

COMMENTS ON THE PROPOSAL FOR THE ARTIFICIAL INTELLIGENCE ACT (EC)¹

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General overview:

The proposed AI Act is an impressive work and provides a great start for the legislative process. Highly welcome things are the risk-based and data-focusing approaches, level of specifications for the core requirements (transparency, human-oversight, data governance, risk management, record-keeping, accuracy, robustness, and security), the introduction of different roles for subjects involved in the AI life cycle with their relevant rights and obligations. The great achievement of the AI Act is the implementation of the proposed requirements into the existing conformity assessment procedures (or when there are no applicable existing procedures – the suggestion of similar ones).

While generally supporting the AI Act, below I suggest six topics that invite the legislator for additional considerations and hopefully, might help making the AI Act even better.

Key takeaways:

1. THE ROLE OF THE SUBJECTS WHO ARE AFFECTED BY THE DECISIONS MADE WITH THE USE OF AI SYSTEMS SHALL BE DEFINED

Reasoning: it is greatly appreciated that the AI Act defines the roles of different subjects engaged in the development, deployment and use of high-risk AI systems³ (provider, user, operator, importer, distributor, supervisory authorities). This way the proposed regulatory approach complements the ones that already exist in the specific sectors of AI's use (such as the medical devices framework),⁴ increases accountability of the relevant actors and generally ensures trust in AI systems at all the stages of its life cycle.

However, the role of one subject – the one who is affected by the decisions made with the use of AI systems – is missing. Although sometimes this kind of subject can overlap with a user of AI system, very often it is not the case. For example, in the healthcare context⁵ the one who actually uses AI systems is a medical professional, while the one who is affected by the decisions of AI systems is a patient. The rights and obligations of healthcare professionals (as users) in the context of AI are defined in the AI Act – they are entitled to receive instructions to use an AI system, information about its purposes, capabilities, and limitations.⁶ The AI Act also establishes their relevant obligations – to use an AI system in accordance with the given instructions and monitor

¹ European Commission, *Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts* (COM (2021) 206 final), April 21, 2021) (EC Proposal for the AI Act).

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The position expressed here is the individual position of Anastasiya Kiseleva and does not present the official position of affiliated organizations.

³ If not stated otherwise, AI systems here refer to high-risk AI systems (which are the main regulatory scope of the EC Proposal for the AI Act).

⁴ In this paper, the Medical Devices Framework includes the Medical Devices Regulation (EU) 2017/745 (MDR) and the In-vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

⁵ In this area in the majority of cases, the use of AI applications will be considered as high-risk and thus will be subject to the requirements established in the proposed AI Act.

⁶ EC Proposal for the AI Act, art. 13 (2) and art. 13 (3).

its functioning.⁷ There is nothing similar to this in the AI Act in relation to patients. **But they need to be informed too - to make their own decisions about health and to enjoy their dignity and self-determination. Also, their relevant obligations might be an important element of AI safety and quality.**

Although the requirements of informed medical consent and transparency obligations under the GDPR⁸ partly cover this issue, a technology-related and harmonized approach is needed. The rules on informed medical consent are not tailored to AI features (opaqueness, complexity, autonomy, self-learning). It might lead to negative effects both for patients (in receiving accessible and meaningful information) and for healthcare professionals (in deciding on their own what kind of information and how to provide to patients). In addition, the rules on informed medical consent are defined by the national EU legislations and the lack of the harmonized approach (that sets at least minimum standards) can hinder the development of the EU-wide relevant initiatives such as the proposed AI Act and creation of the common EU data spaces.⁹

Another aspect is **the obligations of subjects affected by the decisions made with the use of AI.** In the age of the information society, correcting and update of the information about a specific person¹⁰ might be seen not only as a right, but also as an obligation. Taking the healthcare example, it is a patient who observes the final outcomes of the AI system's use. In many cases, it is made in collaboration with doctors, but sometimes the outcome is visible only outside the environment of medical organizations and patients do not always report about the experienced side effects or benefits. This affects not only the non-reporting patient but also the other population (because in this case, AI does not receive the proper information to learn from it).¹¹

The AI Act requires AI users 'to ensure that input data is relevant in view of the intended purpose of the high-risk AI system (to the extent the user exercises control over the input data).'¹² Considering this, the relevant obligation for subjects whose data is used in AI system to provide updates of the information to users seems to be justifiable. It would not only increase the safety and quality of AI applications but also support responsible and sustainable data use.¹³ In addition, it would enable AI users to properly comply with their obligations – on the basis of the information provided by beneficiaries of AI's use.

In a similar way all other requirements for high-risk AI systems and built in the already existing current conformity assessment procedures, the minimum requirements in relation to the role of subjects affected by the decisions made with the use of AI, can complement already existing rules (such the GDPR and domain-specific rights and obligations).

⁷ EC Proposal for the AI Act, art. 29.

⁸ The transparency requirements under the GDPR include, for example, informed consent when applicable and obligations to provide information to data subjects in articles 12-15. But the scopes of the relevant legislations are different and thus influence the types, form, and amount of information provided to beneficiaries of decisions made with the use of AI systems. While the aim of transparency obligations under the GDPR is to protect the interests of data subjects in relation to the use of their personal data, their rights as the subjects affected by decisions made with the use of AI shall be concentrated around the decision and its consequences (like safety and quality of the decisions, respect for fundamental rights, risks and benefits of the use AI). For example, respect for their right to self-determination (referring generally to AI-assisted decisions) is broader than informational self-determination (which is relevant to data protection). Although the specific requirements might be tailored in accordance with the narrow sector of AI use, some broader guidance on the rights of subjects affected by decisions made with the use of AI is needed.

⁹ European Commission, Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'A European Strategy for Data' COM (2020) 66 final (EU Strategy for Data).

¹⁰ Which is guaranteed by the GDPR.

¹¹ Of course, this obligation might be seen as the limitation of informational self-determination, but neither privacy nor data protection are the absolute rights, and they shall be balanced with other important interest (defined by law).

¹² EC Proposal for the AI Act, art. 29 (3).

¹³ See more about sustainable data usage in Linnet Taylor and Nadezhda Purtova, 'What Is Responsible and Sustainable Data Science?' (2019) 1 Big Data & Society July–December 6, 1. How the AI Act is related to data initiatives such as the EU Data Strategy see in Kiseleva, A. & de Hert, P. 'Creating a European Health Data Space: Obstacles in Four Key Legal Areas', European Pharmaceutical Law Review, Volume 5, Issue 1 (2021), pp. 21 – 36.

2. THE CONCEPT OF AI USER SHALL BE CLARIFIED (ESPECIALLY IN MULTI-STAKEHOLDERS ENVIRONMENTS)

Reasoning: in environments with several actors, it is not clear who shall be deemed as a user of an AI system.¹⁴ For example, in the healthcare context, at least two types of actors are involved in the usage of AI systems: healthcare organizations and healthcare professionals (physicians or other specialists (such as radiologists)).¹⁵ But the AI Act does not explain how the rights and responsibilities in relation to the usage of AI systems shall be divided between them.

‘Since the definition of AI user¹⁶ includes both natural persons and legal entities, formally it can be both. Healthcare organization as a legal entity has the authority to apply the specific AI system within its structure. Moreover, a healthcare organization is the entity making decision to purchase an AI system for its physicians and start using it. At the same time, physicians provide the input data to the AI system and interpret its outcome, thus they are the subjects who make actions with AI systems. The definition of the ‘user’ requires authority in AI’s usage, but in the healthcare context, this authority is shared between healthcare organizations and physicians. Thus, it is not really clear who shall be deemed as a user of AI system in a medical context (or any other multi-stakeholders environment).’¹⁷

‘The other rules of the proposed AI Act do not add clarity. On the one side, the proposed act requires AI to be sufficiently transparent to its users meaning that the outcomes of an AI system shall be interpretable to them. Supposedly, interpretation is the activity of the human brain and in healthcare, it is deemed to be done by physicians. It means that it is not the activity carried out by the organization. On the other side, the AI Act states that the user of an AI system has its own discretion in organizing its resources and activities in the implementation of human oversight measures specified by the provider. Resources and activities allocations are usually attributed to organizations, in a medical context – to healthcare organizations. Physicians are not required to allocate resources in the context of AI’s use. It seems that the concept of the ‘user’ suggested in the proposed regulation has a dual character and applies both to organizations applying AI systems and natural persons doing so inside the organization. In this case, the roles and obligations of these subjects have to be clearly distinguished. Otherwise, their proper accountability can be difficult to ensure.’¹⁸

Generally, the concept of AI user shall be defined with more clarity. Article 52 that is devoted to transparency obligations for certain AI systems introduces another category of subjects involved in an AI life cycle – natural persons that interact with AI systems. The article establishes their right – ‘to be informed that they are interacting with an AI system unless this is obvious from the circumstances and the context of use.’¹⁹ It is not clear how this type of subject differs from AI user (it probably does, but the difference shall be explained) and in case if the category of AI beneficiary is introduced in the AI Act in the future, how these categories of subjects are differentiated shall be explained too. **In other words, the system of roles for three subjects – AI user, AI beneficiary, and a natural person interacting with AI – shall be introduced in the AI Act.**

¹⁴ A. Kiseleva, ‘AI as a Medical Device: Between the Medical Devices Framework and the General AI Regulation’, accepted for the conference and relevant publication at the [Time to Re-shape the Digital Society](#) (International Conference celebrating the 40th (+1) Anniversary of CRIDS to be held on 18th and 19th of November 2021, Namur, Belgium).

¹⁵ *ibid.*

¹⁶ Article 2 (4) of the AI Act: ‘user’ means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of personal non-professional activity.

¹⁷ Kiseleva (n 14).

¹⁸ *ibid.*

¹⁹ EC Proposal for the AI Act, art. 52 (1).

3. 'TRANSPARENCY' TERMINOLOGY SHALL BE USED CONSISTENTLY

Reasoning: 'there are two Articles of the AI Act devoted to transparency: the transparency obligation applicable to providers of high-risk AI systems (Article 13) and the transparency obligation applicable to providers of AI systems that interact with natural persons (Article 52). The AI Act does not explain how these two transparency rules relate to each other.'²⁰

'These rules have similar names but imply different concepts. For high-risk AI systems transparency refers to interpretability, for interactive AI systems transparency refers to communication about AI's presence.'²¹ **It might lead to a situation when we would label as transparency one thing (interpretability) for one type of AI systems (high-risk) and another one (communication) – for the other type (interactive).** The lack of legal certainty and the inconsistency in legal compliance are the possible consequences of such a situation.'²² To solve this issue, I suggest introducing the hierarchy of transparency-related concepts where transparency shall be viewed as the broadest one (see below in section 5).

4. 'TRANSPARENCY-INTERPRETABILITY' REQUIREMENT IN ARTICLE 13 SHALL BE CLARIFIED

Reasoning: the main element of the 'transparency' obligation imposed to the providers of high-risk AI systems (which will be applied to a large number of applications in important sectors such as healthcare)²³ is the *interpretability of AI's system output by its users*. However, the AI Act does not explain the concept of interpretability and its correlation with explainability. 'Of course, a very strict definition is not welcome because it would decrease the flexibility of AI providers in defining the measures that are appropriate for the type of technology and the context of use. However, some guidance on interpretability is needed.'²⁴

All the policy documents that preceded the AI Act²⁵ focused on the requirement of explainability instead of interpretability.²⁶ 'In the AI Act, the explainability element disappeared.'²⁷ 'While one concept is included as the obligation for the providers of AI systems (interpretability) and the other one is not (explainability), it is necessary to understand the difference between them, which is not the easiest task.'²⁸

'Scholars and policymakers from different domains have developed their distinct views on interpretability and its correlation with explainability.'²⁹ 'Some people working with or on AI use the terms interpretability and explainability interchangeably,³⁰ others distinguish them.'³¹ 'For example, some define explainability as 'that you can explain what happens in your model from

²⁰ A. Kiseleva, 'MAKING AI'S TRANSPARENCY TRANSPARENT: notes on the EU Proposal for the AI Act' (European Law Blog, July 2021), <https://europeanlawblog.eu/2021/07/29/making-ais-transparency-transparent-notes-on-the-eu-proposal-for-the-ai-act/> (accessed July 29, 2021).

²¹ The rule from Article 52 (1) is also applicable for emotion recognition (Article 52 (2)), biometric categorization (Article 52 (3)), and 'deep fake' systems (Article 52 (4)).

²² Kiseleva (n 20).

²³ *ibid.*

²⁴ *ibid.*

²⁵ The Ethics Guidelines for Trustworthy AI issued by the High-Level Expert Group on AI as of December 2018; the White Paper on AI issued by the European Commission in February 2020 and the European Parliament's Framework of ethical aspects of AI, robotics and related technologies as of October 2020.

²⁶ Kiseleva (n 20).

²⁷ *ibid.*

²⁸ *ibid.*

²⁹ *ibid.*

³⁰ *ibid* referring to: J. Johnson, 'Interpretability vs Explainability: The Black Box of Machine Learning' (BMC Machine Learning & Big Data Blog, July 2020) < <https://www.bmc.com/blogs/machine-learning-interpretability-vs-explainability/> > accessed August 02, 2021.

³¹ Kiseleva (n 20) referring to C. Molnar, *Interpretable Machine Learning. A Guide for Making Black Box Models Explainable.* < <https://christophm.github.io/interpretable-ml-book/> > accessed August 02, 2021.

input to output.³² At the same time, other scholars define interpretability in the same way: ‘when one can clearly trace the path that your input data takes when it goes through the AI model.’³³ The specified definitions might require opening the black-boxes of the most sophisticated algorithms which is not always possible. That is why it is crucial to understand whether the specified or similar definitions (that might lead to the obligation to open black boxes) are intended by the legislator to be applicable to one of the concepts and if so, to which one. **This would define whether the opaquest AI models are eligible for application in high-risk AI systems because if opening the black box is needed for interpretability, providers of such AI systems would not be able to comply with this obligation.**

How interpretability is distinguished (or not) from the explainability requirement of automated decision-making established in the GDPR³⁴ is another relevant question. The issues with alignment of the AI Act with the GDPR has been already mentioned by scholars and policymakers,³⁵ and **correlation between interpretability-transparency requirement in the AI Act and explainability³⁶ in the GDPR** is the example of such non-alignment.

Clarification of the transparency-interpretability requirement is needed not only for defining models that are eligible to be used in high-risk AI systems and for correlating it with explainability, but also for **guiding their providers in compliance**. It is much appreciated that the AI Act gives providers discretion in determining their obligations: ‘*an appropriate type and degree of transparency 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 the Title III.*’³⁷ This way the legislator ensures the risk-based approach established in the AI Act and takes into consideration the technical limitations of AI interpretability that can be an issue for AI providers.

The reference to other obligations of AI providers and users is important for clarifying the interpretability requirement. Obligations of AI users refer to the use of AI systems in accordance with instructions and quality monitoring. The possibility of quality monitoring by users can be deemed as good guidance for interpretability - a user shall be able to interpret AI’s system outcome to such degree that is necessary to see the deviations from expected/normal outcome. Another clarification relates to the human-oversight requirement – it is needed, inter alia, to enable users to interpret the outcome of AI system. Thus, human oversight measures can be deemed as part of interpretability measures.

While these correlations with other requirements are important to direct AI providers in their understanding of the interpretability requirement, more is needed. Considering the variety of interpretability definitions by scholars from different areas, it can be understood very differently. **At least the direction of what shall be deemed as an interpretable outcome of AI system or what is the scale of AI interpretability would be of much help to AI providers.** Otherwise, they are left alone with the most challenging element of AI systems where the highest extent of the compliance with the obligation is not always possible (opening black-box) and the lesser extents

³² Kiseleva (n 20) referring to E. Onose, ‘Explainability and Auditability in ML: Definitions, Techniques, and Tools’ (Neptune Blog, July 2021) < <https://neptune.ai/blog/explainability-auditability-ml-definitions-techniques-tools> > accessed August 02, 2021.

³³ Kiseleva (n 20) referring to B. Dickson, ‘AI models need to be ‘interpretable’ rather than just ‘explainable’ (Neural Today, August 2020) < <https://thenextweb.com/news/ai-models-need-to-be-interpretable-rather-than-just-explainable> > accessed August 02, 2021.

³⁴ GDPR, recital 71.

³⁵ J. Bergholm, ‘The GDPR and the Artificial Intelligence Regulation – it takes two to tango?’ (CiTiP Blog, July 2021) < <https://www.law.kuleuven.be/citip/blog/the-gdpr-and-the-artificial-intelligence-regulation-it-takes-two-to-tango/> > accessed August 02, 2021 and EDPB-EDPS Joint Opinion 5/2021 on the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) as of June 18, 2021 < https://edpb.europa.eu/system/files/2021-06/edpb-edps_joint_opinion_ai_regulation_en.pdf > accessed August 02, 2021.

³⁶ Together with the provision of the meaningful information, recital 71 of the GDPR.

³⁷ EC Proposal for the AI Act, art. 13 (1).

are risky to providers because they can't be sure if they fulfilled the obligation since the legislator did not clarify what is deemed as a proper fulfilment. One of the ways to clarify interpretability is to define what kind of choices/decisions/actions a user or beneficiary of AI systems shall be able to make after interpretations (like assessing the risks and benefits, trust or doubt about the outcome of AI system).

5. THE HIERARCHY BETWEEN TRANSPARENCY AND THE RELATED CONCEPTS SHALL BE DEFINED

Reasoning: the AI Act uses several concepts that are related to transparency: **communication, interpretability, records-keeping and communication, information provision**. The correlation between these concepts and their hierarchy with transparency shall be specified in the AI Act.

Besides the complexities with the **interpretability** requirement itself, another issue with this concept is its correlation with transparency. 'It is not clear if transparency fully overlaps with interpretability, or whether it is a wider category. Article 13 says that transparency is needed for interpretability, but at the same time implies that there are different types and degrees of transparency. However, the AI Act does not explicitly provide examples of types of transparency besides interpretability. It makes it unclear for providers of AI systems whether ensuring interpretability is enough to comply with the transparency requirement. It is also obscure for them what kind of transparency measures besides interpretability are available.'³⁸

Another concept that shall be correspondent to transparency is **information provision**. 'Article 13 of the proposed AI Act has two main types of obligations – transparency and the provision of information to AI users.'³⁹ But again, the correlation between the two obligations - information provision and transparency - is not clear. The text of the legal provision implies that the concepts are very related but still separate: the Article's title uses separate names and different parts of the Article are devoted to two concepts (paragraph 1 – for transparency; paragraphs 2 and 3 – for information provision). However, the provision of information is traditionally one of the main elements of transparency. The EU General Data Protection Regulation (GDPR) is one of the examples of such correlation. Also, all the AI policy documents preceding the AI Act⁴⁰ included the provision of information into the general transparency obligation. To avoid a lack of clarity in applying the two concepts, I suggest that the AI Act should continue the line taken in the previous AI policy documents and consider information provision as part of the general transparency obligation.'⁴¹

'The same situation applies to the correlation between transparency and the obligations of **documentation and record-keeping**. In this case, these obligations are even more explicitly divided because they are stated in different Articles of the proposed AI Act: Article 11 for the technical documentation, Article 12 for record-keeping, and Article 13 for transparency and information provision.'⁴² The inclusion of these obligations and the level of the specification are highly appreciated. But again, they should be correlated with transparency. 'In the previous AI policy documents, either one of these two obligations or both of them were included in transparency obligations.'⁴³ 'Transparency is needed for the *ex-ante* and *ex-post* control mechanisms that ensure that AI technologies are safe, accurate, and respect fundamental rights. Keeping the records and documentation of all the steps taken during AI's development and use is a good way to organize

³⁸ Kiseleva (n 20).

³⁹ *ibid.*

⁴⁰ *supra* note 21.

⁴¹ Kiseleva (n 20).

⁴² Kiseleva (n 20).

⁴³ *ibid.*

such control and thus to ensure transparency. Due to this, the AI Act should consider the relevance between transparency, documentation, and record-keeping.’⁴⁴

A good solution to correlating all the mentioned concepts between each other would be **establishing their hierarchy where transparency is suggested to be the broadest category**.⁴⁵ ‘In a legal sense, it can be seen as the **principle protected under the AI Act**. This way, the other relevant elements analysed here can be seen as the measures to ensure the principle. This hierarchy would follow the approach already existing in the legislation. For example, the GDPR establishes the transparency principle (Article 5) and the obligation to provide the information as the measure to ensure the principle (such as Articles 12-15). In addition, it would follow the approach taken in the previous AI policy documents that also consider transparency as the wider category.’⁴⁶

6. CLARIFICATION ON THE CONCEPT OF ‘BIAS’ IS NEEDED

Reasoning: the AI Act requires AI providers to use data governance practices that allow examining an AI system in view of possible biases. Preventing of bias is a very important element of AI’s ethical use. Especially appreciated that the legislator connected it with data governance because it is one of the most efficient ways to control and check AI.⁴⁷ However, **there is no common understanding of ‘bias’ and the lack of its definition (or of at least of the description of its nature) makes it difficult for AI providers to understand how to comply with the requirement.**

Different views on the nature of biases exist. One way to look at bias is to consider it **as a social construct**. The main element that distinguishes bias in a social sense is the existence of opinions or perceptions by a certain group of people concerning others. In this case, discrimination and stigmatization are the concepts that are relevant to bias in a social sense. The other perspective to look at bias is to perceive it in a **statistical sense** - as a deviation from the output expected from the algorithmic model and the input data.⁴⁸ This point of view is especially important for AI activities because statistics is part of data science and is correlated with machine learning.⁴⁹ But it is important to understand that bias is just a precondition of negative outcomes of AI systems. How bias is understood would define its main consequences and thus what kind of measures shall be applied to prevent them.

If bias is seen in a social sense - as a possible source of discrimination - then the datasets of AI systems shall be checked on discriminatory elements (which are limited to those listed in the EU or national legislations). If bias is viewed in a statistical sense - as a precondition for the inaccuracy of decisions made with the use of AI - then datasets and algorithms shall be checked on the representativeness, accuracy, completeness, relevance to the purposes of AI systems. Of course, these consequences often overlap – when AI makes inaccurate decisions about a specific group of people, in many cases it would lead to discrimination of this group (if the characteristic in question is protected). And vice versa – in the majority of cases (except for intention discrimination) if one group is discriminated it means that the model is trained on non-representative or on non-relevant data. **But this shall be clarified in the AI Act – if bias is viewed from the social perspective,**

⁴⁴ *ibid.*

⁴⁵ *ibid.*

⁴⁶ *ibid.*

⁴⁷ Opaque and autonomous algorithms are more challenging for human control.

⁴⁸ Will Goodrum, ‘Statistical & Cognitive Biases in Data Science: What is Bias?’ (Elder Research, Data Science, AI, Machine Learning, October 2017) < <https://www.elderresearch.com/blog/statistical-cognitive-biases-in-data-science-what-is-bias/>> accessed July 26, 2021.

⁴⁹ Course ‘Elements of AI’, section II ‘Related fields’, University of Helsinki and Reaktor. <<https://course.elementsofai.com/1/2>> accessed July 23, 2021.

from the statistical, or from both.⁵⁰ Otherwise, AI providers would not understand what the appropriate way is to prevent or minimize bias.

More information:

These comments are based on the author's post '[MAKING AI'S TRANSPARENCY TRANSPARENT: notes on the EU Proposal for the AI Act](#)' published on the [European Law Blog](#), article 'AI as a Medical Device: Between the Medical Devices Framework and the General AI Regulation' accepted for the conference and for the relevant publication '[Time to Re-shape the Digital Society](#)',⁵¹ and the article in progress on legal implications of biases in AI's clinical genetics. It is recommended to read the published article for more detailed explanations of the main points provided herein.

⁵⁰ Actually, the AI Act in its recital 44 makes the correlation between statistical and societal views: 'High data quality is essential for the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become the source of discrimination prohibited by Union law.'

⁵¹ International Conference celebrating the 40th (+1) Anniversary of CRIDS to be held on 18th and 19th of November 2021, Namur, Belgium