資料５－１

欧州における経皮・吸入投与による短期毒性試験の要求状況

欧州においては、欧州委員会規則等によりデータ要求を定めており、経口以外の投与経路による短期毒性試験については、専門家の判断による条件付き要求となっている（詳細：表を参照）。

反復経皮投与毒性試験については、「ヒトのリスク評価のため、強い刺激性がなければ、追加の経皮試験はケースバイケースで要求される」としており、具体的な試験方法としては、28 日間反復経皮投与試験及び 90 日間反復経皮投与試験を採用している。

反復吸入毒性試験については、「揮発性の有効成分(蒸気圧が ＞1 ×10 –2Pa)については、吸入投与による短期毒性試験が実施されるべきかの決定には、専門家の判断（例えば、投与特異的な代謝データに基づき）が必要である」としており、具体的な試験方法としては、28 日間反復吸入毒性試験及び 90 日間反復吸入毒性試験を採用している。

表：欧州委員会規則等

Regulation (EU) No 283/2013; ANNEX; SECTION 5 Toxicological and metabolism studies[1]（抄）
5.3. Short-term toxicity 5.3.3. Other routes Circumstances in which required For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant. For volatile active substances (vapour pressure >10^{-2} Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

[1] COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (URL: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013R0283)

Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market[2]（抄）		
Reference to Part A of the Annex to Regulation (EU) No 283/2013	Test methods	Guidance documents
5.3.3. Other routes	Method B8 Repeated dose (28 days) toxicity (inhalation) (Annex to Regulation (EC) No 440/2008). Method B.9 Repeated dose (28 days) toxicity (dermal) (Annex to Regulation (EC) No 440/2008). Method B.28 Sub-chronic dermal toxicity test: 90-day repeated dermal dose study using rodent species (Annex to Regulation (EC) No 440/2008). Method B.29 Sub-chronic inhalation toxicity study 90-day repeated inhalation dose study using rodent species (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 410: Repeated dose dermal toxicity: 21/28-day study. OECD Test Guideline 411: Subchronic dermal toxicity: 90-day study. OECD Test Guideline 412: Subacute inhalation toxicity: 28-day study. OECD Test Guideline 413: Subchronic inhalation toxicity: 90-day study.	—

[2] Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (URL: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013XC0403(02))