European Monitoring Centre
for Drugs and Drug Addiction

EWS in the frame of the Joint Action on NSD and draft Council Decision on new psychoactive substances

Roumen Sedefov, Budapest, March 2005

Synthetic drugs overview 1

EU is concerned because:

- widely consumed in Europe
- Europe is a major producer
- Europe is a major exporter

Confusing classifications/terminologies:

- amphetamine-type stimulants (ATS)
- ‘designer drugs’
- hallucinogens, psychotomimetics, psychedelics
- etc., etc.

Chemical/pharmacological classification

- Phenethylamines
  stimulants; ‘ecstasy’ drugs (‘entactogens’); hallucinogens
- Indolalkylamines (LSD and derivates,tryptamines)
  hallucinogens
- Phencyclidine and congeners (incl. ketamine)
  hallucinogens (dissociative anaesthetics)
- Piperazine derivates
- Pyrrolidine derivates
- Others (GHB)
- Others (synthetic opiates, cannabinoids, delirants, metaqualones)

Synthetic drugs overview 2

Altogether more than 30 NSD found in EU since 1995 most of them are ring-substituted phenethylamines

A substance seen before

- If reported in another member state *or*
- Described in scientific literature *then*
- Analytical details can be circulated *and*
- Reference samples can be produced

A substance never seen before

- For powders and tablets then the only efficient method of identification is Nuclear Magnetic Resonance Spectroscopy (NMR)

General information sources on NSD

- EMCDDA and Europol
- ‘Underground’ books
- Numerous websites
- Scientific journals and books
- Specialist associations
- DEA (USA)
- PIHKAL and TIHKAL

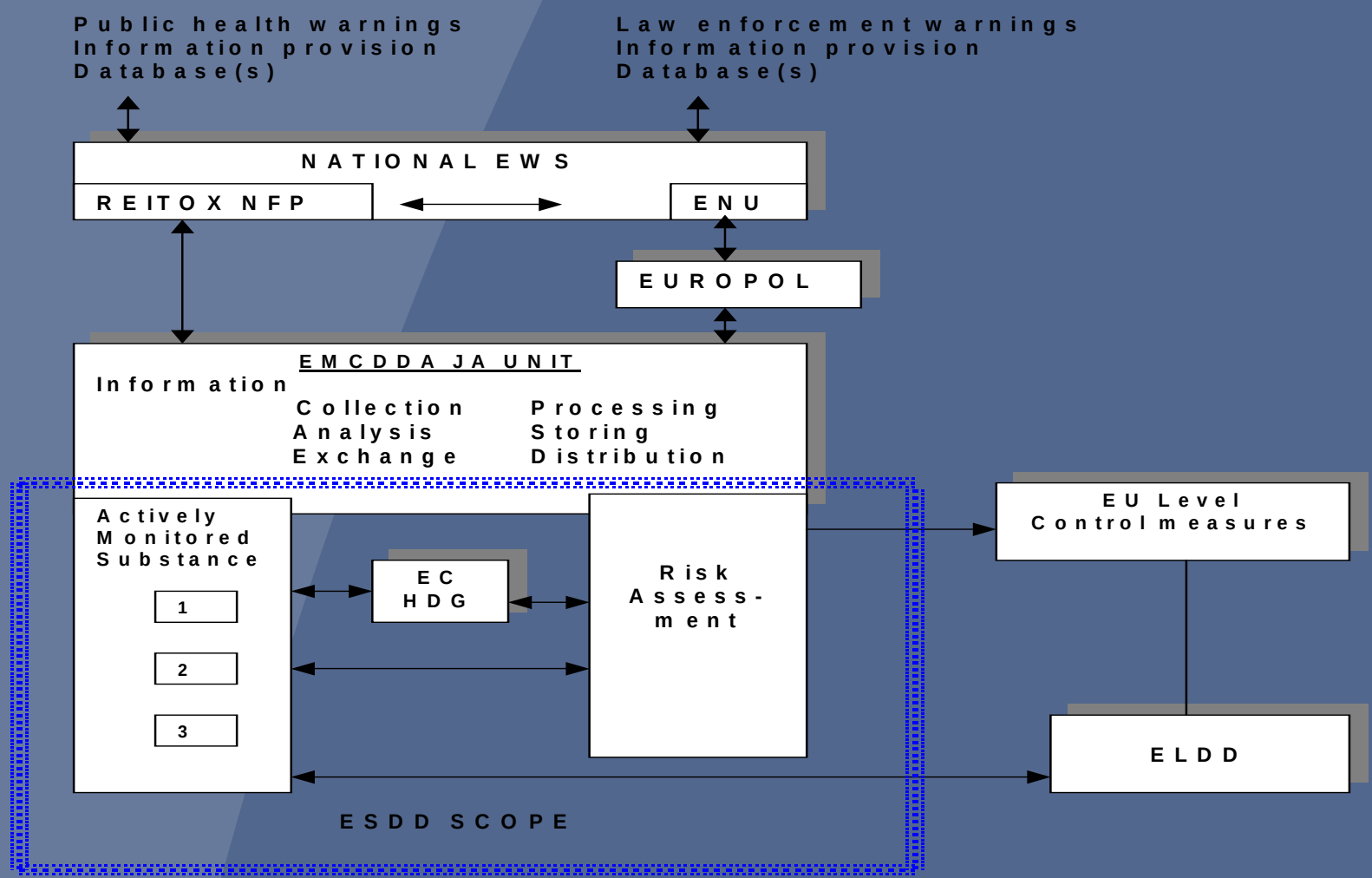
The 1997Joint Action on NSD

- Concernes synthetic drugs (vs. natural)

Manufactured in clandestine labs through a chemical process were essential psychoactive constituents are not delivered from naturally occurring substances

- Relates to end products as distinct from precursors
- In pure form or in preparation (a mixture containing a new psychoactive substance)
- Psychotropic i.e. 1971 UN Convention
- Psychoactive would include: new narcotic drug and new psychotropic drug (i.e 1961 & 1971 UN Convention)

JANSD INFORMATION FLOW



EWS as a public health notion

- EWS aims to detect a significant risk to PH and to inform relevant authorities as quickly as possible

F. e. the second pillar of the communicable disease network is an early warning and response system to alert public health authorities in MS and the Commission on outbreaks with greater than national dimensions, so that a coordinated EU action may be taken

- Existing EWSs cover specific areas, according to the type of threat; this approach may lead to a situation where some very relevant threats to public health are not fully covered (specificity vs. sensitivity)

EWS on new synthetic drugs

- EWS is a combination of rapid exchange, collection and appraisal (input - analysis/validation - output) of information over a short period of time

- The EWS allows for longer-term monitoring of substances and trends in (new) synthetic drugs

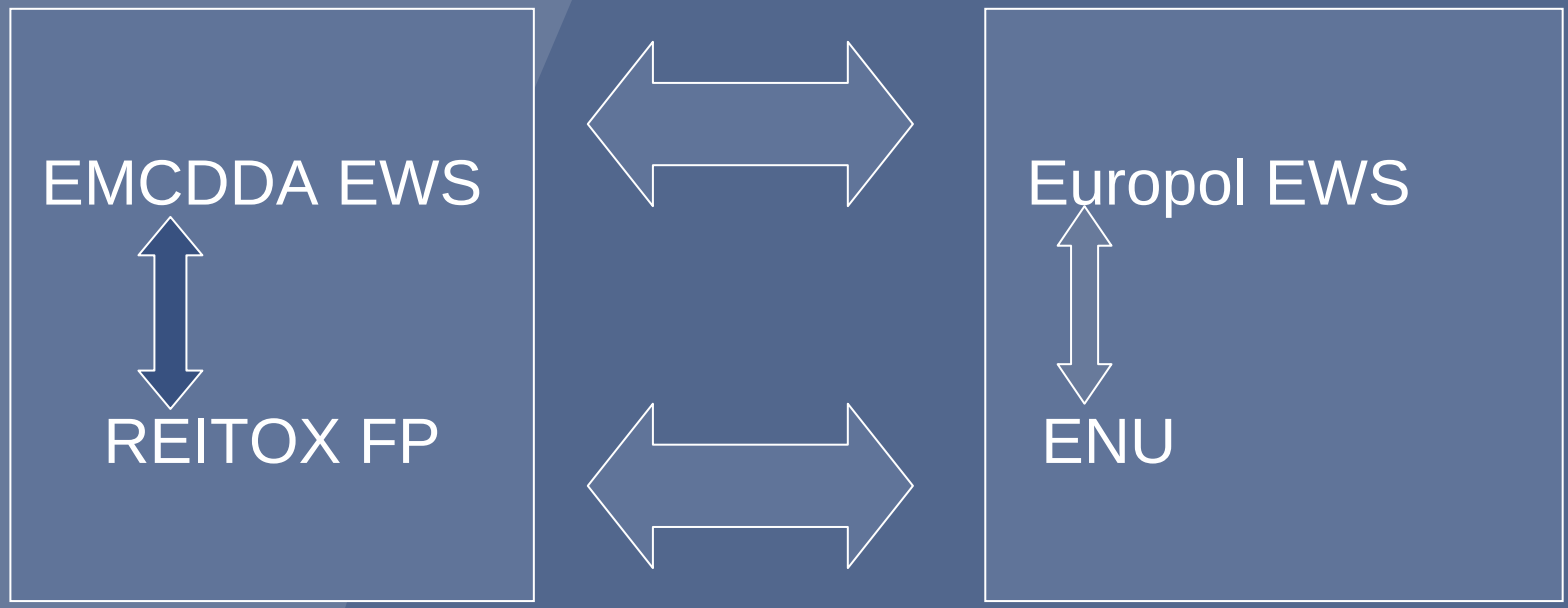
Initiation of the EWS

When a new synthetic drug is first detected, detailed information on its production, trafficking and use is sent:

- to the EMCDDA in Lisbon via the REITOX National Focal Points
- by the EU Member States to the European Police Office (Europol) in the Hague via the Europol National Units

Ideally the information is shared at national level

EWS information flow 1



Types of EWS information

- Informmation usful for the identification of the substance
- Information related to the use of the substance
- Information on the consequences of the use

Is collected and exchanged in two steps (levels)

EWS information content level 1

1. A chemical and physical description of the drug, including the name under which it is commonly known (incl. street names)

2. Details on the frequency, circumstances and/or quantities in which the drug has been encountered (for example, seizures, forensic analysis of seized drugs, toxicological analyses of specimens from deceased persons or analyses of blood and urine samples from individuals - these may include correctional system, the police, health/medical care, social welfare services, outreach services, on-site pill testing, etc., etc.)

3. First indications of the possible risks involved, including health and social risks

EWS information content level 2

3. Further info on the risks of use, toxicity, dosage and duration (immediate, short-term, long-term) of different effects (physical, psychological, behavioral, social)

4. Information on chemical precursors (incl. availability of precursors f.e. if industrially used)

5. The mode and scope of established or expected use of the drug as a psychotropic substance (patterns, settings, expected effects, knowledge of the drug,etc.)

6. Legal status and other uses of the drug (human veterinary medical use, industrial use, nutritional, esthetical, religious rituals, etc.)

Characteristics of EWS (and related information)

At national level

- Clear objectives and case definition (i.e. balance between specificity and sensitivity)
- Coverage - national, regional, local, city, etc.
- Pro-activity vs. reactivity
- Integration of sources
- Validity – the data is true and certain (backed by evidence)
- Reliability – consistent and replicable over time
- and comparability
- Usefulness of information
- Emergency and routine functions
- Ethically correct

Main sources of EWS-related information 1

At national level

- Heath and care system: specialised and non-specialised treatment centres, hospitals' emergency rooms, psychiatric departments, low threshold, outreach and street-work agencies, drug prevention centres, drug help lines, GPs, etc.

- Law enforcement agencies: prosecution authority, police, specialised drug units, customs, border guards, etc.

Main sources of EWS-related information 2

At national level

- Laboratory networks: forensic analysis of seized drugs, toxicological analyses of specimens from deceased persons or analyses of blood and urine samples from living individuals
- ‘Street’ level key informants: users, organizers of youth venues (concerts, raves, etc.), owners and staff of night clubs, cafés, etc.
- Other: Internet, Internet discussion groups and forums, media in general, etc.

Role and capacities of central EWS unit

Role

- Selective management of data input and output
- Provision of added value to primary data (feedback)
- Validation of data
- Maintenance of the EWS human, institutional and technical network
- Interface between the national and the supra-national level

Capacities

- Close link between the EWS unit and the policy level
- Expertise in the field of illicit drugs, toxicology, pharmaceuticals
- Integration in a multidisciplinary network of partners

The Council Decision

- Repeals/replaces the Joint Action while keeping the notion of EWS - risk assessment - control measures
- Extends the scope to all new psychoactive substances i.e. includes new psychotropic and new narcotic drugs alike (1961 & 1971 UN Conventions)
- Introduces stricter deadlines and clearer definitions
- Provides for a possibility for an increased role of EMEA
- Provides for an increased transparency and visibility through an Annual Report to the Council, Parliament and the Commission
- Requires changes in the operation of the EWS and risk assessment

Timeline 1

Notification of a new psychoactive substance by a MS

↓ **6 weeks**

Information collected

↓ **4 weeks**

EMCDDA – Europol Joint Report

↓ **4 weeks**

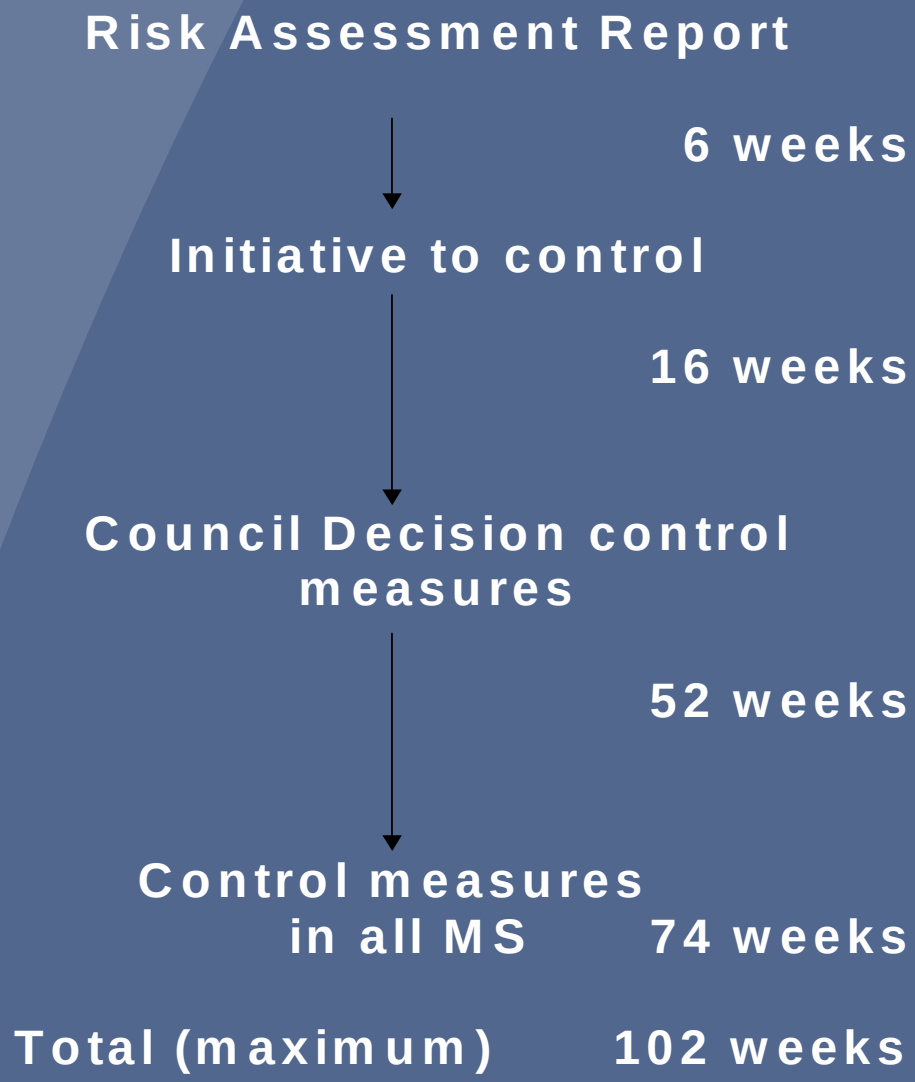
Risk Assessment requested

↓ **12 weeks**

Risk Assessment Report

28 weeks

Timeline 2


Risk Assessment Report
6 weeks
Initiative to control
16 weeks
Council Decision control measures
52 weeks
Control measures in all MS
74 weeks
Total (maximum)
102 weeks

Reporting 1

- Art. 4.1: Notification through a Reporting Form (REITOX NFPs)
- Art.5: Europol-EMCDDA Joint Report (Europol-EMCDDA)
- Art. 6.5: Risk Assessment Report (EMCDDA's extended Scientific Committee)
- Art. 10: Annual EMCDDA-Europol report to the Council, Parliament and the Commission (EMCDDA and Europol with input from EMEA)
- Art. 4.1 & Art. 10 EWS progress and annual report (REITOX NFPs)

Reporting 2

Notification through a Reporting Form is submitted to Europol and EMCDDA by the Member States (ENU and REITOX NFP) as soon as new psychoactive substance is detected.

Definition of Reporting Form: a structured form for notification of a new psychoactive substance and/or preparation containing a new psychotropic substance agreed between the EMCDDA/Europol and their respective networks in the Member States - Reitox and the Europol Nation Units.

Reporting 3

Europol-EMCDDA Joint Report to be available 10 (6+4) weeks from the date of the notification on the Reporting Form:

(a) chemical and physical description, including the name under which the new psychoactive substance is known: NFPs/EMCDDA, ENU/Europol;

(b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance: NFPs/EMCDDA, ENU/Europol;

(c) information on the involvement of organized crime in the manufacture or trafficking of the new psychoactive substance: ENU/ Europol;

Reporting 4

Europol-EMCDDA Joint Report

(d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and on the characteristics of users: NFPs/EMCDDA;

(e) information on whether or not the new substance is currently under assessment, or has been under assessment by the UN-system: EMCDDA;

(f) the date of notification on the Reporting Form of the new psychoactive substance to the EMCDDA or to Europol;

(g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State: NFPs/EMCDDA.

Reporting 5

Europol-EMCDDA Joint Report

(h) As far as possible, information will be made available on:

(i) the chemical precursors, that are known to have been used for the manufacture of the substance: NFPs/EMCDDA, ENU/Europol;

(ii) the mode and scope of the established or expected use of the new substance: NFPs/EMCDDA;

(iii) other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks: NFPs/EMCDDA, ENU/Europol.

Reporting 6

Europol-EMCDDA Joint Report

Information from the EMEA:

(a) the new psychoactive substance has obtained a marketing authorisation;

(b) the new psychoactive substance is the subject of an application for a marketing authorisation;

(c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended.

Reporting 7

Art. 10: Annual EMCDDA-Europol report to the Council, Parliament and the Commission (EMCDDA and Europol with input from EMEA)

The EMCDDA and Europol shall report annually to the Council, the EP, and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision.

The Report shall, in particular, include experiences relating to coordination between the system set out by the Decision and the pharmacovigilance system.

Reporting 8

EWS progress and annual (final) report (REITOX NFPs)

A tool that provides for a longer-term monitoring (regular measurement and analysis) of the situation related to new drugs. It also provides a valuable feedback on developments related to the national EWS. As such it is the basis for the production of three main outputs:

- summaries by substance prepared by the EMCDDA ;
- EMCDDA's Annual Report on the state of the drugs problem in the EU and Norway; and, as of 2005,
- the Annual Report to the Council, Parliament and the Commission

Guidelines for risk assessment of NSD

Principles

- Consider a dual definition of risk (probability and degrees of seriousness)
- Risk is considered independently of legal status
- Consider a wide range of control options
- Consider scientific evidence in relation to better-known drugs
- Consider weighting separately the issues of reliability (quality) of information and relevance (specific risk issues involved such as health and social issues and consequences of prohibition)
- Proportionality and proportion

European Database on New Drugs

EDND will reflect the information flow and content stipulated by the new Council Decision.

Automatic update of the database will make the reported data dynamically available for consultation and rapid extraction in form of reports, early warnings, etc.

EDND is be largely compatible with all reporting tools of the EWS

Contacts

EMCDDA’s Joint Action Programme (P3)

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