

## **Position concerning the proposal for a regulation (EU) on artificial intelligence**

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The Commission for Occupational Safety and Health and Standardization (KAN) is the voice of the German occupational safety and health lobby in standardization. KAN is composed of representatives of the employers, employees, the Federal Government and the Länder, the German Social Accident Insurance Institutions and DIN (German Institute for Standardization). As a neutral liaison body, it coordinates the public interests in occupational safety and health and contributes collective opinions to standardization and legislative projects. It identifies deficits from the point of view of occupational health and safety and makes suggestions for improvement.



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# 1 Legal basis

## The issue

The act is a regulation pursuant to Article 16 and Article 114 of the Treaty on the Functioning of the European Union (TFEU). Article 16 TFEU concerns the right to protection of personal data. Article 114 TFEU governs implementation of the Single Market.

In derogation from the practice of the New Legislative Framework to date, the proposal combines the elimination of barriers to trade with obligations directly addressed to users (in particular Article 29 of the proposal) and far-reaching fundamental right concerns.

## KAN's position

KAN's position is that the following must therefore be clarified (for example by the European Commission) before the regulation is ratified:

- whether the full harmonisation of user requirements concerns only the aspects governed by Art. 29, or – as is implied by Recital 58 – the use of AI systems as a whole;
- in consideration of this, to what extent the legal basis for the regulation is sufficient, since the obligations directly addressed to users, insofar as they affect occupational health and safety requirements, may also fall within the scope of Art. 153 TFEU;
- what consequences the aforementioned derogations from practice to date in the New Legislative Framework have for the individuals concerned.

## 2 High-risk AI systems (Title III)

### 2.1 Classification of AI systems as high-risk (Chapter 1, Article 6 paragraph 1)

#### The issue

Under Art. 6 paragraph 1 of the draft proposal, only AI-based safety components for products harmonised by European acts *and* subject under those acts to a conformity assessment procedure by notified bodies would constitute high-risk AI systems.

This means that, for example

- all AI-based safety components for products within the scope of the Low Voltage Directive, and
- all products and systems not subject to full European harmonisation.

would not be subject to the requirements of Title III – *irrespective of the level of risk* posed by these products or systems. The only exceptions would be AI systems as defined in Annex III, point 2 a), which are intended for use as safety components in the management and operation of road transport and in the supply of water, gas, heat and electricity.

This means that AI-based safety components for these product groups would not be subject to mandatory *AI-specific conformity assessment procedures*. Factors such as risk management, data and data governance, technical documentation, record-keeping requirements, provision of information to users, human oversight, accuracy, robustness and cybersecurity would effectively not need to be considered.

#### KAN's position

KAN therefore advocates specification in Article 84 that other Single Market legislation, such as the Low Voltage Directive, which at present provides only for Module A for the conformity assessment procedure, be reviewed to determine whether it requires amendment regarding the use of artificial intelligence.

## 2.2 Requirements for high-risk AI systems

### 2.2.1 Discrimination caused by data collection (Article 10 paragraph 5)

#### The issue

Indirect discrimination *caused by* collection of personal data is illegal in the EU, at present without exception. The proposal now provides for an exception, but only for AI-based, high-risk systems: the aim is to ensure that an AI application does not endanger groups of people with less common characteristics specifically as a result of its having been trained with data unsuitable for the groups concerned. It is consequently to be permissible for specific categories of data to be collected for these groups of persons.

#### KAN's position

Since this violation of the prohibition of indirect discrimination does not apply to systems *other than* high-risk AI systems (see also the comments on Article 6), KAN advocates specifying within Art. 84 that other internal market legislation, such as the Low Voltage Directive, which as yet provide only for Module A for the conformity assessment procedure, be reviewed to determine whether they require amendment regarding the use of AI.

### 2.2.2 Transparency and provision of information to users (Article 13)

#### The issue

For systems based on machine learning technologies and concepts in particular, considerable research activity is currently in progress with the objective not only of making their behaviour more transparent, but also of *explaining it* and thereby enabling risk assessments to be supported. At present, this aspect is not given consideration in Title III Chapter 2 of the proposed regulation.

ISO/IEC 22989 defines explainability as a "property of an AI system that important factors influencing the prediction decision can be expressed in a way that humans would understand". A definition of interpretability has not yet been agreed.

## **KAN's position**

In the interests of clearer distinction between the aspects of transparency and explainability, Article 13 paragraph 1 should therefore be amended as follows:

*High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to ~~interpret~~ use the system's output ~~and use it appropriately~~. High-risk AI systems shall also be designed and developed in such a way that the results of the system are explainable so that they can be interpreted by the user. An appropriate type and degree of transparency and explainability shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.*

### **2.2.3 Human oversight (Article 14)**

#### **The issue**

Persons tasked with human supervision of a complex high-risk AI system are unlikely to *fully* understand its capabilities and limitations. It is however important that they be equipped with a capacity for awareness of these capabilities and limitations.

#### **KAN's position**

Article 14 paragraph 4 a) should therefore be amended as follows:

*The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:*

*a) ~~fully~~ be aware of and understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;*

## **2.2.4 Accuracy, robustness and cybersecurity (Article 15)**

### **2.2.4.1 The issue of environmental conditions in the context of the intended purpose of high-risk AI systems (Article 15 paragraph 1)**

#### **The issue**

Risk assessment of high-risk AI systems must give consideration to the foreseeable environmental conditions in the context of their intended purpose.

#### **KAN's position**

Article 15 paragraph 1 should therefore be amended as follows:

*1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose including the intended environment - , an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.*

### **2.2.4.2 Accuracy levels and accuracy metrics of high-risk AI systems (Article 15 paragraph 2)**

#### **The issue**

It must be specified that where accuracy levels and accuracy metrics are made available to users of high-risk AI systems in the accompanying instructions for use, they are to have been determined by reliable means.

#### **KAN's position**

Article 15 paragraph 2 should therefore be amended as follows:

*2. The levels of accuracy and the relevant accuracy metrics, which shall be empirically valid and proven in practice, of high-risk AI systems shall be declared in the accompanying instructions ~~of~~ for use.*

### **2.2.4.3 Technical redundancy in connection with the robustness of high-risk AI systems (Article 15 paragraph 3 Sentence 2)**

#### **The issue**

Where resilience of high-risk AI systems to errors, faults or inconsistencies is to be attained through technical redundancy, it must be ensured that this technical redundancy is of intelligent design, i.e. is sufficiently diversified.

#### **KAN's position**

The 2nd sentence of Article 15 paragraph 3 should therefore be amended as follows:

*The robustness of high-risk AI systems may be achieved through diverse technical redundancy solutions, which may include backup or fail-safe plans.*