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MDR Online Conference – Data Protection

Francesca Blythe, Senior Associate, fblythe@sidley.com
Josefine Sommer, Senior Associate, jsommer@sidley.com

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Potentially Relevant European Privacy Laws

EU General Data Protection Regulation (GDPR) and UK GDPR



- Applies to companies located in the EEA/UK and to companies outside of the EEA/UK (e.g., in Switzerland) that:
 - offer goods/services to individuals in the EEA/UK, or
 - monitor the behaviour of individuals in the EEA/UK

Swiss Data Protection Laws



- Federal Act on Data Protection 1992 (FADP)
- A revised version of the FADP was adopted on 25 September 2020
 - Broadly aligned with GDPR
 - Expected to enter into force in Q3/Q4 2022

e-Privacy Directive 2002/58/EC



- Regulates *inter alia* the use of cookies and direct marketing activities
- New e-Privacy Regulation could enter into application in 2023

Hot Topics – (1) Clinical Investigations

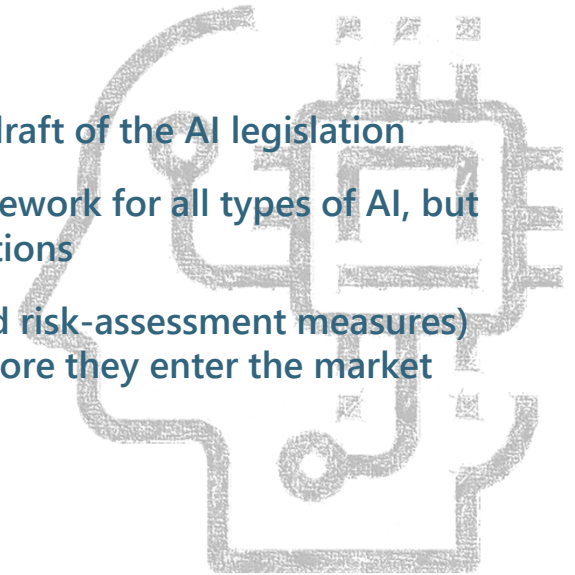
1

- Key-coded data = personal data
- What will the legal basis for processing be?
 - Will consent be valid?
- What role will the site play (i.e., controller, joint controller, processor)?
 - CJEU case law: (i) Schleswig-Holstein, (ii) Tietosuoja- ja tuutett v Jehovan todistajat, and (iii) *Fashion ID v Verbraucherzentrale*
 - 2 September 2020: EDPB published draft guidelines on controller and processor under the GDPR
 - Requires either a “common decision” or a “converging decision”
 - EDPB Example: Clinical Trials

Hot Topics – (2) Artificial Intelligence (AI)

2

- On 21 April 2021, the European Commission is expected to publish the first draft of the AI legislation
 - Expected to follow a risk-based approach to AI – providing a legal framework for all types of AI, but setting out additional mandatory requirements for high-risk AI applications
 - Expected to provide for "ex-ante" controls (e.g. market-surveillance and risk-assessment measures) which will allow the EU to verify and test "high-risk" AI applications before they enter the market



Hot Topics – (3) Data Protection by Design and Default (DPbDD)

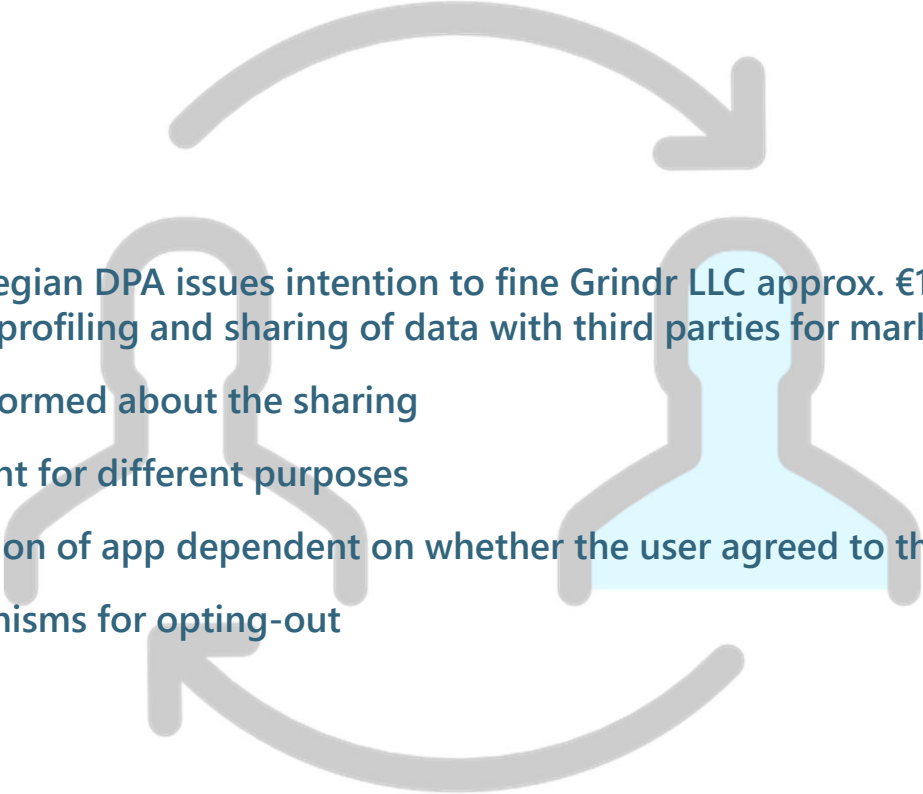
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- GDPR's data protection principles must be designed into and set as a default in processing activities through means of "appropriate measures and safeguards."
 - Data protection by design measures range from the implementation of advanced technical solutions, to the training of personnel and data access restrictions.
 - Data protection by default refers to the setting of pre-selected values in software, applications or devices that lead to GDPR compliance.
- Controller has DPbDD obligations under GDPR, but EDPB recognizes that processors and technology providers play an essential role in facilitating compliance.
- Controllers should maintain comprehensive records of each step in the design of the devices and carry out regular DPIAs.



Hot Topics – (4) Data Sharing

4

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- 16 January 2021 - Norwegian DPA issues intention to fine Grindr LLC approx. €10 million for failure to obtain valid GDPR consent for profiling and sharing of data with third parties for marketing purposes
 - Not adequately informed about the sharing
 - No separate consent for different purposes
 - Access to free version of app dependent on whether the user agreed to the sharing of personal data
 - Insufficient mechanisms for opting-out

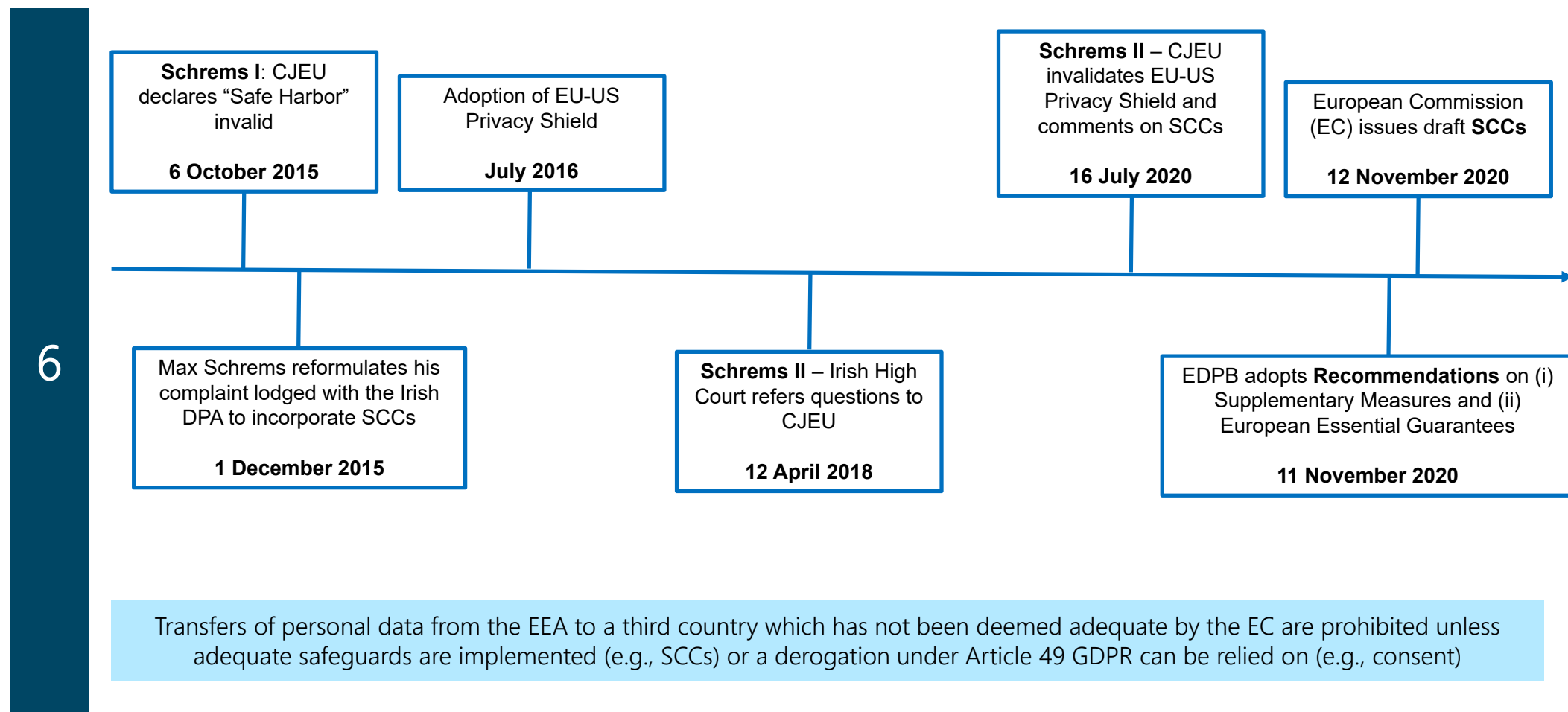
Hot Topics – (5) Cookies and Consent

5

- Regulated in the EU by the e-Privacy Directive and the GDPR
 - Implemented by each EU Member State / UK - so can vary
- Must obtain informed opt-in consent prior to non-essential cookies being dropped
 - Non essential = those not strictly necessary to provide the service requested by the individual
 - Consent must be granular, i.e., ability to consent to some purposes, but not others.
 - Third party cookies must be clearly and specifically named
 - Continuing to use website ≠ valid consent
- December 2020: CNIL fined Google €100 million, and Amazon €35 million, for cookie violations
- New e-Privacy Regulation



Hot Topics – (6) International Transfers



Beijing
Boston
Brussels
Century City
Chicago
Dallas
Geneva
Hong Kong
Houston
London
Los Angeles
Munich
New York
Palo Alto
San Francisco
Shanghai
Singapore
Sydney
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