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Of Hypothesis and Facts: The Curious Origins of the EU's Regulation of High-Risk AI

20.05.2022
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"When all possibilities would become probabilities (…), every possibility is the next thing to a certainty."

Herman Melville, *Moby-Dick; or, The Whale*, New York, Harper & Brothers (1851), at 221.

"When all possibilities would become probabilities (…), every possibility is the next thing to a certainty."

Herman Melville, *Moby-Dick; or, The Whale,* New York, Harper & Brothers (1851), at 221.

"Regulation has an important role to play in connecting the arguments of participants, in facilitating the interpretation of the wide range of views as to the appropriate course that the technology and its regulation should take."

Julia Black, Regulation as Facilitation: Negotiating the Genetic Revolution, Mod.L.Rev. Vol. 61, n° 5 (1998), 621-621, at 621.

Research Questions (RQ)

1. Fact-finding procedures
What type of evidence was collected by the EC in view of drafting the AI Act?

2. Fact/Law correspondence
To what extent does the AI Act rely on the evidence gathered?

3. Epistemic/legal validity
Does the AI Act establish the regulatory framework warranted by the evidence gathered?

RQ

1. **Fact-finding:** What type of evidence was collected by the EC in view of drafting the AI Act?

2. **Fact/Law correspondence:** To what extent does the Ai Act rely on the evidence gathered?

3. **Epistemic/legal validity correspondence:** does the AI Act establish the regulatory framework warranted by the evidence gathered?

Structure

I. Remarks on methodology

II. The Fact-Finding Procedure(s) launched by the EC

III. The EC's interpretation of the facts gathered

IV. Critical analysis

V. Conclusions and prospects

I. Remarks on Methodology

Analytical Framework

Risk

evidence

regulation

AI

Operative Concepts

Schools of thought

Evidence theory

Theory of Normativity

Procedural fairness

I. Remarks on Methodology

Risk

Operative Concepts

"'risk' means in some cases a **quantity susceptible of measurement** (...) and there are far-reaching and crucial differences in the bearings of the phenomena depending on which of the two is really present and operating (...) It will appear that a **measurable uncertainty or 'risk' proper** (...) is so far different from unmeasurable one that it is not in effect an uncertainty at all.''

F.H. Knight FH, *Risk, uncertainty and profit*, Chicago, Univ. of Chicago Press (1971).

I. Remarks on Methodology

Evidence

Operative Concepts

"any **knowable fact or group of facts**, considered with a view of being presented, typically before a court, for the purpose of **making a claim on the truth of a proposition**."

J.H. Wigmore, *Evidence in Trials at Common Law*, Little, Brown (1961), 4th ed. Vol. 11

I. Remarks on Methodology

Regulation

Operative Concepts

"regulation (or regulatory governance) translates to intentional attempts to **manage risk** or alter behavior in order to achieve some **pre-specified goal**."

Karen Yeung, "Algorithmic Regulation: A critical interrogation," Regulation & Governance, 12 (2018), 505-523, at 507

I. Remarks on Methodology

Artificial Intelligence

Operative Concepts

"'Artificial intelligence system' (AI system) means software that is developed with **one or more of the techniques and approaches** (…) and can, for a given set of **human-defined objectives**, **generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with.**"

AI Act (COM(2021)206 final)

(Art. 3, par. 1)

I. Remarks on Methodology

Fact/law correspondence

Reference points in theory

- **Evidence theory/ies – the 'New Evidence Scholarship'**

William Twining, *Rethinking Evidence: Explanatory Essays*, Cambridge Univ. Press (2006)

Douglas Walton, *Argumentation Methods for AI in Law*, Springer (2005)

Nicholas Rescher, *Plausible Reasoning: An Introduction to the Theory and Practice of Plausibilistic Inference*, Assen/Amsterdam, Van Gorcum, (1976)

Robin Pope et al., *The Knowledge Ahead approach to Risk. Theory and Experimental Evidence*, Springer (2007) (…)

I. Remarks on Methodology

Fact/law correspondence

Reference points in theory

- **Theory of normativity / Risk regulation**

Stanley L. Paulson, 'Hans Kelsen's Earliest Legal Theory: Critical Constructivism' Mod. L. Rev. (1996), vol. 59, n° 6, 797-812

Neil McCormick, *Institutions of Law: An Essay in Legal Theory*, Oxford Univ. Press (2007)

Sabine Roeser et al., *Essentials of Risk Theory*, Springer (2013)

Jon Glasby, *Evidence, policy and practice*, Bristol Univ. Press (2011)

Karen Yeung, **Martin Lodge** (ed.), *Algorithmic Regulation*, Oxford Univ. Press (2019)

Julia Black, *Rules and regulators*, Oxford Univ. Press (1997) (…)

I. Remarks on Methodology

Fact/law correspondence

Reference points in theory

- **Explainability of facts / norms and procedural justice**

John Rawls, *A Theory of Justice* (revised ed.), Cambridge, Harv. Univ. Press (1999).

Lawrence B. Solum, *'Procedural Justice,'* Cal. L. Rev., vol. 78, n° 181 (2004), pp. 305-447

Kelly Hannah-Moffat, "*Algorithmic risk governance: Big data analytics, race and information activism in criminal justice debates*", Theoretical Criminology, vol. 23, n° 4, (2019), 453-470

Seth Katsuya Endo, *'Technological opacity & procedural injustice,'* Boston Col. L. Rev. (2018), vol. 59, n° 3, 822-875 (…)

I. Remarks on Methodology

Fact/law correspondance

Reference points in practice (EU)

Better regulation agenda (best evidence rule)

Article 296 TFEU/ 41 ECFR

Judicial review (explainability/evidence-based legislation): e.g. CJEU, 8 September 2011, *Monsanto SAS et al.*, joined cases C-58/10 to C-68/10, EU:C:2011:553; ECJ, 5 February 2004, *Commission v. France*, case C-24/00, EU:C:2004:70.

II. The Fact-Finding Procedure(s) launched by the EC

Structure

I. Type of facts and fact-gathering procedures

   1. Available data

   2. Unavailable data

   3. Inconclusive data

II. Data available and what we did with it

   1. White Paper Public Consultation

   2. Inception Impact Assessment Public Consultation

II. The Fact-Finding Procedure(s) of the EC

Types of facts and fact-gathering procedures

"We cannot say, for example, that the highest permissible impact on privacy is 2.5 'mg' per data subject per year" (Quelle 2018).

"Although evidence for individual legal challenges and breaches of fundamental rights is growing, *robust and representative evidence* for harms inflicted by the use of AI is scarce due to the *lack of data* and mechanisms to monitor AI as a set of emerging technology" (EC, SWD, part. 1/2 p. 51).

"AI is a highly dynamic and rapidly evolving industry so that *not a lot of currently valid evidence is available* at this stage" (EC, Inception Impact Assessment).

"[The Proposal] builds in two years of analysis of evidence and involvement of stakeholders" (EC, SWD, part. 1/2 p. 1).

II. The Fact-Finding Procedure(s) of the EC

Data available (EC, SWD, Part 2/2, pp. 6-7 and 40-41)

- An "external study" that reviewed "available evidence of fundamental rights or safety-related risks created by AI Applications"

- Public consultation on the EC's White Paper on AI

- Public consultation on the Inception Impact Assessment

- Symposium organised by the European AI Alliance

- The participation of Commission representatives to more than fifty online conferences and roundtables

II. The Fact-Finding Procedure(s) of the EC

Data available (EC, SWD, Part 2/2, pp. 6-7 and 40-41)

- Five "closed" expert webinars (online workshop) on:

  1. **Conformity assessment** on 17 July 2020 with 26 participants from the applying industry, civil society and conformity assessment community

  2. **Biometrics** on 3 September 2020 with 17 external participants from stakeholders such as the Fundamental Rights Agency, the World Economic Forum, the French Commission Nationale de l'Informatique et des Libertés and academia

II. The Fact-Finding Procedure(s) of the EC

Data available (EC, SWD, Part 2/2, pp. 6-7 and 40-41)

- Five "closed" expert webinars (online workshop) on:

  3. **standardization** on 29 September 2020 with 27 external participants from UNESCO, OECD, Council of Europe, CEN-CENELEC, ETSI, ISO/IEC, IEEE, ITU

  4. **potential requirements** on 9 October 2020 with 15 external experts on AI, mainly from academia

  5. **children's right and AI** on 12 November 2020 with external experts

II. The Fact-Finding Procedure(s) of the EC

Data available (EC, SWD, Part 2/2, pp. 6-7 and 40-41)

- HLEG's conclusion and results of the piloting phases of their Ethics Guidelines

- An "extensive literature review, covering academic books, journals as well as a wide spectrum of policy studies and reports, including by non-governmental organisations"

- The annex of the European Parliament's Resolution 2020/2012(INL)

- A list of 132 AI use cases identified by the Final Draft of ISO/IEC TR 24030

- AI Watch Analysis

II. The Fact-Finding Procedure(s) of the EC

Data made available

- Public consultation on the EC's White Paper on AI

- Public consultation on the Inception Impact Assessment

Data not made available

- External study

- Closed webinar

"Inconclusive" data

- AI Alliance Symposium, Fifty online conferences

- HLEG's conclusions, Literature review, AI Watch Analysis, EP's Resolution

- ISO's use cases

II. The Fact-Finding Procedure(s) of the EC

What we did with the data available – White Paper Public Consultation

- In the words of the EC, the WP aimed at "*collecting evidence*" (EC, Inception Impact Assessment)

- From February 19th to June 14th, 2020

- 1,216 stakeholders with an interest in AI

Total respondents	1,216	100%
EU citizen	372	30.59%
Company/business organisation	222	18.26%
SMEs	83	6.83%
Large companies	139	11.43%
Academic/research Institution	152	12.50%
Business association	131	10.77%
Non-governmental organisation (NGO)	128	10.53%
Public authority	73	6.00%
Other	72	5.92%
Non-EU citizen	34	2.80%
Trade union	22	1.81%
Consumer organisation	9	0.74%
Environmental organisation	1	0.08%

II. The Fact-Finding Procedure(s) of the EC

Public authority; 73

Other; 72

Non-EU citizen; 34

Trade union; 22

Consumer organisation; 9

Environmental organisation; 1

Non-governmental organisation (NGO); 128

Large companies; 139

Business association; 131

Company/Business organisations; 222

Academic/research Institution; 152

SMEs; 83

EU citizen; 372
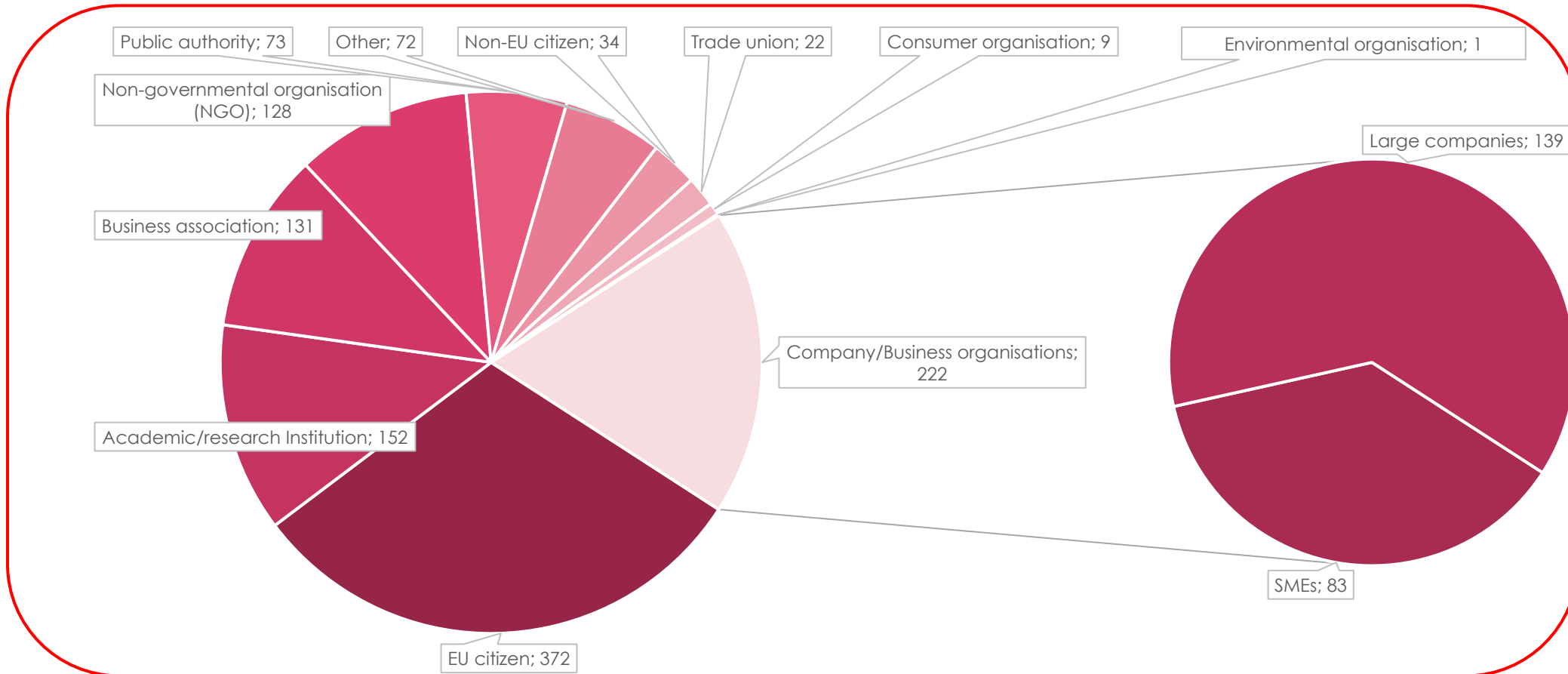
II. The Fact-Finding Procedure(s) of the EC

Geographically mapping the respondents

Country	Count	%	Country	Count	%	Country	Count	%
Germany	251	20.64%	Greece	13	1.07%	Serbia	2	0.16%
Belgium	162	13.32%	Norway	10	0.82%	Latvia	2	0.16%
France	117	9.62%	Hungary	8	0.66%	China	2	0.16%
Spain	105	8.63%	Czech Republic	7	0.58%	Vietnam	1	0.08%
UK	76	6.25%	Japan	6	0.49%	Syria	1	0.08%
United States	60	4.93%	Malta	5	0.41%	Swaziland	1	0.08%
Netherlands	60	4.93%	Lithuania	5	0.41%	South Korea	1	0.08%
Italy	60	4.93%	India	5	0.41%	Mexico	1	0.08%
Austria	33	2.71%	Bulgaria	5	0.41%	Iraq	1	0.08%
Sweden	30	2.47%	Slovenia	4	0.33%	Gibraltar	1	0.08%
Finland	30	2.47%	Slovakia	4	0.33%	Côte d'Ivoire	1	0.08%
Portugal	26	2.14%	Luxembourg	4	0.33%	Costa Rica	1	0.08%
Denmark	26	2.14%	Croatia	4	0.33%	Brazil	1	0.08%
Poland	20	1.64%	Canada	4	0.33%	Albania	1	0.08%
Romania	18	1.48%	Turkey	3	0.25%	Afghanistan	1	0.08%
Ireland	18	1.48%	Estonia	3	0.25%	TOTAL	1216	100%
Switzerland	13	1.07%	Cyprus	3	0.25%			

II. The Fact-Finding Procedure(s) of the EC

60 Questions – First distinction

- 42 closed or predefined answers: Quantitative analysis

- 18 open questions allowing free-text answers: Qualitative analysis

    - Approximately 6,500 comments received

    - We read all of them and discarded conspiracy theories and Orwellian scenario

    - No access to written answers attached to some responses
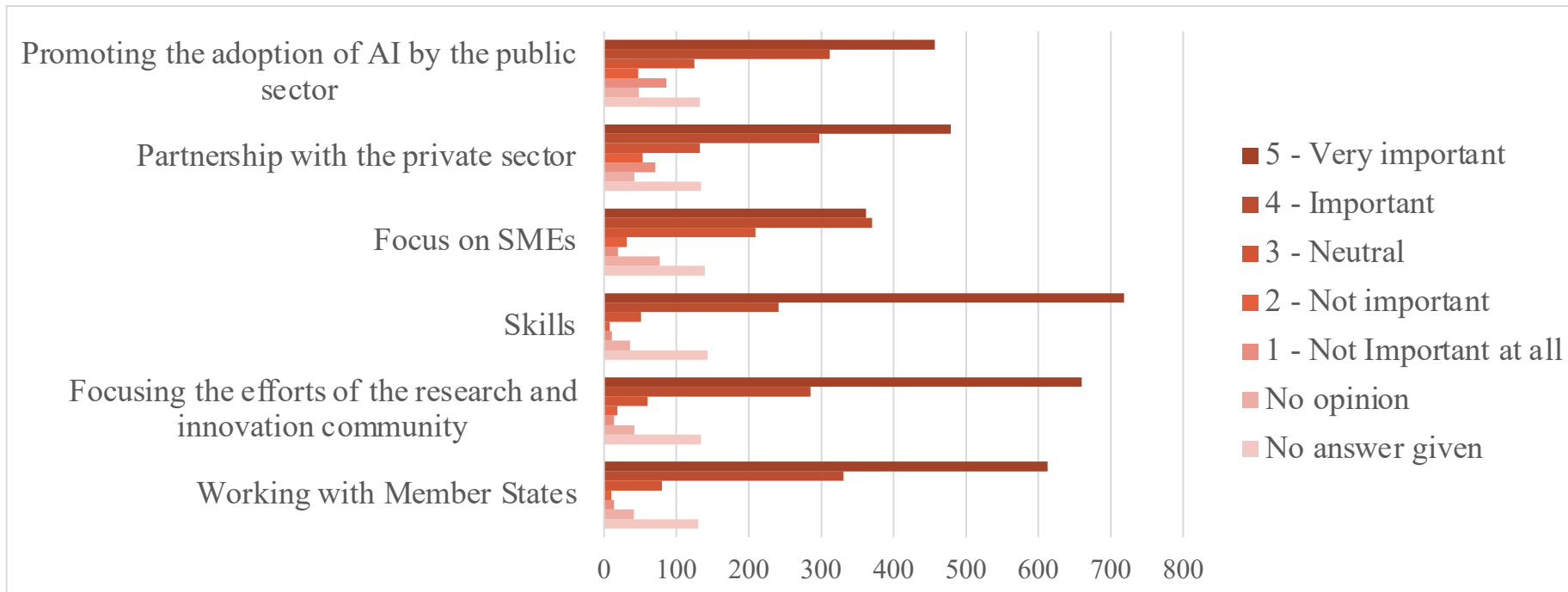
II. The Fact-Finding Procedure(s) of the EC

60 Questions – Second distinction

- Section 4 White Paper (ecosystem of excellence)

- Trustworthy AI (ecosystem of trust)

- Opportunity of (high-risk) AI regulation (excluding biometric identification)

- Update of product safety and liability (excluding product liability)

II. The Fact-Finding Procedure(s) of the EC

An ecosystem of excellence
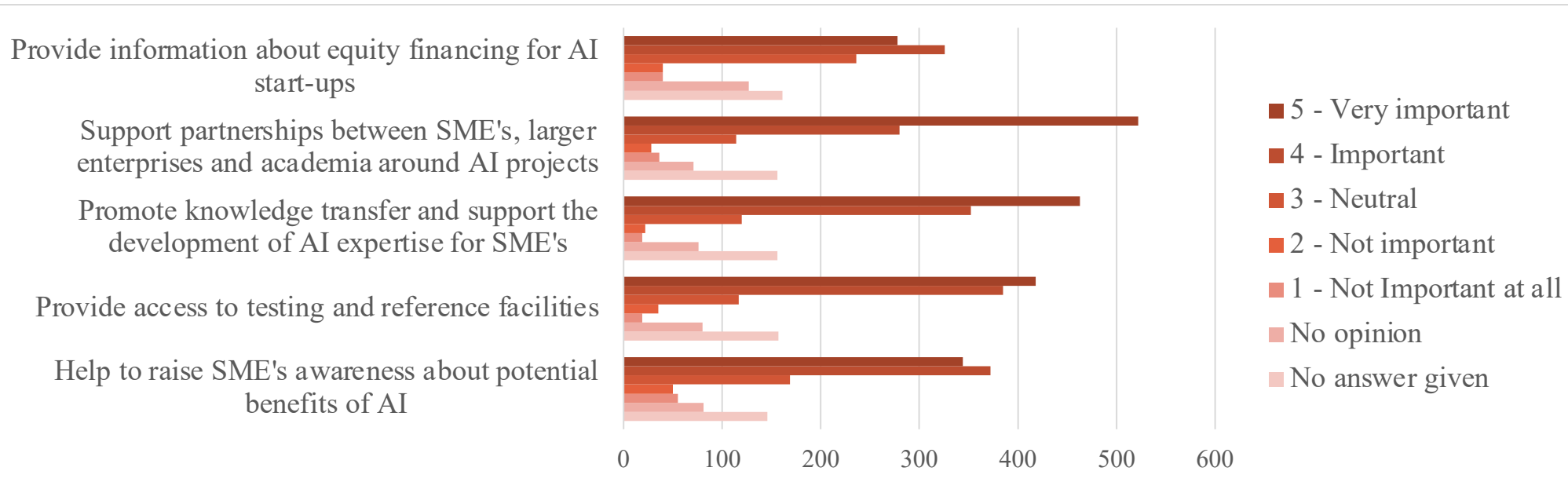
II. The Fact-Finding Procedure(s) of the EC

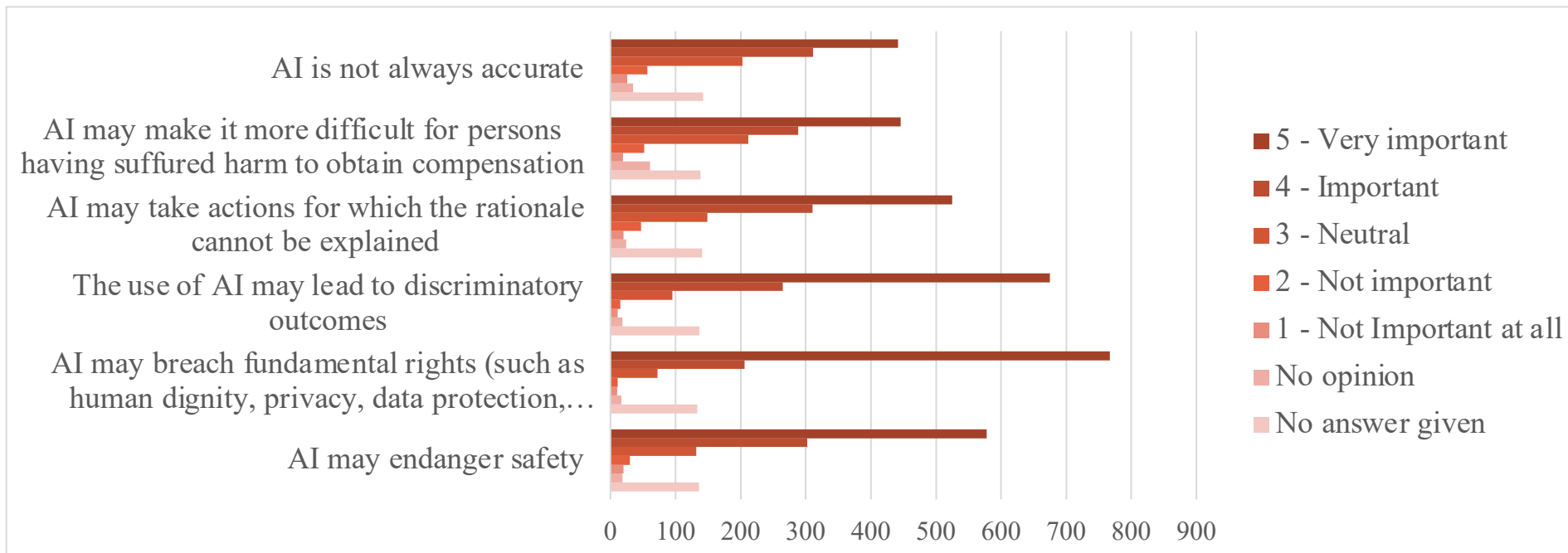**An ecosystem of excellence – Working with Member States**
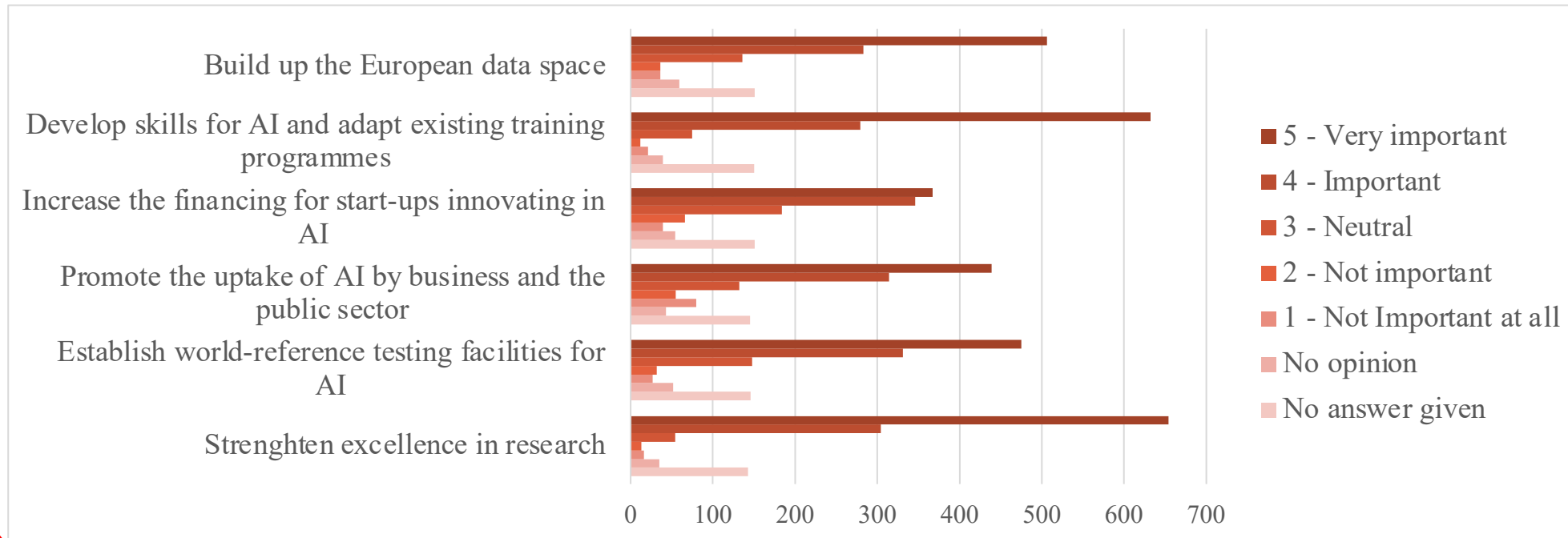
An ecosystem of excellence – other questions
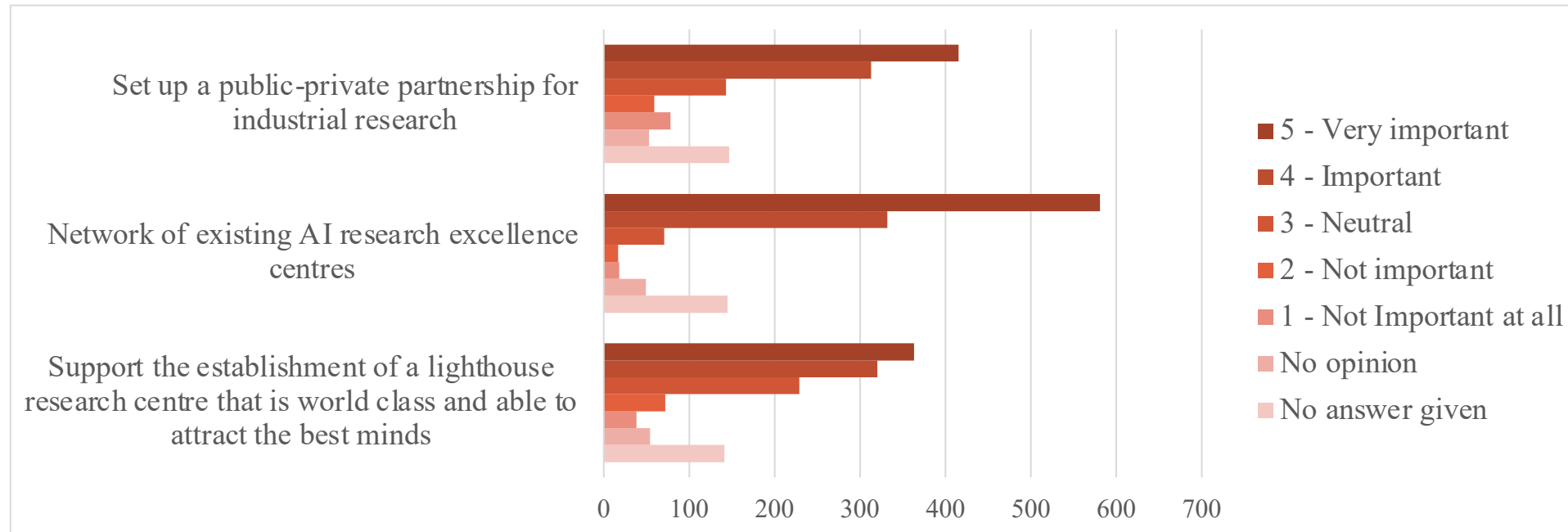
II. The Fact-Finding Procedure(s) of the EC

An ecosystem of excellence – supporting SMEs

An ecosystem of trust – Issues raised by AI

Legend:
- 5 - Very important
- 4 - Important
- 3 - Neutral
- 2 - Not important
- 1 - Not Important at all
- No opinion
- No answer given

Categories (vertical axis):
- AI is not always accurate
- AI may make it more difficult for persons having suffured harm to obtain compensation
- AI may take actions for which the rationale cannot be explained
- The use of AI may lead to discriminatory outcomes
- AI may breach fundamental rights (such as human dignity, privacy, data protection,…
- AI may endanger safety

Horizontal axis: 0, 100, 200, 300, 400, 500, 600, 700, 800, 900

II. The Fact-Finding Procedure(s) of the EC

An ecosystem of trust – Solving AI Issues with Mandatory Requirements
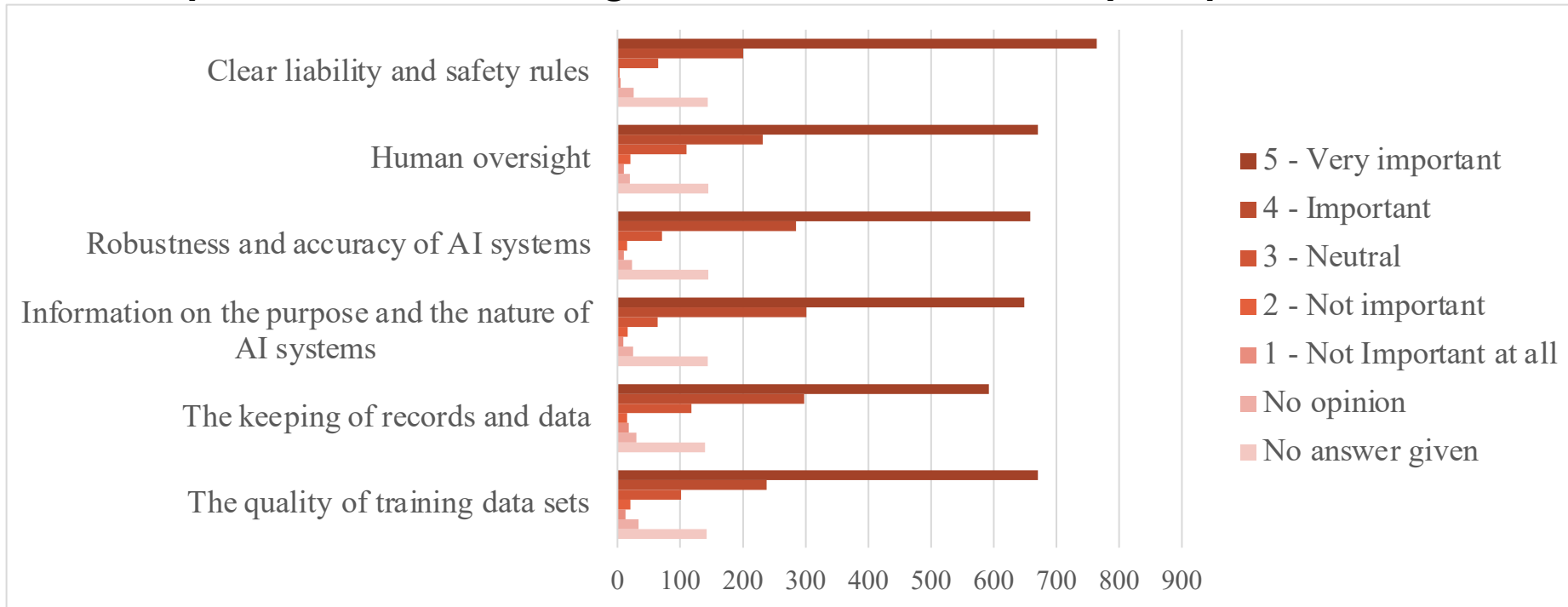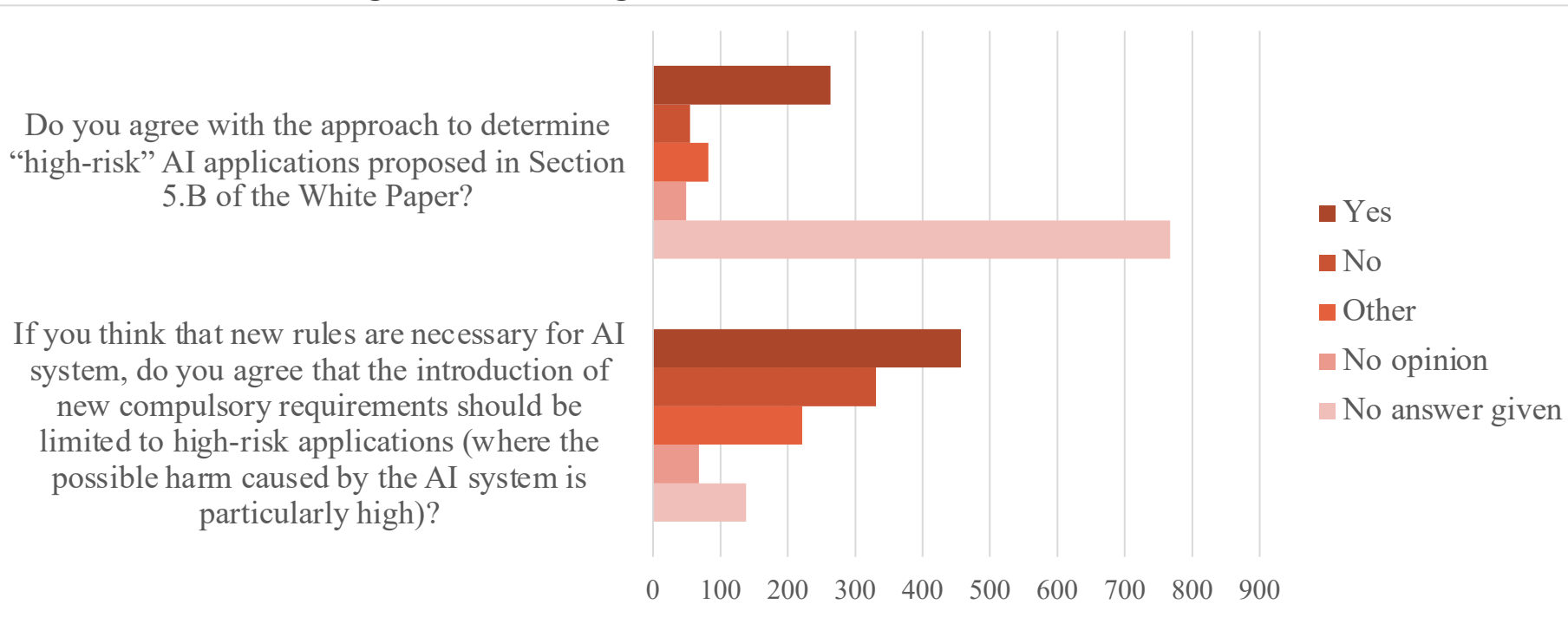
II. The Fact-Finding Procedure(s) of the EC

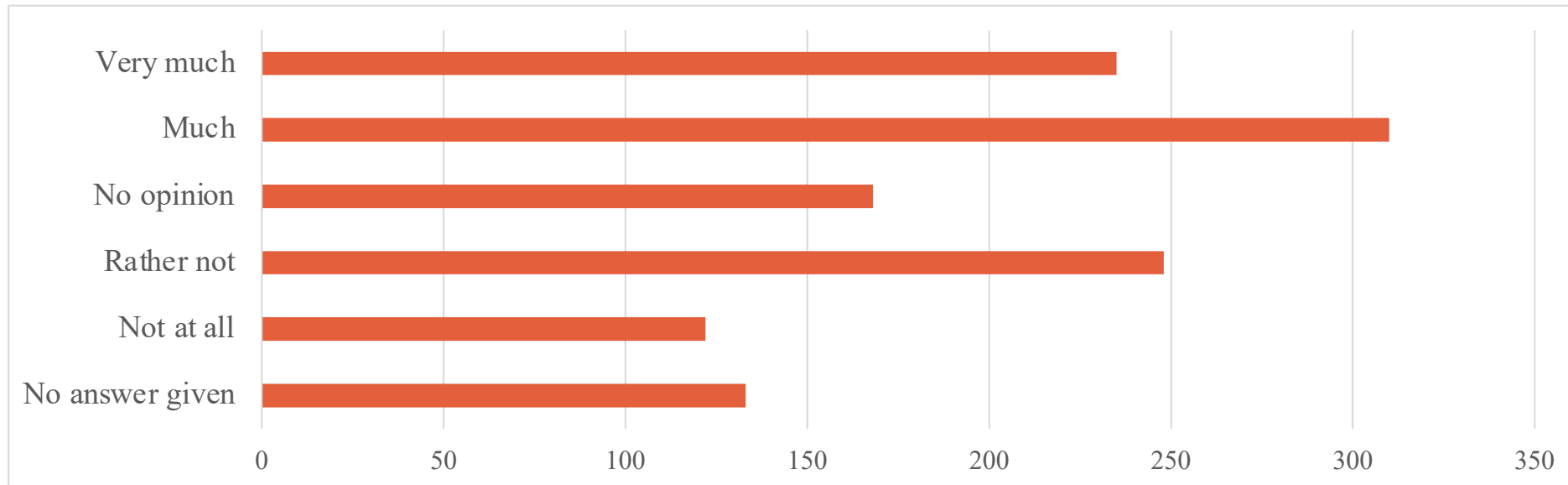**Opportunity of Regulation – Could the AI issues be addressed by existing law?**
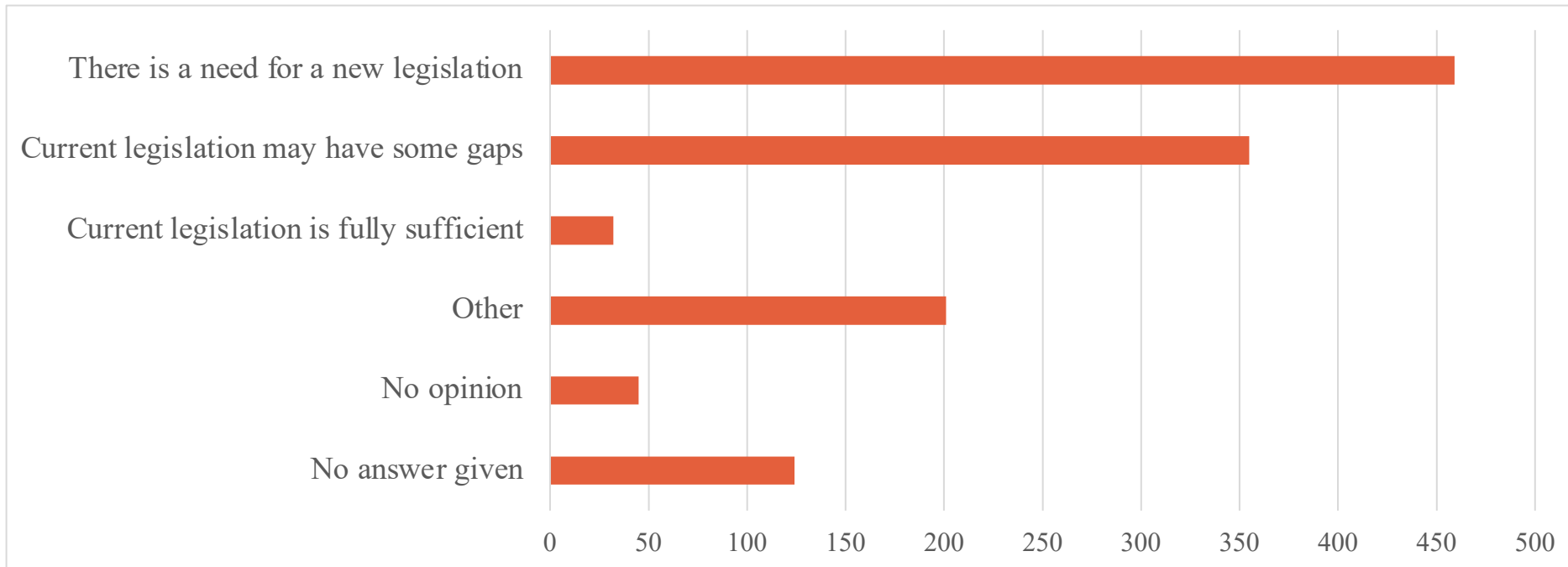
Opportunity of Regulation – High-Risk AI Systems

II. The Fact-Finding Procedure(s) of the EC

Opportunity of Regulation – Usefulness of voluntary labelling for non-high-risk AI systems
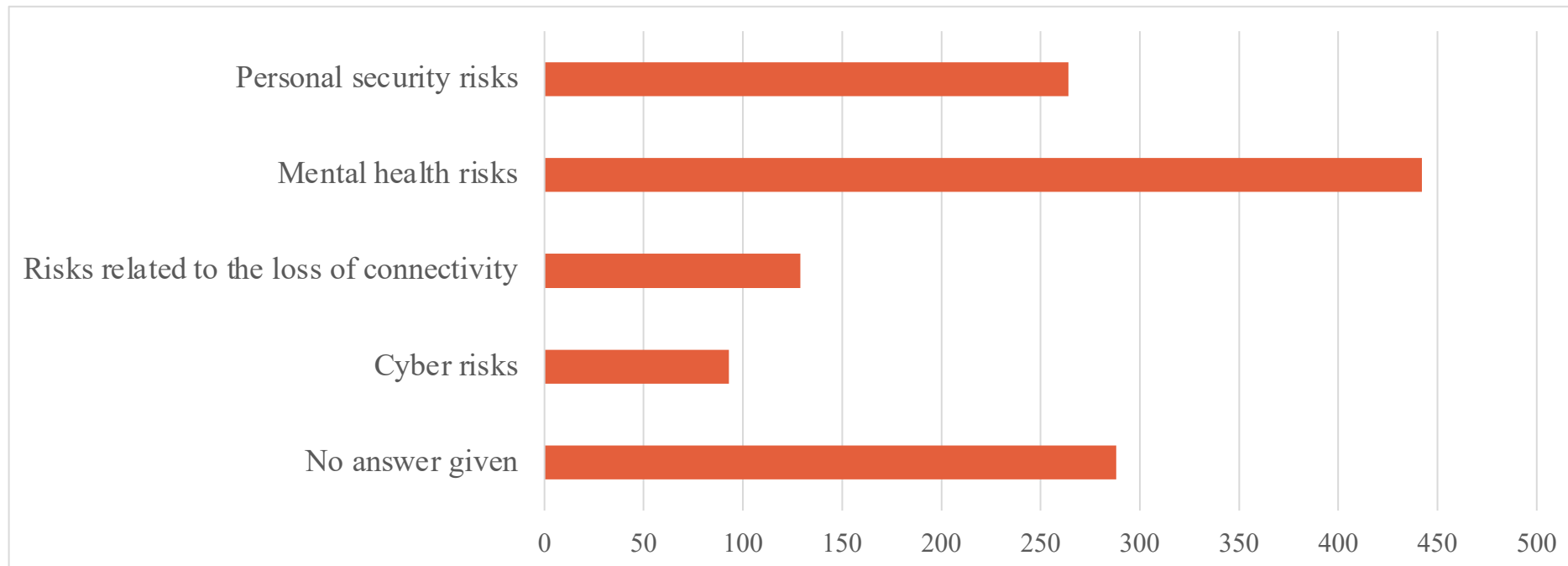
Opportunity of Regulation – Policy Options
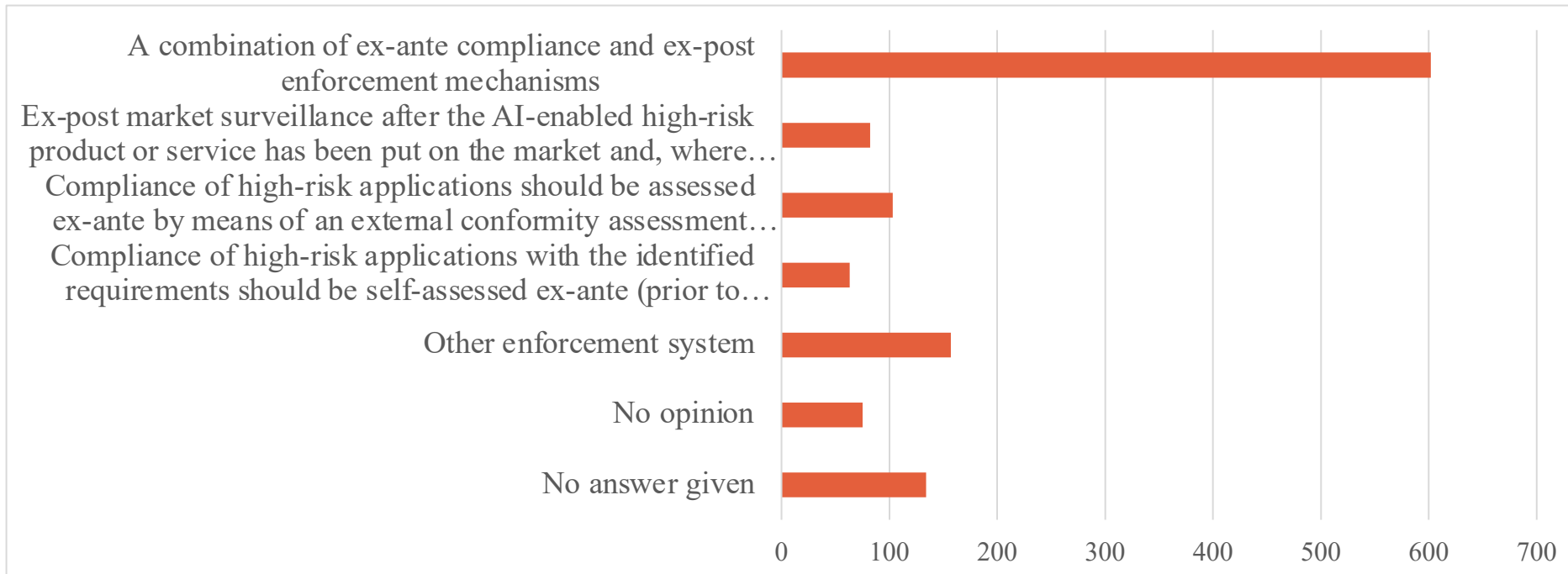
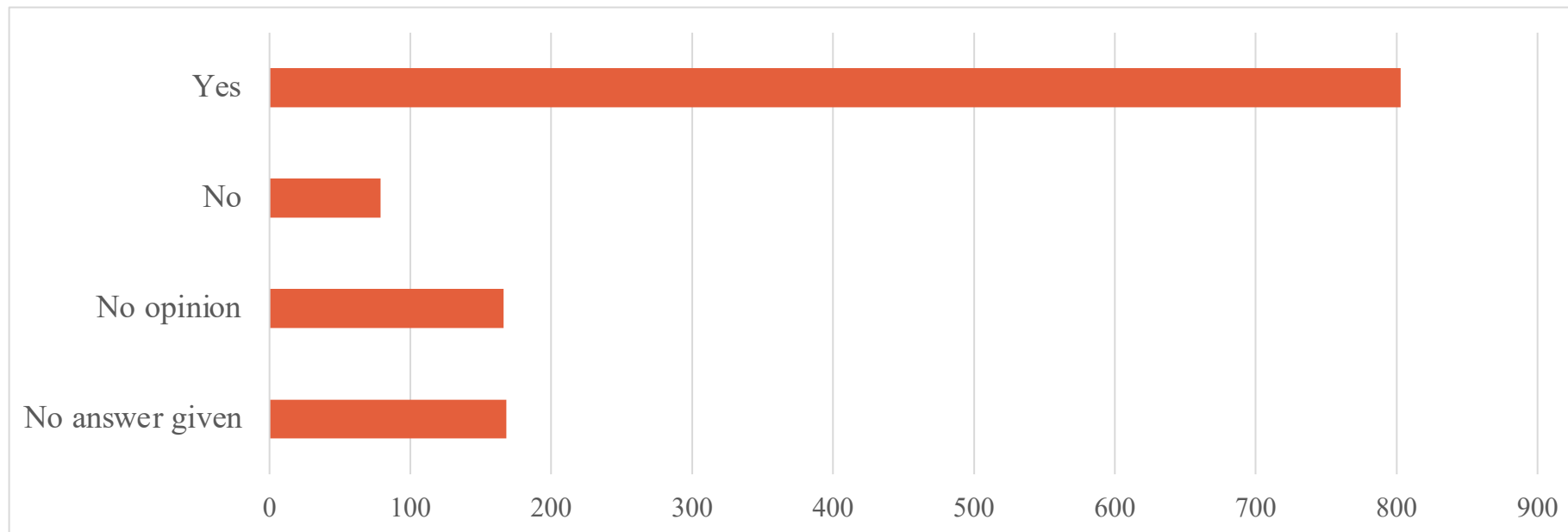# II. The Fact-Finding Procedure(s) of the EC

Updating Safety Framework

II. The Fact-Finding Procedure(s) of the EC

Updating Safety Framework – Updating Risk Assessment Procedure

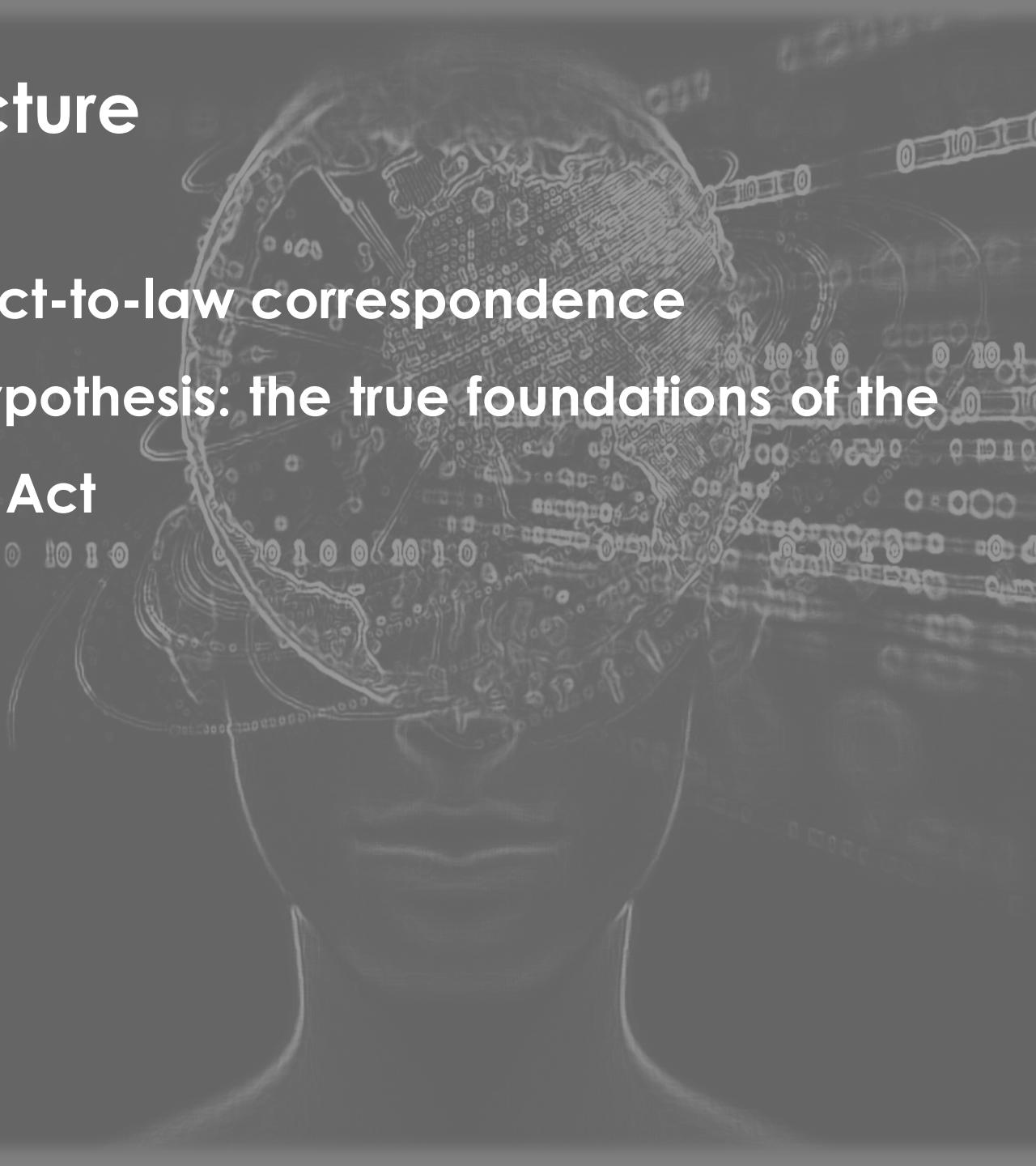# II. The Fact-Finding Procedure(s) of the EC

The Inception Impact Assessment Public Consultation

- 131 valid feedbacks

- Similar conclusions

    - Crucial to define what is "high-risk"

    - Mapping legislative gaps before regulating

    - One-size-does-not-fits-at-all

Structure

I. Fact-to-law correspondence

II. Hypothesis: the true foundations of the AI Act

III. The EC's interpretation of the facts gathered

II. The Fact-Finding Procedure(s) of the EC

Public consultations

- No agreement on the definition of what is high-risk

- No overwhelming majority willing to limit mandatory requirements to high-risk AI system

- Favouring sectoral regulation

- AI makes more difficult for persons having suffered harm to obtain compensation

The AI Act

- The definition of high-risk is maintained

- Mandatory requirements limited to high-risk AI systems

- Horizontal regulation

- No *ex post* mechanism

III. The EC's interpretation of the facts gathered

What are the 'true' foundations of the AI Act?

- Policy objectives

- Ecosystem of trust and ecosystem of excellence

  - Ecosystem of excellence : attracting talent and preserve the EU's technological leadership

  - Ecosystem of trust : the EU market will not flourish if EU citizens do not trust AI system

- Balancing a logic *à la* Dickens' *A Tale of Two Cities*? Reminiscence of the HLEG works

III. The EC's interpretation of the facts gathered

Why a public consultation if the AI Act is mostly policy-driven?

- "The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent" (art. 11 TEU)

- "Before proposing legislative acts, the Commission shall consult widely" (Protocol No. 2 on the application of the principles of subsidiarity and proportionality annexed to the Treaty)

- "Stakeholders should always be consulted when preparing a Commission legislative or policy initiative" (Better Regulation Guidelines)

III. The EC's interpretation of the facts gathered

The transparency of the AI Act

- The AI Act is transparent as it mentions the "evidence" on which it is based

- The AI Act is not transparent as the link between the evidence gathered and the draft proposal is missing

Evidence gathered did not support the AI Act

The AI Act seems therefore shaped more by policy considerations than evidence

Structure

IV. Critical analysis: the true 'foundations' of the AI Act

I. In the exercise of regulatory discretion

II. In the judicial review of the regulatory discretion

III. Intermediary conclusions

IV. Critical analysis (I): the true 'foundations' of the AI Act

What is the authority of evidence for the purpose of policy in EU law?

Evidence gathered (expertise, scientific evidence, consultations ….)

Evidence assessed in light of policy objectives ('*desired level of protection*')

Definition of adequate level of protection (in light of the principle of proportionality)

EU regulatory framework addressing risks

(E.g. Regulation n° 1829/2003, Directive 2001/18 (GMOs))

IV. Critical analysis (I): the true 'foundations' of the AI Act

Principles of exercise of legislative discretion

ECJ, 5 May 1998, *National Farmers' Union et al.*, case C-157/96, EU:C:1998:191, para. 63:

"**policy is to aim at a high level of protection** and is to be based in particular on the **principles of preventive action** (…) and that environmental protection requirements must be integrated into the **definition and implementation of other Community policies**."

COM(2000) 1 final, 2.2.2000: "what is an 'acceptable' level of risk for society is **an eminently political responsibility**. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers."

IV. Critical analysis (I): the true 'foundations' of the AI Act

Does evidence matter at all?

Scientific and political factors conducive to enforcing risk-regulation
(COM(2000) 1 final, 2.2.2000)

- **proportionality**
- **non-discrimination**
- **consistency with similar prior measures,**
- **cost/benefit balance**
- **new scientific data**
- **responsibility for producing scientific evidence necessary for a more comprehensive risk assessment**

Proportionality

"tailoring measures to the **chosen level of protection**. Risk can rarely be reduced to zero, but **incomplete risk assessments may greatly reduce the range of options open to risk managers**. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the **sole possible response to a given risk**."

IV. Critical analysis (I): the true 'foundations' of the AI Act

Does evidence matter at all?

CJEU, 12 November 1996, *UK v. Commission*, case C-84/94, EU:C:1996:431 (minimum requirements aimed at safeguarding a level of health and safety protection of workers)

UK (para. 58): 'neither the Commission's proposal nor the directive *provide any explanation as to why the desired level of protection* could not have been achieved by less restrictive measures, such as, for example, the use of risk assessments if working hours exceed particular norms'

ECJ (para. 59): 'the measures on the organization of working time which form the subject-matter of the directive (...) *contribute directly to the improvement of health and safety protection for workers* (...) and cannot therefore be regarded to the purpose of achieving the objective pursued'

IV. Critical analysis (I): the true 'foundations' of the AI Act

It follows that…

- Policy objectives contribute to **prioritizing risks** to be addressed

- Policy objectives contirbute to enhancing the **consistency** of new regulation with existing regulation

- Policy objectives **do not create a discharge of evidence BECAUSE…**

IV. Critical analysis (I): the true 'foundations' of the AI Act

…(stated) facts enable judicial review

Gen. Court, *Ertico – ITS Europe*, T-604/15, EU:T:2019:348, para. 166:
'the statement of reasons must be appropriate to the measure at issue and **must disclose in a clear and unequivocal fashion the reasoning followed by the institution** which adopted the measure in question, in such a way as **to enable the persons concerned to ascertain the reasons for the measure and to enable the EU courts to carry out their review**.'

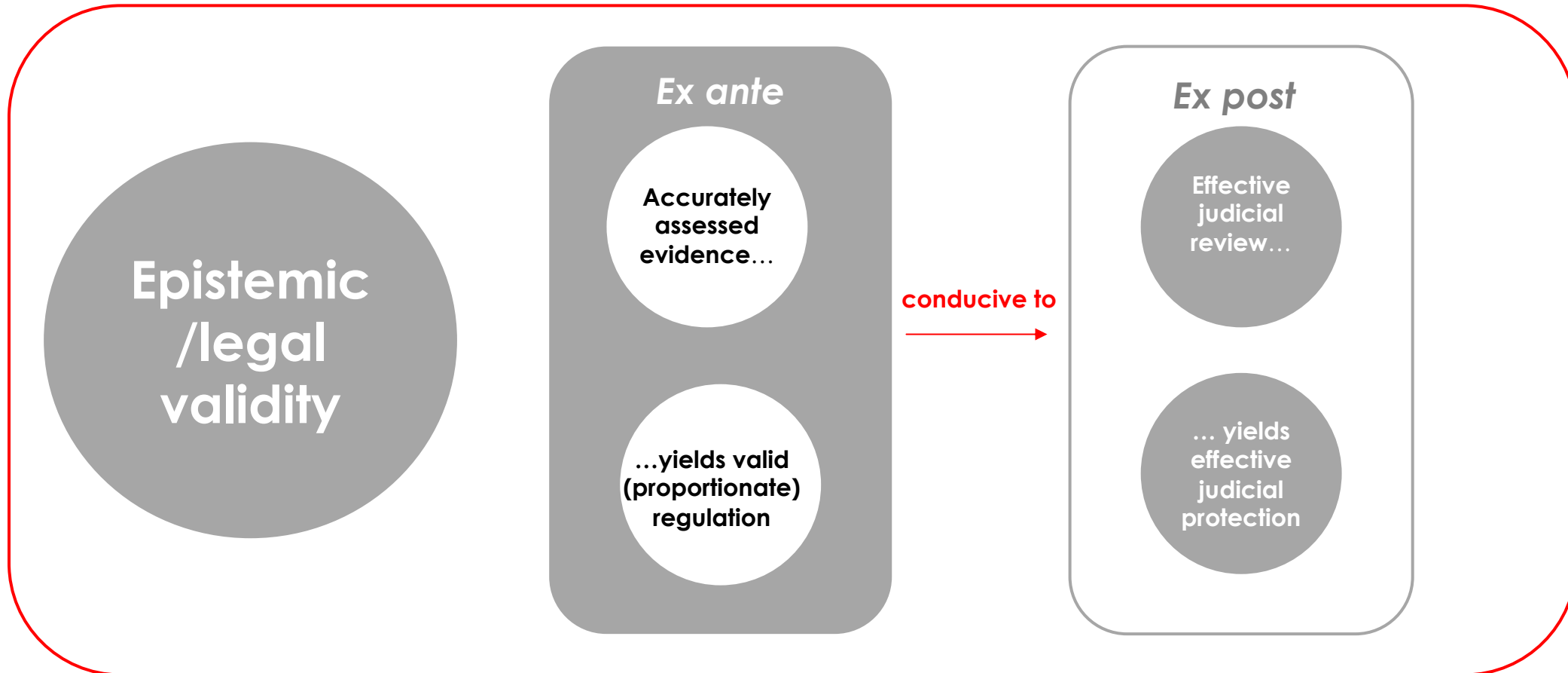# IV. Critical analysis (I): the true 'foundations' of the AI Act

...(stated) facts enable judicial review

Gen. Court, *Ertico – ITS Europe*, T-604/15, EU:T:2019:348, para. 166:

'(...) The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the **content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations**. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements must be assessed with regard not only to its wording but also to its context and all the legal rules governing the matter in question.'

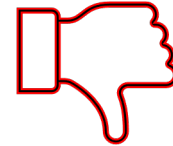# IV. Critical analysis (I): the true 'foundations' of the AI Act

IV. Critical analysis (I): the true 'foundations' of the AI Act

AI Act

Fact/law correspondence 👎

Fact/law discordance 👍

Consequences (and prospects)?

Structure

V. Conclusions and prospects

Is the AI Act in line with 'standard' EU risk regulation?

From a normative point of view:

- **Risk regulation: the regulation of elements and activities that pose risk to society (Black, 2008)**

  - "[Any] governmental interference with market or social processes to control potential adverse consequences" (Hood, Rothstein and Baldwin 2001)

  - Risk is the object of regulation and its justification (Black 2010)

V. Conclusions and prospects

From an institutional point of view:

- **Risk-based (approach to) regulation: how state agencies prioritise their actions (Black 2006, 2008)**

  - Agencies score the risk posed by the regulated and target the riskiest (Baldwin, Cave, Lodge 2012)

V. Conclusions and prospects

Bottom line

- **The AI Act is both risk regulation and risk-based (approach to) regulation**

  - the AI Act "puts in places a proportionate regulatory system centred on a well-defined risk-based regulatory approach" (Explanatory Memorandum)

- Same regulatory structure than the GDPR (Gellert 2020)

- But the GDPR is bottom-up; the AI Act, top-down (De Gregorio and Dunn, 2022)

V. Conclusions and prospects

Between risk- and rights-based approach to AI regulation

- **The foundation of risk regulation: balancing the ecosystems of trust and excellence**

- ***Contra,*** "this proposal seeks to ensure a high level of protection for (…) fundamental rights" (Explanatory Memorandum)

- **Would a rights-based approach have been preferable?**
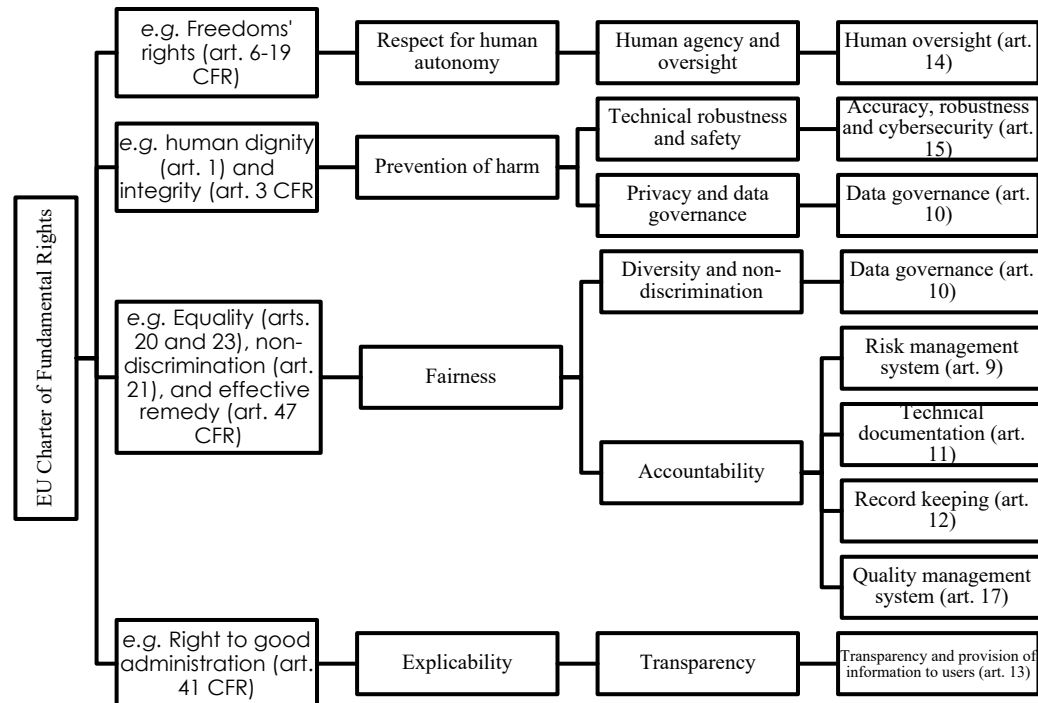
V. Conclusions and prospects

Between risk- and rights-based approach to AI regulation

- **A rights-based approach is rights-conferring or fundamental rights-epitomising (Linksey 2015)**

    - Rights-conferring: Improves the capacity of duty-bearer to meet their obligation and of rights holder to claim their rights (He, 2016)

    - "gives expression to" fundamental rights: holistically provides a set of legal standards that serve as the basis of regulation (Eide 2001)

V. Conclusions and prospects

The AI Act is definitely giving expression to fundamental rights

V. Conclusions and prospects

Fundamental rights-based approach to AI regulation: compatible with "human-centric AI"

- "The values on which our societies are based need to be fully integrated in the way AI develops" (COM(2019) 168 Final)

- AI systems "should empower citizens and respect their fundamental rights" (Ibid).

AI Act north star: protecting natural person from "high risk of harm to the health and safety *or the fundamental rights of person*" (Recital 32 AI Act)

V. Conclusions and prospects

Achieving the fundamental-rights objective through horizontal regulation requiring standardisation and certification?

The AI Act is a fundamental-rights based approach that does not grant rights to EU citizens

Hypothesis: product safety through standardisation and certification will be enough to guarantee no fundamental rights infringement

Upshot? The AI Act is a flawed or incomplete rights-based approach