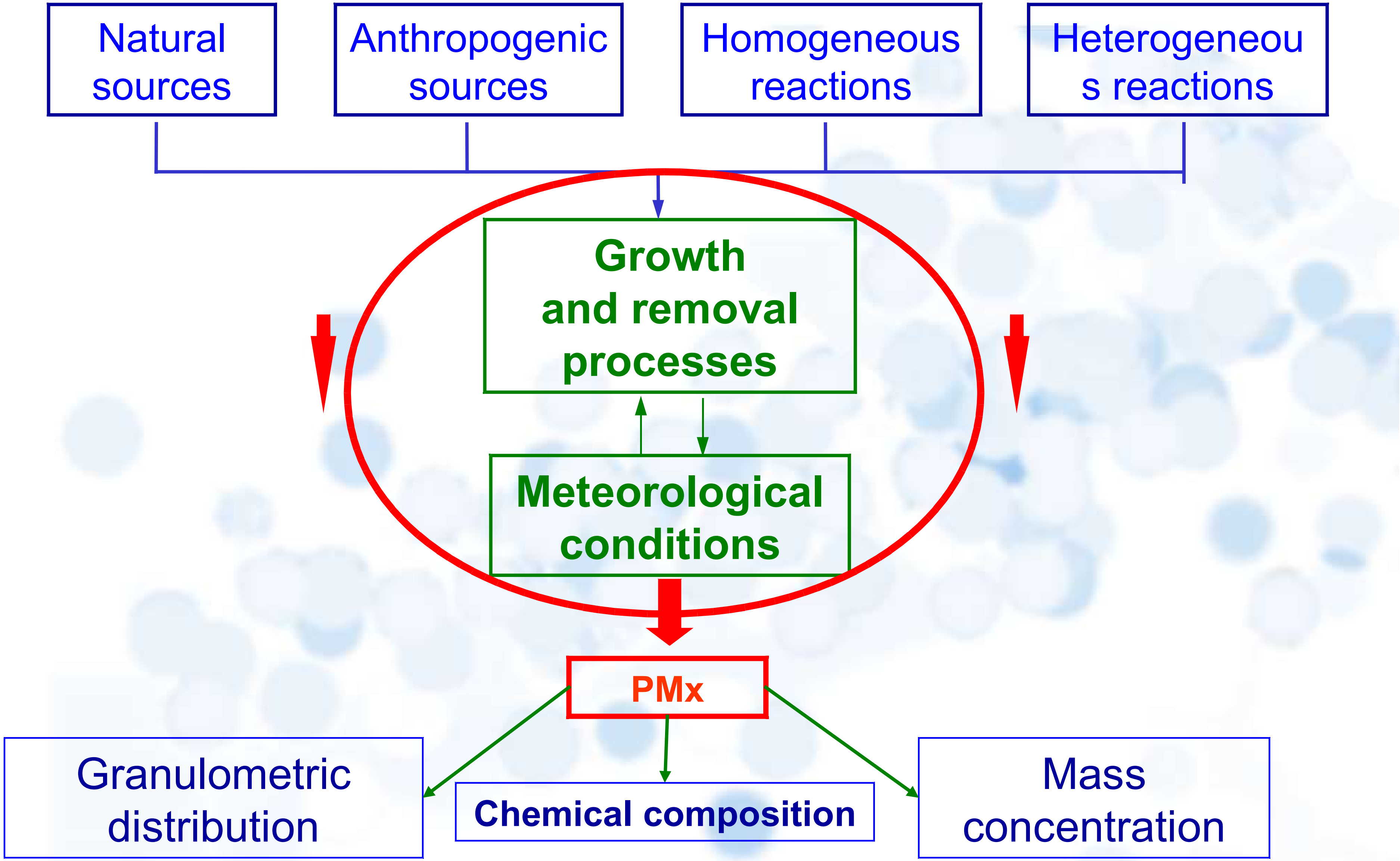
FAI instruments

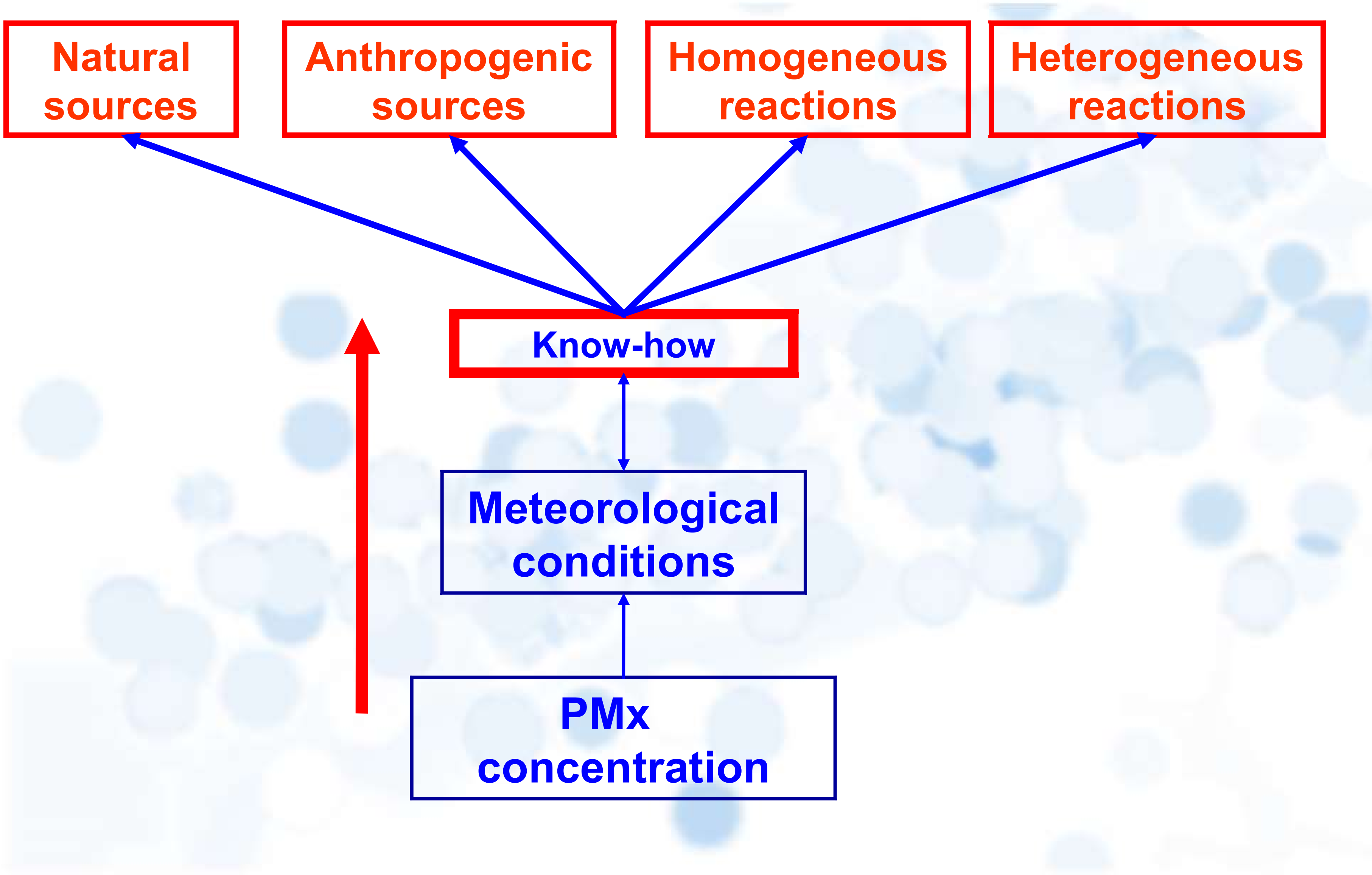
Health impacts of exposure to Particulate Matter

Status of Rules in EU Nations

PMx IN THE ATMOSPHERE

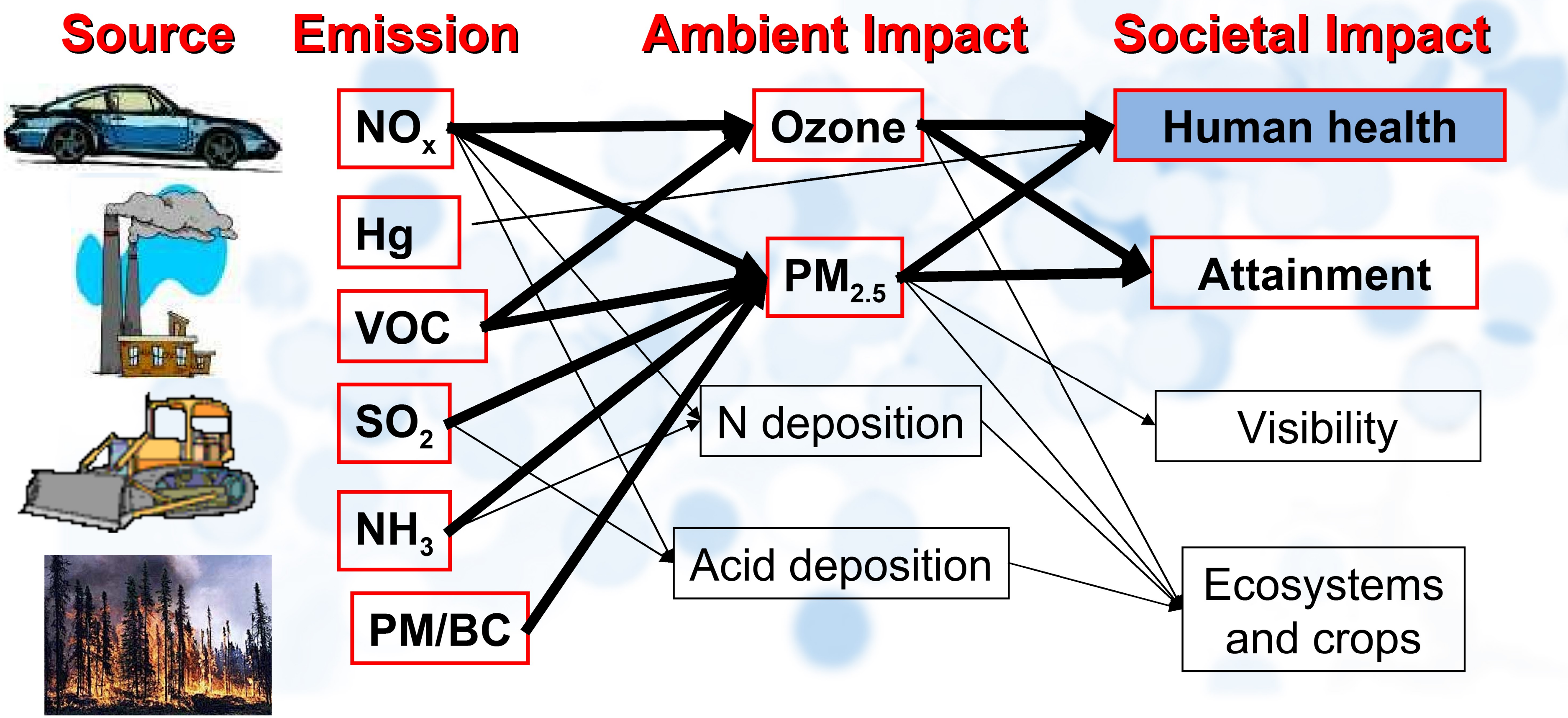


Air Quality Recovery Plans
(Reduction of Emission)



Multi-pollutant Attainment Planning

How can we objectively evaluate disparate control options, impacting different precursors, sectors, and locations?



Particulate Matter Air Pollution

EEA Report | No 13/2017

Air quality in Europe — 2017 report

ISSN 1725-9177

European Environment Agency

Europe's air quality

Particulate matter

Concentrations of PM continued to exceed the EU limit values in large parts of Europe in 2015. For PM with a diameter of 10 µm or less (PM_{10}), concentrations above the EU daily limit value were registered at 19 % of the reporting stations in 20 of the 28 EU Member States (EU-28) and in five other reporting countries; for PM with a diameter of 2.5 µm or less ($PM_{2.5}$), concentrations above the limit value were registered at 6 % of the reporting stations in three Member States and three other reporting countries.

A total of 19 % of the EU-28 urban population was exposed to PM_{10} levels above the daily limit value and approximately 53 % was exposed to concentrations exceeding the stricter WHO AQG value for PM_{10} in 2015. This represents an increase compared with 2014, but the magnitude of the change may be considered as being within the expected year-to-year variability. Regarding $PM_{2.5}$, 7 % of the urban population in the EU-28 was exposed to levels above the EU limit value, and approximately 82 % was exposed to concentrations exceeding the stricter WHO AQG value for $PM_{2.5}$ in 2015 (Table ES.1). This represents a decrease compared with 2014 but is within the expected year-to-year variability.

Ozone

The year 2015 was a historically warm year globally. On average, over Europe, 2015 was the warmest year on record to that point, with a series of heatwaves affecting Europe from May to September that contributed to several intense tropospheric ozone (O_3) episodes.

In 2015, 18 of the EU-28 and four other European countries registered concentrations above the EU O_3 target value for the protection of human health. The percentage of stations measuring concentrations above this target value was 41 %, higher than the 11 % recorded in 2014, and the highest over the previous 5 years. The WHO AQG value for O_3 was exceeded in 96 % of all the reporting stations.

Some 30 % of the EU-28 urban population lived in areas in which the EU O_3 target value threshold for protecting human health was exceeded in 2015. The proportion of the EU urban population exposed to O_3 levels exceeding the WHO AQG was significantly higher, comprising 95 % of the total urban population in 2015 (Table ES.1).

Table ES.1 Percentage of the urban population in the EU-28 exposed to air pollutant concentrations above certain EU and WHO reference concentrations (minimum and maximum observed between 2013 and 2015)

Pollutant	EU reference value ([a])	Exposure estimate (%)	WHO AQG ([a])	Exposure estimate (%)
$PM_{2.5}$	Year (25)	7-8	Year (10)	82-85
PM_{10}	Day (50)	16-20	Year (20)	50-62
O_3	8-hour (120)	7-30	8-hour (100)	95-98
NO_2	Year (40)	7-9	Year (40)	7-9
BaP	Year (1)	20-25	Year (0.12) RL	85-91
SO_2	Day (125)	< 1	Day (20)	20-38

Key				
	< 5 %	5-50 %	50-75 %	> 75 %

Notes: ([a]) In µg/m³; except BaP, in ng/m³.

The reference concentrations include EU limit or target values, WHO air-quality guidelines (AQGs) and an estimated reference level (RL).

For some pollutants, EU legislation allows a limited number of exceedances. This aspect is considered in the compilation of exposure in relation to EU air-quality limit and target values.

The comparison is made for the most stringent EU limit or target values set for the protection of human health. For PM_{10}, the most stringent limit value is for the 24-hour mean concentration and for NO_2 it is the annual mean limit value.

The estimated exposure range refers to the maximum and minimum values observed in a recent 3-year period (2013-2015) and includes variations attributable to meteorology, as dispersion and atmospheric conditions differ from year to year.

As the WHO has not set AQGs for BaP, the reference level in the table was estimated assuming WHO unit risk for lung cancer for PAH mixtures and an acceptable risk of additional lifetime cancer risk of approximately 1 in 100 000.

Source: EEA, 2017d.

Nitrogen dioxide

The annual limit value for nitrogen dioxide (NO_2) continues to be widely exceeded across Europe, with around 10 % of all the reporting stations recording concentrations above that standard in 2015 in a total of 22 of the EU-28 and three other reporting countries. 89 % of all concentrations above this limit value were observed at traffic stations.

Nine per cent of the EU-28 urban population lived in areas with concentrations above the annual EU limit value and the WHO AQG for NO_2 in 2015 (Table ES.1).

Benzo[a]pyrene, an indicator for polycyclic aromatic hydrocarbons

Exposure to benzo[*a*]pyrene (BaP) pollution is quite significant and widespread, in particular in central and eastern Europe. Only 22 Member States and two other countries reported measurements of BaP with enough valid data in 2015. One third of the reported BaP measurement stations in Europe had values above the EU target value in 2015, mostly in urban areas. About 23 % of the European urban population was exposed to BaP annual mean concentrations above the European target value in 2015 and about 88 % to concentrations above the estimated reference level [1] (Table ES.1).

Other pollutants: sulphur dioxide, carbon monoxide, benzene and toxic metals

The EU-28 urban population was not exposed to sulphur dioxide (SO_2) concentrations above the EU daily

Concentrations of arsenic (As), cadmium (Cd), lead (Pb) and nickel (Ni) in air are generally low in Europe, with few exceedances of limit or target values. However, these pollutants contribute to the deposition and accumulation of toxic metal levels in soils, sediments and organisms.

Impacts of air pollution on health

Air pollution continues to have significant impacts on the health of the European population, particularly in urban areas. It also has considerable economic impacts, cutting lives short, increasing medical costs and reducing productivity through working days lost across the economy. Europe's most serious pollutants in terms of harm to human health are PM, NO_2 and ground-level O_3.

Estimates of the health impacts attributable to exposure to air pollution indicate that $PM_{2.5}$ concentrations in 2014 [2] were responsible for about 428 000 premature deaths originating from long-term exposure in Europe (over 41 countries; see Table 10.1), of which around 399 000 were in the EU28. The estimated impacts on the population in these 41 European countries of exposure to NO_2 and O_3 concentrations in 2014 were around 78 000 and 14 400 premature deaths per year, respectively, and in the EU-28 around 75 000 and 13 600 premature deaths per year, respectively.

For this year's report, a sensitivity study has also been performed for the health impacts of $PM_{2.5}$ and NO_2. The lowest concentration used to calculate the health impacts of a pollutant in a baseline scenario is

1.3 Effects of air pollution

1.3.1 Human health

Air pollution is the single largest environmental health risk in Europe and the disease burden resulting from air pollution is substantial (Lim et al., 2012; WHO, 2014). Heart disease and stroke are the most common reasons for premature death attributable to air pollution and are responsible for 80 % of cases; lung diseases and lung cancer follow (WHO, 2014). In addition to causing premature death, air pollution increases the incidence of a wide range of diseases (e.g. respiratory and cardiovascular diseases and cancer), with both long- and short-term health effects, including at levels below the existing World Health Organization (WHO) guideline values (WHO, 2016a, and references therein). The International Agency for Research on Cancer has classified air pollution in general, as well as PM as a separate component of air pollution mixtures, as carcinogenic (IARC, 2013).

Various reports (e.g. WHO, 2005, 2013a) show that air pollution has also been associated with health impacts on fertility, pregnancy, and new-borns and children. These include negative effects on neural

(4) Following the review of the text by the reporting countries, some new values were introduced. These values need to be resubmitted by the Member States to be considered official:

- For PM, a duplicated sampling point from Malta was removed changing the station from above to below the limit value.
- For O_3, Malta submitted correct information for station MT00007, which changed the concentration from below the target value threshold to above, and the Austrian stations with validation flag equal to two were also taken into account.
- For CO, the units of the Slovak stations were changed from mg/m³ to µg/m³.
- For lead, the data reported in ng/m³ by the Czech Republic, Ireland, Slovenia and the United Kingdom were converted into µg/m³ and incorrect data was corrected for Romania, changing the concentrations from above the limit value to below in all cases.
- Belgium corrected the reported As values for seven stations and the Ni values for 11 stations; in this case, there was only one station where the reported concentration was changed from above the target value to below.

Figure 1.1 How air pollution relates to the UN Sustainable Development Goals

1 — Reducing air pollution can help families become healthier, save on medical expenses, and improve productivity.

2 — Air pollution can cause crop damage and affect food quality and security.

3 — Air pollution poses a major threat to human health. It is linked to respiratory infection and cardiovascular disease. It causes increases in population morbidity and mortality.

6 — Pollutants such as sulfur dioxide (SO_2) and nitrogen oxides (NO_x) from open fires and the combustion of fossil fuels mix with precipitation causing harmful acid rain that can compromise water quality.

7 — Electricity from renewable energy rather than fossil fuels offers significant public health benefits through a reduction in air pollution.

8 — Air pollution impacts on health, crop and forest yields, ecosystems, the climate and the built environment, with consequences for productivity and economic growth. Ambient and indoor air pollution also has negative effects on the working environment and its safety.

9 — Power generation, industry and transportation are large contributors to air pollution. A new focus on decreasing energy consumption and on improving sustainable and public transportation could progressively reduce pollution.

11 — Urban areas significantly contribute to air pollution. Making cities sustainable could progressively improve the air quality.

12 — Chemicals released into the air increase air pollution and contribute to harmful effects on human health. Responsible production and consumption could help to reduce these harmful chemicals.

13 — Combustion of fossil fuels plays a key role in the process of climate change, which places food, air and water supplies at risk, and poses a major threat to human health.

14 — Deposition of air pollutants on water may negatively affect its quality and life under water. It can lead to eutrophication and acidification of fresh water bodies, and accumulation of toxic metals and Persistent Organic Pollutants (POPs) in fresh and marine waters.

15 — Emissions from combustion of fossil fuels mixed with precipitation cause acid rains that pose a major threat to forests and ecosystems.

Source: Adapted from UNICEF, 2016.

2.1 Sources of regulated pollutants

The main precursor gases for secondary PM are SO_2, NO_x, NH_3 and VOCs. The gases NH_3, SO_2 and NO_x react in the atmosphere to form NH_4^+, SO_4^{2-} and NO_3^- compounds. These compounds form new particles in the air or condense onto pre-existing ones to form secondary particulate matter (i.e. secondary inorganic aerosols). Certain NMVOCs are oxidised to form less volatile compounds, which form secondary organic aerosols or oxidised NMVOCs.

Primary PM originates from both natural and anthropogenic sources, and it is commonly classified into primary PM_{10} and primary $PM_{2.5}$. Natural sources include sea salt, naturally suspended dust, pollen and volcanic ash, while anthropogenic sources include fuel combustion for power generation, domestic heating and transport, industry and waste incineration, and agriculture, as well as brakes, tyres and road wear and other types of anthropogenic dust. BC is a constituent of $PM_{2.5}$ formed from incomplete fuel combustion, with the main sources including transport and domestic heating.

4 Particulate matter

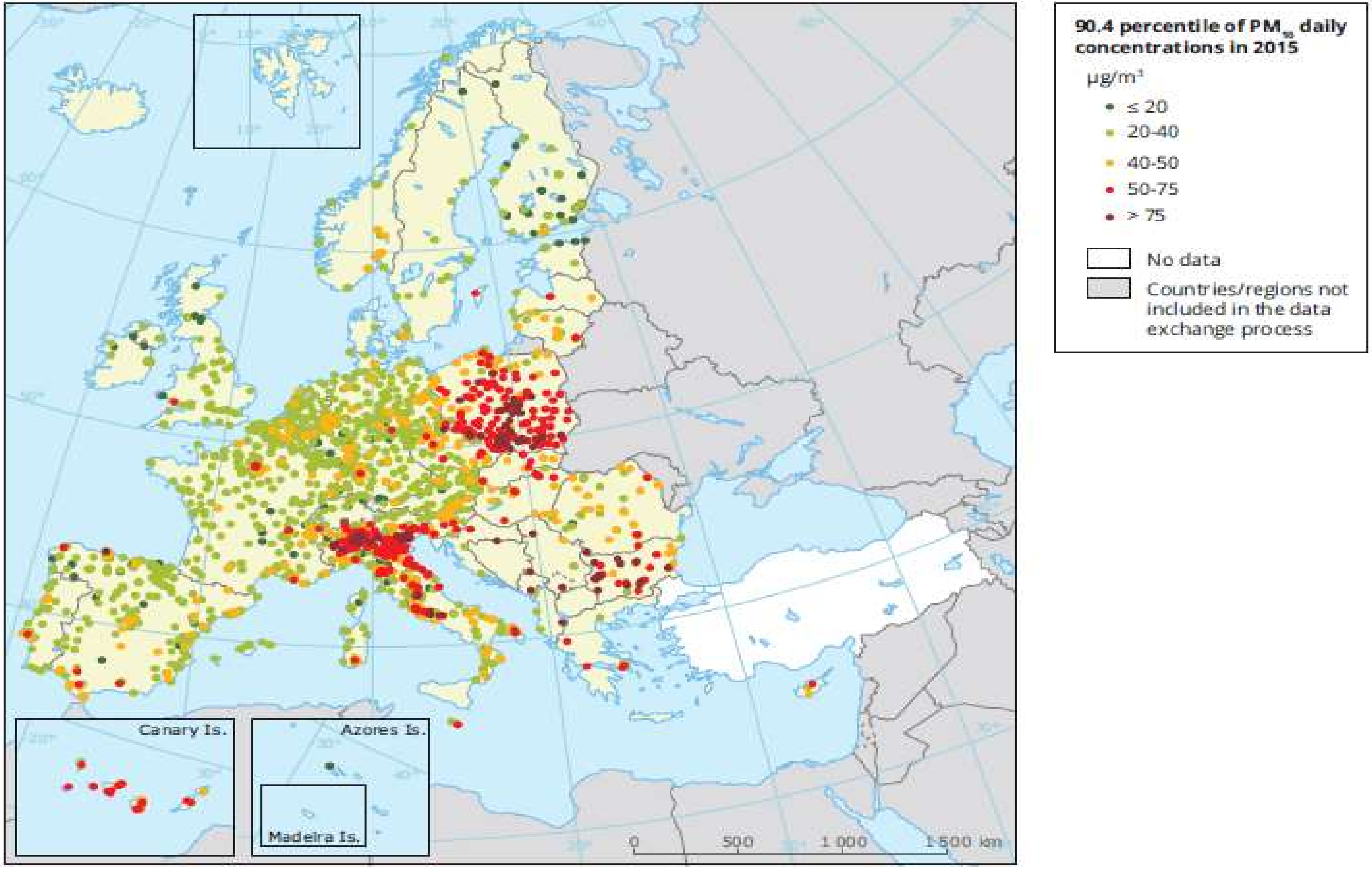
Table 4.1 Air quality standards for the protection of health, as given in the EU Ambient Air Quality Directives

Pollutant	Averaging period	Legal nature and concentration	Comments
PM_{10}	1 day	Limit value: 50 µg/m³	Not to be exceeded on more than 35 days per year
	Calendar year	Limit value: 40 µg/m³	
$PM_{2.5}$	Calendar year	Limit value: 25 µg/m³	
		Exposure concentration obligation: 20 µg/m³	Average Exposure Indicator (AEI) ([a]) in 2015 (2013-2015 average)
		National Exposure reduction target: 0-20 % reduction in exposure	AEI ([a]) in 2020, the percentage reduction depends on the initial AEI

Table 4.2 WHO air quality guidelines (AQG) and estimated reference levels (RL) ([a])

Pollutant	Averaging period	AQG	RL	Comments
PM_{10}	1 day	50 µg/m^3		99th percentile (3 days per year)
	Calendar year	20 µg/m^3		
$PM_{2.5}$	1 day	25 µg/m^3		99th percentile (3 days per year)
	Calendar year	10 µg/m^3		
O_3	Maximum daily 8-hour mean	100 µg/m^3		
NO_2	1 hour	200 µg/m^3		
	Calendar year	40 µg/m^3		
BaP	Calendar year		0.12 ng/m^3	
SO_2	10 minutes	500 µg/m^3		
	1 day	20 µg/m^3		
CO	1 hour	30 mg/m^3		
	Maximum daily 8-hour mean	10 mg/m^3		
C_6H_6	Calendar year		1.7 µg/m^3	
Pb	Calendar year	0.5 µg/m^3		
As	Calendar year		6.6 ng/m^3	
Cd	Calendar year	5 ng/m^3 ([b])		
Ni	Calendar year		25 ng/m^3	

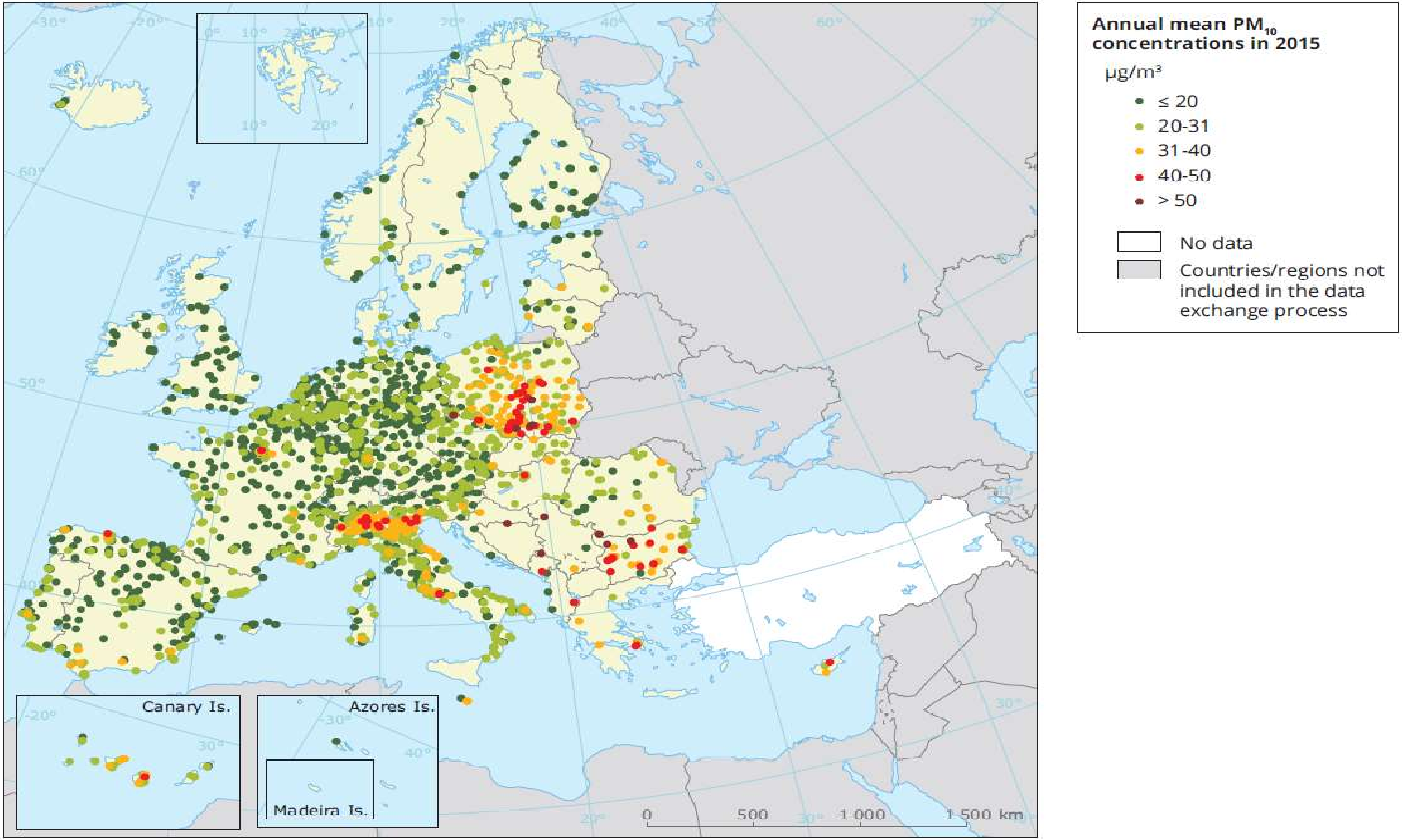
Map 4.1 Concentrations of PM_{10}, 2015 — daily limit value



Note: Observed concentrations of PM_{10} in 2015. The map shows the 90.4 percentile of the PM_{10} daily mean concentrations, representing the 36th highest value in a complete series. It is related to the PM_{10} daily limit value, allowing 35 exceedances of the 50 μg/m³ threshold over 1 year. The red and dark red dots indicate stations with concentrations above this daily limit value. Only stations with more than 75 % of valid data have been included in the map. The stations from the former Yugoslav Republic of Macedonia are not included due to technical issues.

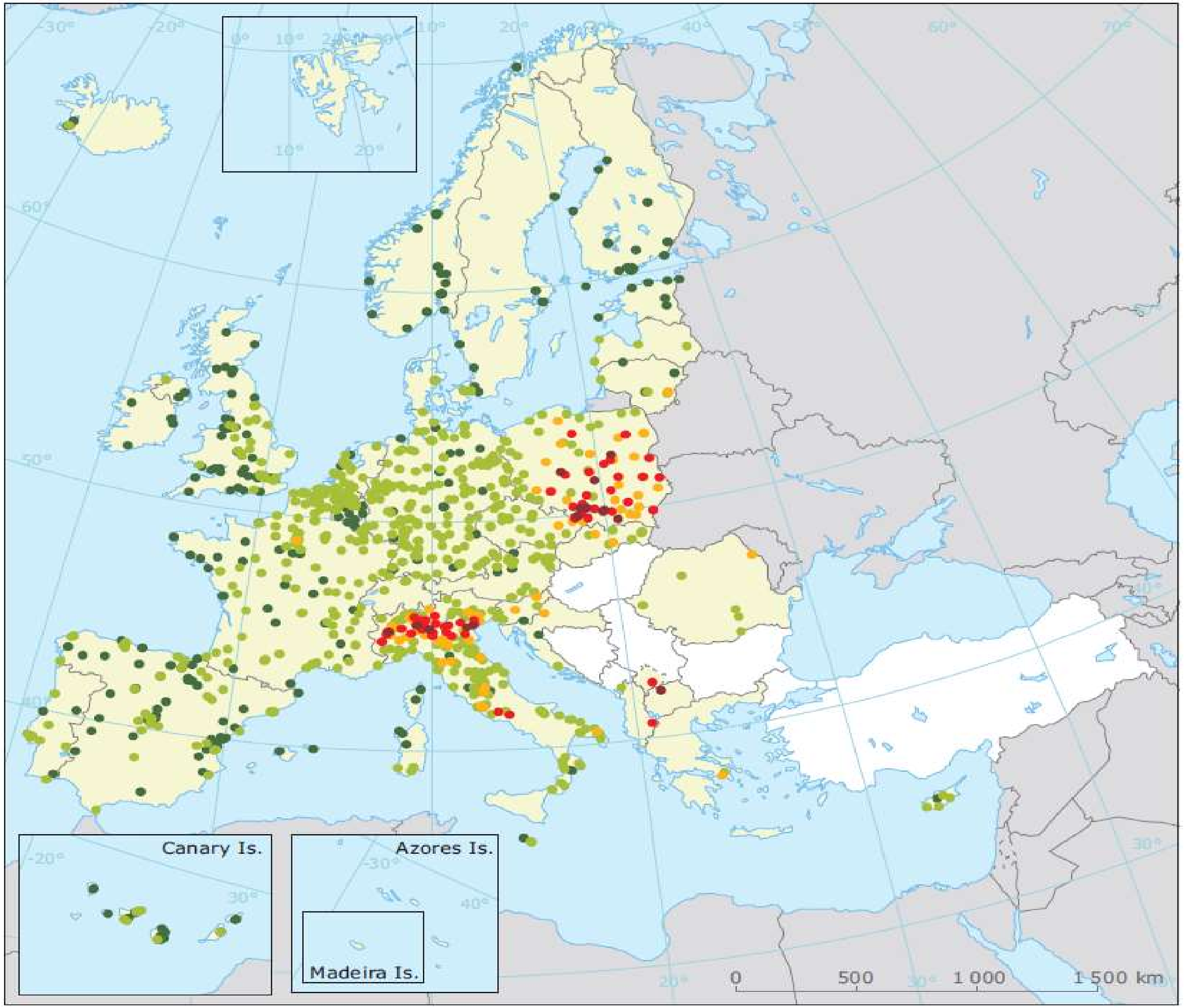
Source: EEA, 2017a.

Map 4.2 **Concentrations of PM_{10}, 2015 — annual limit value**



Notes: The dark red and red dots indicate stations reporting concentrations above the EU annual limit value (40 µg/m³). The dark green dots indicate stations reporting values below the WHO AQG for PM_{10} (20 µg/m³). Only stations with > 75 % of valid data have been included in the map. The stations from the former Yugoslav Republic of Macedonia are not included due to technical issues.

Map 4.3 Concentrations of $PM_{2.5}$, 2015



Annual mean $PM_{2.5}$ concentrations in 2015

μg/m³

- ≤ 10
- 10-20
- 20-25
- 25-30
- > 30

No data

Countries/regions not included in the data exchange process

Notes: The dark red and red dots indicate stations reporting concentrations above the EU annual limit value (25 μg/m³). The dark green dots indicate stations reporting values below the WHO AQG for $PM_{2.5}$ (10 μg/m³). Only stations with > 75 % of valid data have been included in the map.

Source: EEA, 2017a.

9 Population exposure to air pollutants

Health effects are related to both short- and long-term exposure to air pollution. Short-term exposure (over a few hours or days) is linked to acute health effects, whereas long-term exposure (over months or years) is linked to chronic health effects. The Ambient Air Quality Directives and WHO define, respectively, air quality standards and guidelines for the protection of human health (see Tables 4.1 and 4.2, respectively). These standards and guidelines may be set for the protection of human health from both short- and long-term effects, depending on the pollutant and its health effects.

About 7 % of the EU-28 urban population was exposed to $PM_{2.5}$ above the limit value in 2015. The percentage was in the range of 7-16 % in 2006-2015. The urban population's exposure to levels above the more stringent WHO AQG for $PM_{2.5}$ fluctuated between 82 % and 97 % in 2006-2015. It should be noted that 2015 registered the lowest percentage of urban population exposure to $PM_{2.5}$ (for both the EU target value and the WHO AQG).

In 2015, about 30 % of the EU-28 population in urban areas was exposed to O_3 concentrations above the

10 Health impacts of exposure to fine particulate matter, ozone and nitrogen dioxide

The health impacts of air pollution can be quantified and expressed in different ways. These include estimates of premature mortality and morbidity. Mortality reflects reduction in life expectancy owing to premature death as a result of air pollution exposure, whereas morbidity relates to the occurrence of illness and years lived with a disease or disability, ranging from subclinical effects (e.g. inflammation) and symptoms such as coughing to chronic conditions that may require hospitalisation. Even less severe effects might have strong public health implications, because air pollution affects the whole population on a daily basis.

10.1 Methods used to assess health impacts

The health impacts from air pollution can be estimated using different health metrics (Box 10.1). The health impacts estimated for this report are those attributable to exposure to $PM_{2.5}$, NO_2 and O_3 in Europe for 2014 ([41]). This assessment required information on air pollution, demographic data and the relationship between exposure to ambient pollutant concentrations and a health outcome. The maps of air pollutant concentrations used in the assessment are those presented in Section 9.2 (annual mean concentration for $PM_{2.5}$ and NO_2, and SOMO35 for O_3; see Figure 9.1).

Table 10.1 Premature deaths attributable to $PM_{2.5}$ ([a]), NO_2 ([a]) and O_3 exposure in 41 European countries and the EU-28, 2014

		$PM_{2.5}$			NO_2			O_3	
Country	Population (1 000)	Annual mean ([c])	Premature deaths ([a])		Annual mean ([c])	Premature deaths ([a])		SOMO35 ([e])	Premature deaths
			$C_0 = 0$	$C_0 = 2.5$		$C_0 = 20$	$C_0 = 10$		
Austria	8 507	12.9	5 570	4 520	19.2	1 140	3 630	4 423	260
Belgium	11 181	13.7	8 340	6 860	21.9	1 870	6 470	2 297	190
Bulgaria	7 246	24	13 620	12 280	16.5	740	3 570	2 519	200
Croatia	4 247	15.6	4 430	3 750	15.7	300	1 650	4 503	180
Cyprus	1 172 ([d])	17	600	518	12.8	20	130	5 426	30
Czech Republic	10 512	18.6	10 810	9 430	16.8	550	3 640	3 822	310
Denmark	5 627	11.6	3 470	2 740	11	130	790	2 611	110
Estonia	1 316	8.7	750	540	9	10	130	1 991	20
Finland	5 451	7.4	2 150	1 440	8.3	40	450	1 615	60
France	63 798	11	34 880	27 170	17.7	9 330	23 420	3 786	1 630
Germany	80 767	13.4	66 080	54 180	20.2	12 860	44 960	3 287	2 220
Greece	10 927	17	11 870	10 190	14.9	1 660	4 280	5 926	570
Hungary	9 877	17.3	11 970	10 310	17.1	1 210	4 560	3 620	350
Ireland	4 606	9	1 480	1 070	6.1	10	160	868	20
Italy	60 783	15.8	59 630	50 550	22.5	17 290	42 480	5 569	2 900

Table 10.1 Premature deaths attributable to $PM_{2.5}$ (a), NO_2 (a) and O_3 exposure in 41 European countries and the EU-28, 2014 (cont.)

		$PM_{2.5}$			NO_2			O_3	
Country	Population (1 000)	Annual mean ([e])	Premature deaths ([a])		Annual mean ([e])	Premature deaths ([a])		SOMO35 ([e])	Premature deaths
			$C_0 = 0$	$C_0 = 2.5$		$C_0 = 20$	$C_0 = 10$		
San Marino	33	13.5	30	20	14.7	< 5	10	5 949	< 5
Serbia	7 147	21.5	10 770	9 580	19.6	1 380	4 600	2 668	190
Switzerland	8 140	11.6	4 240	3 340	20.9	980	3 560	4 417	220
Total ([c])	534 471	14.1	428 000	356 000	18.6	78 000	241 000	3 501	14 400
EU-28 ([c])	502 351	14.0	399 000	332 000	18.7	75 000	229 000	3 507	13 600

For $PM_{2.5}$, the highest numbers of premature deaths and YLL are estimated for the countries with the largest populations (Germany, Italy, Poland, the United Kingdom and France). However, in relative terms,

Safety& Reference Method

Reference Method

- The need of a reference system is hampered by the absence of a primary standard of particulate matter

- Actual regulations define several parameters which are concurring into the definition of a “Reference Method” **(EN 12341:2014)**

- Reference Method is not an absolute system, but a system which would assume the same result when monitoring at a given site

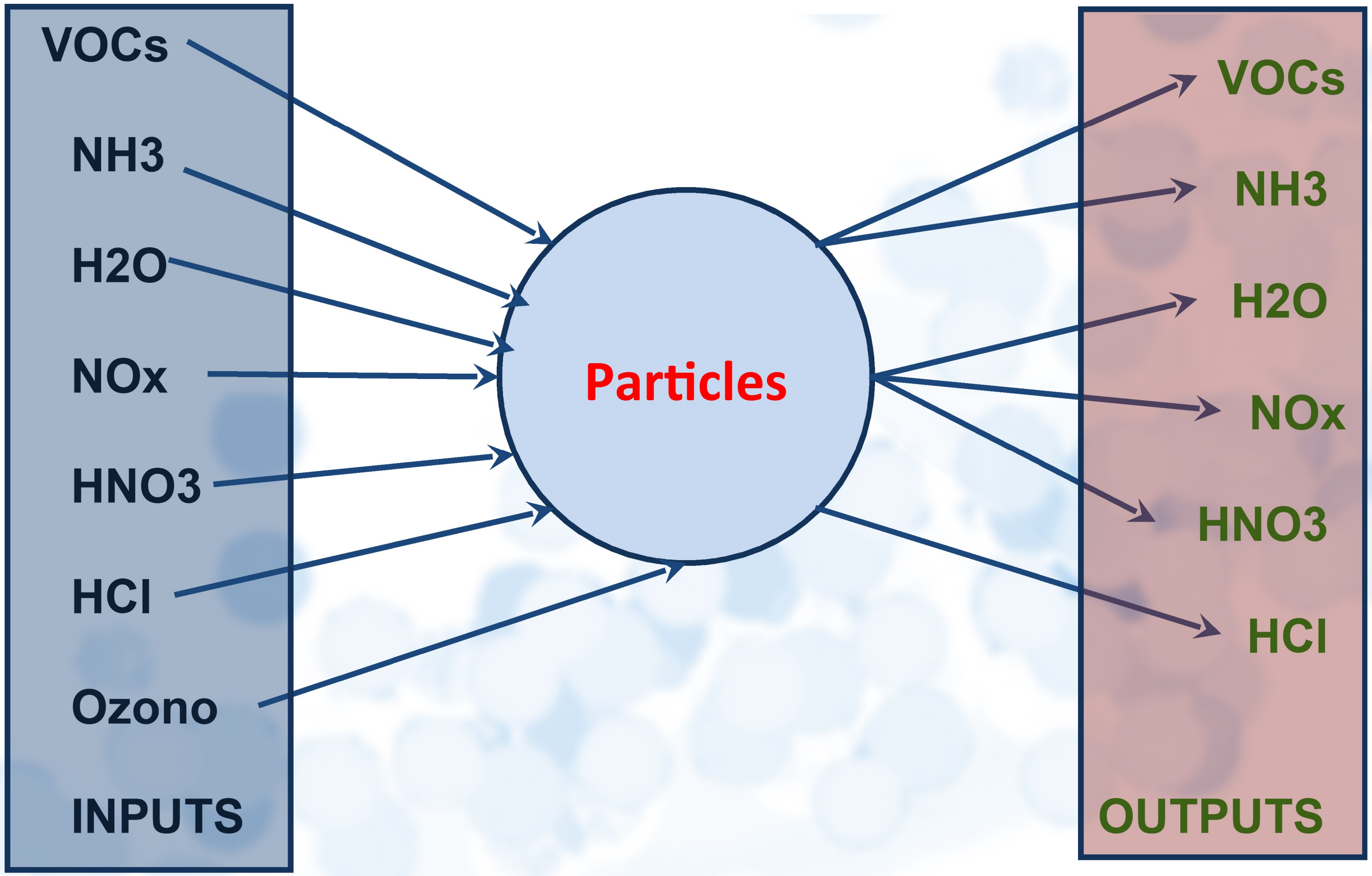
Reference Method

Variables affecting sampling is really very high:

- Temperature
- Relative Humidity
- Backpressure
- Flow rate
- Chemical composition
- Volatile species

Those parameters does not need to be known, **but need to be fully controlled, especially during the sampling step**.

Chemical composition of particulate matter



$$\Delta M = f(C_{i\ldots n}, T, P, X_{i\ldots n}, RH, d, t)$$

C_i= gas pollutants
X_i= particle composition
d= particle dimention

Requirements for the correct operation of the sampling system are specified in Table 1.

Table 1 — Requirements for sampling equipment

	Design/performance characteristic	Requirement [a]	Subclause
1	Sampler design	The sampler shall be designed in a way that it is possible to check and calibrate all sensors important to ensure the correct performance of the sampler. The manual of the sampler shall contain instructions on how to access the sensors.	
2	Inlet design	As prescribed	5.1.2
3	Temperature of filter during sampling	Within 5 °C of ambient temperature for ambient temperatures ≥ 20 °C	5.1.4
4	Nominal flow rate	2,3 m^3/h at ambient conditions	5.1.5
5	Constancy of sample volumetric flow	≤ 2,0 % sampling time (averaged flow) ≤ 5,0 % rated flow (instantaneous flow)	5.1.5
6	Leak tightness of the sampling system	$\varphi_L \leq 1,0$ % of sample flow rate	5.1.7
7	Single-filter sampling period	24 h ± 1 h	5.1.6
8	Uncertainty (95 % confidence) of sampling	≤ 5 min	5.1.6

Table 4 — Required frequency of calibration, checks and maintenance

Calibration, checks and maintenance	Subclause	Frequency	Lab/ field	Action criteria [a]
Regular maintenance of components of the sampler	7.3	As required by manufacturer	L / F	
Checks of sensors for temperatures and pressure in the sampler	7.4	Every 3 months [b]	F	±3 K ±1 kPa
Calibration of sensors for temperatures and pressure in the sampler	7.5	Every year	L / F	±1,5 K ±0,5 kPa
Check of the sampler flow rate	7.6	Every 3 months [b]	F	5 %
Calibration of the sampler flow rate	7.7	Every year	L / F	1 %
Leak check of the sampling system	7.8	Every year	L / F	1 %
Checks of the weighing room sensors for temperature and relative humidity	7.9	Every 6 months	L	±1 K ±3 % RH
Calibration of the weighing room sensors for temperature and relative humidity	7.10	Every year	L	
Calibration of the balance	7.11	Every year	L	

[a] With reference to nominal values.

[b] The frequency of the checks may be relaxed when sufficient history exists demonstrating that drifts of sensor readings and flow rates remain within the specified requirements. Calibrations shall be performed every year.

Reference Method

Consequence of this relevant QA-QC controls:

Fix criteria in order to ensure that instruments working in the same environment are giving the same numerical results.

This is practically achieved through **"technical regulations"**

The regulations are negotiated and shared at international levels through "committees" which are almost permanently established at ISO, EU, National Standardisation bodies, etc.

PM 10 and PM 2.5 EU Committees

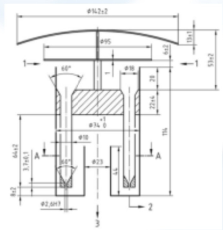
Most relevant working group for PM 2.5 study is:

CEN/TC 264 Air Quality Working Group 15 for

1.Reference gravimetric measurement methods
2.Automated measuring systems for the measurement of the concentration of particulate matter (AMS)

Evolution of decision for standardization:

<u>*Decision 385 of EN 12341*</u>



- WG 15 agrees that more work is required on defining the dimensions/tolerances of the standard PM inlet head
- Definition of test programme for type testing of PM samplers

<u>*Status of EN 16450*</u>

The final English reference version of EN 16450 was published 2017-03-15.
It now has to be published also as a national standard by all NSBs and any conflicting national standards have to be withdrawn.
<u>This has been finalized on 2017-09-30</u>.

Meet regulation by the end users

Once a "reference method" is selected, the process is just at the beginning...
.... potential users and public control Agencies should ensure that:

1. It is incorporated into the instruments intended for monitoring

2. Such "incorporation" should be guarantees by a third independent body

"Equivalence certification"

1. The certification should be maintained in "time and space"

2. In addition to the instruments, also manufacturers need to be certified according to the quality and consistency of production

The main international EU Directives and Standards are listed in a following slides

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12341

May 2014

ICS 13.040.20

Supersedes EN 12341:1998, EN 14907:2005

English Version

Ambient air - Standard gravimetric measurement method for the determination of the PM_{10} or $PM_{2,5}$ mass concentration of suspended particulate matter

Air ambiant - Méthode normalisée de mesurage gravimétrique pour la détermination de la concentration massique MP_{10} ou $MP_{2,5}$ de matière particulaire en suspension

Außenluft - Gravimetrisches Standardmessverfahren für die Bestimmung der PM_{10}- oder $PM_{2,5}$-Massenkonzentration des Schwebstaubes

This European Standard was approved by CEN on 10 April 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 12341:2014 E

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 16450

March 2017

ICS 13.040.20

Supersedes CEN/TS 16450:2013

English Version

Ambient air - Automated measuring systems for the measurement of the concentration of particulate matter (PM10; PM2,5)

Air ambiant - Systèmes automatisés de mesurage de la concentration de matière particulaire (PM10; PM2,5)

Außenluft - Automatische Messeinrichtungen zur Bestimmung der Staubkonzentration (PM10; PM2,5)

This European Standard was approved by CEN on 16 January 2017.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15267-1

March 2009

ICS 13.040.99

English Version

Air quality - Certification of automated measuring systems - Part 1: General principles

Qualité de l'air - Certification des systèmes de mesurage automatisés - Partie 1 : Principes généraux

Luftbeschaffenheit - Zertifizierung von automatischen Messeinrichtungen - Teil 1: Grundlagen

This European Standard was approved by CEN on 14 February 2009.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 15267-2

March 2009

ICS 13.040.99

English Version

Air quality - Certification of automated measuring systems - Part 2: Initial assessment of the AMS manufacturer's quality management system and post certification surveillance for the manufacturing process

Qualité de l'air - Certification des systèmes de mesurage automatisés - Partie 2 : Évaluation initiale du système de gestion de la qualité des fabricants d'AMS et surveillance après certification du procédé de fabrication

Luftbeschaffenheit - Zertifizierung von automatischen Messeinrichtungen - Teil 2: Erstmalige Beurteilung des Qualitätsmanagementsystems des Herstellers und Überwachung des Herstellungsprozesses nach der Zertifizierung

Classification of Changes

The following three classes of changes to certified AMS are defined:

– Type 0: changes that have no measurable influence to the performance of the AMS

– Type 1: changes that can have an influence on the performance of the AMS, but where subsequent tests prove that such changes do not have a significant influence

– Type 2: changes that have a significant influence on the performance of the AMS

A significant influence is considered to be one that reduces the performance of the AMS compared to that recorded in the certificate for the stipulated performance characteristics

The manufacturer shall evaluate all changes to a certified AMS

Where Type 2 changes are identified the manufacturer shall consult the relevant body and test laboratory to confirm whether any additional testing is required to determine the impact of any design changes

The manufacturer shall document all changes and evaluations in accordance with the requirements of this European Standard and in such a way that they can be audited

Impact of “Certification process”

The procedures for approval (certification) and for the maintenance are quite long and costly

- Time for “equivalence certification” around 12 months
- Cost for entire equivalence certification process around 100K €
- Annual maintaining certification cost around 20K €

This assumption hamper the possibility of new changes and/or the improvement of the existing instruments.

In addition, if the technical regulations will change in details, a great efforts (also economic) are needed for the compliance to the new standards.

PM measurements in EU : methods, QA/QC procedures

more than 100 ARPA/APPA (regional) monitoring laboratories and 21 air quality networks across Italy

- assure the quality and comparability of analytical data at national level in support of the environmental policies and in order to assure comparability at EU level through international collaborations (IAEA, EU-JRC: IES & IRMM, IUPAC, Standardization Body CEN TC264 Air Quality)

- This is the mission of Environmental Metrology Service

2. Data Quality Objectives: Annex I

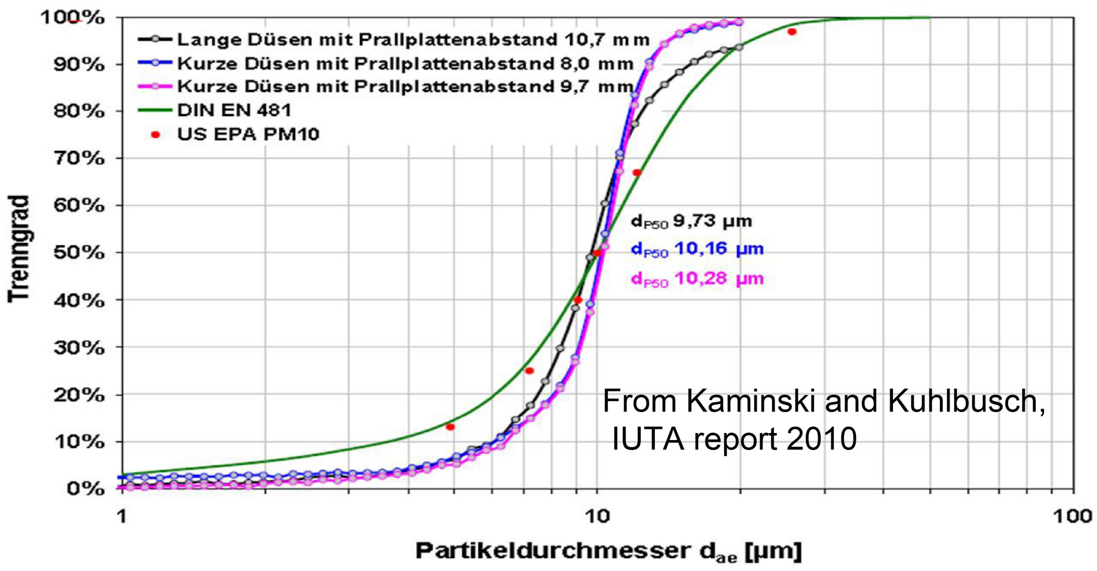
A. **Data quality objectives for ambient air quality assessment**

	Sulphur dioxide, nitrogen dioxide and oxides of nitrogen and carbon monoxide	Benzene	Particulate matter (PM_{10}/$PM_{2,5}$) and lead	Ozone and related NO and NO_2
Fixed measurements (1)				
Uncertainty	15 %	25 %	25 %	15 %
Minimum data capture	90 %	90 %	90 %	90 % during summer 75 % during winter
Minimum time coverage:				
— urban background and traffic	—	35 % (2)	—	—
— industrial sites	—	90 %	—	—
Indicative measurements				
Uncertainty	25 %	30 %	50 %	30 %
Minimum data capture	90 %	90 %	90 %	90 %
Minimum time coverage	14 % (4)	14 % (3)	14 % (4)	> 10 % during summer

The uncertainty (expressed at a 95 % confidence level) of the assessment methods will be evaluated in accordance with the principles of the CEN Guide to the Expression of Uncertainty in Measurement (ENV 13005-1999), the methodology of ISO 5725:1994 and the guidance provided in the CEN report 'Air Quality — Approach to Uncertainty Estimation for Ambient Air Reference Measurement Methods' (CR 14377:2002E). The percentages for uncertainty in the above table are given for individual measurements averaged over the period considered by the limit value (or target value in the case of ozone), for a 95 % confidence interval. The uncertainty for the fixed measurements shall be interpreted as being applicable in the region of the appropriate limit value (or target value in the case of ozone).

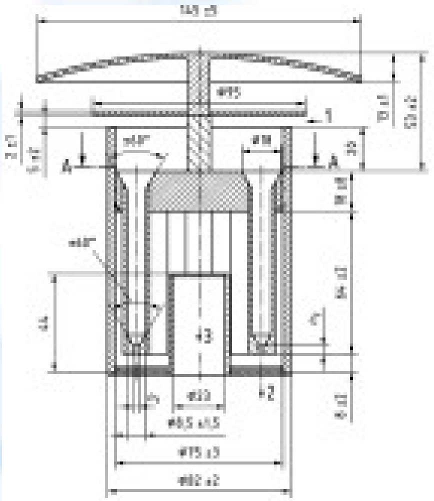
EN12341:2014 key factors affecting measurements results

- (variations in) the design and construction of the size-selective inlet; established tolerances on dimensions
- the sampling flow rate that should be constant;



- deposition losses of PM within the pipework between the inlet and the filter;
- uncontrolled losses within the pipework between the inlet and the filter, and on the filter due to volatilisation of water and semi-volatile PM at any time between collection and weighing;
- changes in weight of the filters or PM due to, e.g., adsorption of water and semi-volatile compounds, spurious addition or loss of material, buoyancy, or static electricity.

Critical issue EN12341:2014: type testing missing



- new items from CEN/TC264/WG15
- **Lab tests proposal**
- Two samplers of the same type.
- Check of inlet dimensions
- Leak tests
- Several tests are combined to check requirements Table 1 Total duration of lab tests 15 days excluding start-up time
- Tests at 3 temperatures: 20 - 23, max and min °C (to be defined)
- Test sequence: installation and calibration of samplers,
  - at each T: measurement of all parameters at Tx, power interruption test
  - pressure drop test and check of restart of sampler;
  - Day 15: recalibration of flow and other parameters to be ready for field testing.

EN12341: QA/QC with a defined frequency

Table 4 — Required frequency of calibration, checks and maintenance.

Calibration, checks and maintenance	Subclause	Frequency	Lab/ field	Action criteria [a]
Regular maintenance of components of the sampler	7.3	As required by manufacturer	L / F	
Checks of sensors for temperatures and pressure in the sampler	7.4	Every 3 months [b]	F	± 3 K ± 1 kPa
Calibration of sensors for temperatures and pressure in the sampler	7.5	Every year	L / F	± 1,5 K ± 0,5 kPa
Check of the sampler flow rate	7.6	Every 3 months [b]	F	5 %
Calibration of the sampler flow rate	7.7	Every year	L / F	1 %
Leak check of the sampling system	7.8	Every year	L / F	1 %
Checks of the weighing room sensors for temperature and relative humidity	7.9	Every 6 months	L	± 1 K ± 3 % RH
Calibration of the weighing room sensors for temperature and relative humidity	7.10	Every year	L	
Calibration of the balance	7.11	Every year	L	

[a] With reference to nominal values.

[b] The frequency of the checks may be relaxed when sufficient history exists demonstrating that drifts of sensor readings and flow rates remain within the specified requirements. Calibrations shall be performed every year.

New standard for PM AMS : EN16450:2017

- EN16450:2017 *Ambient air - Automated measuring systems for the measurement of the concentration of particulate matter (PM10, PM2,5)* deals on AMS based on different measurements methods: beta, optical, oscillating microbalance
- Established construction and minimum performance requirements , tests and procedures for type approval of AMS (performed in lab and field by an accredited laboratory) in order to verify that the AMS meets DQO requirements and so it could be considered equivalent to reference method

	Performance characteristic	Requirement	Location (Lab/Field)	Clause
1	Measuring ranges	0 µg/m³ to 1 000 µg/m³ as a 24-h average value 0 µg/m³ to 10 000 µg/m³ as a 1-h average value, if applicable	L	
2	Negative signals	Shall not be suppressed	L	
3	Zero level and detection limit	Zero level: ≤ 2,0 µg/m³ Detection limit: ≤ 2,0 µg/m³	L	7.4.3
4	Flow rate accuracy [a]	≤ 2,0 % – at 5 °C and 40 °C by default for installation in a temperature-controlled environment or – at minimum and maximum temperatures specified by the manufacturer if these deviate from the default temperatures.	L	7.4.4
5	Constancy of sample volumetric flow	≤ 2,0 % sampling flow (averaged flow) ≤ 5 % rated flow (instantaneous flow)	F	7.4.5
6	Leak tightness of the sampling system	≤ 2,0 % of sample flow rate	L	7.4.6
7	Dependence of zero on surrounding temperature[a]	≤ 2,0 µg/m³ – from 5 °C to 40 °C by default for installation in a temperature-controlled environment or – at minimum and maximum temperatures specified by the manufacturer if these deviate from the default temperatures.	L	7.4.7
8	Dependence of measured value on surrounding temperature[a]	≤ 5 % from the value at the nominal test temperature – from 5 °C to 40 °C by default for installation in a temperature-controlled environment or – at minimum and maximum temperatures specified by the manufacturer if these deviate from the default temperatures.	L	7.4.7
9	Influence of mains voltage on measured signal	≤ 5 % from the value at the nominal test voltage	L	7.4.8

New standard for PM AMS : EN16450:2017

- **3.28 type approval:** decision taken by a competent authority that the pattern of an AMS conforms to the requirements as laid down in this document
- **3.29 type testing:** examination of two or more AMS of the same pattern which are submitted by a manufacturer to a competent body for testing of performance requirements
- Type testing performed by a competent body
- Type testing awarded by the competent authority of a Member State

- Established manufacturer requirements (certification EN15267-1 e 2)
- For the first time established procedures for "*ongoing quality assurance*" – in order to ensure that uncertainty still remain in compliance with limits for extended period of time :
- preliminary QA/QC activities : suitability , first installation tests
- Ongoing QA/QC with a defined frequency : maintenance, checks of sampling and measurement system, flow calibration, sensors and measurement device calibration

AMS preliminary QA/QC: suitability

- During type approval, equivalence tests are performed in different environmental and climate conditions (4 campaign in 2 sites) that could be not representative of monitoring network where it should be installed
- Suitability check respect specific local site conditions (if they are similar to those of type approval)
- If necessary an equivalence test should be done during first installation in 2 sites representative of network to evaluate uncertainty and calibration function (GdE by EC)

Table 3 — Site specific conditions

Parameter	Remarks
Composition of the PM fraction	High or low fractions of semi-volatile particles, to cover the maximum impact of losses of semi-volatiles Substantial fraction of coarse particulates when the inlet design, if any, of the AMS differs from that of the reference sampler
Air humidity and temperature	High or low temperatures and/or relative air humidities to account for loss of semi-volatile constituents of PM or particle growth
Wind speed	High or low wind speed to cover any dependency of inlet performance due to deviations from ideal behaviour as dictated by mechanical design, or deviations from the designated sampling flow rate.

Ongoing QA/QC AMS: EN16450:2017

Calibration, checks and maintenance	Clause	Minimum Frequency[a]	Lab/ field	Action criteria[b]	Uncertainty requirements for transfer standards
Checks of status values of operational parameters (see 7.5.4)	8.4.3	Daily (on working days)	L / F	See below	
Checks of sensors for temperatures, pressure and/or humidity[c]	8.4.4	Every 3 months	F	±2 °C ±1 kPa ±5 % RH	
Calibration of sensors for temperatures, pressure and/or humidity[c]	8.4.5	Every year	L / F		1,5 °C 0,5 kPa 3 % RH
Check of the AMS flow rate(s)	8.4.6	Every 3 months	F	±5 %	2 %
Calibration of the AMS flow rate(s)	8.4.7	Every year	L / F		1 %
Leak check of the sampling system	8.4.8	Every year	F	±2 %	
Zero check of the AMS reading	8.4.9	Every year	L / F	±3 µg/m³	
Check of the AMS mass measuring system	8.4.10	As recommended by the manufacturer and after repair, but at least every year	L / F	as set out by manufacturer, or ± 3 % if necessary	
Regular maintenance of components of the AMS	8.5	As required by the manufacturer	L / F	as set out by manufacturer	

[a] Frequencies of checks and calibrations may be relaxed when sufficient history exists demonstrating that drifts of sensor readings and flow rates remain within the specified requirements.

[b] With reference to nominal values.

[c] For some instruments such checks and calibrations are not possible *in situ* because of the positioning of the sensors within the AMS. Therefore, these checks and calibrations are restricted to sensors that are accessible in the field (typically in the sampling head). As a part of the annual checks, the checks may be performed in a laboratory room with constant temperature and relative humidity by comparing sensor readings (after stabilization) with those of reference standards.

How to achieve “goal of equivalence”