

EWG M2 Recommendation to the ICH Assembly Electronic Standards for the Transfer of Regulatory Information (ESTRI) Information Transfer Recommendation – EDIINT

Version 4.0 – 26JUL2021

Title: EDIINT

Background:

It is recognized that there is a need for secure information exchange over the Internet within the 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 of information exchange messages, text messages and binary files

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

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 AS1 (secure EDI of SMTP) was previously recommended for use by the M2 however it is noted that it is no longer being supported by the majority of ICH regions. AS1 is therefore considered to be deprecated for ICH use.
- EDIINT AS3 (secure EDI over FTP) is available and supported by many of the same products but may not present any advantages over AS2.
- EDIINT AS4 (secure EDI over web services) is based on SOAP and can be implemented as an API. It is better suited to large and complex file exchanges than RESTful based APIs