

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**Information Transfer Recommendation – EDIINT AS1/AS2**

10JUN2010

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**Title: EDIINT AS1 / AS2**

**Background:**

It is recognized that there is need for secure information exchange over the Internet among the three ICH regions. Encryption technology makes secure transfer over the Internet possible.

**Recommendation:**

The Expert Working Group is recommending the use of specifications that comply with the following functionality requirements and standards for successful deployment of secure information exchange over the Internet:

**• Provide**

- Secure EDI over the Internet without use of a Value Added Network (VAN)
- Digital signatures for authentication, data integrity, and non-repudiation
- Compliance with regionally applicable requirements for encryption
- Key management, information exchange tracking, and trading partner profile / agreement facilities

**• Support**

- The transport in English and other EU languages, and Japanese characters (ISO 2022-JP)
- The transport of information exchange messages, text messages and binary files

The IETF EDIINT AS1 and AS2 specification meet all of the above requirements. The Expert Working Group recognizes there are a number of products that that are certified to comply with EDIINT AS1 and AS2 specifications.

**Conditions:**

- Reference guidelines for the appropriate technical and procedural use of identified products must be developed and made available to assist its installation and use.

**Remarks:**

EDIINT AS3 (secure EDI over FTP) is available and supported by many of the same products but may not present any advantages over AS2.