description of hydrolysis and stripping, see Section 12.2. Hydrolysis is carried out at alkaline pH to decompose chloral hydrate from the oxychlorination process. This results in the formation of chloroform which is then removed by stripping, together with EDC and VCM.

BAT-associated environmental performance levels (BAT-AEPLs): See Table 10.3.

BAT-associated emission levels (BAT-AELs) for direct emissions to a receiving water body at the outlet of the final treatment: See Table 10.5.

Table 10.3

BAT-AEPLs for chlorinated hydrocarbons in waste water at the outlet of a waste water stripper

Parameter	BAT-AEPL (average of values obtained during 1 month) (1)
EDC	0,1–0,4 mg/l
VCM	< 0,05 mg/l

(1) The average of values obtained during 1 month is calculated from the averages of values obtained during each day (at least three spot samples taken at intervals of at least half an hour).

The associated monitoring is in BAT 79.

BAT 81: In order to reduce emissions to water of PCDD/F and copper from the oxychlorination process, BAT is to use technique a. or, alternatively, technique b together with an appropriate combination of techniques c., d. and e. given below.

	Technique	Description	Applicability
Process-integrated techniques			
a.	Fixed-bed design for oxychlorination	Oxychlorination reaction design: in the fixed-bed reactor, catalyst particulates entrained in the overhead gaseous stream are reduced	Not applicable to existing plants using the fluidised-bed design
b.	Cyclone or dry catalyst filtration system	A cyclone or a dry catalyst filtration system reduces catalyst losses from the reactor and therefore also their transfer to waste water	Only applicable to plants using the fluidised-bed design
Waste water pretreatment			
c.	Chemical precipitation	See Section 12.2. Chemical precipitation is used to remove dissolved copper	Only applicable to plants using the fluidised-bed design
d.	Coagulation and flocculation	See Section 12.2	Only applicable to plants using the fluidised-bed design
e.	Membrane filtration (micro- or ultrafiltration)	See Section 12.2	Only applicable to plants using the fluidised-bed design

Table 10.4

BAT-AEPLs for emissions to water from EDC production via oxychlorination at the outlet of the pretreatment for solids removal at plants using the fluidised-bed design

Parameter	BAT-AEPL (average of values obtained during 1 year)
Copper	0,4–0,6 mg/l
PCDD/F	< 0,8 ng I-TEQ/l
Total suspended solids (TSS)	10–30 mg/l

The associated monitoring is in BAT 79.

Table 10.5

BAT-AELs for direct emissions of copper, EDC and PCDD/F to a receiving water body from EDC production

Parameter	BAT-AEL (average of values obtained during 1 year)
Copper	0,04–0,2 g/t EDC produced by oxychlorination (1)
EDC	0,01–0,05 g/t EDC purified (2) (3)
PCDD/F	0,1– 0,3 µg I-TEQ/t EDC produced by oxychlorination

(1) The lower end of the range is typically achieved when the fixed-bed design is used.
(2) The average of values obtained during one year is calculated from the averages of values obtained during each day (at least three spot samples taken at intervals of at least half an hour).
(3) Purified EDC is the sum of EDC produced by oxychlorination and/or direct chlorination and of EDC returned from VCM production to purification.

The associated monitoring is in BAT 79.

10.3. **Energy efficiency**

BAT 82: In order to use energy efficiently, BAT is to use a boiling reactor for the direct chlorination of ethylene.

Description:

The reaction in the boiling reactor system for the direct chlorination of ethylene is typically carried out at a temperature between below 85 °C and 200 °C. In contrast to the low-temperature process, it allows for the effective recovery and reuse of the heat of reaction (e.g. for the distillation of EDC).

Applicability:

Only applicable to new direct chlorination plants.

BAT 83: In order to reduce the energy consumption of EDC cracker furnaces, BAT is to use promoters for the chemical conversion.

Description:

Promoters, such as chlorine or other radical-generating species, are used to enhance the cracking reaction and reduce the reaction temperature and therefore the required heat input. Promoters may be generated by the process itself or added.

10.4. **Residues**

BAT 84: In order to reduce the amount of coke being sent for disposal from VCM plants, BAT is to use a combination of the techniques given below.

Technique		Description	Applicability
a.	Use of promoters in cracking	See BAT 83	Generally applicable
b.	Rapid quenching of the gaseous stream from EDC cracking	The gaseous stream from EDC cracking is quenched by direct contact with cold EDC in a tower to reduce coke formation. In some cases, the stream is cooled by heat exchange with cold liquid EDC feed prior to quenching	Generally applicable
c.	Pre-evaporation of EDC feed	Coke formation is reduced by evaporating EDC upstream of the reactor to remove high-boiling coke precursors	Only applicable to new plants or major plant upgrades
d.	Flat flame burners	A type of burner in the furnace that reduces hot spots on the walls of the cracker tubes	Only applicable to new furnaces or major plant upgrades

BAT 85: In order to reduce the amount of hazardous waste being sent for disposal and to increase resource efficiency, BAT is to use all of the techniques given below.

Technique		Description	Applicability
a.	Hydrogenation of acetylene	HCl is generated in the EDC cracking reaction and recovered by distillation. Hydrogenation of the acetylene present in this HCl stream is carried out to reduce the generation of unwanted compounds during oxychlorination. Acetylene values below 50 ppmv at the outlet of the hydrogenation unit are advisable	Only applicable to new plants or major plant upgrades
b.	Recovery and reuse of HCl from incineration of liquid waste	HCl is recovered from incinerator off-gas by wet scrubbing with water or diluted HCl (see Section 12.1) and reused (e.g. in the oxychlorination plant)	Generally applicable
c.	Isolation of chlorinated compounds for use	Isolation and, if needed, purification of by-products for use (e.g. monochloroethane and/or 1,1,2-trichloroethane, the latter for the production of 1,1-dichloroethylene)	Only applicable to new distillation units or major plant upgrades. Applicability may be restricted by a lack of available uses for these compounds

11. BAT CONCLUSIONS FOR HYDROGEN PEROXIDE PRODUCTION

The BAT conclusions in this section apply in addition to the general BAT conclusions given in Section 1.

11.1. Emissions to air

BAT 86: In order to recover solvents and to reduce emissions of organic compounds to air from all units other than the hydrogenation unit, BAT is to use an appropriate combination of the techniques given below. In the case of using air in the oxidation unit, this includes at least technique d. In the case of using pure oxygen in the oxidation unit, this includes at least technique b. using chilled water.

Technique		Description	Applicability
Process-integrated techniques			
a.	Optimisation of the oxidation process	Process optimisation includes elevated oxidation pressure and reduced oxidation temperature in order to reduce the solvent vapour concentration in the process off-gas	Only applicable to new oxidation units or major plant upgrades
b.	Techniques to reduce solids and/or liquids entrainment	See Section 12.1	Generally applicable
Techniques to recover solvent for reuse			
c.	Condensation	See Section 12.1	Generally applicable
d.	Adsorption (regenerative)	See Section 12.1	Not applicable to process off-gas from oxidation with pure oxygen

Table 11.1

BAT-AELs for emissions of TVOC to air from the oxidation unit

Parameter	BAT-AEL ([1]) (daily average or average over the sampling period) ([2]) (no correction for oxygen content)
TVOC	5–25 mg/Nm³ ([3])

([1]) The BAT-AEL does not apply when the emission is below 150 g/h.
([2]) When adsorption is used, the sampling period is representative of a complete adsorption cycle.
([3]) In the case of significant methane content in the emission, methane monitored according to EN ISO 25140 or EN ISO 25139 is subtracted from the result.

The associated monitoring is in BAT 2.

BAT 87: In order to reduce emissions of organic compounds to air from the hydrogenation unit during start-up operations, BAT is to use condensation and/or adsorption.

Description:

For the description of condensation and adsorption, see Section 12.1.

BAT 88: In order to prevent benzene emissions to air and water, BAT is not to use benzene in the working solution.

11.2. **Emissions to water**

BAT 89: In order to reduce the waste water volume and the organic load discharged to waste water treatment, BAT is to use both of the techniques given below.

Technique		Description	Applicability
a.	Optimised liquid phase separation	Separation of organic and aqueous phases with appropriate design and operation (e.g. sufficient residence time, phase boundary detection and control) to prevent any entrainment of undissolved organic material	Generally applicable
b.	Reuse of water	Reuse of water, e.g. from cleaning or liquid phase separation. The extent to which water can be reused in the process depends on product quality considerations	Generally applicable

BAT 90: In order to prevent or reduce emissions to water of poorly bioeliminable organic compounds, BAT is to use one of the techniques given below.

Technique		Description
a.	Adsorption	See Section 12.2. Adsorption is carried out prior to sending waste water streams to the final biological treatment
b.	Waste water incineration	See Section 12.2

Applicability:

Only applicable to waste water streams carrying the main organic load from the hydrogen peroxide plant and when the reduction of the TOC load from the hydrogen peroxide plant by means of biological treatment is lower than 90 %.

12. DESCRIPTIONS OF TECHNIQUES

12.1. **Process off-gas and waste gas treatment techniques**

Technique	Description
Adsorption	A technique for removing compounds from a process off-gas or waste gas stream by retention on a solid surface (typically activated carbon). Adsorption may be regenerative or non-regenerative (see below).
Adsorption (non-regenerative)	In non-regenerative adsorption, the spent adsorbent is not regenerated but disposed of.
Adsorption (regenerative)	Adsorption where the adsorbate is subsequently desorbed, e.g. with steam (often on site) for reuse or disposal and the adsorbent is reused. For continuous operation, typically more than two adsorbers are operated in parallel, one of them in desorption mode.

Technique	Description
Catalytic oxidiser	Abatement equipment which oxidises combustible compounds in a process off-gas or waste gas stream with air or oxygen in a catalyst bed. The catalyst enables oxidation at lower temperatures and in smaller equipment compared to a thermal oxidiser.
Catalytic reduction	NO_x is reduced in the presence of a catalyst and a reducing gas. In contrast to SCR, no ammonia and/or urea are added.
Caustic scrubbing	The removal of acidic pollutants from a gas stream by scrubbing using an alkaline solution.
Ceramic/metal filter	Ceramic filter material. In circumstances where acidic compounds such as HCl, NO_X, SO_X and dioxins are to be removed, the filter material is fitted with catalysts and the injection of reagents may be necessary. In metal filters, surface filtration is carried out by sintered porous metal filter elements.
Condensation	A technique for removing the vapours of organic and inorganic compounds from a process off-gas or waste gas stream by reducing its temperature below its dew point so that the vapours liquefy. Depending on the operating temperature range required, there are different methods of condensation, e.g. cooling water, chilled water (temperature typically around 5 °C) or refrigerants such as ammonia or propene.
Cyclone (dry or wet)	Equipment for removal of dust from a process off-gas or waste gas stream based on imparting centrifugal forces, usually within a conical chamber.
Electrostatic precipitator (dry or wet)	A particulate control device that uses electrical forces to move particles entrained within a process off-gas or waste gas stream onto collector plates. The entrained particles are given an electrical charge when they pass through a corona where gaseous ions flow. Electrodes in the centre of the flow lane are maintained at a high voltage and generate the electrical field that forces the particles to the collector walls.
Fabric filter	Porous woven or felted fabric through which gases flow to remove particles by use of a sieve or other mechanisms. Fabric filters can be in the form of sheets, cartridges or bags with a number of the individual fabric filter units housed together in a group.
Membrane separation	Waste gas is compressed and passed through a membrane which relies on the selective permeability of organic vapours. The enriched permeate can be recovered by methods such as condensation or adsorption, or can be abated, e.g. by catalytic oxidation. The process is most appropriate for higher vapour concentrations. Additional treatment is, in most cases, needed to achieve concentration levels low enough to discharge.
Mist filter	Commonly mesh pad filters (e.g. mist eliminators, demisters) which usually consist of woven or knitted metallic or synthetic monofilament material in either a random or specific configuration. A mist filter is operated as deep-bed filtration, which takes place over the entire depth of the filter. Solid dust particles remain in the filter until it is saturated and requires cleaning by flushing. When the mist filter is used to collect droplets and/or aerosols, they clean the filter as they drain out as a liquid. It works by mechanical impingement and is velocity-dependent. Baffle angle separators are also commonly used as mist filters.

Technique	Description
Regenerative thermal oxidiser (RTO)	Specific type of thermal oxidiser (see below) where the incoming waste gas stream is heated by a ceramic-packed bed by passing through it before entering the combustion chamber. The purified hot gases exit this chamber by passing through one (or more) ceramic-packed bed(s) (cooled by an incoming waste gas stream in an earlier combustion cycle). This reheated packed bed then begins a new combustion cycle by preheating a new incoming waste gas stream. The typical combustion temperature is 800–1 000 °C.
Scrubbing	Scrubbing or absorption is the removal of pollutants from a gas stream by contact with a liquid solvent, often water (see 'Wet scrubbing'). It may involve a chemical reaction (see 'Caustic scrubbing'). In some cases, the compounds may be recovered from the solvent.
Selective catalytic reduction (SCR)	The reduction of NO_x to nitrogen in a catalytic bed by reaction with ammonia (usually supplied as an aqueous solution) at an optimum operating temperature of around 300–450 °C. One or more layers of catalyst may be applied.
Selective non-catalytic reduction (SNCR)	The reduction of NO_x to nitrogen by reaction with ammonia or urea at a high temperature. The operating temperature window must be maintained between 900 °C and 1 050 °C.
Techniques to reduce solids and/or liquids entrainment	Techniques that reduce the carry-over of droplets or particles in gaseous streams (e.g. from chemical processes, condensers, distillation columns) by mechanical devices such as settling chambers, mist filters, cyclones and knock-out drums.
Thermal oxidiser	Abatement equipment which oxidises the combustible compounds in a process off-gas or waste gas stream by heating it with air or oxygen to above its auto-ignition point in a combustion chamber and maintaining it at a high temperature long enough to complete its combustion to carbon dioxide and water.
Thermal reduction	NO_x is reduced at elevated temperatures in the presence of a reducing gas in an additional combustion chamber, where an oxidation process takes place but under low oxygen conditions/deficit of oxygen. In contrast to SNCR, no ammonia and/or urea are added.
Two-stage dust filter	A device for filtering on a metal gauze. A filter cake builds up in the first filtration stage and the actual filtration takes place in the second stage. Depending on the pressure drop across the filter, the system switches between the two stages. A mechanism to remove the filtered dust is integrated into the system.
Wet scrubbing	See 'Scrubbing' above. Scrubbing where the solvent used is water or an aqueous solution, e.g. caustic scrubbing for abating HCl. See also 'Wet dust scrubbing'.
Wet dust scrubbing	See 'Wet scrubbing' above. Wet dust scrubbing entails separating the dust by intensively mixing the incoming gas with water, mostly combined with the removal of the coarse particles by the use of centrifugal force. In order to achieve this, the gas is released inside tangentially. The removed solid dust is collected at the bottom of the dust scrubber.

12.2. **Waste water treatment techniques**

All of the techniques listed below can also be used to purify water streams in order to enable reuse/recycling of water. Most of them are also used to recover organic compounds from process water streams.

Technique	Description
Adsorption	Separation method in which compounds (i.e. pollutants) in a fluid (i.e. waste water) are retained on a solid surface (typically activated carbon).
Chemical oxidation	Organic compounds are oxidised with ozone or hydrogen peroxide, optionally supported by catalysts or UV radiation, to convert them into less harmful and more easily biodegradable compounds
Coagulation and flocculation	Coagulation and flocculation are used to separate suspended solids from waste water and are often carried out in successive steps. Coagulation is carried out by adding coagulants with charges opposite to those of the suspended solids. Flocculation is carried out by adding polymers, so that collisions of microfloc particles cause them to bond to produce larger flocs.
Distillation	Distillation is a technique to separate compounds with different boiling points by partial evaporation and recondensation. Waste water distillation is the removal of low-boiling contaminants from waste water by transferring them into the vapour phase. Distillation is carried out in columns, equipped with plates or packing material, and a downstream condenser.
Extraction	Dissolved pollutants are transferred from the waste water phase to an organic solvent, e.g. in counter-current columns or mixer-settler systems. After phase separation, the solvent is purified, e.g. by distillation, and returned to the extraction. The extract containing the pollutants is disposed of or returned to the process. Losses of solvent to the waste water are controlled downstream by appropriate further treatment (e.g. stripping).
Evaporation	The use of distillation (see above) to concentrate aqueous solutions of high-boiling substances for further use, processing or disposal (e.g. waste water incineration) by transferring water to the vapour phase. Typically carried out in multistage units with increasing vacuum, to reduce the energy demand. The water vapours are condensed, to be reused or discharged as waste water.
Filtration	The separation of solids from a waste water carrier by passing it through a porous medium. It includes different types of techniques, e.g. sand filtration, microfiltration and ultrafiltration.
Flotation	A process in which solid or liquid particles are separated from the waste water phase by attaching to fine gas bubbles, usually air. The buoyant particles accumulate at the water surface and are collected with skimmers.
Hydrolysis	A chemical reaction in which organic or inorganic compounds react with water, typically in order to convert non-biodegradable to biodegradable or toxic to non-toxic compounds. To enable or enhance the reaction, hydrolysis is carried out at an elevated temperature and possibly pressure (thermolysis) or with the addition of strong alkalis or acids or using a catalyst.

Technique	Description
Precipitation	The conversion of dissolved pollutants (e.g. metal ions) into insoluble compounds by reaction with added precipitants. The solid precipitates formed are subsequently separated by sedimentation, flotation or filtration.
Sedimentation	Separation of suspended particles and suspended material by gravitational settling.
Stripping	Volatile compounds are removed from the aqueous phase by a gaseous phase (e.g. steam, nitrogen or air) that is passed through the liquid, and are subsequently recovered (e.g. by condensation) for further use or disposal. The removal efficiency may be enhanced by increasing the temperature or reducing the pressure.
Waste water incineration	The oxidation of organic and inorganic pollutants with air and simultaneous evaporation of water at normal pressure and temperatures between 730 °C and 1 200 °C. Waste water incineration is typically self-sustaining at COD levels of more than 50 g/l. In the case of low organic loads, a support/auxiliary fuel is needed.

12.3. **Techniques to reduce emissions to air from combustion**

Technique	Description
Choice of (support) fuel	The use of fuel (including support/auxiliary fuel) with a low content of potential pollution-generating compounds (e.g. lower sulphur, ash, nitrogen, mercury, fluorine or chlorine content in the fuel).
Low-NO_X burner (LNB) and ultra-low-NO_X burner (ULNB)	The technique is based on the principles of reducing peak flame temperatures, delaying but completing the combustion and increasing the heat transfer (increased emissivity of the flame). It may be associated with a modified design of the furnace combustion chamber. The design of ultra-low-NO_X burners (ULNB) includes (air/)fuel staging and exhaust/flue-gas recirculation.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2017 OF THE COMMITTEE ESTABLISHED UNDER THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

of 28 July 2017

on the amendment of Chapter 4 on medical devices, Chapter 6 on pressure vessels, Chapter 7 on radio equipment and telecommunication terminal equipment, Chapter 8 on equipment and protective systems intended for use in potentially explosive atmosphere, Chapter 9 on electrical equipment and electromagnetic compatibility, Chapter 11 on measuring instruments, Chapter 15 on medicinal products, GMP inspection and batch certification, Chapter 17 on lifts, and Chapter 20 on explosives for civil use, and the update of legal references listed in Annex 1 [2017/2118]

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment ('the Agreement') and in particular Articles 10(4), 10(5) and 18(2) thereof;

Whereas:

(1) The Parties to the Agreement have agreed to adapt Chapter 4, Medical devices, of Annex 1 in order to foster the cooperation among the regulators in the area of medical devices;

(2) The European Union has adopted a new Directive on simple pressure vessels ([1]) and a new Directive on pressure equipment ([2]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(3) Chapter 6, Pressure vessels, of Annex 1 should be amended to reflect these developments;

(4) The European Union has adopted a new Directive on radio equipment ([3]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(5) Chapter 7, Radio equipment and Telecommunications terminal equipment, of Annex 1 should be amended to reflect these developments;

(6) The European Union has adopted a new Directive on equipment and protective systems intended for use in potentially explosive atmosphere ([4]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(7) Chapter 8, Equipment and protective systems intended for use in potentially explosive atmosphere, of Annex 1 should be amended to reflect these developments;

([1]) Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45).
([2]) Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164).
([3]) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).
([4]) Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309).

(8) The European Union has adopted a new Directive on electrical equipment ([1]) and a new Directive on electromagnetic compatibility ([2]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(9) Chapter 9, Electrical equipment and Electromagnetic compatibility, of Annex 1 should be amended to reflect these developments;

(10) The European Union has adopted a new Directive on non-automatic weighing instruments ([3]) and a new Directive on measuring instruments ([4]) Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(11) Chapter 11, Measuring instruments and prepackages, of Annex 1 should be amended to reflect these developments;

(12) The Parties to the Agreement have agreed to amend Chapter 15, Medicinal products GMP Inspection and Batch Certification, of Annex 1 in order to enable the recognition of results of GMP inspections carried out by the relevant inspection services of the other Party in third countries;

(13) The European Union has adopted a new Directive on lifts ([5]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(14) Chapter 17, Lifts, of Annex 1 should be amended to reflect these developments;

(15) The European Union has adopted a new Directive on explosives for civil use ([6]) and Switzerland has amended its legislative, regulatory and administrative provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned European Union legislation;

(16) Chapter 20, Explosives for civil use, of Annex 1 should be amended to reflect these developments;

(17) It is necessary to update the legal references in Chapters 3, 12, 14, 16, 18 and 19 of Annex 1 to the Agreement;

(18) Article 10(5) of the Agreement provides that the Committee may, on a proposal from one of the Parties, modify the Annexes to the Agreement,

HAS DECIDED AS FOLLOWS:

1. Chapter 4, Medical devices, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment A annexed to this Decision.

2. Chapter 6, Pressure vessels, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment B annexed to this Decision.

3. Chapter 7, Radio equipment and Telecommunication terminal equipment, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment C annexed to this Decision.

3. Chapter 8, Equipment and protective systems intended for use in potentially explosive atmosphere, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment D to this Decision.

([1]) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).
([2]) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).
([3]) Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).
([4]) Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149).
([5]) Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).
([6]) Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1).

4. Chapter 9, Electrical equipment and electromagnetic compatibility, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment E to this Decision.

5. Chapter 11, Measuring instruments and prepackages, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment F to this Decision.

6. Chapter 15, Medicinal products, GMP inspection and batch certification, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment G to this Decision.

8. Chapter 17, Lifts, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment H to this Decision.

9. Chapter 20, Explosives for civil use, of Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment I to this Decision.

10. Annex 1 to the Agreement is amended in accordance with the provisions set out in Attachment J annexed to this Decision.

11. This Decision, done in duplicate, shall be signed by representatives of the Committee who are authorised to act on behalf of the Parties. This Decision shall be effective from the date of the later of these signatures.

On behalf of the Swiss Confederation	*On behalf of the European Union*
Christophe PERRITAZ	Ignacio IRUARRIZAGA
Signed in Bern on 28 July 2017	Signed in Brussels on 27 July 2017

ATTACHMENT A

In Annex 1, Product Sectors, Chapter 4, Medical devices should be deleted and replaced by the following one:

'CHAPTER 4

MEDICAL DEVICES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as last amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1)

3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), as last amended by Regulation (EC) No 1882/2003 of the European Parliament and the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and corrected by Corrigenda (OJ L 22, 29.1.1999, p. 75 and OJ L 6, 10.1.2002, p. 70)

4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17)

5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43)

6. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3)

7. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41)

8. Commission Regulation (EC) No 2007/2006 of 22 December 2006 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the importation and transit of certain intermediate products derived from Category 3 material intended for technical uses in medical devices, in vitro diagnostics and laboratory reagents and amending that Regulation (OJ L 379, 28.12.2006, p. 98)

9. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.9.2007, p. 21)

10. Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63)

11. Commission Directive 2011/100/EU of 20 December 2011 amending Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 50)

12. Directive 2011/65/EU of the European Parliament and the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88)

13. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45)

14. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28)

15. Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8)

Switzerland

100. Federal Law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended 1 January 2014 (RO 2013 4137)

101. Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 et RS 4 798), as last amended on 20 March 2008 (RO 2008 3437)

102. Federal Law of 9 June 1977 on metrology (RO 1977 2394), as last amended on 17 June 2011 (RO 2012 6235)

103. Federal law of 22 March 1991 on radiation protection (RO 1994 1933), as last amended on 10 December 2004 (RO 2004 5391)

104. Ordinance of 17 October 2001 on medical devices (RO 2001 3487), as last amended on 15 April 2015 (RO 2015 999)

105. Ordinance of 18 April 2007 on import, transit and export of animals and animal products (RO 2007 1847), as last amended on 4 September 2013 (RO 2013 3041)

106. Ordinance of 17 June 1996 on Accreditation and Designation of Conformity Assessment Bodies (RO 1996 1904), as last amended on 15 June 2012 (RO 2012 3631)

107. Federal Act on Data Protection of 19 June 1992 (RO 1992 1945), as last amended on 30 September 2011 (RO 2013 3215)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies under this Chapter, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and, as laid down in Implementing Regulation (EU) No 920/2013, the assessment criteria set out in Annex XI to Directive 93/42/EEC, in Annex 8 to Directive 90/385/EEC and in Annex IX to Directive 98/79/EC.

Switzerland shall make available assessors for the pool established under Implementing Regulation (EU) No 920/2013.

SECTION V

Supplementary provisions

1. **Registration of the person responsible for placing devices on the market**

Any manufacturer or his authorised representative who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC or Article 10 of Directive 98/79/EC shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in those Articles. The Parties shall reciprocally recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. **Labelling of medical devices**

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices specified in Annex 1, point 13.3(a) to Directive 93/42/EEC and in vitro diagnostic medical devices specified in Annex 1, point 8.4(a), to Directive 98/79/EC. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

For devices imported from third countries, in view of their distribution in the Union and Switzerland, the label, or the outer packaging, or instructions for use, shall contain the name and address of the single authorised representative of the manufacturer established within the Union or Switzerland, as appropriate.

3. **Information exchange**

In accordance with Article 9 of the Agreement, the Parties shall in particular exchange the information referred to in Article 8 of Directive 90/385/EEC, Article 10 of Directive 93/42/EEC, Article 11 of Directive 98/79/EC and Article 3 of Implementing Regulation (EU) No 920/2013.

4. **European databases**

The competent Swiss authorities shall have access to the European databases established under Article 12 of Directive 98/79/EC, Article 14a of Directive 93/42/EEC and Article 3 of Implementing Regulation (EU) No 920/2013. They shall transmit to the Commission and/or body responsible for managing the databases the data provided for in those Articles collected in Switzerland for entry into the European databases.'

ATTACHMENT B

In Annex 1, Product Sectors, Chapter 6, Pressure vessels should be deleted and replaced by the following one:

'CHAPTER 6

PRESSURE VESSELS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45)
	2. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164)
	3. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1), hereinafter referred to as "Directive 2010/35/EU"
	4. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13)
Switzerland	100. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	101. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631)
	102. Ordinance of 25 November 2015 on the safety of simple pressure vessels (RO 2016 227)
	103. Ordinance of 25 November 2015 on the safety of pressure equipment (RO 2016 233)
	104. Ordinance of 31 October 2012 relating to the placing on the market of dangerous goods receptacles and the market surveillance (RO 2012 6607)
	105. Ordinance of 29 November 2002 on the transport of dangerous goods by road (RO 2002 4212), as last amended on 31 October 2012 (RO 2012 6535 and 6537)
	106. Ordinance of 31 October 2012 on the transport of dangerous goods by rail and cableway (RO 2012 6541)
	107. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter 4 of Directive 2014/29/EU, Chapter 4 of Directive 2014/68/EU or Chapter 4 of Directive 2010/35/EU.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Article 6(3) of Directive 2010/35/EU, respectively Articles 6(6) and 8(3) of Directive 2014/29/EU, or Articles 6(6) and 8(3) of Directive 2014/68/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In cases where the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 4(3) and 6(6) of Directive 2010/35/EU, respectively Articles 6(3) and 8(8) of Directive 2014/29/EU or Articles 6(3) and 8(8) of Directive 2014/68/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the product has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 6(4), second subparagraph, and 8(6) of Directive 2014/29/EU or Articles 6(4), second subparagraph, and 8(6) of Directive 2014/68/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 5(2) of Directive 2010/35/EU, respectively Article 7(2) of Directive 2014/29/EU, or Article 7(2) of Directive 2014/68/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 5(1) of Directive 2010/35/EU, respectively Article 7(1) of Directive 2014/29/EU, or Article 7(1) of Directive 2014/68/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 28 of Directive 2010/35/EU, Article 32 of Directive 2014/29/EU and Article 37 of Directive 2014/68/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 29 of Directive 2010/35/EU, Article 33 of Directive 2014/29/EU and Article 38 of Directive 2014/68/EU, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with products presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a product covered by this chapter presents a risk to the health or safety of persons or to other aspects of public interest protection referred to in the relevant legislation in Section I of this Chapter and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operator to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the product being made available on their national market, to withdraw the product from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the product to meet requirements relating to the health or safety of persons or to other aspects of public interest protection in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States other than the Member State initiating the procedure shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should it disagree with the notified national measure in paragraph 5, Switzerland or a Member State shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States and Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measure, in order to determine whether the national measure is justified or not. If the national measure is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant product is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a product that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to other aspects of public interest protection referred to in the relevant legislation in Section I of this Chapter, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT C

In Annex 1, Product Sectors, Chapter 7, Radio equipment and telecommunications terminal equipment should be deleted and replaced by the following one:

'CHAPTER 7

RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union

1. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62)

2. Commission Decision 2000/299/EC of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers (OJ L 97, 19.4.2000, p. 13) ([1])

3. Commission Decision 2000/637/EC of 22 September 2000 on the application of Article 3(3)(e) of Directive 1999/5/EC to radio equipment covered by the regional arrangement concerning radiotelephone service on inland waterways (OJ L 269, 21.10.2000, p. 50)

4. Commission Decision 2001/148/EC of 21 February 2001 on the application of Article 3(3)(e) of Directive 1999/5/EC to avalanche beacons (OJ L 55, 24.2.2001, p. 65)

5. Commission Decision 2005/53/EC of 25 January 2005 on the application of Article 3(3)(e) of Directive 1999/5/EC of the European Parliament and of the Council to radio equipment intended to participate in the Automatic Identification System (AIS) (OJ L 22, 26.1.2005, p. 14)

6. Commission Decision 2005/631/EC of 29 August 2005 concerning essential requirements as referred to in Directive 1999/5/EC of the European Parliament and of the Council ensuring access of Cospas-Sarsat locator beacons to emergency services (OJ L 225, 31.8.2005, p. 28)

7. Commission Decision 2013/638/EU of 12 August 2013 on essential requirements relating to marine radio communication equipment which is intended to be used on non-SOLAS vessels and to participate in the Global Maritime Distress and Safety System (GMDSS) (OJ L 296, 7.11.2013, p. 22)

8. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast) (OJ L 96, 29.3.2014, p. 357) ([2])

9. Directive 2014/30/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 electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79) ([2])

Switzerland

100. Federal Law of 30 April 1997 on Telecommunications (LTC); (RO 1997 2187), as last amended on 12 June 2009 (RO 2010 2617)

101. Ordinance of 25 November 2015 on Telecommunications Equipment (OIT) (RO 2016 179)

102. Ordinance of 26 May 2016 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment; (RO 2016 1673), as last amended on 15 June 2017 (RO 2017 3201)

103. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

104. Ordinance of 9 March 2007 on Telecommunication Services (RO 2007 945), as last amended on 5 November 2014 (RO 2014 4035)

(1) The reference to the class identifier in Article 2 of Commission Decision 2000/299/EC does not apply.
(2) Without prejudice to Chapter 9.

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter IV of Directive 2014/53/EU.

SECTION V

Supplementary provisions

1. **Amendments to legislative, regulatory and administrative provisions of Section I**

Without prejudice to Article 12(2) of this Agreement, the European Union shall notify Switzerland of implementing and delegated acts of the Commission under Directive 2014/53/EU adopted after 13 June 2016 without delay after their publication in the *Official Journal of the European Union*.

Switzerland shall notify the European Union without delay of the relevant amendments of the Swiss legislation.

2. **Economic operators**

2.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 10(7) and 12(3) of Directive 2014/53/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In cases where the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 10(4) and 12(8) of Directive 2014/53/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the radio equipment has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the radio equipment has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 10(5), second subparagraph, and 12(6) of Directive 2014/53/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

2.2. *Provision of information on radio equipment and software by manufacturer*

(a) Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State or Switzerland without infringing applicable requirements on the use of the radio spectrum. In cases of restrictions on putting into service or of requirements for authorisation of use of radio equipment, information on the packaging shall identify restrictions existing in Switzerland, Member States or geographical areas within their territory.

(b) For radio equipment within the scope of Article 4 of Directive 2014/53/EU and the corresponding Swiss legislation, manufacturers of radio equipment and of software allowing radio equipment to be used as intended shall, where required in the legislation under Section I, provide and continuously update the Member States, Switzerland and the Commission, with information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in Directive 2014/53/EU and the corresponding Swiss legislation, in the form of a statement of compliance which includes the elements of the declaration of conformity.

(c) As from 12 June 2018, where required in the legislation under Section I, manufacturers shall, prior to placing on the Parties' markets radio equipment within categories designated by the European Commission as affected by a low level of compliance, register their types within the central system mentioned in Article 5 of Directive 2014/53/EU. The European Commission shall allocate to each registered radio equipment type a registration number, which manufacturers shall affix on radio equipment placed on the market.

The Parties shall exchange information on registered radio equipment types affected by a low level of compliance.

The Parties shall take into account information on compliance of radio equipment provided by Switzerland and Member States when designating categories of radio equipment affected by a low level of compliance.

2.3. *Authorised representative*

For the purpose of the obligation in Article 11(2) of Directive 2014/53/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 11(1) of Directive 2014/34/EU or the corresponding Swiss provisions.

2.4. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of radio equipment with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the radio equipment.

3. **Assignment of radio equipment classes**

Member States and Switzerland shall notify each other the interfaces they intend to regulate on their territory in cases foreseen under Article 8(1) of Directive 2014/53/EU. When establishing the equivalence of regulated radio interfaces and assigning a radio equipment class, the European Union shall take account of the radio interfaces regulated in Switzerland

4. **Interfaces offered by public telecommunications network operators**

The Parties shall inform each other of interfaces offered on their territory by public telecommunications network operators.

5. **Application of essential requirements, putting into service and use**

(a) When the Commission intends to adopt a requirement related to categories or classes of radio equipment pursuant to Articles 2(6), 3(3), 4(2), 5(2) of Directive 2014/53/EU, it shall consult Switzerland on the issue before submitting it formally to the Committee, unless a consultation took place with the Telecommunication Conformity Assessment and Market Surveillance Committee.

(b) Member States and Switzerland shall allow the putting into service and use of radio equipment if it complies with the legislation in Section I when it is properly installed, maintained and used for its intended purpose. They may only introduce additional requirements for the putting into service and/or use of radio equipment for reasons related to the effective and efficient use of the radio spectrum, to the avoidance of harmful interference, to the avoidance of electromagnetic disturbances or to public health.

6. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 38 of Directive 2014/53/EU, directly or by means of designated representatives.

Conformity assessment bodies shall inform the other bodies recognised under this chapter concerning type examination certificates which they have refused, withdrawn, suspended or restricted, and upon request concerning certificates they have issued.

Conformity assessment bodies shall inform the Member States and Switzerland of type examination certificates issued and/or additions thereto, in those cases where harmonised standards have not been applied or not been fully applied. The Member States, Switzerland, the European Commission and the other bodies may, on request, obtain a copy of the type examination certificates and/or additions thereto, a copy of the technical documentation and the results of the examinations carried out.

7. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 37 of Directive 2014/53/EU.

8. **Telecommunication Conformity Assessment and Market Surveillance Committee**

Switzerland may participate as observer in the Telecommunication Conformity Assessment and Market Surveillance Committee work and that of its sub-groups.

9. **Cooperation between market surveillance authorities**

Pursuant to Article 9 paragraph1 of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

10. **Objections to harmonised standards**

Where Switzerland considers that compliance with a harmonised standard does not guarantee that the essential requirements of its legislation as listed in Section I will be fulfilled, it shall inform the Committee and give its reasons.

The Committee shall consider the case and may ask the European Commission to act in accordance with the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council ([1]). The Committee shall be informed of the result of the procedure.

11. **Procedure for dealing with equipment presenting a risk caused by non-compliance not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have found that equipment covered by this chapter does not comply with requirements laid down in the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict equipment being made available on their national market, to withdraw equipment from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant equipment, its origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the radio equipment to meet essential requirements referred to in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the equipment concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the equipment concerned, such as its withdrawal from their market, without delay.

([1]) 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).

12. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 11, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 11, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not. If the national measure is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant equipment be withdrawn or recalled from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 14.

13. **Compliant radio equipment which nevertheless present a risk**

Where a Member State or Switzerland finds that, although radio equipment that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to health and safety of persons or to other aspects of public interest protection, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 14.

14. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures pursuant to paragraphs 10 and 11 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is

(a) unjustified, the national authority of the Member State or Switzerland shall withdraw it;

(b) justified, they shall take the appropriate measures to ensure that products are withdrawn from their market or recalled.'

ATTACHMENT D

In Annex 1, Product Sectors, Chapter 8, Equipment and protective systems intended for use in potentially explosive atmosphere should be deleted and replaced by the following one:

'CHAPTER 8

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERE

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	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 atmosphere (OJ L 96, 29.3.2014, p. 309)
Switzerland	100. Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 20 March 2008 (RO 2008 3437)
	101. Ordinance of 25 November 2015 on the safety of equipment and protective systems intended for use in potentially explosive atmospheres (RO 2016 143)
	102. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	103. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631)
	104. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and assessment criteria set out in Chapter 4 of Directive 2014/34/EU.

SECTION V

Supplementary provisions

1. Economic operators

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 6(7) and 8(3) of Directive 2014/34/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 6(3) and 8(8) of Directive 2014/34/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the product has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Article 6(4), second subparagraph, and 8(6) of Directive 2014/34/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 7(2) of Directive 2014/34/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 7(1) of Directive 2014/34/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 32 of Directive 2014/34/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 33 of Directive 2014/34/EU, directly or by means of designated representatives.

Conformity assessment bodies shall provide the other bodies recognised under this chapter carrying out similar conformity assessment activities covering the same product with relevant information on issues relating to negative and, on request, positive conformity assessment results.

The Commission, the Member States, Switzerland and the other bodies recognised under this chapter may request a copy of the type examination certificates and additions thereto. On request, the Commission, Member States, and Switzerland may obtain a copy of the technical documentation and the results of the examinations carried out by a body recognised under this chapter.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with products presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have found that a product covered by this Chapter does not comply with requirements laid down in the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the products being made available on their national market, to withdraw the product from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant product, its origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the product to meet requirements relating to the health and safety of persons or to the protection of domestic animals or property requirements referred to in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland, or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of product from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to a product is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant product is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a product that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to domestic animals or property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT E

In Annex 1, Product Sectors, Chapter 9, Electrical equipment and electromagnetic compatibility should be deleted and replaced by the following one:

'CHAPTER 9

ELECTRICAL EQUIPMENT AND ELECTROMAGNETIC COMPATIBILITY

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357)
	2. Directive 2014/30/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 electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79)
Switzerland	100. Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 20 March 2008 (RO 2008 3437)
	101. Ordinance of 30 March 1994 on electrical weak current installations (RO 1994 1185), as last amended on 25 November 2015 (RO 2016 625)
	102. Ordinance of 30 March 1994 on electrical heavy current installations (RO 1994 1199), as last amended on 25 November 2015 (RO 2016 119)
	103. Ordinance of 25 November 2015 on electrical low voltage equipment (RO 2016 105)
	104. Ordinance of 25 November 2015 on electromagnetic compatibility (RO 2016 119)
	105. Ordinance of 25 November 2015 on Telecommunications Equipment (OIT); (RO 2016 179)
	106. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter 4 of Directive 2014/30/EU.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Article 7(6) and 9(3) of Directive 2014/30/EU, respectively Articles 6(6) and 8(3) of Directive 2014/35/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer in not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 7(3) and 9(7) of Directive 2014/30/EU, respectively Articles 6(3) and 8(8) of Directive 2014/35/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the equipment has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the equipment has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 6(4), second subparagraph, and 8(6), second subparagraph, of Directive 2014/35/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 8(2) of Directive 2014/30/EU, respectively Article 7(2) of Directive 2014/35/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 8(1) of Directive 2014/30/EU, respectively Article 7(1) of Directive 2014/35/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of equipment with the legislation in section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the equipment.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 35 of Directive 2014/30/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 36 of Directive 2014/30/EU, directly or by means of designated representatives.

4. **Committee on Electromagnetic Compatibility and Committee on Electrical equipment**

Switzerland may participate as an observer in the work of the Committee on Electromagnetic Compatibility and the Committee on Electrical equipment and of their subgroups.

5. **Standards**

For the purpose of this Chapter and according to Article 14 of Directive 2014/35/EU and the corresponding Swiss provisions, competent authorities of Member States and Switzerland shall also regard as complying with their safety objectives for electrical equipment in the scope of Directive 2014/35/EU, equipment manufactured in accordance with the safety provisions of the standards in force in the Member State of manufacture or in Switzerland, if it ensures a safety level equivalent to that required in their own territory.

6. **Conformity assessment bodies**

The Parties shall inform each other of and mutually recognise the bodies responsible for the tasks described in Annex III to Directive 2014/30/EU.

Conformity assessment bodies shall provide the other bodies recognised under this chapter carrying out similar conformity assessment activities covering the same equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

The Commission, the Member States, Switzerland and the other bodies recognised under this chapter may request a copy of the type examination certificates and additions thereto. On request, the Commission, Member States, and Switzerland may obtain a copy of the technical documentation and the results of the examinations carried out by a body recognised under this chapter.

7. **Cooperation between market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

8. **Procedure for dealing with equipment presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that equipment covered by this chapter presents a risk to aspects of public interest protection covered by the legislation in Section I of this Chapter and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict equipment being made available on their national market, to withdraw equipment from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of non-compliant equipment, its origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of equipment to meet requirements referred to in the legislation in Section I, or

— shortcomings in the standards referred to in the legislation in Section I.

Switzerland or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the equipment concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of equipment concerned, such as its withdrawal from their market, without delay.

9. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the national measure in paragraph 8, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 8, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that non-compliant equipment be withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 11.

10. **Compliant equipment which nevertheless present a risk**

Where a Member State or Switzerland finds that, although an equipment within the scope of Directive 2014/35/EU that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to the health or safety of persons, or to domestic animals or to property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of equipment concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and, where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 11.

11. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures pursuant to paragraphs 9 and 10 above, the issue will be forwarded to the Committee established under Article 10 of this Agreement, which will decide on an appropriate course of action, including the possibility to have an expert study carried out. Where the Committee considers that the measure is

(a) unjustified, the national authority of the Member State or Switzerland shall withdraw it;

(b) justified, they shall take the appropriate measures to ensure that products are withdrawn from their market.'

ATTACHMENT F

In Annex 1, Product Sectors, Chapter 11, Measuring instruments and prepackages should be deleted and replaced by the following one:

'CHAPTER 11

MEASURING INSTRUMENTS AND PREPACKAGES

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(1)

European Union

1. Council Directive 71/347/EEC of 12 October 1971 on the approximation of the laws of the Member States relating to the measuring of the standard mass per storage volume of grain (OJ L 239, 25.10.1971, p. 1), as subsequently amended
2. Council Directive 76/765/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcoholmeters and alcohol hydrometers (OJ L 262, 27.9.1976, p. 143), as subsequently amended
3. Council Directive 86/217/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles (OJ L 152, 6.6.1986, p. 48), as subsequently amended
4. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14), as subsequently amended
5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making up by weight or by volume of certain prepackaged products (OJ L 46, 21.2.1976, p. 1), as subsequently amended
6. Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p. 17) applicable as from 11 April 2009

Switzerland

100. Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204), as subsequently amended
101. Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204.1), as subsequently amended

Provisions covered by Article 1(2)

European Union

1. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (Recast) (OJ L 106, 28.4.2009, p. 7)
2. Council Directive 71/317/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to 5 to 50 kilogramme medium accuracy rectangular bar weights and 1 to 10 kilogramme medium accuracy cylindrical weights (OJ L 202, 6.9.1971, p. 14)
3. Council Directive 74/148/EEC of 4 March 1974 on the approximation of the laws of the Member States relating to weights of from 1 mg to 50 kg of above-medium accuracy (OJ L 84, 28.3.1974, p. 3)
4. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40) as last amended by Directive 2009/3/EC of the European Parliament and of the Council of 11 March 2009 (OJ L 114, 7.5.2009, p. 10)

5. Council Directive 76/766/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to alcohol tables (OJ L 262, 27.9.1976, p. 149)

6. Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107)

7. Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149)

8. Directive 2011/17/EU of the European Parliament and of the Council of 9 March 2011 repealing Council Directives 71/317/EEC, 71/347/EEC, 71/349/EEC, 74/148/EEC, 75/33/EEC, 76/765/EEC, 76/766/EEC and 86/217/EEC regarding metrology (OJ L 71, 18.3.2011, p. 1)

Switzerland

102. Federal Law of 17 June 2011 on metrology (RO 2012 6235)

103. Ordinance of 23 November 1994 on units measurement (RO 1994 3109), as last amended on 7 December 2012 (RO 2012 7193)

104. Ordinance of 15 February 2006 concerning measuring instruments (RO 2006 1453), as last amended on 25 November 2015 (RO 2015 5835)

105. Ordinance of the Federal Ministry of Justice and Police of 16 April 2004 on non-automatic weighing instruments (RO 2004 2093), as last amended on 25 November 2015 (RO 2015 5849)

106. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments of length (RO 2006 1433), as last amended on 7 December 2012 (RO 2012 7183)

107. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measure of volume (RO 2006 1525), as last amended on 7 December 2012 (RO 2012 7183)

108. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring systems for liquids other than water (RO 2006 1533) as last amended on 7 December 2012 (RO 2012 7183)

109. Ordinance of the federal Ministry of Justice and Police of 19 March 2006 on automatic weighing instruments (RO 2006 1545), as last amended on 7 December 2012 (RO 2012 7183)

110. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO 2006 1569), as last amended on 7 December 2012 (RO 2012 7183)

111. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO 2006 1591), as last amended on 7 December 2012 (RO 2012 7183)

112. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for exhaust gases of combustion engines (RO 2006 1599), as last amended on 19 November 2014 (RO 2014 4551)

113. Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for the electrical energy and power (RO 2006 1613), as last amended on 7 December 2012 (RO 2012 7183)

114. Ordinance of the Federal Ministry of Justice and Police of 15 August 1986 on weights (RO 1986 2022), as last amended on 7 December 2012 (RO 2012 7183)

115. Ordinance of the Federal Ministry of Justice and Police of 5 November 2013 on taximeters (RO 2013 4333), as last amended on 19 November 2014 (RO 2014 4547)

116. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter 4 of Directive 2014/31/EU and Chapter 4 of Directive 2014/32/EU, as regards the products covered by those Directives.

SECTION V

Supplementary provisions

1. **Prepackages**

Switzerland shall recognise checks carried out in accordance with the provisions of Union legislation listed in Section I by a Union body recognised under this Agreement in the case of Union prepackages placed on the market in Switzerland.

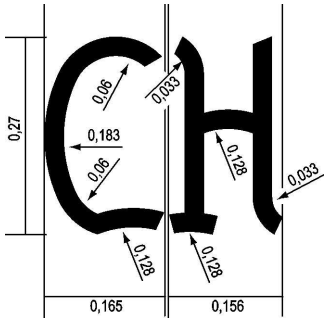
As regards statistical checking of the quantities declared on prepackages, the European Union shall recognise the Swiss method laid down in Annex 3 Point 7 of the Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RS 941.204) as equivalent to the European Union method laid down in Annex II of Directives 75/106/EEC and 76/211/EEC, as amended by Directive 78/891/EEC. Swiss producers whose prepackages conform to Union legislation and have been checked according to the Swiss method shall affix the "e" mark on their products exported to the EU.

2. **Marking**

2.1. For the purposes of this Agreement, the provisions of Council Directive 2009/34/EC of 23 April 2009 shall be read with the following adaptations:

(a) To the first indent of point 3.1.of Annex 1 and to the first indent of point 3.1.1.1 (a) of Annex II, the following shall be added to the text in brackets: "CH for Switzerland".

(b) The drawings to which point 3.2.1 of Annex II refers, are supplemented by the following drawing:



2.2. By the way of derogation from Article 1 of this Agreement, the rules on marking for measuring instruments placed on the Swiss market are as follows:

The marking that must be affixed is the EC marking and supplementary metrology marking or the national sign of the EC Member State concerned as provided in the first indent of point 3.1 of Annex I and the first indent of point 3.1.1.1 of Annex II to Directive 2009/34/EC of 23 April 2009.

3. Non-automatic weighing instruments covered by Directive 2014/31/EU and measuring instruments covered by Directive 2014/32/EU

3.1. *Economic operators*

3.1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 6(6) and 8(3) of Directive 2014/31/EU, respectively Articles 8(6) and 10(3) of Directive 2014/32/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer in not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 6(3) and 8(8) of Directive 2014/31/EU, respectively Articles 8(3) and 10(8) of Directive 2014/32/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the instrument has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the instrument has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 6(4), second subparagraph, and 8(6) of Directive 2014/31/EU, respectively Articles 8(4), second subparagraph, and 10(6) of Directive 2014/32/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

3.1.2. *Authorised representative*

For the purpose of the obligation in Article 7(2) of Directive 2014/31/EU, respectively Article 9(2) of Directive 2014/32/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 7(1) of Directive 2014/31/EU, respectively Article 9(1) of Directive 2014/32/EU or the corresponding Swiss provisions.

3.1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of instrument with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the instrument.

3.2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 34 of Directive 2014/31/EU and Article 39 of Directive 2014/32/EU.

3.3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 35 of Directive 2014/31/EU, respectively Article 40 of Directive 2014/32/EU, directly or by means of designated representatives.

3.4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

3.5. **Procedure for dealing with instruments presenting a risk caused by non-compliance not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that an instrument covered by this chapter presents a risk to aspects of public interest protection covered by Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the instrument's being made available on their national market, to withdraw the instrument from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant instrument, the origin of the instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the instrument to meet requirements relating to aspects of public interest protection laid down in Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions, or

— shortcomings in the harmonised standards referred to in Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions.

Switzerland, or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the instrument concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the instrument concerned, such as withdrawal of an instrument from their market, without delay.

3.6. **Safeguard procedure in case of objections against national measures**

Should it disagree with the notified national measure, Switzerland or a Member State shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 3.4, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to Directive 2014/31/EU or Directive 2014/32/EU, or the corresponding Swiss provisions, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to an instrument is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant instrument is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 3.8.

3.7. **Compliant instruments which nevertheless present a risk to health and safety**

Where a Member State or Switzerland finds that, although an instrument that an economic operator has been made available on the EU and on the Swiss market is in compliance with Directive 2014/31/EU or Directive 2014/32/EU, respectively the relevant Swiss legislation, presents a risk to aspects of public interest protection, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 3.8.

3.8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in subparagraphs 3.6 and 3.7 above, the issue will be forwarded to the Committee, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the instrument is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT G

In Annex 1, Product Sectors, Chapter 15, Medicinal products, GMP Inspection and Batch Certification should be deleted and replaced by the following:

'CHAPTER 15

MEDICINAL PRODUCTS, GMP INSPECTION AND BATCH CERTIFICATION

Scope and coverage

The provisions of this Sectoral Chapter cover all medicinal products which are industrially manufactured and to which Good Manufacturing Practice (GMP) requirements apply.

For medicinal products covered by this Chapter, each party shall recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the competent authorities of the other Party. This includes that each Party recognises conclusions of inspections of manufacturers in third countries carried out by the relevant inspection services of the other Party, inter alia, within the framework of the European Directorate for the Quality of Medicines & HealthCare (EDQM).

The Parties shall cooperate in order to achieve the best use of inspection resources by an appropriate burden sharing.

The manufacturer's certification of the conformity of each batch to its specifications shall be recognised by the other Party without re-control at import. To the products imported from a third country and further exported to the other Party this provision applies only (1) if each batch of the medicinal products has been subject to the re-control in the territory of one of the Parties; and (2) if the manufacturer in the third country has been subject to the inspection by the competent authority of either Party of which the outcome has been that for the products or products category the manufacturer complies with Good Manufacturing Practice. If the above conditions are not met, each Party can require a re-control in its territory.

In addition, official batch releases carried out by an authority of the exporting Party will be recognised by the other Party.

"Medicinal products" means all products regulated by pharmaceutical legislation in the European Union and Switzerland as listed in Section I of this Chapter. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs and, where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products.

"GMP" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and products specifications. For the purpose of this Chapter it includes the system whereby the manufacturer receives the specification of the product and the process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification.

With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, an inspection be made by the locally competent inspection service. This provision shall apply i.a. to the manufacture of active pharmaceutical ingredients, intermediate products and investigational medicinal products, as well as to pre-marketing inspections. Operational arrangements are detailed under Section III, paragraph 3.

Certification of manufacturers

At the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products shall certify that the manufacturer:

— is appropriately authorised to manufacture the relevant medicinal product, or to carry out the relevant specified manufacturing operation,

— is regularly inspected by the authorities,

— complies with the national GMP requirements recognised as equivalent by the two parties, and which are listed in Section I of this Chapter. Should different GMP requirements be used as reference, this is to be mentioned in the certificate.

For inspections in third countries, at the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for the inspection shall certify that the manufacturer complies or does not comply with the GMP requirements recognised as equivalent by the two Parties, and which are listed in Section I of this Chapter.

The certificates shall also identify the site(s) of manufacture (and contract quality control laboratories, if any) and the date of the inspection.

Certificates shall be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, i.e. when a new inspection has to be carried out, this period may be extended to 90 days.

Batch certification

Each batch exported shall be accompanied by a batch certificate established by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active ingredients and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate shall attest that the batch meets its specifications and shall be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer shall take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate shall detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It shall contain a statement that the batch processing and packaging records were reviewed and found in conformity with GM P. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Union the "qualified person" referred to in Article 48 of Directive 2001/83/EC and Article 52 of Directive 2001/82/EC, and in Switzerland the "responsible person" referred to in Articles 5 and 10 of the Ordinance on establishment licences.

Official Batch Release

When an official batch release procedure applies, official batch releases carried out by an authority of the exporting Party (listed in Section II) will be recognised by the other Party. The manufacturer shall provide the certificate of the official batch release.

For the European Union, the official batch release procedure is specified in document "Control Authority Batch Release of Vaccination and Blood Products, 2001" or subsequent versions and in different specific batch release procedures. For Switzerland, the official batch release procedure is specified in Article 17 of the Federal Law on medicinal products and medical devices and in Articles 18-21 of the Ordinance of the Swiss Agency for Therapeutic Products on the requirements for the marketing authorisation of medicinal products.

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1) as last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38) 2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67) as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1)

3. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30)

4. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1) as last amended by Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC as regards variations to the terms of marketing authorisations for medicinal products (OJ L 168, 30.6.2009, p. 33)

5. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22)

6. Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70) and Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42)

7. Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 343, 23.11.2013, p. 1)

8. EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission)

9. Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34) and Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1)

10. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13)

11. Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1)

Switzerland

100. Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 1 January 2014 (RO 2013 4137)

101. Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 1 May 2016 (RO 2016 1171)

102. Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437), as last amended on 1 May 2016 (RO 2016 1171)

103. Ordinance of 20 September 2013 on clinical trials in human research (RO 2013 3407) as last amended on 1 May 2017 (RO 2017 2439)

SECTION II

Conformity assessment bodies

For the purpose of this Chapter "Conformity Assessment Bodies" means the official GMP inspection services of each Party.

The list of the official GMP Inspection Services of the Member States of the European Union and of Switzerland can be found below.

For conformity assessment bodies of the European Union:

Competent Authorities of the European Union are the following authorities of the Member States of the European Union or authorities succeeding them:

Country	For medicinal products for human use	For medicinal products for veterinary use
Austria	Austrian Agency for Health and Food Safety/ Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See responsible authority for human medicinal products
Belgium	Federal agency for medicines and health products/Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/Agence fédérale des médicaments et produits de santé	See responsible authority for human medicinal products
Bulgaria	Bulgarian Drug Agency/ ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/ Българска агенция по безопасност на храните
Cyprus	Ministry of Health — Pharmaceutical Services/ Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment-Veterinary Services/ Κτηνιατρικές Υπηρεσίες- Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος
Czech Republic	State Institute for Drug Control/ Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments/ Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Croatia	Agency for Medicinal Products and Medical Devices/ Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate/ Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane
Denmark	Danish Medicines Agency/ Laegemiddelstyrelsen	See responsible authority for human medicinal products
Germany	Federal Institute for Drugs and Medical Devices/ Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines/Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel Federal Ministry of Health/Bundesministerium für Gesundheit (BMG)/Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) [1]	Federal Office for Consumer Protection and Food Safety/ Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
Estonia	State Agency of Medicines/ Ravimiamet	See responsible authority for human medicinal products
Greece	National Organisation for Medicines/ Ethnikos Organismos Farmakon (EOF) — (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See responsible authority for human medicinal products
Spain	Spanish Agency of Medicines and Medical Devices/ Agencia Española de Medicamentos y Productos Sanitarios [2]	See responsible authority for human medicinal products

Country	For medicinal products for human use	For medicinal products for veterinary use
Finland	Finnish Medicines Agency/ Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)	See responsible authority for human medicinal products
France	French National Agency for Medicines and Health Products Safety/Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety-*National Agency for Veterinary Medicinal Products*/ Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail-Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet/National Institute of Pharmacy and Nutrition	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products/Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for human medicinal products
Italy	Italian Medicines Agency/Agenzia Italiana del Farmaco	Direction General for Animal Health and Veterinary Medicinal Products/ Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari
Latvia	State Agency of Medicines/ Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency/ Valstybinė vaistų kontrolės tarnyba	State Food and Veterinary Service/ Valstybinės maisto ir veterinarijos tarnyba
Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	See responsible authority for human medicinal products
Malta	Medicines Regulatory Authority	Veterinary Medicines and Animal Nutrition section VMANS) (Veterinary Regulation Directorate (VRD) within the Veterinary and Phytosanitary Regulation Department (VPRD)
Netherlands	Healthcare Inspectorate/Inspectie voor de Gezondheidszorg (IGZ)	Medicines Evaluation Board/ Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)
Poland	The Main Pharmaceutical Inspectorate/ Główny Inspektorat Farmaceutyczny (GIF)	See responsible authority for human medicinal products
Portugal	National Authority of Medicines and Health Products/ INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary/DGAV — Direção Geral de Alimentação e Veterinária (PT)
Romania	National Agency for Medicines and Medical Devices/ Agenția Națională a Medicamentului şi a Dispozitivelor Medicale	National Sanitary Veterinary and Food Safety Authority/Autoritatea Națională Sanitară Veterinară şi pentru Siguranța Alimentelor
Sweden	Medical Products Agency/Läkemedelsverket	See responsible authority for human medicinal products

Country	For medicinal products for human use	For medicinal products for veterinary use
Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia/ Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See responsible authority for human medicinal products
Slovak Republic (Slovakia)	State Institute for Drug Control/ Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments/ Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
United Kingdom	Medicines and Healthcare products Regulatory Agency	Veterinary Medicines Directorate

(1) For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as covering all the competent *Länder* authorities issuing GMP documents and conducting pharmaceutical inspections.

(2) For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing GMP documents and conducting pharmaceutical inspections.

For Swiss conformity assessment bodies:

For all products for human and veterinary use:

http://www.swissmedic.ch/?lang=2

For the official batch release of immunobiological products for veterinary use:

http://www.blv.admin.ch/ivi/index.html?lang=en

SECTION III

Additional provisions

1. Transmission of inspection reports

Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing site or, in case analytical operations are contracted out, of the control site. The request may concern a "full inspection report" or a "detailed report" (see item 2 below). Each party shall deal with these inspection reports with the degree of confidentiality requested by the providing Party.

Parties will ensure that inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 days should a new inspection be carried out.

2. Inspection reports

A "full inspection report" comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A "detailed report" responds to specific **queries about a firm by the other Party**.

3. GMP Reference

(a) Manufacturers shall be inspected according to the applicable GMP legislation listed in Section I.

(b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting country, the competent inspection service of the Party willing to carry out an inspection of the relevant manufacturing operations shall inspect according to its own GMP or, in the absence of specific GMP requirements, according to the applicable GMP of the importing Party.

For specific products or classes of products (e.g. investigational medicinal products, starting materials not limited to active pharmaceutical ingredients), equivalence of GMP requirements shall be determined according to a procedure established by the Committee.

4. **Nature of inspections**

(a) Inspections shall routinely assess the compliance of the manufacturer with GM P. These are called general GMP inspections (also regular, periodic, or routine inspections).

(b) "Product- or process-oriented" inspections (which may be "pre-marketing" inspections as relevant) focus on the manufacture of one or a series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) shall be provided in confidence to the inspectorate.

5. **Fees**

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees shall not be charged to manufacturers located on the territory of the other Party.

6. **Safeguard clause for inspections**

Each Party reserves the right to have its own inspection conducted for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party and shall, in accordance with Article 8 of this Agreement, be carried out jointly by the competent authorities of the two Parties. Recourse to this safeguard clause should be an exception.

7. **Exchange of information on manufacturing/import authorisations and GMP compliance**

The Parties shall exchange information on the authorisation status of manufacturers and importers and on the outcome of the inspections, in particular by entering authorisations, GMP certificates and information on GMP non-compliance into the database on GMP managed by the European Medicines Agency (EMA). GMP certificates and information on GMP-compliance shall follow the format in accordance with the procedures published by the EU.

In accordance with the general provisions of this Agreement, the parties shall exchange any information necessary for the mutual recognition of inspections and operation of this chapter.

The relevant authorities in Switzerland and in the European Union shall also keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult the other before their adoption and shall endeavour to proceed towards their approximation.

8. **Inspectors' training**

In accordance with Article 9 of the Agreement, training sessions for inspectors, organised by the authorities, shall be accessible to inspectors of the other Party. The Parties to the Agreement shall keep each other informed on these sessions.

9. **Joint inspections**

In accordance with Article 12 of this Agreement, and by mutual agreement between the Parties, joint inspections may be organised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Committee established under Article 10 of this Agreement.

10. **Alert system**

Contact points shall be agreed between both Parties to permit authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.

The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could have public health implications, are communicated to each other with the appropriate degree of urgency.

11. **Contact points**

For the purpose of this Agreement, the contact points for any technical question, such as exchanges of inspection reports, inspectors training sessions, technical requirements, are:

For the European Union

The Director of the European Medicines Agency.

For Switzerland

The official GMP inspection services listed in Section II above.

12. **Divergence of views**

Both Parties shall use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Committee as established under Article 10 of this Agreement.'

ATTACHMENT H

In Annex 1, Product Sectors, Chapter 17, Lifts should be deleted and replaced by the following one:

'CHAPTER 17

LIFTS

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/33/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 lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251)
Switzerland	100. Federal Law of 12 June 2009 on product safety (RO 2010 2573)
	101. Ordinance of 19 May 2010 on product safety (RO 2010 2583), as last amended on 15 June 2012 (RO 2012 3631)
	102. Ordinance of 25 November 2015 on the safety of lifts (RO 2016 219)
	103. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained this Agreement and the assessment criteria set out in Chapter 4 of Directive 2014/33/EU.

SECTION V

Supplementary provisions

1. **Economic operators**

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 8(6) and 10(3) of Directive 2014/33/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Article 8(3) and 10(8) of Directive 2014/33/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the safety component for lifts has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the safety component for lifts has been placed on the market in either the European Union or Switzerland;

(c) for the purpose of the obligations in Articles 8(4), second subparagraph, and 10(6) of Directive 2014/33/EU and the corresponding Swiss provisions, it shall be sufficient that such obligations be fulfilled by the manufacturer established within the territory of either the European Union or Switzerland, or, in case the manufacturer is not established within the territory of either the European Union or Switzerland, by the importer established within the territory of either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 9(2) of Directive 2014/33/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 9(1) of Directive 2014/33/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. **Exchange of experience**

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 35 of Directive 2014/33/EU.

3. **Coordination of conformity assessment bodies**

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 36 of Directive 2014/33/EU, directly or by means of designated representatives.

4. **Mutual assistance of market surveillance authorities**

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with lifts or safety components for lifts presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that a lift or a safety component for lifts covered by this chapter presents a risk to the health or safety of persons or, where appropriate, to the safety of property, covered by the legislation in Section I of this Chapter, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operators to take,

— where the installer does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the placing on their national market or the use of the lift concerned, or to recall it,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the safety component for lifts being made available on their national market, to withdraw the safety component for lifts from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant lift or safety component for lifts, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the lift or the safety component for lifts to meet requirements relating to the health and safety requirements referred to in the legislation in Section I, or

— shortcomings in the harmonised standards referred to in the legislation in Section I.

Switzerland, or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the lift or the safety component for lifts concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the lift or the safety component for lifts concerned, such as withdrawal of the lift or safety component for lifts from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should Switzerland or a Member State disagree with the notified national measure in paragraph 5, it shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure relating to a lift is considered justified, all Member States and Switzerland shall take the measures necessary to ensure that the placing on the market or use of the non-compliant lift concerned is restricted or prohibited, or that the lift is recalled, and shall inform the Commission accordingly.

If the national measure relating to a safety component for lift is considered justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant safety component for lifts is withdrawn from their markets, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although a lift or a safety component for lifts that an economic operator has made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk to the health or safety of persons and, where appropriate, the safety of property, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the lift or safety component for lifts concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures pursuant to paragraphs 6 and 7 above, the issue will be forwarded to the Committee, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.'

ATTACHMENT I

In Annex 1, Product Sectors, Chapter 20, Explosives for civil use should be deleted and replaced by the following one:

'CHAPTER 20

EXPLOSIVES FOR CIVIL USE

SECTION I

Legislative, regulatory and administrative provisions

Provisions covered by Article 1(2)

European Union	1. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1) [1]
	2. Commission Directive 2008/43/EC of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the indication and traceability of explosives for civil uses (OJ L 94, 5.4.2008, p. 8), as amended by Commission Directive 2012/4/EU (OJ L 50, 23.2.2012, p. 18), hereinafter referred to as "Directive 2008/43/EC"
	3. Commission Decision 2004/388/EC of 15 April 2004 on an Intra-Community transfer of explosives document (OJ L 120, 24.4.2004, p. 43), as amended by Commission Decision 2010/347/EU (OJ L 155, 22.6.2010, p. 54), hereinafter referred to as "Decision 2004/388/EC"
Switzerland	100. Federal Act of 25 March 1977 on explosive substances (Explosives Act) as last amended on 12 June 2009 (RO 2010 2617)
	101. Ordinance of 27 November 2000 on explosives (Explosives Ordinance), as last amended on 25 November 2015 (RO 2016 247)
	102. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)

[1] This Chapter shall not apply to explosives intended for use, in accordance with national law, by the armed forces or the police, to pyrotechnical articles and to ammunition.

SECTION II

Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

SECTION III

Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designation of authorities notified by the Parties.

SECTION IV

Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall comply with the general principles contained in Annex 2 to this Agreement and the assessment criteria set out in Chapter 5 of Directive 2014/28/EU.

SECTION V

Supplementary provisions

1. Economic operators

1.1. *Specific obligations of economic operators pursuant to the legislation under Section I*

Pursuant to the legislation under Section I, economic operators established in the EU or Switzerland are subject to equivalent obligations.

In order to avoid unnecessary duplication of obligations:

(a) for the purpose of the obligations in Articles 5(5)(b) and 7(3) of Directive 2014/28/EU and the corresponding Swiss provisions, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the manufacturer established within the territory of either the European Union or Switzerland can be contacted. In case the manufacturer in not established within the territory of either the European Union or Switzerland, it shall be sufficient to indicate the name, registered trade name or registered trade mark and the postal address at which the importer established within the territory of either the European Union or Switzerland can be contacted;

(b) for the purpose of the obligations in Articles 5(3) and 7(7) of Directive 2014/28/EU and the corresponding Swiss provisions, it shall be sufficient that the manufacturer established within the territory of either the European Union or Switzerland keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the explosive has been placed on the market in either the European Union or Switzerland. In case the manufacturer is not established within the territory of either the European Union or Switzerland, it shall be sufficient that the importer established within the territory of either the European Union or Switzerland keep a copy of the EU declaration of conformity or, where applicable, the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request for 10 years after the explosive has been placed on the market in either the European Union or Switzerland.

1.2. *Authorised representative*

For the purpose of the obligation in Article 6(2) of Directive 2014/28/EU and the corresponding Swiss provisions, authorised representative shall mean any natural or legal person established within the European Union or Switzerland who has received a written mandate from a manufacturer to act on his behalf pursuant to Article 6(1) of Directive 2014/28/EU or the corresponding Swiss provisions.

1.3. *Cooperation with market surveillance authorities*

The competent national market surveillance authority of a Member State of the European Union or Switzerland may, on reasoned request, ask the relevant economic operators in the European Union and in Switzerland to provide all the information and documentation necessary to demonstrate the conformity of a product with the legislation in Section I.

That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request manufacturers or, where applicable, authorised representatives and importers to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product.

2. Exchange of experience

Swiss designating authorities may take part in the exchange of experience between the Member States' national authorities referred to in Article 39 of Directive 2014/28/EU.

3. Coordination of conformity assessment bodies

Swiss designated conformity assessment bodies may take part in the coordination and cooperation mechanisms provided for in Article 40 of Directive 2014/28/EU, directly or by means of designated representatives.

4. Mutual assistance of market surveillance authorities

Pursuant to Article 9(1) of the Agreement, the Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of Member States and Switzerland shall cooperate and exchange information. They shall give each other assistance on an adequate scale by supplying information or documentation concerning economic operators based in a Member State or in Switzerland.

5. **Procedure for dealing with explosives presenting a risk not restricted to the national territory**

Pursuant to Article 12(4) of this Agreement, where the market surveillance authorities of a Member State or Switzerland have taken action or have sufficient reason to believe that an explosive covered by this chapter presents a risk to the health or safety of persons or to the property or the environment covered by Directive 2014/28/EU respectively the relevant Swiss legislation, and if they consider that non-compliance is not restricted to their national territory, they shall inform the European Commission, the other Member States and Switzerland without delay of:

— the results of the evaluation and of the actions which they have required the economic operators to take,

— where the relevant economic operator does not take adequate corrective action, all appropriate provisional measures taken to prohibit or restrict the explosives' being made available on their national market, to withdraw the explosive from that market or to recall it.

This information shall include all available details, in particular the data necessary for the identification of the non-compliant explosive, the origin of the explosive, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, it shall be indicated whether the non-compliance is due to either:

— failure of the explosive to meet requirements relating to the health or safety of persons, or to the protection of property or the environment and safety requirements referred to in the relevant legislation in Section I, or

— shortcomings in the harmonised standards referred to in the relevant legislation in Section I.

Switzerland, or Member States shall without delay inform the European Commission and the other national authorities of any measures adopted and of any additional information at their disposal relating to the non-compliance of the explosive concerned.

Member States and Switzerland shall ensure that appropriate restrictive measures are taken in respect of the explosive concerned, such as withdrawal of an explosive from their market, without delay.

6. **Safeguard procedure in case of objections against national measures**

Should it disagree with the notified national measure in paragraph 5, Switzerland or a Member State shall inform the European Commission of its objections within three months of the receipt of the information.

Where, on completion of the procedure set out in paragraph 5, objections are raised by a Member State or Switzerland against a measure taken by Switzerland or a Member State or where the Commission considers a national measure to be contrary to the relevant legislation referred to in Section I, the European Commission shall without delay enter into consultation with the Member States, Switzerland, and via the Swiss authorities the relevant economic operator or operators. It shall evaluate the national measure, in order to determine whether the national measure is justified or not.

If the national measure is considered:

— justified, all Member States and Switzerland shall take the measures necessary to ensure that the non-compliant explosive is withdrawn from their markets, and shall inform the Commission accordingly,

— unjustified, the Member State concerned or Switzerland shall withdraw that measure.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

7. **Compliant products which nevertheless present a risk**

Where a Member State or Switzerland finds that, although an explosive that an economic operator has been made available on the EU and on the Swiss market is in compliance with the legislation referred to in Section I of this Chapter, it presents a risk for the health or safety of persons or to the property or the environment, it shall take all appropriate measures and immediately inform the Commission, other Member States and Switzerland. That information shall include all available details, in particular the data necessary for the identification of the explosive concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

The Commission shall without delay enter into consultation with the Member States, Switzerland and via the Swiss authorities the relevant economic operator or operators, and shall evaluate the national measures taken, in order to determine whether the national measure is justified or not, and where necessary, propose appropriate measures.

A Party may forward the issue to the Committee established under Article 10 of this Agreement, pursuant to paragraph 8.

8. **Safeguard clause in case of remaining disagreement between the Parties**

In case of a disagreement between the Parties on measures at stake in paragraphs 6 and 7 above, the issue will be forwarded to the Committee, which will decide on an appropriate course of action, including the possibility to have an expert study carried out.

Where the Committee considers that the measure is:

(a) justified, the Parties shall take the measures necessary to ensure that the product is withdrawn from their market;

(b) unjustified, the national authority of the Member State or Switzerland shall withdraw the measure.

9. **Identification of products**

Both Parties shall ensure that undertakings in the explosives sector which manufacture or import explosives or assemble detonators shall mark explosives and each smallest packaging unit with a unique identification. Where an explosive is subject to further manufacturing processes, manufacturers shall not be required to mark the explosive with a new unique identification unless the original unique identification is no longer marked in compliance with Directive 2008/43/EC and/or the Explosives Ordinance.

The unique identification shall comprise the components prescribed in the Annex to Directive 2008/43/EC and Annex 14 to the Explosives Ordinance and shall be mutually recognised by both parties.

Each undertaking in the explosives sector and/or manufacturer shall be attributed a three-digit code by the Member State's or Swiss national authority where it is established. This three-digit code shall be mutually recognised by both Parties if the manufacturing site or the manufacturer is located in the territory of one of the Parties.

10. **Provisions governing the supervision of transfers between the European Union and Switzerland**

1. Explosives covered by this Chapter may be transferred between the European Union and Switzerland only in accordance with the following paragraphs.

2. Approval to transfer explosives shall be obtained by the consignee from the recipient competent authority. The competent authority shall verify that the consignee is legally authorised to acquire explosives and that he is in possession of the necessary licenses or authorisations. The economic operator responsible for the transfer shall notify the competent authorities of the transit Member State or Member States or Switzerland of any movements of explosives through the Member State concerned or Switzerland and shall obtain prior approval of the transit Member State concerned or Switzerland.

3. Where a Member State or Switzerland considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in paragraph 3, that Member State or Switzerland shall forward the available information on the subject to the European Commission which shall inform the other Member States and Switzerland accordingly through the Committee established under Article 10 of this Agreement.

4. Where the competent authority of the consignee in the Member State or Switzerland approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph 10(5). Such a document shall accompany the explosives until they arrive at their stated destination. It shall be produced at the request of the competent authorities. A copy of this document shall be retained by the consignee who shall present it, upon request, for examination by the competent authority of the consignee in the Member State or Switzerland.

5. Where transfers of explosives must be specially supervised in order to comply with special security requirements in the territory or part of the territory of a Member State or Switzerland, prior to the transfer the following information shall be provided by the consignee to the competent authority of the consignee in the Member State or Switzerland:

   (a) the names and addresses of the economic operators concerned;

   (b) the number and quantity of the explosives being transferred;

(c) a full description of the explosive in question and of the means of identification, including the United Nations identification number;

(d) where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;

(e) the means of transfer and the itinerary;

(f) the expected dates of departure and arrival;

(g) where necessary, the precise points of entry to and exit from Member States or Switzerland.

The information referred to in point (a) shall be sufficiently detailed in order to enable competent authorities to contact the economic operators and to obtain confirmation that the economic operators concerned are entitled to receive the consignment.

The competent authority of the consignee in the Member State or Switzerland shall examine the conditions under which the transfer may take place, with particular regard to the special security requirements. If the special security requirements are satisfied, approval for the transfer shall be granted. In the event of transit through the territory of other Member States or Switzerland, those States or Switzerland shall likewise examine and approve, the particulars concerning the transfer.

6. Where the competent authority of a Member State or Switzerland considers that special security requirements referred to in paragraph 10(4) and 10(5) are unnecessary, explosives can be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph 10(5). The recipient competent authority shall then grant an approval for a fixed period and liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph 10(4), which must accompany the explosives until they arrive at their destination, shall refer solely to the abovementioned approval.

7. Without prejudice to the normal checks which the country of departure shall carry out in its territory, at the request of the competent authorities concerned, the consignees and the economic operators concerned shall forward to the authorities of the country of departure and to those of country of transit all relevant information they possess concerning the transfer of explosives.

8. No economic operator may transfer explosives unless the consignee has obtained the necessary authorisations for the transfer in accordance with the provisions of paragraphs 10(2), 10(4), 10(5) and 10(6).

9. For the purposes of implementing paragraphs 4 and 5, the provisions of Decision 2004/388/EC shall apply.

11. **Information exchange**

In accordance with the general provisions of this Agreement, the Member States and Switzerland shall keep at each other's disposal any relevant information needed to ensure a proper implementation of Directive 2008/43/EC.'

ATTACHMENT J

Amendments to Annex 1

CHAPTER 3

TOYS

In Section I, Legislative regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to the European Union and Swiss provisions should be deleted and replaced by the following text:

'European Union	1. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1, as last amended by Commission Directive (EU) 2017/898 (OJ L 138, 25.5.2017, p. 128) (hereinafter referred to as "Directive 2009/48/EC")
Switzerland	100. Federal Law of 20 June 2014 on foodstuffs and commodities (RO 2017 249)
	101. Ordinance of 16 December 2016 on foodstuffs and commodities (RO 2017 283) as last amended on 2 May 2017 (RO 2017 2695)
	102. Ordinance of the Federal Department of Home Affairs (FDHA) of 15 August 2012 on the safety of toys (RO 2012 4717) as last amended on 1 May 2017 (RO 2017 1525)
	103. Ordinance of the FDHA of 16 December 2016 on the enforcement of foodstuff legislation (RO 2017 359
	104. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 20 April 2016 (RO 2016 261)'

CHAPTER 12

MOTOR VEHICLES

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to European Union and Swiss provisions should be deleted and replaced by the following text:

'European Union	1. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1), as last amended by Regulation (EU) 2015/758 of the European Parliament and of the Council of 29 April 2015 (OJ L 123, 19.5.2015, p. 77), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 29 April 2015 (hereinafter together referred to as "Framework Directive 2007/46/EC")
Switzerland	100. Ordinance of 19 June 1995 relating to the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as amended until 16 November 2016 (RO 2016 5195)
	101. Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 16 November 2016 (RO 2016 5213) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1'

In Section V, paragraph 1, Amendments to Annex IV respectively to acts listed in Annex IV of Directive 2007/46/EC should be deleted and replaced by the following text:

'1. **Amendments to Annex IV respectively to acts listed in Annex IV of Directive 2007/46/EC**

Without prejudice to article 12(2), the European Union shall notify Switzerland of amendments to Annex IV and to acts listed in Annex IV of Directive 2007/46/EC after 29 April 2015 without delay after their publication in the *Official Journal of the European Union*.

Switzerland shall notify the European Union without delay of the relevant amendments of the Swiss legislation, at the latest by the date of application of these amendments in the European Union.'

CHAPTER 14

GLP

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to the European Union and Swiss provisions should be deleted and replaced by the following text:

'European Union

Food and feed:

1. Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1)
2. Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 64, 11.3.2011, p. 15)
3. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1)

New and existing chemicals:

4. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1), as last amended by Commission Regulation (EU) No 348/2013 of 17 April 2013 (OJ L 108, 18.4.2013, p. 1)
5. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), as last amended by Commission Regulation (EU) No 944/2013 of 2 October 2013 (OJ L 261, 3.10.2013, p. 5)

Medicinal products:

6. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ L 299, 27.10.2012, p. 1). NB: Directive 2001/83/EC has been amended and the GLP requirement is now contained in the Introduction and General Principles chapter of Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46)
7. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1)

Veterinary medicinal products:

8. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), as last amended by Commission Directive 2009/9/EC of 10 February 2009 (OJ L 44, 14.2.2009, p. 10)

Plant protection products:

9. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)

10. Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1)

11. Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85)

Biocidal products:

12. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)

Cosmetic products:

13. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)

Detergents:

14. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1)

Medical devices:

15. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)

Switzerland

100. Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 20 June 2014 (RO 2016 689)

101. Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 20 June 2014 (RO 2016 689)

102. Ordinance of 5 June 2015 on protection against dangerous substances and preparations (RO 2015 1903), as last amended on 22 March 2017 (RO 2017 2593)

103. Ordinance of 18 May 2005 on biocidal products (RO 2005 2821) as last amended on 28 March 2017 (RO 2017 2441)

104. Ordinance of 12 May 2010 on the authorisation of plant protection products (RO 2010 2331), as last amended on 22 March 2017 (RO 2017 2593)

105. Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 21 June 2013 (RO 2013 4137)

106. Ordinance of 17 October 2001 on medicinal products (RO 2001 3420), as last amended on 23 March 2016 (RO 2016 1171)'

In Section III, Designating authorities, the Contact Details of the GLP 'Monitoring Authorities' of the European Union should be deleted and replaced by the following:

'For the European Union:

http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en'

CHAPTER 16

CONSTRUCTION PRODUCTS

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the first reference to European Union provisions should be deleted and replaced by the following one:

1. 'Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5), as last amended by Commission Delegated Regulation (EU) No 574/2014 from 21 February 2014 (OJ L 159, 28.5.2014, p. 41), as well as implementing and delegated acts of the Commission adopted under this regulation until 1 December 2016 (hereinafter together referred to as Regulation (EU) No 305/2011)'

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to the following European Union provisions should be deleted from the list:

'European Union

8. Commission Decision 96/581/EC of 24 June 1996 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards geotextiles (OJ L 254, 8.10.1996, p. 59)
16. Commission Decision 97/464/EC of 27 June 1997 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards waste water engineering products (OJ L 198, 25.7.1997, p. 33)
48. Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regards the classification of the reaction to fire performance of construction products (OJ L 50, 23.2.2000, p. 14)'

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to the Swiss provisions should be deleted and replaced by the following text:

'Switzerland

100. Federal law of 21 March 2014 on construction products (RO 2014 2867)
101. Ordinance of 27 August 2014 on construction products (RO 2014 2887)
102. Ordinance of the Federal office for Building and Logistics on the designation of European implementing and delegated acts regarding construction products of 10 September 2014 as last amended on 24 May 2016 (RO 2016 1413)
103. Ordinance of 17 June 1996 on the Swiss accreditation system and on the designation of test laboratories and conformity assessment bodies (RO 1996 1904), as last amended on 25 November 2015 (RO 2016 261)
104. Accord intercantonal sur l'élimination des entraves techniques au commerce du 23 octobre 1998 (RO 2003 270)'

In Section V, paragraph 1, Amendments to legislative, regulatory and administrative provisions of Section I should be deleted and replaced by the following text:

'1. **Amendments to legislative, regulatory and administrative provisions of Section I**

Without prejudice to Article 12(2) of this Agreement, the European Union shall notify Switzerland of implementing and delegated acts of the Commission under Regulation (EU) No 305/2011 adopted after 1 December 2016 without delay after their publication in the *Official Journal of the European Union*.

Switzerland shall notify the European Union without delay of the relevant amendments of the Swiss legislation.'

CHAPTER 18

BIOCIDAL PRODUCTS

In Section I, Legislative, regulatory and administrative provisions, Provisions covered by Article 1(2), the reference to the European Union and to the Swiss provisions should be deleted and replaced by the following text:

'European Union

1. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), (OJ L 167, 27.6.2012, p. 1), as last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 (OJ L 103, 5.4.2014, p. 22), as well as implementing and delegated acts of the Commission adopted under this regulation until 3 December 2015

Switzerland	100. Federal Law of 15 December 2000 for the protection against dangerous substances and preparations (RO 2004 4763), as last amended on 13 June 2006 (RO 2006 2197)
	101. Federal Law of 7 October 1983 relating to the protection of the Environment (RO 1984 1122), as last amended on 1 August 2010 (RO 2010 3233)
	102. Ordinance of 18 May 2005 concerning the making available on the market and the use of biocidal products (Ordinance on Biocidal Products, RO 2005 2821), as last amended on 1 September 2015 (RO 2015 2803) (hereinafter "OPBio")
	103. Ordinance of 15 August 2014 of the Department of Home Affairs on implementing rules related to the Ordinance on Biocidal Products (RO 2014 2755), as last amended on 15 September 2015 (RO 2015 3073)'

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