歐盟人工智慧法規草案導讀會

- 主辦單位：經濟部標準檢驗局
- 時　　間：2021 年 12 月 28 日(星期二)上午 10 時
- 地　　點：線上導讀會(會議連結另行發送)

依據世界貿易組織技術性貿易障礙(WTO/TBT)協定規定，WTO 會員於擬訂、採行或適用技術性法規/符合性評鑑程序時，應提出通知文件。經濟部標準檢驗局為我國 WTO/TBT 查詢單位，協助業者瞭解各項技術性法規並採取相關因應作法。

歐盟於 2021 年 11 月 11 日提出人工智慧法規草案通知文件(如附件)，基於該法規草案適用領域廣泛，將對人工智慧系統之開發及市場進入等進行監管，估計有許多軟體或產品受到影響，因此本導讀會由法律專家說明法規草案內容是非常寶貴的機會，歡迎各主管機關及出口人工智慧相關產品之企業踴躍報名參加。另由於該法規草案的評論期到 2022 年 2 月 9 日截止，各參與單位如有評論意見可於 2022 年 1 月 21 日前向標檢局提出，以彙整各界意見向歐盟進一步瞭解法規資訊。

議　程	
講座：財團法人資訊工業策進會科技法律研究所 蔡宜臻 法律研究員	
09:30-10:00	線上報到
10:00-10:10	開幕致詞
10:10-11:00	歐盟人工智慧法規草案導讀
11:00-11:10	中場休息
11:10-12:00	歐盟人工智慧法規草案導讀 Q & A

----------報 名 方 式----------

聯絡人：游小姐，02-23434560，tbtenq@bsmi.gov.tw

本導讀會請於 2021 年 12 月 24 日前完成線上報名

報名網址及條碼：https://docs.google.com/forms/d/e/1FAIpQLSd9sXhGF0PHIe7u2qoZxzUDrO845mMt1d3CObfR7IVUAJB4Q/viewform?usp=sf_link

WORLD TRADE ORGANIZATION

G/TBT/N/EU/850

11 November 2021

(21-8527)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** EUROPEAN UNION **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** European Commission **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** European Commission, EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Software, applications of information technology (for both: included when embedded in hardware); AI as a component of products subjects to product safety legislation (any code); Software (ICS 35.080), Applications of information technology (ICS 35.240)
5.	**Title, number of pages and language(s) of the notified document:** 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) (108 page(s), in English; 17 page(s), in English)
6.	**Description of content:** The draft Regulation defines an 'artificial intelligence system' (AI system) as meaning software that is developed with one or more of the techniques and approaches listed in Annex I 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. The draft Regulation introduces provisions that will regulate the development, marketing and placing on the European Union market of AI systems. These rules are limited to the minimum necessary requirements to protect the safety and fundamental rights of persons considering the risks and challenges posed by AI systems, without unduly constraining or hindering technological development or otherwise disproportionately increasing the cost of placing AI solutions on the market. The draft rules differ according to the degree of risk AI systems are considered to present. AI systems considered a clear threat to the safety, livelihoods and rights of people will be banned in the European Union. This includes AI systems or applications that manipulate human behaviour to circumvent certain users' free will (e.g. toys using voice assistance encouraging dangerous behaviour of minors) and systems that allow 'social scoring' by governments. The prohibitions cover practices that have a significant potential to manipulate persons through subliminal techniques beyond their consciousness or exploit

vulnerabilities of specific vulnerable groups such as children or persons with disabilities in order to materially distort their behaviour in a manner that is likely to cause them or another person psychological or physical harm. In addition, the 'real time' use of remote biometric identification systems in publicly accessible spaces for law enforcement purposes is prohibited in principle. Narrow exceptions are strictly defined and regulated (such as where strictly necessary to search for a missing child, to prevent a specific and imminent terrorist threat or to detect, locate, identify or prosecute a perpetrator or suspect of a serious criminal offence). When permitted, such use is subject to authorisation by a judicial or other independent body and to appropriate limits in time, geographic reach and the data bases searched.

High-risk AI systems will be subject to strict obligations before they can be placed on the European Union market.

AI systems identified as high-risk include AI technology listed in the Annexes of the proposal and used in the following broad areas:

- Real time and ex post remote biometric identification systems;
- Critical infrastructures (e.g. transport), that could put the life and health of people at risk;
- Educational or vocational training, that may determine the access to education and professional course of someone's life (e.g. scoring of exams);
- Safety components of regulated products subject to third party conformity assessment under EU sectoral product safety legislation (e.g. AI application in robot-assisted surgery);
- Employment, workers management and access to self-employment (e.g. CV-sorting software for recruitment procedures);
- Essential private and public services (e.g. credit scoring denying people the opportunity to obtain a loan);
- Law enforcement that may interfere with people's fundamental rights (e.g. evaluation of the reliability of evidence);
- Migration, asylum and border control management (e.g. verification of authenticity of travel documents);
- Administration of justice and democratic processes (e.g. applying the law to a concrete set of facts).

Requirements for high-risk AI systems concern:

- Adequate risk assessment and mitigation systems;
- High quality of the datasets feeding the system to minimise risks and discriminatory outcomes;
- Logging of activity to ensure traceability of results;
- Detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance;
- Clear and adequate information to the user;
- Appropriate human oversight measures to minimise risk;
- High level of robustness, security and accuracy.

Public and private providers of such high-risk AI systems will have to follow conformity assessment procedures to demonstrate compliance with the abovementioned requirements before those systems can be placed on the Union market or used in the Union. To facilitate this, the draft Regulation includes provisions relating to the future harmonisation and drawing up of harmonised technical standards to be adopted by the European standardisation organisations (CEN/CENELEC and ETSI) based on a mandate from the European Commission. Predictable, proportionate and clear obligations are also placed on providers and users of high-risk AI systems to ensure safety and respect of existing

legislation protecting fundamental rights throughout the whole AI systems' lifecycle.

AI systems with specific transparency obligations**:** When using AI systems such as chatbots, people should be aware that they are interacting with a machine so they can take an informed decision to continue or step back. People should also be informed in case they are exposed to emotion recognition and biometric categorisation systems as well as deepfakes.

Minimal risk: Subject to compliance with existing legislation, the proposal allows the free use of all other AI applications that are not prohibited, qualified as 'high-risk' or requiring specific transparency obligations. The vast majority of AI systems fall into this category. The draft Regulation does not intervene here, as these AI systems represent only minimal or no risk for peoples' rights or safety, but providers of non-high-risk AI systems can voluntarily adhere to voluntary codes of conduct to demonstrate trustworthiness of their applications.

In terms of governance, the Commission proposes that national competent market surveillance authorities supervise the new rules, while the creation of a European Artificial Intelligence Board will facilitate their implementation, as well as drive the development of standards for AI. Additionally, specific measures are proposed to support small-scale providers and users as well as regulatory sandboxes to facilitate responsible innovation.

7. Objective and rationale, including the nature of urgent problems where applicable: The use of certain AI applications creates risks to safety and fundamental rights that the European Union considers important to be addressed. Certain characteristics of AI, such as the opacity of many algorithms that make difficult to ascertain how they produce results, pose specific and potentially high risks to safety and fundamental rights that existing legislation is unable to address or in view of which it is challenging to enforce existing legislation. For example, it is often not possible to determine why an AI system has arrived at a specific result or to ensure from the outset that certain discriminatory outputs will not be generated. As a consequence, it may become difficult to assess and prove whether someone has been unfairly disadvantaged by the use of AI systems, for example in a recruitment or promotion decision or an application for a public benefit scheme. The use of AI systems may leave affected people with significant difficulties to correct erroneous decisions. Facial recognition in public spaces can have a very intrusive effect on privacy unless properly regulated. In addition, poor training and design of AI systems can result in significant errors that can adversely affect privacy, personal data protection and the principle of non-discrimination. AI-enabled robots and intelligent systems must be engineered and designed to meet the same high standards of safety and protection of fundamental rights applicable to traditional technologies under European law. Considering the safety objectives of the draft Regulation, consistency with the existing EU product safety legislation is ensured and administrative burden for operators minimised. For products covered by the New Legislative Framework (NLF) legislation (e.g. machinery, medical devices, toys), the requirements for high-risk AI systems set out in the draft Regulation will be checked as part of the existing conformity assessment procedures under the relevant NLF legislation. As regards high-risk AI systems related to products covered by relevant 'Old Approach' legislation (e.g. aviation, cars), the draft Regulation would not directly apply. However, the ex-ante essential requirements for high-risk AI systems set out in this proposal will have to be taken into account when adopting relevant implementing or delegated legislation under those acts. Therefore, the following objectives are pursued:

- Prevention of deceptive practices and consumer protection
- Protection of fundamental rights, human life, health or safety
- Quality requirements
- Harmonisation

Prevention of deceptive practices and consumer protection; Protection of human health or safety; Quality requirements; Harmonization

8.	**Relevant documents:** The draft Regulation introduces amendments to a number of other legislative acts under the 'Old approach' safety legislation: • Regulation (EC) No 300/2008 • Regulation (EU) No 167/2013 • Regulation (EU) No 168/201 • Directive 2014/90/EU • Directive (EU) 2016/797 • Regulation (EU) 2018/858 • Regulation (EU) 2018/1139 • Regulation (EU) 2019/2144
9.	**Proposed date of adoption:** 2-3 years from now (depending on the legislative process) **Proposed date of entry into force:** 20 days after its publication (transitional period of two years until full application foreseen)
10.	**Final date for comments:** 90 days from notification
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** European Commission, EU-TBT Enquiry Point, Fax: + (32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu The text is available on the EU-TBT Website : http://ec.europa.eu/growth/tools-databases/tbt/en/ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206&qid=1619620493851 https://members.wto.org/crnattachments/2021/TBT/EEC/21_7109_01_e.pdf https://members.wto.org/crnattachments/2021/TBT/EEC/21_7109_00_e.pdf