The Paris office of Hogan Lovells is pleased to provide this English language edition of our monthly e-newsletter, which offers a legal and regulatory update covering France and Europe for September 2025.

Please note that French legal concepts are translated into English for information only and not as legal advice. The concepts expressed in English may not exactly reflect or correspond to similar concepts existing under the laws of the jurisdictions of the readers.

If you would like to consult this newsletter from past months, please click here.

For additional information, please speak to your usual contact.

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- **Commercial**

European Union – Implementation of Extended Producer Responsibility for Textile Waste and Consumer Information: Publication of the Waste Directive

Directive (EU) 2025/1892 of 10 September 2025 on waste, amending Directive (EC) 2008/98 of 19 November 2008, was published in the *Official Journal of the European Union* on 26 September 2025. Its objective is to reduce the impact of waste from the food and textile sectors, notably through the implementation of extended producer responsibility (EPR) in the textile sector.

As a reminder, EPR makes producers responsible for financing or organizing the prevention and management of waste generated by these products at the end of their life. It is an application of the polluter-pays principle.

Member States must ensure that textile producers are subject to extended producer responsibility (EPR) for textile products, textile accessories, or footwear that they place on the market for the first time (Article 22 bis of the Directive).

Organizations competent in producer responsibility for textiles must provide end users with information regarding sustainable consumption, possibilities for reuse and repair of products, locations of collection points, donation opportunities, as well as the environmental, human health, and social and human rights impacts related to textile production, especially fast fashion production (Article 22 quater of the Directive).

An EPR scheme for textiles had already been established in France to develop the circular economy, promoting eco-design of products, waste prevention, extending product usage duration, and management of their end of life (Articles L541-10 to L541-10-17 of the French Environmental Code).

Member States have until 17 June 2027 to transpose the Directive.

Source : Directive (UE) 2025/1892 du 10 septembre 2025 relative aux déchets

Authored by Charlotte Haddad and Servane de Maigret

- **Insurance**

France – Publication of an Order establishing the list of entities to which the national financial intelligence unit Tracfin, is authorised to transmit information

On 8 September 2025, the Minister of the Economy, Finance, Industry and Digital Sovereignty published an Order setting out the exhaustive list of forty (40) administrations, entities, and authorities to which the French financial intelligence unit ("**Tracfin**") is authorised to transmit information, in accordance with Article L. 561-31 of the Monetary and Financial Code ("**MFC**").

As a reminder, under Article L. 561-31 of the MFC, Tracfin may only share information with these entities when the data is directly related to their respective missions.

This Order has been in effect since 1st October 2025.

Source: Order establishing the list of entities to which the national financial intelligence unit Tracfin is authorised to transmit information

France – Publication by the ACPR of a user guide for entities subject to one or more reporting obligations via the OneGate Portal

On 11 September 2025, the *Autorité de Contrôle Prudentiel et de Résolution* ("**ACPR**") published a user guide aimed at banking and insurance entities subject to one or more reporting requirements through the ACPR portal ("**OneGate Portal**").

The guide reiterates that the declaration form (*fiche declarative*) is a report used to collect information about the activity and the contact persons of such entities who may be approached by the ACPR. It provides detailed instructions on how to submit and update this form on the OneGate Portal.

The declaration form must be submitted by these entities at the start of their activity on the OneGate Portal, and must be updated systematically throughout their activity whenever any changes occur.

Source: Publication by the ACPR of a user guide for entities subject to one or more reporting obligations via the OneGate Portal

France – Publication by the ACPR of a summary of Recommendation dated 21 November 2024 on duty to advice in insurance

On 22 September 2025, the *Autorité de Contrôle Prudentiel et de Résolution* ("**ACPR**") published a summary of Recommendation 2024-R-03, dated 21 November 2024, concerning the collection of client information regarding the duty to advise and provide personalised recommendations in the insurance sector.

The ACPR notes that this recommendation serves several objectives:

- Support the implementation of the duty to advise throughout the entire life cycle of insurance contracts in the life insurance sector, as well as the introduction of a minimum share of unlisted funds within profiled management products, which include specific buyback compensation mechanisms. These provisions form part of the framework established by the Law of 23 October 2023 (*Loi Industrie Verte)*, which notably includes measures concerning life insurance.
- Integrate the consideration of clients' sustainability preferences into the duty to advise in life insurance, in order to recommend sustainable products that meet their expectations. The ACPR specifically invites insurance distributors to rely on the document issued by the European Insurance and Occupational Pensions Authority ("**EIOPA**") concerning the application of sustainability preferences in the suitability assessment under the Insurance Distribution Directive (EIOPA-BoS-22-391). The ACPR emphasises the need to establish a balanced framework that ensures clients are properly informed about the sustainability characteristics of the products offered and about the extent to which these products meet the preferences they have expressed.
- Take into account the lessons learned from the ACPR's supervisory work, such as the prevention of the unintentional accumulation of insurance policies or the adoption of good practices when redeeming a life insurance contract that is accompanied by the subscription of a new one.

The ACPR also recalls the necessity of establishing the duty to advise continuously throughout the duration of a non-life or pension insurance contract, in order to periodically ensure that the products held by policyholders continue to meet their needs.

The Recommendation 2024-R-03 will enter into force on 31 December 2025.

Source: Publication by the ACPR of a summary of Recommendation dated 21 November 2024 on duty to advice in insurance

European Union – Publication by the European Commission of a draft delegated decision renewing the equivalence of the European solvency regime with the solvency regimes of Brazil, Mexico, and Japan

On 17 September 2025, the European Commission published a draft delegated decision concerning the renewal of the determination of equivalence between the solvency regimes in force in Brazil, Mexico, and Japan - applicable to undertakings with their head offices in those third countries - and the regime set out in Title I, Chapter VI of Directive 2009/138/EC ("**Solvency II Directive**").

Such a renewal may be adopted pursuant to Article 227 of the Solvency II Directive, provided that the criteria set out in paragraph 5 continue to be met.

This draft delegated decision aims to renew, for a period of ten years starting from 1 January 2026, the provisional equivalence recognition granted to these three countries, which will remain valid until 31 December 2035.

Source: Publication by the European Commission of a draft delegated decision renewing the equivalence of the European solvency regime with the solvency regimes of Brazil, Mexico, and Japan

European Union – Publication of three corrigendum amending regulations related to the DORA Regulation

On 11, 12, and 19 September 2025, the European Commission published three corrigendum amending regulations associated with Regulation (EU) 2022/2554 on the digital operational resilience of the financial sector ("**DORA Regulation**").

These corrigendum concern the following texts:

- **Amendment to the French version of Implementing Regulation (EU) 2025/302**, published on 11 September 2025, which sets out implementing technical standards for the application of the DORA Regulation regarding standard forms, templates, and procedures for financial entities to report major information and communication technology ("**ICT**") incidents and to notify significant cyber threats.
  This amendment modifies Annexes I to IV by replacing the term "*indicateur de compromis*" with "*indicateur de compromission.*"
- **Amendment to the French version of Delegated Regulation (EU) 2025/301**, published on 12 September 2025, supplementing the DORA Regulation with regulatory technical standards specifying the content and timelines for the initial notification of major ICT-related incidents, as well as for the related intermediate and final reports, and the content of voluntary notifications concerning significant cyber threats.
  This amendment revises Article 3(l), concerning the specific information to be included in intermediate reports, and Article 6(i), on the content of voluntary notifications of significant cyber threats, by replacing the term *"indicateur de compromis"* with *"indicateur de compromission."*
- **Amendment to Implementing Regulation (EU) 2024/2956**, published on 19 September 2025, concerning the standard templates for submitting the register of information.
  This amendment corrects several column codes appearing on pages 24, 25, 30, 31, and 35.

Source: Corrigendum to Commission Implementing Regulation (EU) 2024/2956, Corrigendum to Delegated Regulation (EU) 2025/302, Corrigendum to Delegated Regulation (EU) 2025/301

Authored by Ghina Farah and Maxime Kaya

- **Intellectual Property**

Europe – EPO – improvement of MyEPO services for the filing and processing of color and grayscale drawings

On 8 September 2025, the European Patent Office (EPO) announced two major enhancements to its MyEPO services, as part of the digital transformation set out in its Strategic Plan 2028.

Both improvements have been developed in direct response to user feedback and will be available from 1 October 2025:

- **Acceptance of colour and greyscale drawings for all European patent applications filed via the EPO's electronic filing tools.** Until now, such drawings were converted to black and white. They will be accepted and processed in colour or greyscale throughout the entire procedure, including at publication and grant stages. However, this feature does not apply to international phase PCT applications. Further details are available in the Notice from the European Patent Office dated 5 September 2025 concerning drawings in colour and greyscale.
- **Option to file drawings as separate PDF files for pilot users filing in DOCX format via Online Filing 2.0 (OLF 2.0).** This development aims to provide greater flexibility in drafting applications and to simplify the filing process.

These features mark a significant step toward the full rollout of the DOCX format in 2026, which aims to standardise and streamline the digital handling of patent applications.

Authored by Anaïs Le Coq and Claire Lemaître

- **Life Sciences**

France – France – New regulatory framework for the online sale of non-prescription veterinary medicinal products

Decree No. 2025-908 of 6 September 2025 on the online sale of veterinary medicinal products has amended the French Public Health Code in order to regulate the online sale of veterinary medicinal products not subject to prescription pursuant to Regulation (EU) 2019/6.

- **New prior declaration requirement with ANSES for online sales websites:** the creation of a website for the online sale of veterinary medicinal products, or the extension to veterinary medicinal products, by a pharmacy, of an e-commerce website for medicinal products already created by the holder of the pharmacy, is now subject to a prior declaration before the launch of the site, by electronic means, to the Director General of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES). The declaration template, the information to be included therein and the supporting documents to be provided are determined by the General Director of ANSES. From the date of filing:
  - if the declarant meets the conditions, the site is registered within seven days;
  - if the declarant does not meet the conditions, ANSES can oppose to the declaration, upon justifications;
  - if the file is incomplete, the declarant has a minimum period of fifteen days to provide the missing documents.

- **Regulation of operators authorised to sell non-prescription medicinal products online:**
    - pharmacists must inform, by any means, the General Director of the regional health agency competent for the territory where their pharmacy is located, as well as the professional board of pharmacists to which they belong, of their online sales activity for veterinary medicinal products and send them a copy of the declaration receipt;
    - veterinarians must inform the regional council of the professional board of veterinarians to which they belong of the creation of their website for the online sale of veterinary medicinal products and send them a copy of the declaration receipt;
    - other individuals or entities, provided they are registered in the French national commercial register, must inform the departmental directorate for employment, labour, solidarity and the protection of populations of their place of residence or registered office of the creation of the website for the online sale of veterinary medicinal products and send a copy of the declaration receipt together with the name of the person responsible for the online sales site and the address of the places where veterinary medicinal products subject to registration are stored.
    - This information must be provided by these operators no later than seven days after the website is launched.
- **Mandatory display:** the websites concerned must (i) indicate ANSES's contact details, (ii) provide the link to the website on the online sale of veterinary medicinal products set up by ANSES and, (iii) on each page of the site, display the common logo, the presentation arrangements for which will be defined by a ministerial order to be published.
- **This ministerial order will also determine:**
    - the general functionalities of the site;
    - how the veterinary medicinal products must be separated from other products sold on the site;
    - the languages used, the nature of the information provided on the veterinary medicinal products sold on the site;
    - the conditions for the use of subcontracting;
    - the presentation modalities of veterinary medicinal products;
    - the conditions relating to the quantities supplied, and to the preparation and delivery of veterinary medicinal products;
    - the conditions relating to customer advice and customer content.
- **In the event of a change to the items in the prior declaration or in the event of the permanent or temporary closure of the online sales site:** the declarant shall inform the General Director of ANSES by any means that confers a certain date to the notification. This information is provided without delay in the event of a change and no later than within 7 days of closure. This information is provided under the same conditions to the authorities mentioned above.

- **Sanctions in the event of non-compliance:** ANSES may sanction online sales carried out in breach of these provisions by financial and administrative penalties (the person concerned must provide its turnover to the ANSES to assess the appropriate amount of the sanction) and may order the temporary closure of the site. In the event of closure, ANSES informs the respective authorities mentioned above.
- **Transitional period:** a period of 1 year is also granted to persons who are not pharmacists or veterinarians and who were selling veterinary medicinal products intended for certain animal species, so that they can comply with the new provisions of the French Public Health Code.

Sources: Publication of a decree on the online sale of veterinary medicinal product

Authored by Joséphine Pour, Gabrièle Grandin de l'Eprevier

- **Litigation**

France – Electronic communication: publication of the official list of authorised systems

Continuing the digital overhaul initiated by the "Magicobus 2" Decree, the *Order of 29 August 2025* (*Official Journal*, 31 August 2025) establishes, for the first time, an exhaustive list of electronic communication systems authorised for the transmissions, submissions and notifications referred to in Article 748-1 of the French Code of Civil Procedure.

This Order repeals all previous technical orders to unify practices around seventeen approved platforms, including e-Barreau, i-Greffes, ComCi CA, SECURIGREFFE, OPALEXE (for judicial expertise), and SECURACT and e-Huissier for judicial officers. Each system is now subject to detailed regulation specifying its scope of application, authorised interconnections, and exchange protocols (electronic signatures, acknowledgements of receipt, automated processing).

The Order also clarifies the technical connections between civil, commercial, and professional courts, ensuring full interoperability between the RPVA (lawyers' private virtual network), RPVJ (justice private virtual network), and the registries' systems. It forms part of the broader strategy to achieve full digitisation of civil procedure by 2026, initiated by the July 2025 decrees and reinforced by the *irrevocable presumption of consent* to electronic exchanges via the Portalis portal.

Source: *Order of 29 August 2025, Official Journal of 31 August 2025*

Authored by Nicolas Rohfritsch and Mizgin Laura Delikaya