Regulation of new psychoactive substances in Hungary

In Hungary a new regulation of new psychoactive substances came into effect on the 3rd of April 2012. The new regulation is based on three regulatory actions:

- *Act XCV of 2005 on medicinal products for human use and on the amendment of other laws regulating the pharmaceutical market* (the amendment to the Act came into effect on the 1st of March 2012)*;*
- *Government Decree 66/2012 (IV. 2.) on activities related to narcotic drugs, psychotropic substances and new psychoactive substances, on scheduling of these substances and on modification of schedules* (repealing Government Decree 142/2004 and Government Decision 1196/2009) (the Decree came into effect on the 3rd of April 2012) and
- *§283/B of Criminal Code* (the amendment to the Criminal Code came into effect on the 1st of March 2012)*.*

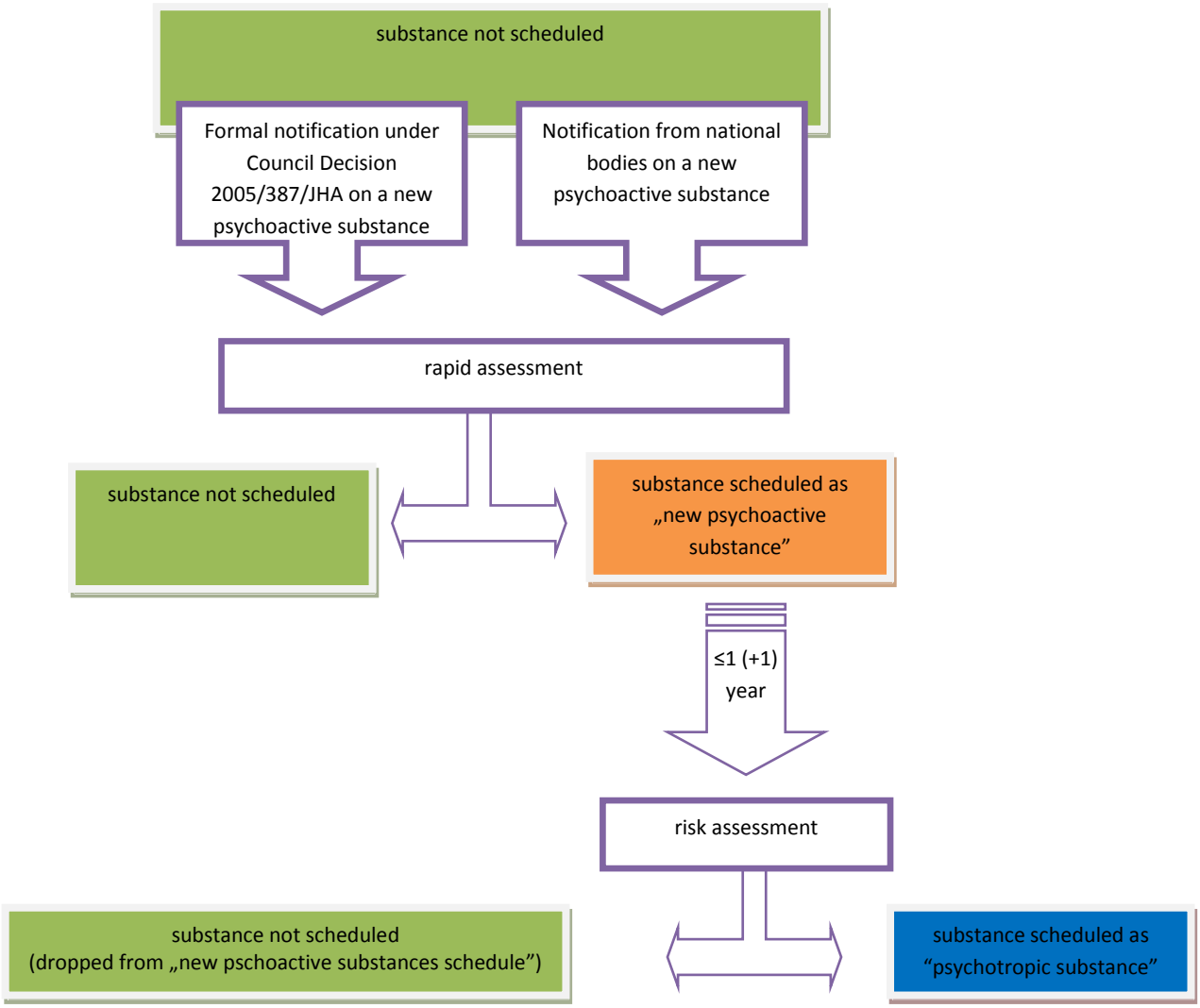
Act XCV of 2005 provides the legal framework (§15/B-F) for the new regulation while *Government Decree 66/2012* specifies the processes and appoints the responsible bodies for reporting new substances, rapid assessment, scheduling and risk assessment. The act creates the definition of „new psychoactive substance" (Act XCV of 2005 §1/37) which is: a compound or chemical compound group that currently appeared on the market; has no therapeutic value; affects the central nervous system so it has the ability to change mental state, behaviour or perception; therefore it can pose as serious a threat to public health as the substances listed on drug schedules; and therefore the Government scheduled it in a decree. The Act and the Government Decree creates a schedule (Schedule C of Annex 1 of Government Regulation 66/2012) for new psychoactive substances that lists individual substances and compound groups (applying the generic approach).

According to the act if a substance is reported in a formal notification under Council Decision 2005/387/JHA it has to be assessed whether it should be scheduled under the Government Decree. The rapid assessment has to prove that no information available at national authorities or professional institutes

- suggests that the given substance has a medical use and
- rules out that it pose as serious a threat to public health as the substances listed on narcotic and psychotropic drug schedules.

A risk assessment shall be carried out in case of all substances listed individually on the (new) schedule within one year of their scheduling. As a result of the risk assessment the substance is either scheduled on psychotropic drugs schedules (schedules of Act XXV of 1998) or dropped from the schedule of new psychoactive substances. If the risk assessment results with the decision 'no sufficient data is available for the assessment' the substance may remain on schedule C for an additional year. Risk assessment is not to be applied in case of compound groups which stay on the schedule as long as any substance that belongs to the given group fulfils the requirements of the rapid assessment. Every activity related to new psychoactive substances defined by regulatory actions might be carried out only with a valid license (obtained from the authority defined by the Act).

According to the new statutory definition of the *Criminal Code (§283/B)* on the misuse of new psychoactive substances whoever (without official authorization) offers or supplies new psychoactive substances, or is engaged in the distribution, trafficking or dealing of such, commits a felony and shall be punishable with imprisonment up to three years.


substance not scheduled
Formal notification under Council Decision 2005/387/JHA on a new psychoactive substance
Notification from national bodies on a new psychoactive substance
rapid assessment
substance not scheduled
substance scheduled as „new psychoactive substance"
≤1 (+1) year
risk assessment
substance not scheduled (dropped from „new pschoactive substances schedule")
substance scheduled as "psychotropic substance"