### AI ACT - COMPROMISE AMENDEMENTS - BATCH 8 - V1-21.10.2022

## **TITLE X - Confidentiality and penalties**

### COMP 10a

Cover: AMs 271, 272, 273, 274, 275, 276 (Rapp), 2795 (EPP), 2796 (RE), 2798 (RE), 2799 (EPP), 2802 (EPP), 2803 (RE), 2806 (S&D), 2807 (ECR), 2809 (S&D), 2810 (EPP), 2811 (EPP)

Fall: AMs 2800 (EPP), 2801 (Greens), 2804 (EPP), 2805 (ECR) (EPP), JURI 152

Parked: AMs 2797 (S&D), 2808 (Greens)

# Article 70 Confidentiality

- 1. National competent authorities and notified *bodies*, *the Commission*, *the [AI Board/Office]* and any other natural or legal person involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular (AM 2796):
  - a. intellectual property rights, and confidential business information or trade secrets of a natural or legal person, *in line with Directive 2016/943/EC and with Directive 2004/48/EC (AM 2799)*, including source code, except the cases referred to in Article 5 of Directive 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure apply.
  - b. the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;
  - c. public and national security interests (AM 271, 272)
  - ca. the principles of purpose limitation and data minimisation, meaning that national competent authorities minimize the quantity of data requested for disclosure in line with what is absolutely necessary for the perceived risk and its assessment, and they do not keep the data for any longer than absolutely necessary (AM 2802, 2803, 2807)
  - d. integrity of criminal or administrative proceedings.
- 1a. The Commission, the Board, national competent authorities and notified bodies involved in the application of this Regulation shall put in place adequate and effective cybersecurity, technical and organisational measures to protect the security and confidentiality of the information and data obtained in carrying out their tasks and activities (AM 273, 2795, 2796, 2806)
- 2. Without prejudice to paragraphs 1 and 1a (AM 274, 2809), information exchanged on a confidential basis between the national competent authorities and between national competent authorities and the Commission shall not be disclosed without the prior consultation of the originating national competent authority and the user when high-risk AI systems referred to in points 1, 6 and 7 of Annex III are used by law enforcement,

immigration or asylum authorities, when such disclosure would jeopardise public and national security interests.

When the law enforcement, immigration or asylum authorities are providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III, the technical documentation referred to in Annex IV shall remain within the premises of those authorities. Those authorities shall ensure that the market surveillance authorities referred to in Article 63(5) and (6), as applicable, can, upon request, immediately access the documentation or obtain a copy thereof. Only staff of the market surveillance authority holding the appropriate level of security clearance shall be allowed to access that documentation or any copy thereof.

- 3. Paragraphs 1, *1a (AM 275)* and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the parties concerned to provide information under criminal law of the Member States.
- 4. The Commission and Member States may exchange, where *strictly (AM 276)* necessary and in full compliance with the provisions of international or trade agreements that may apply (AMs 2810, 2811), confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of confidentiality.

### COMP 10b

Cover: AMs 277, 278, 279, 280, 281 (Rapp), 2812 (S&D), 2815 (EPP), 2817 (EPP), 2818 (EPP), 2820 (RE), 2821 (RE), 2824 (S&D), 2825 (S&D), 2826 (EPP), 2828 (S&D), 2829 (S&D), 2830 (RE), 2831 (RE), 2832 (S&D), 2833 (EPP), 2835 (TheLeft), 2836 (S&D), 2837 (EPP), 2838 (RE), 2839 (RE), 2840 (RE), 2841 (EPP), 2842 (RE), 2843 (EPP), 2844 (S&D), 2845 (RE), 2847 (EPP), 2848 (RE), 2852 (EPP), 2853 (RE), 2855 (EPP), 2862 (EPP), 2863 (EPP), 2864 (RE), 2868 (EPP), 2869 (EPP), 2870 (EPP), 2871 (EPP), 2872 (EPP), 2874 (EPP), 2876 (RE), 2877 (S&D), 2878 (EPP), 2883 (EPP), CULT 62

Fall: 2814 (ID), 2816 (Greens), 2822 (ECR), 2823 (EPP), 2827 (RE), 2834 (ID), 2846 (S&D), 2849 (S&D), 2850 (TheLeft), 2851 (Greens), 2854 (S&D), 2856 (TheLeft), 2857 (Greens), 2858 (S&D), 2859 (EPP), 2860 (Greens), 2861 (S&D), 2865 (S&D), 2866 (RE), 2867 (EPP), 2873 (EPP), 2875 (S&D), 2879 (S&D), 2880 (EPP), 2881 (RE), 2882 (EPP) Parked: AM 2813 (Left) - remedies, 2819 (S&D) - due to separate article on fines

# Article 71 Penalties and fines (AM 277)

- 1. In compliance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Regulation, in particular for infringements which are not subject to administrative fines pursuant to Article 70a/parag 8b (AM2819) and shall take all measures necessary to ensure that they are properly and effectively implemented and aligned with the guidelines issued by the Board/Office, as referred to in Article 58(xxx (AM 2815, 2818). The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the size, the interests of small-scale providers SMEs (AM 2817, 2818, 2820, 2821, 2878) and start-ups and their economic viability.
- 2. The Member States shall notify the Commission and the Board /Office (AM 278) by [3 months following the date of entry into force of this Regulation] (AM 2824, 2825) of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.
- 3. Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5 The following infringements shall be subject to administrative fines of up to 40 30 000 000 EUR or, if the offender is company, up to 7 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher:
  - a. non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;
  - b. non-compliance of the AI system with the requirements laid down in Article 10. (AM 2836 to 2844)
- 3a. Non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is company, up to 4% of its total worldwide annual turnover for the preceding financial year, whichever is the higher (AM 2845)

- 4. **The**-Non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 20 000 000 EUR or, if the offender is a company, up to 4% 2% of its total worldwide annual turnover for the preceding financial year, whichever is higher. (AM 2847, 2848, 2853).
- 5. The supply of incorrect, incomplete or misleading information to notified bodies and national competent authorities in reply to a request shall be subject to administrative fines of up to 10-5 000 000 EUR or, if the offender is a company, up to 2-1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher (AM 2855).
- 6. Fines may be imposed in addition to or instead of non-monetary measures such as orders or warnings (AM 2862). When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
  - a. the nature, gravity and duration of the infringement and of its consequences, taking into account the nature, scope or purpose of the AI system, as well as, where appropriate, the number of affected persons and the level of damage suffered by them (AM 2812, 2863);
  - b. whether administrative fines have been already applied by other market surveillance authorities *of one or more Member States (AM 2864)* to the same operator for the same infringement.
  - c. the size and market share of the operator committing the infringement (AM 2847, 2848)
  - (ca) any action taken by the provider to mitigate the harm of damage suffered by the affected persons (AM 2868, 2812)
  - (cb) the intentional or negligent character of the infringement (AM 2869, 2874, 2812)
  - (cc) the degree of cooperation with the national competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement (AM 2870, 2812)
  - (cbb) the degree of responsibility of the operator taking into account the technical and organisational measures implemented by them; (AM 2812) (cbb)adherence to approved codes of conduct or approved certification mechanisms; (AM 2812)
  - (cd) any relevant previous infringements by the provider (AM 2871, 2812)
  - (ce) any other aggravating or mitigating factor applicable to the circumstances of the case (AM 2872, 2812)
- 7. Each Member State shall lay down rules on *whether and to what extent* administrative fines *to may* be imposed on public authorities and bodies established in

- that Member State with a view to ensure compliance with this Regulation (AM 2876)
- 8. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts of other bodies as applicable in those Member States. The application of such rules in those Member States shall have an equivalent effect.
  - 8a. In accordance with Chapter 4 of Title VIII, the Commission may adopt a decision imposing fines pursuant to paragraphs 3 and 6 on providers and users of high-risk AI systems (AM 279)
  - 8b. In addition to paragraph 8a, the Commission may adopt a decision imposing on the operator concerned fines not exceeding 1% of the total turnover in the preceding financial year, where the operator intentionally or negligently:
  - (a) fails to provide information to the Commission by the deadline set in a Commission decision;
  - (b) fails to rectify by the deadline set in a Commission decision, incorrect, incomplete or misleading information given by a member of staff, or fails or refuses to provide complete information;
  - (c) refuses to submit to a remote or on-site inspection pursuant to Article 68f (AM 280)
  - 8c. The Commission and national supervisory authorities shall, on an annual basis, report to the Board /AI Office about the fines they have issued during that year, in accordance with this Article (AM 281)
  - 8d. The exercise by competent authorities of their powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including judicial remedy and due process (AMs 2812, 2883)

### COMP 10c

Cover: AMs 282, 283 (Rapp), 2885 (S&D), 2886 (S&D), , 2888 (ECR), 2890 (ECR), 2891 (ECR), 2892 (S&D), 2894 (S&D), 2895 (RE), 2896 (S&D), 2899 (S&D), 2900 (S&D), 2901 (RE), 2902 (S&D), 2903 (S&D), 2904 (RE), 2905 (S&D), 2906 (RE), 2909 (S&D), 2910 (RE), 2911 (S&D), 2912 (S&D), 2913 (S&D), 2915 (S&D), 2916 (S&D), TRAN 123, 124, 125,

Fall: AMs 2884 (TheLeft), 2887 (ECR), 2889 (ID), 2893 (ECR) 2897 (ID), 2898 (TheLeft), 2907 (ID), 2908 (TheLeft), 2912 (S&D), 2913 (S&D), 2914 (ID), TRAN 126

#### Article 72

Administrative fines on Union institutions, agencies and bodies

- 1. The European Data Protection Supervisor may impose administrative fines on Union institutions, agencies and bodies falling within the scope of this Regulation. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
  - a) the nature, gravity and duration of the infringement and of its consequences;, taking into account the nature, scope or purpose of the AI system concerned as well as the number of affected persons and the level of damage suffered by them, and any relevant previous infringement (AMs 2885, TRAN 123);
  - (aa) any action taken by the Union institution, agency or body to mitigate the damage suffered by affected persons or harm (AM 2886, 2891, TRAN 125)
  - (ab) the degree of responsibility of the Union institution, agency or body, taking into account technical and organisational measures implemented by them;
  - the *degree of* cooperation with the European Data Protection Supervisor in order to remedy the infringement and mitigate the possible adverse effects of the infringement, including compliance with any of the measures previously ordered by the European Data Protection Supervisor against the Union institution or agency or body concerned with regard to the same subject matter (*TRAN 124, AM 2890*)
  - (c) any similar previous infringements by the Union institution, agency or body (AM 2888)
  - (d) the manner in which the infringement became known to the European Data Protection Supervisor, in particular whether, and if

so to what extent, the Union institution or body notified the infringement (AM 2892);

2. Non compliance with the prohibition of the artificial intelligence practices referred to in Article 5 The following infringements shall be subject to administrative fines of up to 1 000 000 500 000 EUR.

(a)non-compliance with the prohibition of the artificial intelligence practices referred to in Article 5;

- 2a. Non-compliance of the AI system with the requirements laid down in Article 10 shall be subject to administrative fines of up to 600 000 EUR (AM 2894, 2895, 2896, 2899, 2900, 2901, 2902, 2903, 2904, 2905, 2906)
- 3. The non-compliance of the AI system with any requirements or obligations under this Regulation, other than those laid down in Articles 5 and 10, shall be subject to administrative fines of up to 400 000 250 000 EUR (AM 2909, 2910, 2911).
- 4. Before taking decisions pursuant to this Article, the European Data Protection Supervisor shall give the Union institution, agency or body which is the subject of the proceedings conducted by the European Data Protection Supervisor the opportunity of being heard on the matter regarding the possible infringement. The European Data Protection Supervisor shall base his or her decisions only on elements and circumstances on which the parties concerned have been able to comment. Complainants, if any, shall be associated closely with the proceedings.
- 5. The rights of defense of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the European Data Protection Supervisor's file, subject to the legitimate interest of individuals or undertakings in the protection of their personal data or business secrets.
- 6. Funds collected by imposition of fines in this Article shall *contribute to be the income of (AM 282, 2915)* the general budget of the Union.

6a. The European Data Protection Supervisor shall, on an annual basis, notify the Board-AI Office of the fines it has imposed pursuant to this Article (AM 283, 2916)

## TITLE XI - delegation of power and committee procedure

### COMP 11a

Cover: AMs 2920 (EPP), 2924 (Greens), 2926 (RE), 2927 (Greens), 2929 (TheLeft), CULT

63 Fall:

# Article 73 Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall be conferred on the Commission for an indeterminate period of time from [entering into force of the Regulation].
- 3. The delegation of power referred to in Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of power specified in that decision. It shall take effect the day following that of its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 3a. Before adopting a delegated act, the Commission shall consult with the relevant institutions and stakeholders in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making, as well as with the Board/Office and the high level expert Group on AI (CULT 63, AM 2920, 2924)
- 3b. Delegated acts that lead to the modification or the addition of obligations on operators shall specify a proportionate transition period when deemed necessary. This transition period shall no less than 24 months (AM 2926)

Once the Commission decides to draft a delegated act, it shall notify the European Parliament of this fact. This notification does not place an obligation on the Commission to adopt the said act (AM 2927, 2929).

- 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament *and to* the Council *and the AI office (AM 2928)*.
- 5. Any delegated act adopted pursuant to Article 4, Article 7(1), Article 11(3), Article 43(5) and (6) and Article 48(5) shall enter into force only if no objection has been expressed by either the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both

informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.



### Article 74

## Committee procedure

- 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.



### TITLE XII

### FINAL PROVISIONS

### COMP AM 12a

Covers: 284 (Rapp), 285 (Rapp), 286 (Rapp), 2933 (ECR), 2934 (EPP), 2935 (EPP), 1936 (EPP), 2938 (EPP), 2939 (ECR), 2940 (ECR), 2841 (EPP), 2942 (RE), 2945 (RE), 2946 (RE), 2947 (The Left), 2948 (Greens), 2952 (RE), 2953 (S&D, 2954 (Greens), 2957 (RE), 2959 (Greens), 2960 (S&D), 2964 (The Left), 2965 (S&D), 2966 (ECR), 2968 (RE), 2975 (RE), 2977 (RE), 2978 (EPP), 2979 (EPP), 2980 (Greens), 2981 (RE), 2982 (RE), 2983 (RE), 2984 (The Left), 2985 (S&D), 2986 (Greens, RE, EPP), 2987 (Greens), 2988 (RE), 2989 (RE), 2990 (S&D), 2991 (The Left), 2992 (Greens), 2993 (Greens, RE, EPP), 2994 (RE), 2996 (The Left), 2997 (S&D), 2998 (EPP)

**Falls:** 2943 (S&D), 2944 (ID), 2949 (EPP), 2950 (RE), 2951 (The Left), 3000 (EPP), 3001 (RE), 3002 (EPP) 3003 (Greens), 3004 (EPP), 3005 (EPP), 3006 (EPP), 3007 (RE), 2955 (EPP), 2958 (ID), 2961 (RE), 2962 (RE), 2973 (ECR)

**Parked**: 2963 (Greens) - AI in employment, 2967 (EPP) - linked to debate on Article 7, 2975 (S&D), 2971 (RE) - governance and fines, 2995 (Greens) - linked to Governance

# Article 75 Amendment to Regulation (EC) No 300/2008

In Article 4(3) of Regulation (EC) No 300/2008, the following subparagraph is added:

"When adopting detailed measures related to technical specifications and procedures for approval and use of security equipment concerning Artificial Intelligence systems in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Chapter 2, Title III of that Regulation shall be taken into account."

# Article 76 Amendment to Regulation (EU) No 167/2013

In Article 17(5) of Regulation (EU) No 167/2013, the following subparagraph is added:

"When adopting delegated acts pursuant to the first subparagraph concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

# Article 77 Amendment to Regulation (EU) No 168/2013

In Article 22(5) of Regulation (EU) No 168/2013, the following subparagraph is added:

"When adopting delegated acts pursuant to the first subparagraph concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX on [Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

## Article 78 Amendment to Directive 2014/90/EU

In Article 8 of Directive 2014/90/EU, the following paragraph is added:

"4. For Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, when carrying out its activities pursuant to paragraph 1 and when adopting technical specifications and testing standards in accordance with paragraphs 2 and 3, the Commission shall take into account the requirements set out in Title III, Chapter 2 of that Regulation.

# Article 79 Amendment to Directive (EU) 2016/797

In Article 5 of Directive (EU) 2016/797, the following paragraph is added:

"12. When adopting delegated acts pursuant to paragraph 1 and implementing acts pursuant to paragraph 11 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

# Article 80 Amendment to Regulation (EU) 2018/858

In Article 5 of Regulation (EU) 2018/858 the following paragraph is added:

"4. When adopting delegated acts pursuant to paragraph 3 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).".

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).".

Artificial Intelligence] of the European Parliament and of the Council \*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

\* Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).".

## Article 81 Amendment to Regulation (EU) 2018/1139

Regulation (EU) 2018/1139 is amended as follows:

- (1) In Article 17, the following paragraph is added:
- "3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

### Article 81a

### Amendment to Regulation (EU) 2019/1020

In Article 14.4 of Regulation (EU) 2019/1020 the following paragraph is added: "(l) The power to implement the powers provided for in this Article remotely, where applicable." (AM 2937)

- (2) In Article 19, the following paragraph is added:
- "4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."
- (3) In Article 43, the following paragraph is added:
- "4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."
- (4) In Article 47, the following paragraph is added:
- "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."
- (5) In Article 57, the following paragraph is added:

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...)."

- "When adopting those implementing acts concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."
- (6) In Article 58, the following paragraph is added:
- "3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence], the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account."

# Article 82 Amendment to Regulation (EU) 2019/2144

In Article 11 of Regulation (EU) 2019/2144, the following paragraph is added:

"3. When adopting the implementing acts pursuant to paragraph 2, concerning artificial intelligence systems which are safety components in the meaning of Regulation (EU) YYY/ XX [on Artificial Intelligence] of the European Parliament and of the Council\*, the requirements set out in Title III, Chapter 2 of that Regulation shall be taken into account.

# Article 82 a Sound regulation

In taking into account the requirements of this Regulation pursuant to the Amendments in Articles 75, 76, 77, 78, 79, 80, 81, and 82, the Commission shall conduct an analysis and consult relevant stakeholders to determine potential gaps as well as overlaps between existing sectoral legislation and the provisions of this Regulation in order to avoid duplication, overregulation, and the creation of loopholes. (AMs 2942, 2933, 2934, 2935, 1936, 2938, 2939, 2940, 2941)

#### Article 83

AI systems already placed on the market or put into service

Operators of (AM 2946) the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service shall take the necessary steps to comply with the requirements of the present Regulation within two years after the entry into force of this Regulation (AM 2945, 2946, 2947, 2948)

The requirements laid down in this Regulation shall *apply (AMs 2953, 2954)* in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts *and whenever those legal acts are replaced or amended (AM 2952)*.

<sup>\*</sup> Regulation (EU) YYY/XX [on Artificial Intelligence] (OJ ...).".

2. Operators of high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], shall take the necessary steps to comply with the requirements of the present Regulation within 2 years of its entry into force (AMs 2957, 2959, 2960)

# Article 84 Evaluation and review

- 1. In consultation with the AI Board/Office, the Commission (AM 2970) shall assess the need for amendment of the list in Annex III, including the extension of existing area headings or addition of new area headings; ,Article 5's list of prohibited AI practices, and Article 52's list of AI systems requiring additional transparency measures (AMs 2964, 2965, 2969) once a year following the entry into force of this Regulation and on a regular basis following a recommendation of the Board/Office (AM 284, 2971). The findings of that assessment shall be presented to the European Parliament and the Council. (AMs 2966, 2968, 2972)
- 2. By [two years after the date of application of this Regulation referred to in Article 85(2)] and every two (AM 285) years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.
- 3. The reports referred to in paragraph 2 shall devote specific attention to the following:
  - (a) the status of the financial, *technical (AM 2974)* and human resources of the national competent authorities in order to effectively perform the tasks assigned to them under this Regulation;
  - (b) the state of penalties, and notably administrative fines as referred to in Article 71(1), applied by Member States to infringements of the provisions of this Regulation.
  - (ba) the state of the development of harmonised standards and common specifications for Artificial Intelligence; (AM 2977)
  - (bb) the levels of investments in research, development and application of AI systems throughout the Union, (AM 2978)
  - (bc) the competitiveness of the aggregated European AI ecosystem compared to AI ecosystems in third countries. (AM 2979)
  - (bd) the impact of the Regulation with regards to the resource and energy use, waste production and other environmental impact (AM 2980)
- 4. Within [one year after the date of application of this Regulation referred to in Article 85(2)] and every two (AM 2981) years thereafter, the Commission shall evaluate the impact and effectiveness of codes of conduct to foster the application of the requirements set out in Title III, Chapter 2 and possibly other additional requirements for AI systems other than high-risk AI systems.

- 5. For the purpose of paragraphs 1 to 4 the AI Board Office (AM 2983), the Member States and national competent authorities shall provide the Commission with information on its request without undue delay (AM 2982).
- 6. In carrying out the evaluations and reviews referred to in paragraphs 1 to 4 the Commission shall take into account the positions and findings of -AI Office (AM 2989), of the European Parliament, of the Council, of equality bodies (AMs 286, 2984, 2985) and of other relevant bodies or sources and shall consult relevant external stakeholders, in particular those potentially affected by the AI systems, organisations representing their interests, academia, the social partners and civil society which shall be attached to the report. (AMs 286, 2984, 2985, 2986, 2987, 2988)
- 7. The Commission shall, if necessary, submit appropriate proposals to amend this Regulation, in particular taking into account developments in technology the effect of AI systems on health and safety, fundamental rights, the environment, equality, and accessibility for persons with disabilities, and the values of the Union as enshrined in Article 2 TEU (AM 2990, 2991, 2992, 2993, 2994,) and in the light of the state of progress in the information society.
- 7 a. To guide the evaluations and reviews referred to in paragraphs 1 to 4, the Board/Office shall undertake to develop an objective and participative methodology for the evaluation of risk level based on the criteria outlined in the relevant articles and inclusion of new systems in: the list in Annex III, including the extension of existing area headings or addition of new area headings; the list of prohibited practices in Article 5; and the list of AI systems requiring additional transparency measures. (AMs 2996, 2997)
- 7b. Any amendment to this Regulation pursuant to paragraph 7, or relevant future delegated or implementing acts, which concern sectoral legislation listed in annex II section B, shall take into account the regulatory specificities of each sector, and should not interfere with existing governance, conformity assessment and enforcement mechanisms and authorities established therein. (AM 2998)

# Article 85 Entry into force and application

- 1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
- 2. This Regulation shall apply from [24 months following the entering into force of the Regulation].
- 3. By way of derogation from paragraph 2:
  - (a) Title III, Chapter 4 and Title VI shall apply from [three months following the entry into force of this Regulation];
  - (b) Article 71 shall apply from [twelve months following the entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the European Parliament The President For the Council The President