

**EWG M2 Recommendation to the ICH Steering Committee**  
**Electronic Standards for the Transfer of Regulatory Information (ESTRI)**  
**Information Transfer Recommendation - EDIINT AS1** 10NOV2005

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**Title:** EDIINT AS1

**Background:**

It is recognized that there is need for secure information exchange among the three ICH regions. Recent advances in encryption technology make 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 (SMTP/MIME), 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 specification meets all of the above requirements. The Expert Working Group recognizes there are a number of certified products that comply with EDIINT AS1 specification<sup>1</sup>.

**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:**

The IETF EDIINT AS2 specification has been drafted and accepted in some regions. The Expert Working Group will evaluate EDIINT AS2 for inclusion into this document as well as other evolving EDIINT specifications.

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<sup>1</sup> EDIINT AS1 incorporates specifications included in previous versions of this recommendation.