SLOVENSKI STANDARD
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Umetna inteligenca - Koncepti, merila in zahteve za obvladovanje pristranskosti v sistemih umetne inteligence

Artificial Intelligence - Concepts, measures and requirements for managing bias in AI systems

Künstliche Intelligenz - Konzepte, Messmethoden und Anforderungen zum Biasmanagement in KI-Systemen

Intelligence artificielle - Concepts, mesures et exigences pour gérer le biais dans les systèmes d'IA

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35.240.01	Uporabniške rešitve informacijske tehnike in tehnologije na splošno	Application of information technology in general

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prEN 18283

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Artificial Intelligence - Concepts, measures and requirements for managing bias in AI systems

Intelligence artificielle - Concepts, mesures et exigences pour gérer le biais dans les systèmes d'IA

Künstliche Intelligenz - Konzepte, Messmethoden und Anforderungen zum Biasmanagement in KI-Systemen

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/CLC/JTC 21.

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European foreword

This document (prEN 18283:2026) has been prepared by Technical Committee CEN/CLC/JTC 21 "Artificial Intelligence", the secretariat of which is held by DS.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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Introduction

This document provides requirements and guidance for the management of *bias*, in particular *unwanted bias*, throughout the entire life cycle of an *AI system*. This document is particularly suitable for *bias management* in the context of the EU AI Act [1].

The document is structured as follows:

— Clause 6 defines the *bias profile*, a set of documents that track the entire *bias management* process;

— Clause 7 describes the *bias management* process and initiates the *bias analysis*, describing steps such as identifying the *groups* to be compared, and the metrics to use;

— Clause 8 describes the *bias estimation* process, going through the testing needed on data, AI components, system *output* and system *outcome*;

— Clause 9 describes the *bias evaluation* process, providing details on how to use the results from the *bias estimation* process for an assessment of the *risk* arising from observed *bias*;

— Clause 10 defines the various *bias* metrics that can be used in *bias estimation*;

— Clause 11 describes the template according to which *bias* metrics are defined;

— Clause 12 describes various *bias mitigation* methods;

— Clause 13 describes methods for information collection that can be used throughout the *bias management process*, as well as providing details on the consultation of *interested parties* and its use in the *bias management* process.

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Throughout this document, quality management system (QMS) is used to refer to the QMS required under Article 17 of the EU AI Act [1], *risk* management system (RMS) refers to the RMS as required in Article 9, EU AI Act [1], while quality and governance of data sets (QGD) refers to the data governance required under Article 10, EU AI Act [1].

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1 Scope

This document defines concepts, measures and requirements for assessment and treatment of bias in AI systems. This includes bias unwanted by the AI provider and AI deployer according to their specification of the AI system, in the context of the EU AI Act [1].

This encompasses consideration of data bias including any data used to build or assess the AI system, but also system or model bias that can result from algorithmic factors, such as algorithm design choices.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 18284:—,[1] *Artificial Intelligence – Quality and Governance of datasets*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

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3.1 General AI and bias related terms

3.1.1
bias
systematic difference in treatment of certain objects, people or *groups* (3.4.4) in comparison to others

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Note 1 to entry: Treatment is any kind of action, including perception, observation, representation, prediction or decision.

[SOURCE: EN ISO/IEC 22989:2023, 3.5.4]

3.1.2
monitoring
repeatedly determining the status of a system, a process or an activity using inputs including measurements

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.20 modified – added “repeatedly” and “using inputs including measurements” to the definition]

3.1.3
outcome
consequence of the *output* (3.1.4) of an activity or process

[1] Under preparation. Stage at the time of publication: prEN 18284:2026

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3.1.4
output
data that an information processing system, or any of its parts, transfers outside of that system or part

Note 1 to entry: Data includes predictions, content, recommendations, decisions or actions.

[SOURCE: ISO/IEC 2382:2015, 2121303, modified — removed <fundamental terms> domain tag, retained only the admitted term "output", removed notes to entry, added new note to entry]

3.1.5
post-market
every life cycle stage after putting into service or placing on the market the *AI system* (3.2.1)

[SOURCE: EN 18228:—[2], 3.4.3]

3.1.6
task
<AI> function performed by an *AI system* (3.2.1) that can be independently evaluated

Note 1 to entry: Use of different data formats does not constitute a different task.

Note 2 to entry: Use of different methods does not warrant delineating different tasks.

[SOURCE: EN 18229-4:—[3], 3.4.6]

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3.1.7
unwanted bias
bias (3.1.1) that inhibits the *AI system* (3.2.1) from fulfilling its *intended purpose* (3.2.2), or that has the potential to adversely affect the health, safety or *fundamental rights* (3.3.7) of natural persons

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Note 1 to entry: Unacceptable *bias* is unwanted *bias* that fails to meet *risk* (3.3.4) acceptability criteria (e.g. see EN 18228:— [5], 4.4, for more information on *risk* (3.3.4) acceptability criteria).

3.2 Terms related to the EU AI Act

3.2.1
AI system
artificial intelligence system
machine-based system that is designed to operate with varying levels of autonomy and that can exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate *outputs* (3.1.4) such as predictions, content, recommendations, or decisions that can influence physical or virtual environments

[SOURCE: Regulation (EU) 2024/1689, Article 3(1), modified — removed "means a", "may" replaced by "can"]

3.2.2
intended purpose
use for which an *AI system* (3.2.1) is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation

[2] Under preparation. Stage at the time of publication: prEN 18228:2026
[3] Under preparation. Stage at the time of publication: prEN 18229-4:2026

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[SOURCE: Regulation (EU) 2024/1689, Article 3(12), modified — removed “means the”, note to entry added]

3.2.3
reasonably foreseeable misuse
use of an *AI system* (3.2.1) in a way that is not in accordance with its *intended purpose* (3.2.2), but which can result from reasonably foreseeable human behaviour or interaction with other systems, including other *AI systems* (3.2.1)

Note 1 to entry: Reasonably foreseeable human behaviour includes the behaviour of all types of relevant users

Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: Regulation (EU) 2024/1689, Article 3(13), modified — removed “means the”, “may” replaced by “can”, notes 1 and 2 to entry added]

3.2.4
real-world conditions testing
temporary testing of an *AI system* (3.2.1) for its *intended purpose* (3.2.2) in its intended context of use or deployment environment outside a laboratory or otherwise simulated environment

[SOURCE: Regulation (EU) 2024/1689, Article 3(57), modified — removed “means the”, replaced “in real-world conditions” with “in its intended context of use or deployment environment”, removed text after “with a view”]

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3.3 General terms related to risk

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3.3.1
hazard
potential source of *harm* (3.3.3)

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.3.2
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.3.1)

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.3.3
harm
injury or damage to the health of a person or *groups* (3.4.4) of persons, or *interference* (3.3.8) with *fundamental rights* (3.3.7)

Note 1 to entry: For the purpose of this document, damage to property or the environment, and the disruption or destruction of critical infrastructure, are considered harms when they can result in injury or damage to the health of a natural person or *groups* (3.4.4) of persons or *interference* (3.3.8) with *fundamental rights* (3.3.7).

Note 2 to entry: *Interference* (3.3.8) with *fundamental rights* (3.3.7) can be tangible or intangible, physical, psychological, societal or economic, irrespective of the right holder’s awareness, in accordance with EU law, including the EU Charter on Fundamental Rights. [10]

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Note 3 to entry: Safety in product safety *risk* (3.3.4) management standards is understood as the absence of unacceptable *risk* (3.3.4). In the context of this document, safety refers to the protection from *harm* (3.3.3) from the use of the *AI system* (3.2.1).

[SOURCE: EN 18228:—, 3.6.3]

3.3.4
risk
combination of the probability of an occurrence of *harm* (3.3.3) and the severity of that *harm* (3.3.3)

Note 1 to entry: The probability of occurrence includes the exposure to a *hazardous situation* (3.3.2) and the possibility to avoid or limit the *harm* (3.3.3).

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.3.5
test completion report
test summary report
report that provides a summary of the testing that was performed

[SOURCE: ISO/IEC/IEEE 29119-1:2022, 3.87]

3.3.6
risk management file
set of records and other documents that are produced by *risk* (3.3.4) management

[SOURCE: EN 18228:—, 3.2.11]

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3.3.7
fundamental right
basic right(s) and freedom(s) held by every human being irrespective of birth, religion, belief, age, race, ethnicity, sex, gender or any other status

Note 1 to entry: For the purposes of this document, fundamental rights and their applicability are those protected by EU law, including the protection of the rights outlined in EU law, including the Charter of Fundamental Rights of the EU[9] (EU Charter) and the European Convention on Human Rights[10] .

Note 2 to entry: Annex C of EN 18228:— [5] provides information about other sources of applicable law governing fundamental rights.

[SOURCE: EN 18228:—, 3.5.1, modified – added EN 18228:— reference to Note 2 to entry, removed Note 3 to entry]

3.3.8
interference
<fundamental rights> impairment of the protection provided

Note 1 to entry: An interference does not require any material or immaterial detriment whatsoever. For example, if another person accesses my personal information without my consent, this interferes with my right to privacy irrespective of whether it generated any material detriment to me.

Note 2 to entry: The perceptions of *affected persons* (3.4.1) can correlate with a court's determination of whether an individual's *fundamental right* (3.3.7) has been interfered with. Accordingly, individual and *group* (3.4.4) perceptions of *fundamental rights* (3.3.7) adverse impact can be taken into account but are not considered determinative. For example, the use of covert surveillance systems can interfere with an individual's right to privacy, even if the *affected person* (3.4.1) is not aware of this interference.

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[SOURCE: EN 18228:—, 3.5.5, modified – Note 2 to entry, replaced persons affected with affected persons]

3.4 Groups and their identification

3.4.1
affected person
individual, or *group* (3.4.4) of individuals, who is or are directly or indirectly impacted by an *AI system* (3.2.1) when used in accordance with its *intended purpose* (3.2.2) or in the frame of *reasonably foreseeable misuse* (3.2.3)

Note 1 to entry: Within this document, "potentially affected person" shall mean a person who is potentially affected, i.e. "individual, or *group* (3.4.4) of individuals, who can potentially be directly or indirectly impacted by an *AI system* (3.2.1) when used in accordance with its *intended purpose* (3.2.2) or in the frame of *reasonably foreseeable misuse* (3.2.3)".

[SOURCE: EN 18286:2026, 3.4.1, modified – Note to entry added to permit the use of "potentially" to modify the noun phrase "affected person"]

3.4.2
at-risk group
group (3.4.4) of potentially *affected persons* (3.4.1) that can be adversely affected by *unwanted bias* (3.1.7) in the *AI system* (3.2.1) when used in accordance with its *intended purpose* (3.2.2) or in the frame of *reasonably foreseeable misuse* (3.2.3)

Note 1 to entry: Adverse effects include *harm* (3.3.3) to health or safety, or *interference* (3.3.8) with *fundamental rights* (3.3.7).

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Note 2 to entry: At-risk groups can also emerge from intersections of *groups* (3.4.4) as described in CEN/CLC ISO/IEC/TR 24027:2023 [12].

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Note 3 to entry: Unforeseen at-risk groups can emerge due to the use of *AI systems* (3.2.1), as described in CEN/CLC ISO/IEC/TS 12791:2024 [13], 5.1.5.

Note 4 to entry: An at-risk group is not necessarily a *vulnerable group* (3.4.6).

3.4.3
category
set of one or more related characteristics or circumstances that can be used to delineate or distinguish *groups* (3.4.4) of people

Note 1 to entry: Categories can be quantitative (e.g. height, weight, annual income) or qualitative (e.g. nationality, religion).

Note 2 to entry: Categories can be based on demographic criteria (e.g. categories such as age, nationality, ethnicity, gender), socioeconomic criteria (e.g. categories such as class, education level, employment, home ownership), or other criteria related to the person that is the subject of classification (e.g. categories such as language, religion, trade union membership, dress, type of mobile device).

Note 3 to entry: For example, within the category of "sex", one characteristic is "female", while in the category "age", "ages 10-18" is a characteristic.

Note 4 to entry: Categories can be based on one criterion only (e.g. sex, age, nationality), or on multiple criteria (e.g. sex and age; nationality, age and education level). When based on multiple criteria, this gives rise to intersectionality. Examples of intersectional characteristics include: male over 50 (category sex and age), or Austrian aged 30–45 with university degree (category nationality, age and educational level). See 7.2.

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3.4.4
group
subset of objects in a domain that are linked because they have shared characteristics

[SOURCE: CEN/CLC ISO/IEC/TR 24027:2023, 3.2.8]

3.4.5
interested party
stakeholder
individual, *group* (3.4.4) or organization that can affect, be affected by or perceive itself to be affected by a decision or activity

Note 1 to entry: *Affected persons* (3.4.1) are a subset of interested parties.

Note 2 to entry: Interested party includes relevant regulatory bodies, national public bodies, bodies that enforce the protection of *fundamental rights* (3.3.7), and market surveillance authorities.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.2 – modified to change person to individual in the definition, add group to the definition and add notes to entry]

3.4.6
vulnerable group
group (3.4.4) of persons who, due to socio-economic circumstances or protected characteristics, are more exposed to *risk* (3.3.4) than they would be without the circumstance or characteristic

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Note 1 to entry: Vulnerable groups are identified on the basis of the *intended purpose* (3.2.2) and the *reasonably foreseeable misuse* (3.2.3) of the *AI system* (3.2.1). In particular, vulnerability can be linked either to the *intended purpose* (3.2.2) or to *reasonably foreseeable misuse* (3.2.3) and does not necessarily occur under both circumstances.

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Note 2 to entry: Persons under the age of 18 are a vulnerable group.

Note 3 to entry: Persons can be in a vulnerable group when they are in socio-economic circumstances that make them dependent on the *AI system's* (3.2.1) decisions for their livelihood, or entry to or ability to participate in society.

Note 4 to entry: Protected characteristics are listed in Art. 21 of the EU Charter[9].

Note 5 to entry: Vulnerable groups include persons who are unable take care of themselves or protect themselves against *harm* (3.3.3) or exploitation, due to their protected characteristics.

Note 6 to entry: Vulnerable groups can include persons in power imbalance situations, such as lack of availability or access to individual and collective redress actions available to *affected persons* (3.4.1), such as the right to compensation, the right to explanation and the right to contest decisions.

Note 7 to entry: Circumstances and characteristics can be temporary, for example due to life events such as changes in health status, financial distress or transitional periods such as migration or job loss.

Note 8 to entry: A vulnerable group can be an *at-risk group* (3.4.2).

[SOURCE: EN 18228:—, 3.5.10, modified – set replaced by group; clarification added to Note 1 to entry; Note 8 to entry added]

3.4.7
attribute
property or characteristic of an object that can be distinguished quantitatively or qualitatively by human or automated means

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Note 1 to entry: As used in this document, the term object also includes persons, organizations, and entities, as well as software, data and other immaterial artefacts.

[SOURCE: EN 18228:—, 3.5.10, modified – set replaced by group; clarification added to Note 1 to entry; Note 8 to entry added]

3.4.8
feature
quantitative or qualitative representation of an object or event with respect to a set of characteristics

Note 1 to entry: A feature can be part of the input data or computed by the *AI system* (3.2.1).

3.5 Bias management processes

3.5.1
bias management
systematic and continuous application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and *monitoring* (3.1.2) *bias* (3.1.1) throughout the entire life cycle of an *AI system* (3.2.1)

[SOURCE: ISO/IEC Guide 63:2019, 3.15, modified — reference to life cycle of the AI system added; "risk" replaced by "bias"]

3.5.2
bias assessment
overall process comprising a *bias analysis* (3.5.3) and a *bias evaluation* (3.5.6)

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Note 1 to entry: Analysing and evaluating *bias* (3.1.1) supports the examination and detection of *bias* (3.1.1).

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[SOURCE: ISO/IEC Guide 51:2014, 3.11, modified — "risk" replaced by "bias"; note to entry added]

3.5.3
bias analysis
systematic use of available information to identify *bias-related hazards* (3.5.8) and to conduct *bias estimation* (3.5.4)

Note 1 to entry: Identification of *bias-related hazards* (3.5.8) includes the investigation of possible *biases* (3.1.1) and their potentially harmful effects that can arise in the context of the *AI system*'s (3.2.1) *intended purpose* (3.2.2), as well as the examination of *bias* (3.1.1) through a variety of approaches, such as data analysis, testing and impact assessments.

Note 2 to entry: Available information includes, for example, internal knowledge acquired by the provider in a *risk* (3.3.4) analysis, as well as information from media, academic publication or incident reporting about similar *AI systems* (3.2.1).

[SOURCE: ISO/IEC Guide 51:2014, 3.10, modified – replaced "hazards" with "bias-related hazards", and "risk" with "bias-related risk"; notes to entry added]

3.5.4
bias estimation
process used to measure *bias* (3.1.1)

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3.5.5
bias mitigation
bias control
process in which decisions are made and actions taken such that *risks* (3.3.4) associated with *unwanted bias* (3.1.7) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2019, 3.12, modified — inserted "associated with unwanted bias" after "risks"]

3.5.6
bias evaluation
process based on the *bias analysis* (3.5.3) and in particular the *bias estimation* (3.5.4), to provide quantitative, statistical means for assessing measured results, which can be used by the *risk* (3.3.4) assessment to determine whether observed *bias* (3.1.1) is acceptable or not

3.5.7
bias profile
subset of the *risk management file* (3.3.6) consisting of a set of documents that are created for recording the *bias management* (3.5.1) process of an *AI system* (3.1.1) and that are maintained throughout its life cycle

3.5.8
bias-related hazard
hazard (3.3.1) which is a *bias* (3.1.1), or which is caused by a *bias* (3.1.1)

Sample Document

Note 1 to entry: *biases* (3.1.1) that can affect the health and safety of persons, that can have a negative impact on *fundamental rights* (3.3.7) or that can lead to discrimination are either themselves bias-related hazards, or they are the cause of a bias-related hazard.

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3.6 Terms related to data

3.6.1
application domain specification
specification which operationalizes the *intended purpose* (3.2.2) and comprises a description of the real-world process from which samples with the expected occurrence probabilities arise

Note 1 to entry: The *application domain* (3.6.2) specification operationalizes the *intended purpose* (3.2.2) for data set construction, testing and performance evaluation, and can also be used for *risk* (3.3.4) assessment.

Note 2 to entry: The *application domain* (3.6.2) specification provides sufficient information for an independent qualified party to understand the relationship between the *intended purpose* (3.2.2) and the *testing data sets* (3.6.7) used for evaluation. In particular, it enables that party to derive and justify stochastic proxy sampling approaches used to obtain instances of *testing data* (3.6.6) and support the interpretation of resulting performance claims.

[SOURCE: EN 18284:—[4], 3.2.9]

3.6.2
application domain
distribution of samples resulting from the execution of the *application domain specification* (3.6.1)

[SOURCE: EN 18284:—, 3.2.10]

[4] Under preparation. Stage at the time of publication: prEN 18284:2026

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