

COMMISSION DIRECTIVE (EU) 2020/367**of 4 March 2020****amending Annex III to Directive 2002/49/EC of the European Parliament and of the Council as regards the establishment of assessment methods for harmful effects of environmental noise****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Annex III to Directive 2002/49/EC refers to dose-effect relations to be introduced by way of adaptations of that Annex to technical and scientific progress.
- (2) At the time of adoption of this Directive, the high quality and statistically significant information that could be used was that of the World Health Organisation (WHO) Environmental Noise Guidelines for the European Region ⁽²⁾, presenting dose-effect relations for harmful effects induced by the exposure to environmental noise. Consequently, the dose-effect relations introduced in Annex III to Directive 2002/49/EC should be based on those guidelines. In particular concerning the statistical significance, the WHO studies were based on representative populations, and the results of these assessment methods are consequently considered relevant when applied to representative populations.
- (3) Beyond the dose-effect relations developed in the context of the WHO, other studies might show different health effect sizes and other health effects, in particular concerning effects of road, railway and aircraft noise in local situations in specific countries. The alternative dose-effect relations established therein could be used provided that they are based on high quality and statistically significant studies.
- (4) Currently, limited knowledge is available on the harmful effects of industrial noise so that it is not possible to propose a common method for their assessment. Also, country specificities were not assessed in studies and therefore could not be included in this Annex. Likewise, while links between environmental noise and the following harmful effects were found, there is currently no sufficient evidence for determining a common method for the assessment of those harmful effects: stroke, hypertension, diabetes and other metabolic health outcomes, cognitive impairment in children, mental health and wellbeing, hearing impairment, tinnitus, adverse birth outcomes. Finally, while the link between railway noise and aircraft noise to the ischaemic heart disease (IHD) is established, for these two sources the quantification of the increased risk of IHD is premature.

⁽¹⁾ OJ L 189, 18.7.2002, p. 12.

⁽²⁾ Environmental Noise Guidelines for the European Region, World Health Organisation 2018, ISBN 978 92 890 5356 3.

- (5) Directive 2002/49/EC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Committee established under Article 13 of Directive 2002/49/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2002/49/EC is replaced by the text in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 4 March 2020.

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission

ANNEX

ANNEX III

ASSESSMENT METHODS FOR HARMFUL EFFECTS

(Referred to in Article 6(3))

1. Set of harmful effects

For the purposes of the assessment of harmful effects the following shall be considered:

- ischaemic heart disease (IHD) corresponding to codes BA40 to BA6Z of the international classification ICD-11 established by the World Health Organisation;
- high annoyance (HA);
- high sleep disturbance (HSD).

2. Calculation of harmful effects

The harmful effects shall be calculated by either of the following:

- the relative risk (RR) of a harmful effect defined as

$$RR = \left(\frac{\text{Probability of occurrence of the harmful effect in a population exposed to a specific level of environmental noise}}{\text{Probability of occurrence of the harmful effect in a population non exposed to environmental noise}} \right) \quad (\text{Formula 1})$$

- the absolute risk (AR) of a harmful effect defined as

$$AR = \left(\frac{\text{Occurrence of the harmful effect in a population exposed to a specific level of environmental noise}}{\text{to a specific level of environmental noise}} \right) \quad (\text{Formula 2})$$

2.1. IHD

For the calculation of the RR, with respect to the harmful effect of IHD and concerning the incidence rate (*i*), the following dose-effect relations shall be used:

$$RR_{IHD,i,road} = \begin{cases} e^{[(\ln(1.08)/10) * (L_{den} - 53)]} & \text{for } L_{den} \text{ greater than } 53 \text{ dB} \\ 1 & \text{for } L_{den} \text{ equal or smaller than } 53 \text{ dB} \end{cases}$$

(Formula 3)

for road noise.

2.2. HA

For the calculation of the AR, with respect to the harmful effect of HA the following dose-effect relations shall be used:

$$AR_{HA,road} = (78.9270 - 3.1162 * L_{den} + 0.0342 * L_{den}^2) / 100 \quad (\text{Formula 4})$$

for road noise;

$$AR_{HA,rail} = (38.1596 - 2.05538 * L_{den} + 0.0285 * L_{den}^2) / 100 \quad (\text{Formula 5})$$

for railway noise;

$$AR_{HA,air} = (-50.9693 + 1.0168 * L_{den} + 0.0072 * L_{den}^2) / 100 \quad (\text{Formula 6})$$

for aircraft noise.

2.3. HSD

For the calculation of the AR, with respect to the harmful effect of HSD the following dose-effect relations shall be used:

$$AR_{HSD,road} = (19.4312 - 0.9336 * L_{night} + 0.0126 * L_{night}^2) / 100 \quad (\text{Formula 7})$$

for road noise;

$$AR_{HSD,rail} = (67.5406 - 3.1852 * L_{night} + 0.0391 * L_{night}^2) / 100 \quad (\text{Formula 8})$$

for railway noise;

$$AR_{HSD,air} = (16.7885 - 0.9293 * L_{night} + 0.0198 * L_{night}^2) / 100 \quad (\text{Formula 9})$$

for aircraft noise.

3. Assessment of harmful effects

3.1. The exposure of the population shall be assessed independently for each noise source and harmful effect. Where the same people are simultaneously exposed to different noise sources, the harmful effects may -in general- not be cumulated. However, those effects may be compared to assess the relative importance of each noise.

3.2. Assessment for IHD

3.2.1. **For IHD in the case of railway and aircraft noise**, the population exposed above adequate L_{den} levels is estimated as subject to an increased risk of IHD, while the exact number N of cases of IHD cannot be calculated.

3.2.2. **For IHD in the case of road noise**, the proportion of cases of the specific harmful effect in the population exposed to a RR that is calculated to be caused by environmental noise is derived, for the noise source x (road), harmful effect y (IHD) and for the incidence i by:

$$PAF_{x,y} = \left(\frac{\sum_j [p_j \cdot (RR_{j,x,y} - 1)]}{\sum_j [p_j \cdot (RR_{j,x,y} - 1)] + 1} \right) \quad (\text{Formula 10})$$

Where:

- $PAF_{x,y}$ is the population attributable fraction,
- the set of j noise bands is made up of single bands spanning over a maximum of 5 dB (e.g.: 50-51 dB, 51-52 dB, 52-53 dB, etc. or 50-54 dB, 55-59 dB, 60-64 dB, etc.),
- p_j is the proportion of the overall population P in the area assessed that is exposed to the j -th exposure band, which is associated with a given RR of a specific harmful effect $RR_{j,x,y}$. The $RR_{j,x,y}$ is calculated using the formulas described in point 2 of this Annex, calculated at the central value of each noise band (e.g.: depending on availability of data, at 50,5 dB for the noise band defined between 50-51 dB, or 52 dB for the noise band 50-54 dB).

3.2.3. **For IHD in the case of road noise, the total number N of cases of IHD** (people affected by the harmful effect y ; number of attributable cases) due to the source x is then:

$$N_{x,y} = PAF_{x,y,i} * I_y * P \text{ (Formula 11)}$$

for road.

Where:

- $PAF_{x,y,i}$ is calculated for the incidence i ,
- I_y is the incidence rate of IHD in the area under assessment, that can be obtained from statistics on health for the region or country where the area is,
- P is the total population of the area under assessment (the sum of the population in the different noise bands).

3.3. **For HA and HSD in the case of road, railway and aircraft noise, the total number N of people affected by the harmful effect y** (number of attributable cases) due to the source x , for each combination of noise source x (road, railway or aircraft source) and harmful effect y (HA, HSD), is then:

$$N_{x,y} = \sum_j [n_j * AR_{j,x,y}] \text{ (Formula 12)}$$

Where:

- $AR_{x,y}$ is the AR of the relevant harmful effect (HA, HSD), and is calculated using the formulas set out in point 2 of this Annex, calculated at the central value of each noise band (e.g.: depending on availability of data, at 50,5 dB for the noise band defined between 50-51 dB, or 52 dB for the noise band 50-54 dB),
- n_j is the number of people that is exposed to the j -th exposure band.

4. Future revisions

The dose-effect relations introduced by future revisions of this Annex will concern in particular:

- the relation between annoyance and L_{den} for industrial noise,
- the relation between sleep disturbance and L_{night} for industrial noise.

If necessary, specific dose-effect relations could be presented for:

- dwellings with special insulation against noise as defined in Annex VI,
- dwellings with a quiet façade as defined in Annex VI,
- different climates/different cultures,
- vulnerable groups of the population,
- tonal industrial noise,
- impulsive industrial noise and other special cases.'