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Impacts on Human Health and Safety of Naturally Occurring and Supplemental Hormones in Food Animals

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Is there a breakdown by income bracket for percentage of total income spent on food, and if so, are there significant differences between the bottom 20% and the top 20%?

RC: The Economic Research Study cited reported that as their incomes rise, households spend more money on food but it represents a smaller overall budget share. In 2018, households in the lowest income quintile spent an average of $4,109 on food, representing 35.1 percent of income, while households in the highest income quintile spent an average of $13,348 on food, representing 8.2 percent of income. The mean for all brackets of income was 9.5%. The same breakout was not done for other countries but would likely show the same pattern at higher overall budget share. Additionally, households in the lowest income brackets would have access to government support for food purchases.

How often have impact assessments found significant hormone release in to the environment? What has been the most serious case recognized so far?

ZS: Post-approval environmental impact studies are conducted by many institutes. Initial environmental assessment studies are conducted prior to approval of the technology. If there is significant hormone release to the environment, the technology would not be approved for use in the first place. Since wildlife would produce naturally occurring hormones, special surveillance interest for synthetic hormones seems logical. Additionally, steroid hormone metabolism changes the isomer of the hormone from the anabolic β subunit form, to the α subunit that is not anabolic.

JL: Extensive environmental impact assessments (EA) are required for each product approval by the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA). If a significant negative impact due to hormone release into the environment was identified during the extensive environmental assessment studies, that potential product would not be granted regulatory approval for sale/use. Therefore, no serious cases exist of a negative environmental impact due to hormone release associated with an environmental assessment.

Have there been any studies with comparing excretion rates with natural hormonal rates in plants (eg: phytoestrogens?)

RC: The authors are not aware of any studies comparing excretion rates of hormones into the environment from plants versus hormones from ruminants or swine.

Can someone provide links to official confirmations of those statements; the assays and the levels detected/eliciting of biological effects in humans?

JL: 1) Safety evaluation standards in the United States by T. M. Farber, M. Arcos, and L. Crawford, in *Anabolics In Animal Production, Public Health Aspects, Analytical Methods, and Regulation*, pp. 509-514, in Symposium held at OIE, Paris, 15-17 February 1983, Office International des Epizooties, ISBN 92-9044-118-6.
2) Guidance for Industry #3, General Principals for Evaluating the Safety Of Compounds Used in Food-Producing Animals, Food and Drug Administration, Center for Veterinary Medicine.
3) Freedom of Information (FOI) for each hormone product of interest.

Can you comment on the use of bST to INCREASE animal wellbeing and welfare? Further, if established, how do we get that story out there to counter all of the negative stories around bST?

RC: Although beneficial effects of bST have been reported in the literature for reproduction in cattle and transition cow disorders no company has sought approval for use of bST in improving animal welfare and well-being.

What is the range of naturally occurring hormones between different individual animals and different breeds of animals? in Re: setting the boundary at 1% above "normal".

JL: The 1% increase for estradiol, progesterone, and testosterone is derived from *de novo* daily production in the most sensitive population of humans, prepubertal girls and boys. This then allows safe daily exposure levels and muscle tolerances for the entire human population. The FDA/CVM computed incremental exposure permitted are 0.06 micrograms for estradiol, 1.5 micrograms for progesterone, and 0.3 micrograms for testosterone. A further safety factor is that only about 10% of these three steroids are absorbed through the human gastrointestinal tract, i.e. about 0.1% of the *de novo* production rate. Studies are required to measure the concentration of each steroid in the target animal for which each steroid in intended for use. Those studies identify the mean and variance of the natural concentration of each steroid and measure the mean and variance of the hormone concentration following administration of the hormone(s) of interest (estradiol, progesterone, testosterone). The hormone concentration following administration cannot exceed the FDA/CVM mandated numbers of 0.06 micrograms for estradiol, 1.5 micrograms for progesterone, and 0.3 micrograms for testosterone.

Are there surveys that have queried the extent of use of hormonal supplements among livestock producers. For example, is aggregate use 100% of producers (assuming non certified organic producers) or is it a much smaller percentage. These types of data are used in the pesticide "business" to understand better probabilistic population level exposures.

ZS: At least for steroid hormone use in finishing cattle, ~90% of steers and heifers are administered a steroidal implant. This information is released periodically by APHIS of the USDA in a survey of feedlot producers. From my experience, implant technology is not as widely used in calf-hood situations (cow-calf producer) as it has been in the past, I believe it has something to do with perceived increases in calf value when the

technology is not used. Survey of sale barn prices by Dr. Ken Odde at KSU would suggest that non implanted calves do not receive a premium when sold.

JL: For reproduction products, the percentage use is on the order of 10% to 20% for beef and on the order of 50% for dairy. Since these products are used to assist with breeding, and since breeding cattle are not intended for harvest associated with breeding, the percentage of cattle receiving reproduction related hormones at harvest is essentially zero.

Does increasing the use of exogenous hormones does not contribute to increase of cost of production?

RC: The return on investment for use of exogenous hormones is typically at least 3/1 or greater. ($3 return for every dollar invested). This more than covers the additional cost of production. Producers do not use products that are not profitable to them.

What types of current research are on-going to optimize the use of hormones? Are there any impacts of MRLs on animal agriculture trade?

JL: Most current research is directed at current label extensions. MRLs*, per se*, do not impact animal agriculture trade. In-country decisions regarding their perspective on what hormones are "allowed" have the greatest impact on animal agriculture trade.

Given the impact of the COVID-19 on the food system, are practices being modified? What are the impacts on production goals, etc.?

ZS: At least for beta adrenergic agonist, the COVID-19 pandemic has made using these technologies more difficult, from the standpoint of logistic issues related to feeding for the prescribed amount of time and getting cattle harvested in a timely manner. Many folks who could not get a confirmed harvest date for cattle opted out of using a beta-adrenergic agonist. For the steroid hormones, our recommendation when the harvest plants were shutting down was to re-implant if one could handle the cattle and had the available labor resources. Estrogen containing implant delay fattening by influencing long bone growth, plus implants can really be influential on dry matter feed conversion. In any case, the COVID-19 pandemic might have increased adoption of late phase implanting in order to not have cattle go through a time of no implant payout. It is important to realize that steroidal implants have not withdrawal period, so this practice was acceptable.

What percent of dairy herds are currently using rBST? Is it still in use anywhere?

RC: Recombinant bovine somatotropin (Posilac®) is still approved for use in lactating dairy cows to increase milk yield during established lactation. The product is still being sold in the United States although there are no published data on extent of use.

Does the use of exogenous hormones create dependency?

JL: No

What are the biological effects of phytoestrogens when ingested by humans?

JL: Suggested published papers that address this complicated issue are:

1) The potential health effects of dietary phytoestrogens

Ivonne M C M Rietjens, Jochem Louisse, and Karsten Beekmann. 2017.
Br J Pharmacol 174(11): 1263–1280.
Published online 2016 Oct 20. doi: 10.1111/bph.13622
C5429336 PMID: 27723080

2) The pros and cons of phytoestrogens

Heather B. Patisaul and Wendy Jefferson
Front Neuroendocrinol Author manuscript; available in PMC 2011 Apr 12.
Published in final edited form as:
Front Neuroendocrinol. 2010 Oct; 31(4): 400–419.
Published online 2010 Mar 27. doi: 10.1016/j.yfrne.2010.03.003
PMCID: PMC3074428
NIHMSID: NIHMS271669
PMID: 20347861