

**DG SANTE's policy on endocrine disrupting pesticides that are subject to the interim criteria (Regulation 1107/2009, Annex II, 3.6.5) and currently assessed:**  
**Avoiding to apply a ban based on the Interim Criteria.**

	<b>Pesticide</b>	<b>EFSA opinion</b>	<b>State of approval or years of delay* (first deadline-new deadline)</b>	<b>Decision taken</b>
1	Acibenzolar-S-methyl <i>New substance</i>	(tbc) R2 and toxic effects that may-be linked to endocrine organs; endocrine MoA could not be ruled out; data gap for level 2/3 OECD tests	Approved in April 2016 for 15 years	“no interim criteria (IC)” according to DG SANTE
2	Bentazon	(tbc) R2; adverse effects on thyroid; adverse effects on foetus; data gap OECD level 2/3	>6 years delay (2011 – 2018)	Delayed
3	Diquat	(tbc) R2 and toxic for endocrine organs	>5 years delay (2012 – 2018)	Delayed
4	Flutianil <i>New substance</i>	(tbc) R2 plus C2 plus toxic ED organs; CAoC; ED MoA could not be ruled out; data gap OECD level 2/3	Not available	Not yet (EFSA opinion delivered)
5	Flupyr-sulfuron	(tbc) R2 and C2; unlikely to be an ED; no data gap	>6 years delay (2011 – 2018)	No decision yet; industry-solicited studies on derogations are ongoing
6	Isoxaflutole	R2 and (tbc) C2	>4 years delay (2013 – 2018)	Delayed; industry-solicited studies on derogations are ongoing
7	Mesotrione	(tbc) R2 and toxic for ED organs (testis, thyroid);	>4 years delay (2013 – 2018)	Delayed
8	Pendimethalin	(tbc) R2 but no toxicity on ED organs; no IC; but positive ED active substance	>3 years delay (2014 – 2018)	Delayed
9	Pymetrozin	(tbc) R2 and C2; adverse effects on endocrine organs; ED MoA could not be ruled out; data gap OECD level 2	>6 years delay (2011 – 2018)	Delayed; industry-solicited studies on derogations are ongoing
10	Thifensulfuron-methyl	(tbc) R2 plus toxic ED organs (mammary tumours); data gap, ED MoA;	Approved in November 2016 for 15 years	Approval with CD on origin mammary tumours (mechanistic data); no IC

11	Isoproturon	(tbc) R2 plus C2; effects on reproduction might be ED related; data gap OECD level 2	<u>Banned</u> in 2016	Non-approval based on non-IC reasons (groundwater pollution); derogations NE and 4.7 not relevant (other deficiencies preclude)
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\* by a non-legally founded invention called "prolongation"

C2= human carcinogen category 2

R2= toxic to human reproduction category 2

IC = interim criteria (two conditions: C2+R2 substances *or* R2 + toxic for endocrine organs substances)

MoA = Mode of Action

CAoC = Critical Area of Concern = EFSA's description to highlight that based on the available data a substance does not comply with the law

CD = confirmatory data (substance gets approved despite data gaps, which have to be delivered in a later stage but too often are "forgotten")

ED = endocrine disruption

tbc = to be considered = EFSA opinion on classification; still needs to be made official by European Chemical Agency ECHA

NE = derogation/exception in case of negligible exposure, Annex II, 3.6.5

4.7 = derogation/exception in case of serious danger to plant health (art. 4.7, Reg. 2009)

Overall conclusion:

- The first condition of the IC, R2 + toxic for the endocrine organs has never been a reason for a ban;
- Likewise, the second condition of IC, R2 + C2 has never made it as a justification for a ban up to now;
- In the single case of a ban, SANTE has selected another justification than IC (Isoproturon)