U.S.-EU Safe Harbor Framework

A Guide to Self-Certification
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Introduction

Welcome to the U.S.-European Union (EU) Safe Harbor Framework: A Guide to Certification. From this guide, it is our hope that U.S. companies will have a better understanding of the process of self-certification and the resources available to self-certify compliance with the EU’s Directive on Data Protection. Additional information may be found on our website: http://export.gov/safeharbor/

In this guide, we have provided an outline of the most critical pieces of the Safe Harbor Framework. The application is made available, along with a Helpful Hints Guide that explains how to fill it out. The Safe Harbor Principles and FAQs are also provided for easy reference. There is also an explanation and listing of third party dispute resolution providers (or Independent Resource Mechanisms) with descriptions of the services provided by three dispute resolution providers that work with Safe Harbor. Finally, we’ve also included several sample company privacy policies for reference, and a glossary that explains key terms. We’ve broken this Guide into nine major sections, each to address different questions you might have. What follows is a brief description of each section:

Overview: The overview gives some background on the Safe Harbor Framework, how it came about, and explains many of the certification requirements. The overview also lists the principles of the Safe Harbor program.

Application: The Application is provided for easy reference. Applicants should apply online at http://export.gov/safeharbor (click on “Certification Form” in the right sidebar).

Certification Mark: The Commerce Department’s International Trade Administration has recently developed a certification mark for the Safe Harbor Framework. The mark may be used by companies on their websites to signify that they have self-certified compliance with the provisions of the Safe Harbor Framework. Instructions for use of the certification mark are provided.

Helpful Hints Guide (to Certification): The Helpful Hints Guide is meant to give quick answers to any questions a U.S. company might have about the certification process. It should be used in conjunction with the rest of the Guide, however it answers many of the most common questions about the certification process.

Safe Harbor Principles: We have provided the full text of the official declaration of the Safe Harbor Principles as announced on July 21, 2000. This text is helpful for understanding the foundation of the Safe Harbor Principles and the Framework.
Frequently Asked Questions: We have provided the Frequently Asked Questions in full text because they answer many of the most commonly asked questions about the Safe Harbor Framework.

Dispute Resolution Providers: Here we have provided a short description of the role of dispute resolution providers (also referred to as Independent Recourse Mechanisms) and descriptions of the services they offer.

Sample Privacy Policies: Here we have provided three sample privacy policies for reference, which may serve as guidance when creating a new Privacy Policy or updating an existing Privacy Policy to align it with the Safe Harbor Framework. The Safe Harbor Framework requires an affirmative commitment in the Privacy Policy to the principles of the Safe Harbor Framework.

Glossary: A short glossary is also provided for many of the technical terms frequently used in the Guide.

Safe Harbor Overview

Background on the Safe Harbor

When the European Commission’s Directive on Data Protection went into effect in October of 1998, one consequence was to prohibit the transfer of personal data to non-European Union nations that failed to meet the European “adequacy” standard for privacy protection. While the United States and the European Union share the goal of enhancing privacy protection for their citizens, the United States takes a different approach to privacy than that taken by the European Union. To bridge these different privacy approaches and provide a streamlined and cost-effective means for U.S. organizations to satisfy the adequacy requirement of the Directive, the U.S. Department of Commerce in consultation with the European Commission (EC) developed a “Safe Harbor” framework and a website to provide the information an organization would need to evaluate – and then join – the Safe Harbor.

Approved by the EC in 2000, the Safe Harbor Framework helps protect U.S. companies from experiencing interruptions in their business dealings with the EU. Self-certifying to the Safe Harbor will assure that EU organizations know that your company provides “adequate” privacy protection, as defined by the EU Directive.

Safe Harbor Benefits

The Safe Harbor Framework provides a number of important benefits to U.S. and EU firms. Benefits for U.S. organizations participating in the Safe Harbor include:

- All 27 Member States of the European Union will be bound by the European Commission’s finding of adequacy;
- Companies participating in the Safe Harbor will be deemed adequate and data flows to those companies will continue;
- Member State requirements for prior approval of data transfers either will be waived or approval will be automatically granted; and
- Claims brought by European citizens against U.S. companies will be heard in the United States subject to limited exceptions.

The Safe Harbor Framework offers a simpler and cheaper means of complying with the adequacy requirements of the Directive, which should particularly benefit small and medium-sized enterprises.
An EU organization can ensure that it is sending information to a U.S. organization participating in the Safe Harbor by viewing the public list of Safe Harbor organizations posted on the Safe Harbor website: http://export.gov/safeharbor/ (click on “Safe Harbor List” in the right sidebar). This list contains the names of all U.S. companies that have self-certified to the Safe Harbor Framework. This list is updated regularly.

How does an organization join?
The decision by U.S. organizations to enter the Safe Harbor is entirely voluntary. Organizations that decide to participate in the Safe Harbor must comply with the Safe Harbor’s requirements and publicly declare that they do so. To be assured of Safe Harbor benefits, an organization needs to self-certify annually to the Department of Commerce in writing that it agrees to adhere to the Safe Harbor’s requirements, which include elements such as notice, choice, access, and enforcement. It must also state in its published privacy policy statement that it adheres to the Safe Harbor. The Department of Commerce will maintain a list of all organizations that file self-certification letters and make both the list and the self-certification letters publicly available.

To qualify for the Safe Harbor, an organization can (1) join a self-regulatory privacy program that adheres to the Safe Harbor’s requirements; or (2) develop its own self-regulatory privacy policy that conforms to the Safe Harbor. Further, the organization must be subject to the jurisdiction either of the Federal Trade Commission (FTC) or, with respect to air carriers and ticket agents, the Department of Transportation (DOT). The FTC and DOT have authority to take enforcement action against organizations that state they are in compliance with the Safe Harbor framework but then fail to live up to their statements. Organizations currently ineligible for Safe Harbor include financial institutions, including banks, investment houses, credit unions, savings & loan institutions, non-profit organizations, insurance companies and meat processing facilities.

What do the Safe Harbor principles require?
Organizations must comply with the seven Safe Harbor principles. The principles require the following:

1. Notice
Organizations must notify individuals about the purposes for which they collect and use information about them. They must provide information about how individuals can contact the organization with any inquiries or complaints, the types of third parties to which they disclose the information and the choices and means the organization offers for limiting its use and disclosure.

2. Choice
Organizations must give individuals the opportunity to choose (opt out) whether their personal information will be disclosed to a third party or used for a purpose incompatible with the purpose for which it was originally collected or subsequently authorized by the individual. For sensitive information, affirmative or explicit (opt in) choice must be given if the information is to be disclosed to a third party or used for a purpose other than its original purpose or the purpose authorized subsequently by the individual.

3. Onward Transfer (Transfers to Third Parties)
To disclose information to a third party, organizations must apply the notice and choice principles. Where an organization wishes to transfer information to a third party that is acting as an agent, it may do so if it makes sure that the third party subscribes to the Safe Harbor principles or is subject to the Directive or another adequacy finding. As an alternative, the organization can enter into a written agreement with such third party requiring that the third party provide at least the same level of privacy protection as is required by the relevant principles.

4. Access
Individuals must have access to personal information about themselves that an organization holds and be able to correct, amend, or delete that information where it is inaccurate, except where the burden or expense of providing access would be disproportionate to the risks to the individual’s privacy in the case in question, or where the rights of persons other than the individual would be violated.

5. Security
Organizations must take reasonable precautions to protect personal information from loss, misuse and unauthorized access, disclosure, alteration and destruction.

6. Data integrity
Personal information must be relevant for the purposes for which it is to be used. An organization should take reasonable steps to ensure that data is reliable for its intended use, accurate, complete, and current.

7. Enforcement
In order to ensure compliance with the Safe Harbor principles, there must be (a) readily available and affordable independent recourse mechanisms so that each individual’s complaints and disputes can be investigated and
Helpful Hints Guide

This section contains a succinct guide to assist you with the self-certification process for Safe Harbor. It functions as a checklist of questions and a to-do list to help determine your firm’s readiness to begin the certification process. Topics include considering whether your firm falls under the jurisdiction of the U.S. Federal Trade Commission or Department of Transportation; developing a Safe Harbor compliant privacy policy statement; establishing your organization’s independent recourse mechanism, and ensuring it is in place; and designating a contact point within your organization regarding Safe Harbor. This section should be used in conjunction with the rest of the Guide, and the requirements for self-certification detailed in #6, of the FAQs; however it answers many common questions surrounding the certification process.

Helpful Hints Prior to Self-Certifying to the Safe Harbor

1. Confirm That Your Organization is subject to the Jurisdiction of Either the U.S. Federal Trade Commission of the U.S. Department of Transportation:

   Any U.S. organization that is subject to the jurisdiction of the Federal Trade Commission (FTC) or U.S. air carriers and ticket agents subject to the jurisdiction of the Department of Transportation (DoT) may participate in the Safe Harbor. The FTC and DoT have both stated in letters to the European Commission (located under http://export.gov/safeharbor/SH_Documents.asp Letters G & H) that they can take enforcement action against organizations that state that they are in compliance with the Safe Harbor, but then fail to live up to their statements. If you are uncertain as to whether your organization falls under the jurisdiction of either the FTC or DoT, be sure to contact those agencies for more information.

2. Develop a Safe Harbor Compliant Privacy Policy Statement:

   Remember to develop a Safe Harbor compliant privacy policy statement before submitting a self-certification form to the Department of Commerce.

   • Make Sure That Your Privacy Policy Statement Conforms to the Safe Harbor Principles: In order for a privacy policy to be compliant with the Safe Harbor, the privacy policy statement must conform to the seven Privacy Principles and any relevant points that are covered in the Frequently Asked Questions (FAQs) - located in Appendix C or online at: http://export.gov/safeharbor/SH_Documents.asp. In addition, the privacy policy statement should reflect your actual and anticipated information handling practices. It is also important to write a policy that is clear, concise and easy to understand.

For an overview, please visit:

http://www.export.gov/safeharbor/SH_Overview.asp
The U.S.–EU Safe Harbor Guide to Self-Certification

1. Make Specific Reference to Your Organization’s Safe Harbor Adherence in the Text of Your Organization’s Privacy Policy: FAQ 6 requires all organizations that self-certify to state in their relevant published privacy policy statements that they adhere to the Safe Harbor Principles (Appendix B).

2. Provide an Accurate Privacy Policy Statement Location and Make Sure That Your Privacy Policy Statement is Available to the Public:

At the time of self-certification, all organizations must provide an accurate and publicly available location for their applicable privacy statement. If your organization decides to post its privacy policy statement on an Internet or Intranet site, it must provide an accurate link to the statement on the organization’s Safe Harbor self-certification form. In addition, the organization should verify that its privacy policy statement is effective prior to self-certification.

4. Ensure That Your Organization’s Verification Mechanism is in Place:

As discussed in FAQ 7, organizations self-certifying to Safe Harbor are required to have procedures in place for verifying compliance. To meet this requirement, an organization may use a self-assessment or an outside/third-party assessment program. For additional guidance on the Safe Harbor’s verification requirement, please see FAQ 7.

5. Designate a Contact Point Within Your Organization Regarding Safe Harbor:

Each organization is required to provide a contact point for the handling of questions, complaints, access requests, and any other issues arising under the Safe Harbor. This contact point can be either the corporate officer that is certifying the company’s adherence to Safe Harbor, or another official within the organization, such as a Chief Privacy Officer.

The following is the official declaration of the Safe Harbor Principles as announced on July 21, 2000.

The Safe Harbor was founded on seven principles designed to ensure effective privacy protections in a framework that functions both in the European and U.S. privacy contexts. These seven principles include notice; choice; onward transfers to third parties; security; data integrity; access; and enforcement.

5. Establish Your Organization’s Independent Recourse Mechanism:

Under the Safe Harbor’s Enforcement Principle, organizations self-certifying to Safe Harbor must establish an independent recourse mechanism available to investigate unresolved complaints. (See FAQ 11 for more information regarding dispute resolution under Safe Harbor.) The organization must ensure that its recourse mechanism is in place prior to self-certification.

In most cases, organizations self-certifying to Safe Harbor may choose to utilize private sector dispute resolution programs. While programs vary, organizations like BBB OnLine, TRUSTe, AICPA WebTrust, the Direct Marketing Association, the Entertainment Software Rating Board, JAMS and the American Arbitration Association have developed programs that assist in compliance with the Safe Harbor’s enforcement principle and FAQ 11.

Alternatively, organizations may choose to cooperate and comply with the European Data Protection Authorities (DPAs). In doing so, the organization must follow the procedures outlined in FAQ 5. If human resources data is being covered in the organization’s self-certification, the organization must agree to cooperate and comply with the DPAs for purposes of handling unresolved complaints. Additional guidance for the handling of human resources data under the Safe Harbor is provided in FAQ 9.

Please note that organizations who choose to utilize the European Data Protection Authorities for dispute resolution will be required to pay an annual fee of US $50 in order to cover the operating costs of the Data Protection Authorities’ panel. This fee is payable to the United States Council for International Business (c/o Mr. Paul Cronin, U.S. Council for International Business (USCIB); 1212 Avenue of the Americas; New York, NY 10036), which has agreed to act as trusted third party for this purpose.

Please see FAQ 5 for more details regarding the role of the Data Protection Authorities. Should you need further information on how to carry out the payment, please contact Mr. Paul Cronin, USCIB, at 212-703-5088, or pcronin@uscib.org. If, on the other hand, you require more information on how the cooperation/compliance with the EU DPAs works, you should contact the Secretariat of the Data Protection Panel at ec-ddpanel-secr@cec.eu.int.
Safe Harbor Privacy Principles

Issued by the U.S. Department of Commerce on July 21, 2000

The European Union’s comprehensive privacy legislation, the Directive on Data Protection (the Directive), became effective on October 25, 1998. It requires that transfers of personal data take place only to non-EU countries that provide an “adequate” level of privacy protection. While the United States and the European Union share the goal of enhancing privacy protection for their citizens, the United States takes a different approach to privacy from that taken by the European Union. The United States uses a sectoral approach that relies on a mix of legislation, regulation, and self-regulation. Given those differences, many U.S. organizations have expressed uncertainty about the impact of the EU-required “adequacy standard” on personal data transfers from the European Union to the United States.

To diminish this uncertainty and provide a more predictable framework for such data transfers, the Department of Commerce is issuing this document and Frequently Asked Questions (“the Principles”) under its statutory authority to foster, promote, and develop international commerce. The Principles were developed in consultation with industry and the general public to facilitate trade and commerce between the United States and European Union. They are intended for use solely by U.S. organizations receiving personal data from the European Union for the purpose of qualifying for the Safe Harbor and the presumption of “adequacy” it creates. Because the Principles were solely designed to serve this specific purpose, their adoption for other purposes may be inappropriate. The Principles cannot be used as a substitute for national provisions implementing the Directive that apply to the processing of personal data in the Member States.

Decisions by organizations to qualify for the Safe Harbor are entirely voluntary, and organizations may qualify for the Safe Harbor in different ways. Organizations that decide to adhere to the Principles must comply with the Principles in order to obtain and retain the benefits of the Safe Harbor and publicly declare that they do so. For example, if an organization joins a self-regulatory privacy program that adheres to the Principles, it qualifies for the Safe Harbor. Organizations may also qualify by developing their own self-regulatory privacy policies provided that they conform with the Principles. Where in complying with the Principles, an organization relies in whole or in part on self-regulation, its failure to comply with such self-regulation must also be actionable under Section 5 of the Federal Trade Commission Act prohibiting unfair and deceptive acts or another law or regulation prohibiting such acts. (See the annex for the list of U.S. statutory bodies recognized by the EU.) In addition, organizations subject to a statutory, regulatory, administrative or other body of law (or of rules) that effectively protects personal privacy may also qualify for Safe Harbor benefits. In all instances, Safe Harbor benefits are assured from the date on which each organization wishing to qualify for the Safe Harbor self-certifies to the Department of Commerce (or its designee) its adherence to the Principles in accordance with the guidance set forth in the Frequently Asked Question on Self-Certification.

Adherence to these Principles may be limited: (a) to the extent necessary to meet national security, public interest, or law enforcement requirements; (b) by statute, government regulation, or case law that create conflicting obligations or explicit authorizations, provided that, in exercising any such authorization, an organization can demonstrate that its non-compliance with the Principles is limited to the extent necessary to meet the overriding legitimate interests furthered by such authorization; or (c) if the effect of the Directive or Member State law is to allow exceptions or derogations, provided such exceptions or derogations are applied in comparable contexts. Consistent with the goal of enhancing privacy protection, organizations should strive to implement these Principles fully and transparently, including indicating in their privacy policies where exceptions to the Principles permitted by (b) above will apply on a regular basis. For the same reason, where the option is allowable under the Principles and/or U.S. law, organizations are expected to opt for the higher protection where possible.

Organizations may wish for practical or other reasons to apply the Principles to all their data processing operations, but they are only obligated to apply them to data transferred after they enter the Safe Harbor. To qualify for the Safe Harbor, organizations are not obligated to apply these Principles to personal information in manually processed filing systems. Organizations wishing to benefit from the Safe Harbor for receiving information in manually processed filing systems from the EU must apply the Principles to any such information transferred after they enter the Safe Harbor. An organization that wishes to extend Safe Harbor benefits to human resources personal information transferred from the EU for use in the context of an employment relationship must indicate this when it self-certifies to the Department of Commerce (or its designee) and conform to the requirements...
set forth in the Frequently Asked Question on Self-Certification. Organizations will also be able to provide the safeguards necessary under Article 26 of the Directive if they include the Principles in written agreements with parties transferring data from the EU for the substantive privacy provisions, once the other provisions for such model contracts are authorized by the Commission and the Member States.

U.S. law will apply to questions of interpretation and compliance with the Safe Harbor Principles (including the Frequently Asked Questions) and relevant privacy policies by Safe Harbor organizations, except where organizations have committed to cooperate with European Data Protection Authorities. Unless otherwise stated, all provisions of the Safe Harbor Principles and Frequently Asked Questions apply where they are relevant.

“Personal data” and “personal information” are data about an identified or identifiable individual that are within the scope of the Directive, received by a U.S. organization from the European Union, and recorded in any form.

**Notice:** An organization must inform individuals about the purposes for which it collects and uses information about them, how to contact the organization with any inquiries or complaints, the types of third parties to which it discloses the information, and the choices and means the organization offers individuals for limiting its use and disclosure. This notice must be provided in clear and conspicuous language when individuals are first asked to provide personal information to the organization or as soon thereafter as is practicable, but in any event before the organization uses such information for a purpose other than that for which it was originally collected or processed by the transferring organization or discloses it for the first time to a third party.

**Choice:** An organization must offer individuals the opportunity to choose (opt out) whether their personal information is (a) to be disclosed to a third party or (b) to be used for a purpose that is incompatible with the purpose(s) for which it was originally collected or subsequently authorized by the individual. Individuals must be provided with clear and conspicuous, readily available, and affordable mechanisms to exercise choice.

For sensitive information (i.e., personal information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), they must be given affirmative or explicit (opt in) choice if the information is to be disclosed to a third party or used for a purpose other than those for which it was originally collected or subsequently authorized by the individual through the exercise of opt in choice. In any case, an organization should treat as sensitive any information received from a third party where the third party treats and identifies it as sensitive.

**Onward Transfer:** To disclose information to a third party, organizations must apply the Notice and Choice Principles. Where an organization wishes to transfer information to a third party that is acting as an agent, as described in the endnote, it may do so if it first either ascertains that the third party subscribes to the Principles or is subject to the Directive or another adequacy finding or enters into a written agreement with such third party requiring that the third party provide at least the same level of privacy protection as is required by the relevant Principles. If the organization complies with these requirements, it shall not be held responsible (unless the organization agrees otherwise) when a third party to which it transfers such information processes it in a way contrary to any restrictions or representations, unless the organization knew or should have known the third party would process it in such a contrary way and the organization has not taken reasonable steps to prevent or stop such processing.

**Security:** Organizations creating, maintaining, using or disseminating personal information must take reasonable precautions to protect it from loss, misuse and unauthorized access, disclosure, alteration and destruction.

**Data Integrity:** Consistent with the Principles, personal information must be relevant for the purposes for which it is to be used. An organization may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual. To the extent necessary for those purposes, an organization should take reasonable steps to ensure that data is reliable for its intended use, accurate, complete, and current.

**Access:** Individuals must have access to personal information about them that an organization holds and be able to correct, amend, or delete that information where it is inaccurate, except where the burden or expense of providing access would be disproportionate to the risks to the individual’s privacy in the case in question, or where the rights of persons other than the individual would be violated.

**Enforcement:** Effective privacy protection must include mechanisms for assuring compliance with the Principles, recourse for individuals to whom the data relate affected by non-compliance with the Principles, and consequences for the organization when the Principles are not followed. At a minimum, such
mechanisms must include (a) readily available and affordable independent recourse mechanisms by which each individual’s complaints and disputes are investigated and resolved by reference to the Principles and damages awarded where the applicable law or private sector initiatives so provide; (b) follow up procedures for verifying that the attestations and assertions businesses make about their privacy practices are true and that privacy practices have been implemented as presented; and (c) obligations to remedy problems arising out of failure to comply with the Principles by organizations announcing their adherence to them and consequences for such organizations. Sanctions must be sufficiently rigorous to ensure compliance by organizations.

1. It is not necessary to provide notice or choice when disclosure is made to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of the organization. The Onward Transfer Principle, on the other hand, does apply to such disclosures.

Safe Harbor Framework

The following section contains frequently asked questions (FAQs) regarding the Safe Harbor Framework. Divided into fifteen (15) sections, these represent the most commonly asked questions covering the rights of data subjects; obligations and interactions between data subjects, handlers and third parties; and topics including the certification process, liabilities and enforcement, sector-specific rules and exceptions, and potential “what ifs” in the Safe Harbor context.

Safe Harbor Framework Frequently Asked Questions (FAQs)

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I. Sensitive Data
Q: Must an organization always provide explicit (opt in) choice with respect to sensitive data?
A: No, such choice is not required where the processing is: (1) in the vital interests of the data subject or another person; (2) necessary for the establishment of legal claims or defenses; (3) required to provide medical care or diagnosis; (4) carried out in the course of legitimate activities by a foundation, association or any other non-profit body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to the persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects; (5) necessary to carry out the organization’s obligations in the field of employment law; or (6) related to data that are manifestly made public by the individual.

II. Journalistic Exceptions
Q: Given U.S. constitutional protections for freedom of the press and the Directive’s exemption for journalistic material, do the Safe Harbor Principles apply to personal information gathered, maintained, or disseminated for journalistic purposes?
A: Where the rights of a free press embodied in the First Amendment of the U.S. Constitution intersect with privacy protection interests, the First Amendment must govern the balancing of these interests with regard to the activities of U.S. persons or organizations. Personal information that is gathered for publication, broadcast, or other forms of public communication of journalistic material, whether used or not, as well as information found in previously published material disseminated from media archives, is not subject to the requirements of the Safe Harbor Principles.

III. Secondary Liability
Q: Are Internet service providers (ISPs), telecommunications carriers, or other organizations liable under the Safe Harbor Principles when on behalf of another organization they merely transmit, route, switch or cache information that may violate their terms?
A: No. As is the case with the Directive itself, the Safe Harbor does not create secondary liability. To the extent that an organization is acting as a mere conduit for data transmitted by third parties and does not determine the purposes and means of processing those personal data, it would not be liable.

IV. Investment banking and audits
Q: The activities of auditors and investment bankers may involve processing personal data without the consent or knowledge of the individual. Under what circumstances is this permitted by the Notice, Choice, and Access Principles?
A: Investment bankers or auditors may process information without knowledge of the individual only to the extent and for the period necessary to meet statutory or public interest requirements and in other circumstances in which the application of these Principles would prejudice the legitimate interests of the organization. These legitimate interests include the monitoring of companies’ compliance with their legal obligations and legitimate accounting activities, and the need for confidentiality connected with possible acquisitions, mergers, joint ventures, or other similar transactions carried out by investment bankers or auditors.

V. The Role of the Data Protection Authorities
Q: How will companies that commit to cooperate with European Union Data Protection Authorities (DPAs) make those commitments and how will they be implemented?
A: Under the Safe Harbor, U.S. organizations receiving personal data from the EU must commit to employ effective mechanisms for assuring compliance with the Safe Harbor Principles. More specifically as set out in the Enforcement Principle, they must provide (a) recourse for individuals to whom the data relate, (b) follow up procedures for verifying that the attestations and assertions they have made about their privacy practices are true, and (c) obligations to remedy problems arising out of failure to comply with the Principles and consequences for such organizations. An organization may satisfy points (a) and (c) of the Enforcement Principle if it adheres to the requirements of this FAQ for cooperating with the DPAs.

An organization may commit to cooperate with the DPAs by declaring in its Safe Harbor certification to the Department of Commerce (see FAQ 6 on self-certification) that the organization:
1. Elects to satisfy the requirement in points (a) and (c) of the Safe Harbor Enforcement Principle by committing to cooperate with the DPAs;
2. Will cooperate with the DPAs in the investigation and resolution of complaints brought under the Safe Harbor; and
3. Will comply with any advice given by the DPAs where the DPAs take the view that the organization needs to take specific action to comply with
the Safe Harbor Principles, including remedial or compensatory measures for the benefit of individuals affected by any non-compliance with the Principles, and will provide the DPAs with written confirmation that such action has been taken.

The cooperation of the DPAs will be provided in the form of information and advice in the following way:

- The advice of the DPAs will be delivered through an informal panel of DPAs established at the European Union level, which will inter alia help ensure a harmonised and coherent approach.

- The panel will provide advice to the U.S. organizations concerned on unresolved complaints from individuals about the handling of personal information that has been transferred from the EU under the Safe Harbor. This advice will be designed to ensure that the Safe Harbor Principles are being correctly applied and will include any remedies for the individual(s) concerned that the DPAs consider appropriate.

- The panel will provide such advice in response to referrals from the organizations concerned and/or to complaints received directly from individuals against organizations which have committed to cooperate with DPAs for Safe Harbor purposes, while encouraging and if necessary helping such individuals in the first instance to use the in-house complaint handling arrangements that the organization may offer.

- Advice will be issued only after both sides in a dispute have had a reasonable opportunity to comment and to provide any evidence they wish. The panel will seek to deliver advice as quickly as this requirement for due process allows. As a general rule, the panel will aim to provide advice within 60 days after receiving a complaint or referral and more quickly where possible.

- The panel will make public the results of its consideration of complaints submitted to it, if it sees fit.

- The delivery of advice through the panel will not give rise to any liability for the panel or for individual DPAs.

As noted above, organizations choosing this option for dispute resolution must undertake to comply with the advice of the DPAs. If an organization fails to comply within 25 days of the delivery of the advice and has offered no satisfactory explanation for the delay, the panel will give notice of its intention either to submit the matter to the Federal Trade Commission or other U.S. federal or state body with statutory powers to take enforcement action in cases of deception or misrepresentation, or to conclude that the agreement to cooperate has been seriously breached and must therefore be considered null and void. In the latter case, the panel will inform the Department of Commerce (or its designee) so that the list of Safe Harbor participants can be duly amended. Any failure to fulfill the undertaking to cooperate with the DPAs, as well as failures to comply with the Safe Harbor Principles, will be actionable as a deceptive practice under Section 5 of the FTC Act or other similar statute.

Organizations choosing this option will be required to pay an annual fee which will be designed to cover the operating costs of the panel, and they may additionally be asked to meet any necessary translation expenses arising out of the panel’s consideration of referrals or complaints against them. The annual fee will not exceed $500 and will be less for smaller companies.

The option of co-operating with the DPAs will be available to organizations joining the Safe Harbor during a three-year period. The DPAs will reconsider this arrangement before the end of that period if the number of U.S. organizations choosing this option proves to be excessive.

VI. Self-Certification

Q: How does an organization self-certify that it adheres to the Safe Harbor Principles?

A: Safe Harbor benefits are assured from the date on which an organization self-certifies to the Department of Commerce (or its designee) its adherence to the Principles in accordance with the guidance set forth below.

To self-certify for the Safe Harbor, organizations can provide to the Department of Commerce (or its designee) a letter, signed by a corporate officer on behalf of the organization that is joining the Safe Harbor, that contains at least the following information:

1. name of organization, mailing address, email address, telephone and fax numbers;

2. description of the activities of the organization with respect to personal information received from the EU; and description of the organization’s privacy policy for such personal information, including:
   a. where the privacy policy is available for viewing by the public,
   b. its effective date of implementation,
   c. a contact office for the handling of complaints, access requests, and any other issues arising under the Safe Harbor,
An organization does not need to subject all personal information to the Safe Harbor Principles, but it must subject to the Safe Harbor Principles all personal data received from the EU after it joins the Safe Harbor.

Any misrepresentation to the general public concerning an organization’s adherence to the Safe Harbor Principles may be actionable by the Federal Trade Commission or other relevant government body. Misrepresentations to the Department of Commerce (or its designee) may be actionable under the False Statements Act (18 U.S.C. § 1001).

*See FAQ 7 on verification

VII. Verification

Q: How do organizations provide follow up procedures for verifying that the attestations and assertions they make about their Safe Harbor privacy practices are true and those privacy practices have been implemented as represented and in accordance with the Safe Harbor Principles?

A: To meet the verification requirements of the Enforcement Principle, an organization may verify such attestations and assertions either through self-assessment or outside compliance reviews.

Under the self-assessment approach, such verification would have to indicate that an organization’s published privacy policy regarding personal information received from the EU is accurate, comprehensive, prominently displayed, completely implemented and accessible. It would also need to indicate that its privacy policy conforms to the Safe Harbor Principles; that individuals are informed of any in-house arrangements for handling complaints and of the independent mechanisms through which they may pursue complaints; that it has in place procedures for training employees in its implementation, and disciplining them for failure to follow it; and that it has in place internal procedures for periodically conducting objective reviews of compliance with the above. A statement verifying the self-assessment should be signed by a corporate officer or other authorized representative of the organization at least once a year and made available upon request by individuals or in the context of an investigation or a complaint about non-compliance.
Rather, experience has shown that in responding to individuals’ access requests, organizations should first be guided by the concern(s) that led to the requests in the first place. For example, if an access request is vague or broad in scope, an organization may engage the individual in a dialogue so as to better understand the motivation for the request and to locate responsive information. The organization might inquire about which part(s) of the organization the individual interacted with and/or about the nature of the information (or its use) that is the subject of the access request. Individuals do not, however, have to justify requests for access to their own data.

Expense and burden are important factors and should be taken into account but they are not controlling in determining whether providing access is reasonable. For example, if the information is used for decisions that will significantly affect the individual (e.g., the denial or grant of important benefits, such as insurance, a mortgage, or a job), then consistent with the other provisions of these FAQs, the organization would have to disclose that information even if it is relatively difficult or expensive to provide.

If the information requested is not sensitive or not used for decisions that will significantly affect the individual (e.g., non-sensitive marketing data that is used to determine whether or not to send the individual a catalog), but is readily available and inexpensive to provide, an organization would have to provide access to factual information that the organization stores about the individual. The information concerned could include facts obtained from the individual, facts gathered in the course of a transaction, or facts obtained from others that pertain to the individual.

Consistent with the fundamental nature of access, organizations should always make good faith efforts to provide access. For example, where certain information needs to be protected and can be readily separated from other information subject to an access request, the organization should redact the protected information and make available the other information. If an organization determines that access should be denied in any particular instance, it should provide the individual requesting access with an explanation of why it has made that determination and a contact point for any further inquiries.

**2. Q: What is confidential commercial information and may organizations deny access in order to safeguard it?**

A: Confidential commercial information (as that term is used in the Federal Rules of Civil Procedure on discovery) is information which an
The U.S.–EU Safe Harbor Guide to Self-Certification

organization has taken steps to protect from disclosure, where disclosure would help a competitor in the market. The particular computer program an organization uses, such as a modeling program, or the details of that program may be confidential commercial information. Where confidential commercial information can be readily separated from other information subject to an access request, the organization should redact the confidential commercial information and make available the non-confidential information. Organizations may deny or limit access to the extent that granting it would reveal its own confidential commercial information as defined above, such as marketing inferences or classifications generated by the organization, or the confidential commercial information of another where such information is subject to a contractual obligation of confidentiality in circumstances where such an obligation of confidentiality would normally be undertaken or imposed.

3. Q: In providing access, may an organization disclose to individuals personal information about them derived from its data bases or is access to the data base itself required?

A: Access can be provided in the form of disclosure by an organization to the individual and does not require access by the individual to an organization’s data base.

4. Q: Does an organization have to restructure its data bases to be able to provide access?

A: Access needs to be provided only to the extent that an organization stores the information. The access principle does not itself create any obligation to retain, maintain, reorganize, or restructure personal information files.

5. Q: These replies make clear that access may be denied in certain circumstances. In what other circumstances may an organization deny individuals access to their personal information?

A: Such circumstances are limited, and any reasons for denying access must be specific. An organization can refuse to provide access to information to the extent that disclosure is likely to interfere with the safeguarding of important countervailing public interests, such as national security; defense; or public security. In addition, where personal information is processed solely for research or statistical purposes, access may be denied. Other reasons for denying or limiting access are:

a. interference with execution or enforcement of the law, including the prevention, investigation or detection of offenses or the right to a fair trial;
b. interference with private causes of action, including the prevention, investigation or detection of legal claims or the right to a fair trial;
c. disclosure of personal information pertaining to other individual(s) where such references cannot be redacted;
d. breaching a legal or other professional privilege or obligation;
e. breaching the necessary confidentiality of future or ongoing negotiations, such as those involving the acquisition of publicly quoted companies;
f. prejudicing employee security investigations or grievance proceedings;
g. prejudicing the confidentiality that may be necessary for limited periods in connection with employee succession planning and corporate re-organizations; or
h. prejudicing the confidentiality that may be necessary in connection with monitoring, inspection or regulatory functions connected with sound economic or financial management; or
i. other circumstances in which the burden or cost of providing access would be disproportionate or the legitimate rights or interests of others would be violated.

An organization which claims an exception has the burden of demonstrating its applicability (as is normally the case). As noted above, the reasons for denying or limiting access and a contact point for further inquiries should be given to individuals.

6. Q: Can an organization charge a fee to cover the cost of providing access?

A: Yes. The OECD Guidelines recognize that organizations may charge a fee, provided that it is not excessive. Thus organizations may charge a reasonable fee for access. Charging a fee may be useful in discouraging repetitive and vexatious requests.

Organizations that are in the business of selling publicly available information may thus charge the organization’s customary fee in responding to requests for access. Individuals may alternatively seek access to their information from the organization that originally compiled the data.
Access may not be refused on cost grounds if the individual offers to pay the costs.

7. Q: Is an organization required to provide access to personal information derived from public records?

A: To clarify first, public records are those records kept by government agencies or entities at any level that are open to consultation by the public in general. It is not necessary to apply the Access Principle to such information as long as it is not combined with other personal information, apart from when small amounts of non-public record information are used for indexing or organizing public record information. However, any conditions for consultation established by the relevant jurisdiction are to be respected. Where public record information is combined with other non-public record information (other than as specifically noted above), however, an organization must provide access to all such information, assuming it is not subject to other permitted exceptions.

8. Q: Does the Access Principle have to be applied to publicly available personal information?

A: As with public record information (see Q7), it is not necessary to provide access to information that is already publicly available to the public at large, as long as it is not combined with non-publicly available information.

9. Q: How can an organization protect itself against repetitious or vexatious requests for access?

A: An organization does not have to respond to such requests for access. For these reasons, organizations may charge a reasonable fee and may set reasonable limits on the number of times within a given period that access requests from a particular individual will be met. In setting such limitations, an organization should consider such factors as the frequency with which information is updated, the purpose for which the data are used, and the nature of the information.

10. Q: How can an organization protect itself against fraudulent requests for access?

A: An organization is not required to provide access unless it is supplied with sufficient information to allow it to confirm the identity of the person making the request.

11. Q: Is there a time within which responses must be provided to access requests?

A: Yes, organizations should respond without excessive delay and within a reasonable time period. This requirement may be satisfied in different ways as the explanatory memorandum to the 1980 OECD Privacy Guidelines states. For example, a data controller who provides information to data subjects at regular intervals may be exempted from obligations to respond at once to individual requests.

IX. Human Resources

1. Q: Is the transfer from the EU to the United States of personal information collected in the context of the employment relationship covered by the Safe Harbor?

A: Yes, where a company in the EU transfers personal information about its employees (past or present) collected in the context of the employment relationship, to a parent, affiliate, or unaffiliated service provider in the United States participating in the Safe Harbor, the transfer enjoys the benefits of the Safe Harbor. In such cases, the collection of the information and its processing prior to transfer will have been subject to the national laws of the EU country where it was collected, and any conditions for or restrictions on its transfer according to those laws will have to be respected.

The Safe Harbor Principles are relevant only when individually identified records are transferred or accessed. Statistical reporting relying on aggregate employment data and/or the use of anonymized or pseudonymized data does not raise privacy concerns.

2. Q: How do the Notice and Choice Principles apply to such information?

A: A U.S. organization that has received employee information from the EU under the Safe Harbor may disclose it to third parties and/or use it for different purposes only in accordance with the Notice and Choice Principles. For example, where an organization intends to use personal information collected through the employment relationship for non-employment-related purposes, such as marketing communications, the U.S. organization must provide the affected individuals with choice before doing so, unless they have already authorized the use of the information for such purposes. Moreover, such choices must not be used to restrict employment opportunities or take any punitive action against such employees.
It should be noted that certain generally applicable conditions for transfer from some Member States may preclude other uses of such information even after transfer outside the EU and such conditions will have to be respected.

In addition, employers should make reasonable efforts to accommodate employee privacy preferences. This could include, for example, restricting access to the data, anonymizing certain data, or assigning codes or pseudonyms when the actual names are not required for the management purpose at hand.

To the extent and for the period necessary to avoid prejudicing the legitimate interests of the organization in making promotions, appointments, or other similar employment decisions, an organization does not need to offer notice and choice.

3. Q: How does the Access Principle apply?

A: The FAQs on access provide guidance on reasons which may justify denying or limiting access on request in the human resources context. Of course, employers in the European Union must comply with local regulations and ensure that European Union employees have access to such information as is required by law in their home countries, regardless of the location of data processing and storage. The Safe Harbor requires that an organization processing such data in the United States will cooperate in providing such access either directly or through the EU employer.

4. Q: How will enforcement be handled for employee data under the Safe Harbor Principles?

A: In so far as information is used only in the context of the employment relationship, primary responsibility for the data vis-à-vis the employee remains with the company in the EU. It follows that, where European employees make complaints about violations of their data protection rights and are not satisfied with the results of internal review, complaint, and appeal procedures (or any applicable grievance procedures under a contract with a trade union), they should be directed to the state or national data protection or labor authority in the jurisdiction where the employee works. This also includes cases where the alleged mishandling of their personal information has taken place in the United States, is the responsibility of the U.S. organization that has received the information from the employer and not of the employer and thus involves an alleged breach of the Safe Harbor Principles, rather than of national laws implementing the Directive. This will be the most efficient way to address the often overlapping rights and obligations imposed by local labor law and labor agreements as well as data protection law.

A U.S. organization participating in the Safe Harbor that uses EU human resources data transferred from the Europe Union in the context of the employment relationship and that wishes such transfers to be covered by the Safe Harbor must therefore commit to cooperate in investigations by and to comply with the advice of competent EU authorities in such cases. The DPAs that have agreed to cooperate in this way will notify the European Commission and the Department of Commerce. If a U.S. organization participating in the Safe Harbor wishes to transfer human resources data from a Member State where the DPA has not so agreed, the provisions of FAQ 5 will apply.

X. Article 17 contracts

Q: When data is transferred from the EU to the United States only for processing purposes, will a contract be required, regardless of participation by the processor in the Safe Harbor?

A: Yes. Data controllers in the European Union are always required to enter into a contract when a transfer for mere processing is made, whether the processing operation is carried out inside or outside the EU. The purpose of the contract is to protect the interests of the data controller, i.e. the person or body who determines the purposes and means of processing, who retains full responsibility for the data vis-à-vis the individual(s) concerned. The contract thus specifies the processing to be carried out and any measures necessary to ensure that the data are kept secure.

A U.S. organization participating in the Safe Harbor and receiving personal information from the EU merely for processing thus does not have to apply the Principles to this information, because the controller in the EU remains responsible for it vis-à-vis the individual in accordance with the relevant EU provisions (which may be more stringent than the equivalent Safe Harbor Principles). Because adequate protection is provided by Safe Harbor participants, contracts with Safe Harbor participants for mere processing do not require prior authorization (or such authorization will be granted automatically by the Member States) as would be required for contracts with recipients not participating in the Safe Harbor or otherwise not providing adequate protection.
XI. Dispute Resolution and Enforcement

Q: How should the dispute resolution requirements of the Enforcement Principle be implemented, and how will an organization’s persistent failure to comply with the Principles be handled?

A: The Enforcement Principle sets out the requirements for Safe Harbor enforcement. How to meet the requirements of point (b) of the Principle is set out in the FAQ on verification (FAQ 7). This FAQ 11 addresses points (a) and (c), both of which require independent recourse mechanisms. These mechanisms may take different forms, but they must meet the Enforcement Principle’s requirements. Organizations may satisfy the requirements through the following:

1. Compliance with private sector developed privacy programs that incorporate the Safe Harbor Principles into their rules and that include effective enforcement mechanisms of the type described in the Enforcement Principle;

2. Compliance with legal or regulatory supervisory authorities that provide for handling of individual complaints and dispute resolution; or

3. Commitment to cooperate with data protection authorities located in the European Union or their authorized representatives.

This list is intended to be illustrative and not limiting. The private sector may design other mechanisms to provide enforcement, so long as they meet the requirements of the Enforcement Principle and the FAQs. Please note that the Enforcement Principle’s requirements are additional to the requirement set forth in paragraph 3 of the introduction to the Principles that self-regulatory efforts must be enforceable under Article 5 of the Federal Trade Commission Act or similar statute.

Recourse Mechanisms

Consumers should be encouraged to raise any complaints they may have with the relevant organization before proceeding to independent recourse mechanisms. Whether a recourse mechanism is independent is a factual question that can be demonstrated in a number of ways, for example, by transparent composition and financing or a proven track record. As required by the enforcement principle, the recourse available to individuals must be readily available and affordable. Dispute resolution bodies should look into each complaint received from individuals unless they are obviously unfounded or frivolous. This does not preclude the establishment of eligibility requirements by the organization operating the recourse mechanism, but such requirements should be transparent and justified (for example to exclude complaints that fall outside the scope of the program or are for consideration in another forum), and should not have the effect of undermining the commitment to look into legitimate complaints. In addition, recourse mechanisms should provide individuals with full and readily available information about how the dispute resolution procedure works when they file a complaint. Such information should include notice about the mechanism’s privacy practices, in conformity with the Safe Harbor Principles. They should also co-operate in the development of tools such as standard complaint forms to facilitate the complaint resolution process.

Remedies and Sanctions

The result of any remedies provided by the dispute resolution body should be that the effects of noncompliance are reversed or corrected by the organization, in so far as feasible, and that future processing by the organization will be in conformity with the Principles and, where appropriate, that processing of the personal data of the individual who has brought the complaint will cease. Sanctions need to be rigorous enough to ensure compliance by the organization with the Principles. A range of sanctions of varying degrees of severity will allow dispute resolution bodies to respond appropriately to varying degrees of non-compliance. Sanctions should include both publicity for findings of non-compliance and the requirement to delete data in certain circumstances. Other sanctions could include suspension and removal of a seal, compensation for individuals for losses incurred as a result of non-compliance and injunctive orders. Private sector dispute resolution bodies and self-regulatory bodies must notify failures of Safe Harbor organizations to comply with their rulings to the governmental body with applicable jurisdiction or to the courts, as appropriate, and to notify the Department of Commerce (or its designee).

FTC Action

The FTC has committed to reviewing on a priority basis referrals received from privacy self-regulatory organizations, such as BBBOnline and TRUSTe, and EU Member States alleging non-compliance with the Safe Harbor Principles to determine whether Section 5 of the FTC Act prohibiting unfair or deceptive acts
or practices in commerce has been violated. If the FTC concludes that it has reason[s] to believe Section 5 has been violated, it may resolve the matter by seeking an administrative cease and desist order prohibiting the challenged practices or by filing a complaint in a federal district court, which if successful could result in a federal court order to same effect. The FTC may obtain civil penalties for violations of an administrative cease and desist order and may pursue civil or criminal contempt for violation of a federal court order. The FTC will notify the Department of Commerce of any such actions it takes. The Department of Commerce encourages other government bodies to notify it of the final disposition of any such referrals or other rulings determining adherence to the Safe Harbor Principles.

Persistent Failure to Comply

If an organization persistently fails to comply with the Principles, it is no longer entitled to benefit from the Safe Harbor. Persistent failure to comply arises where an organization that has self-certified to the Department of Commerce (or its designee) refuses to comply with a final determination by any self-regulatory or government body or where such a body determines that an organization frequently fails to comply with the Principles to the point where its claim to comply is no longer credible. In these cases, the organization must promptly notify the Department of Commerce (or its designee) of such facts. Failure to do so may be actionable under the False Statements Act (18 U.S.C. § 1001).

The Department (or its designee) will indicate on the public list it maintains of organizations self-certifying adherence to the Safe Harbor Principles any notification it receives of persistent failure to comply; whether it is received from the organization itself, from a self-regulatory body, or from a government body, but only after first providing thirty (30) days’ notice and an opportunity to respond to the organization that has failed to comply. Accordingly, the public list maintained by the Department of Commerce (or its designee) will make clear which organizations are assured and which organizations are no longer assured of Safe Harbor benefits.

An organization applying to participate in a self-regulatory body for the purposes of re-qualifying for the Safe Harbor must provide that body with full information about its prior participation in the Safe Harbor.

XII. Choice - Timing of Opt Out

Q: Does the Choice Principle permit an individual to exercise choice only at the beginning of a relationship or at any time?

A: Generally, the purpose of the Choice Principle is to ensure that personal information is used and disclosed in ways that are consistent with the individual’s expectations and choices. Accordingly, an individual should be able to exercise “opt out” (or choice) of having personal information used for direct marketing at any time subject to reasonable limits established by the organization, such as giving the organization time to make the opt out effective. An organization may also require sufficient information to confirm the identity of the individual requesting the “opt out.” In the United States, individuals may be able to exercise this option through the use of a central “opt out” program such as the Direct Marketing Association’s Mail Preference Service. Organizations that participate in the Direct Marketing Association’s Mail Preference Service should promote its availability to consumers who do not wish to receive commercial information. In any event, an individual should be given a readily available and affordable mechanism to exercise this option.

Similarly, an organization may use information for certain direct marketing purposes when it is impracticable to provide the individual with an opportunity to opt out before using the information, if the organization promptly gives the individual such opportunity at the same time (and upon request at any time) to decline (at no cost to the individual) to receive any further direct marketing communications and the organization complies with the individual’s wishes.

XIII. Travel Information

Q: When can airline passenger reservation and other travel information, such as frequent flyer or hotel reservation information and special handling needs, such as meals to meet religious requirements or physical assistance, be transferred to organizations located outside the EU?

A: Such information may be transferred in several different circumstances. Under Article 26 of the Directive, personal data may be transferred “to a third country which does not ensure an adequate level of protection within the meaning of Article 25(2)” on the condition that it (1) is necessary to provide the services requested by the consumer or to fulfill the terms of an agreement, such as a “frequent flyer” agreement; or (2) has been unambiguously consented to by the consumer. U.S. organizations subscribing to the Safe Harbor provide adequate protection for personal data and may therefore receive data transfers from the EU without meeting those conditions or other conditions set out in Article 26 of the Directive. Since the Safe Harbor includes specific rules for sensitive information, such information
along with other data collected as part of the clinical trial, however, if it was made clear to the participant in the notice at the time he or she agreed to participate.

4. Q: Pharmaceutical and medical device companies are allowed to provide personal data from clinical trials conducted in the EU to regulators in the United States for regulatory and supervision purposes. Are similar transfers allowed to parties other than regulators, such as company locations and other researchers?

A: Yes, consistent with the Principles of Notice and Choice.

5. Q: To ensure objectivity in many clinical trials, participants, and often investigators, as well, cannot be given access to information about which treatment each participant may be receiving. Doing so would jeopardize the validity of the research study and results. Will participants in such clinical trials (referred to as “blinded” studies) have access to the data on their treatment during the trial?

A: No, such access does not have to be provided to a participant if this restriction has been explained when the participant entered the trial and the disclosure of such information would jeopardize the integrity of the research effort. Agreement to participate in the trial under these conditions is a reasonable forgoing of the right of access. Following the conclusion of the trial and analysis of the results, participants should have access to their data if they request it. They should seek it primarily from the physician or other health care provider from whom they received treatment within the clinical trial, or secondarily from the sponsoring company.

6. Q: Does a pharmaceutical or medical device firm have to apply the Safe Harbor Principles with respect to notice, choice, onward transfer, and access in its product safety and efficacy monitoring activities, including the reporting of adverse events and the tracking of patients/subjects using certain medicines or medical devices (e.g. a pacemaker)?

A: No, to the extent that adherence to the Principles interferes with compliance with regulatory requirements. This is true both with respect to reports by, for example, health care providers, to pharmaceutical and medical device companies, and with respect to reports by pharmaceutical and medical device companies to government agencies like the Food and Drug Administration.

7. Q: Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects.
Pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he/she can identify the research subject under special circumstances (e.g. if follow-up medical attention is required). Does a transfer from the EU to the United States of data coded in this way constitute a transfer of personal data that is subject to the Safe Harbor Principles?

A: No. This would not constitute a transfer of personal data that would be subject to the Principles.

XV. Public Record and Publicly Available Information

Q: Is it necessary to apply the Notice, Choice and Onward Transfer Principles to public record information or publicly available information?

A: It is not necessary to apply the Notice, Choice or Onward Transfer Principles to public record information, as long as it is not combined with non-public record information and as long as any conditions for consultation established by the relevant jurisdiction are respected.

Also, it is generally not necessary to apply the Notice, Choice or Onward Transfer Principles to publicly available information unless the European transferor indicates that such information is subject to restrictions that require application of those Principles by the organization for the uses it intends. Organizations will have no liability for how such information is used by those obtaining such information from published materials.

Where an organization is found to have intentionally made personal information public in contravention of the Principles so that it or others may benefit from these exceptions, it will cease to qualify for the benefits of the Safe Harbor.

Appendix A: Sample Safe Harbor Application

Certifying an organization’s adherence to the Safe Harbor

To expedite the certification process, prepare the required information before completing this form. If you have any difficulty completing this form or have any other questions concerning the Safe Harbor self-certification process, please e-mail safe.harbor@mail.doc.gov or contact Damon C. Greer at the International Trade Administration, Department of Commerce, damon.greer@mail.doc.gov, or 202-482-5023.

Public reporting for this collection is estimated to range from 20-40 minutes per response, including the time for reviewing instructions, and completing and reviewing the collection of information. All responses to this collection of information are voluntary, and will be provided confidentially to the extent allowed under the Freedom of Information Act. Notwithstanding any other provisions of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Reports Clearance Officer, International Trade Administration, Department of Commerce, Room 4001, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Organization Information

Organization Name: ____________________________
Address: ________________________________________________
City: ___________________________ State: _______________________
Zip: ________________ Phone: ________________ Fax: ________________
Website (Optional): __________________________________________

Organization Contact Information

(For handling of complaints, access requests, and any other issues arising under the Safe Harbor)

Contact Office: ___________________________________________
Contact Name (Optional): _____________________________________
Contact Title (Optional): _______________________________________

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Contact Phone: ___________________ Contact Fax: ___________________

Contact Email: ___________________________________________________

**Corporate Officer** who is certifying the organization’s adherence to the Safe Harbor Framework

Corporate Officer Name: ___________________________________________

Corporate Officer Title: ___________________________________________

Corporate Officer Phone: __________________________________________

Corporate Officer Fax: ___________________________________________

Corporate Officer Email: ___________________________________________

**Description of the activities** of the organization with respect to personal information received from the EU

____________________________________________________________________

____________________________________________________________________

**Description of the organization’s privacy policy for personal information**

____________________________________________________________________

____________________________________________________________________

Please enter the effective date of your organization’s privacy policy:

____________________________________________________________________

Please provide the location of your organization’s privacy policy:

____________________________________________________________________

Please indicate the appropriate statutory body that has jurisdiction to hear any claims against the organization regarding possible unfair or deceptive practices and violations of laws or regulations governing privacy:

Choose One:  □ Federal Trade Commission (FTC)  □ Department of Transportation

List any privacy programs in which your organization is a member for Safe Harbor purposes (See FAQ 6):

____________________________________________________________________

____________________________________________________________________

What is your organization’s verification method (e.g., In-house, Third Party? (See FAQ 7)

____________________________________________________________________

____________________________________________________________________

What independent recourse mechanism(s) is(are) available to investigate unresolved complaints (e.g., private sector developed dispute resolution mechanisms that incorporate the Safe Harbor framework or EU data protection authorities?) (See FAQ 11)

____________________________________________________________________

____________________________________________________________________

What personal data processed by your organization is covered by the Safe Harbor? (e.g., offline, on-line, manually processed data, human resources data)

____________________________________________________________________

____________________________________________________________________

Do you plan to cover human resources data?  □ Yes  □ No

If yes, you need to agree to cooperate and comply with the European Data Protection Authorities (See FAQs 5 & 9). Do you agree to cooperate and comply with the European Data Protection Authorities?  □ Yes  □ No
Appendix B: Sample Privacy Policies

We have included here three privacy policy examples for your reference; these were chosen at random and are not intended to serve as an official endorsement or a specific U.S. Government standard. They incorporate the requisite tenets of the U.S.-EU Safe Harbor Framework while at the same time uniquely represent their individual company and their industry privacy concerns. Should you have any questions about what is required in the text of a privacy policy in order to be compliant with the U.S.-EU Safe Harbor Framework, please refer to Appendix A, the Helpful Hints Guide.

Privacy Policy Example A
Data Privacy at XYZ
XYZ has established a comprehensive privacy program, including a global privacy office and a chief privacy officer, designed to help us respect and protect your data privacy rights. This statement includes both XYZ’s European Union - U.S. Safe Harbor Privacy Statement and the Website Privacy Statement.

U.S.-EU Safe Harbor Privacy Statement
For personal information of employees, consumers, healthcare professionals, medical research subjects and investigators, customers, investors, and government officials that XYZ receives from the European Economic Area, XYZ has committed to handling such personal information in accordance with the Safe Harbor Principles. XYZ’s Safe Harbor certification can be found at http://web.ita.doc.gov/safeharbor/shlist.nsf/webPages/safe+harbor+list. For more information about the Safe Harbor Principles, please visit the U.S. Department of Commerce’s Website at http://export.gov/safeharbor/.

XYZ Website Privacy Statement
XYZ respects the privacy of visitors to its websites, as a result, we have developed this website privacy policy. This website privacy policy applies only to the operation of websites that directly link to this policy when you click on “privacy statement” in the website footer.

Through this website XYZ will collect information that can identify you, such as your name, address, telephone number, e-mail address, and other similar information (“Your Information”) when it is voluntarily submitted to us (however, see discussion below about “IP Addresses” if you have a broadband connection). We will use Your Information to respond to requests you may make of us, and from time to time, we may refer to Your Information to better
understand your needs and how we can improve our websites, products and services. We may also use Your Information to contact you and/or provide you with general health information (like information on certain health conditions) as well as information about our products and services. We may also enhance or merge Your Information with data obtained from third parties for the same purposes.

Any other information transferred by you in connection with your visit to this site (“Other Information” - that is, information that cannot be used to identify you) may be included in databases owned and maintained by XYZ or its agents. XYZ retains all rights to these databases and the information contained in them. Other Information we collect may include your IP Address and other information gathered through our weblogs and cookies (see below).

This site may use a technology known as web beacons - sometimes called single-pixel gifs - that allow this site to collect web log information. A web beacon is a graphic on a web page or in an e-mail message designed to track pages viewed or messages opened. Web log information is gathered when you visit one of our websites by the computer that hosts our website (called a “webserver”). The webserver automatically recognizes some non-personal information, such as the date and time you visited our site, the pages you visited, the website you came from, the type of browser you are using (e.g., Internet Explorer), the type of operating system you are using (e.g., Windows 2000), and the domain name and address of your Internet service provider (e.g., AOL). We may also include web beacons in promotional e-mail messages in order to determine whether messages have been opened.

This website may use a technology called a “cookie”. A cookie is a piece of information that our webserver sends to your computer (actually to your browser file) when you access a website. Then when you come back our site will detect whether you have one of our cookies on your computer. Our cookies help provide additional functionality to the site and help us analyze site usage more accurately. For instance, our site may set a cookie on your browser that keeps you from needing to remember and then enter a password more than once during a visit to the site.

This website uses Internet Protocol (IP) Addresses. An IP Address is a number assigned to your computer by your Internet service provider so you can access the Internet. Generally, an IP address changes each time you connect to the Internet (it is a “dynamic” address). Note, however, that if you have a broadband connection, depending on your individual circumstance, it is possible that your IP Address that we collect, or even perhaps a cookie we use, may contain information that could be deemed identifiable. This is because with some broadband connections your IP Address doesn’t change (it is “static”) and could be associated with your personal computer. We use your IP address to report aggregate information on use and to help improve the website.

You should be aware that this site is not intended for, or designed to attract, individuals under the age of 18. We do not collect personally identifiable information from anyone we actually know is an individual under the age of 18.

Areas of this website that collect Your Information use industry standard secure socket layer encryption (SSL); however, to take advantage of this your browser must support encryption protection (found in Internet Explorer release 3.0 and above).

We may share Your Information with agents, contractors or partners of XYZ in connection with services that these individuals or entities perform for, or with, XYZ. These agents, contractors or partners are restricted from using this data in any way other than to provide services for XYZ, or services for the collaboration in which they and XYZ are engaged (for example, some of our products are developed and marketed through joint agreements with other companies). We may, for example, provide your information to agents, contractors or partners for hosting our databases, for data processing services, or so that they can mail you information that you requested.

XYZ reserves the right to share Your Information to respond to duly authorized information requests of governmental authorities or where required by law. In exceptionally rare circumstances where national, state or company security is at issue (such as with the World Trade Center terrorist act in September, 2001), XYZ reserves the right to share our entire database of visitors and customers with appropriate governmental authorities.

We may also provide Your Information to a third party in connection with the sale, assignment, or other transfer of the business of this website to which the information relates, in which case we will require any such buyer to agree to treat Your Information in accordance with this Privacy Policy.

As a convenience to our visitors, this Website currently contains links to a number of sites that we believe may offer useful information. The policies and procedures we described here do not apply to those sites. We suggest contacting those sites directly for information on their privacy, security, data collection, and distribution policies.
“Sensitive Personal Information” means personal information that reveals race, ethnic origin, sexual orientation, political opinions, religious or philosophical beliefs, trade union membership or that concerns an individual’s health.

Principles

Notice

Company shall inform an individual of the purpose for which it collects and uses the Personal Information and the types of non-agent third parties to which the Company discloses or may disclose that Information. Company shall provide the individual with the choice and means for limiting the use and disclosure of their Personal Information. Notice will be provided in clear and conspicuous language when individuals are first asked to provide Personal Information to the Company, or as soon as practicable thereafter, and in any event before the Company uses or discloses the Information for a purpose other than for which it was originally collected.

Choice

The Company will offer individuals the opportunity to choose (opt out) whether their Personal Information is (1) to be disclosed to a third party or (2) to be used for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual. For Sensitive Personal Information, the Company will give individuals the opportunity to affirmatively or explicitly (opt out) consent to the disclosure of the information for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual. Company shall treat Sensitive Personal Information received from an individual the same as the individual would treat and identify it as Sensitive Personal Information.

Onward Transfers

Prior to disclosing Personal Information to a third party, Company shall notify the individual of such disclosure and allow the individual the choice (opt out) of such disclosure. Company shall ensure that any third party for which Personal Information may be disclosed subscribes to the Principles or are subject to law providing the same level of privacy protection as is required by the Principles and agree in writing to provide an adequate level of privacy protection.

Data Security

Company shall take reasonable steps to protect the Information from loss, misuse and unauthorized access, disclosure, alteration and destruction. Company has put in place appropriate physical, electronic and management procedures to safeguard and secure the Information from loss, misuse,
Unauthorized access or disclosure, alteration or destruction. Company cannot guarantee the security of Information on or transmitted via the Internet.

Data Integrity
Company shall only process Personal Information in a way that is compatible with and relevant for the purpose for which it was collected or authorized by the individual. To the extent necessary for those purposes, Company shall take reasonable steps to ensure that Personal Information is accurate, complete, current and reliable for its intended use.

Access
Company shall allow an individual access to their Personal Information and allow the individual to correct, amend or delete inaccurate information, except where the burden or expense of providing access would be disproportionate to the risks to the privacy of the individual in the case in question or where the rights of persons other than the individual would be violated.

Enforcement
Company uses a self-assessment approach to assure compliance with this privacy policy and periodically verifies that the policy is accurate, comprehensive for the information intended to be covered, prominently displayed, completely implemented and accessible and in conformity with the Principles. We encourage interested persons to raise any concerns using the contact information provided and we will investigate and attempt to resolve any complaints and disputes regarding use and disclosure of Personal Information in accordance with the Principles.

If a complaint or dispute cannot be resolved through our internal process, we agree to dispute resolution using (an independent resource mechanism) as a third party resolution provider.

Amendments
This privacy policy may be amended from time to time consistent with the requirements of the Safe Harbor. We will post any revised policy on this website.

Information Subject to Other Policies
The Company is committed to following the Principles for all Personal Information within the scope of the Safe Harbor Agreement. However, certain information is subject to policies of the Company that may differ in some respects from the general policies set forth in this privacy policy.

Contact Information
Questions, comments or complaints regarding the Company’s Safe Harbor Policy or data collection and processing practices can be mailed or emailed to:

XYZ
Attn: Legal Department
PO Box ####
City, State Zip
Effective date: January 1, 2008

Privacy Policy Example C
To learn more about our privacy practices, see our Privacy Policy Details.

XYZ believes in protecting your privacy. When we collect personal information from you on our website, we follow the privacy principles of (an independent resource mechanism) and comply with the U.S.-EU Safe Harbor Framework as set forth by the U.S. Department of Commerce regarding the collection, use and retention of personal data from the European Union. These are our promises to you:

1. **Notice.** When we collect your personal information, we’ll give you timely and appropriate notice describing what personal information we’re collecting, how we’ll use it, and the types of third parties with whom we may share it.

2. **Choice.** We’ll give you choices about the ways we use and share your personal information, and we’ll respect the choices you make.

3. **Relevance.** We’ll collect only as much personal information as we need for specific, identified purposes, and we won’t use it for other purposes without obtaining your consent.

4. **Retention.** We’ll keep your personal information only as long as we need it for the purposes for which we collected it, or as permitted by law.

5. **Accuracy.** We’ll take appropriate steps to make sure the personal information in our records is accurate.

6. **Access.** We’ll provide ways for you to access your personal information, as required by law, so you can correct inaccuracies.

7. **Security.** We’ll take appropriate physical, technical, and organizational measures to protect your personal information from loss, misuse, unauthorized access or disclosure, alteration, and destruction.
Appendix C: Dispute Resolution Providers

Under the Safe Harbor's Enforcement Principle, organizations self-certifying to Safe Harbor must establish an independent recourse mechanism available to investigate unresolved complaints.

An organization wishing to certify must ensure that its recourse mechanism is in place prior to self-certification.

The following private sector organizations provide dispute resolution programs that assist in compliance with the Safe Harbor Enforcement Principles:

- **BBB OnLine:** [www.bbbonline.org/]
- **TRUSTe:** [http://www.truste.org/]
- **AICPA WebTrust:** [www.aicpa.org/trustservices/]
- **Direct Marketing Association:** [www.the-dma.org/]
- **Entertainment Software Rating Board:** [www.esrb.org/]
- **JAMS:** [http://www.jamsadr.com/]
- **American Arbitration Association:** [http://www.adr.org/]

This list is not exhaustive, and the Department of Commerce does not require or endorse any particular program.

European Data Protection Authorities

Alternatively, organizations participating in the U.S.-EU Safe Harbor may choose to cooperate and comply with the European Data Protection Authorities (DPAs).

Please note that if human resources data is being covered in the organization's self-certification, the organization must agree to cooperate and comply with the DPAs for the purposes of handling unresolved complaints.

Swiss Federal Data Protection and Information Commissioner

Alternatively, organizations participating in the U.S.-Swiss Safe Harbor may choose to cooperate and comply with the Swiss Federal Data Protection and Information Commissioner (FDPIC).

Following are descriptions of three representative dispute resolution bodies (BBB, DMA and TRUSTe) and the services they offer.

Please note that if human resources data is being covered in the organization's self-certification, the organization must agree to cooperate and comply with the FDPIC for the purposes of handling unresolved complaints.
Direct Marketing Association Member Safe Harbor Program

How Can the DMA Safe Harbor Program Assist Its Participating Member Companies?

◆ The DMA serves as a third-party dispute and enforcement mechanism for unresolved European data privacy complaints (The DMA has at least four decades of experience in addressing and satisfactorily resolving consumer disputes);

◆ The DMA provides technical assistance and extensive educational materials available on the DMA website, www.the-dma.org/safeharbor.

◆ Each participant receives a staff review of the company's Safe Harbor privacy policy statement; and

◆ The DMA provides a DMA Safe Harbor Program mark that companies can display on their relevant online or offline materials.

Who is eligible to participate in the DMA Safe Harbor Program?

The DMA Safe Harbor Program is only available to DMA Members. DMA companies wishing to participate in our Safe harbor program must submit an application which includes: a signed contract, company contact sheet, copy of their Safe Harbor privacy policy statement and annual Safe Harbor fee.

Questions? www.the-dma.org/safeharbor

For more information about membership in the DMA, contact Paulette Peach with our membership department at: 212.768.7277 ext. 1793 or ppeach@the-dma.org.

TRUSTe Safe Harbor Fact Sheet

What is the EU-US Safe Harbor Framework?

If you do business with European citizens, TRUSTe can help you certify your compliance with the EU Directive on Data Protection. The Directive prohibits the transfer of European citizens' personal data to non-European Union nations that do not meet the EU’s “adequacy” standard for privacy protection. The U.S. Department of Commerce, in concert with the European Commission, developed a “Safe Harbor Framework” that allows US organizations to comply with the Directive by abiding by a set of Safe Harbor Privacy Principles. Companies certify their compliance with these Principles on the U.S. Department of Commerce Web site. The Framework was approved by the EU in 2000 and gives companies that abide by the Principles assurance that the EU will consider their practices “adequate” privacy protections for EU citizens.
In 2009, the Department of Commerce and the Federal Data Protection and Information Commission of Switzerland completed negotiations on establishing a data protection framework between the two countries. An exchange of letters was signed by the Acting Under Secretary for International Trade, U.S. Department of Commerce, and the Federal Data Protection and Information Commissioner (FDPIC) on the creation of a ‘U.S.-Swiss Safe Harbor Framework’. The framework will simplify the transfer of personal data by Swiss firms to American companies that self-certify to the U.S. Department of Commerce.

To bridge the different privacy approaches and provide a streamlined means for U.S. organizations to comply with the Swiss data protection law, the U.S. Department of Commerce in consultation with the Federal Data Protection and Information Commission developed a “Safe Harbor” framework.

The process for self-certifying to the U.S.-Swiss Safe Harbor Framework is identical to that for self-certification to the U.S.-EU Safe Harbor Framework. The certification form is identical and we have added Switzerland to the country selection imbedded in the application form.

Please note that you do not have to join the U.S.-EU Safe Harbor in order to self-certify to the U.S.-Swiss Safe Harbor Framework or vice versa. Organizations should also note that when they select “Switzerland” as a country from which they receive personal data, they are self-certifying compliance to the U.S.-Swiss Safe Harbor Framework. It is critically important that the U.S.-Swiss Safe Harbor privacy principles, the 15 FAQs, and the enforcement statement be reviewed before executing the self-certification form. Although the respective U.S.-Swiss Safe Harbor and U.S.-EU Safe Harbor privacy principles, 15 FAQs, and enforcement statements are similar, they are not identical.

Why TRUSTe’s EU Safe Harbor Seal?
The TRUSTe EU Safe Harbor Seal Program verifies your compliance with the Safe Harbor Framework, includes alternative dispute resolution, and helps your organization get ready for self-certification with the U.S. Department of Commerce. Displaying the TRUSTe EU Safe Harbor seal signals to consumers around the globe that you take their privacy seriously.

What are the benefits?
1) Streamline legal compliance with the EU Safe Harbor Framework:
   - Verifies compliance with the Safe Harbor Privacy Principles.
   - Provides dispute resolution of consumer complaints about data collected online or offline, as required for Safe Harbor status.
   - Prepares you for self-certification with the U.S. Department of Commerce.

2) Builds trust and confidence:
   - Brands your organization and Web site as EU-US Safe Harbor compliant by posting the distinctive EU Safe Harbor seal.
   - Third-party certification emphasizes your organization’s commitment to privacy and consumer choice.

TRUSTe EU Members
Many of the world’s leading companies and organizations protect the privacy of their customers with TRUSTe, including:

Adobe Systems          Monster
Apple                 Napster
aQuantive           ORACLE
Avaya                Salesforce.com
Carlson Companies Harrisinteractive.com  SkillSoft
IBM                    Sybase
Logitech                TNS
McAfee, Inc.         Varian Medical Systems
Microsoft
Appendix E: Safe Harbor Certification mark

On July 31, 2008, the International Trade Administration (ITA) announced that it developed a certification mark for the U.S.-European Union (EU) Safe Harbor Framework. The mark may be used by companies on their websites to signify that they have self-certified compliance with the provisions of the Safe Harbor Framework.

The Safe Harbor Framework facilitates secure, uninterrupted transfers of personal information that support billions of dollars in trade from the EU to the United States. By displaying this certification mark, participating companies can more easily illustrate their commitment to ensuring that EU citizens' data is secure, which is critical to the U.S.-EU trade relationship.

In order to display the certification mark, participating U.S. companies must follow specific instructions developed by ITA. Only those organizations that have self-certified and are listed on ITA’s official Safe Harbor Program list will be allowed to use the mark in an appropriate manner. Continued use of the mark is contingent on companies maintaining their status in the program.

Instructions for Self-Certified Organizations on the use of the Safe Harbor Certification mark

Congratulations on your self-certification to the U.S.-EU Safe Harbor Framework. Your self-certification is valid for one year and is renewable annually on or before your anniversary of enrolling in the Framework. In order to continue to take advantage of the benefits that self-certification affords, you must maintain your official filing and inform the Department of any changes in the scope of your organization’s activities within the European Union. The Department provides its “Safe Harbor” certification mark (referred to hereafter as “mark”) to those organizations that maintain their “current” status by self-certifying their practices in an official, annual filing with the Department. This mark must be used in accordance with the following instructions.

Safe Harbor Certification Mark Instructions

1. The mark is a visual manifestation of the commitment your organization makes when it self-certifies that it will comply with the U.S.-EU Safe Harbor Framework.

2. Your organization may announce its self-certification in a press release and include the mark as evidence that it has met the self-certification requirements established by the Department for the U.S.-EU Safe Harbor Framework.

3. Your organization may use the mark for one year from the initial self-certification date. Authorization to use the mark is renewable each year subject to the organization’s reaffirmation to comply with the Safe Harbor Framework.

4. The mark may not be used for marketing or advertisements, and/or to imply any endorsement, authorization, or affiliation that does not exist with respect to the U.S. Department of Commerce or the United States Government.

5. The mark may not be used in a manner that embarrasses the Department or the United States Government.

6. The mark may be placed on the organization’s website on its home page or on the page where the privacy policy is found.

7. In each instance in which you post the mark on your organization’s website, you must:
   a. Immediately above the top edge of the mark, display the following language, in a clear and conspicuous manner not to exceed the width of the mark in a minimum 8 point font, “We self-certify compliance with”.
   With the words “We self-certify compliance with”, provide a link to:
   http://web.ita.doc.gov/safeharbor/shlist.nsf/webPages/safe+harbor+list
   b. With the mark, provide a link to: www.export.gov/safeharbor

8. The mark must be removed from the organization’s website under the appropriate circumstances including, but not limited to: a. the organization withdraws from participation or is removed as a participant in the U.S.-EU Safe Harbor Framework; b. the organization fails to comply with a final ruling of a private sector dispute resolution body, a self-regulatory body, or government body, as applicable, in connection with allegations of Safe Harbor non-compliance; c. the organization fails to renew its commitment to the Framework in a reasonable time and in accordance with the reaffirmation requirements; d. the organization is acquired by another entity that either is not in the Framework or chooses to opt-out of the program; or e. the organization ceases commercial operations.

9. Failure to comply with these instructions may result in enforcement of the certification mark through an action for infringement of the mark, and/or a referral to the Federal Trade Commission for investigation of an unfair or deceptive trade practice under section 5 of the Federal Trade Commission Act.
Appendix F: Glossary*

**Access** – The ability to view personal information held by an organization – this ability may be complemented by an ability to update or correct the information. Access defines the intersection of identity and data; that is, who can do what to which data.

**Adequacy** – As used in EU Data Protection Directive, adequacy refers to the existence of a legal regime in another country that provides sufficient protection for personal information. In other words, a country will be deemed “adequate” if its laws afford individuals rights that are similar to those afforded by the EU Data Protection Directive. If a country offers adequate protection, then data transfers from the European Economic Area (EEA) to that country may occur without any further limitation – provided that the processing meets the other provisions of the Directive. This concept has been expanded to encompass other types of data transfer mechanisms. For example, the U.S. Safe Harbor provides an adequate level of protection, so companies that are in the Safe Harbor may transfer data from the EU to the US. Similarly, the EU Model Contracts provide an adequate level of protection, so data may be transferred from the EU to any country, if the recipient has executed a Model Contract.

**Choice** – An individual’s ability to determine whether or how personal information collected from him or her may be used or disclosed by the entity that collected the information. Also: The ability of an individual to limit certain uses of his or her personal information. For example, an individual may have choice about whether to permit a company to contact the individual or share the individual’s data with third parties.

**Data commissioner** – Government official that runs a data protection office and that is charged with enforcing a country’s data protection laws.

**Data protection authority** – See data commissioner.

**Data subject** – Term used in some data protection litigation to describe an individual who is the subject of a personal data record.

**Directive** – See EU Directive

**Dispute resolution** – The response to a valid complaint or grievance, or the action taken to correct faulty information, or to make amends for harm or inconvenience caused to an individual.

**EU Data Protection Directive** – Several directives deal with personal data usage, but the most important is the general policy approved by the European Commission in 1995 (95/46/EC) which protects individuals’ privacy and personal data use.

**EU Directive** – The EU Directive was adopted in 1995 and became effective in 1998 and protects individuals’ privacy and personal data use. The Directive recognizes the European view that privacy is a fundamental human right, and establishes a general comprehensive legal framework that is aimed at protecting individuals and promoting individual choice regarding the processing of personal data. The Directive imposes an onerous set of requirements on any person that collects or processes data pertaining to individuals in their personal or professional capacity. It is based on a set of data protection principles, which include the legitimate basis, purpose limitation, data quality, proportionality, and transparency principles, data security and confidentiality, data subjects’ rights of access, rectification, deletion, and objection, restrictions on onwards transfers, additional protection where special categories of data and direct marketing are involved, and a prohibition on automated individual decisions. The Directive applies to all sectors of industry, from financial institutions to consumer goods companies, and from list brokers to any employer. The Directive’s key provisions impose serious restrictions on personal data processing, grant individual rights to “data subjects,” and set forth specific procedural obligations, including notification to national authority. The Directive has been supplemented by additional directives including a specific provision for the telecommunications sector (2002/58) as well as for e-commerce.

**European Economic Area (EEA)** – An economic region that includes the European Union (EU) plus Iceland, Norway, and Liechtenstein – the latter are not official members of the European Union but are closely linked by economic relationship.

**European Union (EU)** – The European Union (EU) is an organization of European countries dedicated to increasing economic integration and strengthening cooperation among its members. The European Union was involved in the development of the Safe Harbor Principles that affect data flows from the European Union into the United States. As of July 2008, the member states include: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

**Federal Trade Commission (FTC)** – The U.S. Federal Trade Commission enforces a variety of federal antitrust and consumer protection laws, including the Safe Harbor Principles. The Commission seeks to ensure that the nation’s markets function competitively, and are vigorous, efficient, and free of undue restrictions. The Commission also works to enhance the smooth operation of the marketplace by eliminating acts or practices that are unfair or deceptive.
Member state – In EU documents, this term refers to a country that is a full member of the European Union. As of July 2008, the member states include: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

Notice – A written description of an entity’s practices with respect to its collection, use and disclosure of personal information. A private notice typically includes a description of what personal information the entity collects, how the entity uses the information, with whom it shares the information, whether the information is secured, and whether an individual has any choices as to how the entity uses the information.

Opt-in - A consumer’s expression of affirmative consent based upon a specific act of the consumer.

Opt-out – A consumer's exercise of choice through an affirmative request that a particular use of disclosure of data not occur.

Personal Data – Any and all data that relates to an identifiable individual. See EU Directive.

Personal information – Any information that (i) relates to an individual and (ii) identifies or can be used to identify the individual. Such information may include an individual's name, postal address, e-mail address, telephone number, Social Security number, or other unique identifier.

Privacy – The appropriate use of personal information under the circumstances. What is appropriate will depend on context, law, and the individual’s expectations; also, the right of an individual to control the collection, use, and disclosure of personal information.

Privacy policy – An organization's standard pertaining to the user information it collects and what is done with the information after it is collected.

Privacy seal program – Self-regulatory regimes that certify compliance with a set of standards of privacy protection. Websites display the program’s seal to indicate that they adhere to these standards.

Privacy statement – An organization’s communication regarding its privacy policies, such as what personal information is collected, how it will be used, with whom it will be shared, and whether one has the option to exercise control over how one’s information is used. Privacy statements are frequently posted on Websites.

Safe Harbor – The European Commission's Directive on Data Protection (The EU Directive) prohibits the transfer of personal data to non-European Union nations that do not meet the European “adequacy” standard for privacy protection. While the United States and the European Union share the goal of privacy protection, the United States uses a sectoral approach that relies on a mix of legislation, regulation, and self-regulation, while the European Union relies on comprehensive legislation that requires creation of government data protection agencies, registration of databases with those agencies, and, in some instances, approval before data processing may begin. As a result of these different privacy approaches, the directive could have significantly hampered the ability of U.S. companies to engage in many trans-Atlantic transactions.

In order to bridge these different privacy approaches and provide a streamlined means for U.S. organizations to comply with the directive, the U.S. Department of Commerce and the European Commission developed a “Safe Harbor” framework. The Safe Harbor – approved by the EU in 2001 – is an important way for U.S. companies to avoid interruptions in business dealings with the EU or prosecution by European authorities under European privacy laws.

Certifying to the Safe Harbor assures that EU organizations know that a company provides adequate privacy protection, as defined by the directive. From a U.S. perspective, Safe Harbor is a self-regulatory regime that is only available to companies that are subject to the enforcement authority of the U.S. Federal Trade Commission or the U.S. Department of Transportation. Companies that are outside the jurisdiction of these two agencies are not eligible to join Safe Harbor.

*Definitions for this Glossary are used by permission from the:
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https://www.privacyassociation.org/