

MEMORANDUM OF COOPERATION

between

**The Food Safety Commission of Japan and
the German Federal Institute for Risk Assessment**

The Food Safety Commission of Japan (FSCJ) and the German Federal Institute for Risk Assessment (BfR), hereinafter referred to individually as an “Organization” and jointly as the “Organizations”, having considered that it is necessary to promote scientific cooperation on data collection and data sharing related to risk assessment, accept the following terms for mutual cooperation:

1. Purpose and Nature

- a. The purpose of this Memorandum of Cooperation (MoC) is to enhance the scientific cooperation and dialogue between FSCJ and BfR in the fields of data collection and data sharing related to risk assessment in line with the scope of each Organization’s mission in this area (Article 17 of the Food Safety Basic Act (Act No. 48/2003) with regard to FSCJ, and Gesetz über die Errichtung eines Bundesinstituts für Risikobewertung (BfR-Gesetz, BfRG) with regard to BfR).
- b. This MoC does not imply any legal obligations.
- c. This MoC does not intend to compromise FSCJ’s or BfR’s ability to carry out their respective responsibilities neither does it intend to create any legal rights or obligations.

2. Items

FSCJ and BfR intend to provide mutual support and cooperation on each of the following items in accordance with relevant laws and regulations:

- a. Collection, analysis and sharing of technical information, materials and expertise in the fields of competence of the Organizations, such as:
 - Information on the role and mission of FSCJ in line with the Food Safety Basic Act (No. 48/2003);
 - Information on FSCJ's annual plans and programmes; and
 - Strategic plans, annual reports and other corporate documents as well as published data, or articles.
- b. Sharing views and expertise in the area of methodologies for data collection, risk assessment, risk monitoring and risk communication, such as:
 - Scientific outputs describing the methodologies and approaches used by FSCJ;
 - References to publications and reports and other sources of information and data (*e. g.* databases, monographs from other agencies *etc.*) which are taken into consideration for particular risk assessments of mutual interest; and
 - Information through short term visits (for periods up to a month) and through scientific events to better understand the Organization and the conduct of risk assessment in particular areas of mutual interest such as in the areas of chemical risk assessment and microbiological risk assessment.
- c. Strengthening the capacity building of professionals in each Organization in various forms including participation in specific trainings and scientific events, as well as hosting short term visits for executives and experts of each Organization as guest scientists.

3. Modalities

- a. Exchange of information may take place for the purpose of and in line with the paragraphs of this MoC. To facilitate this exchange of information, both Organizations will designate one staff member as coordinator for the maintenance of close, direct and continuing contacts with a view to ensuring the implementation of the paragraphs of this MoC. These coordinators will keep, and update as necessary, a list of contact persons for the main areas of collaboration.
- b. The data exchanged may only be shared with persons within each Organization who are bound by obligations of confidentiality as defined in their respective laws. This concerns the Organizations' staff and external scientific experts contributing to the preparation of the Organizations' scientific outputs.

- c. The exchange and treatment of information may be accepted, with regard to FSCJ in line with the Food Safety Basic Act (Act No. 48/2003), as well as the Act on Access to Information Held by Administrative Organs (Act No. 42/1999) on public access to documents, the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58/2003), and other relevant laws including the National Public Service Act (Act No. 120/1947) on the protection of personal data; with regard to BfR in line with Federal Act Governing Access to Information held by the Federal Government (IFG), Environmental Information Act (UIG), Consumer Information Act (VIG), Act on the Re-use of Public Sector Information (IWG) and Federal Data Protection Act (BDSG).
- d. An evaluation meeting can be held periodically to summarize progress on cooperation.

4. Confidentiality and Data Protection

- a. Each Organization may disclose non-public information related to products or substances that are in the field of its competence to the other Organization. If there is a risk of bringing detriment or undue benefit to a specific person and/or entity as a result of the disclosure, the written consent of a person and/or entity concerned is necessary in advance.
- b. BfR ensures that non-public information which is shared by FSCJ be treated in line with the contents in the Attachment of this MoC.
- c. Considering its purpose and nature detailed in paragraph 1 above, this MoC does not cover the processing of personal data. Should any personal data processing be envisaged in the context of this MoC, it should happen in full compliance with the legal framework on data protection applicable to both Organizations. For FSCJ, this implies that the conditions for transfers of personal data pursuant to the relevant article of the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58/2003) will be fully adhered to. For BfR, this implies that the conditions for transfers of personal data pursuant to Federal Act Governing Access to Information held by the Federal Government (IFG), Environmental Information Act (UIG), Consumer Information Act (VIG), Act on the Re-use of Public Sector Information (IWG) and Federal Data Protection Act (BDSG) will be fully adhered to.

5. Period of Cooperation

The cooperation described in this MoC will commence on the day on which it is signed by the representatives of the Organizations, and will continue for a period of five years. At the end of this period, the cooperation will continue for further period of five years, unless one of the agencies notifies the other in writing six months before the end of each period its intention to terminate the cooperation.

6. Termination

Notwithstanding the paragraph 5 above, the cooperation under this MoC will be terminated by notifying the other in writing its intention to terminate the cooperation in case of the occurrence of any special reasons by which the cooperation cannot be continued.

The representatives of the Organizations have signed this MoC.

Tokyo, 25 July 2016

Tokyo, 25 July 2016

<p>.....</p> <p>Hiroshi Satoh Chairperson Food Safety Commission of Japan</p>	<p>.....</p> <p>Andreas Hensel President German Federal Institute for Risk Assessment</p>
---	---

Attachment

Confidentiality Commitment From The German Federal Institute for Risk Assessment Concerning Non-public Information Shared By The Food Safety Commission Of Japan

The German Federal Institute for Risk Assessment (BfR) recognizes that some of the information it receives from the Food Safety Commission of Japan (FSCJ) may include non-public information exempt from public disclosure under the laws and regulations of Japan, such as confidential commercial information; trade secret information; personal data; law enforcement information; or internal, pre-decisional information. BfR recognizes that this non-public information is shared in confidence and that FSCJ considers it critical that BfR maintains the confidentiality of the information. Public disclosure of this information by BfR could seriously jeopardize any further scientific and regulatory interactions between FSCJ and BfR. BfR will advise FSCJ about the non-public status of the information at the time that the information is shared.

Therefore, BfR certifies that it:

1. has the authority to protect such non-public information provided to BfR in confidence by FSCJ from public disclosure;
2. will not publicly disclose such FSCJ-provided non-public information without a written consent of the owner of the information, a written consent from an individual who is the subject of the personal data, or a written statement from FSCJ that the information no longer has non-public status;
3. will inform FSCJ promptly of any effort made by a judicial or legislative mandate to obtain FSCJ-provided non-public information. If such a judicial or legislative mandate orders the disclosure of FSCJ-provided non-public information, BfR will take all appropriate measures in an effort to ensure that the information will be shared in a manner that protects the information from public disclosure; and
4. will promptly inform FSCJ of any changes to German laws, or to any relevant policies or procedures that would affect BfR's ability to implement the commitments in this document.

MEMORANDUM OF COOPERATION

between

**The German Federal Institute for Risk Assessment
and the Food Safety Commission of Japan**

The German Federal Institute for Risk Assessment (BfR) and the Food Safety Commission of Japan (FSCJ), hereinafter referred to individually as an "Organization" and jointly as the "Organizations", having considered that it is necessary to promote scientific cooperation on data collection and data sharing related to risk assessment, accept the following terms for mutual cooperation:

1. Purpose and Nature

- a. The purpose of this Memorandum of Cooperation (MoC) is to enhance the scientific cooperation and dialogue between BfR and FSCJ in the fields of data collection and data sharing related to risk assessment in line with the scope of each Organization's mission in this area (Gesetz über die Errichtung eines Bundesinstituts für Risikobewertung (BfR-Gesetz, BfRG) with regard to BfR, and Article 17 of the Food Safety Basic Act (Act No. 48/2003) with regard to FSCJ).
- b. This MoC does not imply any legal obligations.
- c. This MoC does not intend to compromise BfR's and FSCJ's ability to carry out their respective responsibilities neither does it intend to create any legal rights or obligations.

2. Items

BfR and FSCJ intend to provide mutual support and cooperation on each of the following items in accordance with relevant laws and regulations:

- a. Collection, analysis and sharing of technical information, materials and expertise in the fields of competence of the Organizations, such as:
 - Information on the role and mission of BfR in line with Gesetz über die Errichtung eines Bundesinstituts für Risikobewertung (BfR-Gesetz, BfRG);
 - Information on BfR's annual plans and programmes; and
 - Strategic plans, annual reports and other corporate documents as well as published data, or articles.
- b. Sharing views and expertise in the area of methodologies for data collection, risk assessment, risk monitoring and risk communication, such as:
 - Scientific outputs describing the methodologies and approaches used by BfR;
 - References to publications and reports and other sources of information and data (*e. g.* databases, monographs from other agencies *etc.*) which are taken into consideration for particular risk assessments of mutual interest; and
 - Information through short term visits (for periods up to a month) and through scientific events to better understand the Organization and the conduct of risk assessment in particular areas of mutual interest such as in the areas of chemical risk assessment and microbiological risk assessment.
- c. Strengthening the capacity building of professionals in each Organization in various forms including participation in specific trainings and scientific events, as well as hosting short term visits for executives and experts of each Organization as guest scientists.

3. Modalities

- a. Exchange of information may take place for the purpose of and in line with the paragraphs of this MoC. To facilitate this exchange of information, both Organizations will designate one staff member as coordinator for the maintenance of close, direct and continuing contacts with a view to ensuring the implementation of the paragraphs of this MoC. These coordinators will keep, and update as necessary, a list of contact persons for the main areas of collaboration.
- b. The data exchanged may only be shared with persons within each Organization who are bound by obligations of confidentiality as defined in their respective laws. This concerns the Organizations' staff and external scientific experts contributing to the preparation of the Organizations' scientific outputs.

- c. The exchange and treatment of information may be accepted, with regard to BfR in line with Federal Act Governing Access to Information held by the Federal Government (IFG), Environmental Information Act (UIG), Consumer Information Act (VIG), Act on the Re-use of Public Sector Information (IWG) and Federal Data Protection Act (BDSG); with regard to FSCJ in line with the Food Safety Basic Act (Act No. 48/2003), as well as the Act on Access to Information Held by Administrative Organs (Act No. 42/1999) on public access to documents, the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58/2003), and other relevant laws including the National Public Service Act (Act No. 120/1947) on the protection of personal data.
- d. An evaluation meeting can be held periodically to summarize progress on cooperation.

4. Confidentiality and Data Protection

- a. Each Organization may disclose non-public information related to products or substances that are in the field of its competence to the other Organization. If there is a risk of bringing detriment or undue benefit to a specific person and/or entity as a result of the disclosure, the written consent of a person and/or entity concerned is necessary in advance.
- b. FSCJ ensures that non-public information which is shared by BfR be treated in line with the contents in the Attachment of this MoC.
- c. Considering its purpose and nature detailed in paragraph 1 above, this MoC does not cover the processing of personal data. Should any personal data processing be envisaged in the context of this MoC, it should happen in full compliance with the legal framework on data protection applicable to both Organizations. For BfR, this implies that the conditions for transfers of personal data pursuant to Federal Act Governing Access to Information held by the Federal Government (IFG), Environmental Information Act (UIG), Consumer Information Act (VIG), Act on the Re-use of Public Sector Information (IWG) and Federal Data Protection Act (BDSG) will be fully adhered to. For FSCJ, this implies that the conditions for transfers of personal data pursuant to the relevant article of the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58/2003) will be fully adhered to.

5. Period of Cooperation

The cooperation described in this MoC will commence on the day on which it is signed by the representatives of the Organizations, and will continue for a period of five years. At the end of this period, the cooperation will continue for further period of five years, unless one of the agencies notifies the other in writing six months before the end of each period its intention to terminate the cooperation.

6. Termination

Notwithstanding the paragraph 5 above, the cooperation under this MoC will be terminated by notifying the other in writing its intention to terminate the cooperation in case of the occurrence of any special reasons by which the cooperation cannot be continued.

The representatives of the Organization have signed this MoC.

Tokyo, 25 July 2016

Tokyo, 25 July 2016

.....
Andreas Hensel President German Federal Institute for Risk Assessment	Hiroshi Satoh Chairperson Food Safety Commission of Japan

Attachment

Confidentiality Commitment From the Food Safety Commission Of Japan Concerning Non-public Information Shared By The German Federal Institute for Risk Assessment

The Food Safety Commission of Japan (FSCJ) recognizes that some of the information it receives from the German Federal Institute for Risk Assessment (BfR) may include non-public information exempt from public disclosure under the laws and regulations of Germany, such as confidential commercial information; trade secret information; personal data; law enforcement information; or internal, pre-decisional information. FSCJ recognizes that this non-public information is shared in confidence and that BfR considers it critical that FSCJ maintains the confidentiality of the information. Public disclosure of this information by FSCJ could seriously jeopardize any further scientific and regulatory interactions between BfR and FSCJ. FSCJ will advise BfR about the non-public status of the information at the time that the information is shared.

Therefore, FSCJ certifies that it:

1. has the authority to protect such non-public information provided to FSCJ in confidence by BfR from public disclosure;
2. will not publicly disclose such BfR-provided non-public information without a written consent of the owner of the information, a written consent from an individual who is the subject of the personal data, or a written statement from BfR that the information no longer has non-public status;
3. will inform BfR promptly of any effort made by a judicial or legislative mandate to obtain BfR-provided non-public information. If such a judicial or legislative mandate orders the disclosure of BfR-provided non-public information, FSCJ will take all appropriate measures in an effort to ensure that the information will be shared in a manner that protects the information from public disclosure; and
4. will promptly inform BfR of any changes to the Japanese laws, or to any relevant policies or procedures that would affect FSCJ's ability to implement the commitments in this document.