SQUIRE PATTON BOGGS

The EU AI Act and The Automotive Sector

Why Are Product Conformity Regimes Relevant to High-risk AI Systems?

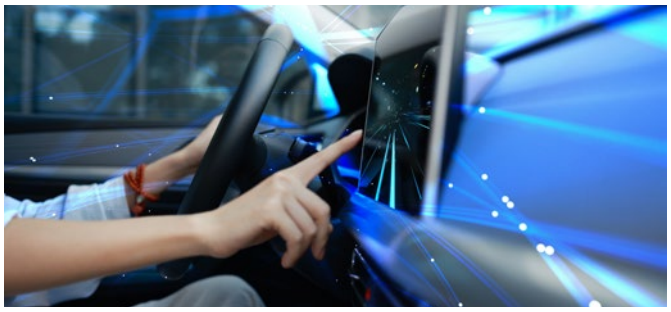
Introduction

From autonomous-driving to ADAS (Advanced Driver Assistance Systems), to the potential for Artificial Intelligence (AI) to transform the aftermarket, AI is much-discussed as being transformational in the automotive sector; and there are numerous reported examples of AI being used already, for design, validation and performance management, connected with the manufacturing process.

However, automotive businesses developing, supplying and/or using AI tools now, or planning to do so in future, should be aware of emerging legislation that may impose mandatory legal obligations on parties involved in the AI system "life-cycle".

Within the EU, for example, Regulation (EU) 2024/1689 (the "EU AI Act") was adopted in March 2024 and entered into force on 1 August 2024. It is a legislative framework relating to the development, placing on the market, putting into service and use of AI systems in the EU, partly with the intention of ensuring the protection of health and safety and "fundamental rights", such as democracy, the rule of law and environmental protection, as well as supporting the proper functioning of the internal market, including fair and undistorted competition.

The requirements of this legislation intersect with the more-traditional realm of conformity assessment obligations for "physical" products. A key consequence is that many AI systems used in the automotive sector are likely to be treated as "high-risk AI systems" under the EU AI Act by virtue of being safety components of vehicles or parts subject to EU type-approval regimes, or other harmonised legislative frameworks, creating many regulatory obligations on the providers (as well as deployers, importers and distributors) of such systems. Since the EU AI Act provides for significant penalties for infringement, it is important that any company operating in the automotive sector that is using, or plans to use, AI systems or products that include AI systems as components, is aware of its obligations and ensures effective compliance.



Overview of EU AI Act

The EU AI Act lays down harmonised rules for the development, placing on the market, putting into service and use of AI in the EU; and there are obligations under the legislation for both providers and deployers (as well as importers and distributors) of AI systems in this context. The requirements are being introduced on a phased basis over a two-year period. Provisions relating to AI literacy and prohibited AI practices have applied since 2 February 2025. Automotive businesses are, therefore, already required to ensure compliance with these provisions, where relevant.

Other key provisions of the EU AI Act, including those related to AI systems that are classified as "high-risk", mostly come into force on 2 August 2026, although the provisions relating to classification of an AI system as high-risk due to it being covered as a product, or safety component of a product, under certain EU harmonised legislation, and the corresponding obligations, do not apply until 2 August 2027.

The EU AI Act will impact businesses both inside and outside of the EU. To the extent that a non-EU business sells or otherwise places an AI system on the EU market, or if, when deployed, the output of an AI system developed by that business is intended to be used in the EU, the legislation will have extraterritorial effect. However, its application is role-specific and does not necessarily attach to both "ends" of the supply chain in every scenario.

So, for example, if a business that develops software is based in the US, China or the UK and sells that software to a German original equipment manufacturer (OEM) or a Spanish Tier-1 supplier for integration into a vehicle or component part, the requirements under the EU AI Act will apply to that software (assuming that the software is an AI system within the meaning of the legislation and is within scope, and not otherwise exempt). However, the non-EU developer would not typically be regarded solely by virtue of development as a provider under the EU AI Act. It will be the EU based supplier of the vehicle or component who will likely be regarded as the "provider" of the AI system where it integrates the AI system or AI-enabled component, as applicable, and places the resulting AI-enabled vehicle or component on the EU market under its own name or trademark (i.e., unless the non-EU software developer retains branding, defines the intended purpose, or otherwise assumes responsibility for conformity assessment).

Conversely, where a non-EU established Tier-1 supplier of a vehicle part embedding an AI system as a safety component of that part, supplies that part to OEM customer in France, the French customer of the non-EU business would likely be regarded as the "importer" of the relevant software, being a person located or established in the EU, that first makes available the software for distribution or use, on the EU market.

Because importers must ensure that any high-risk AI system conforms with the requirements under the EU AI Act (by various means, including by verifying that the provider has appointed an authorised representative, established in the EU, with the authorised representative themselves separately obliged to verify certain matters and keep various records) the French customer should themselves insist that the non-EU provider supplies evidence of compliance, where relevant.

Furthermore, direct and certain downstream customers in the EU will be required to check that the non-EU provider has complied with the relevant requirements for an AI system, because there are additionally obligations for importers and distributors in the EU under the legislation.

Link between the Type Approval Regime and High-risk Classification

In the EU (and the UK under provisions grandfathered over on Brexit) motor vehicles (and their trailers, systems, components and separate technical units intended for such vehicles) must be approved before they go on sale against safety and environmental rules, by an approval authority. This is commonly known as the "type approval regime". The administrative processes related to this regime are set out in Regulation (EU) 2018/858 (the "Type Approval Regulation").

The Type Approval Regulation is supplemented in the EU, by Regulation (EU) 2019/2144, which provides for type approval related to the general safety and protection of vehicle occupants and vulnerable road users (Vehicle General Safety Regulation). The Vehicle General Safety Regulation has mandated type-approval against additional technical requirements on new vehicles and ADAS features such as autonomous emergency braking (AEB) and emergency lane-keeping systems. It also includes further mandated technologies from July 2026, such as advanced driver distraction warning systems (ADDW) and additional pedestrian and cyclist AEB.

Against this background, automotive sector businesses should note that where an AI system is itself a product covered by the type approval regime in the Type Approval Regulation and/ or the Vehicle General Safety Regulation, or is intended to be used as a safety component of a product covered by the type approval regime, and as such, is required to undergo a third-party conformity assessment under that regime, the AI system will be categorised as high-risk under the EU AI Act.

Only certain provisions of the EU AI Act apply directly to AI systems which are high-risk AI by virtue of the fact they are products or safety components of products, which are covered by the Type Approval Regulation or the Vehicle General Safety Regulation (although those provisions might nevertheless apply directly if the relevant AI system: (i) is also within scope of another relevant product-regime, such as that relating to radio equipment, as detailed below, or (ii) or falls to be treated as a high-risk AI system in any event under Annex III of the EU AI Act).

However, requirements for high-risk AI systems will very likely apply in practice in any event. This is because delegated acts (in respect of the Type Approval Regulation) or implementing acts (in respect of the Vehicle General Safety Regulation) adopted by the European Commission under those respective regulations (for the purposes of amending the list of requirements/regulatory acts for type approval, to take into account technological and regulatory developments or to adopt provisions concerning uniform procedures and technical specifications to ensure the safe operation of automated and fully automated vehicles) must take into account certain requirements for high-risk AI under the EU AI Act.

Therefore, in practice, sector-specific laws under the type-approval regime are very likely to align with the requirements under the EU AI Act for high-risk AI, in future. This means that those in the automotive sector should ensure that they are familiar with and ready for, requirements under the EU AI Act relating: to the establishment and implementation of a documented risk management system; data and data governance; technical documentation; record-keeping; transparency and provision of information to deployers; human oversight; and accuracy, robustness and cybersecurity.

High-risk AI systems, which are high-risk because they are products, or safety components of products, which are covered by the Type Approval Regulation or the Vehicle General Safety Regulation, are also subject to the obligation on the European Commission to review various aspects of the EU AI Act and the need for amendments by 2028 and every four years thereafter, which means that additional requirements could also be imposed on such high-risk AI systems in future, even though they are separately regulated under the type-approval regime.

High-Risk Classification of Components, Spare Parts and Other Products under Other Regimes

For AI systems that are, or are used in, components, spare parts and other products, which are not covered by the type approval regime outlined above (i.e. which are not covered by the Type Approval Regulation or the Vehicle General Safety Regulation), but are potentially governed by other product-compliance regimes or which are covered by another product-compliance regime, in addition to the type approval regime, it will be necessary to consider whether the AI system could be classified as "high-risk" AI, on the basis of other provisions in Article 6 of the EU AI Act (assuming there is no relevant exemption under the legislation). If such AI is classified high-risk AI, additional requirements will apply, from August 2026 or August 2027 (depending on the basis of classification).

One possible reason for such classification would be that the relevant AI system is included in the list of high-risk AI contained in Annex III of the EU AI Act (essentially, AI systems used within certain specific areas of use, such as permitted biometrics or where used as safety components in critical infrastructure, including in the management and operation of road traffic).

These examples, or other specified uses in the Annex III list are perhaps unlikely to be generally applicable to the automotive industry, although there may be one or two exceptions for certain operators or certain types of vehicles, where the Annex III list could be relevant and with rapidly emerging technology, this should be kept under review. For example, smart roads are already in operation in certain parts of Europe (the Ursa Major 2 project, involved public authorities, road administrators and traffic information service providers to ensure tariff management and traveller information services). If AI systems were incorporated into vehicles to interact with smart road AI systems, in a way that meant they could be defined as safety components in the management of road traffic, they could potentially be classified as high-risk AI under the part of Annex III relating to critical infrastructure.

However, AI systems developed or used in the automotive sector (as well as others) will also be considered high-risk if: (i) the AI system is covered as a product or as a safety component of a product by other harmonised EU legislation, which is specified in Annex I of the EU AI Act; and (ii) that product is required to undergo a third party conformity assessment. One piece of harmonised EU legislation specified for this purpose under the EU AI Act, that is likely to be relevant in the automotive sector, is the Radio Equipment Directive (Directive 2014/53/EU)(RED).

There has historically been some confusion over the applicability of RED alongside other product-regulatory regimes, but a guide from the European Commission on RED (the "RED Guide"), published in 2018, provides that where RED is applicable simultaneously with other EU legislation covering the same hazard (safety or electromagnetic compatibility), the issue of overlap can be resolved by giving preference to the more specific legislation; and radio equipment for vehicles, which might also be subject to the type approval regime is a named example of equipment where RED is applicable simultaneously. The RED Guide also says that where radio equipment is installed in vehicles such as cars (normally falling under type approval legislation) the radio equipment has to comply with RED, unless the specific equipment falls within any of the exceptions (under RED).

Therefore, if a vehicle component or spare part is covered by RED (even if that is in addition to or alongside the type approval regime), that component or spare part may also be subject to the general requirements for high-risk AI under the EU AI Act (as well as the requirements under the RED), where the RED-covered component or spare part is required to be assessed by a notified body under the RED-regime and incorporates, an AI system within the meaning of the EU AI Act. It is not clear within the legislation, though, how this potential cross-over between products which are covered both by the type-approval regime and RED should be navigated.

Other EU harmonised legislation that is contained in the list in Annex I of the EU AI Act includes legislation relating to personal protective equipment (PPE) and toys (in addition to various other pieces of EU legislation). While such product-types are not obviously relevant to the vehicle itself, they may have relevance to ancillary products produced or supplied by OEMs (and others).

For example, many OEMs also supply branded products for consumers, such as toy vehicles (regulated under toys legislation) and products such as earmuffs and sunglasses (regulated as PPE). Thus, the full list of harmonised legislation may need to be reviewed by an automotive business, in the context of the particular AI systems developed, supplied, or used (or intended to be developed, supplied or used).

High-risk Classification of Machinery

EU legislation governing machinery (currently, Directive 2006/42/EC) is also included in the list of harmonised legislation under Annex I of the EU AI Act. That legislation is unlikely to be relevant in the vehicle context, because vehicles are generally excluded from the scope of the machinery regime.

However, to the extent that OEMs use, in the production process, machinery that is required to be conformity assessed by a notified body, the high-risk AI provisions could be relevant for any AI system used, or to be used, as a safety component of such machinery. OEMs should therefore ensure that they are aware of any relevant deployer obligations that they may bear under the legislation.

Conformity Assessment Processes for High-risk AI

Requirements for high-risk AI outside of the type-approval context, will include (among other matters) requirements for technical documentation, conformity assessment, CE marking, declarations of conformity, name and address labelling and document retention, under the EU AI Act itself (in addition to any similar requirements under other applicable product-compliance regime(s)). These types of requirements will likely be familiar to those in the automotive sector responsible for product compliance under other regimes, but less so to those involved before now in the development and supply of "pure" software.

Well ahead of the relevant "in-force" date, potentially affected businesses along the supply chain for the AI system should consider how to ensure compliance with these and other requirements for high-risk AI under the EU AI Act.

One requirement of particular note is that the conformity assessment process under the EU AI Act for high-risk AI will need to be undertaken by a notified body, i.e. a third-party "expert" who will be responsible for performing testing, certification and inspection activities. This will be in addition to any conformity assessment that is required, and/ or undertaken under other harmonised EU legislation.

There is some concern across different industries that there might be insufficient notified bodies that have been assessed and designated under the EU AI Act in time for relevant conformity assessments to have been undertaken. In short, it is possible that demand for notified bodies will exceed supply. In certain sectors, therefore, there have already been calls for notified bodies to be designated swiftly, without delays at the European or member state level.

Conclusion

The penalties for non-compliance with the EU AI Act could be significant. Historically, EU "product" legislation did not commonly provide for enforcement or penalties (this being addressed by domestic legislation, which provides for enforcement in each relevant member state).

However, (in common with other more recent EU legislation, such as those relating to deforestation and corporate sustainability due diligence), the EU AI Act provides that penalties must be effective, proportionate and dissuasive, and administrative fines for most non-compliances under the legislation are specified to be up to €15 million, or up to 3% of total worldwide annual turnover, for the preceding financial year, whichever is higher (except for small- and medium-sized enterprises (SMEs) where it is the lower figure that is relevant). Those are pretty eye-watering sums, but even those are not the highest penalties: for non-compliance with the prohibition of certain practices under the EU AI Act, the relevant sums are the higher of €35 million, or up to 7% of total worldwide annual turnover, respectively (or, again, the lower of those figures for SMEs). Therefore, the impact on those who don't get this right could be very significant.

But even that is not where the story ends. Automotive businesses must also consider that the EU AI Act is just one piece of the puzzle that is the regulation of AI. Even those AI systems that are not classified as high-risk AI under the EU AI Act may be subject to requirements under other regimes (in addition to the requirements for lower-risk categories of AI under the AI Act).

For example, under general product safety legislation (which will apply to the extent that there are no specific provisions in Union harmonisation legislation with the same objective) the obligation to only supply safe products, will be relevant to the supply or use of AI systems intended to be used by, or which can reasonably be expected to be used by, consumers. Indeed, one of the stated reasons for introduction of the EU general product safety regulation (Regulation (EU) 2023/988) in place of the previous directive, was to explicitly take into account new technologies, which might substantially modify an original product through software updates; and also to take into consideration cybersecurity risks where sectoral legislation does not apply.

Of course, the requirements of the General Data Protection Regulation (GDPR) may also need to be considered, for example where personal data will be processed from connected vehicles. Intellectual property laws may also be relevant if an AI system uses or generates content that is protected by third-party rights, or which the business itself may wish to protect.

For products outside of the automotive context, but which may perhaps be supplied separately by OEMs as branded accessories, the Product Security and Telecommunications Infrastructure (Project Security) regime, which essentially relates to consumer connectable products, may also need to be considered in the UK.

In the EU, the EU Data Act, which also relates to "connected products", does apply to vehicles (and there is specific guidance on vehicle data, relating to the Data Act 2023/2854, which was published by the European Commission in September 2025).

For all of these reasons, businesses should ensure that they fully understand the implications of the legal landscape well ahead of full implementation of the provisions, to be in the best position to comply and avoid potentially hefty penalties.

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