

1 May 2024

## Deadlines for sequential testing used in dossier and substance evaluation

The table covers the deadlines for most commonly requested sequential testing under dossier evaluation and substance evaluation.

Please note that when one cell contains multiple tests it either means that they are alternatives or that they run in parallel.

1st request(s)	2nd request(s)	3rd request(s)	4th request(s)	Deadline (months)
Growth inhibition (algae) and/or Short-term toxicity on invertebrates (Daphnia sp.) and/or Short-term toxicity on fish	Long-term toxicity testing on invertebrates (Daphnia sp.)			<b>12</b>
Growth inhibition (algae) and/or Short-term toxicity on invertebrates (Daphnia sp.) and/or Short-term toxicity on fish	Fish early-life stage (FELS) toxicity (and Long-term toxicity testing on invertebrates (Daphnia sp.))			<b>18</b>
Simulation study in sediment with identification of degradation products	Simulation study in soil with identification of degradation products			<b>24*</b>
Simulation study in water with identification of degradation products	Simulation study in sediment with identification of degradation products	Simulation study in soil with identification of degradation products		<b>30*</b>
1 simulation study with identification of degradation products	Bioaccumulation in aquatic species (fish)			<b>30*</b>
Simulation study in sediment with identification of degradation products	Simulation study in soil with identification of degradation products	Bioaccumulation in aquatic species (fish)		<b>36*</b>
Simulation study in water with identification of degradation products	Simulation study in sediment with identification of degradation products	Simulation study in soil with identification of degradation products	Bioaccumulation in aquatic species (fish)	<b>42*</b>

\*For the sequential simulation studies the procedural time is shortened as learnings from preparation and conduct of the first test can be re-used for the second/third tests.

1 May 2024

<b>1st request(s)</b>	<b>2nd request(s)</b>	<b>3rd request(s)</b>	<b>4th request(s)</b>	<b>Deadline (months)</b>
Acute toxicity (any route)	Acute toxicity (any route)			<b>12</b>
Skin sensitisation (in vitro test)	Skin sensitisation (in vivo study)			<b>12</b>
Skin corrosion/irritation (in vitro test)	Skin corrosion/irritation (in vivo study)			<b>12</b>
Serious eye damage/eye irritation (in vitro test)	Serious eye damage/eye irritation (in vivo study)			<b>12</b>
Skin corrosion/irritation (in vivo study)	Serious eye damage/eye irritation (in vivo study)			<b>12</b>
Skin irritation/corrosion (in vitro test)	Eye irritation (in vitro test) and Skin sensitisation (in vitro + in vivo)			<b>12</b>
In vitro cytogenicity (mammalian cells)	In vitro gene mutation (mammalian cells)			<b>12</b>
In vitro gene mutation (bacteria) and In vitro cytogenicity (mammalian cells)	In vitro gene mutation (mammalian cells)			<b>12</b>
In vitro cytogenicity (mammalian cells)	In vivo micronucleus combined with In vivo Comet assay			<b>24</b>
In vitro cytogenicity (mammalian cells)	In vivo mutagenicity (TGR - somatic cell)			<b>24</b>

1 May 2024

<b>1st request(s)</b>	<b>2nd request(s)</b>	<b>3rd request(s)</b>	<b>4th request(s)</b>	<b>Deadline (months)</b>
Pre-natal developmental toxicity in a 1st species (rat or rabbit)	Pre-natal developmental toxicity in a 2nd species (rabbit or rat)			<b>24</b>
Screening for reproductive/developmental toxicity	Pre-natal developmental toxicity (rat)			<b>18</b>
Screening for reproductive/developmental toxicity	Pre-natal developmental toxicity in a 1st species (rat or rabbit) and Sub-chronic toxicity (90-day), one species, rodent			<b>24</b>
Screening for reproductive/developmental toxicity	Pre-natal developmental toxicity in a 1st species (rat or rabbit) and Sub-chronic toxicity (90-day), one species, rodent	Pre-natal developmental toxicity in a 2nd species (rabbit or rat)		<b>30</b>
Pre-natal developmental toxicity in a 1st species (rat or rabbit) and In vivo mutagenicity	Pre-natal developmental toxicity in a 2nd species (rabbit or rat)			<b>24</b>
Pre-natal developmental toxicity in a 1st species (rat or rabbit) and Sub-chronic toxicity (90 day), one species, rodent	Pre-natal developmental toxicity in a 2nd species (rabbit or rat)			<b>24</b>

1 May 2024

<b>1st request(s)</b>	<b>2nd request(s)</b>	<b>3rd request(s)</b>	<b>4th request(s)</b>	<b>Deadline (months)</b>
In vivo mutagenicity (not TGR)	EOGRTS (independent of design)			<b>30</b>
In vivo mutagenicity (TGR)	EOGRTS (independent of design)			<b>36</b>
Pre-natal developmental toxicity (rat or rabbit)	EOGRTS (independent of design)			<b>36</b>
Pre-natal developmental toxicity in a 1st species (rat or rabbit)	Pre-natal developmental toxicity in a 2nd species (rabbit or rat) and EOGRTS (independent of design)			<b>36</b>
Pre-natal developmental toxicity in a 1st species (rat or rabbit) and In vivo mutagenicity	(Pre-natal developmental toxicity in a 2nd species (rabbit or rat) and) EOGRTS (independent of design)			<b>36</b>