これらのことから、塩酸ラクトパミンのヒト循環器系への影響を評価するにあたっては、イヌよりもサルを用いた試験結果を外挿することが適当と考えられる。

【エンドポイントの選択について】

各種の遺伝毒性試験及び慢性毒性/発がん性併合試験の結果から、塩酸ラクトパミンは遺伝毒性発がん性を示さないと考えられ、ADI を設定することが可能である。

亜急性毒性、慢性毒性/発がん性併合、催奇形性、繁殖毒性試験等の通常評価に用いられる各種試験に加え、ラクトパミンについてはβ-作動薬の薬理作用に関連する指標として、心拍数、血圧、心電図等の循環器系への影響がイヌ、サル及びヒトにおいて調べられている。このうち、最も低い用量で被験物質投与の影響が認められたと考えられる指標は循環器系への影響に関するもので、イヌでは 0.002mg/kg 体重/日、サルでは 0.125mg/kg 体重/日、ヒトでは 0.066mg/kg 体重であった。3 者の比較ではイヌで最も低い値で影響が認められているが、循環器系への影響については、先にも触れたように、イヌでは動脈圧を降下させるのに対しヒトでは上昇させる等、ヒトとイヌではその影響に相違点が認められているのに対し、サルとヒトでは類似している。また、サルとヒトの試験を比較すると、サルの試験が 1 年間の長期投与でかつ病理組織学的検査を含めたフルセットの検査が行われているのに対し、ヒトの試験は 6 名のボランティアに対し単回漸増投与計画法で心臓血管系機能に関するパラメーターのみの測定となっている。

このことから、ヒトに対する食品健康影響評価を実施する上でのエンドポイントとしては、サルにおける 1 年間慢性毒性試験における循環器系への影響を採用することが最も適当であると考えられた。ただし、ヒトにおいて直接の知見が得られていることから、これについてもあわせて考慮すべきであるとされた。

【一日摂取許容量(ADI)の設定について】

塩酸ラクトパミンの ADI はサルの 1 年間慢性毒性試験の NOEL 0.125mg/kg 体重/日に種差 10、個体差 10 の安全係数 100 を考慮して、0.00125mg/kg 体重/日と設定されると考えられる。

なお、6 名のヒトボランティアにおける心臓血管系の作用についての試験(経口)からは、NOEL 5mg/ヒトが得られており、試験に参加した 6 名の平均体重 75.5kg で体重あたりに補正すると、0.066mg/kg 体重である。ヒト試験については、安全係数として個人差 10 のみが適用される。しかしながら、他のβ作動薬の副作用として、動悸、頻脈、心(筋)虚血、不整脈、血圧上昇と心拍数増加等が知られており、冠動脈疾患、心房細動等の心疾患に対してはこの作用が時に強く表れるとされている[5]ように、高リスクと思われる心臓疾患のバックグラウンドレベルがある程度見込まれるのに対して、この試験の対象は限られた人数の健常男性であり限定的であることから、追加の安全係数が適用されるべきであろうと考えられる。また、NOEL の特定で考慮された影響は心電図の微細な変化であり、心拍数や血圧に変化が認められるのは 15mg/ヒト以上の用量である。これらのことを総合的に考慮し、追加の安全係数については 5 を適用するのが適当とされた。安全係数として、個人差 10、追加 5 の合計 50 を用いた場合、ADI は 0.00132mg/kg 体重/日となる。

これらの知見と現時点における国際的慣行[85]で ADI は数的に最も意味のある 1 桁で示すとされていることを考慮すると、塩酸ラクトパミンの残留基準を設定するに際しての ADI としては、0.001mg /kg 体重/日と設定することが適当であると考えられる。

無毒性量(NOEL)	0.125 mg/kg 体重/日
	動物種　サル
	投与量/投与経路　0.125mg/kg 体重/日　/　経鼻胃挿管
	試験期間　1 年間
	試験の種類　1 年間慢性毒性
安全係数	100
ADI	0.001mg/kg 体重/日

【食品健康影響評価について】

以上より、塩酸ラクトパミンの食品健康影響評価については、ADI として次の値を採用することが適当と考えられる。

塩酸ラクトパミン　0.001 mg/kg 体重/日

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