Receieved via email on October 7, 2016 From: Shalene McNeill, The Beef Checkoff

Comments:

Dear Dr. Boyd:

The Beef Checkoff appreciates the opportunity to submit scientific evidence to the Office of Health Assessment and Translation (OHAT) in response to the September 9, 2016, Federal Register (80 FR 62513-14) request for information regarding the possible evaluation of consumption of red meat, processed meat, and meat cooked at high temperatures for non-cancer health outcomes (e.g. development, reproductive, or immunological disorders).

In response to the request for data on dietary intake estimates of red meat, processed meat, or meat cooked at high temperatures, we submit the following:

The National Toxicology Program (NTP) reports the following definitions and dietary intake estimates of red meat and processed meat

(https://ntp.niehs.nih.gov/pubhealth/roc/noms/index.html):

Red meat refers to meat that has more red than white fibers such as beef, goat, lamb and pork. People are exposed to red and processed meat in their daily diet. In the United States, daily total meat intake is 128 g, of which 55% is red meat.

Processed meat is meat that is preserved by smoking, curing, salting and adding chemical preservatives. In the United States, daily processed meat is estimated to be 23 g.

Although NTP does not provide a source of the reported dietary intake estimates of red meat and processed meat, it appears the information is from The National Health and Nutrition Examination Survey (NHANES) 2003-2004 data as evaluated by the National Cancer Institute in their publication: Daniel et al, 2011. However the authors report that 58% of the total meat intake was red meat and 22% of the meat consumed in the U.S. is processed. This is slightly different from the numbers reported by NTP.

As Klurfeld (2015) discusses, there is a lack of valid biomarkers for meat-related intake or exposures available in the scientific literature, thus observational studies must be used to determine dietary intake (exposure) estimates which are primarily obtained via memory-based dietary assessment methods such as NHANES. NHANES is based on the subject's self-reported, retrospective perceptions of food and beverage consumption in the recent 24 hours (CDC/NCHS, 2015). This self-reported food recall limits the reliability of NHANES in providing a true and accurate representation of the meat-related exposures as discussed by Mitka (2013) and Archer and colleagues (2015). Relevant to the limitations of self-reported food recall, a research study by Nicklas and colleagues (2015) compared statistical approaches to examine potential associations between a commonly food consumed in the diet and health risk factors and concluded that "all traditional dietary analyses in epidemiology share one strong but incorrect assumption: that exposures, such as foods or nutrients, were measured with great accuracy". In addition, Archer and colleagues (2013), who conducted an evaluation of the validity of 4 decades of NHANES data, concluded that the "NHANES dietary measurement protocols have failed to provide accurate estimates of the habitual caloric consumption of the U.S. population" and data of the majority of subjects in NHANES intake data collected from 1971-2010 were not "physiologically plausible". Specific to meat-related exposure, Hallström and Börjesson (2013) report various factors that may affect reliability and accuracy in how meat-consumption data is produced and presented, including but not limited to weight of bones, food losses and waste, cook vield and meat content in processed meat.

To further demonstrate the complexity of estimating dietary meatrelated exposures, and even more relevant for this evaluation, Oostindjer et al (2014) highlights the nomenclature discrepancies of meat related terminology as "meat" is a broad food category that is not standardized in the nutritional epidemiology literature. Observational studies commonly report intake of "red meat" or "red and processed meat" without further definition and there is often no intake data to distinguish fresh meat from processed meat, or lean meat from higher fat sources, as discussed by McNeill and Van Elswyk (2016). This issue was made apparent in the Scientific Report of the 2015 Dietary Guidelines Advisory Committee (DGAC) as the lack of definitions of meat, red meat, and "red and processed meats" made it difficult to collectively interpret results from the literature. The 2015 DGAC ended up using a general label of "red and processed meat" in the concluding statements of their report. For example, the defined processed meat vs. lean meat but their definition overlaps with processed meat as they both include "smoked/cured ham". The DGAC (2015) included a footnote in their executive summary stating "As lean meats were not consistently defined or handled similarly between studies, they were not identified as a common characteristic across the reviews. However, as demonstrated in the food pattern modeling of the Healthy U.S.-style and Healthy Mediterranean-style patterns, lean meats can be a part of a healthy dietary pattern". The American Meat Science Association raised their concern about this footnote in their public written comments submitted to the federal government on the Scientific Report of the 2015 Dietary Guidelines Advisory Committee, where they stated "Confusing the issue is the report's footnote regarding "lean meats." The statement and footnote contradict each other and run counter to numerous published studies and ongoing research that continue to show that meat and poultry play a vital role in a healthy diet (Mabry, 2015 on behalf of AMSA)." Oostindjer and co-workers (2014) concluded that the development of standardized terminology could clearly distinguish between fresh and processed red meat, processed meat from beef vs. pork, and poultry, and plant vs. animal-derived protein.

To illustrate the inconsistencies in meat terminology across the scientific literature, in their publication, Daniel and colleagues (2011) defined the "red meat" category as beef, pork, veal, lamb, game as well as the respective components of processed meat and organ meats. Similarly, the "white meat" category was defined as poultry and the processed and organ components from poultry (Daniel et al, 2011). However "total meat" was the sum of fresh (not processed) red and white meat, plus cured meat, such as bacon and ham, as well as organ meats and fish (Daniel et al, 2011). Processed meat included frankfurters, sausage and luncheon meats (made from meat or poultry), but did not include cured meats, such as ham or bacon (Daniel et al, 2011).

The definitions described above are also inconsistent with the definitions used by the International Agency for Research on Cancer (IARC), who defined "red meat" as unprocessed mammalian muscle meat—for example, beef, veal, pork, lamb, mutton, horse, or goat meat—including minced or frozen meat; it is usually consumed cooked Bouvard et al (2015). Bouvard et al (2015), on behalf of IARC, define "Processed meat" as "…meat that has been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavor or improve preservation. Most processed meats, poultry, offal (eg, liver), or meat byproducts such as blood." Using these definitions, the IARC working group classified consumption of processed meat as "carcinogenic to

humans" (Group 1) on the basis of sufficient evidence for colorectal cancer and classified consumption of red meat as "probably carcinogenic to humans" (Group 2A). By the IARC definition, low sodium, low-fat deli turkey meat would be considered "carcinogenic to humans". Oostindjer and colleagues (2014) conclude that "ambiguous categorization can become a problem for consumers when they learn about the cancer risk associated with red meat, as they may not know which specific products are referred to."

As outlined by Bidlack and co-workers (2009), exposure assessments are also limited by the methodology necessary to convert NHANES data (What We Eat in America; WWEIA) to per capita average intakes using the MyPyramid Equivalents Database (MPED) or to estimate exposure using the Food Commodity Intake Database (FCID 2005-2010). As described in detail by Daniel and co-workers (2011), MPED is used to convert dietary intake data into ounceequivalents after disaggregating mixtures and discretionary fats. Daniel notes "Allowable fat in the meat group includes that present in lean cuts of meat trimmed of all fat and poultry without skin". Eliminating the portion of meat that is fat may not provide a reliable exposure estimate of any substance that may accumulate in the fat of meat or be created during the process of cooking meat fat (Gibis, 2016). In addition, WWEIA provides only population averages which do not permit assessment of high or low consumers (Bidlack et al., 2009). The FCID database is designed to improve the usefulness of WWEIA data for exposure assessments by providing grams of food commodity consumed per kg bodyweight per day. Importantly, however, the FCID database has several limitations of use which are outlined in detail at http://fcid.foodrisk.org/faq/#q8. Most relevant to the assessment of meat exposure is the fact that the FCID is driven by commodity categories that are representative of agricultural products, not highly processed foods (EPA/OPP, 2016). As such, there is no mechanism within FCID to separate fresh meat from processed meat but rather both are combined (EPA/OPP, 2016).

In conclusion, reports of dietary intakes vary depending on the method of data collection (Fehrenbach et al, 2016) and the name or definition used to describe red meat (Belk, 2016) and/or the cooking method (McCarty, 2010). The NHANES 2003-2004 data is in excess of 10 years old and Americans are eating differently today than when their intakes were recorded as illustrated in Food Availability data presented by the Economic Research Service (USDA/ERS, 2016). Since the 1980's, the Dietary Guidelines for

Americans have emphasized the consumption of lean meats (USDA/HHS, 1980). During the past four decades, changes in cattle breeding and management along with trimming practices of processors, retailers and foodservice operators resulted in an estimated 44% reduction in available total fat (from 13% to 7%) and a 29% reduction in saturated fat per capita (from 13% to 9%) contributed by beef as highlighted by McNeill and colleagues (2012). Intake of total red meat has decreased over this time period matched by an increase in poultry consumption as illustrated with food availability data, presented by Daniel and colleagues (2011) as well as the National Chicken Council (2016). In addition, cooking methods are changing, which are not fully taken into consideration in NHANES data collection. For example, McCarty (2010) states that spaghetti and skillet meals are the most common way beef is enjoyed at home, as opposed to burgers or steaks. Oostindjer and colleagues (2014) conclude that "Epidemiological and mechanistic data on associations between red and processed meat intake and CRC are inconsistent and underlying mechanisms are unclear. There is a need for further studies on differences between white and red meat, between processed and whole red meat and between different types of processed meats, as potential health risks may not be the same for all products. Better biomarkers of meat intake and of cancer occurrence and updated food composition databases are required for future studies." Efforts by the American Meat Science Association are currently underway to develop more standardized terminology; their expertise may be a resource for NTP (AMSA, 2016).

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