



**Decision approving Controller Binding Corporate Rules  
of Fresenius Group**

1. Having regard to Article 47(1) of the EU General Data Protection Regulation 2016/679 (GDPR), the Hessian Commissioner for Data Protection and Freedom of Information (Hessian SA) shall approve Binding Corporate Rules (BCRs) provided that they meet the requirements set out under this Article.

Whereas:

2. In accordance with the cooperation procedure as set out in the Working Document WP263 rev.01<sup>1</sup>, the Controller BCRs application of Fresenius SE & Co. KGaA and Fresenius Kabi AG as joint applicants (Fresenius Group) were reviewed by the Hessian SA, as the competent supervisory authority (SA) for the BCRs (BCR Lead) pursuant to Article 55(1) of the GDPR, Section 40(1) of the German Federal Data Protection Act in conjunction with Section 13(1) of the Hessian Data Protection and Freedom of Information Act and by the SAs of Czech Republic and Lithuania acting as co-reviewers. The application was also circulated to all European Economic Area (EEA) SAs for further review and comments as part of the cooperation procedure.
3. The review concluded that the Controller BCRs of Fresenius Group comply with the requirements set out by Article 47(1) of the GDPR as well as the Working Document WP256 rev.01<sup>2</sup> and in particular that the aforementioned BCRs:
  - i) Are legally binding and contain a clear duty for each participating member of the Group including their employees to respect the BCRs by
    - (a) requiring all participating members of Fresenius Group to enter an intra-group agreement called Framework Agreement in which each participating member of Fresenius Group gives mutually legal binding commitments to implement and adhere to the BCRs as well as accept their enforcement and liability for any violation of the BCR (see Section 6.3 of the Framework Agreement and Section 4.1 of the Application Form); and
    - (b) requiring that the BCRs are incorporated in binding working instructions, contractual obligations set out in employment agreement, collective agreement (such as work council agreements) and/or binding internal policies (see Section 4.ii. of the BCR Policy and Section 4.1.1.2 of the Application Form);

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<sup>1</sup> Endorsed by the EDPB on 25 May 2018.

<sup>2</sup> Endorsed by the EDPB on 25 May 2018.

- ii) Expressly confer enforceable third party beneficiary rights to data subjects with regard to the processing of their personal data as part of the BCRs (see Sections 3.3, 3.4, 4, 6, 9, 10.1 and 10.3 of the BCR Policy and Section 4.2 of the Application Form);
  - iii) Fulfil the requirements laid down in Article 47(2) of the GDPR (see BCR Policy and Application Form).
4. The EDPB provided its opinion 10/2022 in accordance with Article 64(1)(f) of the GDPR. The Hessian SA took utmost account of this opinion.

DECIDES AS FOLLOWING:

5. The Controller BCRs of Fresenius Group provide appropriate safeguards for the transfer of personal data in accordance with Article 46(1) and (2)(b) and Article 47(1) and (2) of the GDPR and hereby the Hessian SA approves the Controller BCRs of Fresenius Group.
6. However, before making use of the BCRs, it is the responsibility of the data exporter in a Member State, if needed with the help of the data importer, to assess whether the level of protection required by EU law is respected in the third country of destination, including onward transfer situations. This assessment has to be conducted in order to determine if the guarantees provided by BCRs can be complied with in practice, in light of the circumstances of the possible impingement created by the third country legislation with the fundamental rights and the circumstances surrounding the transfer. If this is not the case, the data exporter in a Member State, if needed with the help of the data importer, should assess whether it can provide supplementary measures to ensure an essentially equivalent level of protection as provided in the EU.
7. Where the data exporter in a Member State is not able to implement supplementary measures necessary to ensure an essentially equivalent level of protection as provided in the EU, personal data cannot be lawfully transferred to a third country under these BCRs. Therefore, the data exporter is required to suspend or end the transfer of personal data.
8. The approved BCRs will not require any specific authorization from the concerned SAs.
9. In accordance with Article 58(2)(j) of the GDPR, each concerned SA maintains the power to order the suspension of data flows to a recipient in a third country or to an international organization whenever the appropriate safeguards envisaged by Controller BCRs of Fresenius Group are not respected.

## **ANNEX TO THE DECISION**

The Controller BCRs of Fresenius Group that are hereby approved cover the following:

a. Scope

Only members of Fresenius Group acting as Controllers, that are legally bound by the BCRs (see Section 3.2 and Schedule 1 of the BCR Policy and Annex 2 of the Application Form);

b. EEA countries from which transfers are to be made

Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Spain and Sweden (see Schedule 1 of the BCR Policy and Annex 2 of the Application Form);

c. Third countries to which transfers are to be made

Argentina, Australia, Brazil, Chile, China, Colombia, Dominican Republic, Egypt, Ecuador, Great Britain, Hong Kong, India, Japan, Korea, Mexico, New Zealand, Pakistan, Peru, Puerto Rico, Russian Federation, Serbia, South Africa, Switzerland, Thailand, Tunisia, Turkey, Uruguay, United Arab Emirates, United States of America (see Schedule 1 of the BCR Policy and Annex 2 of the Application Form);

d. Purposes of the transfer

(see Schedule 2 of the BCR Policy and Sections 2 and 7 of the Application Form);

e. Categories of data subjects concerned by the transfer

(see Schedule 2 of the BCR Policy and Sections 2 and 7 of the Application Form);

f. Categories of personal data transferred

(see Schedule 2 of the BCR Policy and Section 2.1 of the Application Form).

## **APPLICATION DOCUMENTS**

The attached application documents form part of this decision of approval:

1. Application Form WP 264 rev.01
2. BCR Policy
3. Referential WP 256 rev.01
4. Framework Agreement