

議題研析

一、題目：歐盟機械規則規範簡介

二、議題所涉法規

無

三、背景說明（緣起）

論者指出¹，隨自動化及人機協作技術快速發展，AI 機械及機器人產品之商業價值與日俱增，歐盟為因應新興科技為機械產業帶來知風險與挑戰，於 2023 年 6 月公布機械規則（Regulation (EU) 2023/1230），並自 2027 年 1 月 20 日起全面適用，取代施行近 20 年之機械指令（Directive 2006/42/EC），建立 AI 機械產品之規範，爰簡介歐盟機械規則相關規範。

四、問題爭點

歐盟機械指令之範疇，AI、自主機器/系統、協作機器人、移動機器人等新興技術產品，尚未被納入規範，致欠缺標準化之管制措施；尤以工業安全面向觀之，隨著人機協作比例持續攀升，該等工作場域之風險管理實應受到高度重視；復以機器學習技術之廣泛應用，諸多機械產品均已運用此類技術，故運用機器學習之機械產品於投入市場前應進行全面性之風險評估，以確保其安全性²，爰簡介歐盟機械規則相關規範，以供參考。

五、探討研析

（一）適用範圍

¹ 劉心妍，〈歐盟機械法制變革—建立 AI 機械產品安全框架〉，《科技法律透析》，第 37 卷，第 1 期，114 年 3 月，頁 60。

² 同前註，頁 61-62。

依歐盟機械規則第 2 條及第 3 條規定³，機械係指「透過特定用途的零組件，或至少其中一個零組件用以驅動、非由人類或動物驅動之系統；上述之零組件，不包含連接能源或動力源之零組件；上述零組件，可立即安裝，並且僅安裝在具備運輸工具或安裝在建築物、構造物中正常運作之功能；上述之零組件或半成品機械，未達到共同目的，具有作為整體或部分被控制之功能；上述之零組件中，不含製造商預期之特定用途的軟體」；機械相關產品則指：可互換設備、安全元件、起重配件、鍊條、繩索與織帶、可拆卸式機動傳動裝置⁴，安全元件即為機械相關產品類型之一。

依歐盟機械規則第 3 條第 3 款規定⁵，安全元件係指屬機械產品範疇內之實體或數位元件（含軟體），其設計目的在確保安全功能，且獨立於市場流通，其故障或失靈將危及人身安全。

鑒於近年機械產品普遍運用軟體以協助運作，且基於機器學習方法以達成、部分自我進化行為的安全元件，對機械之運作可能產生風險，故修正安全元件之定義，將「軟體」明確納入規範，其修正後之

³ 歐盟法律網，機械規則第 2 條規定：「1.This Regulation applies to machinery and the following related products: (a) interchangeable equipment; (b) safety components; (c) lifting accessories; (d) chains, ropes and webbing; (e) removable mechanical transmission devices. This Regulation also applies to partly completed machinery. For the purposes of this Regulation, machinery, the related products listed in the first subparagraph and partly completed machinery shall together be referred to as ‘products within the scope of this Regulation’ ……」第 3 條規定：「For the purposes of this Regulation, the following definitions apply: (1) ‘machinery’ means: (a) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application; (b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion; (c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure; (d) assemblies of machinery referred to in points (a), (b) and (c), or of partly completed machinery, which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole; (e) an assembly of linked parts or components, at least one of which moves, and which are joined together, intended for lifting loads and whose only power source is directly applied human effort; (f) an assembly as referred to in points (a) to (e) missing only the uploading of the software intended for the specific application foreseen by the manufacturer; ……」，網址：<https://eur-lex.europa.eu/eli/reg/2023/1230/oj/eng>。

⁴ 同註 1，頁 65。

⁵ 歐盟法律網，機械規則第 3 條第 3 款規定：「‘safety component’ means a physical or digital component, including software, of a product within the scope of this Regulation, which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endanger the safety of persons, but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function。」，網址：<https://eur-lex.europa.eu/eli/reg/2023/1230/oj/eng>。

定義為「法規範圍內之機械產品的實體、數位元件或混合型元件，包含軟體，其設計旨在確保功能之安全性並可安全的投入市場中使用」⁶。

（二）具機器學習功能之產品納入較嚴格合規性評估類別，應有第三方機構參與

歐盟機械規則將產品依風險採不同流程之合規性評估。其中，就機械規則附件一 A 部分⁷列有 6 類應適用第 25 條第 2 項合規性評估程序之機械及相關產品。除可拆卸機械傳動裝置及其防護裝置、可拆卸機械傳動裝置之防護裝置、車輛維修升降機，以及攜帶式火藥擊發固定機械及其他衝擊機械等 4 類項目外，另增列 2 類涉及人工智慧中機器學習技術之項目：其一為具有完全或部分自我演進行為，並運用機器學習方法確保安全功能之安全元件；其二為內嵌具有前述特徵、尚未獨立投放市場之系統的機械，惟僅就該內嵌系統適用附件一 A 部分規定。

前述 6 類機械及相關產品，均須由歐盟公告機構進行第三方驗證⁸；本規則前言第 54 點亦說明⁹，確保安全功能之自我演進安全元件或系統，不論係獨立投放市場或內嵌於機械，原則上均應由第三方辦理

⁶ 同註 1，頁 66。

⁷ 歐盟法律網，機械規則 附件一 PART A：「Categories of machinery or related products to which a procedure referred to in Article 25(2) shall be applied：1.Removable mechanical transmission devices including their guards. 2.Guards for removable mechanical transmission devices. 3.Vehicle servicing lifts. 4.Portable cartridge-operated fixing and other impact machinery.5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions. 6. Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems……。」，網址：<https://eur-lex.europa.eu/eli/reg/2023/1230/oj/eng>。

⁸ 歐盟法律網，機械規則第 25 條第 2 項規定：「“Where the category of machinery or related product is listed in Annex I, Part A, the manufacturer or the natural or legal person referred to in Article 18 shall apply one of the following procedures: (a) EU type-examination (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII; (b) conformity based on full quality assurance (module H) set out in Annex IX; (c) conformity based on unit verification (module G) set out in Annex X.”」，第 26 條規定：「Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks in accordance with this Regulation.」，網址：<https://eur-lex.europa.eu/eli/reg/2023/1230/oj/eng>。

⁹ 歐盟法律網，機械規則 前言 (54)：「“……Therefore, the conformity assessment of a safety component or a system with self-evolving behaviour ensuring safety functions should be carried out by a third party, whether or not the safety component has been placed independently on the market or is part of a system embedded in machinery that is placed on the market.……”」，網址：<https://eur-lex.europa.eu/eli/reg/2023/1230/oj/eng>。

符合性評估。

因此，論者認¹⁰歐盟機械規則之規範內容，擴大其適用範圍涵蓋機械消費性產品、工業機械及數位化機械產品；復將「軟體」納入安全元件之定義；新增高風險機械項目，將使用機器學習的安全元件與嵌入式機械系統列入並要求製造商須進行第三方驗證；以及加強製造商義務規範等舉措，相較於原有機械指令，均彰顯歐盟於推動科技創新發展之際，亦就機械及人員於安全之高度重視。

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¹⁰ 同註 1，頁 71。